Steps towards Improved Microbiological Performance of Food Safety Management Systems in Kenyan Fish Industry

By

Adawo Onjong' Hillary

A dissertation submitted to the Board of Postgraduate Studies in Partial Fulfillment of the Requirements for the Degree of Masters of Science in Food Safety and Quality of the University of Nairobi

Department of Food Science, Nutrition and Technology

September, 2013

DECLARATION

I declare that this research project is my original work and has not been previously presented for the award of a degree in any other University.

Onjong' H. Adawo

Signed _____ Date _____

Recommendation

This project paper has been submitted for examination with our approval as University supervisors.

Dr. P. Kamau Njage

Signed _____ Date 13th November 2013_____

Dr. John Wangoh

Signed_____ Date_____

DEDICATION

To my wonderful dear wife Candy and, my lovely children Shelley and Shawn for your encouragement, patience and moral support.

ACKNOWLEDGEMENT

Thanks to almighty God for his abundant grace that enabled me to successfully complete this programme.

My most sincere gratitude and deepest thanks go to my supervisors Dr. John Wangoh and Dr Kamau Njage for their priceless ideas, energetic and helpful advice and many hours they devoted to the improvement of this study.

I would like to acknowledge the teaching staff at department of Food Science, Nutrition and Technology for the knowledge and skills they provided to me during my entire period in undertaking this study.

I am also grateful to the Association of Fish Processors and Exporters of Kenya (AFIPEK) for organizing fish processors to participate in this project.

Finally I thank, my sister Judy for the financial support, all relatives and friends whose support kept me going in my two years study.

To all of you much love! And God bless you all.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

AFIPEK	Association of Fish Processors and Exporters of Kenya
CSL	Critical Sampling Location
EurepGAP	Euro- Retailer Produce Working Group
FBO	Food Business Operators
FS	Food Safety
FSMS	Food Safety Management System
FSMS-DI	Food Safety Management System Diagnostic Instrument
GHP	Good Hygienic Practices
HACCP	Hazard Analysis and Critical Control Points.
ICMSF	International Commission on Microbiological Specifications for Foods
ISO	International Organization for Standardization
MAS	Microbiological Assessment Scheme
MSLP	Microbial Safety Level Profiles
PRP	Pre-requisite programs,
QA	Quality Assurance
SOP	Standard Operating Procedures
SQF	Safe Quality Food
TVCs	Total Viable Counts

General abstract

Despite the existence of several Quality Assurance (QA) standards and implemented food safety management systems (FSMS), fish processing plants are still facing food safety performance challenges worldwide. This includes food borne outbreaks and the associated economic losses. This study aimed to assess performance of fish safety management systems and the microbial performance of core control and assurance activities implemented by the fish processors in Kenya and recommend appropriate measures for their improvement. Kenyan fish processing plants that have recently improved their FSMS after major export bans from the European Union were selected for case study. Nine fish processing companies were selected randomly for analysis and grouped into three classes that typically represent small, medium and large sized; based on varying utilized operational capacities, number of employees and certified FSMS. A FSMS diagnostic tool with checklist was used to assess the context characteristics, core control and assurance activities and food safety (FS) performance level of the production units for each company. A microbiological assessment tool was also used to systematically analyze microbial counts of selected safety, utility and hygiene indicator microorganisms at identified critical sampling locations in order to evaluate the actual microbiological performance of implemented FSMS

Majority (6/9) companies operated at moderate to high risk context but with an average performing FSMS. This situation could be insufficient to deal with ambiguity, uncertainty and vulnerability issues in the plants context characteristics. The contextual environment in which companies operated posed high demand on their FSMS in terms of risk posed by product characteristics (nature of raw materials) and chain environment characteristics. In terms of the latter, the risk posed by low power in supplier relationships was high coupled with low degree of

authority in customer relationships. Lack of authority in relationship with suppliers would lead to high raw material risk situation. Even though cooling facilities (a key control activity), was at an advanced level, there was inadequate packaging intervention equipment which coupled with inadequate physical intervention equipment could lead to further weakened FSMS performance. However, most of the FSMS indicators revealed that the sector performed at average in its control and assurance activities. The microbiological assessment scheme revealed that *Salmonella* was absent in all critical sampling locations indicating effectiveness of the implemented FSMS against this organism. End product (fish) analysis showed that more than 67% of the studied companies had microbial counts within the legally accepted microbiological limits, hence good performance. The hands or gloves of food handlers from majority of companies (89%) were highly contaminated with *S. aureus* above the recommended limits. Performance of large sized companies was better than medium and small sized ones in majority (4/6) of the critical sampling locations. High variability in *Enterobacteriacea* was noticed in 56% of the companies while for TVCs it was 78% of the companies. This indicated a weak FSMS incapable of handling the microorganisms.

For the fish companies to improve their FSMS in terms of their microbiological performance to higher level and enhanced predictability, it is suggested that they base their FSMS on scientific information sources, historical results and own experimental trials in their preventive, intervention and monitoring systems. Specific suggestions are derived for improvements towards higher FSMS activity levels or lower risk levels in context characteristics and enhance their microbiological performance.

Key words: Food Safety Management System Diagnosis, Microbiological assessment scheme, Fish industry, Context characteristics, Control Activities, Assurance Activities

CHAPTER ONE

1.0 Introduction

Current annual Kenyan fish export value is estimated to be over 5 billion Kenya shillings. Nile perch is leading in export value (Ministry of fisheries Kenya, 2012). It is estimated that the fishing industry employs over 50,000 fishermen and women in Kenya. About 800,000 persons are also engaged in fish processing and trade (USAID, 2008). Fish safety concerns in Kenya increased between the year1997 and 2000, when EU banned fish imports from Kenya due to *salmonellae, cholera* and pesticides residues issues. This led to a 68 percent decline in fish exports and foreign exchange earnings (Abila, 2003). Dynamic environment of quality management systems (QMS) have been continuously under pressure. Emerging pathogens, consumer concerns and developments in preservation techniques puts a lot of pressure on QMS, requiring systematic evaluation of FSMS for improvement (Van der Spiegel et al., 2006, Manning et al., 2006).

Globalization of food supply chain and customer requirements for high quality and safe agro industrial products is constantly increasing (EU food law, 2006). Guaranteeing food safety and quality along with environmental protection and social responsibility is the responsibility of food operators at all stages of production, processing, handling and distribution (Will and Guenther, 2007). Large efforts and investments are being made by Food business operators (FBO) all over the world in designing, improvement and implementing Food Safety Management System (FSMS). This is done in compliance to different stakeholder's requirements for safe food (Karipidis et al., 2009).

Documented production practices are the most cost effective means of reducing food safety hazards that are expensive to analyze (Unnevehr, 2000). Agribusiness and food industry companies are required to apply recognized quality assurance systems. These should be implemented within their company specific quality management systems (Luning and Marcelis, 2007). To evaluate various implemented food safety management systems (FSMS) diagnostic instrument which has control and assurance activities is suggested with an aim of keeping product and process conditions within acceptable safety limits. It also enables to set systems requirements (Luning and Marcelis, 2007).

FSMS Diagnostic instrument (FSMS-DI) enables assessment of context characteristics, core control and assurance activities in a company. This is done independently from the implemented quality assurance guidelines and standards that exist (Luning et al., 2009). The MAS (Microbiological assessment scheme) protocol analyzes actual microbiological performance of an implemented FSMS to indicate the food safety output. Its principle is that when results show low numbers of microorganisms and small variations in the counts it indicates an effective and well functioning FSMS (Jacxsens et al., 2009b). Besides official inspections, the tools provide a differentiated insight in performances of crucial safety management activities, in view of the riskiness of context factors that also affect food safety (Luning et al., 2013). The combined diagnosis provides clear directions for improvement to move towards more advanced FSMS activity levels and reduce riskiness in context. This helps in the formation a sound basis for development of improvement strategies and offers companies opportunities for upgrading their own specific system.

The study was conducted to (1) Evaluate performance of the fish safety management systems against preset requirements. (2) Analyze the critical control points in the FSMS against the preset limits.

1.2 Problem statement

Kenyan fish processors make large efforts and investments in designing and implementing fish safety management systems (FSMS). Developing countries are increasingly becoming part of the global fish markets which demands that their FSMSs adapt to the stringent quality and safety standards and regulations in these markets (Unnevehr, 2000; Trienekens and Zuubier, 2008). This is in order to comply with demands of different stakeholders to deliver safe food products (Karipidis et al., 2009; Soderlund et al., 2008). Despite the increased efforts, food borne outbreaks are still reported (Sala et al., 2005; Van Duynhoven et al., 2005; Abila 2003).

The effectiveness of currently applied FSMSs in preventing and controlling food safety hazards has therefore been questioned (Jacxsens et al., 2010; Luning et al., 2011; 2013). FSMS evaluation has commonly focused on verification of actual microbiological safety output and audit of an implemented FSMS against specified requirements. Despite the fact that these FSMS evaluation methods presume a safer food when control and assurance activities are properly executed, they do not assess actual activities in the FSMS (Luning et al., 2011). It is therefore important to independently assess the FSMS performance irrespective of the existing FSMS. This will enable determination of the effectiveness of the interventions used to assure safety as well as further identification of

measures for further improvement of the FSMS (Fraser and Monteiro, 2009; Luning et al., 2009b).

1.3 Aim

To support fish business operators in assessing and enhancing their safety management systems to accommodate different stakeholder's requirements and reduce safety problems.

1.4 General objective

To assess performance of fish safety management systems in Kenya's fish processing plants.

1.4.1 Specific objectives

1. To assess and provide insight on pressure upon the food safety management systems due to riskiness of the context provided by the environmental situation in which the companies operate.
2. To assess and provide insight on performance of core control activities, assurance activities and the food safety output from the fish industries.
3. To assess the actual microbiological performance of core control and assurance activities of the implemented FSMS.

1.5 Literature Review

1.5.1 Food safety challenges in agricultural trade.

Trade in agricultural produce is characterized by complex, mandatory and stringent standards. The standards are expected to satisfy food safety requirements of importing countries. There is a shift from product standards testing at borders towards controls all over the entire food chain (i.e. at production, harvesting, processing and transportation) (UNIDO, 2006).

Food industries continuously move towards adopting management practices that focus on prevention and control of food safety hazards (Martin and Anderson, 2000). Public mandatory standards are increasingly being complemented by collective private standards such as Eurep GAP and Safe Quality Food (SQF) (UNIDO, 2006). Food businesses are however challenged in the process of combining and implementing different stakeholders requirements into a company specific FSMS (Jacxsens, Devlieghere and Uyttendaele, 2009a).

1.5.2 Fish safety and trade in developing countries

Fish production is very significant for global food trade and food security. It provides more than 15% of total animal protein supplies and averaged at 128.7 million metric tons (MMT) during the period 1998–2003, with a record high of 133.0 MMT in 2002 (Ababouch, 2006). For many developing countries, fish exports have become an important source of foreign exchange earnings. About 38% of world fish production enters international trade and around 50% (in value terms) of this trade originates in developing countries (Ababouch, 2006). Fisheries resources to Kenya are important

sources of food, employment and foreign exchange. It is driven by a 6% GDP growth rate in recent years and continuous change in consumer habits.

Fish has become an important part of the Kenyan household's diet directly and indirectly (USAID, 2008).

Main markets for Kenya's fish are the export markets for industrially processed fresh and frozen nile perch filets and the domestic markets for fresh tilapia, artisanal processed fish (nile perch, tilapia, and omena). These freshwater species markets handle 96% of Kenya's annual fish production of around 175,000 MT. In addition, a fifth set of markets are those related to Kenya's marine capture fisheries (shrimp, tuna, octopus, crab, etc.) (USAID, 2008).

Fish Export value from Africa has doubled during the last decade to US$3.2 billion. African exporters are countries with major marine catches, although some of them (e.g. Tanzania and Uganda) have large inland fisheries (WHO/FAO, 2004). At present, they represent the most important item in terms of net export value in developing countries (FAO, 2004). However, Post harvest losses are a prominent feature of African fisheries combined with scarcity of comprehensive and reliable information generally (Doherty, 2010).

Developed world impose stringent and rigorous fish safety measures in fish chain. There is pressure on fish exporters to match private quality standards set by buyers under the specifications of fish processors and supermarket chains in Europe and elsewhere (Ponte, 2005). This is coupled with limited capacity to invest in rigorous fish safety measures (Abila, 2003). The challenge is great in accessing major markets such as the European

Union (EU) and United States of America (USA) (Henson, Brouder and Mitullah, 2000a; Rahman, 2001). However, these standards and codes of conduct are being viewed as measures necessary for sustainable development (World Bank, 2005).

1.5.3 Food safety challenges in Kenyan fish industry

Kenya is faced with great challenges in implementing stricter food safety measures set by different stakeholders. This is because of its small development budget. It therefore exports fish under huge costs (Abila, 2003). The stakeholders have both competing and complementary interests. These include the numerous fishermen and a small number of industrial processing plants. However, their overall strategy is to target satisfaction of specific international consumer preferences (Thorpe and Bennett, 2004).

Implementation of private quality standards set by buyers' faces challenges. The standards implementation requires huge financial and organizational resources that most developing economies find it difficult to meet (Henson, Brouder and Mitullah, 2000a; Henson and Traill, 1993). As a result over seven fish processors in Kenya are unable to upgrade their facilities to stricter EU requirements and they have consequently stopped operations (Ministry of Fisheries Kenya, 2012).

The supply chain involves the direct supply of fish to agents from fishers or through their cooperative society or fisher association with very limited use of wholesalers (Henson and Mitullah, 2004). At the processing plant the facilities are expected to comply with the food safety standards of export markets. The processing involves filleting of fish which is then packaged mostly in 6kg labeled cartons then either exported chilled by airplane or frozen by boat (USAID, 2008).

Fishery industry in Kenya is affected by many issues besides different and strict stakeholders' requirements. These include poor distribution of the fisheries values, inadequate technologies for value addition and conflicting values in export versus consumption (Odongkara, Abila and Luomba, 2009).

Hygiene conditions by fishers are a problem in relation to the facilities for handling the fish and their storage temperatures. European Commission identified weaknesses in hygiene standards at landing beaches in all of their inspection reports the (European Commission, 1998; 1999; 2003).

There is inadequate use of ice characterized by lack of knowledge on the hygiene requirements among the people involved in the capture, handling and transport of the fish (Doherty, 2010). However, Beach Management Units (BMUs) have been established at landing sites to monitor and ensure hygiene handling standards (Henson and Mitullah, 2004). There is need to integrate local communities to play a role in the fishery for its better management. This should be done through upgrading their capacities in fundamental infrastructure in most landing beaches (Henson and Mitullah, 2004).

A significant proportion of traders and processors experience problems with fish spoilage (Lake Victoria fish processors association (LVFRP, 1999a)). These problems are related to poor storage conditions and open air trading (Henson and Mitullah, 2004). Ice plant operators around Lake Victoria either do not sell ice or sell volumes far below capacity, while at the same time there is a large unmet demand by fishers (USAID, 2008). The high levels of post catch losses indicate that the introduction of coolers and improved ice distribution systems would be an upgrade strategy that could stimulate value chain growth (USAID, 2008).

A number of processors supply fishing equipments to fishers through agents. This is an effort to establish sole supplier relations. There is no formal written contract on price, size and quality characteristics involved (Henson and Mitullah, 2004). However, efforts are being made to upgrade hygiene and other food safety controls in the supply chain by the processors. This is because of earlier restrictions on exports to the EU. Another challenge is that the sector is still characterized by low levels of value addition. Most exports are in the form of block frozen bulk packs of semi processed filets (Henson and Mitullah, 2004).

European Commission inspections in1998 found that, despite significant improvements made in the light of previous inspection reports, deficiencies remained especially on inspection, landings beaches hygiene conditions, approval of processing facilities, laboratory infrastructure and identification marks on consignments (European Commission, 1998). The report also revealed non compliance to pesticide monitoring programs and lack of improvements on procedures for laboratory analysis and processing establishments (European Commission, 2003).

1.5.4 Safety Management Legislation and Enforcement

At least six sets of standards operated by EU and several agencies govern fish industry in Kenya. Fisheries Department a national institution has the mandate to implement Kenya Fisheries Act (Cap 378) and Fish Quality Assurance Regulation 2000. It also enforces EU directives 91/493/EEC and 98/83/EEC on HAACP principles and construction requirements (Ministry of fisheries, Kenya, 2012). At the processing EU hygiene directive (91/493/EEC) standards are adhered to by most factories, on design and construction specified. Fish is washed, sorted then chilled and kept in ice until ready for

processing for maximum of one day. The fish then filleted by hand without gutting, fish then skinned and trimmed. Some processors have installed mechanical skinners (Fish industries Kenya, 2012).

Although fish processors are required to comply with various stakeholders standards (e.g. EU hygiene directive (91/493/EEC and 98/83/EEC) and Kenya fisheries act 2000, many challenges still persist. Major challenge areas are in control and prevention of food borne diseases and implementation of various conflicting stakeholders requirement on FSMS standards (Ministry of fisheries Kenya, 2012).

Fisheries Department carries out inspection and approval of processing establishments for export to the EU. It facilitates development and implementation of controls for effective timely response to emerging issues (Ministry of Fisheries Kenya, 2012). Additionally, Kenya Bureau of Standards (KS 1399-1: 2012 and KS 1399-2: 2012) for fin fish defines standards for fish processing and exports (Abila, 2003). Association of fish processors and exporters of Kenya (AFIPEK) tasked with harmonization of quality standards in all member industries fosters cooperation and collaboration between industrial fish processors (AFIPEK, 2012). It also ensures that processing plants obtain certificate of compliance to operate and mandatory export health certificate for each consignment. This is verified by Fisheries department which also trains fish inspectors and industry quality managers and offers refresher courses on HACCP and quality control principles (Ministry of Fisheries Kenya, 2012).

Microbiological laboratory analysis is done both internally by the industries and externally by Kenya bureau of standards (KEBS) and other ISO17025 accredited

laboratories. The total cost of laboratory upgrading and renovations is estimated to be over US$11,100 for compliance to EU standards (Ministry of Fisheries Kenya, 2012).

Traceability usually has an impact on upstream processors. This demands a reliable system to enable identification of the source of individual consignments in case problems arise. It also identifies origin and handling of some captures (Doherty, 2010). Requirements by EU standards for fish and fishery products encompass the entire supply chain, it requires processors to institute 'own checks' to have full control of the production process (Henson and Mitullah 2004).

1.5.5 Microbial contaminations of fish

Food processing industries endeavor to provide safe, wholesome and acceptable food to the consumer. Microorganisms control is essential to meet this objective (Baggen-Ravn et al., 2003). Many pathogenic bacteria are naturally present in aquatic environments, animal and human reservoir (e.g. *Salmonella, Shigella, E. coli*, enteric virus). There is a chance that these microorganisms may be passed on to the raw material during production and processing (Huss et al., 2000).

Fish products contamination has also been observed in many cases (Reij et al., 2004). Insufficiently cleaned processing equipment has been identified as a source of bacterial contamination in processed seafood (Reij et al., 2004). Transfer of microorganisms by personnel especially from hands, is of great importance (Chen et al., 2001; Montville et al., 2001). During handling and preparation, bacteria can be transferred from contaminated hands of food workers to food and to other surfaces (Montville et al., 2002). Water is also vehicle for the transmission of many agents of disease. It continues

to cause significant disease outbreaks in developed and developing countries (Kirby et al., 2003). Microbiological testing of foods is useful in monitoring actual effectiveness of sanitation procedures, raw material safety compliance; safety of products held for corrective action and finished products safety (Kvenberg and Schwalm, 2000).

Despite increased efforts in implementing FSMS and decreasing trends in prevalence of some food borne diseases, food borne outbreaks are still reported (Sala et al., 2005; Samuel et al., 2004). Inadequate FSMS contribute to the incidence of food borne diseases in many parts of the world (Luning et al., 2006a; Sumner et al., 2004).

1.5.6 Current Approaches to Food Safety Management System Diagnostics

1.5.6.1 Food Safety Management System Diagnostic Instrument

Besides the implemented FSMS like GMP and HACCP guidelines (like General Principles of food hygiene (CAC, 2003)), GFSI guidance document (GFSI, 2007) and quality assurance standards (e.g. ISO Standards), there is still variability in their performance (Luning et al., 2009). The highest challenge for food business operators (FBO) is to translate and implement stakeholders requirements into a company specific FSMS, for food safety assurance and also food quality. A company specific FSMS should aim at translating Good Hygienic Practices (GHP), Hazard Analysis Critical Control Point system (HACCP), management policies, traceability and recall systems into company specific circumstance (Jacxsens et al., 2009a and WHO, 2007).

Continuous pressure by fish importing countries on improvement of FSMS increases the demand to improve current systems. Therefore, FBO needs to diagnose the currently

implemented FSMS to assess their weaknesses and identify potential points for improvement (Luning et al., 2008).

High food safety requirements has made it necessary for agricultural based food companies to critically judge and improve their FSMS performance in the context in which they operate (Luning et al., 2009). This has shifted attention of food business operators from implementing QA standards to increased understanding of the performance of FSMS (Stringer and Hall, 2007 and Luning et al., 2008).

The project FOOD-CT-2005-007081 (Pathogen Combat) supported by the European Commission therefore developed some tools like FSMS-DI (Food safety management system diagnostic instrument) (Annex 2) and MAS (Microbiological assessment scheme) to be used in diagnosing microbial performance of a FSMS and improve the existing control and assurance systems. Careful diagnosis of these systems provides the basis for their improvement (Luning et al., 2008).

Diagnostic tools are used to analyze FSMS activities, context characteristics and microbiological food safety output of a company. This provides insight on the sufficiency of FSMS performance and also indicates directions for improvements towards advance FSMS activity levels or lower risk levels in context characteristics (Oses et al., 2012). Such assessment is independent of the implemented quality assurance guidelines and standards (Luning et al., 2009).

Context factors are structural elements in the whole company's environmental situation that affect decision making activities in the FSMS and the microbiological food safety

(FS) output. They include such as product, production process, organization, and chain environment characteristics (Luning et al., 2011a).

Diagnostic tools (Annex 2) differentiate and assess the riskiness of the context wherein an FSMS operates. The relevant context factors are represented by indicators on three levels of riskiness from the viewpoint of decision making namely ambiguity, uncertainty and vulnerability (Luning et al., 2011a).

When the FSMS context is more risky, advance activity levels based on scientific knowledge, adequate information, systematic methods, and independent positions will be needed that deal better with ambiguity, uncertainty, and vulnerability (Luning et al., 2008, 2009 and 2011a). Major reason for context evaluation is that, a FSMS should be adapted to the riskiness of its context situation in order to realize a stable and predictable food safety output (Luning et al., 2013).

Control activities are the ongoing process of evaluating performance of both technological and human processes and taking corrective actions when necessary aimed at realizing food safety. The diagnostic instrument provides a comprehensive checklist of crucial control activities, addressing major technology dependent and managerial activities in design and operation of preventive measures, intervention processes, and monitoring systems. It also provides detailed grids describing three levels of execution for each safety control activity to enable a differentiated assessment of the food safety control system situation (Luning et al., 2008).

Assurance activities on the other hand involve setting the system requirements, evaluating its performance, and organizing necessary changes to provide confidence that safety requirements will be met (Luning et al., 2006b, 2007, and 2009). Typical assurance

activities in a FSMS involve developing a sampling plan, performing internal audits, validation and verification activities (Jacxsens, Devlieghere and Uyttendaele, 2009a). Indicators describing control and assurance activities consist of four different levels (i.e. 0, 1, 2, and 3 representing from not present, simple, generic and advanced respectively) (Luning et al., 2008,2009).

Food safety (FS) performance diagnosis is incorporated into the FSMS-DI. It is based on seven indicators and their grids that can be applied instead of microbiological analysis to get a first insight of the microbiological performance of an implemented FSMS (Table 6). It assumes that a more structured, very strict assessment of FSMS performance using specific criteria result in a better insight of actual microbiological FS performance. This is because of systematic detection of food safety problems (Jacxsens et al., 2010).

FSMS diagnosis tool operates on the principle that companies operating in a high-risk context require advanced FSMS activities, while those operating in a low risk context require lower levels of control and assurance activities which will be sufficient to realize a good FS output (Jacxsens et al., 2011).

The basic assumption underlying the diagnostic instrument is that activities on a higher level are more predictable and better able to achieve a desired safety outcome, due to more insight in underlying mechanisms and more accurate information. The instrument may contribute in finding effective types and levels of control activities within given context situation (Luning et al., 2008).

1.5.6.2 Microbial Assessment Scheme

Microbial assessment scheme (MAS) tool involves systematic analysis of microbial counts to assess microbial performance of an implemented FSMS (Jacxsens et al., 2009b, 2011). This includes identification of critical sampling locations (CSL), the selection of microbiological parameters, the assessment of sampling frequency, the selection of sampling method, method of analysis and finally data processing and interpretation (Jacxsens et al., 2009b, 2011).

Microbial safety level profiles (MSLP) are then derived indicating which microorganisms and to what extent they contribute to microbiological safety for a specific food processing company. Low numbers of microorganisms and small variations in microbial counts indicate an effective FSMS (Jacxsens et al. 2009b, 2011). When MAS tool and FSMS-DI (Food safety management system diagnostic tool) are used together to diagnose actual microbiological performance and the control and assurance activity levels and context level they provide distinct insight in possible causes of insufficient performance of the FSMS. The combined diagnosis gives a clear indication of food safety performance, in relation to FSMS activities and context level and can support companies in focusing on improvements strategies (Jacxsens et al., 2011).

Results from MAS give information concerning the performance of a specific control activity in an FSMS. The microbial safety profiles provide additional information concerning the nature of the microbiological problem which can be used to compare the current microbiological performance of different companies with the same type of production processes and food products (Jacxsens et al. 2009b, 2011).

For instance FSMS-DI and MAS were used to assess FSMS along the lamb chain in Castilly León, Spain. Their combined use provided insight in the insufficient performance by indicating that slaughter houses were the main bottleneck. The tools also gave directions for improvements (Osés et al., 2012). The tools were also used in a semi quantitative study to evaluate performance of a HACCP-based food safety management system in Japanese milk processing plants . The results revealed that the microbial food safety output was higher for companies with national HACCP approval (Sampers et al., 2012).

References

Ababouch, L. (2006). Assuring fish safety and quality in international fish trade. *Marine Pollution Bulletin*, 53(10-12), 561–568.

Abila, R. O. (2003). *Food safety in food security and food trade case study: Kenyan fish exports* (International Food Policy Research Institute**,** Focus 10, Brief 8 of 17). Retrieved September 6, 2012, from www.ifpri.org/publication/food-safety-food-security-and-food-trade

Bagge-Ravn, D., Ng, Y., Hjelm, M., Christiansen, N.J., Johansen, C., & Gram, L. (2003). The microbial ecology of processing equipment in different fish industries-analysis of the micro flora during processing and following cleaning and disinfection. *International Journal of Food Microbiology*, 87(3), 239-250.

Chen, Y.H., Jackson, K.M., Chea, F.P., & Schafftner, D.W. (2001). Quantification and variability analysis of bacterial cross contamination rates in common food service tasks. *Journal of Food Protection*. 64(1), 72-80.

Doherty, M. (2010). *The importance of sanitary and phytosanitary measures to fisheries negotiations in economic partnership agreements* (Series on Fisheries, Trade and Sustainable Development, Issue Paper No. 7). Retrieved October 7, 2012, from http:// www.ictsd.org

European Commission (1998). *Final report on a mission to kenya: fisheries products* (23 to 27 November 1998). Retrieved November 5, 2012, from http://ec.europa.eu/food/fvo/annualreports/vi_pol02_en.pdf

European Commission. (2003). *Final report on a mission carried out in Kenya 14 to 22 March 2002 carried out to assess the conditions of production of fisheries products* (Council Directive 91/493/EEC and the verification of the measures on pesticides in fish. European Commission, Brussels). Retrieved November 6, 2012, from http://*ec.europa.eu/food/fs/.../reports/kenya/vi_rep_keny_8586-2002_en.pdf*

European Food Law. (2006). *Import conditions for seafood and other fishery products (Brussels: European Commission, Health and Consumer Protection Directorate-General).* (EC 178/2002). Retrieved December 8, 2012, from http:// www.europa.eu.int/comm/food/international/trade/ im_cond_fish_en.pdf

FAO. (2004). *The state of world fisheries and aquaculture 2004*. Retrieved November 12, 2012, from http:// www.fao.org/docrep/007/y5600e/y5600e00.htm

Food and Agriculture Organization of the United Nations/World Health Organization. (2004). *Strengthening official food safety control services (Paper presented at the second FAO/WHO global forum of food safety regulators, Bangkok, Thailand*. Retrieved January 2, 2013, from http://ftp://ftp.fao.org/docrep/fao/meeting/008/y5871e/y5871e00.pdf

Fraser, R., & Monteiro, D. S. (2009). A conceptual framework for evaluating the most cost effective intervention along the supply chain to improve food safety. *Food Policy*, 34, 477–481.

Henson, S. J., & Traill, W. (1993). "Economics of food safety." *Food Policy*, 18 (2), 152–162.

Henson, S. J., Brouder, A. M., & Mitullah, W. (2000a). Food Safety Requirements and Food Exports from Developing Countries: The Case of Fish Exports from Kenya to the European Union. *American Journal of Agricultural Economics*, 82 (5), 1159-1169.

Henson, S., & Mitullah, W. (2004). *Kenyan Exports of Nile Perch: The Impact of Food Safety on an Export-Oriented Supply Chain* (World Bank Policy Research Working Paper 3349). Retrieved January 2, 2013, from http://elibrary.worldbank.org/docserver/download/3349.pdf

Huss, H. H., Reilly, A., & Embarek, P. K. B. (2000). Prevention and control of hazards in seafood. *Food Control*, 11(2), 149-156.

Jacxsens, L., Devlieghere, F., & Uyttendaele, M. (2009a). *Quality management systems in the food industry*. Ghent University, ISBN 978-90-5989-275-0.

Jacxsens, L., Kussaga, J., Luning, P. A., Van der Spiegel, M., Devlieghere, F., & Uyttendaele, M. (2009b). A microbial assessment scheme to support microbial performance measurements of food safety management systems. *International Journal of Food Microbiology*, 134(1-2), 113–125.

Jacxsens, L., Luning, P. A., Marcelis, W. J., Van Boekel, T., Rovira, J., Oses, S., Kousta, M., Drosinos, E., Jasson, V., & Uyttendaele, M. (2011). Tools for the performance assessment and improvement of food safety management systems. *Trends in Food Science & Technology*, 22(1), S80–S89.

Jacxsens, L., Uyttendaele, M., Devlieghere, F., Rovira, J., Oses Gomez, S., & Luning, P. A. (2010). Food safety performance indicators to benchmark food safety output of

food safety management systems. *International Journal Food Microbiology*, 141(Suppl 1), S180-S187.

Karipidis, P., Athanassiadis, K., Aggelopoulos, S., & Giompliakis, E. (2009). Factors affecting the adoption of quality assurance systems in small food enterprises. *Food Control*, 20 (2), 93–186.

Kirby, R. M., Bartram, B., & Carr, R. (2003). Water in food production and processing-Quality and quality concerns. *Food Control*. 14(5), 283-299.

Kvenberg, J. E., & Schwalm, D. J. (2000). Use of microbial data for HACCP- food and drug administrative perspective. *Journal of Food Protection*, 63(6), 810–814.

Luning, P. A., & Marcelis, W. J. (2006a). A techno-managerial approach to food quality management. *Trends in Food Science and Technology*, 17(7), 378–385.

Luning, P. A., & Marcelis, W. J. (2007). A conceptual model of food quality management functions based on a techno-managerial approach. *Trends in Food Science and Technology*, 18(3), 159-166.

Luning, P. A., & Marcelis, W. J. (2009). *Food Quality Management; technological and managerial principles and practices*. Wageningen: Wageningen Academic Publishers. ISBN: 987-90-8686-116-3.

Luning, P. A., Bango, L., Kussaga, J., Rovira, J., & Marcelis, W. J. (2008). Comprehensive analysis and differentiated assessment of food safety control systems: a diagnostic instrument. *Trends in Food Science and Technology*, 19(10), 522–534.

Luning, P. A., Chinchilla, A. C., Jacxsens, L., Kirezieva, K., & Rovira, J. (2013). Performance of safety management systems in Spanish food service establishments in view of their context characteristics. *Food Control*, 30(1), 331-340.

Luning, P. A., Marcelis, W. J., and van der Spiegel, M. (2006b). *Quality assurance systems and food safety*. In: Luning, P. A., Devlieghere, F., and Verhé, R. (Hg.): Safety in the agri-food chain. 1. Aufl. . Wageningen: Wageningen Academic Publisher: 249–301.

Luning, P. A., Marcelis, W. J., Rovira, J., Van der Spiegel, M., Uyttendaele, M., & Jacxsens, L. (2009). Systematic assessment of core assurance activities in a company specific food safety management system. *Trends in Food Science and Technology*, 20(6), 300–312.

Luning, P. A., Marcelis, W. J., van Boekel, M. A., Rovira, J., Uyttendaele, M., & Jacxsens, L. (2011a). Diagnostic tool to analyze riskiness of context factors which impact food safety management system performance. *Trends in Food Science and Technology*, 22(1), S67-S79.

LVFRP (1999a). *Marketing study. lake victoria fisheries research project*. Kisumu.

Manning, L., Baines, R., & Chadd, S. (2006). Food safety management in broiler meat production. *British Food Journal*, 108(8), 605–621.

Martin, S. A., Anderson, D. W. (2000). *HACCP adoption in the US food industry* (In: Unnevehr, L.J. (Ed.), The Economics of HACCP: studies of costs and benefits. Eagan Press, Saint Paul, MN). University of Nairobi.

Montville, R., Chen, Y., & Schaffner, D.W. (2001). Determination of bacterial cross-contamination rates from hand to food through a glove barrier. *Journal of Food Protection*, 64(6), 845-849.

Montville, R., Chen, Y., & Schaffner, D.W. (2002). Risk assessment of hand washing efficacy using literature and experimental data. *International Journal of Microbiology*, 73(2-3), 305-313.

Odongkara, K. O., Abila, R. O., & Luomba, J. (2009). The contribution of lake Victoria fisheries to national economies. *African Journal of Tropical Hydrobiology and Fisheries*, 12, 47-51.

Osés, S. M., Luning, P. A., Jacxsens, L., Santillanab, S., Jaimea, I., & Rovira, J. (2012). Food safety management system performance in the lamb chain. *Food Control*, 25(2), 493–500.

Ponte, S., & Gibbon, P. (2005). 'Quality standards, conventions and the governance of global value chains.' *Economy and Society*, 34(1), 1-31.

Rahman, M. (2001). EU ban on shrimp imports from Bangladesh: a case study on market access problems faced by the LDCs**.** *CUTS Centre for International Trade*, Dialog, Bangladesh, 2001. Retrieved January 20, 2012, from *www.cuts.org/sps-analysis-sps_case_bdesh.htm*>

Reij, M. W., Den Aantrekker, E. D., & ILSI Europe Risk Analysis in Microbiology Task Force. (2004). Recontamination as a source of pathogens in processed foods. *International Journal of Food Microbiology*, 91(1), 1-11.

Sala, M.R., Cardenosa, N., Arias, C., Llovet, T., Recasens, A., Domi´ nguez, A., & Salleras, L. (2005). An outbreak of food poisoning due to a genogroup I norovirus. *Epidemiology and Infection*, 133(1), 187–191.

Sampers, I., Toyofuku, H., Luning, P. A., Uyttendaele, M., & Jacxsens, L. (2012). Semi-quantitative study to evaluate the performance of a HACCP-based food safety management system in Japanese milk processing plants. *Food Control*, 23(1), 227-233.

Samuel, M. C., Vugia, D. J., Shallow, S., Marcus, R., Segler, S., McGivern, T., et al. (2004). Epidemiology of sporadic Campylobacter infection in the United States and declining trend incidence. *Clinical Infectious Diseases*, 38 (Suppl. 3), S165-S174.

Soderlund, R., William, R., & Mulligan, C. (2008). Effective adoption of agri-food assurance systems. *British Food Journal*, 110(8), 745-761.

Stringer, M. F., Hall, M. N. (2007). A generic model of the integrated food supply chain to aid the investigation of food safety breakdowns. *Food Control*, 18(7), 755–765.

Sumner, J., Raven, G., & Givney, R. (2004). Have changes to meat and poultry food safety regulation in Australia affected the prevalence of Salmonella or of Salmonellosis. *International Journal of Food Microbiology*, 92(2), 199–205.

Thorpe, A., & Bennett, E. (2004). Market-driven international fish supply chains: the case of Nile Perch from Africa's Lake Victoria. *International Food and Agribusiness Management Review*, 7(4), 40-57.

Trienekens, J., & Zuubier, P. (2008). Quality and safety standards in food industry, developments and challenges. *International Journal of Production economics*, 113(1), 107-122.

United nations industrial development organization (UNIDO). (2006). *Global Value Chains in the Agri-food Sector. Working papers*. Retrieved December 20, 2012, from http://www.unido.org

United States Agency for International Development (USAID). (2008). *The Kenya capture fisheries value chain: an amap-fskg value chain finance case study* (Micro report # 122). Retrieved January 3, 2012, from http://*www.spcrp-mp.com/.../Reports/complete%20RED-SEA%20market%20st*

Unnevehr, L. (2000). "Food Safety Issues and Fresh Food Product Exports from LDCs." *Agricultural Economics*, 23(3), 231–240.

Van der Spiegel, M., Luning, P. A., de Boer, W. J., Ziggers, G. W., & Jongen, W. M. F. (2006). Measuring effectiveness of food quality management in the bakery sector. *Total Quality Management and Business Excellence*, 17 (6), 691-708.

Van Duynhoven, Y. T. H. P., de Jager, C. M., Kortbeek, L. M., Vennema, H., Koopmans, M. P.G., van Leusden, F., van der Poel, W. H. M., et al. (2005). A one-year intensified study of outbreaks of gastroenteritis in The Netherlands. *Epidemiology and Infection*, *133*(1), 9-21.

Will, M., & Guenther, D. (2007). *Food quality and safety standards as required by EU law and the private industry*. Retrieved December 3, 2012, from http://www.gtz.de/de/dokumente/en-bulletin15_2007.pdf

World bank. (2005). *Food safety and agricultural health standards: challenges and opportunities for developing country exports* (Report No. 31207). World bank Policy Research Working Paper series. Retrieved August 26, 2012, from http://www.worldbank.org/trade/standards

World Health Organization (WHO). (2007). *Food safety and food borne illness.* Retrieved November 18, 2012, from http://www.who.int/mediacentre/factsheets/fs237/en/index.html

CHAPTER TWO

Title: The performance of food safety management systems in fish exporting companies in relation to the riskiness of company's environmental situation.

Abstract

Despite the existence of several Quality Assurance (QA) standards and implemented food safety management systems (FSMS), fish processing plants are still facing food safety performance challenges. This study aimed to assess performance of fish safety management systems in an export situation and recommend appropriate measures for their improvement. The Kenyan fish processing plants affected by major export bans by the European Union were selected for case study. These plants were forced to implement major improvement in their FSMS. Nine fish processing companies were selected randomly for analysis and grouped into three classes namely small, medium and large sized based on their installed and utilizable capacities, number of employees and whether their FSMS is certified. A FSMS diagnostic tool with checklist was used to assess the context, FSMS and food safety (FS) performance level representative of each characteristic production unit.

Majority (6/9) companies operated at moderate to high risk context but with an average performing FSMS. This situation could be insufficient to deal with ambiguity, uncertainty and vulnerability issues in the plants context characteristics. The contextual environment in which companies operated posed high demand on their FSMS in terms of risk posed by product characteristics (nature of raw materials) and chain environment characteristics. Risk posed by low power in supplier relationships was high coupled with

low degree of authority in customer relationships. Lack of authority in relationship with suppliers would lead to high raw material risk situation due to absence of influence on suppliers product specifications and FSMS. Even though cooling facilities (a key control activity), was at an advanced level, there was inadequate packaging intervention equipment which coupled with inadequate physical intervention equipment could lead to further weakened FSMS performance. However, most of the FSMS indicators revealed that the sector performed at average in its control and assurance activities.

For the fish companies to improve their FSMS to higher level and enhance predictability, it is suggested that they base their FSMS on scientific information sources, historical results and own experimental trials in their preventive, intervention and monitoring systems. Specific suggestions are derived for improvements towards higher FSMS activity levels or lower risk levels in context characteristics.

Key words: Food Safety Management System Diagnosis, Fish industry, Context characteristics, Control Activities, Assurance Activities

2.0 Introduction

Fish production is very significant for global food trade and food security. It provides more than 15% of total animal protein supplies and averaged at 128.7 million metric tons (MMT) during the period 1998–2003, with a record high of 133.0 MMT in 2002 (Ababouch, 2006). About 38% of world fish production enters international trade and around 50% (in value terms) of this trade originates in developing countries (Ababouch, 2006). Fish export value from Africa has doubled during the last decade to US$3.2 billion. African exporters are countries with major marine catches, although some of

them (e.g. Tanzania and Uganda) have large inland fisheries (WHO/FAO, 2004). For many developing countries, fish exports have therefore become an important source of foreign exchange earnings.

However, post-harvest losses are a prominent feature of African fisheries combined with scarcity of comprehensive and reliable information (Doherty, 2010). Such cases happen where failure to apply adequate safety and quality measures leads to losses at various stages of fish chain. The losses include: physical from poor handling and preservation, economic when spoilage occurs or when higher costs are incurred in reprocessing (Abila, 2003). Hygiene conditions in relation to the fish handling facilities and storage temperatures are also a big challenge. European Commission identified weaknesses in hygiene standards at landing beaches in all of their inspection reports by European Commission (1998, 2003).

Stringent and rigorous fish safety measures have been imposed on the market chain. There is pressure on fish exporters to match private quality standards set by buyers under the specifications of fish processors and supermarket chains in Europe and elsewhere (Ponte and Gibbon, 2005). Developing countries are constrained in their attempts to meet these stringent and strict food safety requirements because they have limited capacity to invest in rigorous fish safety measures (Abila, 2003). The challenge in accessing major markets such as the European Union (EU) and United States of America (USA) is great (Rahman, 2001). However, these standards and codes of conduct are necessary measures for sustainable development (World Bank, 2005).

Documented production practices are the most cost effective means of reducing food safety hazards that are expensive to test (Unnevehr, 2000). Agribusiness and food

industry companies are required to apply acknowledged quality assurance systems. These should be implemented in their company specific quality management system (Luning and Marcelis, 2007).

Despite the implementation of FSMS like GMP and HACCP guidelines (like General Principles of food hygiene (CAC, 2003)), GFSI guidance document (GFSI, 2007) and quality assurance standards (e.g. ISO Standards), there is still variability in their performance (Luning et al., 2009). The highest challenge for fish processors is to translate and implement stakeholders requirements into a company specific FSMS, for food safety assurance and also food quality. A company specific FSMS should aim at translating Good Hygienic Practices (GHP), Hazard Analysis Critical Control Point system (HACCP), management policies, traceability and recall systems into company specific circumstance (Jacxsens et al., 2009b). Continuous pressure on FSMS performance and on improvement of safety control measures increases the demand to improve current systems. Therefore, fish processors need to diagnose the currently implemented FSMS to assess their weaknesses and identify potential points for improvement (Luning et al., 2008). It is therefore important to undertake FSMS assessment with independent of the implemented quality assurance guidelines and standards (Luning et al., 2009).

The FSMS diagnostic tool (Annex 2) differentiate and assess the riskiness of the context wherein an FSMS operates. The relevant context factors are represented by indicators on three levels of riskiness from the viewpoint of decision making namely ambiguity, uncertainty and vulnerability (Luning et al., 2011a).When the FSMS context is more risky, advance activity levels based on scientific knowledge, adequate information,

systematic methods, and independent positions will be needed that deal better with ambiguity, uncertainty, and vulnerability (Luning et al., 2008, 2009 and 2011a). Major reason for context evaluation is that, a FSMS should be adapted to the riskiness of its context situation in order to realize a stable and predictable food safety output (Luning et al., 2013). The basic assumption underlying the diagnostic instrument is that activities on a higher level are more predictable and better able to achieve a desired safety outcome, due to more insight in underlying mechanisms and more accurate information. The instrument may contribute in finding effective types and levels of control activities within given context situation (Luning et al., 2008). The diagnosis provides clear directions for improvement to move towards more advanced FSMS activity levels and reduce riskiness in context. This is a sound basis for development of improvement strategies and opportunities for upgrading the specific systems of different companies. FSMS-DI also recommended different interventions based on assessment results for specific fish processors.

This study therefore used the FSMS-DI tool to investigate the performance of the fish safety management systems in fish exporting industries in the presence of the contextual pressure from the environment in which they operate.

2.1 Materials and methods

2.1.1 Characterization of companies

There are 17 industrial fish processing companies in Kenya all of which are export oriented and can be classified as either land based establishments or water based freezer vessels. These companies mainly produce frozen and chilled fish for export to European and other non European markets.

The companies deal in different fish species including Nile perch, prawns, lobsters, octopus, cuttlefish and squids. Nile perch is the dominant fish species in Kenya's trade, accounting for about 91% of total fish export volume.

The companies were grouped into three classes that typically represent small, medium and large sized companies based on varying installed and utilized capacities, number of employees and certified FSMS (e.g. HACCP, PRP, ISO standards, E.U and Government regulation) (Table 1) from which nine companies were selected randomly for analysis.

The total installed capacity by all the processors is 437 Metric tons per day however only 213.4 metric tons per day is utilized. The sector is controlled and regulated by the Fisheries Department, which falls under the Ministry of Livestock & Fisheries (Table 1).

Table 1. Characteristics of fish companies diagnosed for food safety management systems

Company	Total employees number	QA Standards implemented	QA Department personnel number	Specific product group	Installed capacity per Day (Metric tons)
A	50-249	HACCP, ISO 22000:2005	5	Nile perch	L
B	10--49	HACCP, PRP ,ISO 9001	3	Frozen octopus	S
C	10--49	HACCP,PRP	4	Frozen octopus	M
D	50-249	HACCP,PRP,ISO 22000:2005	12	Nile perch	L
E	10--49	HACCP,PRP	6	Nile perch	S
F	50-249	ISO 22000:2005	8	Nile perch	M
G	50-249	HACCP,PRP,ISO 22000:2005	5	Nile perch	M
H	10--49	HACCP,PRP	3	Frozen octopus	L
I	50-249	HACCP	1	Frozen octopus, fin fish	S

L-large sized (installed capacity of 60-30metric tons/day), M-medium size (installed capacity of 30-10 metric tons/day), S- small size (installed capacity of 10-0.5 metric tons/day), HACCP -Hazard analysis and critical control points, PRP-Pre-requisite programs, QA-Quality Assurance

2.1.2 Food safety management system diagnosis

The FSMS diagnosis (Annex 2) involved an interview with the responsible quality assurance (QA) manager of the respective companies. The QA managers responded to and chose FSMS activity level and context level for each indicator that mostly represents their characteristic production unit within their factory. Interview was then followed by an onsite visitation to confirm the assessment (Luning et al., 2008, 2009, 2011a).

2.1.2.1 Context factors

FSMS diagnostic tool (Annex 2) first differentiated and assessed the riskiness of the context in which a FSMS operate. FSMS context factors include product, production process, organization and chain environment and compose the structural elements of the situation. They affect decision making activities in the FSMS and the FS output (Luning et al. 2011a) (Table 4).

Context factors also affect the microbiological food safety (FS) output through assurance and control activities in a FSMS (Jacxsens et al., 2010). The relevant context factors are represented by indicators on three levels of riskiness (Luning et al., 2011a, 2011b). Each context factor has a defined limited set of indicators and grids with the different levels describing the ambiguity, uncertainty and vulnerability of the company's FSMS (Luning et al., 2011a).

Grids describe low, moderate and high decision making risk situations in the FSMS activities. For product and process characteristics; low risk (level 1), moderate risk (level 2), high risk (level 3) situations represent low, potential and high chance of

contamination respectively likely to allow growth of undesired pathogens and microorganisms (Luning et al., 2011a).

Raw materials situation is moderate or high risk when it is associated with high initial microbial levels (pathogens) and therefore must be stored below room temperature. High requirements on storage are crucial for prevention of undesired growth of microorganism for high risk situation (Luning et al., 2011a).

A product characteristic has three indicators related to distinct product properties that cannot be changed or modified easily on a short term. Susceptibility of final products is affected by the intrinsic properties (such as water activity, pH and preservatives) in the inactivation processes (Luning et al., 2011a).

Extent of safety contribution of packaging describes degree a packaging concept design that contributes to safety of product in the protection from mechanical injuries and contamination from the environment (Luning et al., 2011a; Luning and Marcelis, 2009).

Organizational characteristics involve administrative conditions, such as people characteristics organizational structures and information systems that affect people's decision making behavior (Luning and Marcelis, 2009). Organizational characteristics can be low risk (level 1), moderate risk (level 2) and high risk (level 3) situations describe supportive, constrained or restricted and lack of administrative conditions respectively for appropriate decision making (Luning et al., 2011a, 2011b).

Chain environment characteristics include supplier, customer and stakeholders relationships that make a company more dependent on other actors thus making the

company to be susceptible to safety problems (Luning and Marcelis, 2007). Chain environment characteristics are represented by low risk (level 1), moderate risk (level 2) and high risk (level 3) situations describing low, restricted and high dependability on other chain actors respectively (Luning et al., 2011a).

When FSMS context is more risky, activity levels will be needed that deal better with ambiguity, uncertainty and vulnerability (Luning et al., 2011a). Ambiguity is reduced by scientific technological knowledge aimed at improving understanding of the product composition, dynamic processes in the food product and the influence of technological conditions on these product properties (Luning et al., 2011a). Uncertainty is reduced by more adequate information provided for the problem situation, systematic methods and or scientifically supported processes of control decisions (Luning et al., 2011a). Vulnerability is reduced by use of more systematic methods and independent positions of activities execution according to predesigned and prescribed system to ensure careful decision-making processes that prevent conflicting interests and undesirable risk behavior (Luning et al., 2009).

2.1.2.2 Core control activities

Control activities (Table 5) in an FSMS aims at prevention, reduction of microbial and pathogens contamination and growth in production process (Jacxsens et al., 2009b) and keeping product and process conditions within acceptable safety limits (Luning and Marcelis, 2007).

Comprehensive checklist (Annex 2) was used which contains crucial control activities and grids for each control activity with descriptions of three different levels to describe

the activities, design and operation in the company's own system (Luning et al.,2008) . Three different control strategies that contribute to food safety namely preventive measures, intervention processes, and monitoring systems are distinguished (Luning et al., 2008).

Preventive measures are aimed at creating circumstances that prevent entry and or growth of pathogens in food production systems, reducing chance of cross contamination or growth and may improve efficiency and effectiveness of an FSMS by decreasing the number of critical control points (Luning et al., 2008). Intervention processes are aimed at inactivating or eliminating pathogens to reduce them to acceptable levels and may include physical, chemical and biological means (Luning et al., 2008). Monitoring systems provide information on the actual status of product or process conditions with an aim of enabling process corrections, removal of non-conforming products and system improvements in case of structural deviations (Luning et al., 2008). These include measuring systems and methods of microbial analysis.

Food safety control systems include design aspects, operation practice and deficiencies, compliance to procedures by preventive measures, intervention and monitoring equipment that affect safety outcomes (Luning et al., 2008). Four different grids are used to assess design and operation of the control strategies with each activity having an indicator to describe how it may impact microbial safety in the three levels low, medium, and high (Annex 2).

High/advance levels (level 3) are associated with scientifically underpinned systems which are accurate, complete, stable, predictable and tailored for the specific food

production process. Medium levels (level 2) are associated with best practice knowledge or equipment, variable, at times not predictable and usually based on generic information for the product sector. Low levels (level 1) describes lack of scientific evidence, use of company experience or history, variable unpredictable, unknown and based on common materials or equipment. The control measures are neither specific nor adapted for own production system. Level 0 (absent) meant that the activities/ measures were not important, used, implemented nor known. Control activities if performing at higher level is more predictable therefore can achieve good safety outcome due to less ambiguity and uncertainty (Luning et al., 2008).

2.1.2.3 Core assurance activities

These are activities that specifically aim at controlling and assuring microbiological food safety in a quality management functions (Annex 2). These activities control the system and provide evidence and confidence to stakeholders about meeting the set requirements (Luning et al., 2009).

Assurance activities involve setting requirements on the system, evaluating system performance and organizing necessary changes with assumption that assurance activities performed on a higher level is able to provide better guarantee to meet food safety requirements due to effective and reliable FSMS (Luning et al., 2009). The assessed core assurance activities included defining of system set up, validation, verification, documentation and record keeping activities (Luning et al., 2009). Grids with descriptions of different levels of assurance activities (low, medium, and high) were deduced from two general criteria namely validity and reliability (Luning et al., 2009).

Validity and reliability criteria are used to differentiate 'what' (content) and 'how' (structure) of assurance activities. Validity concerns rightness and precision (specificity of the information) and reliability includes consistency and ability of verification (knowledge on which the information is based) (Luning et al., 2009). Level 0 (absent) meant that the activities/ measures were not important, used, implemented nor known. Low performance (level 1) meant that the content of activities was based on general information and historical data. Validation involved checking and problem driven for their structure, and were done on ad hoc basis and not independent. Medium performance (level 2) described activities that were based on standard information and expert knowledge. Their structure involved analysis and feedback driven, and done regularly but partly independent. High/advance performance (level 3) described activities that were based on specific information and scientific knowledge, done procedurally and after criticism. They were also systematic and fully independent (Luning et al., 2009).

2.1.2.4. Food safety (FS) performance activities

These are measurable parameter that gives an indication about the performance of microbiological food safety. They help to obtain a first indication of the microbiological food safety performance of an implemented FSMS (Jacxsens et al., 2010) (Annex 2).

Qualitative (descriptive) indicators are used judge how a FSMS has been appreciated by independent experts while quantitative indicators (based on microbiological analysis) are used to get insight in the microbiological performance of the FSMS. A total of four FS performance indicators are used to analyze the external judgment of the FSMS

performance whereas internal food safety performance evaluation of the actual performance judgment has three indicators (Annex 2).

A total of seven food safety performance indicators are used namely FSMS evaluation, seriousness of remarks, microbiological food safety complaints, hygiene complaints by customers, product sampling, judgment criteria, hygiene and pathogen non conformities.

Grids are used to describe different levels for each indicator i.e. Level 0 (absent) means that evaluation is not done, and or that the specific food safety performance information is not known. Level 1 (poor performance) means there is various food safety problems due to different problems in the FSMS. Level 2 (moderate performance) meaning presence of restricted food safety problems mainly due to one (restricted) type of problem. Level 3 (good performance) meaning absence of safety problems (Jacxsens et al., 2010) (Annex 2). An overall score and assigned score can then be defined based on the scores for the individual indicators to give an overall judgment of the food safety performance of the implemented FSMS according to Luning et al (2011a) (Table 2).

The assumption behind the FS performance diagnosis is that fish processors that evaluate performance of their implemented FSMS in a more structured and very strict manner using specific criteria will have a better insight in their actual microbiological food safety performance. This is because of a more systematic detection of food safety problems that it offers (Jacxsens et al., 2010). Findings by internal and external system evaluations support the reliability of the FSMS performance judgment (Block et al., 2007).

2.2 Data processing and analysis

Data analysis and processing was done according to Jacxens et al., 2009b, Luning et al., 2011b and Sampers et al., 2010. Tables were used to illustrate visually the scores for the separate indicators for core control, core assurance activities and contextual factors (Annex 1).

Mean values were then calculated and transformed to assigned scores to obtain an overall impression of core control, core assurance activities and contextual factors as described by Luning et al. (2011b) and Jacxsens et al. (2009b) (Table 2). The assigned scores were then used to obtain an overall indication of the FSMS and its contextual situation. Individual scores were used for detailed analysis (Table 2).

Table 2. Conversion of mean scores into assigned scores of context, food safety management systems and food safety performance activities

Activities	Mean scores	Assigned scores
Context characteristics	1.0-1.2	1[a]
	1.3-1.7	1-2
	1.8-2.2	2
	2.3-2.7	2-3
	2.8-3.0	3
FSMS activities		
	0.0-1.2	1[b]
	1.3-1.7	1-2
	1.8-2.2	2
	2.3-2.7,	2-3
	2.8-3.0	3
FS Performance activities	0.0-1.2	1[c]
	1.3-1.7	1-2
	1.8-2.2,	2
	2.3-2.7	2-3
	2.8-3.0	3

After Luning et al. (2011b); [a]Context factors assigned score 1=low, 1-2=low to moderate, 2=moderate, 2-3=moderate to high,3=High; [b]FSMS assigned score 1=Low, 1-2=Low to average, 2=Average, 2-3=Average to advance,3=Advance; [c]FS performance activities assigned score 1=Poor, 1-2=Poor to moderate, 2=Moderate, 2-3=Moderate to good, 3=Good.

Analysis of variance was also carried out to assess the groups and sub-groups of contextual characteristics, core control and assurance activities and food safety performance indicators which had a significantly different impact on the FSMS. Scale of

production and product group were also assessed for their influence on FSMS performance. Means were significantly different when the p-value was equal to or less than 0.05 and Tukey Post-hoc separation of means was performed. Analysis was performed using IBM SPSS Statistical software version 20.

2.3 Results and discussion

The FSMS diagnosis results did not differ significantly with product type ($p>0.05$) except for seriousness of remarks given to nile perch processing plants which scored significantly higher ($p = <0.05$); mean score 2.8 ± 0.5) than those processing frozen octopus (1.8 ± 0.5). There was no significant effect ($p \geq 0.05$) of process scale on performance of FSMS indicators except for the extent verifying people related performance ($p=0.05$), sophistication in translating external requirements into internal FSMS requirements ($p<0.05$) and degree production process changes ($p<0.05$).

2.3.1 Overall Context, FSMS and FS performance

The principle behind FSMS diagnosis is that companies operating in a high risk environment (overall score 3) require an advanced FSMS (overall score 3) to achieve a good FS output (overall score 3). Those operating in a moderate risk context (overall score 2) need an average FSMS (overall score 2) for a good FS output (overall 3) while for those in a low-risk context (overall score 1) even basic FSMS (overall score 1) is adequate for a good FS output (overall score3) (Luning et al., 2008, 2009).

Seventy eight percent (7/9) of the companies had moderate to high risk context (score 2-3) and only one company had adequate overall FSMS (score 2-3) (Table 3). This

company was medium sized, implemented ISO 22000: 2005 and also had adequate number of eight QA personnel (Table 1).

Table 3. Assigned scores for context, Food Safety Management System (FSMS) performance and Food Safety (FS) output for 9 Kenyan Fish companies

[a]Context	[b]FSMS	[c]FS	Companies
2-3	2-3	3	F
2-3	2	3	G
2-3	2	2-3	A, C, H
2-3	2	2	B, E
2	2-3	2-3	I
2	2	2-3	D

[a]Context levels 1 to3 represents low to high-risk levels, [b]FSMS performance levels 1 to 3 represents low to advanced level, [c]FS output 1 to 3 represents poor to good food safety output levels.

The six companies had risk context ranging from moderate to high (score 2-3) but with medium scores in their FSMS (score 2) (Table 3). This situation is insufficient to consistently deal with ambiguity, uncertainty and vulnerability issues in the plants context characteristics (Luning et al., 2008, 2009, 2011a). The overall medium FSMS (score 2) for 67 % of companies was mainly due to unpredictable control and assurance

activities. FSMS activities were partially designed and not modified for the fish sector. They also lacked physical and packaging intervention measures.

A large company had medium overall FSMS (score 2) while a small sized company had medium to high overall FSMS (score 2-3) (Table 3) which resulted in moderate risk context (score 2). They were able to realize a good FS output due to effective overall FSMS able to meet the level of challenge posed by their level of risk context.

Overall FS performance output of companies B and E were moderate (score 2). This was mainly because of several microbiological and hygiene related complaints from customers they registered. It is suggested that they should do proper analysis of activities to get the possible causes of hygiene and pathogen non conformities (Sampers et al., 2010, Luning et al., 2011 and Jacxsens et al., 2010)

Fifty six percent (5/9) of the companies had moderate to good FS performance (score 2-3) while two companies had good FS output performance (score 3) (Table 3). Results from their internal and external assessment of activities were better, especially product sampling and judgment criteria.

2.3.2 Context situation

Product characteristics

When degree of production process changes were considered, large sized companies had significantly lower risk (mean score of 1.7±0.6) than small and medium ones (mean score of 3 for both). Effect on FSMS by risk posed by raw materials, risk associated with product group (fish) and safety contribution by packaging concept was significantly

different ($p < 0.001$). Risk of raw materials (mean score 3) and risk of product groups (mean score 2.7±0.5) posed higher contextual pressure on FSMS than safety contribution by packaging concept (mean score 1.8±0.4) (Table 4). All the companies scored high risk level (score 3) for risk of raw material (Table 4). Fish is associated with high initial microbial levels and pathogens. Microorganisms in fish gut and skins can potentially affect safety of final product. It requires high storage conditions to prevent growth of undesired microorganism and a more advanced control and assurance measures (Luning et al., 2011a). FSMS performance in such products highly depends on reliability and validity of the designed preventive and monitoring of control activities. This is so especially when working with high risk products and processes (Sampers et al., 2010). The condition creates likelihood of microbiological contamination especially in high typical product and process characteristics (Luning et al., 2013).

Table 4. Scores by percentage and means of context factors for nine fish processing plants

Context Factors	Risk level			
	1[a]	2[b]	3[c]	Mean Scores*
Product characteristics				
Risk raw materials	0	0	100	3[b]
Risk product groups	0	33	67	2.7±0.5[b]
Safety contribution packaging concept	22	78	0	1.8±0.4[a]
Process characteristics				
Extent intervention steps	33	44	22	1.9±0.7
Degree production process changes	11	22	67	2.6±0.7
Rate product/process design changes	11	78	11	2±0.5
Organizational characteristics				
Presence of technological staff	0	100	0	2[a]
Variability workforce composition	22	78	0	1.8±0.4[a]
Sufficiency operators' competence	0	100	0	2[a]
Extent of management commitment	0	89	11	2.1±0.3[a]
Degree of employee involvement	0	33	67	2.7±0.5[b]
Level of formalization	0	89	11	2.1±0.3[a]
Sufficiency supporting information systems	0	100	0	2[a]
Chain environmental characteristics				
Degree safety contribution in chain position	0	100	0	2
Extent of power in supplier relationships	0	0	100	3
Degree of authority in customer relationships	0	0	100	3
Severity of stakeholders' requirements	0	100	0	2

[a]Score 1 indicates low risk, [b]Score 2 indicates moderate risk, [c]Score 3 represent high-risk; *Mean scores with similar superscript lower case letter within a column for each group of characteristics were significantly different ($p \leq 0.05$)

Majority of the companies (67 %) scored high (score 3) on product risk. This follows from the fact that fish products have a very high water activity (aw > 0.98) and a

pH>6.5and therefore provides a good medium for microbial growth. They are also sensitive to post contamination and furthermore no antimicrobial agents were used by the companies. This demands high requirements on FSMS and storage conditions (Sospedra et al., 2009, Luning et al., 2011a).

Seventy eight percent of the companies scored moderate (score 2) on risk posed by lack of a packaging concept contributing to safety (Table 4). They used cartons, polybags, waxed boxes and Styrofoam as packages to prevent microbial contaminations. However, these kinds of packages are not dedicated at preventing growth and contamination with microorganisms.

Process characteristics

The process characteristic indicators rate product/ process design changes, degree production process changes and extent intervention steps) had no significant difference ($p>0.05$) in their impact on FSMS (Table 4). Sixty seven percent of the companies had higher risk context levels (score 3) for degree of production process changes. Process in the six companies involved intermittent handling of small products in batches. Continuous flow and automated process is important to prevent cross contaminations and lower risk (Luning et al., 2011a). High degree of automation in product movement restricts people's interference.

Rate of product and process design changes 78 % of the companies was at moderate risk level (score 2) but company B was at high risk level for (score 3) (Table 4). Packaging and process modifications were done in less than 2 years to accommodate their less than five different products from fish. This may lower FSMS performance due to continuous

adaptations (Luning et al., 2011a). Higher rates of changes in process design have negative impact on operation of FSMS performance (Luning et al., 2011a). It is suggested that the companies should lower rates of process and product design changes to have stable performance of FSMS (Luning et al., 2011a).

Organizational characteristics

There was a significant difference between the seven indicators of organizational characteristics on the pressure they put upon the FSMS ($p<0.001$). Degree of employee involvement provided a significantly higher contextual pressure (mean score 2.7±0.5) on FSMS compared to other indicators (Table 4). Sixty seven percent of the scored high risk level (score 3) on degree of employee involvement. Operators were only informed about modifications by production and QA managers. They were not asked to provide ideas or suggestions for FSMS improvement. This may result in less committed and unmotivated operators to lower their productivity (Luning et al., 2011a). Operators should be explicitly involved in design and modifications of safety control systems. They should be encouraged to bring in their knowledge in FSMS improvement. This reduces demands of more instructions, trainings and operator control. It also enhances operators decision making behavior and motivate them for proper task execution to low risk level (Luning and Marcelis, 2009; Luning et al., 2013). Performance of FSMS is greatly reduced by lack of employee's motivation (Garayoa,Vitas, Diez-Leturia, and Garcia-Jalon, 2011).

All the companies had moderate risk (score 2) concerning the presence of technological staff. They had small QA teams and departments. Only three companies had graduates in food safety. The companies engage external experts in research and have external

microbiological analysis. Understaffing in critical quality based areas was prevalent in the industry. Lack of enough QA personnel (Table 1) may contribute to inadequate decision making which might result into underperformance due to lack of right expertise (Luning et al., 2011a). Adequate professional staffing in the field of food safety helps in the realization of low risk levels (Luning et al., 2011a).

All the companies did complex microbiological analysis at external laboratories. Companies with their own analytical laboratories are better able to promptly understand the product composition and dynamic processes which aids enhanced decision making (Luning et al., 2011a).

Seventy eight percent of the companies had moderate (score 2) variability in employee turnover (Table 4) which was within one to five years. They hired temporary operators seasonally to boost their production. Low turnover of employees enable realization of low risk level as it reduces loss of company specific experience and enhances execution of safety tasks (Luning et al., 2011a).

All the nine companies had moderate risk levels (score 2) for sufficiency of operator competence. They required minimal experience on operators and operators had no basic food safety training. Lack of ability to institutionalize robust procedures and operator control has been found to increase chance of poor execution of food safety tasks (Osimani et al., 2011; Luning et al., 2011a). To realize lower risk level operators should have high and specific requirements with broad experience in food safety. This should be combined with specific language skills to reduce uncertainty in solving problems due to

adequate information that improves decision making (Oses et al., 2012, Seaman and Eves, 2010).

Eighty nine percent of the companies operated at moderate risk level (score 2) in the extent of management commitment. They had a general written vision statement on safety. The companies' official QA department had regular meetings on food safety though they worked on a restricted budget. However, a small sized company which was ISO 22000 certified had high context risk (score 3) on extent of management commitment. This company did not have a written vision statement on safety. It lacked specific budget for QA department. Meetings on safety control were only held in cases of safety problems. A previous study showed that managers in small organizations tend to talk to people directly. They do not implement rules, procedures and structures to control people's behavior on safety as done in larger organizations (Luning and Marcelis, 2007, 2009).

Low levels of management commitment may shift employees' attention to other issues which may increase chances of poor operation of FS activities. The situation can negatively affect performance by putting demands on FSMS (Sampers et al., 2012). It is recommended to train managers to improve their knowledge and commitment on their roles (Luning et al., 2011a).

Inclusion of a detailed written vision statement on fish safety in conjunction with clear and measurable objectives would further improve management commitment. An official quality management team with formalized meetings and own budget is also necessary for good administrative conditions. This is expected to favor appropriate decision making processes and lower risk levels (Luning et al., 2011a).

Eighty nine percent of the companies scored moderate risk level (score 2) in their formalization of procedures and meetings (Table 4). The procedures were restricted to crucial processes typically related to FSMS. Meetings were held regularly with no structured documentation of minutes. Low risk levels on formalization of procedures and meetings can be realized when companies describe their activities in standard operating procedures (SOP). They should also formalize meetings for all issues and document minutes (Luning and Marcelis, 2009, Luning et al., 2011a).

All the companies operated at moderate risk level (score 2) in their supporting information systems. They used production information system which was not specific for QA purposes towards making food safety control decisions. Their system was only accessible to authorized people. This may affect availability of accurate information for safety tasks (Luning et al., 2011a). Accessibility of Quality Information Management (QIM) system to all personnel would enable further lowering of risk levels resulting from insufficient support of information to a score of one. This facilitates timely retrieval of information for execution of food safety tasks (Luning et al., 2011a) and appropriate decision making in food safety measures (McMeekin et al., 2006). It also puts fewer requirements on verification activities (Luning et al., 2009).

Chain environmental characteristics

The four chain environment characteristics did not differ significantly in their impact on FSMS ($p>0.05$). Extent of power in supplier relationships and degree of authority in customer relationships however exacted high contextual pressure on FSMS (mean score 3 for both) whereas degree of safety contribution in chain position and severity of stakeholders' requirements provided moderate risk (mean score 2) (Table 4). All the

companies scored moderate risk level (score 2) on the final safety contribution in chain. They prevented growth of pathogens through cold chain maintenance. Consumers were required to contribute to the final reduction of pathogens to acceptable level before consumption through proper and adequate fish preparation. A previous study similarly showed that the fish sector is still characterized by low levels of value addition. Most exports are in the form of block frozen bulk packs of semi processed filets (Henson and Mitullah, 2004).

All companies indicated high risk levels (score 3) on the extent of power in supplier relationships. They had no influence on product specifications and FSMS of their major suppliers. The companies only checked specifications and measured quality parameters of raw materials. A number of processors have similarly only supplied fishing equipment to fishermen through agents in an effort to establish sole supplier relations. In such situations, there is lack of formal written contract on price, size and quality characteristics (Henson and Mitullah, 2004). This lack of power in supplier relationship by all the companies meant that they had less influence on their FSMS. This may result in unpredictable safety levels of incoming materials. Involvement of the companies in development of product specifications of major suppliers is important. This could be done by auditing suppliers FSMS to reduce food safety problems (Luning et al., 2011a, 2011b, Oses et al., 2012).

All the companies scored high risk levels (score 3) for the degree of authority in customer relationships (Table 4). They had no ability to determine the nature of their customer's FSMS and product usage which may result in unpredictable use. They were also presented with different conflicting customer requirements of fish handling and quality

levels. To lower the risk levels on customer relationships, it is suggested that the companies have an advisory input on theuse of product by major critical customers. Companies should also audit customer FSMS so as to mutually ensure authority over and predictability in the safe usage of products (Luning et al., 2011a). A high risk situation for supplier and customer relations especially in terms of unpredictability requires more systematic and advanced control of supplied raw materials and final products (Sampers et al., 2012).

All companies had moderate context risk level (score 2) on the severity of requirements by stakeholders. They had additional QA requirements (Kenya fisheries act cap 378, HACCP, PRPs, and ISO standards 9000, 9001, 22000: 2005) in addition to E.U 91/493/EEC and 98/83/EEC which were similar for major stakeholders. Strict and different FSMS requirements set by stakeholders put demands for advanced FSMS. It is recommended that companies should adopt general legislative requirements on food safety (PRP and HACCP) according to Codex Alimentarius. This enables for focused decision making processes that prevent conflicting interests and undesirable risk behavior to (Luning et al., 2011a).

2.3.3 Food safety management systems (FSMS) activities

2.3.3.1 Core control activities

Design of preventive measures

The six indicators had significantly different ($p<0.001$) effect on performance of control activities in the FSMS. Adequacy of cooling facilities (mean score 3), extent of personal hygiene requirements (mean score 2.8±0.4) and specificity of product specific preventive

measures (mean score 2.8±0.4), performed significantly better than specificity of sanitation program (mean score 2.6±0.5) and adequacy of raw material control which were rated moderate (2.4±0.5 respectively). However, sophistication in hygienic design of equipment and facilities was rated significantly poorest (mean score 2.1±0.3) (Table 5).

Sophistication of hygienic design for equipment and facilities for 89 % of the companies was at medium FSMS level (score 2) (Table 5). Large sized companies had significantly lower performance ($p<0.05$, mean score 2) than small sized (mean score 2) and medium sized ones (mean score 2.7±0.6) on sophistication in translating external requirements into internal FSMS. Equipment and facilities were hygienically designed by suppliers according to Kenya Bureau of Standards (KEBS) requirements. They however lacked adaptation and testing according to the individual companies specific fish production circumstances. Company equipment and facilities hygiene design need to be modified for specific fish production characteristics in collaboration with equipment and cleaning suppliers. They should also adopt integrated hygienic designs in order to realize low risk levels (Aarnisalo et al., 2006). Integrated hygienic design of equipment and facilities decreases chance of cross contamination (Luning et al., 2008).

Table 5. Scores by percentage and means of control activities and core assurance activities for nine fish companies

FSMS activities	Performance level 0[a]	1[b]	2[c]	3[d]	Mean Scores
Core control activities					
Design preventive measures					
Sophistication hygienic design equipment and facilities	0	0	89	11	2.1±0.3[a]
Adequacy cooling facilities	0	0	0	100	3[c]
Specificity sanitation program	0	0	44	56	2.6±0.5[ab]
Extent personal hygiene requirements	0	0	22	78	2.8±0.4[c]
Adequacy raw material control	0	0	56	44	2.4±0.5[ab]
Specificity product specific preventive measures	0	0	22	78	2.8±0.4[c]
Design intervention processes					
Adequacy physical intervention equipment	100	0	0	0	0[a]
Adequacy packaging intervention equipment	100	0	0	0	0[a]
Specificity maintenance/calibration programs intervention equipment	100	0	0	0	0[a]
Specificity of intervention methods	0	0	44	56	2.6±0.5[b]
Design monitoring system					
Appropriateness CCP analysis	0	11	44	44	2.3±0.7
Appropriateness standards and tolerances design	0	0	44	56	2.6±0.5
Adequacy analytical methods to assess pathogen levels	0	0	22	78	2.8±0.4
Adequacy measuring equipment to monitor process/product	0	0	44	56	2.6±0.5
Specificity calibration/verification program measuring and analytical equipment	0	0	56	44	2.4±0.5
Specificity sampling design and measuring plan	0	0	89	11	2.1±0.3
Extent corrective actions	0	0	22	78	2.8±0.4
Operation control strategies					
Actual availability of procedures	0	0	67	33	2.3±0.5 [b]
Actual compliance to procedures	0	0	33	67	2.7±0.5[b]
Actual hygienic performance equipment and facilities	0	0	11	89	2.9±0.3[b]
Actual cooling capacity	0	0	11	89	2.9[b]

Actual process capability physical intervention equipment	100	0	0	0	0[a]
Actual process capability of packaging intervention equipment	100	0	0	0	0[a]
Actual measuring equipment performance	0	22	11	56	2.1±1.2[b]
Actual analytical equipment performance	11	0	11	78	2.6±1[b]
Core assurance activities					
Defining system requirements					
Sophistication translating external requirements into internal FSMS requirements	0	0	44	56	2.6±0.5
Extent systematic use of feedback information to improve FSMS	0	0	22	78	2.8±0.4
Validation					
Sophistication validating preventive equipment and facilities, sanitation and personal hygiene programs	0	0	67	33	2.3±0.5
Sophistication validating effectiveness intervention equipment and methods	0	0	56	44	2.4±0.5
Sophistication of validating monitoring systems	0	11	56	33	2.2±0.7
Verification					
Extent verifying people related performance	11	0	33	56	2.3±1
Extent verifying equipment and methods related performance	0	0	33	67	2.7±0.5
Documentation and record-keeping					
Appropriateness documentation system	0	0	89	11	2.1±0.3
Appropriateness record-keeping system	0	0	100	0	2

[a]Score 0 – absent/not performed, [b]Score 1 - low, [c]Score 2 - average, [d]Score 3 – advanced/high level; *Mean scores with similar superscript lower case letter within a column for each group of characteristics were significantly different ($p \leq 0.05$)

All the companies were at an advanced level (score 3) in the adequacy of their cooling facilities (Table 5). Their cooling facilities were specifically modified for their specific fish production circumstances. They were tested by temperature check of products for different process and storage stages. The aim was to maintain strict temperature conditions and prevent growth of microorganisms.

Specificity of sanitation program for 56 % of the companies was at advanced level (score 3) (Table 5). The companies had complete sanitation programs tailored for different equipment and facilities which enhances their sanitation effectiveness (Luning et al., 2008). Cleaning agents should be specifically modified and tested on their effectiveness for specific product production systems. Similarly they should have instructions on use and frequency based on test results to better prevent contamination (Luning et al., 2008).

Majority of companies (78 %) had advanced level (score 3) extent of personal hygiene requirements (Table 5). They had high and specific requirements for handling and storage conditions of clothing for all food operators. Personal care and health facilities were also tailored to support personal hygiene. Such specific training on hygiene matters assist in the reduction of chance of contamination (Luning et al., 2008; Nel et al., 2004).

Fifty six percent of the companies performed at medium level (score 2) in their adequacy of raw material control (Table 5). The procedures were systematic and based on E.U. HACCP and legislative guidelines only. Use of statistical underpinned acceptance sampling in addition to guidance documents for fish sector will enable companies these companies improve their raw material control. They should also use clearly defined sampling frequency, location, analysis and rejection criteria based on actual historical

data of suppliers (Duarte and Saraiva, 2008). Clearly defined sampling frequency based on actual historical data of suppliers enhances realization of more predictable good safety outcome due to less ambiguity and uncertainty (Luning et al., 2008).

Product specific preventive measures for 78 % of the companies was at an advanced level (score 3) (Table 5). The measures were based on legislative requirement documents and tested for specific fish production circumstances. The aim was to prevent entry, growth and cross contamination of pathogens for efficiency and effectiveness of FSMS (Luning et al., 2008).

Design of intervention processes

Physical intervention equipment, packaging intervention equipment, and specificity in maintenance of calibration programs and intervention equipment were significantly poorly rated ($p \leq 0.05$; mean score 0 for each) compared to specificity of intervention methods (mean score 2.6±0.5) (Table 5). Physical intervention equipment was absent (score 0) in all the companies (Table 5). The companies had only sterilizers for utensils meant for filleting and cutting the fish. Intervention equipment aid in process predictability through improved compliance to standards (Luning et al., 2008).

Packaging intervention equipment were absent (score 0) in all the companies (Table 5). The companies manually packaged the products using cardboard boxes, poly bags and Styrofoam. These packages are not meant to reduce nor inactivate pathogens. In order for companies to improve to advance level (score 3), they should have packaging intervention equipment designed and adapted specifically for fish (Luning et al., 2008). Such intervention equipment should be well maintained and process documented. This

supports realization of stability and predictability of production outcomes (Luning et al., 2008).

Fifty six percent of the companies were advanced (score 3) in their specificity of chemical and biological methods of intervention (Table 5). The methods were modified for specific fish production system characteristics. The actual effective levels were known from the internal test that was conducted and there was proper documentation. Specific intervention lower contamination load of raw materials and enhance food safety performance (Luning et al., 2008).

Design of monitoring system

All the performance indicators for design of monitoring system showed no significant difference ($p \geq 0.05$) (Table 5). More than half of the companies (56 %) ranged between basic (score 1) and average I (score 2) in the appropriateness of critical control points (CCP) analysis. Hazard identification, risk analysis and allocation of CCPs for four companies were based on general hygiene codes and were implemented by consultants working according to Codex guidelines. They also determined their CCPs by microbial product tests. For the companies to improve to advanced (score 3) level in their critical control points (CCP) analysis, they should include scientific literature, own knowledge and experience in addition to microbial product tests and modeling of hazard behavior. This is expected to result in more reliable and accurate control points (Luning et al., 2008)**.**

Appropriateness of standards and tolerances design for 56 % of the companies was at advance level (score 3). They had clearly specified standards and tolerances derived from

legal requirements, hygiene codes, literature and tests. Standards and tolerances design for these companies was tailored for their own production system with design specifically done for critical process and product parameters.

Adequacy of analytical methods for assessing pathogen levels was at advance level (score 3) for 67 % of companies (Table 5). They used ISO standards which are more sensitive, specific and reproducible. ISO standards are fast, internationally validated and accredited methods. This is suggested to provide adequate determination of pathogens (Luning et al., 2008).

Measuring equipment of 56 % of the companies were at advanced level (score 3). They specifically selected equipment that are adapted to their specific fish production process and tested on accuracy. The equipment had in line measurement and automated for immediate response and visual information history. This is expected to monitor critical process and product parameters well (Luning et al., 2008).

Calibration program for measuring and analytical equipment for 56 % of the companies was medium rated (score 2). They were outsourced at equipment suppliers and even though the task and frequency were based on international standards the calibration programs were not specific for fish production. Advance level (score 3) calibration programs are specifically designed based on data from own fish production system and according to international standards where tasks and frequency should be clear, documented and kept in house for a reliable test data (Luning et al.2008).

Sampling design for microbial assessment and measuring plan was at medium level (score 2) for all except one company. The designs were based on common sampling plans

for the fish sector as available in literature. Microbial assessment and measuring plan should be based on statistical analysis of pathogen distribution in own fish production process. This increases reliability of information on actual product and process status (Luning et al., 2008).

Extent of corrective actions for 78 % of the companies was advance (score 3). The actions were based on systematic causal analysis of own product and process deviations. There was also complete descriptions of process adjustments and handling of noncompliant products. Structured analysis of causes of deviations and their corrective actions was also present.

Operation of food safety control activities

The eight indicators representing operation of food safety control activities had a significantly different influence on performance of control activities of the fish industry FSMS ($p<0.001$). Indicators that had significant good performance included actual availability of procedures (mean score 2.9), actual cooling capacity (mean score 2.7±0.5), actual hygienic performance of equipments and facilities (mean score 2.9±0.3) and actual compliance to procedures (mean score 2.3±0.5). Indicators which had significantly moderate performance included actual analytical equipment performance ($p\leq0.05$; mean score 2.6±1) and actual measuring equipment performance (mean score 2.1±1.2). However, actual process capability of both physical and packaging intervention equipment demonstrated a significantly poor performance (mean score 0) (Table 5).

Actual availability of procedures for 56 % of the companies was rated average (score 2) (Table 5). Paper based procedures were available at various locations but were updated

when need arises. It is recommended that, the procedures be easily available (e.g. digitized), designed for specific users and updated on a regular basis. This enhances peoples' decision making behavior (Luning et al., 2008).

Sixty seven percent of the companies had advance level (score 3) compliance to procedures. All operators were aware of the existence and content of procedures and consciously following them. Furthermore, safety tasks were internalized and employees' exercised self-control on compliance to procedures. Internalized procedures support appropriate decision making process, reduces variation and helps to achieve safety and quality objectives (Luning and Marcelis, 2006a, 2006b, 2007).

Actual hygienic performance of equipment and facilities all of companies except one was at advance level (score 3). They had stable and well noticed hygienic performance of equipment and facilities. Hygiene performance tests were conducted regularly according to KEBS. This is expected to better control cross contamination (Luning et al., 2008).

Actual cooling capacity of 89 % of the companies was at advanced scored (score 3). They had stable performance of cooling facilities. The environmental temperature of cooling facilities was automatically monitored and deviations systematically analyzed. The aim was to provide constant low product temperatures. This ensures that few variations are attained and well noticed to reduce pathogens growth (Luning et al., 2008).

Five companies scored advanced (score 3) on actual performance of measuring equipments (Table 5). The equipments were highly stable under all different production circumstances. Equipment stability gives more reliable information on product and process status and positively contributes to food safety (Luning et al., 2008).

Seventy eight percent of the companies had advanced level (score 3) analytical equipment performance. Most analysis was conducted by KEBS accredited laboratories. The results were highly stable under different product compositions and analytical circumstances. This is expected to provide reliable information about contamination levels (Luning et al., 2008).

2.3.3.2 Food safety assurance activities

Defining system requirements

There was no significance difference (($p \geq 0.05$) between the influence of translation of external stakeholder requirements into internal FSMS requirements and the extent of systematic use of feedback information to improve FSMS in their effect on definition of system requirements by the companies (Table 5). Fifty six percent of the companies had advance level performance (score 3) concerning translation of stakeholder requirements (Table 5). The companies proactively translated external assurance requirements. These were done after systematic analysis of possible changes in stakeholder requirements such as new legislation. Stakeholder requirements were also evaluated based on critical aspects of own fish production system and documented.

Majority of the companies (78 %) were at an advanced (score 3) level in the extent of systematic use of feedback information to improve FSMS. Systematic analysis of information were done from validation and verification reports and translated into sound FSMS. There were clear procedures for modifications and assigned responsibilities which were well documented.

Validation

There was no significance difference ($p>0.05$) in how the three validation activities influence performance of assurance activities in the fish industries (Table 5). Sophistication of validating preventive equipment and facilities, sanitation and personal hygiene programs was medium level (score 2) in majority of the companies (67 %) (Table 5). The programmes were based on expert knowledge (i.e. consultancy), regulatory documents and historical results. The activities were done on regular basis usually after system modifications. Findings were then described in reports. To improve this situation, the measures should be based on specific scientific sources, historical results and own experimental trials by independent experts (Luning et al., 2009).

Validation of intervention equipment and methods was medium (score 2) in 56 % of the companies. The activities were based on opinion of consultants, regulatory documents and historical results. Validation was also done on regular basis after system modifications and findings described in reports. To attain advance systematic validation, the procedures should be conducted by independent experts, be based on specific scientific sources, historical results and own experimental trials. This should be conducted on regular basis and after system modifications. Activities and results should also be well documented (Luning et al., 2009).

Fifty six percent of the companies performed at medium level (score 2) in their validation of monitoring systems. Validation was based on comparison with regulatory documents, specific hygiene codes and external expert advice. This was done on regular basis and findings described in expert report. For companies A, B, C, D and H to attain advance

level in validation of monitoring systems, they need procedures that are based on scientific sources and expert's data. Activities and results should also be well documented (Luning et al., 2009). Scientific validation studies tools such as microbiological challenge testing, storage testing, and predictive modeling has also been suggested to give information of what happens during food processing, distribution and handling (CAC, 2008). More scientific evidence based systematic and independent validation is suggested to enhance monitoring activities of the companies (Sampers et al., 2012).

Verification

Large and small sized companies had significantly lower extent of verifying people related performance of ($p<0.05$; mean score 2.3 and 2.6 respectively), than medium sized companies (mean score 3). There was no significance difference ($p> 0.05$) in the extent of verifying people related performance (mean score 2.3±1) and extent of verifying equipment and methods related performance (mean score 2.7±0.5) in their influence on performance of verification activities (Table 5). Fifty six percent of the companies had advance level (score 3) verification of people related performance procedures and compliance to procedures. They analyzed their procedures, records and observations by independent experts on defined frequency. Activities were also documented and reports made. Better verification and compliance to people related performance procedures enhances reliability of an FSMS (Luning et al., 2009).

Sixty seven percent of the companies had advanced level (score 3) verification of equipment and method related performance. Performances were confirmed by actual tests

(microbial) done by independent experts. Verification activities had defined frequency especially after system modifications. The findings were reported and activities well documented.

Documentation and record-keeping

There was no significant difference ($p \geq 0.05$) in the influence of appropriateness of documentation system (mean score 2.1±0.3) and the record-keeping system (mean score 2) on documentation and record keeping (Table 5). Documentation system for 89 % of the companies was medium (score 2) (Table 5). They were structured, decentralized and updated. System was partially automated and access to external sources was not formalized i.e. used individual contacts. Advanced documentation systems which are structured, updated, centrally organized and with responsibilities assigned to individuals are required for optimum system in these companies. Documents also need to be automated for all to access. This is expected to improve effective information supply and support validation and verification activities (Luning et al., 2009). Better documentation supports food processors to ensure safety of products for sale (Cullor, 1997; Stefan, 1997) and can help in the validation of FSMS (Ilyukhin et al., 2001).

Record keeping system for all the processors was at medium level (score 2). The companies had full registration of critical product and process data in separated systems but not integrated. Accessibility to records was also through specific authorized personnel. Central integrated systems which are available on line and accessible to all persons support validation and verification activities better in addition to full registration of critical product and process data (Luning et al., 2009).

Assurance activities are highly long term based (Sporleder and Goldsmith, 2001). Companies consider them as difficult to implement and time consuming (Jacxsens et al., 2011). However, it should be a company objective to enforce a sustainable FSMS as validation, verification, sampling plans and documentation are critical in ensuring food safety (Luning et al., 2009; Taylor and Kane, 2005).

2.3.4 Food Safety performance activities

External assessment

There was no significance difference ($p \geq 0.05$) between the four external assessment indicators in their influence on food safety performance (Table 6). Sixty seven percent of the companies had a good FS performance (score 3) (Table 6). Audits and inspections of the FSMS of the companies were performed by several accredited third parties (i.e. KEBS, SGS and ministry of fisheries inspectors). This is expected to give an external and independent evaluation of the implemented FSMS (Jacxsens et al., 2010).

Table 6. Scores by percentage and means of food safety output indicators for nine fish processing companies

Food Safety performance activities	Performance level				
	0[a]	**1[b]**	**2[c]**	**3[d]**	**Mean Scores**
External assessment					
FSMS Evaluation	0	11	22	67	2.6±0.7
Seriousness of remarks	0	11	44	44	2.3±0.7
Microbiological food safety complaints	0	11	33	56	2.4±0.7
Hygiene complaints by customers	0	11	33	56	2.4±0.7
Internal assessment					
Product sampling	0	0	11	89	2.9±0.3
Judgment criteria	0	11	0	89	2.8±0.7
Hygiene and pathogen non conformities	0	0	44	56	2.6±0.5

[a]Score 0, indicates not applied, [b]Score1, indicates poor, [c]Score 2, indicates moderate, [d]Score 3, indicates good level; *Mean scores with similar superscript lower case letter were significantly different ($p \leq 0.05$).

Seriousness of remarks on FSMS evaluation for more than half (56 %) of the companies ranged from poor to moderate. Major and minor remarks were made on their various and specific aspect of FSMS especially hand hygiene, cleaning and disinfection. The situation meant that all requirements of the stakeholders could not be met adequately (Jacxsens et al., 2010). The low microbiological food safety complaints for fifty six percent of the companies contributed to the good FS performance (score 3). The companies had not recorded any microbiological related food safety complaints. Microbiological related complaints indicate multiple problems in the functioning of the FSMS. A good food safety output was therefore expected from the companies (Jacxsens et al., 2010).

Fifty six percent of the companies had good FS performance (score 3) concerning hygiene complaints by customers. There were no complaints regarding microbiological

hygiene indicators by customers. This is an indicator of a well functioning FSMS expected to give a good FS output (Jacxsens et al., 2010).

Internal assessment

There was no significant difference ($p \geq 0.05$) between the performance of product sampling criteria, judgment criteria and, hygiene and pathogen non conformities in their effect on external assessment results on food safety (Table 6). All except one of the companies showed a good performing FS output (score 3) on product sampling aimed at confirmation of microbiological performance (Table 6). They had structured sampling involving fixed frequency and own company sampling plan. Samples were taken from final food product, raw material and environmental samples. Documented sampling plan supports reliability of FSMS due to comprehensive and accuracy in actual microbiological performance (Jacxsens et al., 2010).

There was a good performance (score 3) in judgment criteria used to interpret microbiological results for 89 % of the companies (Table 6). They used combination of legal criteria requirements of Kenya fisheries act cap 378, EU specifications (EC No 2073/2005) and company specifications established by internal guidelines mostly for surfaces swabs. This is suggested to enhance accuracy of microbiological performance indicators of the companies' FSMS (Jacxsens et al., 2010).

Fifty six percent of the companies had good hygiene and low pathogen non conformities output (score 3). No cases regarding microbiological food safety and hygiene indicators non conformities had been reported. This indicated a well functioning FSMS therefore a good FS performance output is expected (Jacxsens et al., 2010).

2.4. Conclusion

Majority of the companies operated under moderate to high risk context environment. Most of them had moderate FSMS except one company which had moderate to advance overall FSMS. The FSMS of majority of the companies in the fish sector were therefore incapable of consistently handling risky context characteristics. Context characteristics diagnosis indicated that all the fish processors work with high risk raw fish products which requires advance levels of FSMS. All of them also scored higher risk posed by inadequate power in relationships with suppliers and customers since they did not have influence on supplier's production activities and usage of products by their customers. This could lead to unpredictable safety level of incoming raw materials and in the conditions of end products usage. High contextual pressure was noted in the performance of the traceability system in majority of the companies. It is suggested that the companies may need more information collection points, more detailed information, more data processing, and a structured collection of samples (Mgonja and Kussaga, 2012).

All the companies had adequate cooling facilities which is a core control activity aimed at maintainance of the cold chain. However, all of them did not implement any physical or packaging intervention method. External assessment of food safety performance activities like FSMS evaluation, complaints on hygiene and microbiological problems indicated good performance for majority of the companies. However, majority of the companies had poor to moderate performance in the seriousness for safety of remarks they received. However, auditing results indicated some minor and major remarks on various FSMS activities. For the companies to improve their FSMS to higher level, it is suggested that they use scientifically underpinned processes in preventive, intervention and monitoring

systems in order to enhance predictability. They should also set their system requirements, evaluate their performance and organize necessary changes for effective and reliable FSMS.

REFERENCES

Aarnisalo, K., Tallavaara, K., Wirtanen, G., Maijala, R., & Raaska, L. (2006). The hygienic working practices of maintenance personnel and equipment hygiene in the Finnish food industry. *Food Control*, 17(2), 1001–1011.

Ababouch, L. (2006). Assuring fish safety and quality in international fish trade. *Marine Pollution Bulletin*, 53(10-12), 561–568.

Abila, R. O. (2003). *Food safety in food security and food trade case study: Kenyan fish exports* (International Food Policy Research Institute**,** Focus 10, Brief 8 of 17). Retrieved September 6, 2012, from www.ifpri.org/publication/food-safety-food-security-and-food-trade

Block, C., Van Gerven, T., & Vandecasteele, C. (2007). Industry and energy sectors in Flanders: environmental performance and response indicators. *Clean Technologies and Environmental Policy*, 9(4), 43–51.

Cullor, J. S. (1997). HACCP (Hazard Analysis Critical Control Points): is it coming to the dairy? *Journal of Dairy Science*, 80(12), 3449-3452.

Doherty, M. (2010). *The importance of sanitary and phytosanitary measures to fisheries negotiations in economic partnership agreements* (Series on Fisheries, Trade and Sustainable Development, Issue Paper No. 7). Retrieved October 7, 2012, from http:// www.ictsd.org

Duarte, B. P. M., & Saraiva, P. M. (2008). An optimization-based approach for designing attribute acceptance sampling plans. *International Journal of Quality and Reliability Management,* 25(8), 824-841.

European Commission (1998). *Final report on a mission to Kenya: fisheries products* (23 to 27 November 1998). Retrieved November 5, 2012, from http://ec.europa.eu/food/fvo/annualreports/vi_pol02_en.pdf

European Commission. (2003). *Final report on a mission carried out in Kenya 14 to 22 March 2002 carried out to assess the conditions of production of fisheries products* (Council Directive 91/493/EEC and the verification of the measures on pesticides in fish. European Commission, Brussels). Retrieved November 6, 2012, from http://*ec.europa.eu/food/fs/.../reports/kenya/vi_rep_keny_8586-2002_en.pdf*

Food and Agriculture Organization of the United Nations/World Health Organization. (2004). *Strengthening official food safety control services (Paper presented at the second FAO/WHO global forum of food safety regulators, Bangkok, Thailand*. Retrieved January 2, 2013, from http://ftp://ftp.fao.org/docrep/fao/meeting/008/y5871e/y5871e00.pdf

Garayoa, R., Vitas, A. I., Diez-Leturia, M., & Garcia-Jalon, I. (2011). Food safety and the contract catering companies: food handlers, facilities and HACCP evaluation. *Food Control*, 22(12), 2006-2012.

Henson, S., & Mitullah, W. (2004). *Kenyan exports of nile perch: the impact of food safety on an export-oriented supply chain* (World Bank Policy Research Working

Paper 3349). Retrieved January 2, 2013, from http://elibrary.worldbank.org/docserver/download/3349.pdf

Ilyukhin, S. V., Haley, T. A., & Singh, R. K. (2001). A survey of control system validation practices in the food industry. *Food Control*, 12(5), 297–304.

ISO 22000: 2005. (2005). *Food safety management systems – requirements for any organization in the food chain*. Retrieved October 3, 2012, from http://www.iso.org/iso

ISO 9000. (2008). *Quality management systems -fundamentals and vocabulary*. Retrieved October 3, 2012, from http://www.iso.org/iso

Jacxsens, L., Kussaga, J., Luning, P. A., Van der Spiegel, M., Devlieghere, F., & Uyttendaele, M. (2009b). A microbial assessment scheme to support microbial performance measurements of food safety management systems. *International Journal of Food Microbiology*, 134(1-2), 113–125.

Jacxsens, L., Luning, P. A., Marcelis, W. J., Van Boekel, T., Rovira, J., Oses, S., Kousta, M., Drosinos, E., Jasson, V., & Uyttendaele, M. (2011). Tools for the performance assessment and improvement of food safety management systems. *Trends in Food Science & Technology*, 22(1), S80–S89.

Jacxsens, L., Uyttendaele, M., Devlieghere, F., Rovira, J., Oses Gomez, S., & Luning, P. A. (2010). Food safety performance indicators to benchmark food safety output of food safety management systems. *International Journal Food Microbiology*, 141(Suppl 1), S180-S187.

Luning, P. A., & Marcelis, W. J. (2006a). A techno-managerial approach to food quality management. *Trends in Food Science and Technology*, 17(7), 378–385.

Luning, P. A., & Marcelis, W. J. (2007). A conceptual model of food quality management functions based on a techno-managerial approach. *Trends in Food Science and Technology*, 18(3), 159-166.

Luning, P. A., & Marcelis, W. J. (2009). *Food Quality Management; technological and managerial principles and practices*. Wageningen: Wageningen Academic Publishers. ISBN: 987-90-8686-116-3.

Luning, P. A., Bango, L., Kussaga, J., Rovira, J., & Marcelis, W. J. (2008). Comprehensive analysis and differentiated assessment of food safety control systems: a diagnostic instrument. *Trends in Food Science and Technology*, 19(10), 522–534.

Luning, P. A., Chinchilla, A. C., Jacxsens, L., Kirezieva, K., & Rovira, J. (2013). Performance of safety management systems in Spanish food service establishments in view of their context characteristics. *Food Control*, 30(1), 331-340.

Luning, P. A., Jacxsens, L., Rovira, J., Osés, S. M., Uyttendaele, M., & Marcelis, W. J. (2011b). A concurrent diagnosis of microbiological food safety output and food safety management system performance: cases from meat processing industries. *Food Control*, 22(3-4), 555–565.

Luning, P. A., Marcelis, W. J., and van der Spiegel, M. (2006b). *Quality assurance systems and food safety*. In: Luning, P. A., Devlieghere, F., and Verhé, R. (Hg.): Safety in the agri-food chain. 1. Aufl. . Wageningen: Wageningen Academic Publisher: 249–301.

Luning, P. A., Marcelis, W. J., Rovira, J., Van der Spiegel, M., Uyttendaele, M., & Jacxsens, L. (2009). Systematic assessment of core assurance activities in a company specific food safety management system. *Trends in Food Science and Technology*, 20(6), 300–312.

Luning, P. A., Marcelis, W. J., van Boekel, M. A., Rovira, J., Uyttendaele, M., & Jacxsens, L. (2011a). Diagnostic tool to analyze riskiness of context factors which impact food safety management system performance. *Trends in Food Science and Technology*, 22(1), S67-S79.

McMeekin, T. A., Baranyi, J., Bowman, J., Dalgaard, P., Kirk, M., & Ross, T. (2006). Information systems in food safety management. *International Journal of Food Microbiology*, 112(3), 181-194.

Mgonja, J. T., & Kussaga, J. B. (2012). Evaluation of traceability systems in fish supply chains: A case study of Tanzania. *Pakistan. Journal of food science*, 22(3), 133 - 142.

Montville, R., Chen, Y., & Schaffner, D.W. (2001). Determination of bacterial cross-contamination rates from hand to food through a glove barrier. *Journal of Food Protection*, 64(6), 845-849.

Nel, S., Lues, J. F. R., Buys, E. M., & Venter, P. (2004). The personal and general hygiene practices in the deboning room of a high throughput red meat abattoir. *Food Control*, 15(7), 571–578.

Osés, S. M., Luning, P. A., Jacxsens, L., Santillanab, S., Jaimea, I., & Rovira, J. (2012). Food safety management system performance in the lamb chain. *Food Control*, 25(2), 493–500.

Osimani, A., Aquilanti, L., Babini, V., Tavoletti, S., & Clementi, F. (2011). An eight-year report on the implementation of HACCP in a university canteen: impact on the microbiological quality of meals. *International Journal of Environmental Health Research*, 21(2), 120-132.

Ponte, S., & Gibbon, P. (2005). 'Quality standards, conventions and the governance of global value chains.' *Economy and Society*, 34(1), 1-31.

Rahman, M. (2001). EU ban on shrimp imports from Bangladesh: a case study on market access problems faced by the LDCs**.** *CUTS Centre for International Trade*, Dialog, Bangladesh, 2001. Retrieved January 20, 2012, from *www.cuts.org/sps-analysis-sps_case_bdesh.htm*>

Sampers, I., Jacxsens, L., Luning, P. A., Marcelis, W. J., Dumoulin, A., & Uyttendaele, M. (2010). Performance of food safety management systems in poultry meat preparation processing plants in relation to the Campylobacter ssp.contamination. *Journal of Food Protection*, 73(8), 1447-1457.

Sampers, I., Toyofuku, H., Luning, P. A., Uyttendaele, M., & Jacxsens, L. (2012). Semi-quantitative study to evaluate the performance of a HACCP-based food safety management system in Japanese milk processing plants. *Food Control*, 23(1), 227-233.

Seaman, P., & Eves, A. (2010). Perceptions of hygiene training amongst food handlers, managers and training providers-A qualitative study. *Food Control*, 21(7), 1037-1041.

Sospedra, I., Rubert, J. V., Soler, C., Soriano, J. M., & Manes, J. (2009). Microbial contamination of milk and dairy products from restaurants in Spain. *Food borne Pathogens and Diseases*, 6(10), 1267-1272.

Sporleder, T. L., & Goldsmith, P. D. (2001). Alternative firm strategies for signaling quality in the food system. *Canadian Journal of Agricultural Economics*, 49(4), 591-604.

Stefan, G. (1997). Food safety issues affecting the dairy beef industry. *Journal of Dairy Science*, 80(12), 3458-3462.

Taylor, E., & Kane, K. (2005). Reducing the burden of HACCP on SMEs. *Food Control*, 16(10), 833-839.

Unnevehr, L. (2000). "Food Safety Issues and Fresh Food Product Exports from LDCs." *Agricultural Economics*, 23(3), 231–240.

World bank. (2005). *Food Safety and Agricultural Health Standards: Challenges and Opportunities for Developing Country Exports* (Report No. 31207). World bank

Policy Research Working Paper series. Retrieved August 26, 2012, from http://www.worldbank.org/trade/standards

CHAPTER THREE

Title: Semi quantitative analysis of microbiological effectiveness of core control and assurance activities in fish processing plants in Kenya

Abstract

Although fish business operators worldwide implement several food safety management systems (FSMS), fish processing plants still face microbial food safety related product rejections and the associated economic losses. This study aimed to assess the microbial performance of core control and assurance activities implemented by the fish processors, identify their weaknesses and offer suggestions for their improvements using a case study. Nine Kenyan fish processing plants were selected randomly for this study. A microbiological assessment scheme tool was used to systematically analyze microbial counts of selected critical sampling locations in nine Kenyan fish processing plants. Nine small, medium and large sized companies with certified FSMS (HACCP, PRP, ISO standards, E.U and Government regulation) were studied three times in four months and total of 324 samples were taken. A total of six critical sampling locations were selected and microbial parameters analysed including *Salmonella* spp (food safety indicator), *Escherichia coli* (hygiene indicator), *Enterobacteriaceae* (hygiene indicator), total viable counts (TVCs) (overall microbiological performance) and *Staphylococcus aureus* (indicator of personal hygiene). Microbiological distribution and safety profile levels were calculated for the critical sampling locations. Food safety management system diagnosis of risk context wherein the firms operate, core control and core assurance activities in the factories was performed using previously described tool. Final product sample analysis indicated that more than 67% of the companies had microbial count

analysis for selected parameters within the legally accepted microbiological guideline limits hence good performance. *Salmonella* was found to be absent in all critical sampling locations. Majority of hands or gloves of the fish handlers were highly contaminated with *S. aureus* at levels above the recommended limits. Large sized companies' performances were better in terms of *Enterobacteriacea, E. coli* and *S. aureus* than medium and small sized ones at the CSLs, receipt of raw fish materials, heading and gutting, and at fish contact processing tables and facilities before cleaning and sanitation. High variability in *Enterobacteriacea* count was noted in fish products of three companies, and on surfaces of two companies. Fish products from majority the of companies (78%) showed high variability in TVCs. Processing surfaces of four companies also showed a high variability in TVCs. Various improvements in risk of context environment, core control and assurance activities associated with sampling locations showing poor performance are recommended.

Key words: Food safety management system, Microbiological assessment scheme**,** Fish industry, control activities, assurance activities.

3.0 Introduction

Trade in fishery commodities reached US$ 58.2 billion in 2002 in the global trade. A net trade surplus of US$ 17.4 billion was registered by the developing countries in 2002 which accounted for almost 50% by value and 55% of fish exports by volume (Ababouch, 2006). The total annual production of fish in Kenya is approximately 180,000 metric tons and earns about US$ 50 million of foreign exchange through export, contributing 0.5% to the GDP (Ministry of fisheries Kenya, 2013; Abila, 2003).

About 10 percent (13 million metric tons) of the world's total fish production is lost due to spoilage. Between the year 2001 and 2002, seafood formed about 1/10 of the refused food products of imports to the United States with *Salmonell*a detection forming 25% of the reasons after filth at 50% (Huss et al., 2003). Additionally, the consumption of unwholesome fish and fishery products accounts for as much as 30 percent of the worldwide food-borne illnesses (Abila, 2003).

Food processing industries major goal is to control microorganisms in order to provide safe, wholesome and acceptable food to the consumers (Baggen-Ravn et al., 2003). However, this can be very challenging as contamination of products take place at all stages of the food chain (De Rover, 1999; Unnevehr, 2003). Fish contamination may also occur naturally from the environment where fish are harvested, during harvesting, processing and food preparation. During food processing or preparation cross contamination may occur where bacteria may be transferred from raw fish and or contaminated surfaces and or from utensils to hygienically safe fish. Contaminated water may also be a source of microorganisms into the food during processing. Inadequate methods of handling, hygiene, sanitation and distribution may provide ideal conditions for the pathogens to proliferate and reach infective levels (Wekell et al., 1994). Fish contamination especially with pathogens like *Salmonella* sp., *Staphylococcus aureus, Campylobacter jejuni*, *Escherichia coli* 0157:H7, *Vibrio parahaemolyticus*, *Yersinia enterocolitica*, and *Listeria monocytogenes*, may occur at various stages of fish chain including prior to harvest, during capture, processing, distribution and/or storage (Venugopal, 2002).

There was a series of restrictions on exports from Kenya to the EU by the European Commission between the years between 1997 and 1999 due to poor food safety management systems (FSMS) in the fish chain. In such circumstances, response by the government and the private sector is largely in response to regulatory changes or to demand from major customers (Henson and Jaffee, 2006). The most significant regulations for this fisheries sector are EU directives 91/493/EEC and 98/83/EEC which lays down the requirements for handling and marketing of fishery products. They are enforced by Fisheries Department with periodic audits by EU inspectors (Abila, 2003). However, the sector still faces constraints in reduction in post harvest losses, fish safety and quality assurance (Ministry of fisheries Kenya, 2013).

Existence of safety and quality challenges despite current FSMS being efficiently applied demands adoption of improved scientific tools and novel flexible approaches to safety. This will ensure that regulatory actions reflect the most current scientific evidence. Improved scientific tools for diagnosis of microbial performance of a FSMS and improvement of existing control and assurance systems have recently been described by the European Commission project Pathogen Combat (Jacxsens et al., 2009b, 2011). Microbiological assessment scheme (MAS) is used for systematic analysis of microbial counts in a FSMS. The analysis provides in-depth understanding on the contamination profiles taking into account the distribution in microbial contamination and maximum level of microbial counts in an implemented FSMS. It also assesses the microbial performance of core control and assurance activities and indicates changes necessary to improve their performance (Jacxsens et al., 2009b, 2011).

The principle behind MAS is that an effective FSMS results in products with lower contamination levels and less variation in contamination loads (Lahou et al., 2012). The systematic evaluation of microbiological performance targets selected critical sampling locations and links the information to the descriptive diagnosis of the FSMS. This is contrary to the traditional practice of microbial final products testing aimed at acceptance or rejection of a batch and the quantitative risk profiling that identifies the risk of a product or process aimed at providing remedial measures (Jacxsens et al., 2011).

The MAS tool has been effectively validated and offered insight into performance of existing FSMS in food service establishments (Lahou et al., 2012), pork processing plants (Jacxsens et al., 2009b), lamb processing chain (Osés et al., 2012), poultry processing (Sampers et al., 2010) and dairy industry (Opiyo et al., 2013). However such studies and therefore insight into microbial performance of current FSMS is not available for the fish industry.

The MAS tool was therefore used in this study to evaluate the microbiological performance of a fish exporting sector applying current FSMS so as to examine the effectiveness of control and assurance activities and suggest potential improvements.

3.1 Methodology

3.1.1 Description of the fish processing plants studied

Nine companies were grouped into three classes that typically represent small, medium and large sized companies based on varying installed and utilized capacities, number of

employees and certified FSMS (e.g. HACCP, PRP, ISO standards, E.U and Government regulation) (Table 1).

3.1.2 Critical sampling locations (CSL)

A total of six CSLs where loss of control may lead to unacceptable food safety problems due to contamination with or growth and or survival of microorganisms were selected. The CSL 1 was receipt of raw fish materials (skin intact) which was expected to provide information on the potential safety risks of the raw fish. It was also selected to establish fitness of use and effectiveness of the raw material control measures like suppliers procedures and fish specification. Sampling at this point helps to determine the initial contamination level with microorganisms and verifies appropriate supplier selection (Lahou et al., 2012; Jacxsens et al., 2009b). Codex Alimentarius Commission (2003) also recommends laboratory tests and inspection of raw materials before processing as a requirement in establishing fitness for use of raw materials.

CSL 2 was at heading and gutting. This stage may be potential source of cross contamination especially from fish contact surfaces, equipments and fish handling operators. Samples analysis result from this intermediate product point were expected to indicate adequacy of the implemented preventive measures like personal hygiene, sanitation programs, specific preventive measures for fish and hygienic design of equipment and facilities (Jacxsens et al., 2009b).

CSL 3 was the final fish product after candling, trimming and final washing. The location was expected to indicate performance of the overall technological and managerial control activities implemented to reduce microorganism in the FSMS (Jacxsens et al., 2009b). In

addition, the location is an important indicator for final product safety and quality (Opiyo et al., 2013).

CSL 4 was the fish contact processing tables and facilities before cleaning and sanitation. The tables are frequently touched by workers and microorganisms can attach on to directly contaminate the fish and specifically if are moist for longer periods before use after cleaning (Rusin et al., 1998; Evans et al., 2004). According to DeVere and Purchase (2007) working surfaces like packaging tables are usually the most contaminated of food contact surfaces and are believed to allow cross-contamination because they are in direct contact with food. The location was therefore selected to indicate the actual status of the sophistication of hygienic design of the tables and facilities (Jacxsens et al., 2009b).

CSL5 was processing tables and facilities after cleaning and disinfection. The location was to provide insight on adequacy of cleaning and sanitation procedures present as a preventive measure in the FSMS (Jacxsens et al., 2009b). In addition, it was to indicate the quality of water used in the cleaning procedures.

CSL 6 was the operator's hands or gloves. This was because personnel skins harbor various microorganisms which can be transmitted to fish and environment through hands. Hands can also act as a source of *Staphylococcus aureus* (Aarnisalo et al., 2006). The location was selected to provide insight into the performance of personal hygiene as a preventive measure in the FSMS (Jacxsens et al., 2009b; Luning et al., 2009).

3.1.3 Selection of microbiological parameters

Microorganisms that are relevant to fish safety problems were monitored as described by Jacxsens et al. (2009b). *Salmonella* spp a pathogen was selected as food safety indicator

for all companies. This was because of high incidences of *Salmonella* related food borne outbreaks from fish and seafood consumption. In addition, *Salmonella* outbreak is linked to the fish bans by importing countries (Heinitz et al., 2000; Henson and Mitulla, 2004). *Escherichia coli* and *Enterobacteriaceae* were analyzed as hygiene (fecal) indicators (ICMSF, 2005; European Commission, 2005). Total viable counts (TVCs) were analyzed as indicator of overall microbiological performance (utility parameter) (ICMSF, 2005) and *Staphylococcus aureus* as indicator of personal hygiene (Aarnisalo et al., 2006).

3.1.4 Sampling frequency

Companies were visited three times in 4 months. In each visit fish raw materials, fish at heading and gutting stage and fish fillets after final washing were sampled once per day for 3 different days (n = 9). Surfaces of facilities and working tables before and after cleaning, and operator's hands or gloves were sampled three times in the morning, afternoon and evening to capture the daily variations for 3 different days (n=27). A total of 36 samples per company were taken adding up to 324 samples for all the companies over the 4 months period. The samples provided insight in the extent of microbiological distribution and profile in the selected critical sampling locations (Jacxsens et al., 2009b).

3.1.5 Sampling methods

Environmental sampling from surfaces was done by contact plates and swabs using horizontal method for collecting samples in accordance to ISO 18593: 2004. The method was also applied in detection and enumeration of viable microorganisms from food contact surfaces. Sampling area of 50 cm^2 was used for facilities, crates and tables while for knives was 10 cm^2 due to the limited surface area. For the hands or gloves of food

handlers, swabs covered 25 cm^2 (5 by 5 cm square) of each handler. Swabbing area was delineated by a sterilized steel template. The swabs were put back aseptically into its tube, stored and transported in a cool box at ≤ 4 °C to the laboratory for microbial analyses. ISO 6887-3: 2003 was used in the preparation of fish and fishery products for microbiological examination.

3.1.6 Analytical methods

For enumeration purposes, the following methods were used, ISO 4833:2003 for Total viable count (TVC) i.e. aerobic mesophilic bacteria. Duplicate pour plates on Plate Count Agar were used. Incubation of plates was then done at 30±1ºC for 72±3 hrs**.** Microbial counts were expressed as numbers of microorganisms were done per milliliter or per gram of the sample from the number of colonies obtained in the plates chosen.

ISO 16649-2: 2001 was used for enumeration of *E. coli*. Quantities of 10 grams of product sample were homogenized in 90 ml peptone water (PW, Oxoid CM9) for isolation. Decimal serial dilutions of the homogenate in sterile PW were plated in duplicate on the selective agar plates. TBX agar (Oxoid CM945) which is a chromogenic selective culture medium was then inoculated with the initial suspension of sample dilutions. Typical blue green colonies for *E. coli* were counted after 24 and 48 h of incubation of the dishes at 44°C. The number of colony-forming units (CFU) of presumptive *Escherichia coli* per gram or per milliliter of sample was then calculated.

ISO 6579: 2002 was used for enumeration of *Salmonella* species. Dilution (1:10) of 25g sample which was blended and enriched in buffered peptone water at 37 ± 1^0C for 18 h ± 2 h. The inoculums from pre-enrichment broth was transferred to Rappaport-vassiliadis broth and Selenite cystine broth and then incubated at 41.5±1°C and 37±1 °C respectively

for 24h for selective enrichment. Cultures (a loopful) was obtained from the selective enrichment and streaked onto two solid selective media: Brilliant green agar (BGA) and Xylose lysine desoxycholate agar (XLD**))**. XLD agar was incubated at 37 ± 1^0C and examined after 24 h ± 3 h. Typical *Salmonella* colony had a slightly transparent red halo and a black centre. A pink-red zone in the media were expected to surround the colonies on the XLD plates while on the BGA plates, typical *Salmonella* colonies were expected to appear red and impart a red/pink color to the surrounding agar. Other enteric bacteria appear typically green or yellow.

ISO 21528-2:2004 was used for *Enterobacteriaceae* enumeration. Duplicate pour plates were prepared using a solid selective culture medium (Violet red bile Glucose (VRBG)). Incubation of the plates were carried out at 37±1°C for 24±2 h. Colonies of presumptive *Enterobacteriaceae* were sub cultured on non–selective medium (nutrient agar plates) and confirmed by test for fermentation of glucose and presence of oxidase. Number of *Enterobacteriaceae* per milliliter or per gram of the test samples were calculated from the number of confirmed typical colonies per plate.

EN ISO 6888-1:1999 was used for enumeration of *Staphylococcus aureus*. A sterile pipette was used to transfer 0.1 ml of the appropriate dilutions of the test samples and inoculated in duplicate onto the surface of Baird Parker agar. The plates were incubated for 24 h ± 2 h then re-incubate for a further 24 h ± 2 h at 35 °C - 37 °C. Typical colonies were black or grey, shining and convex (1 mm to 1, 5 mm in diameter after incubation for 24 h, and 1, 5 mm to 2, 5 mm in diameter after incubation for 48 h) and were surrounded by a clear zone which were partially opaque. After incubation for at least 24 h an opalescent ring immediately in contact with the colonies appeared in the clear zone. The

number of coagulase positive staphylococci were calculated and expressed as cfu/g or ml sample.

3.2 Data processing and interpretation of the results

Microbial Safety Level Profiles (MSLP) was calculated according to Jacxsens et al. (2009b, 2010); Opiyo et al. (2013); Lahou et al. (2012). Microsoft Office Excel 2007 (Microsoft, Redmond, WA) was used to make graphs and tables to illustrate visually the levels and distribution of microbial contamination of the analyzed critical sampling locations (CSLs) (Fig 1). The procedure showed maximum level of microbial counts and distribution in the selected CSL points of the FSMS.

Counts from each analyzed microbiological parameter in a specific CSL were first compared with those of EU standard (EC) No 2073/2005 and The International Commission on Microbiological Specifications for Foods (ICMSF) recommended Microbiological limits for seafood (Table 7). The microbiological values established by the Laboratory of Food Microbiology and Food Preservation at the University of Gent (LFMFP-UGhent) (Uyttendaele et al., 2010) and its recommendations were used to compare the results of the food contact surfaces and operator's hands or gloves (Table 7). If the legal requirements or the guide values that aid in evaluating whether the production process took place under controlled conditions were exceeded for a specific microorganism in a CSL, it indicated that the specific control activity in the FSMS dedicated towards the defined CSLs was not working properly.

Table 7. Critical sampling locations (CSLs) encompassing food products and production environment with the corresponding requirements of generally accepted microbial guidelines for fish

		Critical sampling locations			
Parameter	**Analytical method**	**Fish arrival skin intact (CSL 1)**	**Heading, gutting & Fillets after washing (CSL 2 &3)**	**Working tables &facilities surfaces (Before &after cleaning/ disinfection) (CSL 4 & 5)**	**Operator's hands/gloves (CSL 6)**
		Log CFU/cm^2	Log CFU/g	Criteria[b] Log CFU/cm^2	
Total viable bacteria	ISO 4833 :2003	m[c] =5.0;M[c] =7.0	M [a] =6.0	Good, ≤1; average, ≤1.8; bad, ≤2.5;ntolerable,>2.5	Good, ≤1; average, ≤1.8; bad, ≤2.5;ntolerable,>2.5
Enterobacteriaceae	ISO 21528-2:2004	M [a] =2.0	M [a] =2.0	Good, ≤1; average,≤1.8; bad, ≤2.5;ntolerable,>2.5	Good, ≤1; average,≤1.8; bad, ≤2.5;ntolerable,>2.5
E. coli	ISO 16649-2 :2001	m[c] =1.0;M[c] =2.5	M[a] =1.0	Absent on tested Surface	Absent in the area tested
Salmonella	ISO 6579: 2002	[a] Absent in 25g the area tested	[a] Absent in 25g sample	Absent in the area tested	Absent in the area tested
S. aureus	EN ISO 6888-1:1999	m[c] =3.0;M[c] =4.0	m[c]=3.0;M[c]=4.0	Absent on tested Surface	Absent in the area tested

[a]According to Kenya legal standards (KS 1399-1: 2012 and KS 1399-2: 2012); [b]According to microbiological guide values of LFMFP-U Gent for food service operation; [c]According to ICMSF, 1986; m= maximum level of bacteria per test volume considered acceptable, M= maximum level of bacteria per test volume considered marginally acceptable (values at or above M are unacceptable).

Results evaluation involved the use of score attribution system (Table 8). A score of zero indicating poor performance was given when the legal criteria or the guideline values were exceeded for a particular microorganism at a specific CSL or when *Salmonella* was present. This meant that specific hygiene practices of control activities in the FSMS at that location were inadequate therefore corrective action(s) was required to change the noncompliance situation for improvement of the FSMS. A score of 1 indicating poor to average performance was given when the microbial results were equal to the maximum marginally acceptable level. A score of 2 indicating average performance was given whenever the results were less than the maximum level considered marginally acceptable but more than maximum level considered acceptable. A score of 3 indicating good performance was awarded when bacterial counts were below the minimum acceptable value for a specific microorganism at a specific CSL or when *Salmonella* was absent. The situation meant that the specific hygiene practices of core control and assurance activities in the implemented FSMS at that CSL were considered to be adequate.

The individual results for each analyzed parameter were then assessed across the six CSLs by assignment of an MSLP score to each. It consisted of a sum of scores attributed

to each of the parameters for all the CSL. The maximum MSLP score was 15 because five parameters were analyzed per CSL with an assigned score of level 3 each.

Table 8. Score attribution system for assignment of microbial food safety level profile scores

Score	Benchmark	Performance level	Food contact surfaces (LFMFP-UGent)
0	R > M, organism present in x grams or on the surface	Poor	R > 350 CFU/16 cm^2 Present on surface[a]
1	R = M	Poor to average	69 CFU/ 16 cm^2 < R≤350 CFU/16 cm^2
2	m < R <M	Average	10 CFU/16 cm^2 < R≤69 CFU/16 cm^2
3	R < m, organism absent in x grams and on the surface	Good	R ≤ 10 CFU/16 cm^2 Absent on surface[a]

R= Results obtained from analysis; m= Maximum level of bacteria per test volume considered acceptable, M= Maximum level of bacteria per test volume considered marginally acceptable (values at or above M are unacceptable); [a]Specifically for *E. coli*, *S. aureus* and *Salmonella*.

3.3 Results and discussions

The effect of implemented food safety management system by the fish processors on the microbiological quality of raw fish material, heading and gutting, fillets after washing, fish contact surfaces before and after cleaning and sanitation, and food handlers' hands or gloves was studied. *Salmonella* was absent in all the CSLs for all the companies therefore they had good performance (score 3) for this safety indicator. Additionally, at receipt of raw fish materials (CSL 1), all the companies had good performance (score 3) for *S.*

aureus. At this CSL, 67% of companies had good performance (score 3) in terms of *E. coli* and *Enterobacteriaceae*. The rest (33%) had average performance (score 2) and poor performance (score 0) in terms of *E. coli* and *Enterobacteriaceae* respectively. For TVCs, 89% of the companies had good performance (score 3) with 11% performing averagely (score 2). Absence of *Salmonella* which is a pathogen in all the CSLs might have indicated adequate raw material control measures. Effective cooling facilities implemented by the processors coupled with high sophistication in translation of external requirements such as EU hygiene directive (91/493/EEC and 98/83/EEC into internal FSMS were implemented by the companies. This is expected to result in production of safe fish fillets by all the companies (Luning et al., 2008). The result was very important because the pathogen has been reported earlier as one of the cause of previous fish export ban from Kenya by EU (Henson and Mitullah, 2004). Majority of companies used statistical underpinned acceptance sampling in addition to guidance documents for fish sector. They also used clearly defined sampling frequency, location, analysis and rejection criteria based on actual historical data of suppliers. This is suggested to improve raw material control (Duarte and Saraiva, 2008). Clearly defined sampling frequency based on actual historical data of suppliers enhances realization of more predictable good safety outcome due to less ambiguity and uncertainty (Luning et al., 2008). The companies effectively applied various QA requirements (Kenya fisheries act cap 378, HACCP, PRPs, and ISO standards 9000, 9001, 22000: 2005) in addition to E.U 91/493/EEC and 98/83/EEC.

Table 9. Detailed results of microbial analysis at critical sampling locations conducted at nine fish processing companies.

Critical Sampling Location (CSL)	n	Food safety indicator	Hygiene Indicators			Utility parameter
		Salmonella	*E. coli*	*Enterobacteriaceae*	*S. aureus*	TVC
COMPANY A						
CSL1	3	A	<1.0	62-TNTC	<1.0	5.8×10^{4} -6.3×10^{4}
CSL2	3	A	A	A	A	$<1.0\times10^{1}$
CSL3	3	A	13-54	A	A	2.1×10^{4}-6.2×10^{4}
CSL4	9	A	A	A	<1.0	$<1.0\times10^{1}$
CSL5	9	A	A	A	A	1.0×10^{1}-2.0×10^{1}
CSL6	9	A	NIL-3	NIL-15	<1.0	1.8×10^{3}-7.4×10^{3}
COMPANY B						
CSL1	3	A	5 -87	NIL-108	A	5.4×10^{4}-6.7×10^{7}
CSL2	3	A	23-67	A	<1.0	4.5×10^{3} -4.8×10^{4}
CSL3	3	A	2-8	A	A	2.3×10^{2}-4.0×10^{2}
CSL4	9	A	NIL-4	NIL-122	<1.0	A
CSL5	9	A	A	A	A	A
CSL6	9	A	NIL-3	NIL-3	A	2.0×10^{1} -3.1×10^{2}
COMPANY C						
CSL1	3	A	A	<3	2.4×10^{1}-4.6×10^{1}	4.5×10^{3}-5.6×10^{3}

CSL2	3	A	A	<3	1.9×10^{1}-3.6×10^{1}	4.1×10^{3}-5.2×10^{3}
CSL3	3	A	A	NIL-2	A	$<2.1\times10^{3}$
CSL4	9	A	NIL-4	A	A	2.3×10^{1}-3.6×10^{1}
CSL5	9	A	A	A	A	$<2.5\times10^{1}$
CSL6	9	A	A	A	<I.0	1.8×10^{1}-3.7×10^{1}
COMPANY D						
CSL1	3	A	NIL-6	80-112	NIL-5	4.2×10^{4}-7.5×10^{5}
CSL2	3	A	A	NIL-4	A	5.3×10^{3}-7.2×10^{3}
CSL3	3	A	A	A	A	$<2.3\times10^{2}$
CSL4	9	A	A	A	A	7.2-7.5×10^{7}(3/9)
CSL5	9	A	A	A	A	20-80
CSL6	9	A	NIL-1	NIL-5	NIL-4	24-240
COMPANY E						
CSL1	3	A	NIL-12	A	A	2.4-1.43×10^{2}
CSL2	3	A	A	A	A	NIL-3.2
CSL3	3	A	1-3	20-28	19-32	2.5×10^{4}-3.0×10^{4}
CSL4	9	A	A	NIL-34	<1.0	18-37
CSL5	9	A	A	A	A	20-37
CSL6	9	A	A	NIL-1	A	5-29
COMPANY F						
CSL1	3	A	1.0×10^{1}-1.3×10^{1}	TNTC	26-80	23-103
CSL2	3	A	A	<10	10-42	<10
CSL3	3	A	A	4.0×10^{4}-8.2×10^{4}	A	1-23
CSL4	9	A	A	<10	A	7-41
CSL5	9	A	A	<10	A	NIL-4
CSL6	9	A	A	1-4	<1.0	<10

COMPANY G						
CSL1	3	A	A	NIL-56	<1.0	2.5×10^{3}-3.0×10^{4}
CSL2	3	A	NIL-2	<10	A	NIL-2
CSL3	3	A	A	A	<10	A
CSL4	9	A	A	<10	A	NIL-4
CSL5	9	A	A	A	A	NIL-9
CSL6	9	A	A	2-43	<1.0	NIL-4
COMPANY H						
CSL1	3	A	A	NIL-43	A	1.3×10^{2}-2.2×10^{3}
CSL2	3	A	NIL-2	NIL-35	A	1.1×10^{2}-2.0×10^{3}
CSL3	3	A	A	1.2×10^{3}-4.2×10^{3}	A	A
CSL4	9	A	A	NIL-69	A	NIL-35
CSL5	9	A	A	A	A	A
CSL6	9	A	A	NIL-4.8×10^{4}	NIL-4	A
COMPANY I						
CSL1	3	A	A	1.0×10^{2}-2.2×10^{3}	<1.0	1.7×10^{2}-2.6×10^{3}
CSL2	3	A	A	1.0×10^{1}-2.0×10^{3}	A	< 1.0
CSL3	3	A	A	A	<1.0	<1.0
CSL4	9	A	A	A	A	1.0×10^{1}-7.6×10^{4}
CSL5	9	A	A	A	A	<1.0
CSL6	9	A	A	A	<1.0	<1.0

A, absent in 25-g sample or on 50 or 10 cm^2. Bacterial levels are reported in log CFU per gram for fish products, log CFU/50 cm^2 for environment samples and log CFU per 25 cm^2 for workers' hands and/or gloves. TVC, total viable bacteria count. TNTC, too numerous to count.

For heading and gutting (CSL 2) 89% of companies showed good performance (score 3) on *E. coli* and *Enterobacteriaceae* counts, but 11% of the companies performing poorly (score 0) (Table 9). All companies showed good performance (score 3) in their TVCs at this CSL. Actual hygienic performance of equipment and facilities for heading and gutting in majority of companies was at advance level (score 3) (Table 5). They had stable and well noticed hygienic performance of equipment and facilities. Hygiene performance tests were conducted regularly according to KEBS. This is expected to better control cross contamination (Luning et al., 2008).

For final fish product after candling, trimming and final washing (CSL 3), 100% of the companies had good performance (score 3) in terms of TVCs. There was good performance (score 3) in 89% and 78% of the companies in terms of *E. coli* and *Enterobacteriaceae* respectively. However, the rest of the companies performed poorly in their *E. coli* and *Enterobacteriaceae* (score 0) (Table 9). *E. coli* detection above the set limits (Table 9) in company A fish fillets indicated poor hygiene handling of the fillets. Cross contamination probably occurred from operator's hands or gloves or from wash water. Operators in majority of the companies were aware of the existence and content of procedures and consciously followed them. Furthermore, safety tasks were internalized and employees exercised self-control on compliance to candling, trimming and washing procedures. Internalized procedures support appropriate decision making process, reduces variation and helps to achieve safety and quality objectives (Luning and Marcelis, 2007). Standards and tolerances for critical process and fish fillets parameters were clearly specified in majority of the companies. Assessment of critical process and final fillet standards and tolerances were also derived from process parameters, legal requirements,

hygiene codes, literature, and tested and tailored for own fish production system. This resulted in result in more accurate CCPs, which is expected to positively contribute to food safety (Luning et al., 2008).

For fish contact processing tables and facilities before cleaning and sanitation (CSL 4), 78% of companies had good performance (score 3) on *E. coli* count while 22% showed poor performance (score 0). For *Enterobacteriaceae* count, 44% of the companies had good performance (score 3), 33% had average to poor performance (score 1) while 22% performed poorly (score 0). For *S. aureus*, 67% of companies had good performance (score 3) while 33% had poor performance (score 0). For TVCs 22% of the companies had average performance (score 2), 22% had average to poor performance (score 1) while the remaining 56% showed poor performance (score 0) (Table 9). Companies that performed poorly on the parameters had incomplete sanitation program not differentiated for specific equipment or facilities. Common cleaning agents were also not specific for production system. Instructions were only derived from information on label or company experience. It was also noted that hygienic design for equipment and facilities for majority of the companies was at average FSMS (Table 5). They were hygienically designed by suppliers according to Kenya bureau of standards (KEBS) requirements. However, they lacked adaptation and testing according to the individual companies specific fish production circumstances. It is recommended that company's equipment and facilities hygiene design should be modified for specific fish production characteristics in collaboration with equipment and cleaning suppliers. They should also adopt integrated hygienic designs in order to realize low risk levels (Aarnisalo et al., 2006). Integrated hygienic designs of equipments and facilities decreases chance of cross contamination. It

also contributes to food safety due to higher predictability arising from less ambiguity and uncertainty (Luning et al., 2008). For instance *E. coli* counts exceeded limits in company B tables and facilities surfaces before cleaning and disinfection and at heading and gutting. This could be associated with poor hygiene of surfaces and lack of regular cleaning operations specifically designed and modified for fish production. Running tap water was also lacking at heading and gutting step for this company. The high prevalence of *S. aureus* in the food contact surfaces of the companies could have originated from operators hands since they were detected also on food handlers' hands. *S. aureus* counts exceeded limits in companies A, B and E surfaces and the organism were detected in higher numbers on operator's hands or gloves except company B (Fig 1D). Samakupa et al. (2003) similarly found that low numbers of fecal coliforms found on fish samples and food contact surfaces in processing environment (i.e. filleting machine and conveyor belts before and underneath the trimming/candling table) were transferred to the fish by food handlers.

When processing tables and facilities were sampled after cleaning and disinfection (CSL 5) *E. coli, Enterobacteriaceae* and *S. aureus* counts showed good performance (score 3) in all the companies. However, 22% of the companies performed averagely (score 2) in their TVCs, 56% had average to poor performance (score 1) while 22% performed poorly (score 0) (Table 9). The companies with good performance had complete sanitation programs tailored for different equipment and facilities. This enhances sanitation effectiveness (Luning et al., 2008). Cleaning agents were also specifically modified and tested on effectiveness for specific fish production system. Similarly they had instructions on use and frequency based on test results that better prevents contamination (Luning et

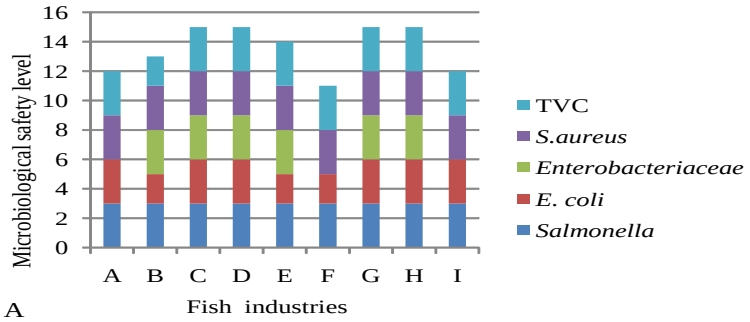
al., 2008). Poor performance on TVCs indicated overall poor microbiological performance in the cleaning and sanitation procedures. The food contact surfaces with the lowest TVCs scores were manually cleaned. Cleaning activities in company F were not effective against the organism since it was still present at higher levels (score 2) on surfaces after cleaning. It was also observed that some surfaces were rough such as tables and fish transfer crates. Effective cleaning of food contact surfaces is an important component of an FSMS (Joint Hospitality Industry Congress, 1995). Poor performance was also attributed to lack of well-defined and/or documented procedures and guidelines for cleaning of such equipment in the companies. Verifications to confirm the adequacy of cleaning operations were also conducted irregularly. The companies could improve their sanitation programs by tailoring them for different equipment and facilities which is known to enhance sanitation effectiveness (Luning et al., 2008). Cleaning agents should also be specifically modified and tested on their effectiveness for specific fish production systems. Similarly they should have instructions on use and frequency based on test results to better prevent contamination (Luning et al., 2008). The activities are expected to reduce the microbiological load of food contact surfaces (Luning et al., 2011a and Jacxsens et al., 2009b).

Samples from hands or gloves of operators (CSL 6) revealed that 78% of the companies had good performance (score 3) in their *E. coli* counts while 22% showed poor performance (score 0) (Table 9). For *Enterobacteriaceae* at CSL 6 only 22% of the companies had good performance (score 3), 44% performed averagely (score 2), 22% had average to poor performance (score 1) while 11% performed poorly (score 0). Additionally 89% of the companies performed poorly (score 0) in their *S. aureus* counts

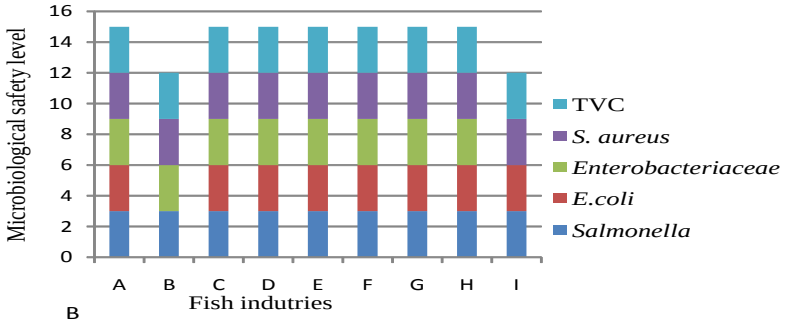
and only 11% had good performance (score 3) (Table 9). In terms of the TVCs, 44% of the companies performed poorly (score 0) 33% had average to poor performance (score 1) while 22% performed averagely (score 2) at CSL 6 (Table 9). The presence of *E. coli* in the hands of operators in companies A and B posed cross-contamination risks to fish products. This was because all the companies engaged in manual packing of fish (used Styrofoam, Cartons and Polybags). Majority of the companies therefore scored moderate level (score 2) on safety contribution by packaging concept (Table 4). Cross-contamination of fish products and packaging material could result from the food handlers, resulting in *E. coli* in the final product as was found by Opiyo et al. (2013) in a study of dairy industries. Companies that had good performance on all the parameters had high and specific requirements for handling and storage conditions of clothing for all food operators. Personal care and health facilities were also tailored to support personal hygiene (Annex 1 & Table 5). Specific training on hygiene matters was also conducted. This could assist in the reduction of contamination chance (Luning et al., 2008). Sophistication of validating preventive equipment and facilities, sanitation and personal hygiene programs for the same companies was based on expert knowledge (i.e. consultancy), regulatory documents and historical results. The activities were done on regular basis usually after system modifications. Findings were then described in reports as majority of the companies had average FSMS (Table 5).

The differences in performance were also related to the production scale of the industry. At raw fish material reception (CSL 1), large sized and medium sized companies D, H, C and G attained maximum MSLP (score 15). Large sized company A and medium sized company F scored 12 and 11 respectively for raw material at reception. None of the

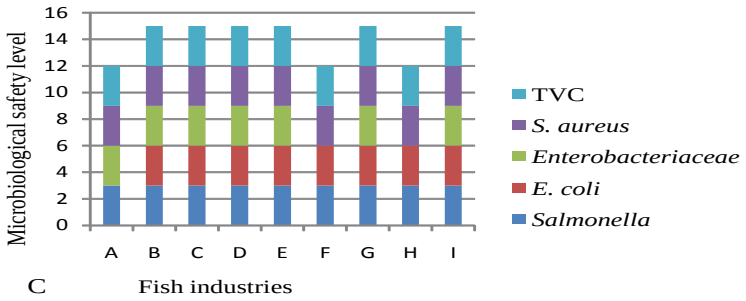
small sized companies B, E and I attained maximum MSLP at CSL 1 (Fig 1A). It was observed that large and medium sized companies (Table 9) had adequate supply chain coupled with properly cleaned and sanitized delivery vans. The activities resulted in delivery of high-quality raw fish material which enhanced the performance of their FSMS (Luning et al., 2011b). According to Lahou et al. (2012) low initial contamination levels of raw materials is greatly enhanced by high-quality raw materials which also contribute to a low-risk environment. All the companies had high risk levels on the extent of power in supplier relationships (Table 4). They were highly dependent on the microbiological level of their incoming fish materials and thus on the FS output of their suppliers (fishers) (Table 4). Mead et al. (1993) found that, high initial contamination of the raw materials can be reflected at all CSLs throughout the processing line due to lack of a subsequent intervention steps which the companies lacked. The companies therefore might reduce the risks of insufficient raw materials by critically evaluating their implemented specifications and by systematically inspecting FSMS of their suppliers (Luning et al., 2011a, 2011b). Another option is to introduce intervention processes to have the ability to reduce initial levels on fish to acceptable levels such as washing the fish with hot water or antimicrobial compounds like lactic acid, nisin solution (DeMartinez et al., 2002).


Microbiological safety level
16
14
12
10
8
6
4
2
0
A B C D E F G H I
Fish industries
TVC
S.aureus
Enterobacteriaceae
E. coli
Salmonella

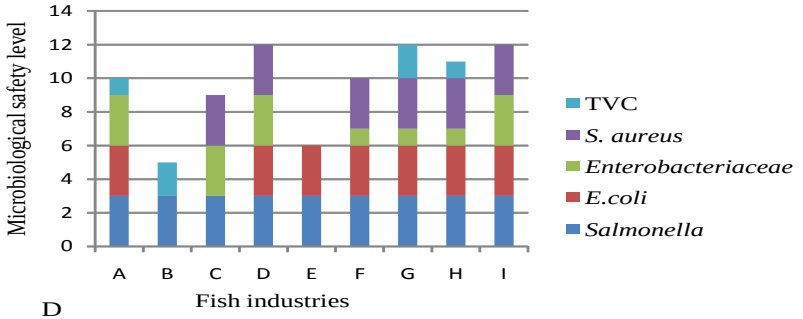
A


Microbiological safety level
16
14
12
10
8
6
4
2
0
A B C D E F G H I
Fish indutries
TVC
S. aureus
Enterobacteriaceae
E.coli
Salmonella

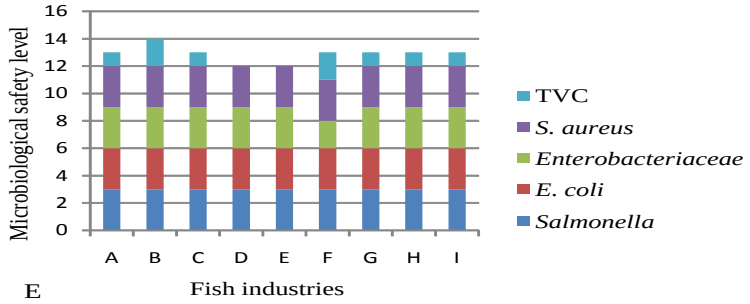
B


Microbiological safety level
16
14
12
10
8
6
4
2
0
A B C D E F G H I
Fish industries
TVC
S. aureus
Enterobacteriaceae
E. coli
Salmonella

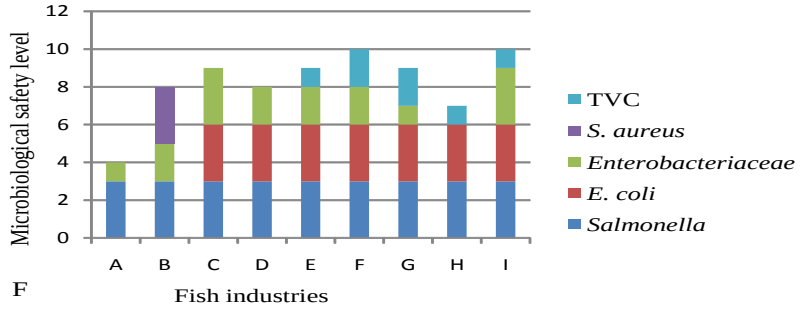
C


Microbiological safety level
14
12
10
8
6
4
2
0
A B C D E F G H I
Fish industries
TVC
S. aureus
Enterobacteriaceae
E.coli
Salmonella

D


Microbiological safety level
16
14
12
10
8
6
4
2
0
A B C D E F G H I
Fish industries
TVC
S. aureus
Enterobacteriaceae
E. coli
Salmonella

E


Microbiological safety level
12
10
8
6
4
2
0
A B C D E F G H I
Fish industries
TVC
S. aureus
Enterobacteriaceae
E. coli
Salmonella

F

FIGURE 1. Microbial safety level profile scores for critical sampling locations (CSL1 through CSL 6) at 9 Fish processing plants. A (CSL1), raw fish with skin intact; B (CSL2), fish at heading and gutting; C (CSL3), final fish fillet product after candling, trimming and final washing; D (CSL4), fish contact processing tables and facilities before cleaning and sanitation; E (CSL5), processing tables and facilities after cleaning and disinfection; F (CSL6), operator's hands or gloves.

For heading and gutting microbiological performance of both large sized companies (A, D and H) and medium sized companies (C, F and G) were good because all attained maximum MSLP (score 15) (Fig 1B). However, the small sized companies (B and I) scored 12 MSLP with exception of company E that scored maximum MSLP (score 15) (Fig 1B). Companies B and I performed poorly (score 0) in terms of *E. coli* and *Enterobacteriaceae* counts respectively in this CSL (Table 9). They were among the companies that had paper based procedures for heading and gutting at various locations that were only updated when need arises (Table 5). It is recommended that, the procedures be easily available (e.g. digitized), designed for specific users and updated on a regular basis. This enhances peoples' decision making behavior (Luning et al., 2008). The two companies were also involved in intermittent heading and gutting of small fish products in batches rather than continuous flow and automated process (Table 5) which is important in preventing cross contaminations and lowering risk (Luning et al., 2011a). High degree of automation in product movement also restricts people's interference.

For the final fish product after candling, trimming and final washing (CSL 3) small sized companies (B, E and I) performance was superior as all attained maximum MSLP (score 15) (Fig 1C). This was followed by medium sized companies in which majority of

companies (C and G) attained maximum MSLP (score 15) with exception of one company F which had a MSLP score of 12. Two of large sized companies (A and H) had MSLP of 12 with exception of company D that had maximum MSLP (score 15) (Fig 1C). Companies A and F performance was poor (score 0) on *Enterobacteriaceae* counts (Table 9) while company A performed poorly (score 0) on *E. coli* count (Table 9). The bacterial counts exceeded generally accepted microbial guidelines for fish (Table 9). Operator's hands and gloves in the companies were highly contaminated by the microorganisms (Fig 1C) this suggests possibility of cross contamination to the final fish fillets. In addition, the companies hygiene design for their equipment and facilities were at medium FSMS level (score 2) (Table 5). They were hygienically designed by suppliers according to Kenya Bureau of Standards (KEBS) requirements. They however lacked integration, adaptation and testing according to the individual companies specific fish production circumstances which decreases chance of cross contamination (Luning et al., 2008). They also had medium level (score 2) on adequacy of raw fish material control (Table 5) (i.e. no statistical underpinned acceptance sampling procedures). Corrective actions for all small sized companies were advance (score 3) (Annex 1, 2 & Table 5). The actions were based on systematic causal analysis of own product and process deviations. There was also complete descriptions of process adjustments and handling of noncompliant products. Structured analysis of causes of deviations and their corrective actions was also present. The situation probably enhanced the microbiological performance of their final fish fillets.

For fish contact processing tables and facilities before cleaning and sanitation (CSL 4) all companies had MSLP of 12 and below with large size companies (MSLP 10, 12 and 11

for A, D and H respectively) performing better compared to medium sized companies (C, F and G). However, small sized companies B, E and I performed least scoring MSLP of 5, 6 and 12 respectively (Fig 1D).

When tables and facilities were studied after cleaning and disinfection all companies still scored less than the maximum with highest score of 14 in a small sized company B (Fig 1E). This was mainly attributed to *E. coli* detection in companies B and C and *Enterobacteriaceae* in companies B, E, F, G and H which indicated poor hygiene standards of working tables and facilities surfaces during production (Fig 1E). Possible causes in such scenario is fecal contamination, which might be due to malfunctioning or poorly done gutting, cross-contamination during production and inadequate personnel hygiene as indicated in the study of microbiological quality of broilers during processing (Abu-Ruwaida et al., 1994). Poor performance could be attributed to lack of well-defined and/or documented procedures and guidelines for cleaning of the fish contact surfaces in the companies because it was observed that cleaning was only done at the end of the shift (Table 5). Effective cleaning of food contact surfaces (cleaning as you go policy) is therefore recommended (Joint Hospitality Industry Congress, 1995) which additionally reduces the probability of biofilm formation and cross-contamination (Oliveira et al., 2010).

Large sized companies performed least (A, D and H scoring MSLP of 4, 8 and 7 respectively) on operators hands or gloves (CSL 6) compared to small and medium sized companies majority of which scored MSLP of 9 or 10 (Fig 1F). Majority of large sized fish industries with the poorest MSLP on hand hygiene performance were those in which most operations were done manually and food handlers were not well trained on technical

and hygiene matters (Annex 1, 2 & Table 4). The situation could have facilitated cross contamination with *S. aureus* from operator's hands to the food contact surfaces particularly of companies A an E (Fig 1D). This demonstrates that the hand hygiene was insufficiently respected. The companies could consider more strict personal hygiene requirements such as special hand washing facilities and provision of basic information (Nel et al., 2004) coupled with provision of clearly understandable procedures for crucial hygiene related activities. Such specific training on hygiene matters assist in the reduction of chance of contamination (Luning et al., 2008). Although basic personal and hygiene practices were available they required optimization and regular checking for their effectiveness (Table 5). Azanza and Zamora-Luna (2005) also argued that, even if the basic personal and hygiene practices design is good, inadequate compliance to procedures and instructions and/or their misinterpretation may contribute to safety problems. Food operators should be trained on good personnel hygiene and practices, wear gloves and change them on a regular basis (Dijk et al., 2007; Simoes et al., 2010).

Possibility of cross contamination or build up was revealed by MAS. In company A fish raw materials were highly contaminated by *Enterobacteriaceae* (MSLP 12). Heading and gutting seemed to be conducted properly (MSLP 15) but final fillets after washing showed an increase in contamination (MSLP 12) particularly by *E. coli.* This trend was almost similar to company F where *Enterobacteriaceae* was the major problem in raw fish (MSLP 11) and fillets after washing (MSLP 12) (Fig 1A, B and C). It is possible that contamination may have taken place before the fish was brought into the factory for processing since *E. coli* was present in the raw fish of company A and were also linked to operator's hands. Other studies on different processing operations have similarly

concluded that the plant and processing environment contributes highly to product contamination rather than the raw material. However, this does not exclude the possibility that the raw fish material is an important initial source for contaminating processing equipment and environment (Vogel et al. 2001). Water, like food, is a vehicle for the transmission of many agents of diseases (Kirby et al., 2003). Contamination of fish products through unclean, insufficiently or inadequately cleaned processing equipment have also been identified as a source of bacterial contamination in processed seafood (Reij et al., 2004). Cleaning and sanitation procedure for company A enabled an increase in MSLP from 10 to 13. However, operators hands and gloves were highly contaminated (MSLP 4) particularly by *E. coli, S. aureus* and TVCs (Fig 1D, E and F). The findings were almost similar to company H results, where cleaning and sanitation procedure increased MSLP from 11 to 13, while operator's hands and gloves had MSLP of 7 (Fig 1D, E and F). In company D and C microbiological analysis of fish products across CSL 1 to CSL 3 revealed good performance (MSLP 15) (Fig 1A, B and C). However, whereas cleaning and sanitation of surfaces resulted in reduction of contamination in company C (MSLP 9 to 13), this was not the case for company D (MSLP 12 was maintained) (Fig 1D and E). Personal hygiene of the operators at the two companies (D and C) were poor (MSLP 8 and 9 respectively) (Fig 1F) since TVCs and *S. aureus* counts were found at higher levels (score 0) (Table 9) on their hands or gloves. Company's H fish fillets indicated an increase in contamination (MSLP 15 to 12) (Fig 1A, B and C) mainly due to *Enterobacteriaceae* (score 0) (Table 9). This might be due to cross contamination from its operators in which *Enterobacteriaceae* scored 0 (Table 9). Even though small sized companies B and I had the highest contamination levels at heading and gutting (MSLP

12) the final fillets after washing performed well in their microbiological quality (MSLP 15) (Fig 1B and C). Surfaces of companies B and E showed poor performance with MSLP of 5 and 6 respectively during operations before cleaning and sanitation. However, their cleaning and sanitation procedures enabled them to attain improved MSLP of 14 and 12 respectively (Fig 1D and E). Utensils, particularly filleting knives and crates, were not replaced or sterilized regularly during the production period in company B and E. Improvement in core control activities of the FSMS in the fish processing plants was therefore needed, e.g., cleaning and disinfection of food contact surfaces and properly cleaning of utensils during production (Shojaei et al., 2006).

High variability in *Enterobacteriaceae* count was noted in fish products of companies A (0 to 4.1 log CFU/g), F (0.6 to 4.53 log CFU/g) and I (0 to 3.41 log CFU/g) (Fig 2c). Surfaces of companies B and H showed the highest variability of 0 to 2.21 log CFU/ml and 0 to 4.27 log CFU/ml respectively in *Enterobacteriaceae* (Fig 2c). The high variability at these locations indicated weaknesses of the implemented FSMS to effectively address the organism.

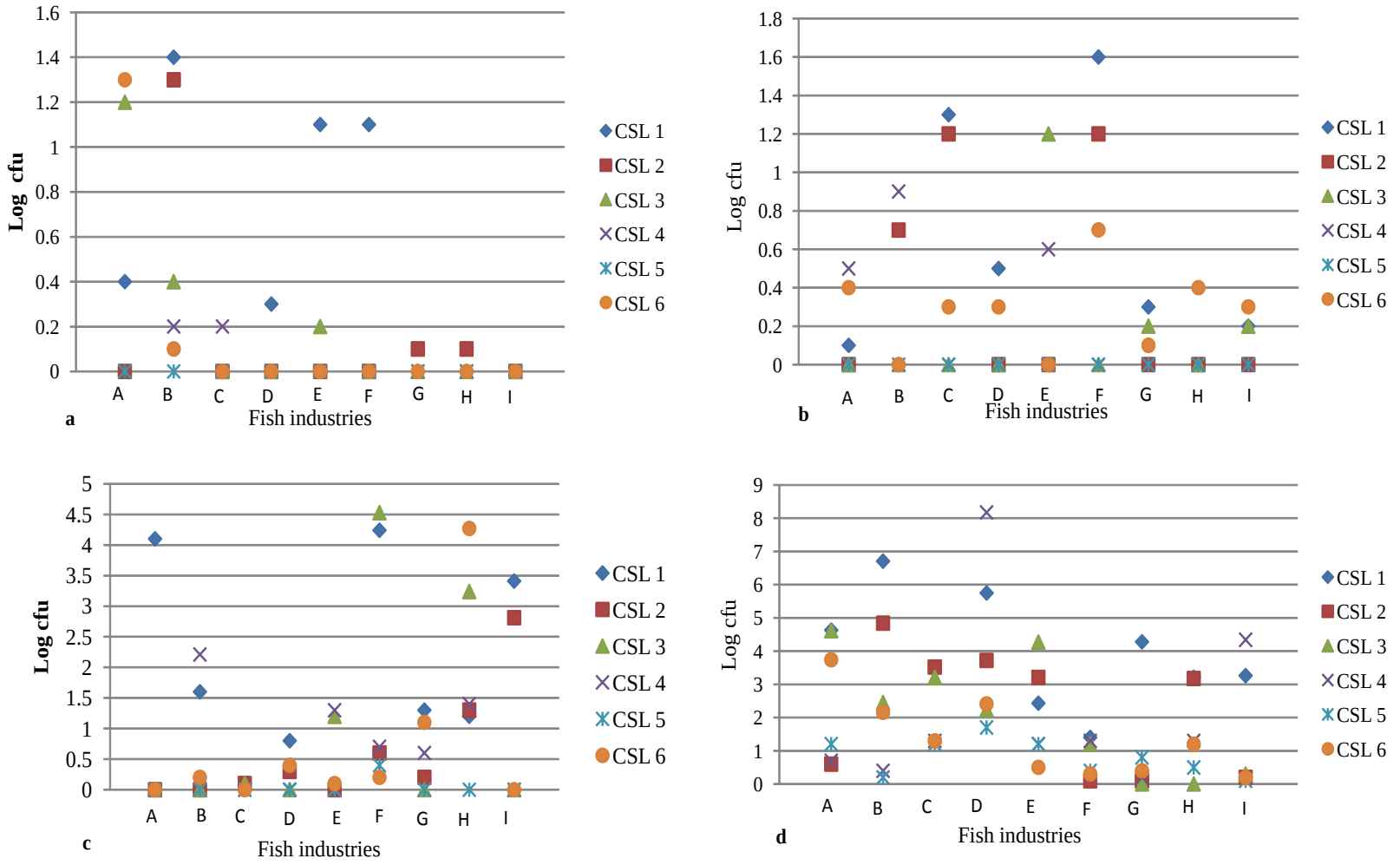


FIGURE 2: Distribution of *E. coli* (a), *S. aureus* (b), *Enterobacteriaceae* (c) and TVCs (d) for fish critical sampling locations. Units are log CFU/cm^2 for all surface samples and log CFU/g for product samples.

High variability in TVCs was also noted in fish product from companies A (0.6 to 4.63 log CFU/g), B (2.45 to 6.71 log CFU/g), D (2.23 to 5.75 log CFU/g), E (2.43 to 4.27 log CFU/g), G (0 to 4.28 log CFU/g), H (0 to 3.21 log CFU/g) and I (0.2 to 3.26). Additionally, high variability in TVCs from surfaces in companies A (0.7 to 3.74 log CFU/ml), B (0.2 to 2.16 log CFU/ml), D (1.7 to 8.17 log CFU/ml) and I (0.1 to 4.34) were noted (Fig 2d). Low variability was noted for *E. coli* and *S. aureus* (Fig 2a and b).

3.4 Conclusion

Absence of salmonella in all sampling locations indicates that the FSMS implemented by the fish exporting industries were effective against the pathogen. More than 67% of the companies had good performance for fish product samples. However, surface samples showed that majority of the companies performed poorly and averagely on TVCs before and after cleaning respectively. Hands or gloves of operators from majority of the companies were contaminated by *S. aureus* above the generally accepted microbial guidelines for fish indicating inadequate personal hygiene. Generally large sized processors performance was better than medium and small sized ones in terms of MSLP across the CSLs indicating presence of advance FSMS.

There were high initial levels of *Enterobacteriaceae* in the raw fish and TVCs on surfaces and their subsequent cross-contamination from operators, contact materials and equipments coupled with higher variability revealed in their counts across the CSLs. This may require the companies to consider more advanced control and assurance activities particularly in their raw material control, personal hygiene and, cleaning and sanitation programmes.

REFERENCES

Aarnisalo, K., Tallavaara, K., Wirtanen, G., Maijala, R., & Raaska, L. (2006). The hygienic working practices of maintenance personnel and equipment hygiene in the Finnish food industry. *Food Control,* 17(2), 1001–1011.

Ababouch, L. (2006). Assuring fish safety and quality in international fish trade. *Marine Pollution Bulletin*, 53(10-12), 561–568.

Abu-Ruwaida, A. S., Sawaya, W. N., Dashti, B. H., Murad, M., & Al-Othman, H. A. (1994). Microbiological quality of broilers during processing in a modern commercial slaughterhouse in Kuwait. *Journal of Food Protection*, 57(10), 887–892.

Azanza, M. P.V., & Zamora-Luna, M. B. V. (2005). Barriers of HACCP team members to guideline adherence. *Food Control,* 16(1), 15–22.

Bagge-Ravn, D., Ng, Y., Hjelm, M., Christiansen, N. J., Johansen, C., & Gram, L. (2003). The microbial ecology of processing equipment in different fish industries-analysis of the micro flora during processing and following cleaning and disinfection. *International Journal of Food Microbiology*, 87(3), 239-250.

De Martinez, Y. B., Ferrer, K., & Salas, E. M. (2002). Combined effects of lactic acid and nisin solution in reducing levels of microbiological contamination in red meat carcasses. *Journal of Food Protection,* 65(11), 1780-1783.

De-Roever, C. (1999). Microbiological safety evaluations and recommendations on fresh produce. *Food Control,* 9(1), 321-347.

DeVere, E., & Purchase, D. (2007). Effectiveness of domestic antibacterial products in decontaminating food contact surfaces. *Food Microbiology*, 24(4), 425–430.

Dijk, R., van den Berg, D., Beumer, R. R., de Boer, E., Dijkstra, A., Kalkmand, P., Stegeman, H., Uyttendaele, M., & Veenendaal, H. (2007). *Microbiologie van Voedingsmiddelen: methoden, principes en criteria* (vierde druk). Uitgeverij Keesing Noordervliet, Houten, Nederland — ISBN 978-90-72072-77-1, pp. 186-187. Retrieved July 2, 2013, from http://*dspace.ou.nl/bitstream/1820/3648/1/NWFVLandeghem2009.pdf*

Duarte, B. P. M., & Saraiva, P. M. (2008). An optimization-based approach for designing attribute acceptance sampling plans. *International Journal of Quality and Reliability Management*, 25(8), 824-841.

European Commission. (2005). Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. *Official Journal of European Union*, L 338, 1–29.

Evans, J. A., Russell, S. L., James, C., & Corry, J. E. L. (2004). Microbial contamination of food refrigeration equipment. *Journal of food Engineering*, 62(3), 225–232.

Heinitz, M. L., Ruble, R. D., Wagner, D. E., Tatini, S. R. J. (2000). Incidence of Salmonella in fish and seafood. *Food Protection*, 63(5), 579-92.

Henson, S., & Jaffee, S. (2006). *A strategic perspective on the impact of food safety standards on developing countries* (Invited paper prepared for presentation at the International Association of Agricultural Economists Conference). Gold Coast,

Australia, August 12-18. Retrieved June 12, 2013, from http://ageconsearch.umn.edu/bitstream/25456/1/ip06he13.pdf

Henson, S., & Mitullah, W. (2004). *Kenyan Exports of Nile Perch: The Impact of Food Safety on an Export-Oriented Supply Chain* (World Bank Policy Research Working Paper 3349). Retrieved January 2, 2013, from http://elibrary.worldbank.org/docserver/download/3349.pdf

Huss, H. H., Gram, L., Ababouch, L. (2003). *Assessment and management of seafood safety and quality*. FAO Fisheries Technical Papers, Rome, Italy.

International Commission on Microbiological Specifications for Foods (ICMSF). (1986). Recommended Microbiological Limits for Sea foods. Retrieved June 10, 2013, from http://seafood.ucdavis.edu/organize/icmsf.htm

International Commission on Microbiological Specifications of Foods (ICMSF). (2005). *Microorganisms in Foods 6. Microbial Ecology of Food Commodities* (2nd Edition). Kluwer Academic/Plenum Publishers, New York.

International Organization for Standardization. (2001). *Microbiology of food and animal feeding stuffs--Horizontal method for the enumeration of beta-glucuronidase-positive Escherichia coli -- Part 2: Colony-count technique at 44 degrees C using 5-bromo-4-chloro-3-indolyl beta-D-glucuronide* **(**ISO 16649-2:2001**).** International Organization for Standardization, Geneva.

International Organization for Standardization. (2002). *Microbiology of food and animal feeding stuffs - Horizontal method for detection of Salmonella spp* (ISO 6579:2002). International Organization for Standardization, Geneva.

International Organization for Standardization. (2003). *Microbiology of food and animal feeding stuffs. Horizontal method for the enumeration of microorganisms—colony counts technique at* 30^0C (ISO 4833:2003). International Organization for Standardization, Geneva.

International Organization for Standardization. (2003). *Microbiology of food and animal feeding stuffs. Horizontal method for the enumeration of coagulase positive Staphylococcus aureus and other species, part 1. Technique using Baird-Parker agar medium. Amendment 1: inclusion of precision data* (ISO 6888-1:1999/Amd. 1:2003). International Organization for Standardization, Geneva

International Organization for Standardization. (2003). Microbiology of food and animal feeding stuffs -- Preparation of test samples, initial suspension and decimal dilutions for microbiological examination -- Part 3: Specific rules for the preparation of fish and fishery products (ISO 6887-3:2003). International Organization for Standardization, Geneva.

International Organization for Standardization. (2004). Microbiology of food and animal feeding stuffs. Horizontal methods for sampling techniques from surfaces using contact plates and swabs (ISO 18593:2004). International Organization for Standardization, Geneva.

International Organization for Standardization. (2004). *Microbiology of food and animal feeding stuffs. Horizontal method for the detection and enumeration of Enterobacteriaceae, part 2. Colony-count method* (ISO 21528-2:2004). International Organization for Standardization, Geneva.

Jacxsens, L., Kussaga, J., Luning, P. A., Van der Spiegel, M., Devlieghere, F., & Uyttendaele, M. (2009b). A microbial assessment scheme to support microbial performance measurements of food safety management systems. *International Journal of Food Microbiology*, 134(1-2), 113–125.

Jacxsens, L., Luning, P. A., Marcelis, W. J., Van Boekel, T., Rovira, J., Oses, S., Kousta, M., Drosinos, E., Jasson, V., & Uyttendaele, M. (2011). Tools for the performance assessment and improvement of food safety management systems. *Trends in Food Science & Technology*, 22(1), 80–89.

Jacxsens, L., Uyttendaele, M., Devlieghere, F., Rovira, J., Oses Gomez, S., & Luning, P. A. (2010). Food safety performance indicators to benchmark food safety output of food safety management systems. *International Journal Food Microbiology*, 141(Suppl 1), S180-S187.

Joint Hospitality Industry Congress (JHIC). (1995). *Industry guide to good hygiene practice: catering guide* (Food safety (general food hygiene) regulations). Chadwick House Group, London. Retrieved June 3, 2013, from http://*archive.food.gov.uk/dept_health/pdf/catsec.pdf*

Kenya Bureau of Standards. (2012). *Specification for fresh and frozen fish fillet* (KS 1399-2: 2012). ICS 67.120.30. Kenya Bureau of Standards, Nairobi.

Kenya Bureau of Standards. (2012). *Specification for fresh fin fish* (KS 1399-1: 2012). ICS 67.120.30. Kenya Bureau of Standards, Nairobi.

Kirby, R. M., Bartram, B., & Carr, R. (2003). Water in food production and processing-Quality and quality concerns. *Food Control*, 14(5), 283-299.

Lahou, E., Jacxsens, L., Daelman, J., Van Landeghem, F., & Uyttendaele, M. (2012). Microbiological performance of a food safety management system in a food service operation. *Journal of Food Protection*, 75(4), 706–716.

Luning, P. A., & Marcelis, W. J. (2007). A conceptual model of food quality management functions based on a techno-managerial approach. *Trends in Food Science and Technology*, 18(3), 159-166.

Luning, P. A., Bango, L., Kussaga, J., Rovira, J., & Marcelis, W. J. (2008). Comprehensive analysis and differentiated assessment of food safety control systems: a diagnostic instrument. *Trends in Food Science and Technology*, 19(10), 522–534.

Luning, P. A., Jacxsens, L., Rovira, J., Osés, S. M., Uyttendaele, M., & Marcelis, W. J. (2011b). A concurrent diagnosis of microbiological food safety output and food safety management system performance: cases from meat processing industries. *Food Control*, 22(3-4), 555–565.

Luning, P. A., Marcelis, W. J., Rovira, J., Van der Spiegel, M., Uyttendaele, M., & Jacxsens, L. (2009). Systematic assessment of core assurance activities in a company specific food safety management system. *Trends in Food Science and Technology*, 20(6), 300–312.

Luning, P. A., Marcelis, W. J., van Boekel, M. A., Rovira, J., Uyttendaele, M., & Jacxsens, L. (2011a). Diagnostic tool to analyze riskiness of context factors which impact food safety management system performance. *Trends in Food Science and Technology*, 22(1), S67-S79.

Mead, G. C., Hudson, W. R., & Hinton, M. H. (1993). Microbiological survey of five poultry processing plants in the UK. *British Poultry Science*, 34(3), 497–503.

Ministry of fisheries Kenya. (2013). *Fisheries industries challenges*. Retrieved May 20, 2013, from http://www.fisheries.go.ke/about/fisheries-sector/fisheries-industry-challenges

Nel, S., Lues, J. F. R., Buys, E. M., & Venter, P. (2004). The personal and general hygiene practices in the deboning room of a high throughput red meat abattoir. *Food Control*, 15(7), 571–578.

Oliveira, M., Usall, J., Vinas, I., Anguera, M., Gatius, F., & Abadias, M. (2010). Microbiological quality of fresh lettuce from organic and conventional production. *Food Microbiology*, 27(5), 679–684.

Opiyo, B. A., Wangoh, J., & Njage, P. M. K. (2013). Microbiological Performance of Dairy Processing Plants Is Influenced by Scale of Production and the

Implemented Food Safety Management System: A Case Study. *Journal of Food Protection*, 76(6), 975–983.

Osés, S. M., Luning, P. A., Jacxsens, L., Santillanab, S., Jaimea, I., & Rovira, J. (2012). Food safety management system performance in the lamb chain. *Food Control*, 25(2), 493–500.

Reij, M. W., Den Aantrekker, E. D., & ILSI Europe Risk Analysis in Microbiology Task Force. (2004). Recontamination as a source of pathogens in processed foods. *International Journal of Food Microbiology*, 91(1), 1-11.

Rusin, P., Orosz-Coughlin, P., & Gerba, C. (1998). Reduction of fecal coliform, coliform and heterotrophic plate count bacteria in the household kitchen and bathroom by disinfections with hypochlorite cleaners. *Journal of applied microbiology*, 85(5), 819–828.

Samakupa, A. P., Einarsson, H., Eyþórsdóttir, A. (2003). *Hygiene indicators in a fish processing establishment-a case study in a white fish processing establishment*. UNU-Fisheries Training Programme. Retrieved June 20, 2013, from http:// *www.unuftp.is/static/fellows/document/alberthprf.pdf*

Sampers, I., Habib, I., De Zutter, L., Dumoulin, A., & Uyttendaele, M. (2010). Survival of Campylobacter spp in poultry meat preparations subjected to freezing, refrigeration, increased salt concentration, and heat treatment. *International Journal of Food Microbiology*, 137(2), 147–153.

Shojaei, H., Shooshtaripoor, J., & Masoud, A. (2006). Efficacy of simple hand-washing in reduction of microbial hand contamination of Iranian food handlers. *Food Research International,* 39(5), 525–529.

Simoes, M., Simoes, L. C., & Vieira, M. J. (2010). A review of current and emergent biofilm control strategies. *Food Science and Technology,* 43(4), 573–583.

Unnevehr, L. J. (2003). *Food safety in food security and food trade* (IFPRI 2020 vision focus brief 10, brief 1 of 17, September 2003). Retrieved May 15, 2013, from http://www.ifpri.org/pubs/catalog.htm#focus

Uyttendaele, M., Jacxsens, L., De Loy-Hendrickx, A., Devlieghere, F., & Debevere, J. (2010). Microbiologische richtwaarden en wettelijke microbiologische criteria. Laboratory of Food Microbiology and Food Preservation, University of Ghent, Ghent, Belgium.

Venugopal, V. (2002). Biosensors in fish production and quality control. *Biosensors and Bioelectronics*, 17(3), 147-157.

Vogel, B. F., Huss, H. H., Ojeniyi, B., Ahrens, P., & Gram, L. (2001). Elucidation of Listeria monocytogenes contamination routes in cold-smoked salmon processing plants detected by DNA-based typing methods. *Applied and Environmental Microbiology*, 67(6), 2586-2595.

Wekell, M. M., Manger, R., Kolburn, K., Adams, A., & Hill, W. (1994). *Microbiological quality of Sea foods: viruses, bacteria and parasites* (In Shahidi F., & Botta R. J (Eds). Sea foods Chemistry, Processing Technology and Quality, (pp 220-232). University of Nairobi.

CHAPTER FOUR

Title: General conclusions and recommendations

4.1 General Conclusions

4.1.1 Fish industry food safety management system diagnosis in

Contextual risk: The study found that majority of the companies (78%) were operating under moderate to high risk context (score 2-3) environment. Most of them had moderate FSMS (score 2) except company F which had moderate to advance overall FSMS (score2-3). The FSMS of majority of the companies in the fish sector were therefore incapable of consistently handling risky context characteristics.

Context characteristics diagnosis indicated that all the fish processors work with high risk raw fish products which requires advance levels of FSMS. All of them also scored higher risk levels on extent of power in supplier's and customer's relationships since they did not have influence on supplier's production activities and usage of products by their customers. This could lead to unpredictable safety level of incoming raw materials and in the conditions of end products usage.

Organizational characteristics for all the companies performed moderately on presence of technological staff, sufficiency in operators' competence and sufficiency of supporting information systems. They had restricted number of qualified technological staff especially in their QA departments. Operators had inadequate education level coupled with restricted trainings however most had enough experience. Their information systems were only accessed by specific personnel.

Core control activities: All the companies performed well (advance) in cooling facilities which is a core control activity with the aim of maintaining the cold chain. However, all of them did not implement any physical or packaging intervention method. Majority had advance levels in the operation of control strategies like compliance to procedures, equipment and facilities hygienic performance, cooling capacity measuring and analytical equipments but majority performed moderately on the actual availability of procedures.

Core assurance activities: Majority of the companies had advance activities for defining system requirements and verification of core assurance activities. They proactively translated external assurance requirements and systematically analyzed information from validation and verification reports. They also confirmed performance by actual tests on defined frequency. However, validation activities, documentation and record keeping for the majority were moderately rated since they lacked central integrated systems which could be assessed by everybody. Validation was based on and compared to expert knowledge and regulatory documents but not scientific sources.

Food safety output: Performance of external assessment of food safety performance activities like FSMS evaluation, complaints on hygiene and microbiological problems was good for majority of the companies. However, seriousness of remarks for majority was poor to moderate in performance. Several accredited third parties and ministry of fisheries did inspection and auditing of the plants furthermore they had not received any microbiological or hygiene complaints from their customers. However, auditing results indicated some minor and major remarks on various FSMS activities. Internal evaluation for majority indicated structured product sampling with fixed frequency while judgment

criteria involved usage of legal fisheries act. They had also not received any hygiene and pathogen non conformity complaint.

4.1.2 Microbiological assessment of effectiveness of control and assurance activities

Absence of salmonella in all sampling locations indicates that the FSMS implemented by the fish exporting industries were effective against the organisms. More than 67% of the companies had good performance for all the parameters from fish product samples. However, surface samples showed that 56% of the companies performed poorly and averagely on TVCs before and after cleaning respectively. Hands or gloves of operators from 89% of the companies were contaminated with *S. aureus* above the generally accepted microbial guidelines for fish indicating inadequate personal hygiene. Performance of large sized processors was better than medium and small sized ones in terms of MSLP in all the CSLs indicating presence of fish safety specific FSMS.

There were high initial levels of *Enterobacteriaceae* in the raw fish and TVCs on surfaces which were coupled with cross-contamination from operators, contact materials and equipment. Furthermore, a higher variability was revealed in *Enterobacteriaceae* and TVC counts across the CSLs. More advanced control and assurance activities particularly in their raw material control, personal hygiene and cleaning and sanitation programmes were needed.

4. 2 Recommendations

- To reduce high contextual pressure by the traceability system, it is suggested that the companies may need more information collection points, more detailed

information, and more data processing, collection of more samples and collection of samples at a higher levels.

- The companies should implement physical or packaging intervention methods which are specifically designed for fish safety. This will complement the advances already made in their cooling facilities.

- The companies should implement complete sanitation program differentiated for specific equipment or facilities. Common cleaning agents should also be specific for their production system. The companies' equipment and facilities hygiene design should be modified for specific fish production characteristics in collaboration with equipment and cleaning suppliers. They should also adopt integrated hygienic designs in order to realize low risk levels. Integrated hygienic designs of equipments and facilities decreases chance of cross contamination and contribute to food safety due to higher predictability arising from less ambiguity and uncertainty.

- Personal care and health facilities for the companies should be tailored to support personnel hygiene. Specific training on hygiene matters should also be conducted to assist in the reduction of chance of contamination. Validation of preventive equipment and facilities, sanitation and personal hygiene programs should also be based on expert knowledge (i.e. consultancy), regulatory documents and historical results. The activities should be done on regular basis usually after system modifications and findings described in reports. High counts of *S. aureus* in hands or gloves of fish handlers in majority of the companies could be reduced by use of

more strict personal hygiene requirements. These include special hand washing facilities and provision of basic information coupled with provision of clearly understandable procedures for crucial hygiene related activities. Such specific training on hygiene matters assist in the reduction of chance of contamination. The operators should be trained on good personnel hygiene and practices, wear gloves and change them on a regular basis. Although basic personal and hygiene practices were performed they required optimization and regular checking for their effectiveness.

- The companies can reduce the risks of insufficient raw materials by critically evaluating their implemented specifications and by systematically inspecting FSMS of their suppliers. Another option is to introduce intervention processes to have the ability to reduce initial levels on fish to acceptable levels. High variability in *Enterobacteriaceae* and TVCs counts across the CSLs in majority of the companies may require advance raw fish material control. This can be achieved by implementation of clearly defined sampling frequency based on actual historical data of suppliers. This enhances realization of more predictable good safety outcome due to less ambiguity and uncertainty. The companies should also inspect FSMS of their suppliers.

- Physical and packaging intervention equipment should be designed and adapted specifically for fish to aid in process predictability through improved compliance to standards. They also help in realization of stability and predictability of production outcomes.

- The stakeholders should consider developing microbiological guidelines criteria for fish processing to include the environmental samples analysis which was lacking. The companies used differing internally developed microbiological guidelines for surface samples.

APPENDIXES

Annex 1. Results for context, FSMS and FS output performance diagnosis for the nine fish processing companies.

Indicators	**Companies**								
	A	B	C	D	E	F	G	H	I
CONTEXT FACTORS(OVERAL)	**2-3**	**2-3**	**2-3**	**2**	**2-3**	**2-3**	**2-3**	**2-3**	**2**
Product characteristics									
Risk raw materials	3	3	3	3	3	3	3	3	3
Risk product groups	3	3	2	2	3	3	2	3	3
Safety contribution packaging concept	1	2	2	2	2	2	2	2	1
Process characteristics									
Extent intervention steps	3	2	1	1	3	1	2	2	2
Degree production process changes	2	3	3	1	3	3	3	2	3
Rate product/process design changes	1	3	2	2	2	2	2	2	2
Organizational characteristics									
Presence of technological staff	2	2	2	2	2	2	2	2	2
Variability workforce composition	2	2	2	1	2	1	2	2	2
Sufficiency operators' competence	2	2	2	2	2	2	2	2	2
Extent of management commitment	2	3	2	2	2	2	2	2	2
Degree of employee involvement	3	3	3	2	3	2	3	3	2
Level of formalization	2	3	2	2	2	2	2	2	2
Sufficiency supporting information systems	2	2	2	2	2	2	2	2	2
Chain environmental characteristics									
Degree of safety contribution in chain position	2	2	2	2	2	2	2	2	2
Extent of power in supplier relationships	3	3	3	3	3	3	3	3	3

Degree of authority in customer relationships	3	3	3	3	3	3	3	3	3
Severity of stakeholders' requirements	2	2	2	2	2	2	2	2	2
FSMS ACTIVITIES(OVERAL)	**2**	**2**	**2**	**2**	**2**	**2-3**	**2**	**2**	**2-3**
Core control activities									
Design preventive measures									
Sophistication hygienic design equipment and facilities	2	2	2	3	2	2	2	2	2
Adequacy cooling facilities	3	3	3	3	3	3	3	3	3
Specificity sanitation program	3	2	3	2	3	3	2	2	3
Extent personal hygiene requirements	3	2	3	3	3	3	3	2	3
Adequacy raw material control	2	2	2	3	3	2	3	2	3
Specificity product specific preventive measures	3	3	2	3	2	3	3	3	3
Design intervention processes									
Adequacy physical intervention equipment	0	0	0	0	0	0	0	0	0
Adequacy packaging intervention equipment	0	0	0	0	0	0	0	0	0
Specificity maintenance/calibration programs intervention equipment	0	0	0	0	0	0	0	0	0
Specificity of chemical &biological intervention methods	3	2	3	3	3	2	2	2	3
Design monitoring system									
Appropriateness CCP analysis	2	2	3	3	1	3	2	2	3
Appropriateness standards and tolerances design	3	2	3	3	2	2	3	2	3
Adequacy analytical methods to assess pathogen levels	3	3	3	3	2	3	2	3	3

Adequacy measuring equipment to monitor process/product	3	3	2	2	2	2	3	3	3
Specificity of calibration/verification program measuring and analytical equipment	2	3	2	3	2	3	3	2	2
Specificity sampling design and measuring plan	2	2	2	2	3	2	2	2	2
Extent corrective actions	2	3	2	3	3	3	3	3	3
Operation control strategies									
Actual availability of procedures	2	2	2	3	2	3	2	3	2
Actual compliance to procedures	2	2	3	3	3	3	3	2	3
Actual hygienic performance equipment and facilities	3	3	3	2	3	3	3	3	3
Actual cooling capacity	3	3	2	3	3	3	3	3	3
Actual process capability physical intervention equipment	0	0	0	0	0	0	0	0	0
Actual process capability of packaging intervention equipment	0	0	0	0	0	0	0	0	0
Actual measuring equipment performance	1	2	0	3	1	3	3	3	3
Actual analytical equipment performance	3	3	0	2	3	3	3	3	3
Core assurance activities									
Defining system requirements									
Sophistication translating external requirements into internal FSMS requirements	2	3	3	2	3	3	2	2	3
Extent systematic use of feedback information to improve FSMS	3	2	3	3	3	3	3	2	3
Validation									
Sophistication validating preventive equipment and facilities, sanitation and personal hygiene programs	2	2	2	2	2	3	2	3	3

Sophistication validating effectiveness intervention equipment and methods	2	2	2	3	2	3	2	3	3
Sophistication of validating monitoring systems	2	2	2	2	1	3	3	2	3
Verification									
Extent verifying people related performance	2	2	3	2	3	3	3	0	3
Extent verifying equipment and methods related performance	2	3	3	2	2	3	3	3	3
Documentation and record-keeping									
Appropriateness documentation system	2	2	2	2	2	3	2	2	2
Appropriateness record-keeping system	2	2	2	2	2	2	2	2	2
Food Safety performance activities(OVARAL)	**2-3**	**2**	**2-3**	**2-3**	**2**	**3**	**3**	**2-3**	**2-3**
External assessment									
FSMS Evaluation	3	3	2	3	1	3	3	3	2
Seriousness of remarks	3	2	2	3	2	3	3	1	2
Microbiological food safety complaints	2	1	3	2	2	3	3	3	3
Hygiene complaints by customers	2	1	3	2	2	3	3	3	3
Internal assessment									
Product sampling	3	3	3	3	2	3	3	3	3
Judgment criteria	3	3	3	3	3	3	3	1	3
Hygiene and pathogen non conformities	2	2	3	2	2	3	3	3	3

Annex 2: Food safety management system-Diagnostic instrument

Introductory section

The self assessment tool starts with
A. General questions about your company
B. Questions to formulate a representative production unit (RPU). Only for this
C. Situations of **contextual factors** that are typical for your company
D. Levels at which **core control activities** are addressed in your FSMS
E. Levels at which **core assurance activities** in your FSMS
F. Rough indication about **food safety performance** level.

Please fill in the questions with a *, other questions are optional to fill in.

1. Is your company part of a larger (inter/national) company? *

=Yes
=No

2. Name (mother) company:

3. Location of your company:

4. Total number of employees in your company (in this location): *
1-9
10-49
50-249
249

5. Which production sector (e.g. dairy, vegetable, beef/lamb, poultry) are you in? *

6. Which Quality Assurance (QA) standards/guidelines have been implemented? *
PRP (GMP, GHP, GDP)
HACCP
ISO 9001
ISO 22000
BRC
IFS
GLOBALGAP (previously EUREP-GAP)
SQF 1000
SQF 2000
Auto-control system

7. For which QA standards is your company certified? *
ISO 9001
ISO 22000
BRC
IFS
GLOBALGAP/EUREP GAP
SQF 1000
SQF 2000
Auto-control system

8. Do you have a QA manager? *
Yes
No

9. Do you have a QA department? *
Yes
No

10. How many people are working in the QA department? *

11. Which **specific product group** is made in this production unit? (e.g. fermented cheese, fruit yoghurts, cut meat parts, fermented sausages, ready to eat meals etc.)

12. Who are the **major customers** of this specific product group? (e.g. business to business, retailers, food processing companies, catering, etc.)

13. What are major **basic (bulk) raw materials** (from suppliers) you use for this product group? (e.g. carcasses (for meat preparation), raw milk (for dairy products), major ingredients (as mentioned on packaging label), mention them

14. What are major **(minor) ingredients** of this product group? (e.g. spices, colorants, emulsifiers, flavouring agents)

15. What is **packaging concept** used for this product group? (e.g. vacuum, MAP, PE film, carton, bag in box, no packaging, etc)

16. Who are **major suppliers** of basic (bulk) raw materials and (minor) ingredients? (e.g. slaughter houses, meat chopping factory, milk collection centres, farmers, ingredient suppliers, etc.)

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

18. What are major **production process** steps to make this product group (e.g. skin

removal, deboning, curing, salting, fermentation, pasteurisation, sterilisation, high pressure, drying etc.)

19. What are **major equipments/machines** used of this product group (e.g. cooling equipment, slicing machines, pasteurizer, fermenter, dryer, packaging equipment, etc.)?

ASSESSMENT OF CONTEXTUAL FACTORS

Assessment of product and process characteristics

A1. Risk of raw materials

1. In which situation would you place the risk of your raw materials in your RPU (representative production unit)?

Situation 1	Situation 2	Situation 3
Basic/major raw materials are not associated with high initial microbial levels and pathogens. - Storage at (uncontrolled) room temperature conditions	Minor raw materials/ingredients associated with high initial microbial levels and pathogens, which potentially can affect safety of final product. - Storage at lower than room temperature but no specific, strict control requirements	Basic/major raw materials associated with high initial microbial levels and pathogens, which potentially can affect safety of final product

Supporting information to differentiate situation 2 and 3

- When your raw materials are associated with high initial microbial levels and or pathogens, and when they should be stored below room temperature, then it is level 2 or 3.
- Crucial for level 3 is that high requirements on storage are crucial for prevention of undesired growth of micro-organism (including pathogens).

A2. Risk of product(s) (groups)

2. In which situation would you place the risk of product(s) (groups) of your RPU?

Situation 1	**Situation 2**	**Situation 3**
- Low risk products (microbiologically stable) (aw < 0.6 or pH < 4.2 or intrinsic antimicrobial agents) - and or sterilised products (inactivation complete flora, post contamination not likely).	- Medium risk products (0.98 >aw > 0.6, or 4.2< pH <6.5, no antimicrobials) - and/or in-pack pasteurised, UHT (ultra high temperature), frozen (post contamination not likely).	- High risk products (aw > 0.98, pH 6.5-7.5, or no antimicrobials), - and fresh or pasteurised products (inactivation of original flora and chance on post contamination

Supporting information to differentiate situation 2 and 3

- When your final products (groups) have a water activity aw > 0.6 and or a pH>4.2, and or contains intrinsic antimicrobials, then it is situation 2 or 3.
- Crucial for situation 3 is that your final products have a very high water activity (aw > 0.98) and or a pH>6.5, and or are sensitive to post contamination (not in-pack pasteurised)

A3. Safety contribution of packaging concept

3. In which situation would you place the **safety contribution of the packaging concept** used in your **RPU**?

Situation 1	**Situation 2**	**Situation 3**
- Packaging concept not aimed at influencing microbial safety - like no packaging, open boxes, containers, or simple mechanical barrier (paper, mono layered plastics)	- Packaging concept with specific mechanical barrier properties to prevent microbial contamination, - like multilayered plastics, plastic crates with plastic bag linings	- Dedicated packaging concept which is aimed at reducing and/or preventing growth and contamination of micro-organisms - like active packaging, Modified Atmosphere Packaging (MAP), vacuum packaging.

Supporting information to differentiate situation 2 and 3

- When packaging contributes to prevention of contamination by micro-organisms then situation 2 or 3.
- Crucial for situation 3 is that packaging is specifically designed to prevent as well contamination as growth of micro-organisms (e.g. by changing internal gas conditions).

B4. Extent of intervention steps

4. In which situation would you place the **extent of intervention steps** in your RPU?

Situation 1	**Situation 2**	**Situation 3**
- Process with a lethal intervention step resulting in full inactivation of pathogens and spores	- Process with a restricted set of intervention steps resulting in inactivation of pathogens to acceptable level, but spores not inactivated	- Process with no inactivation steps or a (complex) combination of steps aimed at reducing pathogens to certain level (spores not inactivated, and pathogens not fully inactivated)

Supporting information to differentiate situation 2 and 3

-When your production is characterised by intervention steps that do not fully inactivate both spores and pathogens to acceptable levels, then situation 2 or 3

- Crucial for situation 3, is that none of the steps contribute to reduction of pathogens, or that only a combination of steps results in reduction to an acceptable pathogen level.

B5. Production process changes

5. In which situation would you place **production process changes** in your RPU?

Situation 1	Situation 2	Situation 3
- Core process is characterised by continuous flow processes. - High degree of automation, restricted interference of people. - Cleaning in place (fully automated)	Core process characterised by repetitive flow, i.e. relatively large batches with minor equipment modifications between batches. - Partly automated, still people interference. - Cleaning intervention between batches necessary (partly/not automated).	- Core process characterized by intermittent flow, i.e. relatively small batches, with major modifications between batches (daily batches). - Low degree of automation, clear interference of people with physical system. - Cleaning between batches very critical, not automated.

Supporting information to differentiate situation 2 and 3

- When you have **no** continuous (partly) automated processes for production and cleaning, then situation 2 or 3.

- Crucial for situation 3 is **small** batches (i.e. production of several product groups in a day) and **major people activities** between batches (cleaning between batches/product groups critical and not automated and or major changes in equipment)

B6. Rate of product/process design changes

6. In which situation would you place **rate of product/process design changes** of your RPU?

Situation 1	**Situation 2**	**Situation 3**
- Relatively stable product assortment. - Between 1–5 product and or packaging modifications and/or innovative product (line) per 1–2 years.	- Medium variable product assortment. - Between 1-5 product and or packaging modifications and/or innovative product (line) per 1-2 years.	- Highly variable product assortment. - More than 5 product and or packaging modifications, and/or innovative product (line) per ½-1 year.

Supporting information to differentiate situation 2 and 3

- When no product and or packaging modifications and or innovative product (line) in last 1-2 years, then it is situation 2 or 3.
- Crucial for situation 3 is more than 5 product and or packaging modifications, and/or innovative product (line) per ½-1 year.

Assessment of organization characteristics

C7. Technological staff

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

Situation 1	**Situation 2**	**Situation 3**
- 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 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); - microbial analyses, safety controls at external labs.

Supporting information to differentiate situation 2 and 3

- When there is no QA department with own staff and experts and an own research lab for all microbial analyses and safety controls, then it is situation 2 or 3.
- Crucial for situation 3 is that the person responsible for QA has no specific food safety expertise.

C8. Variability in workforce composition

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

Situation 1	**Situation 2**	**Situation 3**
- - 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

Supporting information to differentiate situation 2 and 3

- When employees typically leave your company within 5 years or when structurally temporary operators are hired, then situation 2 or 3.
- Crucial for situation 3 is a rather high turnover of employees (< 1 year) and temporary operators at whole year around.

C9. Operator competences

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

Situation 1	**Situation 2**	**Situation 3**
- 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 FS 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 than 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

Supporting information to differentiate situation 2 and 3

- When people in your production typically have a low level of education, and or less than 1 year experience in agri-food production, and when restricted training then situation 2 or 3.
- Crucial for situation 3 is not any requirements on basic education level or experience and only a basic training (or instructions) in food safety control without any follow up

C10. Management commitment

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

Situation 1	**Situation 2**	**Situation 3**
- Company has detailed written vision statement on safety with clear measurable objectives. - It has an official quality (safety) team - with formalised meetings and own budget	- Company has general written vision statement on safety. - It has an official quality (safety) team - with regular meetings and restricted budget	- Company has no written vision statement on safety. - It has no official quality (safety) team, - only meetings on safety control in case of recalls, problems, no specific budget.

Supporting information to differentiate situation 2 and 3

- When no detailed written vision statement on safety and or no official quality team with its own budget, then situation 2 or 3.
- Crucial for situation 3 is that management only reacts in case of recalls and comparable safety problems.

C11. Employee involvement

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

Situation 1	**Situation 2**	**Situation 3**
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	- Operators are only informed about modifications in FSMS by production or QA manager. - They are not asked to provide ideas/suggestions for improvements

Supporting information to differentiate situation 2 and 3

- When operators are not fully involved in design and improvement of the safety control system, then situation 2 or 3.
- Crucial for situation 3 is that operators are only informed afterwards about changes in the safety control system.

C12. Formalisation

12. In which situation would you place **formalisation** in your company?

Situation 1	**Situation 2**	**Situation 3**
- All activities are described in SOPs (standard operating procedures)/procedures - formalised 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

Supporting information to differentiate situation 2 and 3

- When not all activities are provided with formal procedures and well organised formal meetings, then situation 2 or 3.
- Crucial for situation 3 is that basically all contacts on food safety decisions are informal and not documented

C13. Information systems

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

Situation 1	**Situation 2**	**Situation 3**
- 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 authorised people	- Company has standard information system for bookkeeping (incoming and outgoing materials); information is not very accurate for food safety control decisions - system is only accessible to authorised people

Supporting information to differentiate situation 2 and 3

- When there is no specific well accessible quality information system, then situation 2 or 3.
- Crucial for situation 3 is that there is even no production information system that is useful for food safety purposes

Assessment of chain environment characteristics

D14. Safety contribution in chain position

14. In which situation would you place the **safety contribution in chain** with respect to your RPU?

Situation 1	**Situation 2**	**Situation 3**
- No contribution to final safety any microbial contamination is reduced to acceptable level further in the chain. Examples	Contribution to final safety by prevention of growth of pathogens but no significant reduction to acceptable level for final consumption	- Critical contribution to final safety by significant reduction of pathogens to acceptable level, and or prevention of post contamination and or growth of pathogens to maintain acceptable level.

Supporting information to differentiate situation 2 and 3

- When your company is (due to its position in the chain) expected to contribute to the prevention or reduction of pathogens in end-products for consumption, then situation 2 or 3.
- Crucial for situation 3 is that the company critically reduces and or prevents contamination and or growth of pathogens

D15. Supplier relationships

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

Situation 1	**Situation 2**	**Situation 3**
- Company is explicitly involved in development of product specifications of major suppliers - and can influence their food safety management system (FSMS), quality management system (QMS) (e.g. via audits	- Company can discuss about product specifications of major suppliers - but has no influence on their FSMS/QMS	- Company has no influence on product specifications nor the FSMS/QMS of major suppliers - only possibility to check specifications and or measure raw materials

Supporting information to differentiate situation 2 and 3

- When your company is not able to put specific requirements on quality systems of major suppliers, then situation 2 or 3.
- Crucial for situation 3 is that you can also not set specific requirements on the supplies of major suppliers

D16. Customer relationships

16. In which situation would you place **customer relationships** with respect to your company?

Situation 1	**Situation 2**	**Situation 3**
- Company has ability to put demands on product use of major critical customers - and can influence their food safety management system (FSMS)/quality management system (QMS) (e.g. audits)	- Company has ability to discuss product use of major critical customers - but has no influence on their FSMS/QMS	- Company has no ability to influence product use by major critical customers and is confronted with conflicting customer requirements, - and has no influence on their FSMS/QMS

Supporting information to differentiate situation 2 and 3

- When the company is not able to put specific requirements on the quality system of the customers, then it is situation 2 or 3.
- Crucial for situation 3 is that the company has to deal with conflicting requirements

D17. Requirements of stakeholders

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

Situation 1	**Situation 2**	**Situation 3**
- General legislative requirements on food safety (PRP/HACCP according to Codex Alimentarius)	- Additional QA requirements (e.g. BRC, IFS) but similar for major stakeholders	- Additional (sometimes conflicting) QA requirements (e.g. BRC, IFS) which are different for major stakeholders

Supporting information to differentiate situation 2 and 3

- When the company has to meet additional QA requirements from stakeholders, then it is situation 2 or 3.
- Crucial for situation 3 is that different stakeholders ask for different (sometimes conflicting) QA requirements.

ASSESSMENT OF FOOD SAFETY CONTROL ACTIVITIES

Assessment of preventive measures design

E18. Hygienic design of equipment and facilities

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

Level 0	Level 1	Level 2	Level 3
Hygienic design of equipment and facilities not important/ not an issue	- Critical equipment not hygienically designed, - facilities meet basic requirements for food production	- Critical equipment purchased from suppliers of standard equipment designed in line with hygiene requirements. - Facilities comply with specific hygiene requirements	- Integrated hygienic design of critical equipment and facilities (according to EHEDG or comparable design criteria) - adapted and tested in the companies' specific food production circumstances in collaboration with equipment and cleaning suppliers

Supporting information to differentiate situation 2 and 3
- When critical equipment and facilities comply with EHEDG or comparable hygienic design criteria then level 2 or 3.
- Crucial for level 3 is that hygienic design is adapted and tested for your production circumstances

E19. Cooling facilities

19. At which level would you place the **cooling facilities** relevant for your RPU?

Level 0	Level 1	Level 2	Level 3
Cooling facilities not used in production	- Domestic/general cooling facilities; - principal cooling capacity not known nor testing product temperature	- Industrial cooling facilities - information about principal cooling capacity from suppliers, no testing of product temperature for different circumstances	- Industrial cooling facilities specifically adapted for companies' specific food production circumstances, - capacity tested by temperature check of environment and products, for different circumstances

Supporting information to differentiate situation 2 and 3
- When capacity of cooling facilities known then level 2 or 3.
- Crucial for 3 is that cooling facilities are adapted (modified) and tested for your production circumstances, and actual product temperature checked for different circumstances

E20. Sanitation programs

20. At which level would you place the **sanitation programs** relevant for your RPU?

Level 0	Level 1	Level 2	Level 3
No specific sanitation programs in place	- Incomplete program not differentiated for specific equipment/facilities; - common cleaning agents not specific for production system;	- Complete program and differentiated for equipment and facilities. - Cleaning agents (i.e. detergents and disinfectants) selected based on advices of suppliers.	- Complete programs, tailored for different equipment & facilities, - cleaning agents specifically modified and tested on effectiveness in the companies' specific food production system,

Supporting information to differentiate situation 2 and 3

- When complete (full-steps) sanitation program(s) then level 2 or 3.
- Crucial for level 3 is that sanitation agents and their use are tested for your specific production circumstances

E21. Personal hygiene requirements

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

Level 0	Level 1	Level 2	Level 3
Personal hygiene requirements are not implemented	- Standard requirements for all employees on clothing (caps, gloves, jacks). - Idem 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/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

Supporting information to differentiate situation 2 and 3

- When specific personal hygiene requirements (clothes, personal care, health), and facilities and instructions then level 2 or 3.
- Crucial for 3 is that specific (high) personal hygiene requirements are for all employees and that facilities and instructions are tailored (i.e. specific/special) for your production circumstances

E22. Raw material control

22. At which level would you place your **raw material control** relevant for your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
No control on food safety level of incoming raw material	- Raw material control on food safety level is ad hoc and is mainly based on historical experience with suppliers	- Raw material control on food safety level is systematic and is based on guidelines, or legislative requirements, or guidance document for sector	- Raw material control on food safety level is systematic using statistical underpinned acceptance sampling (i.e. sampling frequency, location, analysis, rejection criteria, etc) based on actual historical data of suppliers

Supporting information to differentiate situation 2 and 3

- When raw materials are systematically controlled then level 2 or 3.
- Crucial for situation 3 is that acceptance sampling is based on statistical analysis of actual historical data of suppliers

E23. Product specific preventive measures

23. At which level would you place your **product specific preventive measures** relevant for your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
No product specific measures used	- Raw material control on food safety level is ad hoc and is mainly based on historical experience with suppliers	- Product specific preventive measure is based on guideline, legislative requirement, guidance document, expert knowledge, - but not tested.	- Product specific preventive measure is based on legislative requirement/guidance documents - and tested for specific food production circumstances.

Supporting information to differentiate situation 2 and 3

- When effect of product specific preventive measure is supported with expert knowledge/scientific information then level 2 or 3.
- Crucial for level 3 is that the product specific measure is tested for your production circumstances (it is known to what extent the measure can reduce cross contamination, high initial loads, etc).

Assessment of intervention processes design

F24. Physical intervention equipment

24. At which level would you place your **physical intervention equipment** relevant for your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
No physical intervention equipment 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

Supporting information to differentiate situation 2 and 3
- When process capability of intervention equipment is known then level 2 or 3.
- Crucial for 3 is that intervention equipment is specifically designed (modified) and tested for your production circumstances

F25. Packaging intervention equipment

25. At which level would you place your packaging intervention equipment (i.e. MAP, vacuum, active packaging) relevant for your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
Packaging concept is not specifically aimed at reducing, inactivating pathogens	- Packaging conditions selected based on company knowledge - General packaging equipment not product specific - Packaging equipment capability not known	- Packaging conditions selected based on expertise of suppliers of dedicated packaging concepts (MAP, active packaging) -'Best standard' packaging equipment available in practice, product specific - Packaging 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	- Packaging conditions are adapted and tested for the company specific circumstances - Intervention equipment specifically modified for companies' specific food production circumstances and Packaging equipment capability is tested in company specific circumstances and information is well-documented

Supporting information to differentiate situation 2 and 3
- When effect of packaging conditions (e.g. film properties, gas composition, product/headspace ratio) and capability of packaging equipment is known then level 2 or 3
- Crucial for level 3 is that the packaging conditions and packaging equipment are specifically designed (modified) and tested for your production circumstances

F26. Maintenance and calibration program for (intervention) equipment

26. At which level would you place your **maintenance and calibration program for (intervention) equipment** relevant for your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
No maintenance applied	- Maintenance is basically initiated by problems, ad hoc. - no (clear) instructions about frequency and maintenance tasks; - not well documented	- Maintenance program developed 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 using data from regular inspections and breakdown analyses, - specific instructions on frequency maintenance tasks; - well documented (at company).

Supporting information to differentiate situation 2 and 3
- When structural maintenance program for intervention equipment available then level 2 or 3.
- Crucial for 3 is that the maintenance program is specifically designed for your production process (based on actual process data and analysis).

F27. Intervention methods

27. At which level would you place your **(chemical and biological) intervention methods** relevant for your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
No chemical or biological intervention methods used	- Intervention methods are applied based on company knowledge, and experience, - potential reduction level not known.	- Application of intervention method based on advices of specialised suppliers, but not tested for specific food production system characteristics, - potential reduction level	- intervention method is modified for the companies' specific food production system characteristics - Actual reduction level is known by testing in the real production system conditions

	known based on literature or expert knowledge.	and is well-documented

Supporting information to differentiate situation 2 and 3
- When effect of the intervention method is supported with expert knowledge, scientific information then level 2 or 3.
- Crucial for situation 3 is that the intervention method is tested for your production circumstances

Assessment of monitoring system design

G28. CCP/CP Analysis

28. At which level would you place the **analysis of CCP/CPs** with respect to your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
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/CP 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 modelling of hazard behaviour and/or challenge tests

Supporting information to differentiate situation 2 and 3
- When your CCP/CP analysis is executed in a systematic way and based on expert knowledge, scientific information then level 2 or 3.
- Crucial for level 3 is that CCP/CPs are tested for your actual production circumstances

G29. Standards and tolerances design

29. At which level would you place your **standards and tolerances design** with respect to your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
No written standards for product and process parameters	- Standards for critical product parameters 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.

Supporting information to differentiate situation 2 and 3
- When standards and tolerances are clearly specified and minimally based upon (available) legislative requirements then level 2 and 3.
- Crucial for 3 is that standards and tolerance are scientifically underpinned and adapted for your production circumstances.

G30. Analytical methods to assess pathogens

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

Level 0	**Level 1**	**Level 2**	**Level 3**
Pathogens are not analysed (not 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	- 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)	- 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

Supporting information to differentiate situation 2 and 3
- When internationally validated methods are used for pathogen testing then level 2 or 3.
- Crucial for level 3 is that the method is also accredited

G31. Measuring equipment to monitor process/product status

31. At which level would you place **measuring equipment to monitor process / product status** in your company/RPU?

Level 0	Level 1	Level 2	Level 3
No measuring equipment	- No standardised 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 recognised) 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.

Supporting information to differentiate situation 2 and 3
- When internationally acknowledged (in line) measuring equipment recording history information then level 2 or 3.
- Crucial for 3 is that the measuring equipment is adapted and tested on accuracy for your production circumstances

G32. Calibration program for measuring and analytical equipment

32. At which level would you place your **calibration program for measuring and analytical equipment** in your company/RPU?

Level 0	Level 1	Level 2	Level 3
No calibration/verification program for measuring nor analytical equipment	- Calibration of measuring and or analytical equipment on ad-hoc basis. - tasks and frequency not clear, and not (well) documented.	- calibration outsourced at equipment suppliers or at external laboratories for analytical equipment - task and frequency based on international standards, not specific for food production system, documentation at equipment suppliers	- Calibration program specifically designed based on data from your own food production system, according to international standards - tasks and frequency in-house documented

Supporting information to differentiate situation 2 and 3
- When structural calibration/verification program (for measuring and or analytical equipment) according to international standards available then level 2 or 3.

- Crucial for 3 is that the calibration/verification program is specifically designed (or adapted) based on actual process data and analysis of for your own production process

G33. Sampling design (for microbial assessment) and measuring plan

33. At which level would you place **sampling design (for microbial assessment) and measuring plan** with respect to your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
No sampling design nor a measuring plan in place	Sampling design and measuring 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 (e.g. meat, chicken, etc) as available in literature (e.g. EU guidelines, or ICMSF)	Sampling design and measuring plan based on statistical analysis of pathogen distribution in own food production process

Supporting information to differentiate situation 2 and 3
- When sampling design and measuring plans are based on acknowledged guidelines/scientific information then level 2 or 3.
- Crucial for level 3 is that sampling design and measuring plans are adapted based on statistical analysis of pathogen distribution in your production

G34. Corrective actions

34. At which level would you place **corrective actions** with respect to your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
No corrective actions have (yet) been described	- 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 adjustements and handling of non-compliance products. - Structural analysis of cause of deviations, differentiated measures.

Supporting information to differentiate situation 2 and 3
- When complete description of corrective actions (minimally based on hygiene codes) then level 2 or 3.
- Crucial for 3 is the structural analysis of causes of product/process deviations and differentiated corrective actions specific for your production.

Assessment of operation of food safety control activities

H35. Actual availability of procedures

35. At which level would you place **actual availability of procedures** in your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
No procedures in place	- Procedures are sometimes/partly available on location (often paper-based), - difficult to understand by users - and are not kept up-to-date	- Procedures are available at location (often paper-based) - and well to understand for most users - but are kept up-to-date on ad-hoc basis	- Procedures very easily available (digital, on-line) at location, - and are designed for specific users - and updated at a regular basis

Supporting information to differentiate situation 2 and 3
- When procedures available at appropriate locations then level 2 or 3.
- Crucial for level 3 is that procedures are specifically designed for the users and kept systematically up to date.

H36. Actual compliance to procedures

36. At which level would you place the **actual of compliance to procedures** in your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
No procedures; no idea about compliance to procedures of operators	- 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 internalised. - Self control of compliance to procedures

Supporting information to differentiate situation 2 and 3
- When majority of employees are familiar with existence of procedures for core control activities then level 2 or 3.
- Crucial for level 3 is that safety tasks are internalised (i.e. employees know well content of procedures) and they control themselves (not by chief/QA)

H37. Actual hygienic performance of equipment and facilities

37. At which level would you place **actual hygienic performance of equipment and facilities** with respect to your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
- Hygienic design is no issue. - 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

Supporting information to differentiate situation 2 and 3
- When stable hygienic performance of equipment and facilities with only few contamination problems then level 2 and 3.
- Crucial for level 3 is that actual hygiene performance is systematically/regularly tested according to acknowledged guidelines/criteria (like described by EHEDG).

H38. Actual cooling capacity

38. At which level would you place the **actual cooling capacity** with respect to your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
Cooling facilities not used. No cooling performance information known	- Regularly unstable performance with significant variations in facility temperature - no automatic temperature devices and deviations not systematically analysed, - no information about product temperature	- Sometimes unstable performance, - automatic temperature control but no systematic analysis of deviations, - ad hoc information about product temperature	- Stable performance of cooling facilities, - environmental temperature is automatically monitored and deviations are systematically analysed; - constant information about product temperatures

Supporting information to differentiate situation 2 and 3
- When stable cooling capacity with no or sometimes unexpected deviations based on information from (automatic) environmental temperature control then level 2 or 3.
- Crucial for level 3 is that actual cooling capacity is also stable based on regular analysis of actual product temperature under your production circumstances

H39. Actual process capability of physical intervention processess

39. At which level would you place the **actual process capability of physical intervention processes** with respect to your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
No intervention equipment in place; 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

Supporting information to differentiate situation 2 and 3
- When individual physical intervention equipment performs rather stable (i.e. constant variation around target value) with no or sometimes unexpected deviations and actual performance is known based on information from actual process data then situation 2 or 3
- Crucial for situation 3 is that only minor deviations exist between similar process equipment and performance is systematically analysed.

H40. Actual process capability of packaging intervention

40. At which level would you place the **actual process capability of packaging intervention** (MAP, vacuum, active) processes with respect to your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
- no packaging intervention equipment in place - 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

Supporting information to differentiate situation 2 and 3

- When individual packaging intervention equipment performs rather stable (i.e. constant variation around target value) with no or sometimes unexpected deviations and actual performance is known based on information from actual process data then level 2 or 3
- Crucial for level 3 is that only minor deviations exist between similar packaging equipment and performance is systematically analysed

H41. Actual performance of measuring equipment

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

Level 0	**Level 1**	**Level 2**	**Level 3**
- No measuring equipment used; - 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

Supporting information to differentiate situation 2 and 3

- When measuring equipment not very sensitive towards changes in production systems then level 2 or 3.
- Crucial for 3 is that measuring equipment is stable under all different circumstances

H42. Actual performance of analytical equipment

42. At which level would you place the **actual performance of analytical equipment** relevant for your RPU?

Level 0	Level 1	Level 2	Level 3
- No analytical analyses executed (nor by company nor by external lab); - sensitivity analytical equipment unknown	Analytical equipment very sensitive towards minor changes in product composition (interference of compounds) and or other analytical circumstances	Analytical equipment sensitive for few specific well known product compounds, and or analytical circumstances	- Analytical equipment very stable under different product compositions and analytical circumstances -Analytical equipment at accredited laboratories are assumed to be stable under different product and analytical circumstances

Supporting information to differentiate situation 2 and 3

- When analytical equipment not very sensitive towards changes in product composition then level 2 or 3.
- Crucial for 3 is that analytical equipment is stable for all different product compositions (also in case analyses are done by external accredited laboratories)

ASSESSMENT OF FOOD SAFETY ASSURANCE ACTIVITIES

Assessment of use of internal information and data

I43. Translation of stakeholder requirements into own FSMS requirements

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

Level 0	Level 1	Level 2	Level 3
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.

Supporting information to differentiate situation 2 and 3
- When external assurance requirements systematically translated into (new) requirements on own food safety control systems then level 2 or 3.
- Crucial for 3 is that assurance requirements are evaluated on your critical production circumstances and translation activities well-documented

I44. Systematic use of feedback information to modify FSMS

44. At which level would you place the **systematic use of feedback information to modify FSMS** related to your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
FSMS has not (yet) ever been modified	- Ad hoc modification of FSMS 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 and verification reports, translations into concrete modifications in FSMS are established in clear procedures with assigned responsibilities; - well documented

Supporting information to differentiate situation 2 and 3
- When systematically information is used from food production system to modify food safety control system, then level 2 or 3.
- Crucial for 3 is the use of verification and validation information established in procedures and all is well-documented

Assessment of validation

J45. Validation of preventive measures

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

Level 0	**Level 1**	**Level 2**	**Level 3**
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, and - findings scarcely (not) described	- Effectiveness of preventive measures is validated based on opinion of independent expert, using expert knowledge, regulatory documents and historical results; - on regular basis and after system modifications; - findings described in reports	- Effectiveness of preventive measures is systematically validated, by independent experts, based upon specific scientific sources (like scientific data/literature on validation studies, predictive modelling), historical results, and own experimental trials; - on regular basis and after system modifications, - activities and results well documented

Supporting information to differentiate situation 2 and 3

- When preventive measures independently (not by own people) validated based on expert knowledge and or scientific sources on a regular basis, then level 2 or 3.
- Crucial for level 3 is that actual effectiveness is tested with experimental trials and validation activities are established in procedures and well documented

J46. Validation of intervention systems

46. At which level would you place **validation of intervention systems** with respect to your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
Intervention systems have (yet) never been validated	- Effectiveness of intervention systems is validated based on historical knowledge only, judged by own people - on ad-hoc basis, and - findings scarcely (not) described	- Effectiveness of intervention systems is validated based on opinion of independent expert, using expert knowledge, regulatory documents and historical results; - on regular basis and after system modifications; - findings described in reports	- Effectiveness of intervention systems is systematically validated, by independent experts, based upon specific scientific sources (like scientific data/literature on validation studies, predictive modelling), historical results, and own experimental trials; - on regular basis and after system modifications, - activities and results well documented

Supporting information to differentiate situation 2 and 3

- When intervention systems are independently (not by own people) validated based on expert knowledge and or scientific sources on a regular basis, then level 2 or 3.
- Crucial for level 3 is that actual effectiveness is tested with experimental trials and validation activities are established in procedures and well documented

J47. Validation of monitoring systems

47. At which level would you place **validation of monitoring systems** with respect to your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
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 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 well documented

Supporting information to differentiate situation 2 and 3
- When monitoring systems at CCP's are independently (not by own people) validated based on expert knowledge and or scientific sources on a regular basis, then level 2 or 3.
- Crucial for level 3 is that actual effectiveness is tested with experimental trials, and Crucial for 3 is that the actual performance is confirmed by real observations, and validation activities are established in procedures and well documented

Assessment of verification

K48. Verification of people related performance

48. At which level would you place **verification of people related performance** with respect to your RPU?

Level 0	**Level 1**	**Level 2**	**Level 3**
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 analysing procedures (both content and presence) and records, - on regular basis, - by independent internal staff, - internal report	- Verification of procedures and compliance based on analysing procedures and records, and observations, - with defined frequency and when system modifications, - by independent external (official) expert; - activities and results well documented

Supporting information to differentiate situation 2 and 3
- When verification of performance of people related activities is based on independent analysis of procedures, records, etc on a regular basis, then level 2 or 3.
- Crucial for 3 is that the actual performance is confirmed by real observations, and verification activities are established in procedures and well documented

K49. Verification of equipment and methods related performance

49. At which level would you place **verification of equipment and methods related performance** with respect to your RPU?

Level 0	Level 1	Level 2	Level 3
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 working in the system and provide the information,	- Verification of equipment and methods performance based on analysing records (e.g. control charts, records data loggers, etc.) and calibration activities, restricted testing of actual performance, - on regular basis	- Verification of equipment/methods performance based on analysing records, calibration activities, and confirmation of performance by actual (e.g. microbial) testing - with defined frequency and after system modifications,

Supporting information to differentiate situation 2 and 3
- When verification of equipment and methods performance is based on independent analyses of records, data, calibration activities, etc on regular basis, then level 2 or 3.
- Crucial for 3 is that the actual performance is confirmed by testing (e.g. microbial tests) and or real measuring, and verification activities are established in procedures and well documented

Assessment of documentation and record-keeping

L50. Documentation

50. At which level would you place **documentation** with respect to your company?

Level 0	Level 1	Level 2	Level 3
No documentation of procedures, information, knowledge at all.	No structured documentation system, ad hoc	Structured documentation system, de-centrally organised and kept up to date, (partly) automated, available via specific persons; access to external sources not formalised (individual contacts)	Structured documentation system, kept-up-to-date with assigned responsibilities, centrally organised, automated and on-line available for all, and with access to external sources of information (libraries, databases, etc).

Supporting information to differentiate situation 2 and 3
- When structured documentation system that is kept-up-to date is available then level 2

or 3.
- Crucial for level 3 is that it is a central and integrated documentation system, which is on line available and for all accessible, and has links to external sources of information (like libraries, data banks, etc)

L51. Record keeping system

51. At which level would you place your **record keeping system** with respect to your company?

Level 0	**Level 1**	**Level 2**	**Level 3**
No record keeping of product nor process data at all	Ad hoc registration of record keeping data.	Full registration of critical product and process data in separated systems (not integrated), accessible via specific (authorised) persons.	Full registration of critical product and process data, in central integrated system, on line available and accessible to all persons

Supporting information to differentiate situation 2 and 3
- When full registration of critical data then level 2 or 3.
- Crucial for level 3 is that it is a central and integrated system, which is on line available and for all accessible

ASSESSMENT OF FOOD SAFETY PERFORMANCE

Assessment of external

M52. Food Safety Management System evaluation

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

Level 0	**Level 1**	**Level 2**	**Level 3**
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 accreditated third party	Audits/inspections of the FSMS performed by several accreditated third parties and/or national food safety agency

Supporting information to differentiate situation 2 and 3
- If the FSMS is evaluated by an audit performed by an accredited third party then level 2 or 3.
- Crucial for level 3 is that more than one audit (or combined with an inspection) is performed by accredited third party(s) or in combination with an inspection by the national food safety agency. (For example a BRC audit by accredited third party and inspection of the national food safety agency).

M53. Seriousness of remarks

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

Level 0	**Level 1**	**Level 2**	**Level 3**
Not appropriate because never an inspection or an audit of the FSMS was performed	Major remarks on various aspects of the FSMS	Major remark on one specific aspect of FSMS (eventually additional minor remarks on other aspects of the FSMS	No remarks or only minor remarks on specific or various aspects of the FSMS

Supporting information to differentiate situation 2 and 3
- If remarks are clearly attributed to one specific aspect of the FSMS (e.g. HACCP or preventive measure temperature) then level 2 or 3
- Crucial for level 3 is that the remarks are only minor remarks

M54. Microbiological food safety complaints

55. How would you typify the microbiological food safety complaints of customers?

Level 0	**Level 1**	**Level 2**	**Level 3**
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

Supporting information to differentiate situation 2 and 3
- If restricted or no complaints regarding microbiological food safety then level 2 or 3
- Crucial for level 3 is that there are no complaints about microbiological food safety whereas at level 2 the reason of the complaints can be dedicated to one specific aspect of the FSMS (e.g. control of temperature, hand hygiene, cleaning and disinfection)

M55. Hygiene related complaints

56. How would you typify the **hygiene related complaints by customers?**

Level 0	**Level 1**	**Level 2**	**Level 3**
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 hygiene indicators

Supporting information to differentiate situation 2 and 3
- If restricted or no complaints regarding hygiene then level 1 or 2
- Crucial for level 3 is that there are no complaints about hygiene whereas at level 2 the reason of the complaints can be dedicated to one specific aspect of the FSMS (e.g. control of temperature, hand hygiene, cleaning and disinfection)

Assessment of internal

N56. Product sampling

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

Level 0	**Level 1**	**Level 2**	**Level 3**
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	Regular sampling conducted on both final food product and raw material(s)	Structured sampling (with fixed frequency and company own sampling plan is present) and conducted on final food product, raw material(s) and environmental samples

N57. Judgement criteria
59. Which **judgement criteria** are used to interpret microbiological results?

Level 0	**Level 1**	**Level 2**	**Level 3**
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

Supporting information to differentiate situation 2 and 3
- If more than only legislative criteria are used then level 2 or 3
- Crucial for level 3 that the company has in addition to legal and external party requirements, own company specific specifications accompanied with strict guidelines

N58. Hygiene and pathogen non conformities

60. How would you typify your **hygiene and pathogen non conformities**?

Level 0	**Level 1**	**Level 2**	**Level 3**
Not known because no internal product analysis, and no non 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 indicators

Supporting information to differentiate situation 2 and 3

- If restricted or no hygiene and pathogen non-conformities then level 2 or 3
- Crucial for level 3 is that there are no non-conformities, whereas at level 2 the reason of non-conformities can be dedicated to one specific aspect of the FSMS (e.g. control of temperature, hand hygiene, cleaning and disinfection)