The Evolution and Cultural Framing of Food Safety Management Systems – Where from and Where next?

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ABSTRACT:

The aim of this paper is to review the development of food safety management systems (FSMS) from their origins in the 1950s to the present. The food safety challenges in modern food supply systems are explored and it is argued that there is the need for a more holistic thinking approach to food safety management. The narrative review highlights that whilst the transactional elements of how FSMS are developed, validated, implemented, monitored and verified remains largely unchanged, how organizational culture frames the operation and efficacy of FSMS is becoming more important. The evolution of a wider academic and industry understanding of both the influence of food safety culture (FS-culture) and also how such culture frames and enables, or conversely restricts the efficacy of the FSMS is crucial for consumer wellbeing. Potential research gaps worthy of further study are identified as well as recommendations given for the application of the research findings within the food industry.

Keywords: Food safety, HACCP; Food safety culture; risk assessment; Private food safety and quality standards

1. Introduction

Individuals have the right to expect the food that they eat is safe and suitable for consumption (Codex Alimentarius Commission CAC/RCP, 1969:3). Food safety is the concept that “food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use” (BS EN ISO 22000 2005; Codex, 2003, British Retail Consortium BRC, 2015:112). An organization will develop a formal food safety management system (FSMS) to ensure that food is safe for consumption and also to mitigate foodborne illness, food poisoning or wider considerations of contamination that can cause harm and injury. Therefore, FSMS must be developed, validated and then appropriately applied to ensure their efficacy at all steps in the food supply chain from origin in primary production through to the final consumer. Global distribution of food between multiple supply chain sectors relies upon a consistent understanding by all those concerned as to what food safety is and how it is effectively managed to prevent harm. A universal approach to address food safety hazard identification and assessment, and then FSMS development, validation, implementation, monitoring and verification is the use of the hazard assessment tool Hazard Analysis Critical Control Point (HACCP) based on Codex Alimentarius Principles (Codex, 2009). Indeed, within the European Union (EU) the use of a HACCP-based FSMS is mandatory post-harvest and post slaughter within the food supply chain (EU 852/2004). Moreover, in the last few decades, various consortia of stakeholders have introduced multiple private standards in order to guide/direct the design, implementation, and verification of FSMS. These include the British Retail Consortium (BRC) standard, BS EN ISO22000, Safe Quality Food (SQF), and International Featured Standards (IFS-Food). However, an organizational FSMS is not situated in isolation. People design, implement, monitor and verify the efficacy of a FSMS so their personal interaction with the transactional (technical) elements of both the formal system and other informal practices will impact on the ability of an organization to grow, process, distribute and/or sell safe and wholesome food.

Food safety culture (FS-Culture) is the overarching organizational framework associated with food safety formed by the interplay of actors within the organization (De Boeck, Jacxsens, Bollaerts, & Vlerick, 2015). FS-Culture develops through the interlinking of three theoretical perspectives: organizational culture, food science and social cognitive science (Jespersen, Griffiths, Maclaurin, Chapman & Wallace 2016). An

An understanding how a FSMS is developed and implemented, is also influenced by internal and external pressures and then interacts with the FS-Culture is critical to consistent achievement of food safety requirements. In order to identify the direction and strategy of future empirical research, this narrative review contextualizes the historical development of the theory associated with the development and adoption of FSMS. The review then considers the evolution of a wider academic and industry understanding of the influence of FS-Culture and how such culture frames and enables, or conversely restricts, the efficacy of the FSMS. The systematic approaches to managing food safety using HACCP as a food safety hazard assessment tool and the evolution of private safety and quality assurance standards are critiqued, with particular emphasis on the underlying drive for benchmarking and isomorphism (i.e. reducing differentiation to create increased uniformity in private standard requirements). Further, the food safety challenges in modern food supply systems are explored and the potential requirement for a holistic approach to food safety management and performance is examined. The review is then drawn together to identify potential research gaps worthy of further study and provide direction for application in the food industry.

2. Evolving definitions and the meaning of food safety

A food hazard is defined in classic food safety vocabulary as "a biological, chemical, or physical agent in, or condition of, food with the potential to cause an adverse health effect." (CAC, 2003:5; BS EN ISO 22000; 2005; Wallace, Sperber & Mortimore, 2011:65; Manning, 2017a). The Campden BRI Guide G42 (Gaze, 2009; 2015) expands on this tri-categorization to include food allergens as a fourth category. Mortimore and Wallace (1994; 1998; 2013) use the CAC (2003) categories, and include allergens within the category of a chemical hazard (Luning & Marcelis, 2009; Manning, 2017a). Further to the above definitions, BRC (2015:112) has an evolved definition for a hazard as being an agent of any type with the potential to cause harm (usually, biological, chemical, physical or radiological), thus no longer differentiating allergens as a separate category but including the new category of radiological hazards which is gaining wider industry attention. Although Aladjadjiyan (2006) defines radiological agents as physical hazards, there is limited guidance on how this group of hazards should be characterized. The Food and Agriculture Organization's Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems publication (FAO, 2003:3) in their definition of food safety differentiate between chronic and acute food safety hazards stating that: "food safety refers to all those hazards, whether chronic or acute, that may make food injurious to the health of the consumer." Further, food safety has also been described as 'limiting the presence of those hazards, whether chronic or acute, that may make food injurious to the health of the consumer' (WHO, 2015). Thus, whilst contemporary thinking about food safety still revolves around the control of hazards in food, the concept of acute and chronic illness that is related to those hazards is important. The term "acute" suggests sudden or short term onset (Sprenger, 2014). Chronic hazards are those hazards that have medium to long-term onset, examples being carcinogens, mutagens and teratogenic and immunosuppressive agents (FAO, 1994) or sequelae of acute foodborne illness, e.g. irritable bowel syndrome or Guillain Barre syndrome associated with Campylobacter infection (Ternhag, Törner, Svensson, Ekdahl, & Giesecke, 2008; Kirkpatrick & Tribble, 2011). Therefore, depending on the toxic agent of concern, the term food poisoning is considered as being either acute or chronic in terms of onset period and duration of illness (Manning, 2017a). Commonly, the term food poisoning focuses on notions of toxicity specifically i.e. the agent that causes food poisoning being a toxin of either a microbiological origin or other source, whereas foodborne disease or foodborne illness are broader terms relating to infection and/or toxicity. Manning (2017a) suggests that chronic non-communicable diseases (NCDs) such as heart disease, type 2 diabetes, obesity, cancers and illnesses associated with accumulative toxicity could be revisited within organizational hazard assessment. Thus, based on Manning's (2017a) definition, illness, poisoning or intoxication associated with food can be redefined as being:

> "*a health disorder with symptoms of either of short [acute] or long [chronic] term duration with a specific onset period that is induced by consuming food that is contaminated by biological organisms or agents that have the ability to invade host cells and/or produce toxins once ingested, or food that contains toxic material at the time of consumption, or by consuming an unbalanced diet over a prolonged period of time, leading to over and under nutrition.*"

Moreover, historical and current thinking limits the scope of FSMS to the control and management of the aforementioned food hazards and does not included the wider consideration of prevention of NCDs. Although it can be argued that NCDs may involve 'conditions of food with the potential to cause an adverse health effect'. Indeed, the advent of personalized medicine and personalized healthcare especially around food allergy (Ferrando et al. 2017) means that organizations need to consider how these developments will influence the categorization of food hazards and intoxication in the future (Manning & Soon, 2017) and the impact on management approaches to food hazard control and management. The evolution of HACCP-based FSMS for control of food hazards is now considered.

3. Systematic approaches to food safety management using HACCP

3.1 Evolution of HACCP-based FSMS

The adoption of HACCP as a means to develop FSMS evolved from the 1950s and the early days of the United States (US) manned space program (Ross-Nazzal, 2007) (Figure 1). The HACCP approach resulted from a need to identify a preventative assurance approach that could give a high degree of confidence in the food safety program employed rather than a reactive, control-based end-product testing approach. Despite having proved its utility in developing the processes for food production for the US space program nearly sixty years ago, take-up of the HACCP innovation by the food industry was slow. Although the philosophy of analyzing food safety hazards and identifying critical control points (CCPs) came out of this initial National Aeronautics and Space Administration (NASA) work, there was no clearly defined requirement for teams to apply the principles employed. Indeed the term HACCP itself had not been determined initially. Instead, the term was used later by the Pillsbury Company (La Chance, 2006; Wallace, Holyoak, Powell, & Dykes, 2012). HACCP was not shared publicly in the food industry until 1971 when the Pillsbury Company (part of the NASA space foods program team) presented the initial concept at the Conference on Food Protection (Bauman, 1974; 1990; 1993; Mayes, 1992; Wallace et al. 2012). Further, the technical approach of HACCP has evolved in terms of how to do it; when to do it; what products and processes to cover; what food safety controls to implement at the process level; and lastly which food safety hazards to manage at CCPs, as opposed to those hazards would be more effectively managed through prerequisite programs such as good manufacturing practice (GMP) and good hygienic practice (GHP).

Take in Figure 1

Early HACCP had three principles equating to principles 1, 2 and 4 of the current seven principles Codex Alimentarius Commission approach (CAC/RCP, 1969; rev. 4, 2003). Initially, the use of HACCP focused on microbiological hazards, although the physical condition of food was considered in the space program as a potential hazard to instrumentation failure (Ross-Nazzal, 2007; Wallace et al. 2011, Wallace, Sperber & Mortimore, 2018). The Pillsbury Company expanded the use of HACCP more generally throughout the 1970s in their consumer food manufacturing processes. The spread of HACCP more widely within the food industry was promoted initially in the US by Pillsbury’s training of Food and Drug

Administration (FDA) canned foods inspectors in 1972 followed by the publication of the US canned foods regulations in 1973 (Wallace et al. 2011, 2018). International diffusion of the HACCP approach by US bodies was promoted firstly by a focus in the microbiological area through the US National Research Report, *An evaluation of the role of microbiological criteria for foods and food ingredients* (NRC, 1985). Subsequently, 1988 saw the formation of the US National Advisory Committee on Microbiological Criteria for Foods (NACMCF) (Wallace et al. 2011, 2018), a body which remains important in international HACCP to this day. The similarly named but independent international body, the International Commission on Microbiological Specifications for Foods (ICMSF), which was established in 1962, also took on the HACCP mantle and in 1988, published the first complete book devoted solely to HACCP (ICMSF, 1988; Wallace et al. 2011). A third group, that began working around the same time, was the Codex Alimentarius Commission's Committee on Food Hygiene (CCFH). The CCFH and NACMCF groups both started working on documents to define the HACCP system and provided guidelines on its application, resulting in the first definitive HACCP reports: NACMCF in 1992 and CCFH, generally known as Codex, in 1993 (Wallace et al. 2011, 2018). There were a number of similarities between the two reports (NACMCF, 1992; Codex, 1993), largely due to overlap between membership of the committees and the US serving as permanent chair of CCFH (Wallace et al. 2011, 2018).

The adoption of the HACCP principles by the food industry as a common approach for managing food safety follows the diffusion of innovation (DoI) theory (Rogers, 2003). Diffusion is 'the process by which an innovation is communicated through certain channels over time among the members of a social system' (Rogers, 2003:11). The DoI theory explains the narrative of innovators, early adopters, majority players and laggards. Existing regulatory bodies and industry food safety communication channels spread the message about HACCP as an innovation in food safety hazard assessment and control, convincing more people, companies and/or organizations to become adopters. A number of factors affect the rate of diffusion of any innovation, including social structures and system norms, the presence and reaction of opinion leaders, and the perceived consequences of the innovation (Rogers, 2003). With regard to the HACCP approach specifically, the perceived consequences of safer food and protection of public health remain the principal reasons for adoption.

Following the initial communication from Pillsbury to the wider US food industry (Bauman, 1993), the flow of HACCP throughout the world was influenced by opinion leaders; initially Howard Bauman himself and then groups of scientific experts who recognized the theoretical benefits of HACCP and/or were involved in early adopter companies. This ‘invisible college of HACCP experts’ (Demortain, 2007, p9) acted as change agents (Rogers, 2003), influencing the innovation adoption decisions of others via the national (e.g. US NACMCF) and international (e.g. Joint FAO/WHO Codex Alimentarius) food safety committees and conference platforms (e.g. the five Food Safety and HACCP Forums held between 1997 and 2002 in Noordwijk, the Netherlands). These developments led to the publication and adoption of HACCP Principles and guidelines (NACMCF, 1992, 1997; Codex, 1993, 1997, 2003, 2009). Positive views about HACCP and its preventative advantages led to its adoption by many large food companies around the world. This led to further diffusion of innovation to other and smaller companies, driven by continued communication and the development of mandatory legislative frameworks (e.g. Regulation EC No. 852/2004) and private standards (Kotsanopoulos & Arvanitoyannis, 2017). In addition, the global reach of HACCP, as the chosen approach for developing a FSMS, was facilitated greatly by the status of Codex as an organization i.e. that it is jointly chaired by the UN FAO and the World Health Organization (WHO). This means that between UN trading partners, who are signatories to the World Trade Organization (WTO), Codex reports have the equivalence of legal frameworks (Wallace et al. 2011, 2018).

From these early beginnings, HACCP was gradually accepted around the world, first in manufacturing but later the approach was extended into catering, retail, food packaging and other applications (Figure 1). Thus the seven Codex HACCP principles have become the cornerstone of the systematic design of FSMS in all sectors. However, whilst perceptions of the benefits of the use of HACCP principles are now universal, how HACCP is applied varies in practice. Initially, development of HACCP based FSMS focused on product specific ‘HACCP studies’ (Mortimore & Wallace, 2013). Over time, a more generic approach was used where products considered intrinsically to be highly similar to each other, and as a result deemed to have the same inherent food safety hazards, were grouped e.g. meat or seafood products. This *product-led approach* to HACCP, whether single products or generic groups of products, was then joined by a *process-led HACCP approach* whereby the hazard assessment is undertaken based on the specific process or processes that are employed in the manufacturing situation (Mortimore and

Wallace, 1998). The process-led approach considers food safety hazards associated with the ingredients and the role of the process step itself in delivering food safety. The process-led approach assesses how food safety hazards are managed effectively by process CCPs e.g. cooking, pasteurization, metal detection etc. In complex processing operations, typically most manufacturing situations, individual products are made via a combination of processes, e.g. a prepared meal may consist of components that undergo different initial processes, sometimes in different manufacturing locations, and that are then combined before undergoing further processes. This means that the process-led “modular” approach is applied either to individual processes or alternatively to sets of processes that make up the overall product portfolio of an operation (Mortimore & Wallace, 1998, 2013).

The challenge of trying to manage large numbers of individual HACCP plans and the associated management records, meant the application of HACCP through the modular process-led approach started to take root in the 1990s (Mortimore & Wallace, 1994; 1998; 2013; 2015; Wallace, 2006; Williams, 2010). The operational challenge outlined here was also a road-block to the early application of HACCP in catering businesses where early adopters wrestled with developing HACCP plans for every single menu item and found that the system was unmanageable and unsustainable. Multiple authors have considered the barriers to the adoption of HACCP especially for small businesses (Vela & Fernández, 2003; Baş, Yüksel & Çavuşoğlu, 2007; Taylor, 2008). These barriers include technical barriers and a lack of pre-requisites and operational plans (Panisello & Quantick, 2001; Galstyan & Harutyunyan, 2016); a lack of knowledge and skills (Galstyan & Harutyunyan, 2016); a lack of motivation (Toropilová & Bystrický, 2015); concern over the depth of change required to implement HACCP (Herath & Henson, 2010); associated perceptions of bureaucracy (Taylor & Taylor, 2004; Lowe & Taylor, 2013); and concern over the associated costs, investment requirements and financial impact (Panisello & Quantick, 2001; Nguyen, Wilcock & Aung, 2004; Herath & Henson, 2010; Galstyan & Harutyunyan, 2016). However, a key driver to adopt HACCP is that it is a retailer pre-requisite for market access to the food supply chain (Mortimore & Wallace, 1994, 1998, 2013; Herath & Henson, 2010; Lowe, & Taylor, 2013).

The commonly held belief amongst many organizations that the product-led approach was the only “way to do HACCP”, i.e. the requirement for multiple specific HACCP plans for all individual recipes and products, was a barrier that certainly did not help promulgate the system beyond the manufacturing stage of the food supply chain. This barrier was gradually overcome by pressure from legislation and the need to demonstrate compliance, market requirements and the development of more simplified 'HACCP-based' approaches. Sector specific hygiene codes or self-checking guides were developed in some countries, often aimed to help businesses meet their responsibilities under regulations such as EU No. 852/2004. For example, *Safer Food Better Business* (FSA, 2017) was first launched in the UK in 2005, Belgium developed self-checking systems for multiple sectors (Jacxsens et al. 2015), and in the Netherlands sector specific HACCP hygiene codes were developed to support food businesses in designing their FSMS (Luning et al. 2002; Van der Spiegel et al. 2005).

Around the same time that modular HACCP systems started to evolve in manufacturing, a further key development in FSMS design emerged, the concept of formalized prerequisite programs (PRPs). Food businesses had previously understood the need for GHPs or GMPs and most applied these within their operations, albeit with a lack of formality in terms of monitoring and verification. Early HACCP teams had a tendency to identify repetitive general hygiene issues as the cause of potential food safety hazards and this, combined with a lack of understanding of the hazard analysis process itself (Wallace, Holyoak, Powell, & Dykes, 2014) led to identification of large numbers of CCPs, e.g. 600 CCPs in a dry goods mixing operation (Wallace & Williams, 2001). Although there were critics in the early days (Wallace & Williams, 2001), the PRP concept is successful because it reduces the complexity of HACCP systems, and recognizes the difference between process CCPs and PRPs (Escriche, Domenech & Baert, 2006; Mortimore & Wallace, 1998, 2011). Several definitions of PRPs have been published such as the basic conditions and activities that are necessary within the organization and throughout the food chain to maintain food safety (ISO, 2018). Process CCPs, situated at a process step such as cooking, metal detection, sieving etc., are specifically designed to reduce a food safety hazard to a safe level. Procedures and protocols under the umbrella of a PRP reduce overall food safety risk e.g. cleaning and disinfection, pest control, effective maintenance programs, etc. Therefore, PRPs address and mitigate the general food hygiene issues in any food operation in a foundational way allowing the HACCP approach to focus on specific process hazards that are significant for food safety (Figure 2).

Take in Figure 2

Further development of the PRP concept came with the understanding that some general hygiene considerations required an additional, tighter or enhanced level of control, usually to prevent cross-contamination risks that would lead to the ingress of significant hazards, for example allergen control where special measures are required to prevent cross-contact (Manning & Soon, 2017). These types of food safety issues cannot be managed as process CCPs; however, they require more focus than general PRPs that are global rather than hazard specific in nature (Figure 2). This development led to the introduction of the Operational Prerequisite Program (OPRP) concept within BS EN ISO 22000:2005 (Gaze, 2009, 2015). Use of OPRPs tends to be in those organizations seeking certification to ISO 22000:2005 or similar schemes, but there has been much debate among practitioners as to whether OPRPs are a useful addition to FSMS or whether they lead to an extra level of confusion as to how food safety hazards are managed (Mortimore & Wallace, 2013). The evolving definitions of OPRPs from being 'a PRP defined by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards to and/or the contamination or proliferation of food safety hazards in the products or in the processing environment' (ISO, 2005) to a 'control measure or combination of control measures applied to prevent or reduce a significant food safety hazard to an acceptable level, and where action criterion and measurement or observation enable effective control of the process and/or product' (ISO, 2018) may not have helped to reduce confusion.

For early adopters and other subsequent organizations, the application of HACCP principles came as a form of retro-fit for existing products and processes, perhaps as a result of the need for compliance with third party supply chain standards or as new legislation made the application of HACCP-based systems mandatory, such as Regulation EU No. 852/2004. Applying HACCP to existing processes and products requires a mindset to assess existing food safety hazards and develop strategies to manage them as well as considering additional and emerging food safety hazards and the controls required to reduce the likelihood of their occurrence. The application of HACCP in terms of managing hazards and food safety risk is now considered.

3.2 Application of HACCP – managing hazards and risk

The determination of which hazards in a given situation are significant for food safety and, therefore, need to be controlled at CCPs within the HACCP plan, or by operational PRPs, has historically been addressed by the application of HACCP principle 1 (Codex, 2009). However, this area of HACCP has been both poorly understood and poorly applied (Wallace et al. 2014). Often HACCP teams are able to identify potential food safety hazards of interest, but then fail to analyze them effectively in terms of their food safety significance in the context of the specific products produced and the processes employed and/or their potential effect on consumers i.e. the assessment of risk is not adequately situated. This is an area where further guidance was recommended by the Majvik Expert Colloquium on 'HACCP – the way ahead' (Codex, 2014) for consideration in the next Codex review, which is currently at Step 3 of the Codex process (Codex, 2017).

Whilst HACCP is commonly described as a risk management system, it is interesting that the term 'risk' is not used in the application of HACCP principles (Codex, 2009). In fact, 'risk' is not defined within the HACCP principles at all and the word only appears once in the Codex HACCP Annex, in the preamble, which states that 'implementation should be guided by scientific evidence of risks to human health' (Codex, 2009). This omission of the term 'risk' is considered surprising by some food safety practitioners and, whilst many HACCP teams do use the term 'risk assessment' as part of HACCP, it too is not included in the Codex international HACCP standard. This may lead to substantial confusion about the process of risk evaluation regarding the responsibilities of food companies and those of national/regulatory agencies (Mortimore & Wallace, 2013).

Sperber (2001) states that hazard analysis is a qualitative, local decision-making process conducted by a manufacturing organization's HACCP team taking several weeks or months to complete. In contrast, quantitative risk assessment is a decision-making process in which a numerical degree of risk is calculated for a particular hazard. Usually, large consortia that include regulatory, public health, academic, and industry partners conduct quantitative risk assessment activity typically requiring several months or years for completion (Sperber, 2001). The clear distinction made by Sperber (2001) that hazard analysis is qualitative whereas risk assessment is quantitative is of value. Despite the Codex HACCP Guidelines requiring hazard analysis and the determination of significant hazards rather than risk assessment, problems around understanding of the nuances of terminology have contributed to the confusion about the appropriate application of HACCP principle 1 (Wallace et al. 2014). Monaghan, Augustin, Bassett, Betts, Pourkomailian and Zwietering (2017:726) report that risk assessment is a term that can lead to confusion as it is applied to both “a scientific process consisting of formal components and quantification of levels of risk as outlined by the Codex Alimentarius Commission (CAC, 2003) and a more general, qualitative approach based more on expert opinion.” In addition, Jacxsens et al. (2016) report that risk assessment is hard to elaborate and to understand, and discuss the need for, and development of, training approaches for (semi-) quantitative probabilistic risk assessment calculations or qualitative risk rankings. Thus, the duality of use of the term risk assessment is a weakness in the evolution of FSMS. Whilst food safety risk is described at the regulatory level as “a function of the probability of an adverse health effect, and the severity of that effect, consequential to a hazard(s) in food” (EC, 1997), risk is not always seen purely in this way (Manning & Soon, 2013). Therefore, qualitative assessment of food safety risk can be influenced by scientific considerations, situational risk assessment, individual perceptions and the propensity and willingness of the organization to eliminate, mitigate, accept or outsource risk as highlighted in BS EN ISO 31000 (2018) and by Kleboth, Luning and Fogliano (2016).

Current approaches to hazard analysis and the identification of significant hazards involve the consideration of likelihood of occurrence and severity of potential effect for each hazard. Codex HACCP guidelines (2009) require the hazard analysis process to identify ‘hazards that are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food’. Further, the guidance for conducting hazard analysis states that ‘the likely occurrence of hazards and severity of their adverse health effects’ should be included, and that ‘qualitative and/or quantitative evaluation’ of the presence, survival, multiplication, production or persistence of hazards should be considered. Historically, this has been difficult for organizations, in particular small businesses with limited or no technical resource. More recently, semi-quantitative assessment matrices have been developed that allow for a weighting of both the likelihood of the hazard or the severity of the hazard should it occur (Mortimore & Wallace, 2013, Manning, 2013, Manning & Soon, 2013). This can lead to a more priority-focused HACCP approach, but appropriate expertise and experience is still required to apply these matrices effectively (Wallace et al. 2014).

Following hazard analysis, CCPs are identified, either via HACCP team decisions and experience or through use of the Codex HACCP decision tree, a binary questioning process with YES or NO answers resulting in the control of food safety hazards at a given point where deemed critical. The remaining Codex

HACCP principles describe how to manage, validate and verify CCPs, and the operation and effectiveness of the FSMS. The application of HACCP is just one element of a series of building blocks that underpin a FSMS: namely application of HACCP, safe design, development of appropriate PRPs, and adoption of essential management practices (Wallace et al. 2011) see Figure 3.

Take in Figure 3

The essential management practices that are elements of GMP and good agricultural practice (GAP) include: senior management commitment to food safety in terms of overall mission right through all layers of management within the organization; clear definition of roles and responsibilities with regards to managing food safety; and appropriate training and education. Further, the consideration of the resources required to develop and effectively implement the food safety program; the development of a documented and formalized FSMS with associated process records; and a drive for continuous improvement in meeting pre-defined food safety management goals and objectives are essential practices to adopt. Supplier–customer protocols require a clear definition of the inputs and outputs for given processes within the internal food manufacturing system and at interfaces between one organization and another. The clear communication of food safety criteria at these interfaces e.g. between supplier and manufacturer and manufacturer to distribution system is essential to ensure consistently safe food product and safe working practices (Manning, Baines & Chadd, 2006).

Despite decades of encouragement and mandatory requirements to adopt HACCP approaches to develop FSMS, the global food sector still experiences major acute and chronic food safety incidents. Examples of product recalls in 2017 alone include for the US Food and Drug Administration (FDA) ninety five recalls, market withdrawals or food safety alerts for *Listeria monocytogenes*, twenty three for *Salmonella* spp. and, an emerging health hazard in 2017, eleven recalls for undeclared sildenafil (Viagra) in dietary supplements (FDA, 2017a). In the EU, an emerging food safety hazard too was fipronil, a toxigenic chemical. Globally, the 2017 European fipronil incident with direct and composite products affected 56 countries and led to 117 notifications on the Rapid Alert System for Food and Feed database (RASFF, 2017). In 2018, the “needles in strawberries” incident in Australia brought concerns over deliberate contamination of food (Manning, 2019). So does the HACCP hazard analysis approach deliver especially when considering emerging food safety hazards?

3.3 Challenges associated with the HACCP approach.

Has HACCP as a management tool been oversold as a total solution; a silver bullet? Should regulatory bodies and food manufacturers recognize that undertaking hazard analysis and developing an associated FSMS does not deliver zero food safety risk in food supply chains? Should there be more focus on FS-Culture, and its impact on how the FSMS is implemented and verified? These are all questions that arise when considering the challenges associated with implementing the HACCP approach.

Food safety incidents have been associated with multiple weaknesses and factors of influence. These include lack of knowledge, training and expertise (Wallace et al. 2005; Mensah & Julien, 2011; Wallace et al. 2012, 2014); a lack of awareness and commitment and failures in management or leadership (e.g. Peanut Corporation of America see Manning, Wallace & Soon, 2016; Manning 2017b); a breakdown in the implementation of a PRP or process design or a lack of resources (see case study of Maple Leaf Foods in Manning, 2017b), weak verification (Powell, Jacob & Chapman, 2011); or weak maintenance of the FSMS (see case study of XL Foods Inc. in Manning, 2017b). Many of these factors reflect a failure in organizational culture and conditions of control i.e. there is a cultural framing of a food safety program and FSMS that requires consideration.

In addition, it is important to recognize that HACCP is a tool for assessment and management of food safety hazards and is implemented effectively only if both the hazards and the means for their control are clearly identified, understood and communicated within the organization. Emerging types of food safety hazard, if unknown by those in the HACCP team tasked with developing, reviewing or re-validating a HACCP Plan and associated food safety program, will simply go under the radar until there is an incident associated with that hazard. Whilst pathogens may be recognized as potential food safety hazards, emerging chemical hazards such as fipronil, sildenafil, or pieces of golf ball in frozen hash browns (FDA, 2017a) may not. Further, the HACCP approach is often difficult to apply at farm level and there is a growing trend instead to develop risk-based preventive control processes (Monaghan et al. 2017).

A further contemporary challenge to the implementation of HACCP is the very definition of what a food safety hazard is and what it is not especially in wider considerations of food safety, food quality, food fraud, and food defense. Spink and Moyer (2011) in seeking to characterize food fraud and food safety, and by inference the food safety hazards that need to be considered within hazard analysis as part of a HACCP approach, state that food safety addresses only the unintentional actions that make food injurious to health, whilst food fraud concerns intentional actions of adulteration, substitution and tampering. The Global Food Safety Initiative (2013) describes food defense as "*the process to ensure the security of food and drink and their supply chains from all forms of intentional malicious attack including ideologically motivated attack leading to contamination or supply failure*". BRC (2015) considers food defense as the procedures adopted to assure the safety of raw materials and products from malicious contamination or theft whilst FDA (2017b) defines it as "the effort to protect food from intentional acts of adulteration where there is an intent to cause wide scale public health harm". Recent literature has sought to create a typology for food defense to aid its assessment and mitigation (Manning, 2019). Therefore, in theory food defense concerns now sit outside the HACCP process, as these intentional contaminants are distinct from food safety hazards (Manning & Soon, 2016a). However, in practice within food businesses, the identification of areas that are vulnerable to food fraud and/or may require food defense countermeasures may involve the same personnel as those who implement HACCP and thus there is potential for confusion for organizations on where HACCP processes sits within wider aspects of food safety, food defence and food crime (Yoe & Schwartz, 2010; Wiśniewska, 2015). This may be exacerbated by the use of similarly named systems of control, e.g. threat analysis critical control point (TACCP) and vulnerability analysis critical control point (VACCP) methodologies (Manning & Soon, 2016; Manning, 2019). Ultimately, as Kleboth et al. (2016) summarize, in ever more complex food supply chains, scandals and incidents persist and concerns over food safety, authenticity and wider aspects of food integrity mean that multi-layered private and public standards have evolved and these interact with the HACCP approach in a transactional approach to ensure food safety. These generic and often third party standards follow a risk reduction approach that seeks to consistently deliver safe and legal food and prevent harm to individuals and prevent organizational or reputational damage. Thus, regulatory bodies and food manufacturers recognize that undertaking hazard analysis and developing an associated FSMS alone does not deliver zero food safety risk in food supply chains and that additional, agile mechanisms need to be in place. The need to verify implementation of

FSMS means that there needs to be more focus on the associated FS-Culture. However what cultural factors are of influence that drive compliance with such public and private standards?

4. Compliance approaches to food safety using food supply chain standards

4.1 Evolution of food supply chain standards

Increasingly, the impact of food safety failures on consumer health, reputation damage, confidence loss, and future sales, and associated safety and quality standards have gained wider interest in the food supply chain (Fulponi, 2006). Multiple terms about standards exist and for ease of differentiation these has been synthesized (Table 1) so they can be referred to in the paper.

Take in Table 1

As required by their stakeholders (e.g. government, retailers, customers), and often as a pre-requisite to either operating the business and/or as a means of accessing specific markets, companies use both public and private product and process standards to provide the basis upon which to design their food safety programs. In this context, the food safety program is considered to be the written document indicating how a food business will assure that food safety hazards associated with food handling activities of the business are effectively controlled (Luning et al. 2008, 2009; Jacxsens et al. 2015). Private standards are commonly stricter in terms of requirements than the public standards established in local legal frameworks (Fulponi, 2006), i.e. they go beyond legislative compliance or 'safe to supply' and include the adoption of additional requirements and standard elements. Compliance with these private standards by a potential supplier is often a pre-requisite to market access i.e. if the organization cannot demonstrate compliance with these food safety standards then they cannot supply. Therefore, food business operators (FBO) translate these stakeholder requirements into their specific food safety programs and adapt the requirements of given system standards to their particular food business context (Luning et al. 2009, 2011a; Kirezieva et al. 2013). This strategy then frames, shapes and affects the actual FSMS that is adopted and its ongoing performance (Herath, Hassan & Henson, 2007; Luning et al. 2011b; Luning et al. 2015; Kirezieva et al. 2015a). Since the 1990s, the number of private third party standards has increased substantially (Table 2). This is due in part as a reaction to multiple food safety incidents and a need to regain consumer trust, developments in product liability law, and the limited capacity of public bodies (Fulponi, 2006; Schulze, Albersmeier, Gawron, Spiller, & Theuvsen, 2008).

Take in Table 2

From a market perspective, imposed retailer requirements, reduction of transaction costs, mitigation of supply chain risks, and to a lesser extent productivity and efficiency improvement have also stimulated the adoption of private standards by food organizations (Fulponi, 2006; Schulze et al. 2008; Spadoni, Lombardi, & Canavari, 2013; Latouche & Chevassus-Lozza, 2015). Indeed there are multiple drivers for standards development and adoption and also barriers to their adoption too (Figure 4). Private standards, such as the BRC Standard, IFS-Food, GLOBALG.A.P, SQF, and the Foundation for Food Safety Certification, (FSCC2000), have been widely adopted by the European food industry (Schulze et al. 2008; Herzfeld, Drescher, & Grebitus, 2011; Spadoni et al. 2013), and beyond at a global scale (Herzfeld et al. 2011). Particularly in emerging countries with poor institutions and legal frameworks (Henson & Humprey, 2010), private standards can support design and operation of FSMS and create access to global markets (e.g. Kirezieva et al. 2015a, 2015b; Kussaga, Luning, Tiisekwa, & Jacxsens, 2015; Nanyunja et al. 2016) or address the governance void for organizations seeking to extend their operation to those countries. The interplay between regulation and private food standards with regulation evolving from a 'one size fits all' to risk based-regulation is leading to a hybridization of food governance between public and private instruments (Verbruggen & Havinga, 2017a), which impacts FSMS design and operation (Kirezieva & Luning, 2017). Hybridization of food governance has occurred in two distinct dimensions: firstly the national and international dimension with the interplay of public governance and institutions such as Codex or the International Standards Organization (ISO); and secondly between government, producers and third-party organizations (Zhang, Qiao, Wang, Pu, Yu & Zheng, 2015; Verbruggen, 2016; Verbruggen & Havinga, 2017b; Zhu, Huang & Manning, 2019).

Take in Figure 4

The role of the state and the role of the market can often be fluid, which suggests that there is dynamic coupling of societal and institutional risks, as described by the theory of risk colonization (Rothstein, Huber

& Gaskell, 2006). Prevalence of certification of private standards seems more likely in developed markets and food economies especially in countries with established trade relations with other countries or trading blocs, such as the EU where these standards have been developed and adopted for some time (Herzfeld et al. 2011). Since 2005, most of the private standards previously described have evolved rapidly and, through industry input and an iterative approach, new versions are launched on a regular basis (Table 2). Development and modification of these standards sometimes reveal a mosaic approach where owners and developers of private standards take elements from different standards such as CAC Standards or ISO standards and integrate criteria with specific elements that address supply chain actors' concerns with regard to a given food safety or other supply chain risk. Common tendencies observed in the evolution of private standards are an increase in strictness and a more prescriptive character in the discourse that surrounds the requirements, and the continuous addition of new clauses, sections, and modules (Table 2). Examples of this are the requirement for the use of HACCP as a baseline and the increasing numbers of additional risk assessments in the BRC Global Food Standard version 7, including that of the vulnerabilities associated with food crime and the inclusion of a clause on FS-Culture in version 8. Furthermore, various scheme owners (e.g. IFS, GLOBALG.A.P, and BRC) introduced multiple new system standards for other (or upcoming) actors in the food supply chain, such as catering, packaging suppliers, food stores, distribution centers, and global markets (Table 2).

Some standards (e.g. SFQ and GLOBALG.A.P) have modular approaches to enable "new entrants" to third party certification to allow organizations to sequentially advance the depth and scope of their FSMS i.e. the standard owners have a baseline "fit to supply" level standard as well as a higher level standards within their overall portfolio. The first iterations of the BRC standard (e.g. 1997) also had two levels: foundation and higher level and recommendations for good practice. For the same reason, in some countries local versions of GLOBALG.A.P standards were developed, like JapanGap, ChinaGap, MyGaP (Tey et al. 2016). Table 2 shows the increasing requirements of schemes with regards to verification activities and, therefore, auditor competences have become more formalized and rigorous, which leaves less room for nuanced interpretation and application of private standards in view of the specific business context. There has also been increased focus on 'managerial' requirements, such as senior management commitment, training, policy setting, and competence requirements, and recently attention is also given to

FS-Culture and unethical or illicit behavior. All these developments have contributed to a proliferation of elements and requirements within a given system standard often leading to extensive "checklist-based" approaches to product and system verification (Powell et al. 2011; Manning, 2018a).

4.2 Challenges associated with third-party certification

Whilst there are advantages to using a checklist type approach in terms of auditor consistency, conversely this approach can cause "audit fatigue" (Petersen, 2009; Martz, 2010). Auditor fatigue will decrease the reliability of the verification activity and due to the rigid application and non-reflective use of a checklist can also drive "evaluation myopia". This also may lead to an inability of the auditor to identify side effects or side impacts during the audit i.e. they have a linear rather than a holistic auditing approach (Martz, 2010; Manning, 2013, Manning & Soon, 2014, Manning, 2018a). Even though checklist based auditing might be technically correct, there may be no incentive for the auditor to identify wider material weaknesses or deficiencies in the FSMS (Flores-Miyamoto, Reij & Velthuis, 2014). Indeed, the considerable resources employed in developing manuals, guidebooks, protocols, and checklists for audits are wasted when the contribution of such tools to audit efficiency and effectiveness is unclear (Leeuw, 2011, Läikkö-Roto & Nevas, 2014). Albersmeier, Schulze, Jahn, & Spiller (2009) differentiated between what they described as checklist governance and contrasted this with the concept of risk-based audit programs that ensure optimum and cost effective utilization of verification resources (van Asseldonk & Velthuis, 2014). For micro and small sized organizations, the costs of demonstrating compliance with private standards can be challenging. Kleboth et al. (2016) proposed that complex systems risk-based auditing, rather than considering and increasing the amount of audit criteria and the level of detail or depth of audit, should focus on the identification, analysis and evaluation of evidence-based, actual, pressing and emerging systemic risks. As a result, such verification is more effective in determining the current state of the FSMS.

In practice, food quality managers indicate that reactive, stricter and more specific requirements do not necessary lead to better performance of the FSMS (Kleboth & Strasser, 2013). The multiplication of certifications, the overlap in standards, the difficulty to integrate all standards in a given organization's FSMS, and the inconsistencies in food product standards mean that many food supply chain actors suffer "audit fatigue" with regard to private standards resulting in the rising costs of assurance whilst retail prices remain stable (Sonntag, Theuvsen, Kersting, & Otter, 2016). As previously described, the commonly used private standards in the food supply chain, have a typical checklist compliance based structure and it can be argued that due to the reactive nature of private standards' evolution, issues are often addressed in multiple sections potentially leading to duplication and confusion. Moreover, the structure and elements included in private standards are not necessarily based on scientific concepts or quantitative risk assessment and as a result can seem arbitrary, especially where they are addressing an issue where the food safety risk to consumers is deemed as negligible (see also Monaghan et al. 2017).

Other challenges that have been associated with private standards are the limited flexibility allowed in the auditors' approach towards different situations that may arise within the organization, and the continued requirement for retailer driven supplier auditing, even though the organization may hold current, valid third party certification (Spadoni et al. 2014). If the private standard is very detailed with multiple clauses that need verification during an audit this may result in lower auditing quality in the longer term due to time pressure. Audits are only ever a 'snapshot' of actual performance (Powell et al. 2011) and third party certification relies on the organizational integrity of the auditee organization to reflect their daily practices during the audit. Moreover, the commercially driven limit on the time available to undertake the audit also results in frustrated companies that may have to meet/fulfill system standard requirements that do not make sense for their particular context or where, in their particular situation, the risk the standards are seeking to mitigate is minimal (Albersmeier et al. 2009; Kleboth et al. 2016).

However, some organizations may be happy to comply with a prescriptive private standard because they are simply willing to allow others to make decisions for them. This can result in reduced agency and influence the degree of organizational engagement with the derived FSMS. The more prescriptive style of standard, aimed at supporting small and medium sized enterprises (SME's) to facilitate the implementation of private standards is a form of paternalism. Prescriptive paternalism shifts the sense of ownership of the FSMS from having the full engagement of the organization's management and staff to develop appropriate protocols to meet the needs of the organization, and instead accepting a FSMS development and implementation approach that can be described as a "line of least friction" application or a cost-benefit trade-off. Decisions in this context on how a FSMS is developed and implemented are affected by the dynamic aspects of the given task environment such as multi-level trade-offs, time pressure, weak feedback on the effect of management actions, the level of uncertainty, and perceived risk (Kerstholt, 1994).

4.3 Risk-based standards and transformational management

The only private standard that uses the widely acknowledged iterative “process approach” rather than the prescriptive-approach just described is ISO 9001. The process approach concept is clearly grounded in science-based management principles. The fully restructured 2015 revision (ISO9001: 2015) evolved into a high level structure of the Plan-Do-Check-Act (PDCA) cycle (based on Deming, 1986) and allows for more tailored translation of requirements by explicitly acknowledging the business context with its typical internal and external challenges, focused on both risks and opportunities. Indeed an Annex of the ISO 22000: 2018 Standard for food safety management systems cross references between Codex HACCP principles (Codex 2009) and the requirements of the standard and includes the PDCA cycle approach and the interrelationship with HACCP. Panghal, Chhikara, Sindhu & Jaglan (2018) assert that ISO 22000 embeds HACCP in a form that leads to a more effective and auditable FSMS that includes the need for continuous improvement.

Prescriptive private standards, on the other hand, via their rigid structure and emphasis, may favor and/or create a reactive rather than a proactive mentality (culture) in those organizations seeking to implement the said standards. As the certificates (linked to the standards) are a form of “license to produce”, this then directly affects market access for individual organizations. This framing of third party certification may shift ownership of the need for compliance within the organization from being proactive and strategic to reactive and tactical. Across global supply chains, organizational motivation to gain certification may reflect a spectrum of cultural approaches to adopting the standards, systems and protocols required for regulatory compliance and to demonstrate compliance with procurement pre-requisites to supply.

Commonly, food industries tend to implement supply chain standards in a transactional rather than a transformational way (Manning, 2017b). The transactional approach is often simply a technical goal and compliance driven, demanding that staff work according to prescribed requirements such as specifications, work instructions and procedures and determines appropriateness through prescribed compliance audits and other verification activities (Manning, 2017b). Transformational management is more culturally orientated and reflects activities to empower staff to implement system requirements and to “feel” that compliance is important, in fact essential, as most private standards drive the visual, concrete formalization of FSMS through requiring protocols, procedures, and associated compliance documentation; the element that is most often used for verification. A prescriptive approach to developing and implementing private standards has been considered here, but a third approach is posited by the authors i.e. using a more holistic and cultural framing of the FSMS. Whilst a move away from compliance (checklist) based system design and verification to an outcomes based approach is of value, there are obvious concerns about bias being introduced and a lack of consistency of how standards are verified across the food supply chain. In a more risk-based, situational and targeted approach to verification, there is a drive for efficacy and efficiency and for continuous improvement in both the design and implementation of FSMS and in the third party certification process itself (Albersmeier et al. 2009). Developing third party verification approaches into the future to become more outcomes-based or to use multiple sources of data is an emerging theme in the literature. The use of triangulation allows for comparison between different sources of evidence, especially in complex, socio-technical situations by counterbalancing the strengths and weaknesses of different methodologies and approaches and in doing so increase the credibility and depth of audit processes (Yeasmin & Rahman, 2012; Carugi, 2016; Jespersen & Wallace, 2017; Manning, 2018b; De Boeck, E., Jacxsens, L. Vanoverberghe, P. & Vlerick, P. 2018). This line of enquiry then gives rise to some questions. Does this result in the organization simply honing its FSMS to meet a set of prescribed and specific standard(s) rather than reflecting on the bespoke challenges associated with the food they produce and developing an FSMS that is situationally appropriate and valid? If instead, the FSMS design is driven by the need to comply with private standards that are specific, static/rigid, with strict/prescriptive requirements, is there then a trade-off taking place? As a result of this trade-off does the organization lose staff buy-in, a sense of ownership, and then as a result carry reduced operability and practicability within the resultant FSMS they implement?

The argument put forward here is that the design of private standards should be flexible enough that the organization can comply, and gain continued certification, through tailoring and allowing their FSMS to continually evolve to meet the dynamic requirements of the product, process, and the internal and external characteristics associated with the organization. Therefore, rather than simply a hazard-based transactional approach to food safety management, should organizations follow a more transformational systems-led and risk-based approach and as a result focus more on realizing the minimization of food safety risk in a given situation and context? A more holistic approach to food safety is now presented.

5. Holistic approaches to food safety and developing FSMS

5.1 Risk and Context

Perceptions of risk, held collectively or individually by stakeholders and actors in the food supply chain, including consumers, influence how FSMS are developed and implemented, as well as the degree of actor engagement with the processes that are required to ensure food is consistently safe and wholesome (Manning & Soon, 2016b). It is important to recognize that risk is being considered here and in the supply chain context, as previously outlined, this largely determined in a qualitative, or semi-quantitative approach that is framed by uncertainty, and ambiguity. Higher order systems driven by the interaction of regulation and enforcement surveillance and the interaction between international and national policy and associated market governance are interwoven and complex (Manning & Luning, 2018). Luning and Marcelis (2006) describe these higher order systems as chaotic, having greater *ambiguity* i.e. lack of clarity about the mechanisms of influence and *uncertainty* due to lack of information. As a result, such systems have less linearity, rationality and stability. Vulnerability, uncertainty, and ambiguity are inherent attributes of internal and external organizational context factors, such as product and production related characteristics of the environment in which a FSMS operates (Luning & Marcelis, 2007, Luning et al. 2011a). Internal and external context factors influence the degree of risk associated with food products, processes and the associated public and private standards developed to mitigate such risk (Manning & Luning, 2018). In addition, context factors can be *active* i.e. influencing the organisation on a continuous basis or alternatively *dormant* awaiting a trigger factor that will then enact them. Luning et al. (2011a) distinguish four main context factors, which can affect control and assurance activities in a FSMS (Luning & Marcelis, 2007; Luning et al. 2011a; Kirezieva et al. 2013; Manning & Luning, 2018):

- **Product characteristics** i.e. the *intrinsic* properties of initial materials and final products.
- **Production characteristics** i.e. the *extrinsic* conditions utilized during primary production, processing, or handling.
- **Organisational characteristics** specific to the organisation itself. These can be further subdivided into **individual** (people) characteristics, **group** characteristics (transformational characteristics

associated with food safety culture and quality culture), **organisational** structures (transactional division of tasks, responsibilities, rules, procedures), and **information systems**, which affect peoples' decision-making behavior (see De Boeck, Jacxsens, Mortier & Vlerick, 2018); and

- **Chain characteristics** i.e. the conditions during supply, and relationships within the supply chain.

Context factors are characteristics of a system environment that can affect its performance and cannot be (easily) changed (Kirezieva et al. 2013:109). More specifically, FSMS context factors are situational, structural elements in the FSMS that affect decision-making activities and as a result the output derived (Luning et al, 2011), and can be further characterized as narrow and broad context factors, or internal and external business characteristics (Table 3).

Take in Table 3

External context factors that exert influence from the broader context include supply chain, socio-political, legal and national factors (Kirezieva et al. 2015b). These are also called macro factors by Nayak and Waterson, (2016). Internal (or narrow) context factors include product, production, and organizational characteristics (Luning et al. 2011a; Kirezieva et al. 2013), and from a systems viewpoint are termed meso factors with the individual being the micro level (Nayak & Waterson, 2016). It is important to recognize that the context in which the FSMS operates is narrower than the overall operating environment (broad context) of the organization. The external environment can encompass wider context factors that can still affect overall food safety output and delivery of safe food (Luning et al. 2011b, Kirezieva et al. 2015b). Using a process (input-activity-output) approach, *triggers* can be described as the inputs/influence on an organization that arise from the business environment, either internal or external to the organization. Extrinsic triggers can be initiated and driven by a range of supply chain actors and wider stakeholders and include changes in customer requirements that influences intrinsic and extrinsic product characteristics which in turn may have an impact on food safety, for example reformulation of products to reduce salt and sugar levels. Triggers can influence an organization singularly or in consort, harmoniously or in discord. The impact of the combination of individual or concerted internal and/or external triggers is to create organizational and wider supply chain uncertainty. It can be postulated that internal trigger factors include changes such as new production systems, technology, and new individuals in key management positions.

Examples of potential internal and external triggers have been synthesized (Table 4).

Take in Table 4

The structure of the organization and the associated FSMS will be specific to the given business i.e. it can have either a central focus of food safety control or a more decentralized hierarchy (Luning & Marcelis, 2009). The interactions of strategic, tactical, and operational decision-making are as a result, situationally framed. Moreover, the hierarchy of decision-making and given determination of food safety “meaning” has a strong influence on the culture that surrounds the FSMS and thus is worthy of consideration here (Nyarugwe, Linnemann, Hofstede, Fogliano, & Luning, 2016).

Take in Table 5

Table 5 provides examples of the types of decision-making that occurs at these three levels within an organization: strategic, tactical, and operational. Nayak and Waterson (2017) argue that management and decision-making at levels of an organization matters in terms of FS-Culture stating that if senior management is too focused on profit generation, and this combines with a dissonance between senior management and employees then the result is a failure to set the example of a positive FS-Culture. Furthermore, social networks affect the efficacy of the FSMS. The overall food safety climate (FS-Climate) of an organization is the convergence of individual characteristics such as beliefs, values, and perceptions into group characteristics (De Boeck et al. 2015). Thus the socio-technical interactions that frame the development, validation and implementation of the FSMS are crucial to its efficacy and alternatively if there is a negative socio-techncial influence can underpin its vulnerability and potential failure too.

5.2 Socio-technical systems

Luning and Marcelis (2006) suggest that a techno-managerial approach with increased levels of information reduces uncertainty; and if as a result greater knowledge is instilled into individuals also reduces ambiguity. However, dynamic FSMS remain difficult to fully predict in terms of both human behavior and also product and production failure (Luning & Marcelis, 2007). De Boeck et al. (2015) combine in their study, the techno-managerial route (based on Luning & Marcelis, 2006, Luning et al. 2011a) to assess FSMS and also the individual human factors, as they influence the implementation of the FSMS. People in organizations interacting with the technological system create "socio-technical systems" (Bronfenbrenner, 1986; Bostrom & Heinen, 1977; Ghaffarian, 2011; Winter, Berente, Howison & Butler, 2014). It is important to recognize that FSMS are not operating in isolation, instead they are an element within wider organizational and supply chain socio-technical systems, and the influence of internal and external triggers means that they operate in a situational business/environment context that can set boundaries on the design, application and implementation of the FSMS i.e. the socio-technical system can be multi-level. Further, effective FSMS require the embedding of systems thinking and a clear acknowledgement and understanding of the complexity of the socio-technical systems that provide the context in which they operate (Kirezieva et al. 2015a; 2015b). Nayak and Waterson (2016) analysed the causes of two foodborne outbreaks rooted in six system levels, which together shape the socio-technical system in which an organization and its FSMS operate:

1. **Government level**: Where regulation is developed to control food safety.
2. **Regulatory bodies and association level**: Where regulation is translated into industry rules and standards designed to address food safety.
3. **Organizational level**: Where the industry rules and regulation are integrated into the organizational and situational rules and policies.
4. **Management level**: Where the staff activities and roles are specified and overseen with reference to the organizational level rules and policies.
5. **Staff level:** Where the staff or work force are required to follow the rules set by their managers, and
6. **Equipment and surroundings level**: Where the organization's situational rules and policies are applied to ensure compliance with government regulations, industry rules and standards and organizational rules and policies.

Further, using this approach means there needs to be a shift from hazard-orientated (particularly microbiological hazard-oriented) food safety management approaches to a more holistic socio-technical approach that address the causes of food safety issues that occur at each level (Nayak & Waterson, 2016) and it could also be argued at the interfaces between different levels (Manning, 2017b; Jespersen et al. 2019). Indeed, perceptions of food safety risk at the organizational level are neither quantitative nor necessarily a 'qualitative approach based on expert opinion' (Monaghan et al. 2017). In reality, food safety risk assessment at the organizational and supply chain level is influenced by perceptions, social norms, and constructs of meaning. Thus, the role of these cultural influences on FSMS design and application cannot be ignored.

5.3 influence of FS-Culture and FS-Climate

Social representations drive collective meaning-making and common recognition produces social bonds based on dialogues, discourse, emotions, attitudes, and judgments that unite organizations and groups (Höijer, 2011). Thus, social representations bound the implementation of FSMS and the associated decision-making that occurs. Worldviews are the social, psychological, and political factors that influence an individual's risk judgments (Slovic, 1999) and thus are of importance when considering individual and collective perceptions of food safety risk and its meaning both to consumers and to individuals that work within food businesses throughout the supply chain. Worldviews are generalized attitudes towards the world and its social organization (Peters, Burraston & Mertz, 2004); or the shared mental representations, values and general social, cultural and political attitudes held by a group of individuals (Leiserowitz, 2003). Van der Linden (2015) considers the concept of "values" as differing from worldviews in two ways: firstly, that values precede worldviews and secondly that values are guiding principles with greater specificity and are more stability than worldviews. These socio-cultural factors can influence the organization in terms of how people interact with complex systems and context factor characteristics and the need, on occasions, to make decisions based on limited information. In this circumstance, meaning is an important personal construct that links people to their environments and as a result influences their perception of a given function or activity (Rapoport, 1988; Coolen & Ozaki 2004) and potentially their perception of a given food safety risk. Translating from their original subject area to consideration of food safety, Rapoport's (1988) three levels of meaning suggests that: **high-level or macro meanings** are related to worldviews, heuristics and philosophical systems for example consideration of the cost of implementing the FSMS versus the benefit derived; **middle level or meso meanings** convey latent functions such as group identity, status, wealth, power, and are represented via organizational structures and hierarchy within a given business; and **lower-level or micro meanings** are everyday and instrumental meanings and identity as perceived by the individual. In all organizations an informal, often invisible, system derived from these cultural aspects operates alongside the formal visible processes of the FSMS (see the work of Schein, 1985; Griffith, 2014 and others). Interpreting the FS-Culture levels of Griffith (2014) suggests that each organization e.g. a food manufacturing business, will be unique in terms of the exact combination and interaction of these levels of organizational culture and as a result this will influence the effectiveness of the FSMS (Manning, 2017b).

Culture as a construct describes the emergent history and traditions that give meaning to the underlying values and beliefs held by members of formal and informal social groupings (Buchann & Huczynski, 2004; Griffith, Livesey & Clayton, 2010). For any given organization there will be a distinct set of values and beliefs (Powell et al. 2011) that form a heterogeneous rather than singular framing (Griffiths et al. 2010) that is described in the context of this paper, specifically as FS-Culture. FS-Culture is defined as shared values, beliefs and norms that affect mindset and behavior toward food safety in, across and throughout an organization (GFSI, 2018). Griffith (2014) described three levels of FS-Culture:

Level 1 - **Food safety climate (FS-Climate)**: the outermost layer of food business culture that is considered during verification, auditing and inspection activity and is observable (Griffith, 2014). This level of FS-Culture can be modified depending on the situation and the internal and external conditions or constraints e.g. lack of resources, people, or an event such as the presence of the auditor/inspector. De Boeck et al. (2015) describe food safety climate as the relative priority or the "meaning" given to food safety in an organization or work unit as perceived individually or collectively by employees.

Level 2 - **Underpinning culture:** the middle layer includes the organization's espoused values (often unspoken) and guides the employees' behavior and attitudes to authority and legislation. Depending on the depth of verification activity, this level of culture can be examined and measured.

Level 3 – **Core culture**: the innermost layer that contains all the beliefs and assumptions by staff as individuals or groups about what the organization stands for. This level includes core values that are invisible and often assumed. Depending on the depth and scope of any verification activity this level may remain hidden.

Nayak and Waterson (2017) summarize the difference between FS-Culture and FS-Climate as FS-Culture referring to behavioral aspects i.e. what people do; and also the situational aspects of the organization i.e. what the company has in terms of products, processes and facilities; whilst FS-Climate refers to the psychological characteristics of employees in an organization i.e. how people feel and the meanings they derive with regard to food safety. FS-Climate is alternatively defined as the employees' (shared) perceptions of leadership, communication, commitment, resources and risk awareness concerning food safety and hygiene within their current work organization, however the construct is more temporal and subjective than representing the individual employee's perception of an organization (De Boeck et al. 2015, 2018). Third party verification activities can only ever capture a "brief glimpse" of the FS-Climate and, to date the third party audit approach has not been developed to assess FS-Culture specifically. However, a requirement for objective evidence of planning for the continual improvement of FS-Culture is being introduced into private standards (BRC, 2018).

Sub-cultures are separate from the dominant, overarching culture and can be categorized functionally (Hofstede, 1997), geographically (Hofstede, 2001), nationally (Hofstede, 2001; Jespersen & Huffman, 2014) or by the collective identity or values that are shared by the members of the sub-culture (Khatib, 1996). In addition, contingency situations, such as product failure, increased orders, or inadequate training can influence the interfaces between sub-cultures, causing competitive interaction, barriers and conflict to occur especially where primary values and worldviews within sub-cultures are not congruent across the organization (Manning, 2017b). Functional interfaces such as those between quality and production; production and engineering; production and finance; production and procurement all influence both the formal and the informal aspects of an organization's FS-Culture. Indeed, Jespersen et al. (2019) propose a dynamic model of food safety culture based on the building blocks a) organizational effectiveness, b) organizational culture norms, c) working group learned and shared assumptions and behaviors and d) individual intent and behaviors, and highlight the integration of and the interactions between these building blocks as crucial to the necessary maturation of FS-Culture. Multi-level interactions and interfaces may be visible during the monitoring and verification activities undertaken to measure the

FS-Culture maturity and effectiveness, but equally may also be translucent or invisible during formal processes such as an external audit (Manning, 2017b). The formalization of food safety controls and management systems evolve from the FS-Culture and FS-Climate in a given organization and thus the FS-Culture frames and, depending on its level of maturity, enables the FSMS. Conversely a weak FS-Culture would be expected to restrict the efficacy of the FSMS, but further empirical research is needed to support this conclusion. The mechanisms of both formalization and informal drivers are considered in various studies (e.g. Nyarugwe et al. 2016; Manning 2017b; Nyarugwe, Linnemann, Nyanga, Fogliano, & Luning, 2018). Therefore, developing FSMS in isolation without regard for the perceptions and meaning of food safety, FS-Culture and FS-Climate, or sub-cultures within that organization is of limited value. Whilst FSMS are formally developed to address the requirements of public or private standards and/or the context of a specific business setting they may firstly be inappropriate for the FS-Culture or FS-Climate in the given organization and secondly may not be effectively and consistently implemented throughout the organization.

Moving from a static approach to food safety management (i.e. focused on system elements and product and process compliance with prescribed standards) to a more dynamic, holistic and risk-based approach with a focus on the interactions and dynamics of the organization itself requires new forms of socio-technical systems thinking. The cultural and behavioral factors associated with the people employed in the organization means that primarily the organization must truly understand itself in terms of structure, and internal and external triggers, which are often specific to its activities. Most importantly, the meaning of food safety within the organization, which is far more nuanced than simply undertaking hazard analysis, and defining risk appetite, risk management and mitigation, must be defined and understood. This holistic approach extends beyond the narrow use of HACCP principles and the development of a food safety plan; is mediated by both internal and external triggers, which are constantly evolving and changing; and is framed by contextual factors that are specific to the organization and its wider supply chain. A static FSMS and associated FS-Culture will be limited with its modus operandi in terms of addressing and mediating the uncertainty and ambiguity associated with ever changing food safety risk. Whilst seeking to measure and determine FS-Culture is important (Emond & Taylor, 2018; Nayak & Taylor, 2018), there are however challenges to assessing FS-Culture effectively in practice (Nayak & Waterson, 2015; Jespersen et al. 2017;

Jespersen & Wallace 2017; Nyarugwe at al., 2018; Kane, Taylor & Teare, 2018; Taylor, Caccamo, Daniel & Bulatovic-Schumer, 2018; Taylor & Rostron, 2018). The conceptualization of a holistic view of the FSMS is therefore much more multi-layered and nuanced than the simple development of PRPs, OPRPs, and identifying and managing process CCPs for food safety. A failure to implement a systems based approach means the use of private standards will continue to be a shallow, rather than a deep form of implementation and verification with associated limitations in the ability to deliver in terms of reducing the likelihood of food safety incidents. However, it is questionable what supply chain incentives exist for a more thorough evaluation and adoption of the holistic approach, e.g. by deepening third party certification, supplier, and internal audits and by augmenting these with valid FS-Culture measurement systems. The hybridization of food governance and retreat of regulatory mechanisms in favor of private standards and earned recognition should mean that private verification mechanisms will be driven to be deeper and more holistic in nature. However, the exact combination and form that these mechanisms need to take is yet to be determined and further research is needed both to establish the precise nature of this holistic culture-systems-practice approach and how to assess maturity and effectiveness of the associated holistic FSMS and FS-Culture.

6. **The evolution of FSMS – where next?**

Food companies operate in an increasingly complex highly interdependent food supply chain network and face multiple challenges associated with developing, implementing and verifying their FSMS in order to effectively manage food safety. Varzakas and Jukes (1998) argued that globalization has driven global integration and standardization of markets and complex interdependence that has then led to the emergence of isomorphism in structures, attitudes, and norms especially within transnational corporations. Manning, Soon, de Aguiar, Eastham and Higashi (2017) noted that the concept of supply chain pressure has increasingly emerged within supply chain literature over the last decade especially the notion of integration and greater isomorphic pressure (DiMaggio & Powell, 1983; Delmas & Toffel, 2004; van Plaggenhoef, 2007; Sarkis, Zhu & Lai, 2011; Gimenez, Sierra & Rodan, 2012; Esfahbodi, Zhang, Watson & Zhang 2017; Manning, 2018c). In essence, homogenization, or isomorphism, creates and spreads a common set of values, norms, and rules, which then results in similar practices and organizational structures (Othman, Ahmad & Zailani, 2009) often driven by a need to conform not only to the external environment, but also the context that the environment itself promotes (Czinkota, Kaufmann & Basile, 2014). Indeed, isomorphism occurred in the work to establish international HACCP guidance through the 'invisible college of HACCP experts (Demortain, 2007, p9) and can be seen as a natural effect of the comments and critical review cycles that form the step procedure for elaborating Codex Standards (FAO, no date a & b) and within the consensus approach of industry benchmarking of private standards, as undertaken through both GLOBALG.A.P activities and the work of the Global Food Safety Initiative (GFSI). The process of benchmarking itself can drive isomorphism as private standard owners seek to demonstrate private standard equivalence. Therefore, both the resultant organizational FSMS and FS-Culture that are informed by these standards are influenced a series of rational myths. Institutionalized rules, and norms, and increasingly the structural similarity of private standards creates contiguous cultural myths, symbols, rules and regulations (see DiMaggio & Powell, 1983) across the food industry.

Customer pressure for a supplying organization to use a certain third party private standard or the customer's own standards requirements further complicates the picture. This supply chain pressure of compliance can result in a transactional approach that seeks to develop an FSMS to meet the required standards rather than because it is the right approach for the products manufactured and the processes employed, and the right way to protect the consumer. Indeed the drive for compliance and to eliminate deviance may weaken FSMS in the future. The deviance of employees from organizational norms can have negative outcomes for the organization, but can also be a form of *constructive deviance* that is beneficial and leads to positive change that drives innovation and entrepreneurship in food safety management as products, systems and processes (Spreitzer & Sonenshein, 2003; Galperin & Burke, 2006). Questions remain as to whether the current transactional industry approach to managing food safety is sufficient. Nevertheless, further research is needed to establish what a more systems and risk-based holistic food safety management framework would look like, how it would address both formal and informal aspects of FSMS and FS-culture and how it would work in practice within food organizations. The reactive mindset of managing as a result of external triggers is well established and further clarity is needed about the roadmap to develop a more proactive mindset that is dynamic enough to meet the needs of a given organization and wider supply chain.

Organizations are experiencing greater proliferation of private standards and the implementation of ever more requirements, standards and additional protocols, but it is unknown whether this transactional, compliance-driven supply chain approach can actually lead to better (predictable and consistent) product safety; in fact it is proposed that a saturation point has been reached (Kleboth et al. 2016) and the food sector may be facing a simple process of ever diminishing returns. Kleboth et al. (2016) describe this approach as the 'reactive food control vicious cycle'. This situation is caused initially after a food incident when the degree of mistrust in the food industry increases and then, depending on the degree of personal and financial impact of the given food safety incident, there is pressure from food chain actors and stakeholders to implement appropriate corrective actions. Consequently, to avoid incidents in the future, more and/or stricter standards are required; and then the cycle starts over again when a new food scandal occurs. This approach could also be called "protocolization", i.e. the formalization of organizational operations as a response to minimizing issues of blame and liability (Hood & Rothstein, 2001); and increasing bureaucratization (DiMaggio & Powell, 1983).

Rothstein et al. (2006:97) assert that assessment of risk is "*a way of formalizing organizational operations in order to provide bureaucratically rational 'due diligence' defenses in the face of increased accountability pressures."* Due diligence in itself drives the complexity and scale of risk elimination and risk management approaches (Manning & Luning, 2018). As has been explored in this paper a risk assessment is a much more in-depth and quantitative approach when compared with the process of hazard assessment. Thus food safety risk assessment extends beyond the use of HACCP as a tool to develop, implement and verify a FSMS. The construct of HACCP uses hazard analysis as a transactional tool to determine the likelihood and severity of food safety hazards at the food business level and to identify the measures that can be implemented to reduce the likelihood of occurrence or the severity should they occur. In wider business literature, risk is described as a combination of the probability of an occurrence of a particular threat and the possible subsequent impacts (Slovic, 2002); or as a measure of a hazard that can result in 'threat to people and what they value' (Kates & Kasperson, 1983). Whilst there are clear similarities between these definitions, there are also differences in the way that risk is being expressed and this suggests there is an inherent meaning to an individual or group associated with the qualitative determination of risk. Therefore, risk is determined through a politicized process and contextualized as a social construct

(Masuda and Garvin, 2006) influencing at the supply chain level who manages, mitigates, reduces or outsources any given risk. Managing risk in a holistic way is an integrative process where different actors may bring their different interpretations of risk but the focus on the interactions and dynamics of the organization and its environment is to consistently produce safe and legal food. Thus understanding the cultural aspects that frame food safety risk assessment is crucial to ensuring that the systems used are appropriate, valid and effective. The food industry is recognizing the importance of FS-Culture and the necessity to consider at the food organization level how FS-Culture informs and frames the perceptions of food safety risk and the implementation of FSMS and PRPs. Understanding the prevailing FS-Culture and how, where it is necessary, to improve it remains a key challenge for every organization.

7. Conclusion

The concept and factors that influence the structure of FSMS in individual organizations has evolved over the last 75 years. Key milestones include the international acceptance of HACCP principles and their application in food businesses to develop appropriate, valid and effective FSMS. However the application of HACCP principles is not without its challenges and retrospective investigation and analysis of foodborne illness data demonstrates that HACCP systems are not always working effectively in practice. HACCP principles have been one of the cornerstones of the development of private food safety standards, but these standards have tended to evolve in a mosaic way, with new topics and requirements being added each time they are revised. This can result in standards that are prescriptive and inflexible and drive the development of a least cost FSMS rather than the development of an appropriate outcomes based food safety system. This mindset has led not only to questions about where this trend will end but also has led to a type of food safety management in food organizations that is more transactional and compliance driven than transformational and having cultural maturity. The realization that FSMS cannot be stand-alone technical systems but are part of and impacted by the social context within which they operate has been an important driver for evolution. Research has led to the cultural framing of FSMS through better understanding of the FS-Culture and FS-Climate constructs. As these academic approaches cascade down to the development of private systems standards this should allow further enhancement of food safety performance and also industry mechanisms for verification of FSMS.

The concept of socio-technical systems is now being used to inform food safety management research, but further work is needed to establish how FSMS, practices and culture relate to and interact with each other at multiple system levels, and at cultural interfaces in order to reveal a model of the risk-based holistic approach to food safety management that can be widely adopted and inform better food safety management in the future.

8. Author Contributions (required for *JFS* original research manuscripts)

All authors designed and contributed to all the sections in the review. Initially each author concentrated their efforts in specific sections: L. Manning, sections 1, 2 and 5; P Luning, section 4; C Wallace, section 3. The review then progressed through an iterative development process involving all 3 authors in critically reviewing, extending and developing the initial drafts.

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Table 1: Multiple definitions and descriptions associated with public and private standards (Adapted from Meuwissen, Velthuis, Hogeveen & Huirne, 2003; Henson & Reardon 2005; Fulponi, 2006; Theuvsen & Spiller 2007; Schulze, Albersmeier, Gawron, Spiller, & Theuvsen, 2008; Schaarschmidt, 2016)

Term	Description / definition
Certification	The (voluntary) assessment and approval by an accredited party on an accredited standard
Legally-mandated private standards	Standards developed by the private sector, which are then made mandatory by public bodies.
Private standard/ Optional laws	Public (voluntary) standards are created by public bodies and the adoption is voluntary, these standard are also called ‘optional laws’. Standards developed and adopted by private bodies.
Process-oriented standards	Standards aimed at assuring that processes are designed, validated and verified in accordance to certain requirements on e.g. food safety, quality, environment-friendly, welfare etc.).
Product-oriented standards	Set requirements on particular products and or ingredients. Define specifications for individual products or product groups aimed at harmonizing product quality to facilitate trade and to avoid consumer fraud. Examples are: gluten free, ISO product standards with requirements on pesticides, mycotoxins, heavy metals, etc.
Public standard/regulations	Standards enacted in laws, also called regulations.
Quality standards	Quality standards refer to specific schemes for assurance of high quality line products usually associated with culinary products with particular gustative attributes.
Standard	Measures by which products, processes and producers are judged
Standard owner	Standard owners can be (local) governments (state-run systems e.g., organic farming in Denmark); international standardization organisations (e.g., ISO 9001 and 22000), specific stakeholders (e.g., Fairtrade); producer schemes (e.g., farmers' associations); private inspection bodies (e.g. Lloyds); retailer driven schemes (e.g., BRC Global Standard and IFS)
System-oriented standards	Standards setting requirements on (e.g. management) systems (like IFS, ISO9001:2015)

Table 2: Evolution of internationally acknowledged private standards used in food supply chains- illustrations of changes in standards

Period	Introduction standard	Time periods wherein major modifications of standards were launched			
		2000-2005	2006-2010	2011-2015	>2015
1985-1994	1987-ISO9000 Series	**2000-ISO9001** -**structural change** towards process model; - based on **management principles** -customer focus, consistency & traceability; - focus on leadership; - people involvement; - systems approach; - continual improvement; - factual decision-making; -mutual beneficial supplier relations	**2008-ISO9001** clarification of requirements and consistency with ISO14.000	**2015-ISO9001** -**structural change** to high level structure plan-do-check-act; -new clause structure based on **management principles** - context (e.g. know all stakeholders, process risks); -leadership (e.g. alignment quality policy with strategic decisions on risks); -focus on risks and opportunities; support (meet e.g. customer demands); -operation (e.g. contingency planning, control outsourced activities); - performance evaluation; -structured approach for continual improvement	
1995-2000	1995-SQF1000/ SQF2000			**2010-2013** -**new safety fundamentals** for animal production, animal conversion, feed, storage & distribution **2014-SQF** -redesigned **for all sectors** (replaced **SQF2000 and SQF1000;** -**new sections added**; -scored surveillance **audits**; -new guidance documents	**2016-SQF(vs8)** -**tighter practitioners requirements**; -unannounced audits; -recall tracking; -**fraud** GFSI tool; -revision technical elements
	1997-EUREP GAP		2007-GLOBALG.A.P renaming 2007-local GAPS e.g. Asian GAPS, China GAP, JapanGap, VietGAp, MyGap_ national GAPS	-2013 GLOBALG.A.P + Add-on product. - introduction of GLOBALG.A.P Risk Assessment on Social Practice (GRASP), which includes a voluntary module for risk assessment on **social practice**, addressing specific aspects of workers' health, safety and welfare. 2014- GLOBALG.A.P - introduction new Harmonized Produce Safety Standard (HPSS) to serve need of US fruit & vegetable producers to align with FDA	**2018 GLOBALG.A.P** -**addition** Produce Handling Assurance Standard (PHAS) covering pre- process production after harvesting **2016- GLOBALG.A.P** -**modular approach** with modules for al farm types; part I quality management rules, part II certification and accreditatio rules **2015 GLOBALG.A.P** -Revision of GRASP

	1997- BRC	2005-BRC -introduction **additional BRC standards** (packaging, consumer products, storage & distribution)	2007-BRC **- emphasize senior management** commitment; -**new sections** (allergens); - rigorous grading system for **auditing**; - auditor competence requirements	**2011-BRC** -emphasize on GMP; - reduction multiple customer audits; - **more detailed prescriptive requirements**; - unannounced **audit** scheme; - new **auditor** training **2015 BRC** -audit process consistency; -requirement on system to reduce **fraud exposure**; -supply chain transparency & traceability; - adoption for small sites; - **new sections and clauses added**; - **new voluntary modules**: - trade goods, - management animal feed; - Global GAP chain of custody; - meat supply chain assurance, - gluten free products; - food safety culture, - BRC FSMA	**2018 BRC (version 8)** Some major changes - encouraging development food safety culture -expanding requirements for environmental monitoring - section on high risk, high care and ambient high care requirements - Requirements on traded goods -whistleblower system must be integrate to ensure all food safety concerns can b reported and handled confidentially -addition cyber security clause on how t handle cyber attacks or failures in intern security
2001- 2005	2003-IFS food	Introduction **other IFS standards** logistics, global markets, food store, etc.	2008-IFS food -**focus senior management**	**2012-IFS food** - more weight to quality criteria; - packaging risks; - **food defense** requirements; - integrity program to **monitor auditors**; -**additional requirements** on validation, verification and documentation	
	2005- ISO22000 FSMS		2007-ISO22005 **- traceability** in feed and food chain 2009-ISO22002 - specific prerequisites food manufacturing	**2011-ISO22001** -prerequisites farming **2013-ISO22002** -prerequisites catering and packaging -ISO22003 guidelines for **audit** and certification bodies	**2018-ISO222000** -**structural revision** based on revision ISO9001:2015; with the high level structure, plan-do-check-act; -focus on business context and intereste parties -Strengthened emphasis on **leadership** and **management commitment** -Risk management (impact assessment positive and negative) -Strengthened focus on objectives as drivers of improvement - Extended requirements on communication

					- Less strict requirements on food safety manual -management facilitate understanding food safety policies by employees -establishing FSMS objectives - control externally provided processes, products or services
2006-2010	2009-FFSC22000			**2012-FFSC 22000** -**adds** new scope for food packaging manufacturers **2014-FFSC 22000** -**adds** new scope for manufacturing animal feed **2015-FFSC22000** **-adds** voluntary model based on ISO9001	2016-FFSC22000 -**new requirements**; -unannounced **audits**; - critical nonconformities; -standardized audit report; - prevention **intentional product contamination**; -requirements for transport & storage, food services, retail/wholesale

BRC (2015, 2018), https://brc.org.uk/about-brc; FSSC 22000, http://www.fssc22000.com/documents/home; GLOBALG.A.P https://www.globalgap.org; ISO 9000 (2015), https://www.iso.org/; ISO (2005, 2018); IFS (2018), https://www.ifs-certification.com/index.php/en/standards; SQF https://www.sqfi.com/standards).

Table 3 – Characterization of context factors that frame the FSMS (Adapted from Luning et al. 2011a; Kirezieva et al. 2013, 2015b)

Characteristics	Examples
External characteristics	
Legal context	Internal framing driven by enforcement philosophy and practices. Sufficiency of food safety authorities
National culture	National values, beliefs, norms related to food safety
Socio-political context	Corruption index, stability, economic situation
Supply chain context	Transparency in the supply chain network, power relations, domestic versus export markets, competitiveness, and interconnectedness. Severity and flexibility of stakeholder requirements. Information exchange and degree of asymmetry. Sophistication of logistic infrastructure. Degree of globalization of the supply chain and degree of interaction of national cultures and their approach to food safety.
Internal characteristics	
Business and Administrative	Communication - Vision, mission, policy, strategy on FS-culture and FSMS development - skills, different languages/culture, message consistency, along all channels, crucial role middle management. Leadership - moral engagement, enlightenment, reinforcement, employee involvement, truly involvement leaders, empower people. Training and learning - Both operator/management training, create FS-culture learning environment, respectful feedback, trust, connect information to action, learning from peers, tailored to users/company specific, knowing controls and consequences of failures, share experiences with other businesses, use various techniques (story telling, movies). Recruitment and employee development - effective interviewing and appointment, setting basic requirements, personal development, incentives/rewards, moral, feedback. Use of artefacts and symbols.
Group (Group, department or team)	Objective characteristics such as multidisciplinary, cross functional collaboration, type and size e.g. HACCP team, shift operators, group roles. Subjective or social interactions e.g. communication styles, group behaviour, conflicts, power relations, individual versus group decision behaviour and more individuals acting at the group level. Group and social norms e.g. normative standards, attitudes, perceived degree of behavioural control. Recognition and acceptance of group member differences in communication styles, in understanding, in culture. Engagement - common ownership, all group members being ambassadors of food safety in their work area
Individual	Demographics e.g. age, gender, seniority, education. Psychological e.g. attitude, beliefs, values, norms, habits, personality, personal perception of risks, safety, hazards, etc. Knowledge and understanding of food safety/risks, awareness, experience. Psycho-social wellbeing i.e. stress, job satisfaction, perceived reward, etc.
Organizational	Level of formalization (formal/informal) structured systems i.e. degree of adoption of manuals, procedures, work instructions. Level of information system: record keeping, data collection, archiving and retrieval. Organizational arrangements size & complexity, definition and division of tasks, responsibility, rules, authority. Structure i.e. central focus or decentralized, hierarchy, and the interaction of strategic, tactical and operational decision-making. Stability of workforce, competence level of workforce, staff turnover. Resource use – primarily financial, physical, human capital. Workforce composition and variability
Product	Intrinsic properties of raw materials, in-process material and finished products. Food safety risk associated with the initial materials and product (risk associated with allergenic, biological, chemical and physical hazards)
Production	Conditions during production including operational design, technical infrastructure. Food safety risk associated with the production site and the physical processes employed. Vulnerabilities and susceptibility to loss of control or contamination.
Technical	Technical resources e.g. facilities, equipment, personnel. Control activities including preventative measures, monitoring and verification systems in FSMS. Facility design e.g. hygienic zoning, lay-out, routing. Process design e.g. hygienic design, process capability. Equipment

	and tools e.g. hygienic design, tailored, availability. Cleaning and disinfection programmes. Maintenance of process and technical equipment. Traceability system design and implementation (see Chhikara, Jaglan, Sindhu, Veera, Charan, & Panghal, 2018).

Table 4. Internal and external triggers that influence FSMS and FCS (Adapted from: Leat & Revoredo-Giha, 2003; Kleboth et al. 2016; Manning & Soon, 2016a)

Internal triggers	**External triggers**
Wake up call –internal incident/company recall	Wake up call –incident in sector
New CEO	Negative media attention on an issue e.g. foof safety, food fraud
Internal policy changes	Regulatory and legislative changes
New products/product areas	Industry or trade association drive new standards or criteria for compliance
New brands/existing brands extension	Lobby groups
New technologies	Changing consumer demands
Audit results	Market and pricing strategies; low operating margins
Changing customer requirements	Natural disasters, technological accidents, infectious disease (Leat &)

Table 5. Hierarchy in decision making within a food organization (adapted from Luning & Marcelis, 2007, 2009; Nyarugwe et al. 2016)

Strategic level **CEO and executive board**	**Tactical level** **Middle management**	**Operational level** **Food handlers, operators**
• Content vision mission, etc.; food safety focus; • Investment in technical & human resources; • Horizon scanning, risk anticipation; systemic risks • Investment in food safety research; benchmarking, projects	• Design, implementation & maintenance FSMS; • Dealing with audit & review findings; • Data analysis for continuous improvement; • Dealing with daily safety & hygiene issues; • Training, instruction, feedback operators	• Compliance to safety & hygiene procedures • Feedback to peers & supervisors • Communication observations (near misses) etc.

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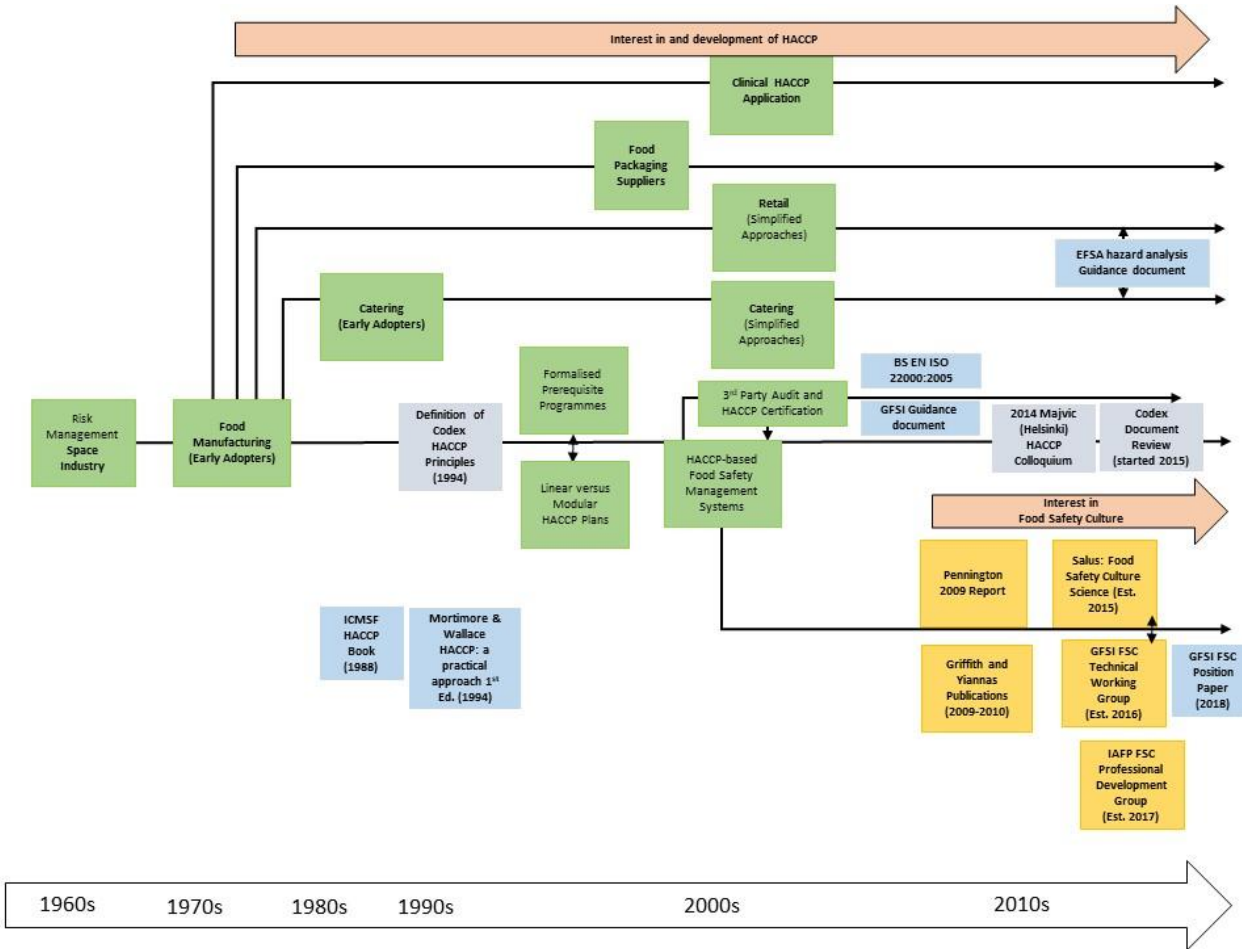


Figure 1: Timeline for the adoption of HACCP based approaches to managing food safety (Wallace, 2014)

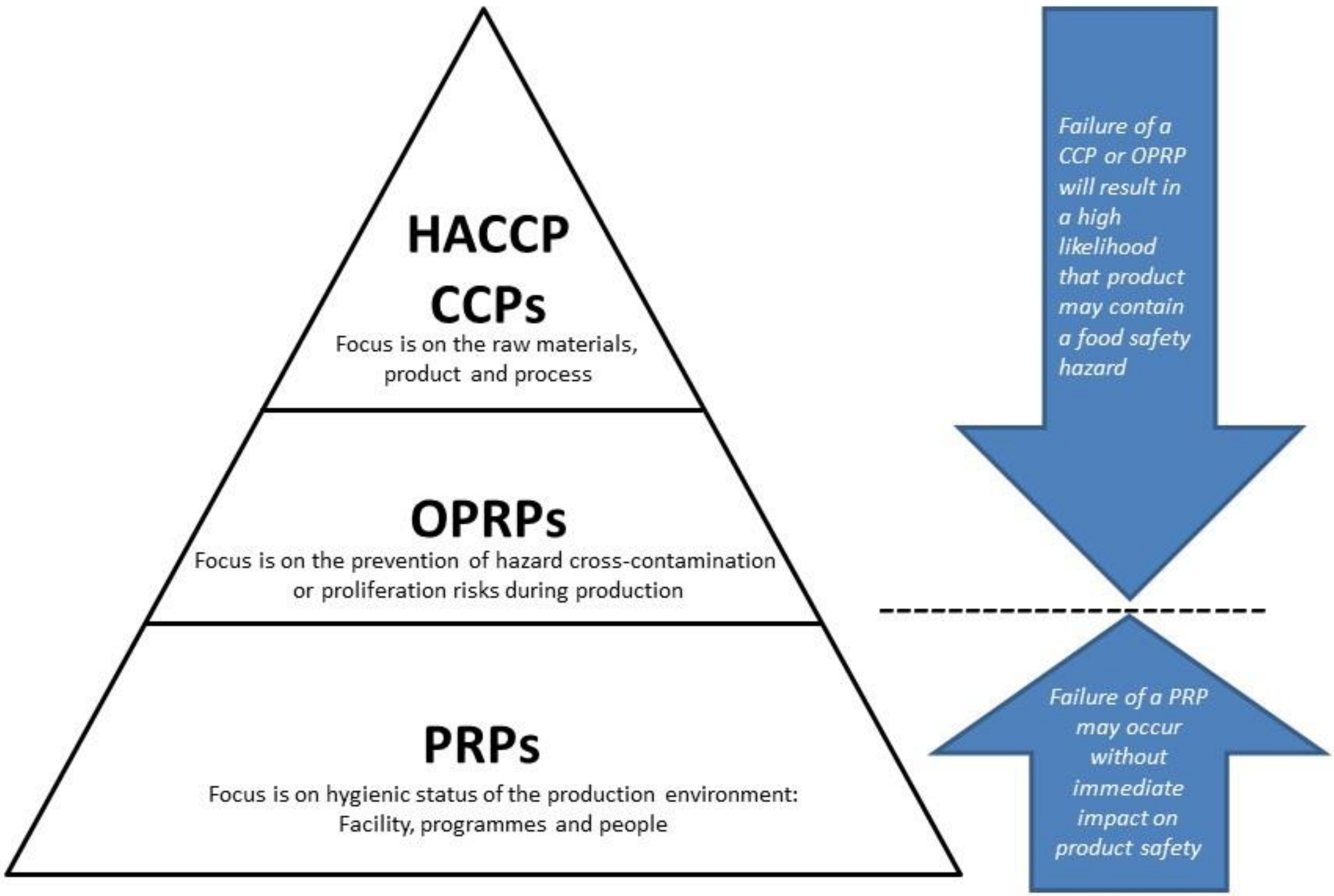


Figure 2. The relationship between HACCP, OPRPs and PRPs (adapted from Mortimore & Wallace, 2013)

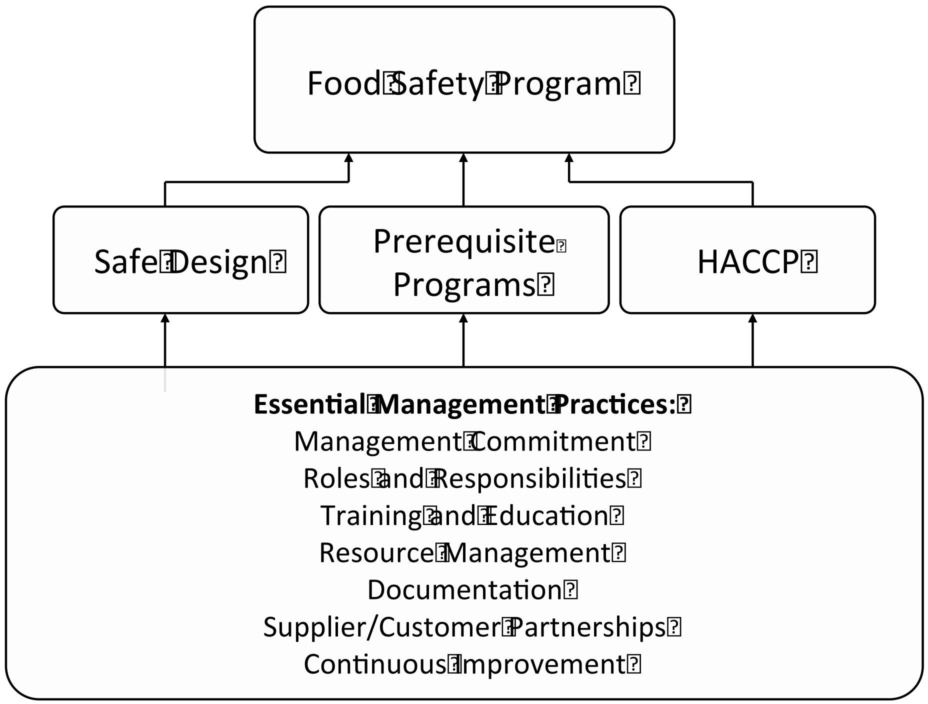
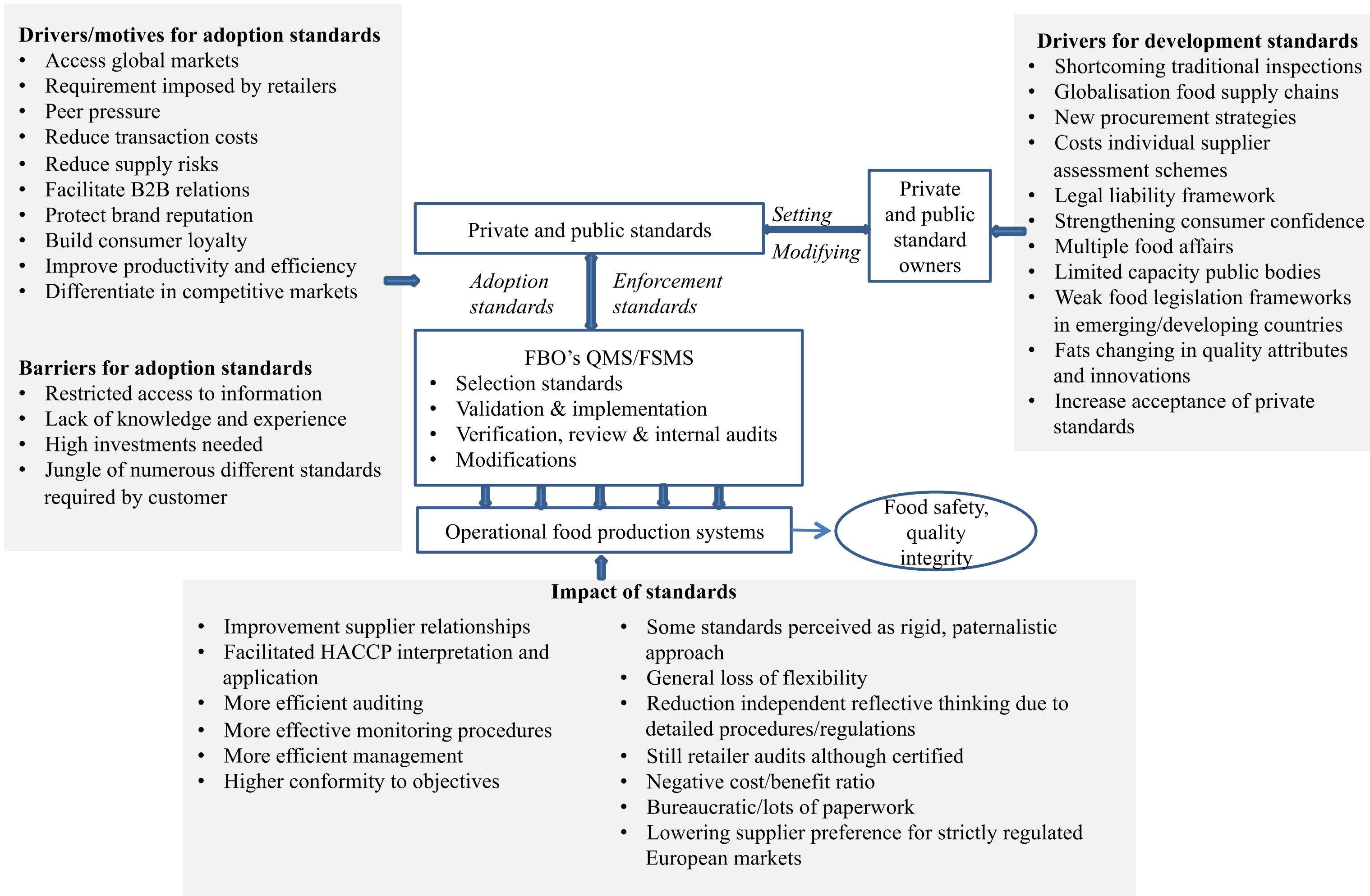


Figure 3. HACCP as a building block of a food safety management program (Source: Wallace, Sperber & Mortimore, 2011)



Drivers/motives for adoption standards
• Access global markets
• Requirement imposed by retailers
• Peer pressure
• Reduce transaction costs
• Reduce supply risks
• Facilitate B2B relations
• Protect brand reputation
• Build consumer loyalty
• Improve productivity and efficiency
• Differentiate in competitive markets
Barriers for adoption standards
• Restricted access to information
• Lack of knowledge and experience
• High investments needed
• Jungle of numerous different standards required by customer
Private and public standards
Setting
Modifying
Private and public standard owners
Adoption standards
Enforcement standards
FBO's QMS/FSMS
• Selection standards
• Validation & implementation
• Verification, review & internal audits
• Modifications
Operational food production systems
Food safety, quality integrity
Drivers for development standards
• Shortcoming traditional inspections
• Globalisation food supply chains
• New procurement strategies
• Costs individual supplier assessment schemes
• Legal liability framework
• Strengthening consumer confidence
• Multiple food affairs
• Limited capacity public bodies
• Weak food legislation frameworks in emerging/developing countries
• Fats changing in quality attributes and innovations
• Increase acceptance of private standards
Impact of standards
• Improvement supplier relationships
• Facilitated HACCP interpretation and application
• More efficient auditing
• More effective monitoring procedures
• More efficient management
• Higher conformity to objectives
• Some standards perceived as rigid, paternalistic approach
• General loss of flexibility
• Reduction independent reflective thinking due to detailed procedures/regulations
• Still retailer audits although certified
• Negative cost/benefit ratio
• Bureaucratic/lots of paperwork
• Lowering supplier preference for strictly regulated European markets

Figure 4: Drivers and barriers for standard development and adoption, and their impact; model based on Luning & Marcelis (2009) and drivers, barriers and impact derived from academic reviews and empirical studies (Latouche & Chevassus-Lozza, 2015; Spadoni, Lambardi & Canavari, 2013; Herzfeld, Drescher & Grebitus, 2011; Henson & Humphrey, 2010; Schulze, Albersmeier, Gawron, Spiller & Theuvsen, 2008; Theuvsen & Spiller, 2007; Fulponi, 2006; Henson & Reardon, 2005)