Determining the Barriers to Effective Food Safety Governance in Food Manufacturing: A Case Study

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Abstract

Food businesses bear the main responsibility for food safety. They are legally mandated to use preventative food safety management systems, yet food incidents occur regularly. Little research exists on these systems or failures from a management control perspective. This thesis addresses this gap through the question "Why do food safety systems fail and how does this relate to the governance and management control of food safety in food manufacturers?"

Two manufacturers, with the pseudonyms LiquiComp UK and PowderCo UK, act as case studies, each with an embedded critical case of a non-reportable food incident. Data was collected through semi-structured interviews, observation and documents. An inductive, thematic analysis identified nine themes, using within and cross-case comparison. A second analytical stage used the management control paradigm Pragmatic Constructivism (H. Nørreklit, L. Nørreklit, & Mitchell, 2010), mapping codes and themes against the four dimensions of values, facts, possibilities and communication.

A key finding was that the incidents were considered "unforeseeable", challenging the use of conventional food safety management systems based on risk assessment, for if the hazards leading to failures are not identified, preventative controls cannot be put in place. Pragmatic Constructivism suggests that the companies failed to identify the causes of the incidents as "factual possibilities", related to an unshakeable trust in their control systems and an over-reliance on specific expertise. The implications for practice in developing and reviewing food safety management plans are considered, e.g. to involve staff who are knowledgeable and curious, but not necessarily experts in food safety, in order to develop plans based on both breadth and depth of insight.

Pragmatic Constructivism posits that success requires a functional organisational topos, involving integration of the four dimensions. Inadequate integration was observed in the LiquiComp UK case, whereas in PowderCo UK, very tight integration

was seen. "Over-integration" is introduced as a new theoretical concept, which enriches the use of Pragmatic Constructivism in analysing and interpreting complex, real world situations, particularly system failures.

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Declaration

Whilst registered as a candidate for the above degree, I have not been registered for any other research award. The results and conclusions embodied in this thesis are the work of the named candidate and have not been submitted for any other academic award.

Word Count: 88,969

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List of Abbreviations

BRC: British Retail Consortium

CAPA: corrective action, preventative action

CCP: Critical Control Point

CDC: USA Centers for Disease Control and Prevention

CEO: chief executive officer

CI: continuous improvement

CP: Control Point

CRQ: critical research question

EFSA: European Food Safety Authority

EHO(s): Environmental Health Officer(s)

EU: European Union

FAO: Food and Agricultural Organization of the United Nations

FBO: food business organisation

FDA: Food and Drug Administration of the USA

FSA: UK Food Standards Agency

FSC: food safety culture

FSMS(s): food safety management system(s)

FSMnS(s): food safety monitoring system(s)

GFSI: Global Food Safety Initiative

GMP: good manufacturing practice

HACCP: hazard analysis critical control point

IIC: initial incident committee

IR: incident report

IRC: incident review committee

ISO: International Organization for Standardization

JECFA: Joint FAO/WHO Expert Committee on Food Additives

KAP: knowledge, attitude, practice model

LIC: local incident committee

MCS(s): management control system(s)

NASA: National Aeronautics and Space Administration

NGO: non-governmental organisation

PAF model: prevention, appraisal and failure quality cost model

PC: pragmatic constructivism

PDP: performance development plan

PRP(s): pre-requisite programme(s)

QCP: quality control point

QMS(s): quality management system(s)

RASFF: the EU Rapid Alert System for Food and Feed

RCA: root cause analysis

R&D: research and development

SMC: senior management committee

SME(s): small and medium sized enterprise(s)

SOP: standard operating procedure

TSO(s): Trading Standards officer(s)

US(A): United States (of America)

WHO: World Health Organization

Dedication

This thesis is dedicated to the memory of my parents, Elsie and Ron Poore, and my father-in-law Jan Krzyzaniak. Loved always and greatly missed.

Acknowledgements

I would like to thank a number of people for their support with this thesis. Firstly, to Prof Lisa Jack and Prof Mark Xu who supervised my work, offering guidance and encouragement and helping me to develop my academic skills and knowledge.

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Lastly, but not least, to my husband Martin, who has supported me every step of the way in pursuing my dream of studying for a PhD. Your patience and good humour are unrivalled. Thank you for everything.

Dissemination

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Krzyzaniak, S.C. (2016, September). *Key Determinants for the Governance of Food Safety in Food Business Organisations.* Paper presented at the Doctoral Colloquium of the 10th Management Control Association Research Conference, University of Antwerp.

Krzyzaniak, S.C. (2016, November). *An Analysis of the Governance of Food Safety in Food Business Organisations Utilising a Case Study Approach.* Paper presented at the 37th Management Accounting Research Group / Management Control Association Conference, Aston University.

1.0 Introduction

> *"I realise that food is never just an object on a plate or a menu. Food always does something more than just being there. It nurtures. It speaks. It travels. It calculates. It identifies. It joins. It separates. It demarcates. It historicises. It symbolises. It empowers. It disempowers." (Coveney, 2014, p2)*

For food to play any positive role in the lives of individuals or society in general it must be safe. Indeed, food safety is recognised as being fundamental to food security (Food and Agricultural Organization of the United Nations, 2015, p53). Even in developed countries a focus on food safety remains vital, as illustrated by estimates that 1 in 6 Americans suffer from a foodborne illness annually, with an associated cost of $15.6 billion (Centers for Disease Control and Prevention, 2016).

There is much research on the science, behavioural practices and laws governing food safety. However, within food business organisations (FBOs) food safety is managed and controlled by processes and systems and there is a gap in the literature in the study of food safety from a management control perspective. By using case studies of non-reportable food incidents, examined through the lens of a management control paradigm, this thesis addresses the literature gap.

This chapter sets out the background and rationale for the study (section 1.1), examines its theoretical background and identifies the objectives and research question to be addressed (section 1.2). Section 1.3 sets out the design and methodology used in the research study. The findings and contributions of the research are given in section 1.4, whilst section 1.5 outlines how the rest of the thesis is organised.

1.1 Background

In the 21st Century the food manufacturing industry plays a central role in supplying food and drink; it is also a major employer and economic contributor. In fact, in the European Union (EU) the industry forms the largest manufacturing sector, with a combined turnover of €1,089 billion, employing 4.25 million people in 289,000 companies (FoodDrinkEurope, 2016a). The industry has become increasingly complex with interconnected supply chains spanning different countries, continents and regulatory frameworks, forming a complex socio-technical system (Nayak & Waterson, 2016).

Yet this success story of a global industry can also be seen as separating producers from consumers. As Coveney (2014, p 2) states "... starting about 100 years ago, and more rapidly in the last 30 years, we have let go of food. We have outsourced it to others who are largely invisible and unknown to us". Food has become big business and as consumers we are obliged to trust that the actors in the food supply chain do the right thing; to supply, as it is put in section 14 (1) of the UK Food Safety Act 1990, food of the "nature, quality and substance demanded by the purchaser".

Unfortunately, in recent years the reputation of the food industry has come under fire, with a perceived plethora of food safety and integrity scandals. Even those which do not impact food safety, such as the 2013 EU horsemeat scandal, have been shown to affect consumers' trust in the food supply chain and change their purchasing behaviour (Yamoah & Yawson, 2014).

Food safety governance is complex and multi-layered, with stakeholders ranging from government, to the food industry and consumers themselves. Historically, food safety legislation operated on a "command and control" basis; enforcement authorities, on behalf of government, took the major role in discovering food safety contraventions through inspection and testing of premises and products (Fairman & Yapp, 2005). In the 1960's a new form of food safety control – Hazard Analysis Critical Control Point (HACCP) - was developed by the Pillsbury Company when working with the National

Aeronautics and Space Administration (NASA) to produce food for the USA space programme (Hulebak & Schlosser, 2002). HACCP is a preventative system that seeks to identify hazards (chemical, biological, physical) and set appropriate controls in place. The requirement for FBOs to implement HACCP based food safety management systems (FSMSs) sits at the core of modern food safety legislation. This places the main burden of responsibility for food safety governance on FBOs, in a form of "enforced self-regulation" (Fairman & Yapp, 2005).

Whilst HACCP principles are well established and standardised (Codex Alimentarius Commission of the FAO and WHO, 2003), each FBO has a specific FSMS, based on their unique requirements (products, equipment, compliance with voluntary standards etc.) (Fotopoulos, Kafetzopoulos, & Gotzamani, 2011). Thus, there is management discretion in the development, implementation and maintenance of the FSMS. FSMSs can be considered a specialised form of management control system (MCS) and the impact of the FSMS on assuring food safety varies between companies.

1.2 Theoretical Background, Research Objectives and the Research Question

The academic literature underpinning this research study covers two fields: the mainstream "technical" literature on food safety management and food incidents, and that of management control.

In the mainstream literature, HACCP and HACCP-like systems are widely recognised as enhancing food safety, reducing the burden of foodborne illness and providing benefits to FBOs, e.g. in waste and cost reduction, quality improvement, wider market access and defence against litigation (Food and Agriculture Organization of the United Nations, 2006). However, implementation of HACCP based FSMSs by FBOs is challenging, particularly in small and medium sized enterprises (SMEs) (e.g. Cobanoglu, 2012; E. A. Taylor, 2001), which account for 90% of European food businesses (FoodDrinkEurope, 2016b).

Research has therefore concentrated on determining the barriers to and drivers for FSMS implementation, particularly HACCP based systems. A number of models have been developed to categorise and explain both barriers and drivers. The work of researchers from Salford University has been key and Gilling, E. A. Taylor, Kane and J. Z. Taylor (2001) classified 11 factors affecting HACCP compliance under the categories of knowledge, attitude and behaviour. The model was later expanded (J. Z. Taylor, 2008a) and used to develop systems to facilitate HACCP implementation in the UK hospitality sector (E. A. Taylor & J. Z. Taylor, 2008).

Whilst the Salford model was developed using a qualitative, psychological research approach, the barriers identified encompassed both people and process related issues. Subsequent work continued to find barriers related to both areas (e.g. Kafetzopoulos & Gotzamani, 2014). Despite this, the people side of the challenge has risen to prominence in recent years, with the emergence of academic work and commercial systems to define, categorise, measure - and potentially improve - food safety culture (FSC). Interest in FSC rose following high profile food safety failures which were blamed on adverse FSCs, such as the John Tudor and Son case which resulted in 157 reported cases of food poisoning and the death of a 5-year-old boy (Powell, Jacob, & Chapman, 2011).

The final thread of mainstream literature pertinent to this research concerns food incidents. Whilst information is collected and reported on cases of foodborne illness and food incidents by regulatory bodies, e.g. the EU Rapid Alert System for Food and Feed (RASFF), little work has been conducted to understand if reported incidents are due to people or process elements of FSMS failures, or whether the barriers to the implementation of FSMSs can also explain these incidents.

This literature therefore informs the first three objectives for the research[1]:

[1] Although these research objectives and central research question are pertinent to all FBOs, the majority of reported food safety incidents refer to processed foods, hence a focus on food manufacturers is relevant to this research study.

1. To determine whether food incidents can be related to specific people or process elements of FSMS failure.

2. To determine the extent to which the barriers to the implementation and maintenance of FSMSs (particularly HACCP) found in the literature can be used to explain failures in FSMSs.

3. To evaluate the relationship of FSC to failures in FSMSs.

Notable in this review of the literature is the absence of studies which examine FSMSs as a form of MCS, using management control theories or paradigms. Management control therefore forms the second field which underpins this research study.

There are many definitions of management control. Central to many definitions are the principles of processes and systems (both “hard” systems such as accounting and financial systems and “soft” systems such as organisational culture) being used by management to influence behaviour to achieve organisational goals (e.g. Anthony & Govindarajan, 2007; Malmi & Brown, 2008).

Using these definitions, management control and MCSs can be considered as forms of mechanical governance (L. Nørreklit, 2011; L. Nørreklit, 2017a). However, management control can alternatively be viewed as an activity set in a social context, where organisational leaders co-author the firm’s activities with other staff. In this approach, set out as the “actor-reality construction”, the role of leaders is to create business specific guidelines or concepts – a “topos” - to enable a successful or functioning business reality. This conceptual paradigm is termed Pragmatic Constructivism (PC), with the “topos” being achieved through the integration of four dimensions of reality: values, facts, possibilities and communication (H. Nørreklit, Mitchell, & Raffnsoe-Moller, 2017; L. Nørreklit, 2017a).

Positioned as a middle ground between social constructivism and a realist, scientific approach (H. Nørreklit et al., 2017), PC fits the philosophical needs of this research study. This study also offers opportunities to contribute to the growing research on PC, expanding its use into the study of a non-accounting MCS, and using it to frame and explain the study of a system failure, rather than a 100% successful or functioning business.

This second stream of research, combined with the identified gap in the mainstream literature, therefore leads to the fourth objective of the study:

4a. To investigate food safety management from the perspective of management control, utilising PC, in order to ascertain the utility of PC for studying control systems outside of the mainstream of accounting.

4b. To gain insight on the use of PC in cases of management system failure, as well as management systems under control.

Taken together these objectives will inform the answers for the overall research question:

> "Why do food safety systems fail and how does this relate to the governance and management control of food safety in food manufacturers?"

1.3 Methodology

To address the research objectives and answer the research question, a qualitative, case study approach was taken. Two food manufacturers were selected using purposive sampling. Both organisations had well developed FSMSs / quality management systems (QMSs) and good track records of food safety. Nevertheless, both organisations had suffered a recent non-reportable food incident[2]. These incidents acted as embedded critical cases within the overall organisational case studies. Therefore, both the general organisation and running of the organisations' FSMSs and the incidents were investigated in a real-world context using multiple research methods: semi-structured interviews with individuals and groups, observation and document analysis.

A "roadmap" to guide the research was created by combining the framework of PC (H. Nørreklit et al., 2010), with the additional dimensions of "FBO People" and "FSMS Process" to reflect the two clusters of barriers to FSMS implementation and maintenance identified in the mainstream literature. This was used to develop three theoretical themes, related theoretical questions, and detailed interview questions used in the semi-structured interview guide, in an approach adapted from Wengraf (2001, p 63).

The data was analysed thematically (Braun & Clarke, 2006; Guest, MacQueen, & Namey, 2012, p 21-48), first by hand, with coding then transferred into NVivo (version 10, upgraded to version 11) for ease of data management. Codes were developed inductively, then clustered into themes. After several rounds of checking and reviewing, a total of nine themes were identified, seven of which describe the embedded cases, with six describing the overall organisations.

Subsequent to the inductive, thematic analysis, a second round of analysis was completed, mapping themes and codes against the four dimensions of PC. The case study findings were re-interpreted and re-presented in the light of the dimensions and related constructs.

[2] Due to the sensitive nature of food safety, it was not possible to recruit companies to the study who had experienced reported food incidents. Non-reportable food incidents, akin to "near misses," were substituted as the embedded critical cases. Further details are given in Chapter 4.

1.4 Findings and Contributions

The first significant finding of the study concerns the people / process elements of FSMSs and the non-reportable food incidents. Five barriers to food safety governance were identified through the thematic analysis of the cases, of which four – **system swamping, constrained communication, culture and values and organisational culture** – were related to barriers to FSMS implementation in the extant literature. The case studies, and these barriers, demonstrate failures in both elements of food safety management, but failures by the people implementing and maintaining the processes were established as the core of the quality failures examined. This finding makes a contribution to knowledge, as it forms the first examination of non-reportable food incidents from this perspective.

Furthermore, whilst there were commonalities between barriers identified in the literature and the causes of the case study incidents, neither incident was adequately explained by these. Indeed, in both cases some potential barriers to FSMS implementation were organisational strengths. This finding is of significance as it indicates that simply addressing barriers to FSMS implementation will not, by itself, be an adequate safeguard against future food incidents.

Additionally, this study raises a challenge to the reliance of the industry on risk assessment based processes such as HACCP. The fifth barrier to food safety governance identified in this research is that the incidents were considered **unforeseeable,** and hence appropriate controls for the underlying cascades of equipment and control system failures had not been put in place. The finding that incidents were unforeseeable is itself a contribution to knowledge; indeed, it is contrary to the expectation that during the investigation of failures they are often viewed, in hindsight, as “inevitable” or “waiting to happen” (Fischhoff & Beyth, 1975). Further research is required to establish if this situation is replicated in other food incidents.

The unexpected nature of the failures was also explored through the lens of PC and it was concluded that there was a failure by the organisations to consider the hazards which led to the failures as "factual possibilities". There a lack of recognition of the truth gap between the proactive truth of "our FSMSs are effective" and the pragmatic truth of "we've experienced a failure which resulted in a non-reportable food incident" and both organisations continued to have an unshakeable faith in their QMSs and FSMSs. This, combined with an over-reliance on narrowly focussed "expert opinion" to form HACCP plans, was suggested as potential reasons the possibilities were not identified. This offers opportunities for improving organisational practices in developing FSMSs.

From a theoretical perspective, a key contribution of the study relates to the use of PC within the "roadmap" to guide the case study investigation and analysis. The utility of PC in studying non-accounting MCSs been established, as has its use in exploring and understanding cases of organisational failure.

Central to PC and the actor-reality construction is the concept that integration of the four dimensions (values, facts, possibilities and communication) is essential for construct causality and an effective functioning topos, with a lack of integration being associated with MCS failure. The LiquiComp UK case demonstrated a relative lack of integration. However, very close integration was seen in PowderCo UK. This leads to the proposal that "over-integration" of the PC dimensions can also lead to a dysfunctional topos and a scale of integration of the PC dimensions has been developed and presented in Chapter 8. This enriches the PC paradigm, offering the potential for finer grained analysis and interpretation of organisational topoi, better reflecting the complexities of real world situations.

1.5 Structure of the Thesis

The thesis comprises eight chapters. After this introduction, Chapter Two sets out the background to the thesis, justifying the central role of FBOs in food safety governance and positioning FSMSs within the field of management control.

Chapter Three reviews the mainstream literature on FSMSs, food safety incidents and FSC, seeking to answer the question that when FSMSs fail is it due to process or people issues, or both. A short review on the use of Quality Costing in the food industry is also given. The research objectives and overall research question are identified from this literature review.

Chapter Four addresses the philosophical underpinning and research methodology of the study. PC is identified as a management control paradigm suitable for use in the research study. The key concepts of PC are presented and critiqued with reference to the existing management control literature, followed by a detailed explanation of the research design, methodology, methods and ethical considerations of the current research.

Chapters Five and Six present the empirical findings of this research, in the form of two case studies: PowderCo UK and LiquiComp UK. Each chapter comprises an introduction to the organisation, details the data collection and presents a thematic analysis, comparing and contrasting the overall case of the generally successful organisation with that of the embedded non-reportable food incident.

Chapter Seven discusses the case study findings, using a cross case comparison (both the organisational and embedded cases) and in relation to the mainstream "technical" literature. The cases are then further analysed and discussed using the paradigm of PC.

The thesis concludes with Chapter Eight, showing how the research study has addressed the research objectives, identifying the contributions of the research, its limitations and making recommendations for further work. The final section of this chapter is a personal reflection on the research process.

2.0 Background

The requirement for FBOs to provide safe food is enshrined in law across the world, e.g. Section 7 of the UK Food Safety Act, 1990 (as amended); article 14 of EU Regulation (EC) no. 178/2002 (as amended); in the USA the Food and Drug Administration (FDA) Food Safety Modernization Act of 2011; the Food Safety Law of the People's Republic of China, 2009 (USDA Foreign Agricultural Service, 2015); and in Australia, the Australia New Zealand Food Standards Code, Standard 3.1.1, 2005 (as amended 2009). Despite these laws, the incidence of foodborne disease remains high, indeed as Krebs (2013, p 59) states "Almost everyone has suffered from a bout of 'food poisoning'...".

This chapter provides a background to the research study, by looking first at the size of the burden of foodborne disease and the nature and extent of reported food safety incidents. Section 2.2 examines food safety governance and management control, before moving on to address the regulatory framework for food safety governance (section 2.3). The relationship between food quality and food safety is explored in Section 2.4 and HACCP is introduced as the main component of modern food safety management systems, whilst monitoring systems are considered in section 2.5. The argument that food safety is socially constructed is also presented in this last section. The chapter concludes by highlighting that the central responsibility for food safety rests with FBOs and the role that FSMSs play as a specialised form of MCS. This sets the scene for the literature review in Chapter 3, which concentrates on the mainstream "technical" literature, seeking to understand the barriers to and drivers for FSMS implementation, the role of FSC and whether food safety incidents can be explained by the barriers to FSMS implementation.

2.1 The Ongoing Challenge of Food Safety

The WHO estimated that 600 million cases of foodborne illness occurred in 2010, resulting in 420,000 deaths (World Health Organization, 2015). Even in developed countries, foodborne illness remains commonplace, e.g. the US Centers for Disease Control and Prevention (CDC) (2016) estimates that 48 million Americans suffer from foodborne illness each year. In the UK, data published by the Food Standards Agency (FSA) showed that over 500,000 cases of infectious intestinal disease due to known pathogens were identified in 2009, with poultry being the food commodity related to almost half these cases (Tam, Larose, & O'Brien, 2014).

Such data on foodborne illness generally concentrates on illness due to the microbiological contamination of food. However, food safety relates not only to microbiological contamination, but other hazards such as contamination with physical or chemical residues harmful to health and in recent years, much attention has also been paid to the control and labelling of allergens as another type of food safety risk. Indeed, food safety is not a static concept, but one which evolves as new information about food, health and potential risks to health are discovered. For example, acrylamide, a chemical formed in foods by the Maillard reaction (Mottram, Wedzicha & Dodson, 2002), is now recognised as a potential carcinogen and hence a chemical hazard in foods, so the EU has introduced legislation to control the level of acrylamide in foods such as potato products and coffee (Commission Regulation (EU) 2017/2158).

Food safety can therefore be considered to be “socially constructed”, in that what conditions are classified as a foodborne illness, or what factors are classified as food safety hazards, are determined by society. Manning (2017), for example, argues that a broader spectrum of conditions, such as type 2 diabetes and cardiovascular disease, should be classified as foodborne illness with the factors in foods associated with these conditions (i.e. the nutritional composition of foods) considered as hazards and controlled in the same way as any other form of foodborne hazard. The inclusion of a broader range of criteria to define food safety is supported by research with US consumers (Ringquist et al., 2016), which found that aspects such as “clear and accurate labelling" and "nutritional composition" were considered to be part of food safety by a significant proportion of consumers.

Whilst the nutritional composition of food is not, as yet, risk assessed and controlled by FBOs in the same way as pathogenic microorganisms, Governments are putting in place legislation aimed at influencing both FBOs and consumers to alter their perception of certain food ingredients and modify both the composition of foods and dietary intake. For example, a "sugar tax" has been placed on soft drinks in the UK (The Soft Drinks Industry Levy Regulations, 2018). However, the "classical" view of food safety, pertaining to microbiological, chemical and physical hazards, rather than nutritional hazards, is the focus for the current research study.

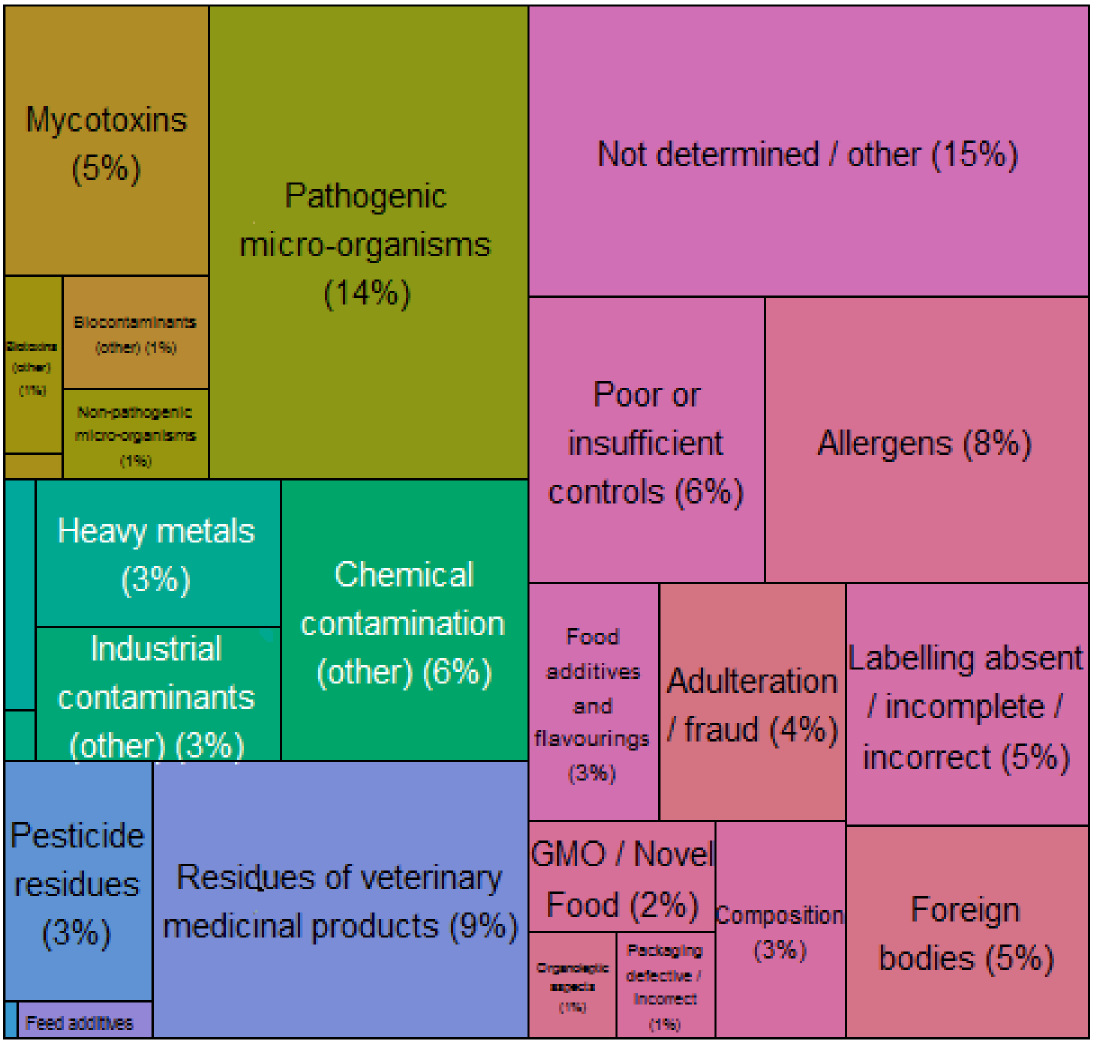
This perspective fits with the UK FSA definition of a food incident as "an event where, based on the information available, there are concerns about actual or suspected threats to the safety or quality of food and/or feed that could require intervention to protect consumers' interests"[3] (Food Standards Agency, 2017a). 2,265 incidents were notified and investigated in 2016/17 (Food Standards Agency, 2017b). Figure 2.1 overleaf shows the relative number of incidents, by hazard type.

It is pertinent to note that in the EU, FBOs are only legally obliged to notify the authorities of any products placed on the market which they believe may be "injurious to health" (Regulation (EC) No 178/ 2002, Article 19). Thus, whilst the FSA definition of an incident encompasses "quality" as well as "safety" threats, FBOs are not legally obligated to report non-safety related quality issues, or issues which pertain to products which have not left their control. However, the FSA data includes notifications from other categories of informants, including local authorities and the European Commission. Hence the incidents recorded by the FSA include some incidents which may impact the quality of a food but not necessarily its safety, e.g. "organoleptic aspects". Nevertheless, looking at the categories of incidents reported, it is clear that the vast majority of incidents pertain to potential food safety threats, e.g.

[3] Note that food incidents relate to actual or suspected threats to food safety; not all incidents will result in actual foodborne illness.

mycotoxins, allergens, pathogenic organisms etc. and of particular note for this research study is the category of "foreign bodies", which accounts for 5% of reported incidents[4] [5].

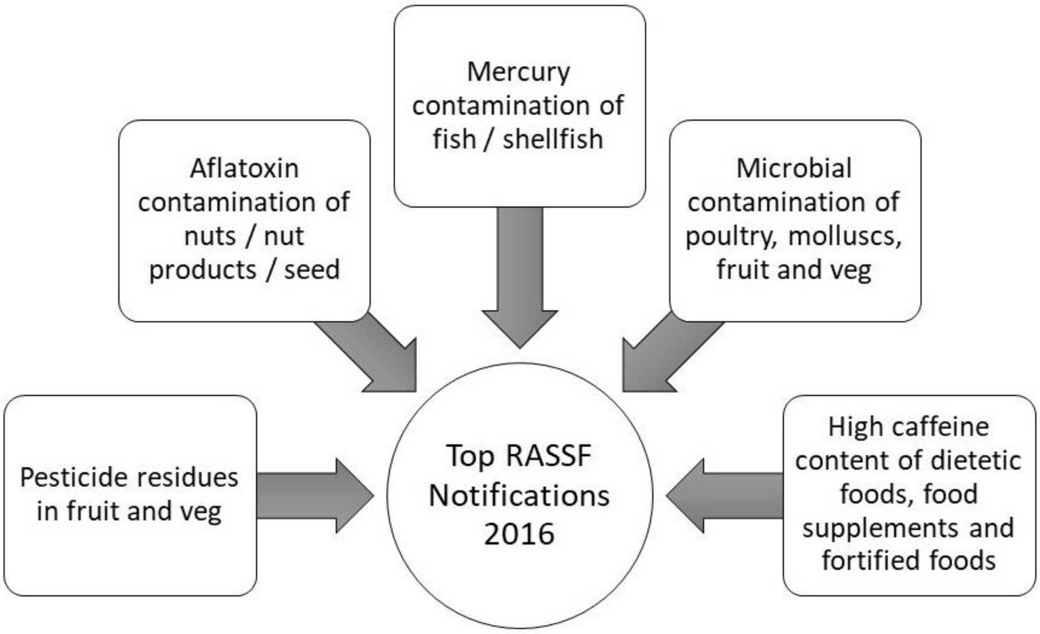
Figure 2.1: UK Food Incidents 2016/17. Relative Numbers by Suspected or Actual Hazard Type[6] (Food Standards Agency, 2017b)



[4] This thesis concerns two organisational case studies, each involving an embedded case of an incident involving a form of potential physical contamination.
[5] A recent analysis of FSA reports published by the insurance company Lockton Companies LLP (2017) suggests a much higher incidence of recalls – 23% - due to "choking hazards" (physical contamination by glass, metal, plastic etc.), but it is impossible to ascertain from their report how these figures were derived from the FSA data.
[6] Hazard classification as per the EU RASFF database. Some categories have a broader definition than might be expected by their titles e.g. adulteration / fraud includes counterfeit products; illegal import / export (including documentation irregularities) and use of unauthorised food production premises. Not determined / other includes "clandestine entrants", where a person hides in a vehicle to avoid immigration controls, which presents a potential risk of contamination of the food load. 2016/17 UK figures show a large increase in reports of this type over previous years.

At the European level, an online tool called RASFF (Rapid Alert System for Food and Feed) is used to identify, trace and inform member states and other countries about actions taken on food, animal feed and food contact materials identified as having safety concerns. Reports cover both imported and EU produced goods. In 2016, 2,993 original notifications were transmitted through RASFF; the most common notification types are shown in Figure 2.2 (European Commission Directorate-General for Health and Food Safety, 2017).

Figure 2.2: Top Notification Types in RASFF 2016 (European Commission Directorate-General for Health and Food Safety, 2017)



These figures speak for themselves in demonstrating the ongoing challenge facing society in assuring food safety. This thesis addresses an element of this challenge by determining barriers to the effective governance of food safety from the perspective of food manufacturers.

2.2 Food Safety Governance and Management Control

To address food safety governance, it is important to first consider what this means.

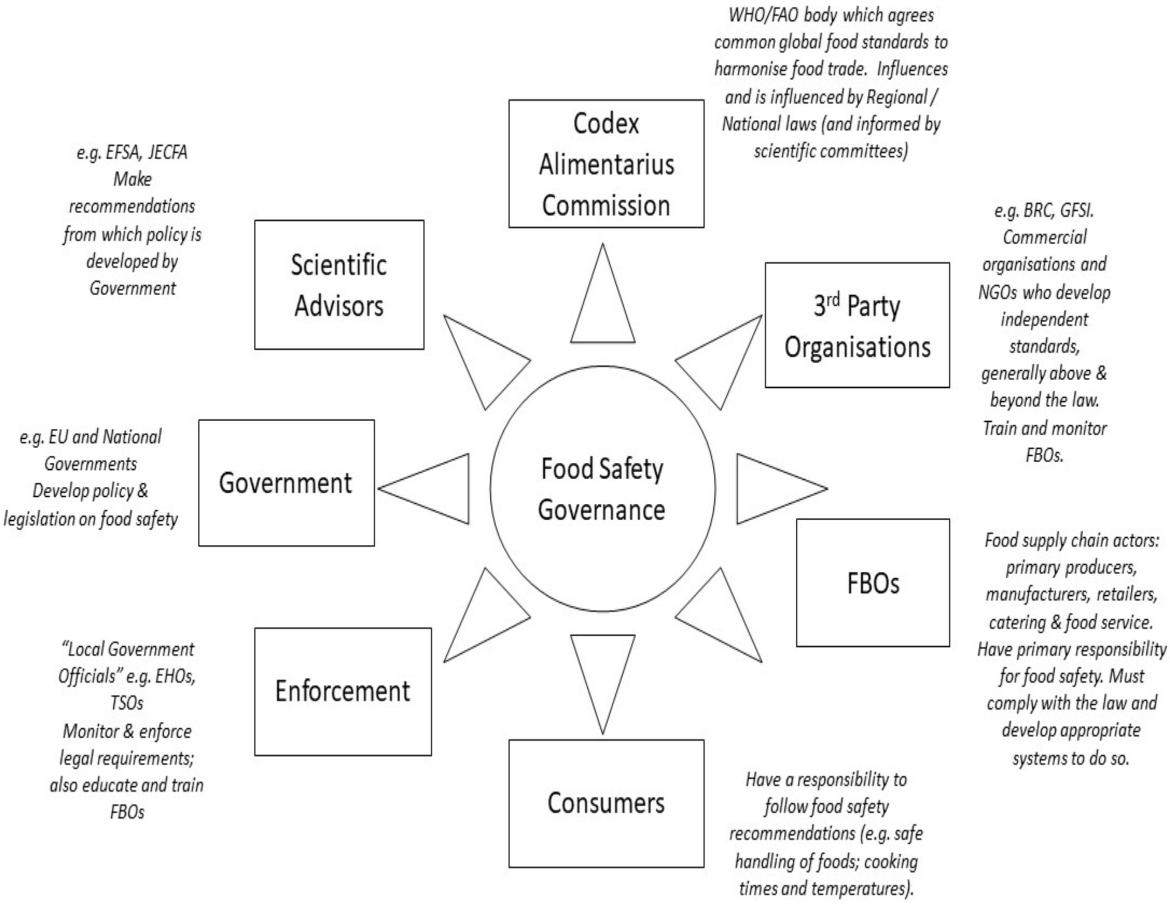
The Shorter Oxford English Dictionary defines “governance” as “the action, manner or fact of governing, government ... conduct of life or business; behaviour”, ("governance," 2002) whilst the verb “to govern” is defined as “(to) rule with authority, conduct the policy, actions and affairs of (a State, subjects) … regulate the proceedings of (a corporation etc.); control, influence, regulate or determine (a person, another’s action, the course or issue of events); guide, direct, lead (in some course ...)” ("govern," 2002).

In business, governance is most often used in terms of corporate governance. This refers to the system by which companies are directed and controlled, and in recent years has broadened from a consideration of purely financial prudence to a more inclusive interpretation involving a concern with “leadership systems, management control protocols, property rights, decision rights, and other practices that give organizations their authority and mandates for action” (Tihanyi, Graffin, & George, 2014).

Similarly to general corporate governance, the governance of food safety involves a concern with rules and regulations set by the state which control and influence aspects of business conduct and behaviour. However, food safety governance is multilevel and complex, involving multiple stakeholders, with interrelated responsibilities, as illustrated in Figure 2.3.

Whilst food safety legislation is a key component of food safety governance, for FBOs it also concerns internal processes and controls which determine organisational actions, i.e. it can be considered from a management control perspective.

Figure 2.3: Key Stakeholders of Food Safety Governance



There are numerous definitions of management control and MCSs. For example, Anthony and Govindarajan (2007) define management control as "the process by which managers influence other members of the organisation to implement organisational strategies", whilst Malmi and Brown (2008) specify that management control encompasses "systems, rules, practices, values and other activities management put in place in order to direct employee behaviour". Traditionally management control has focussed on financial systems and processes, but Merchant and Otley (2007, p 785) posit that an MCS "is designed to help an organisation to adapt to the environment in which it is set and to deliver the key results desired by stakeholder groups". They also stress that the role of an MCS is to "keep organisations reliably on track" (Merchant & Otley, 2007, p 786). As such it can be argued that a control system for food safety is a specialised MCS through which an FBO addresses food safety governance.

One challenge to this perspective rests on whether control systems for food safety can be seen as being under management control or simply dictated by the law. This is explored in the following section.

2.3 Food Safety Governance: the Regulatory Framework and Responsibilities

As might be expected, much previous research on food safety governance has focussed on the regulatory environment (e.g. Caduff & Bernauer, 2006; Hutter, 2011). Historically, the legal basis for food safety was based on “command and control” systems (Fairman & Yapp, 2005), where the role of enforcement authorities was to discover, through inspection and testing, contraventions to food safety.

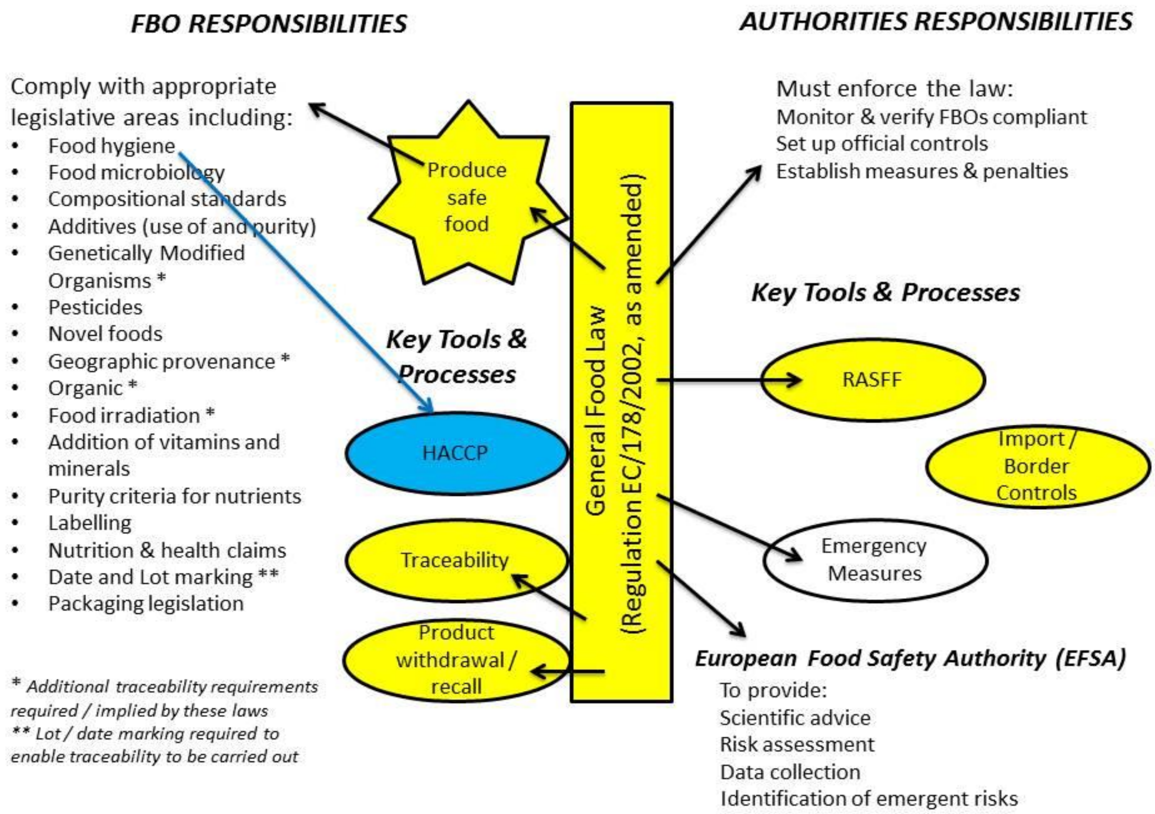
However, over the past 30 years, in many countries and most clearly within the EU[7], the regulatory approach has changed towards one of co-regulation (Rouvière & Caswell, 2012) or, as described by Fairman and Yapp (2005), “enforced self-regulation”. Under this regime the primary responsibility for food safety rests with FBOs, who are required to put in place systems and processes to manage risk and assure food safety, whilst the role of enforcement authorities has changed to one of assessing these systems[8].

This responsibility was put in place in the UK in the 1990 Food Safety Act, and across the EU was established with the enactment of Regulation (EC) 178/2002 on general food law. This regulation, developed to strengthen and harmonise food safety law

[7] UK and EU legislation are used as the primary focus of discussion on food safety legislation, being the primary legislation impacting the case study organisations on which this research study is based.
[8] In the EU, this has also been reflected by a move away from prescriptive, “vertical” compositional legislation (e.g. Council Directive of 22 July 1074 on the harmonization of the laws of Member States relating to honey (74/409/EEC)) which encompassed safety as well as quality criteria, to “horizontal” legislation which applies across all food groups.

across the region, now forms the cornerstone of food safety law in the EU. Figure 2.4 (Bitzios, Jack, Krzyzaniak & Xu, 2017) illustrates the central role of Regulation (EC) No 178/2002 in food safety law, its relationship with other pertinent legislation and the central role of HACCP as a key tool / process for food safety and hygiene.

Figure 2.4: Regulation (EC) 178/2002: Roles, Responsibilities, Tools and Processes and Relationship to Other EU Food Laws (Bitzios et al., 2017)



Unlike “command and control” processes which rely on the testing of finished products to assure their safety, HACCP and HACCP-like systems focus on the verifiable control of the food production process to ensure food safety. Each business is required to develop their own FSMS, using HACCP-like systems, but with the discretion to design it to meet individual business needs and take into account not only the type of food business (retail, catering, manufacturing etc.) and product type (e.g. dairy, confectionery) but also the processes, equipment and environment in which the business operates. As such, these systems fit with Merchant and Otley's (2007) description of an MCS, as the unique FSMS both helps the organisation adapt to its environment and to deliver the key results (safe food) desired by stakeholder groups (regulators, customers, shareholders etc.).

As HACCP / HACCP-like systems form the backbone of modern FSMSs, the principles of HACCP are detailed further in section 2.4. However, before examining HACCP in more detail, the relationship between food safety and food quality, and between FSMSs and QMSs must be considered.

2.4 Food Quality, Food Safety and the Role of HACCP

There is no universally accepted definition of an FSMS, but as stated previously, HACCP is generally accepted as the core of any modern FSMS. To form a comprehensive and effective FSMS, HACCP must be supported by good manufacturing practice (GMP) and pre-requisite programmes (PRPs) for general hygiene (e.g. cleaning protocols, pest control), plus processes for specific activities such as traceability and recall systems (Food and Agriculture Organization of the United Nations, 2006).

Although HACCP was developed as a system to manage food safety (Hulebak & Schlosser, 2002), there is considerable overlap between food safety and food quality, and between systems to manage both, in the literature. For example, Caswell (1998), sets out five categories of quality attributes of food products: food safety attributes; nutrition attributes; value attributes; package attributes and process attributes. Likewise, Sikora and Strada (2005), set out four attributes of food quality: safety (hazard free) and nutritional values (which they combine as an intermediate quality attribute named food health quality); sensory values and convenience. From a systems perspective, classic texts on quality management in the food industry include the management of food safety as an integral part of such systems; for example, Early (1995, p. 167), notes that "food safety management is an aspect of quality management which food manufacturers cannot ignore".

Other research suggests that consumers also appear to consider food safety as a quality attribute. Verbeke (2005), in his work on drivers of consumers' information needs in respect of food, states that "Safety is one of the food product attributes that can be used by consumers in their evaluation of product alternatives and their formation of quality expectations", whilst Röhr, Lüddecke, Drusch, Müller and Alvensleben (2005) consider food safety to be "an important food quality attribute", and classify it as a credence quality attribute, i.e. one which is worthwhile, but which cannot be evaluated in normal use (Darby and Karni, 1973). Likewise, van Rijswijk and Frewer (2008) demonstrate that consumers see food quality and food safety as interlinked concepts, with, in general, people perceiving high quality products to be safe, rather than safe products to be of good quality, i.e. safety is seen as an attribute of quality.

In contrast, in the publication "Assuring food safety and quality: guidelines for strengthening national food control systems" (Food and Agricultural Organization of the United Nations & World Health Organization, 2003) food quality and safety are viewed as separate attributes. This separation is also reflected in a number of publications which have touched on the relationship between food safety and food quality as part of a broader concern with food fraud and food crime. Spink and Moyer (2011) developed a matrix which delineates food quality, food safety, food fraud and food defence incidents[9] as separate risk categories, distinguished by intentionality of action and motivation. Similarly, Manning and Soon (2016) examine the relationship between the four risk categories and against an overarching category of food crime, again separating food quality and food safety. However, considering the four same risk categories, the Global Food Safety Initiative (GFSI) portrays them as overlapping (GFSI, 2014). Manning and Soon (2016) suggest that this aspect of the GFSI work merely reflects the use of a Venn diagram to describe the interaction of the categories.

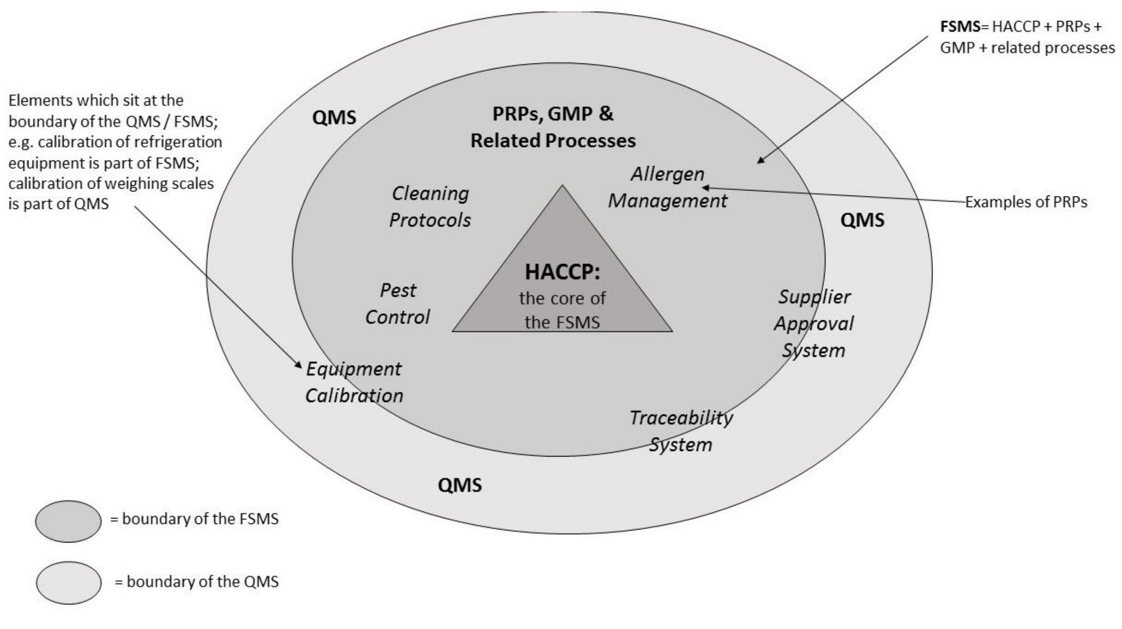
[9] Food fraud is defined as "the deliberate and intentional substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging; or false or misleading statements made about a product, for economic gain", whilst a food defence incident is defined as one which is perpetrated for ideological reasons with the intent to cause harm (Spink and Moyer, 2011)

In fact, this overlap better reflects that any intentional modification of a food product, its ingredients or packaging - be it motivated by monetary gain (food fraud) or ideology (a food defence incident) - may be injurious to the health of a consumer; i.e., it can have a food safety impact even if that was not an intended outcome.

Considering the audit standards used across the food industry to monitor food safety, Mensah and Julien (2011) show that both safety and quality form an integral part of many standards. Indeed, version 8 of the British Retail Consortium (BRC) Global Standard for Food Safety, (BRC Global Standards, 2018) not only combines food safety and quality systems into one section, but includes the requirement that organisations undertake both threat and vulnerability risk assessments, i.e. food fraud and food defence concerns have also been interwoven into this food safety standard.

It therefore appears that whilst there is an academic interest in separating food safety and quality (and indeed food fraud and food defence), from a practitioner perspective these concepts remain strongly linked and there continue to be strong links between FSMSs and QMSs. Figure 2.5 illustrates how just some elements of a typical QMS and FSMS inter-relate.

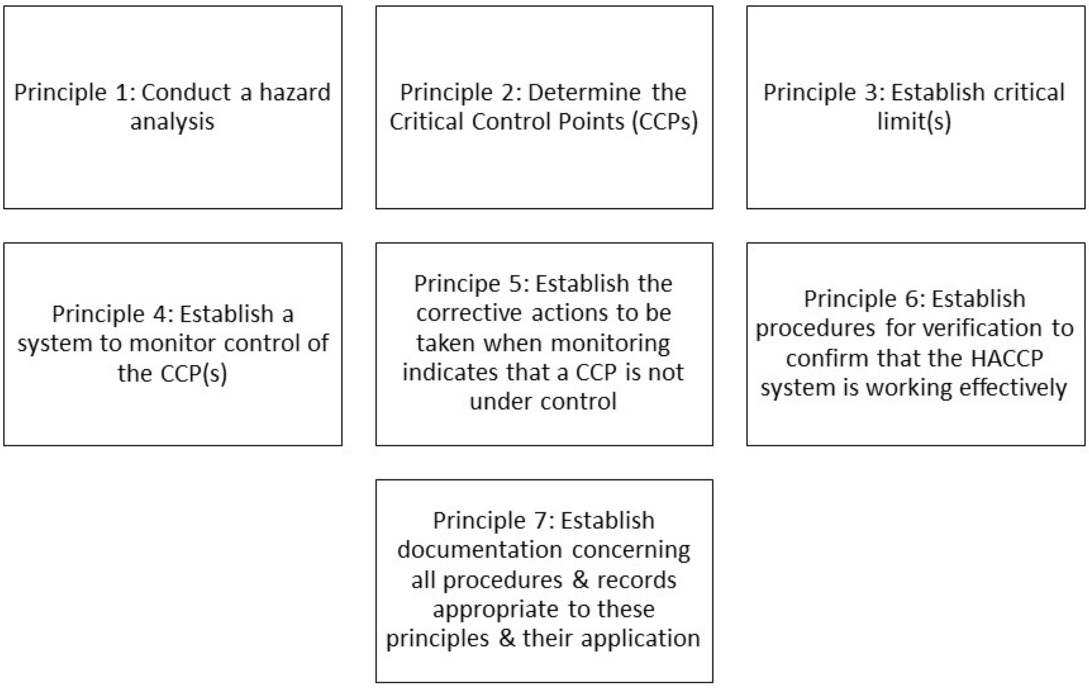
Figure 2.5: An Illustration of the Inter-Relationship of a typical FSMS and QMS



HACCP more specifically, is a scientifically based system which allows FBOs to identify hazards and establish effective measures for their control. HACCP is also a preventative system, in that it seeks to identify and control hazards (biological, chemical or physical agents in food, or a condition of food, which have the potential to cause an adverse health effect) before an adverse effect occurs. HACCP based systems can be seen as diametrically opposed to traditional FSMSs which rely on testing of end products to determine whether they are safe or not. Under HACCP, end product sampling and testing still exists, but is used as a verification of the control system, not as the main means of control.

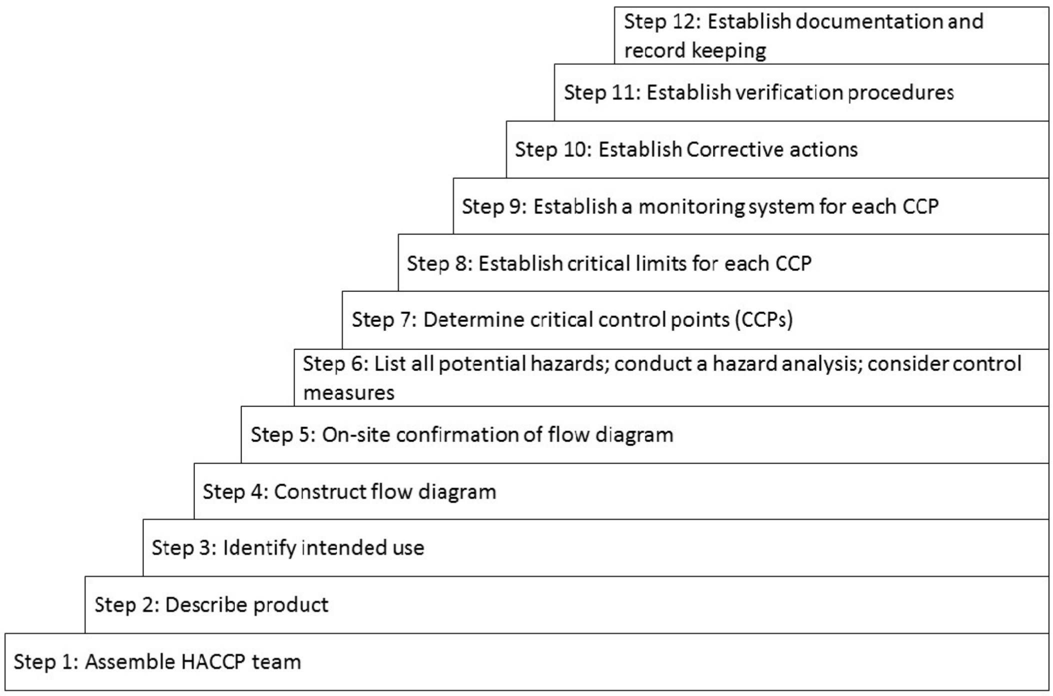
In 2003 HACCP was adopted as the preferred approach to food hygiene and safety by the Codex Alimentarius Commission of the Food and Agricultural Organization of the United Nations (FAO) and World Health Organization (WHO) (Codex Alimentarius Commission of the FAO and WHO, 2003).   Under the CODEX approach, often referred to as "full HACCP", seven principles for a HACCP system are set out (see Figure 2.6).

Figure 2.6: The Seven Principles of HACCP (Codex Alimentarius Commission of the FAO and WHO, 2003)



In order to help FBOs apply HACCP effectively in the workplace, the CODEX approach also sets out twelve "logical" steps for HACCP implementation (see Figure 2.7) and gives additional information on the determination of CCPs.

Figure 2.7: Sequence for the Application of HACCP (Codex Alimentarius Commission of the FAO and WHO, 2003)



In Europe, HACCP principles were set in general food hygiene legislation in the early 1990's (COUNCIL DIRECTIVE 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs). Whilst full HACCP became mandatory for certain food sectors such as meat in the early 2000's (COMMISSION DECISION of 8 June 2001), HACCP principles were enshrined for all food categories in EU Regulation (EC) No 852/2004 on the hygiene of foodstuffs.

HACCP or HACCP principles have also been embraced in other countries. In the USA, HACCP was initially limited to specific high-risk sectors with, for example, so-called "Seafood HACCP" (60 FR 65096, Federal Register, 1995). However, there has been a move towards a general use of preventative food safety with the enactment of the Food Safety Modernization Act in 2011. In other less developed countries, HACCP based approaches may be recommended, but not mandatory, such as in Thailand (Food and Drug Administration Thailand, 2014), or only be mandatory for exported products, such as in China (Balzano, 2014). Even in developed countries it is recognised that the universal application of HACCP has lagged behind the legislative requirement, particularly in smaller and less developed businesses (Food and Agriculture Organization of the United Nations, 2006). This in itself forms a concern for public health, as a large percentage of food is supplied from micro enterprises and SMEs. Figures published by the EU trade association FoodDrinkEurope (FoodDrinkEurope, 2016a) show that of the €1,089 billion turnover of food and drink production in the EU, 49.5% comes from SMEs. This sector also provides employment for 2.8 million people, 65.9% of the total number employed in food manufacturing.

Given the central role that HACCP now plays in FSMSs in many parts of the world, the definition of such systems which is proposed for use in this research study is as follows:

Food safety management system (FSMS) - a comprehensive and integrated system devised to identify and control food safety risks within an FBO, including HACCP and HACCP-like systems and supporting processes. May be considered as a subset of an FBO's QMS[10].

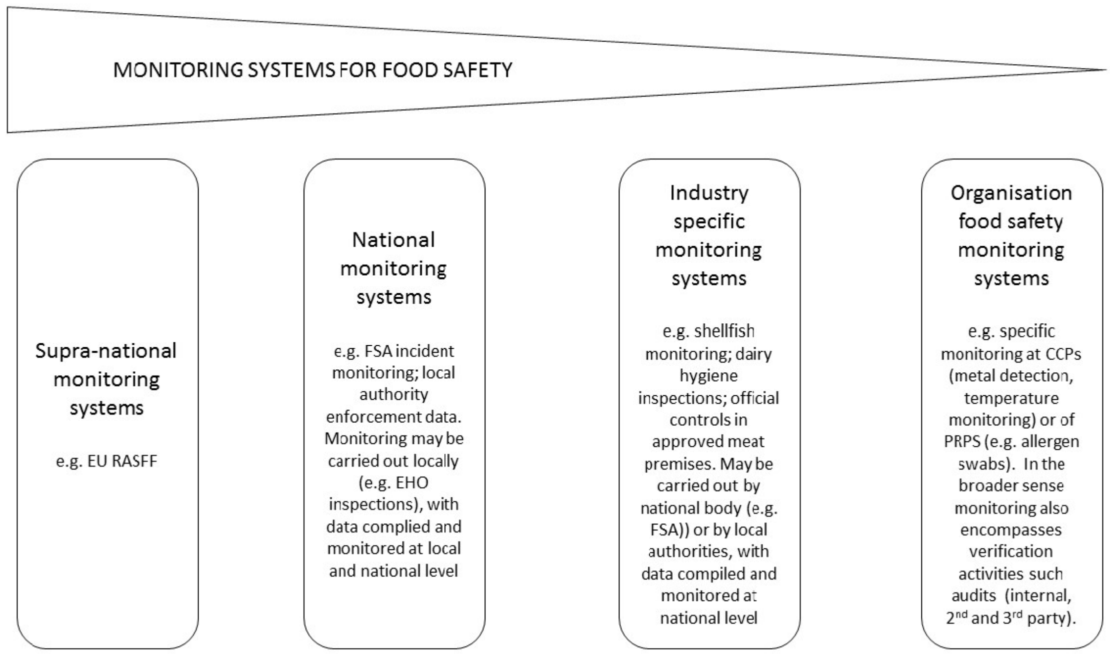
2.5 Measurement and Monitoring of Food Safety

The verb "to monitor" is defined as "to observe, supervise, keep under review, measure or test at intervals, especially for the purpose of regulation or control …"

[10] As previously outlined, food safety and quality can also be impacted by the deliberate adulteration or misrepresentation of foods, whether this is ideologically motivated (a food defence issue) or economically motivated (a food fraud issue). However, systems specifically to guard against these risks are not specifically considered within this research.

("monitor", 2002). Many different systems to monitor food safety exist, ranging from supra-national systems such as the EU RASSF system, through national systems (such as FSA incident monitoring), through to industry specific schemes (such as the official controls of approved meat premises) and monitoring within individual FBOs and of specific products, as illustrated in Figure 2.8.

Figure 2.8: Monitoring Systems for Food Safety



However, within HACCP, a distinction is drawn between monitoring and verification. Monitoring is defined as "the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control", (Codex Alimentarius Commission of the FAO and WHO, 2003). Monitoring therefore concerns the routine observation and recording of the control of the specific hazards identified in the FBO's HACCP plan and can be supported by a range of technological solutions[11]. For example, commercial systems can now be used to automatically

[11] Monitoring systems for CCPs may be seen as operating at the "task control" level described by Anthony and Govindarajan (2007), i.e. they are transaction oriented, ensuring that individual tasks are

record the temperature of cold storage facilities and provide alerts if the temperature increases above the safe range for storing perishable foodstuffs.

Verification, on the other hand, is defined as "the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan" (Codex Alimentarius Commission of the FAO and WHO, 2003). In fact, step 6 of the HACCP principles encompasses validation (to assure that the right controls points and limits been selected and the HACCP plan will be effective), verification that the plan is adhered to in practice and the regular review (and re-validation) of the plan (Food Standards Agency, 2018).

End product testing is therefore a verification activity under HACCP, as are audits, carried out by the FBO themselves, by a second party (generally buyers) or by a third party (independent specialist organisations). As mentioned in section 2.4, many different audit standards exist, often combining food safety and food quality elements, along with other criteria such as crisis management preparedness (see Table 2.1).

With the plethora of standards available, in 2000 the food industry set up the Global Food Safety Initiative (GFSI, 2014) in an attempt to prevent manufacturers from undergoing multiple audits to potentially conflicting standards. However, since the European horsemeat contamination scandal in 2013 (Elliott, 2014), the major retailers (who form the main customers for audit results) have, to a large degree, reverted to working to their own specific standards and audits (B. Stevens, personal communication, 30 October, 2017).

Despite the high reliance on audits across the food industry, they have been highly criticised as a means of assessing the status and success of an FBO's FSMS as they generally assess or measure the performance of an organisation at only one point in

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performed according to the rules set in the MCS. For example, a monitoring system for temperature control operates at the point in the system set within the MCS (decided upon by the food safety / HACCP team), and monitors against the rule / standard for temperatures set by the team in the HACCP plan.

time. Indeed, a number of organisations which go on to have serious breaches in food safety have a history of successful audits, suggesting that audits cannot successfully detect the risk of future FSMS failure (Powell et al., 2013). Likewise, researchers have demonstrated that the food inspection ratings of FBOs do not accurately predict the likelihood of occurrence of a food safety incident (Mullen, Cowden, Cowden, & Wong, 2002). This demonstrates the importance of the on-going monitoring of CCPs (and appropriate elements of pre-requisites) alongside the use of audits as a form of FSMS verification.

Table 2.1: Key Common Requirements for Food Safety Standards (adapted from Mensah & Julien, 2011)[12]

FSMS Elements Required & Audited	BRC	HACCP	ISO 22000	SQF	Dutch HACCP	IFS
Management system	✔	✔	✔	✔	✔	✔
PRPs	✔	✔	✔	✔	✔	✔
HACCP	✔	✔	✔	✔	✔	✔
Validation & Verification	✔	✔	✔	✔	✔	✔
Emergency preparedness / crisis management	✔		✔			
Quality management	✔			✔	✔	✔

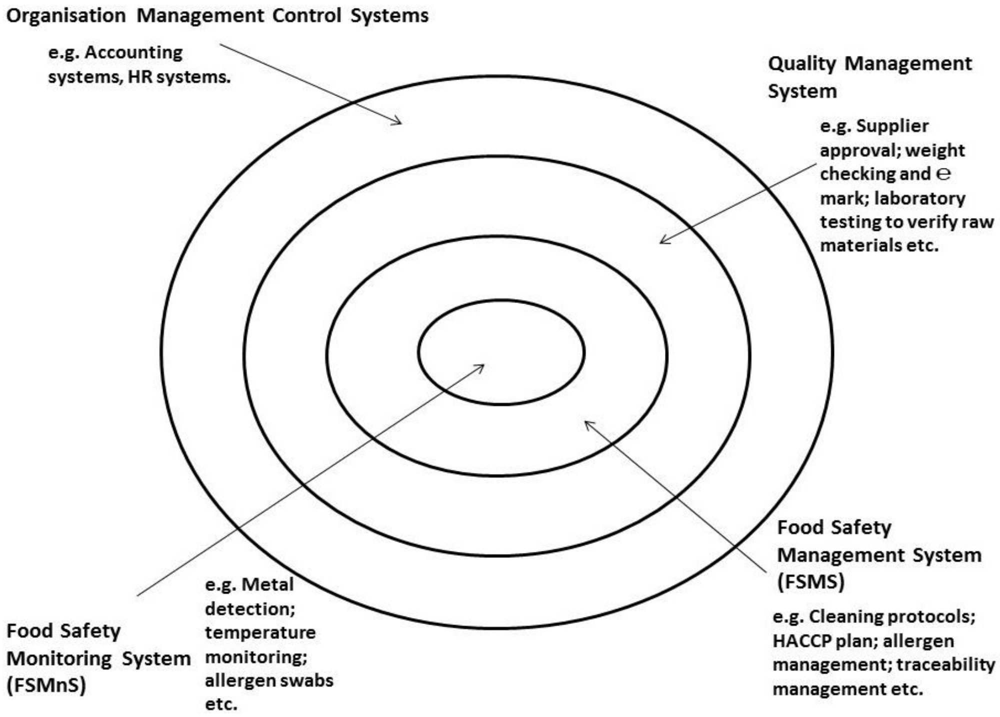
As this research study is focused at the individual business level, and both on-going, day-to-day monitoring of CCPs and pre-requisites is relevant, along with verification activities (including audits), a broad definition of FSMnSs which combines these activities will be used within this work:

[12] BRC: British Retail Consortium global food standard; HACCP: CODEX HACCP; ISO 22000: International Organisation for Standards FSMS; SQF: Safe Quality Food 2000 level 2; Dutch HACCP: HACCP scheme designed by Dutch National Board of Experts; IFS: International Food Standard.

Food safety monitoring system (FSMnS) – a system put in place to observe, check and record food safety controls at CCPs and relevant elements of PRPs which together form part of the overall FSMS. Food safety audits (internal, second and third party) will also be considered as part of an FBOs overall monitoring of food safety.

FSMnSs can be seen as part of a suite of tools which form the overall FSMS, as shown in Figure 2.9.

Figure 2.9: The Relationship of MCSs, the QMS, FSMSs and FSMnSs



Before leaving the topic of the measurement and monitoring of food safety, it is pertinent to return to the nature of food safety. In section 2.1 it was outlined that food safety can be considered to be socially constructed, in that society decides which aspects of the relationship between food and health should be encompassed by a classification of food safety and considered as food safety hazards.

However, the establishment of FSMnSs, which require us to measure and assess food safety against a standard, implies that food safety is an absolute: that we can assess and categorise foods as safe or unsafe.

Given that the use of HACCP and HACCP-like systems is mandated by legislation, it is relevant to consider whether the regulatory bodies enforcing the laws, or the laws themselves, consider food safety as absolute.

Using the UK as an example, the views of the FSA can be seen in their 2015 strategy document (Food Standards Agency, 2015), where they explain how they translate their legal responsibilities under the Food Standards Act 1999 and propose a definition of consumers' interests in relation to food:

> "Food is safe and what it says it is, and we have access to an affordable diet, and can make informed choices about what we eat, now and in the future."

This implies that for consumers, and hence for the FSA who have a mandate to protect the interests of consumers, food safety is absolute.

In contrast, food safety legislation sets out a more complex picture. For example, Regulation (EC) 178/2002 states in Article 14.1 that "food shall not be placed on the market if it is unsafe". However, in this case safe food – or rather unsafe food – is not absolute, but is qualified in the legislation. The normal conditions of use of the food and the information provided to the consumer are just two of the factors that influence whether a food could be considered as safe or unsafe.

Furthermore, it can be argued that with the change in the regulatory environment from "command and control" to "enforced self-regulation", there has been a concomitant transition from food safety being an absolute (enforcement authorities judge and determine food as safe or unsafe) to one where it is socially constructed by FBOs through the use of individually tailored HACCP based systems. This view is echoed in Jackson's (2010) work on consumer trust and anxiety about food, where he states that "the food industry have moved on from a concern with food safety in the absolute sense to one of risk management in relative terms", quoting the head of food technology at a major UK food retailer as saying "'No longer do people … aspire to make safe food, they manage risk'.

This change in approach from food safety as an absolute to a social construction has not been without problems for FBOs, as will be discussed in the literature review in Chapter 3, when the barriers to, and drivers for, the implementation of FSMSs are reviewed. Furthermore, this perspective of food safety as socially constructed is one of the considerations which influences the philosophical approach of the current research study, which will be presented in Chapter 4.

2.6 Conclusion

Foodborne disease and food safety incidents present ongoing challenges to society and the governance of food safety sits with a network of stakeholders. Government oversight, to develop and enforce legislation, is a key factor in food safety governance. However, it is FBOs who have the primary responsibility for food safety under the law. The processes and systems they use to manage food safety such that they are compliant with legal requirements and meet the demands of stakeholders (consumers, shareholders, staff etc.) for safe food, are critical. FSMSs and FSMnSs have been defined, with HACCP presented as a key component of modern FSMSs.

Importantly for this research, it has been argued that food safety is both a social construct and that food safety forms a critical aspect of the quality of a food product. Moreover, FSMSs have been shown to fit with Merchant and Otley's (2007) definition of MCSs, being systems that enable the delivery of a key stakeholder requirement (safe food) and which help the organisation adapt to its environment (the type of food product, the processes, equipment etc.). This sets the scene for using concepts drawn from management control to investigate and analyse the case studies which form the empirical element of this research study. This approach will be covered in detail in the research methodology in Chapter 4.

However, before moving on to discuss the methodology, a more detailed review and analysis of the literature is required. This is completed in two parts. Chapter 3 concentrates on the “technical” literature, critiquing models which identify barriers to and drivers for the implementation of FSMSs, plus models of FSC. Literature on food safety incidents is also considered, to identify whether these can be explained by failures in the same areas which pose barriers to FSMS implementation. Finally, a short overview of quality costing in the food industry is presented. The second aspect of the literature review, addressing underlying concepts in management control, is covered in Chapter 4.

3.0 Literature Review

3.1 Introduction

The previous chapter set the scene for this research study by examining the challenge facing society with ongoing food safety issues, defining food safety governance and identifying FSMSs as a form of management control used by FBOs in the discharge of their responsibilities for food safety governance.

For FBOs to address food safety governance, effective implementation and maintenance of FSMS and FSMnSs is required. With the intended focus on FSMSs and FSMnSs at the organisational level, and given that FSMnSs form a part of an overall FSMS (as previously described in Chapter 2), a review of the literature describing possible barriers to and drivers of FSMS implementation and use was undertaken. An examination of the literature pertaining to reported food safety incidents was also carried out, as such incidents may identify specific issues with the implementation or operation of FSMS or FSMnS.

There have been numerous publications identifying a range of factors said to contribute to the challenges in implementing FSMSs, primarily looking at HACCP as the FSMS element[13] of choice. Ehiri, Morris and McEwen (1995) identified organisational factors (the costs and time taken for implementation and on-going maintenance of a system and for staff training, and the concern of the applicability of HACCP for all food business operations) and individually focused factors, such as the knowledge and understanding of HACCP by food operators, as potential barriers for successful FSMS implementation. This was supported by work in the UK dairy industry carried out by Henson, Holt and Northen (1999), which also identified employee motivation as a key challenge to implementing HACCP. Another barrier, resistance to cultural change, was

[13] As explained in Chapter 2, HACCP forms the core of modern FSMSs, but is combined with PRPs (such as cleaning and pest control plans, allergen management) and GMP for a fully comprehensive FSMSs. However, in the literature reviewed, there appear to be common concerns whether HACCP or HACCP-like systems specifically or FSMSs in the broader sense are considered and research covering both is presented and critiqued in this chapter.

highlighted in a study conducted in the meat industry (Holt & Henson, 2000a). Motivation and resistance to change might be in part be explained by a lack of "ownership" felt by FBOs for FSMS development. This was illustrated in the findings of a survey of FBOs in Ireland (n=710) (Food Safety Authority of Ireland, 2001) when almost 50% of respondents felt that it should be the responsibility of local or national enforcement bodies, rather than the FBO itself, to develop their FSMS. This perhaps represents a lag between the change in the regulatory environment towards enforced self-regulation described in Chapter 2 and the recognition and acceptance of this change by FBOs.

Business size and the amount of resources available for FSMS implementation have also been raised as key concerns, with the suggestion that SMEs may lack appropriate resources for effective HACCP implementation (Pritchard & Walker, 1998; E. A. Taylor, 2001). Other research has found the employment of a technical manager as the most important factor influencing success in adopting good food hygiene practices (Holt & Henson, 2000b), a resource that SMEs may not be willing or able to afford.

In 1998, the challenge of HACCP implementation was recognised by an official from the Ministry of Agriculture, Fisheries and Food, at that time the UK Government department responsible for food safety, with the question posed:

> "When HACCP appears to fail, is it the fault of the HACCP system itself or does the real failure lie with the people who are trying to implement it?" (R. T. Mitchell, 1998).

Although this question is 20 years old, recent research shows challenges still exist with the understanding of, implementation and maintenance of HACCP systems, even in FBOs which are subject to the highest level of regulatory scrutiny. For example, in a case study on Halal meat preparation in a UK slaughterhouse, HACCP was openly dismissed as "rubbish" by the owner of the company (Thomas, White, Plant, & Zhou, 2017). This question is therefore still pertinent, and the aim of this literature review is to ascertain if it can be answered from the extant literature. By doing so, gaps in the literature will be identified, enabling the development of the central research question and objectives of this research study.

The remainder of this literature review is structured as follows. Section 3.2 identifies and critiques a number of models which have been developed showing barriers to and drivers of FSMS implementation. Section 3.3 examines the literature on reported food safety incidents, whilst section 3.4 explores FSC as a development of the people element of the question. Section 3.5 returns to the financial resources required for the implementation and maintenance of FSMSs, and considers the use of "quality costing" in the food industry. Section 3.6 concludes the chapter, with the identification of the research question and objectives of the thesis.

3.2 Process or People? Models of the Barriers to FSMS Implementation

Whilst there is a body of literature identifying barriers and drivers of the implementation of FSMS, few researchers have sought to structure their data in terms of models which can be used by FBOs to guide FSMS implementation and so address food safety governance, or which can be used by academia to direct future research. The models discussed in this section have been identified from the literature search as the key papers where structured models of barriers to and / or drivers for FSMSs have been proposed. As SMEs have been recognised as a particularly challenging sector for FSMS implementation (Food and Agriculture Organization of the United Nations, 2006), the models chosen for detailed review include a focus on this type of organisation, in order that the fullest range of barriers and drivers can be considered.

3.2.1 Models of Food Safety Management Barriers and Drivers

3.2.1.1 Model to Prioritise the HACCP Plan (Panisello & Quantick, 2001)

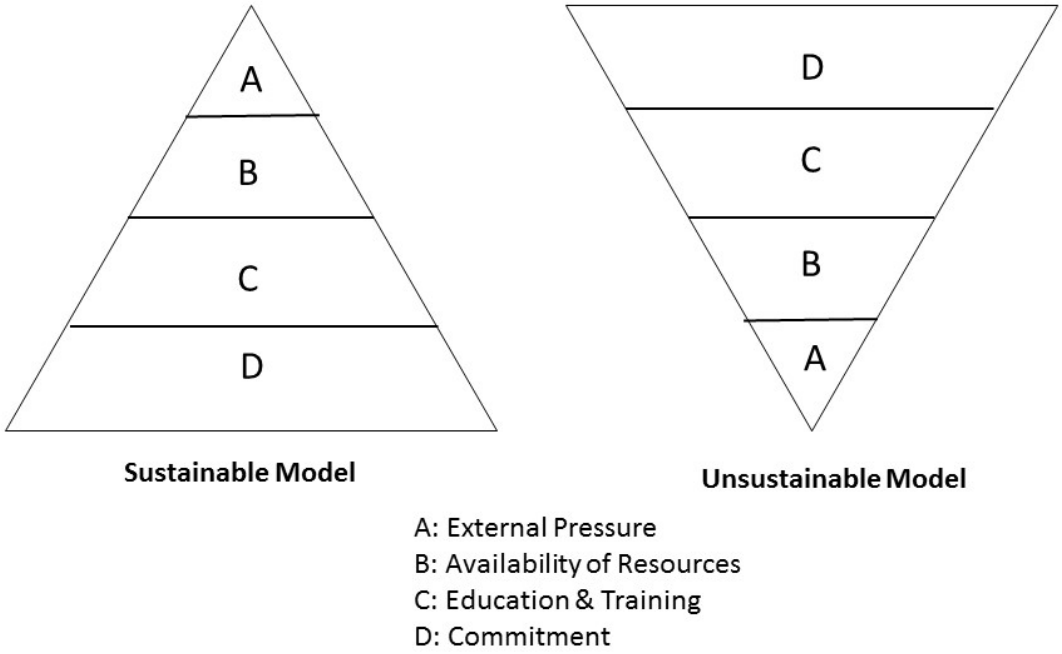
Panisello and Quantick (2001) suggested that a successful HACCP plan should be built on four "pillars": management commitment; education and training; availability of resources and external pressures. They postulated that for success and sustainability, these pillars need to be prioritised from commitment up to external pressures and that inverting this pyramid results in instability and HACCP failure (see Figure 3.1).

The authors also summarised a large number of technical barriers which could impede the effectiveness of HACCP, before, during and after implementation. These ranged from physical organisational and process related factors, such as company size, type of product, plant layout and availability of equipment, through to people related factors such as management commitment, the relationship between companies and enforcement authorities and the behaviour and motivation of staff.

Whilst these barriers have been identified in numerous other studies (for reviews see Fotopoulos et al., 2011; Jevšnik, Hlebec, & Raspor, 2006), Panisello and Quantick (2001) presented no detailed empirical data to further describe or quantify the relative importance of the technical barriers.

Likewise, there was no attempt to "map" the technical barriers described into the four pillars for HACCP success. Indeed, many of the technical barriers can be mapped across two or more of the pillars. For example, the barrier "persistence of habits and attitudes" can feasibly be mapped across the pillars of "commitment", reflecting the role of management commitment in driving organisational culture and worker behaviour; "resources", reflecting that the availability of time and equipment (physical resources) impacts behaviour patterns; "education and training", reflecting that appropriate knowledge can be viewed as part of the requirement for changing attitudes and behaviours, and even "external pressure", where the requirements of customers (e.g. in catering outlets, for meals to be served promptly after ordering) can impact on staff habits and attitudes.

Figure 3.1: Model to Prioritise the HACCP Plan (Panisello & Quantick, 2001)



This model therefore has limitations for practitioners, as it offers little guidance on how to address the technical barriers to strengthen the core pillars in an appropriate order of priority. However, its use as a theoretical model to address the debate on a focus between process and people to drive success in FSMS and FSMnS implementation is clearer, as the fundamental pillars of commitment and education and training are people orientated at heart.

3.2.1.2 HACCP Awareness to Adherence Model (Gilling, et al., 2001)

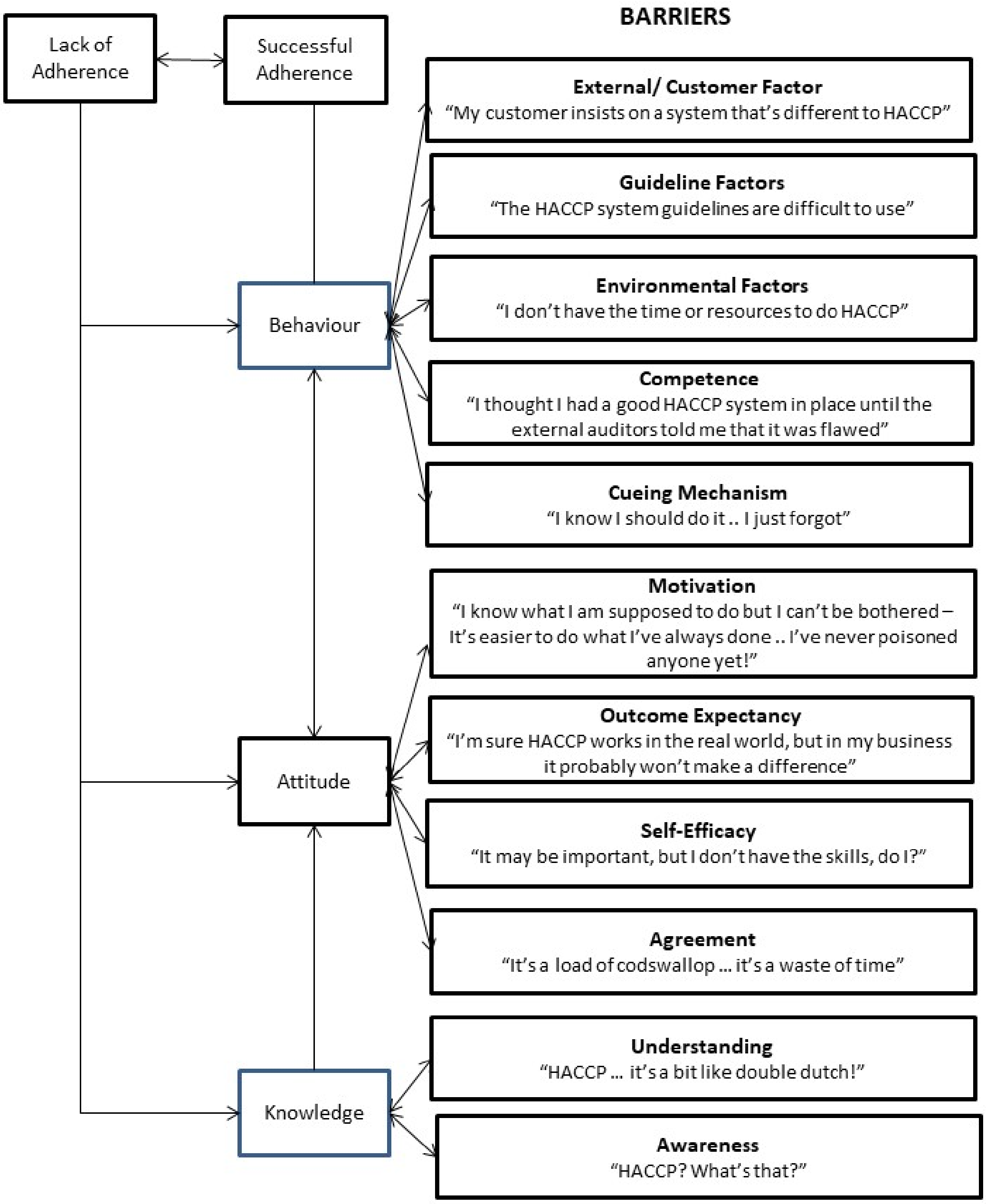
Gilling et al. (2001) used a psychological approach to identify factors influencing HACCP adoption, building upon models previously developed of barriers to clinical practice and extending the psychological frameworks identified into the area of compliance to FSMSs. They conducted a large-scale qualitative study (n=200), interviewing by telephone owners or managers of small businesses and technical managers from individual sites of larger businesses in northwest England. In addition, five in-depth, face-to-face, narrative interviews were conducted to confirm and further elaborate the barriers identified during the telephone interviews. The awareness to adherence model identifies 11 factors underpinning barriers to compliance, built around knowledge, understanding and behaviours (see Figure 3.2).

The qualitative, inductive research framework utilised by Gilling et al. (2001) fits well with the psychological approach of this study. Whilst the direction and approach of the research is clear, it is nevertheless disappointing that the authors did not take the opportunity to report additional data on their survey population. No information is given on the distribution of the sample between micro, small, medium and large businesses. Therefore, whilst, it is reported, for example, that "awareness" was identified as a barrier in 15 micro businesses, it is impossible to know if this represents a large proportion of all micro businesses interviewed. Likewise, the large sample size used in the telephone interviews implies that the results should be representative for SME food enterprises in the UK, and indeed the authors comment that all sectors of the industry from primary producers through to caterers were represented in the sample. However, no data is reported of the barriers to FSMS implementation by industry sector, so it is impossible to judge if, for example, manufacturers report less barriers than caterers. Reporting such basic quantitative data would better enable a judgement as to whether the model can be reasonably applied across the diversity of the British food industry.

Additionally, Gilling et al. (2001) report some of the identified barriers in terms of non-psychological factors. Whilst the issues raised – time, financial and human resources – have been reported by earlier researchers to be barriers to FSMS implementation (Ehiri et al., 1995; Panisello & Quantick, 2001; Panisello, Quantick, & Knowles, 1999; Pritchard & Walker, 1998), the inclusion of these items means that the model cannot be considered as purely based on mental rather than physical factors.

Breaking down the model in terms of the literature review question, i.e. does FSMS failure lie with the process or the people involved, it can be seen that Gilling et al. (2001) express the first level of barriers in people terms: knowledge, attitude, behaviour and adherence. At the second, detailed level, the barriers are a mixture of people and process related factors. Thus, whilst the model has its roots in a people oriented, psychological approach, the authors have found process and people related barriers and it is not clear which area should be prioritised to improve FSMS implementation.

Figure 3.2: HACCP Awareness to Adherence Model (Gilling et al., 2001)



3.2.1.3 Cognitive and Behaviour Model to HACCP Principle Adherence (Azanza & Zamora-Luna, 2005)

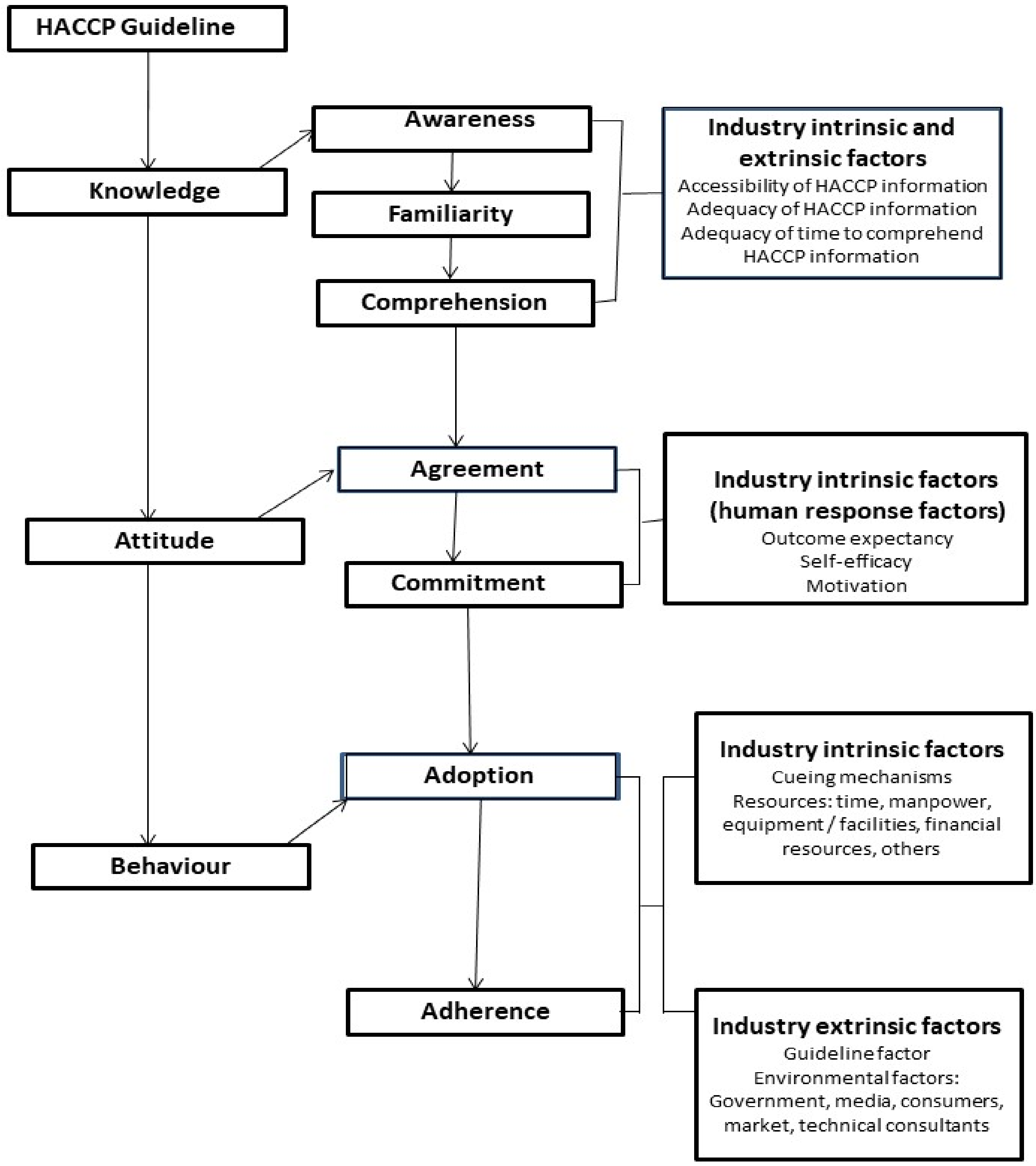
In common with Gilling et al. (2001), Azanza and Zamora-Luna (2005) also utilised a psychological approach in developing their model. They also reference a theoretical background of models from the assessment of adherence to medical guidelines.

However, their methodology of model development differed from that used by Gilling et al. (2001), in that they first proposed their model and then validated this through a face-to-face survey with HACCP team members (n=27) in four micro- to small-scale food processors (meat processing and beverage manufacturers) in the Philippines. The model can be considered an extension of the work of Gilling et al. (2001), being based on the same platforms of knowledge, attitudes and behaviour but identifying seven steps and 18 sub-items impacting HACCP compliance (see Figure 3.3). Again, the model is not completely psychological in nature; e.g. industry intrinsic factors presented as barriers to adoption and adherence to HACCP include time, manpower, equipment and facilities.

In contrast to Gilling et al. (2001), Azanza and Zamora-Luna (2005) present basic quantitative data from the surveys to support the identified barriers. The small number of participants is not conducive to the use of more advanced statistical analysis, e.g. to understand if there are significant differences in barriers identified in different industry sectors or with organisational size. Whilst the empirical findings validate the model to some degree, the nature of the questionnaire method and the highly limited scope of the research does not allow significant interpretation of the data or extrapolation to a wider population.

Considering the people versus process question, Azanza and Zamora-Luna (2005) present both the first and second level of barriers in people terms, whilst the detailed third level barriers combine people and process. This indicates again a lack of clarity as to which barriers should form the priority for ensuring effective implementation of FSMSs.

Figure 3.3: Cognitive and Behaviour Model to HACCP Principle Adherence (Azanza & Zamora-Luna, 2005)

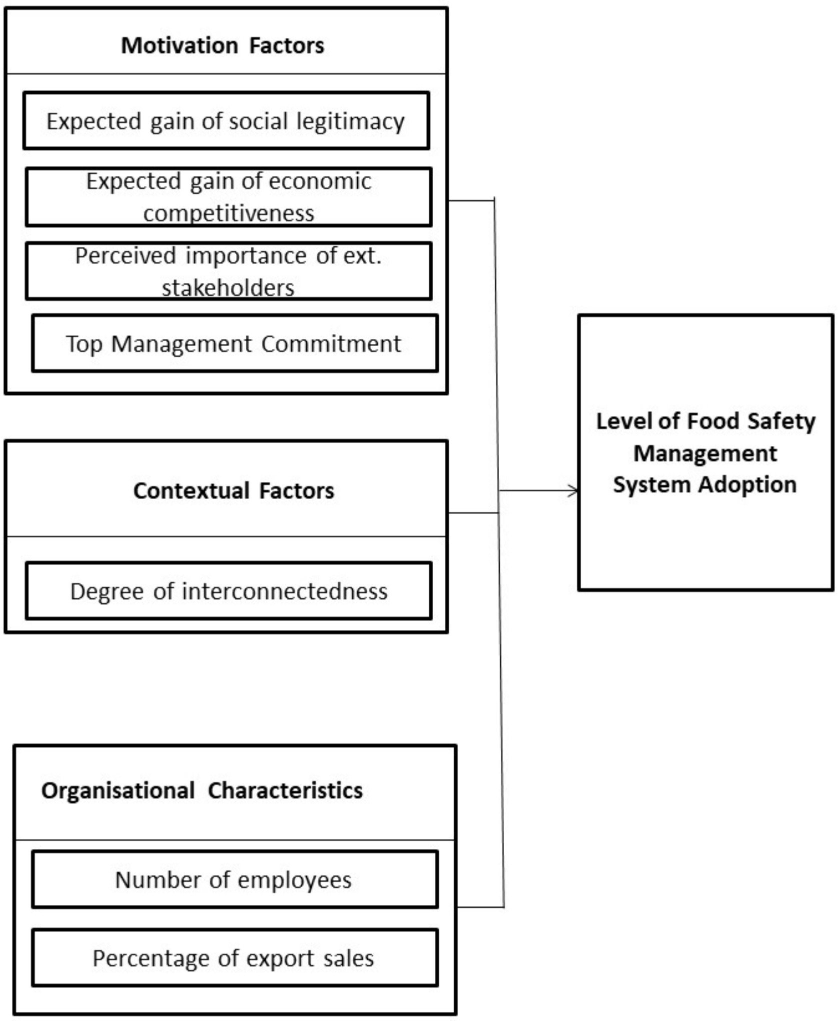


3.2.1.4 A Model of Food Safety Management System Adoption (A Tested Model) (Arpanutud, Keeratipibul, Charoensupaya & E.A. Taylor, 2009)

In contrast with the previous models, Arpanutud et al. (2009) utilised a deductive, quantitative approach. They researched a range of factors (physical, financial and psychological) which they hypothesised would impact adoption of FSMSs in food manufacturing in Thailand. These were tested using a postal survey questionnaire (n=217), designed to enable multiple regression analysis. Stratified random sampling was used to ensure that findings could be applied across the Thai food industry, and the sample size was calculated to allow for the examination of nine independent variables.

Following regression analysis, seven hypotheses were supported as statistically significant, explaining 69.4% of the variance in the dependent variable (the level of food safety management adoption). The proposed model splits these seven key determinants into three sections: motivational factors, contextual factors and organisational characteristics, as shown in Figure 3.4.

Figure 3.4: A Model of Food Safety Management Adoption (a Tested Model), (Arpanutud et al., 2009)



An additional point of contrast to the previous models presented, is that this one explicitly considers expected benefits of implementing FSMSs as key determinants of successful implementation (expected gain of economic competitiveness and expected gain of social legitimacy) rather than considering only barriers to the implementation or success of FSMS.

The strength of this study lies in the perceived robustness of the quantitative approach. The consideration of required sample size (to ensure the study is sufficiently powered), the use of stratified random sampling and the relatively high response rate (45.2%) suggests that the data should be reliable and generalizable, at least within the Thai food manufacturing environment. Care must be taken in extrapolating the results to other countries with different regulatory requirements, as some of the identified barriers / drivers may not be appropriate. For example, in the EU, where a HACCP-based FSMS is mandatory by law, there would be no expectation of competitive advantage in installing such a system.

Moreover, other research has demonstrated that there can be a clear mismatch between the reports of success in implementing FSMSs given by FBOs versus enforcement officials views (Yapp & Fairman, 2005), suggesting that there are severe limitations in using quantitative research methods to investigate FSMS compliance. Whilst Arpanutud et al. (2009) were not studying FSMS compliance per se, many of the survey questions relate to the respondents' own views on the extent and quality of their own FSMS (e.g. "the company has a review process on the performance of FSMS"). Hence their survey responses may have been impacted in a similar way to that found by Yapp and Fairman (2005). It is not possible to ascertain the veracity of the responses to the survey, and no independent review of the organisations' FSMSs was undertaken, but the robustness of this research may not be as great as suggested by the statistical analysis.

Considering the people versus process debate, Arpanutud et al. (2009) present the barriers as a mixture of people and process related factors, so again, there is at this stage no definitive answer to the question.

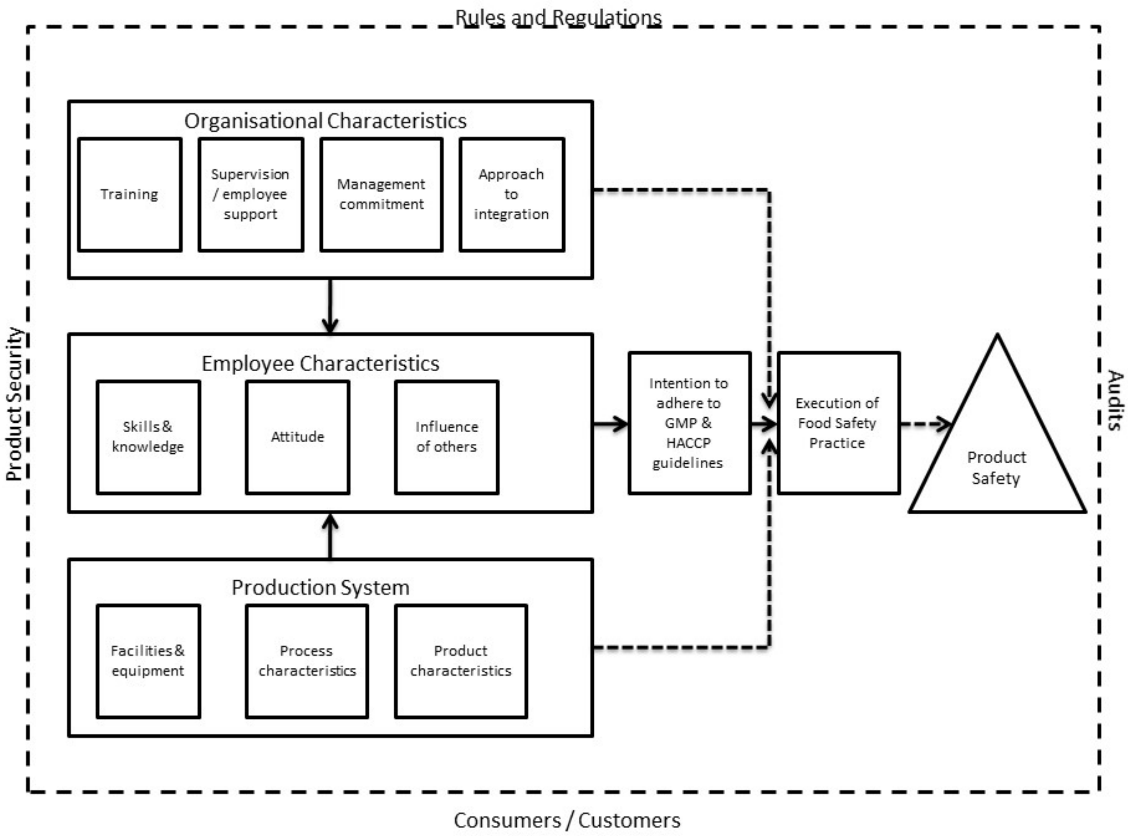
3.2.1.5 Factors Influencing the Implementation of Food Safety Systems (Ball, Wilcock & Aung, 2009)

In this research study Ball et al. (2009) conducted in-depth interviews with owners / general managers and employees (food safety coordinators and production employees) at five SME meat processing plants in Ontario, Canada. The firms were selected as a purposive sample, to give insight into firms at different stages of FSMS implementation. In addition, two focus group sessions were held with eight opinion leaders in food safety (employees of the Ontario Ministry of Agriculture, Food and Rural Affairs and employees of three different food processing trade associations based in Ontario).

The data was analysed to identify patterns and themes. A model was then proposed, based on these findings together with earlier work (van der Wende, 2006), and framed using the theory of planned behaviour (Ajzen, 1991). The model (shown in Figure 3.5) presents three main themes which influence FSMS implementation: production system, organisational characteristics and employee characteristics.

In common with the other models presented, Ball et al. (2009) found that a mixture of physical / process related factors and psychological/ people related factors influence successful adoption of FSMSs. However, the model is more sophisticated than those previously presented, in that the authors illustrate more clearly how the production system and organisational characteristics directly impact on employee characteristics, i.e. they show how the attitudes and subsequent behaviour of individual workers are changed by their experience of the environment in which they work. The model also shows the difference between the intention to follow food safety practices and the actual execution of these practices, recognising that the production system and organisation characteristics can also act as barriers stopping workers from executing good intentions. Thus unlike the four pillars model of Panisello and Quantick (2001), where no help was given to FBOs in prioritising which technical barriers to resolve, this model clearly implies that an FBO should resolve issues in production systems and organisational characteristics – i.e. process related factors - before or alongside addressing employee characteristics, in order to achieve satisfactory and lasting implementation of an FSMS. Thus, this model implies a dominance to addressing the FSMS process in order to ensure effective FSMS implementation.

Figure 3.5: Factors Influencing the Implementation of Food Safety Systems (Ball et al. 2009, adapted from van der Wende, 2006)



Ball et al. (2009) acknowledged that this model helped to describe factors influencing food safety behaviours, but could not be used as a predictive model without further validation. Other limitations of the study include the relatively limited sample and industry specific nature of the study population.

3.2.1.6 Critical Factors for the Effective Implementation of ISO 9001 and HACCP (Kafetzopoulos & Gotzamani, 2014)

The models presented so far have focussed on barriers to and drivers for the implementation of FSMSs, particularly HACCP. Kafetzopoulos and Gotzamani (2014) take a somewhat different approach, by conflating the study of HACCP implementation with that of the ISO 9001 QMS. This approach has merit, given that previous work has illustrated the inter-relationship of FSMSs and QMSs (e.g. Chountalas, Tsarouchas, & Lagodimos, 2009; Mensah & Julien, 2011) as discussed in Chapter 2.

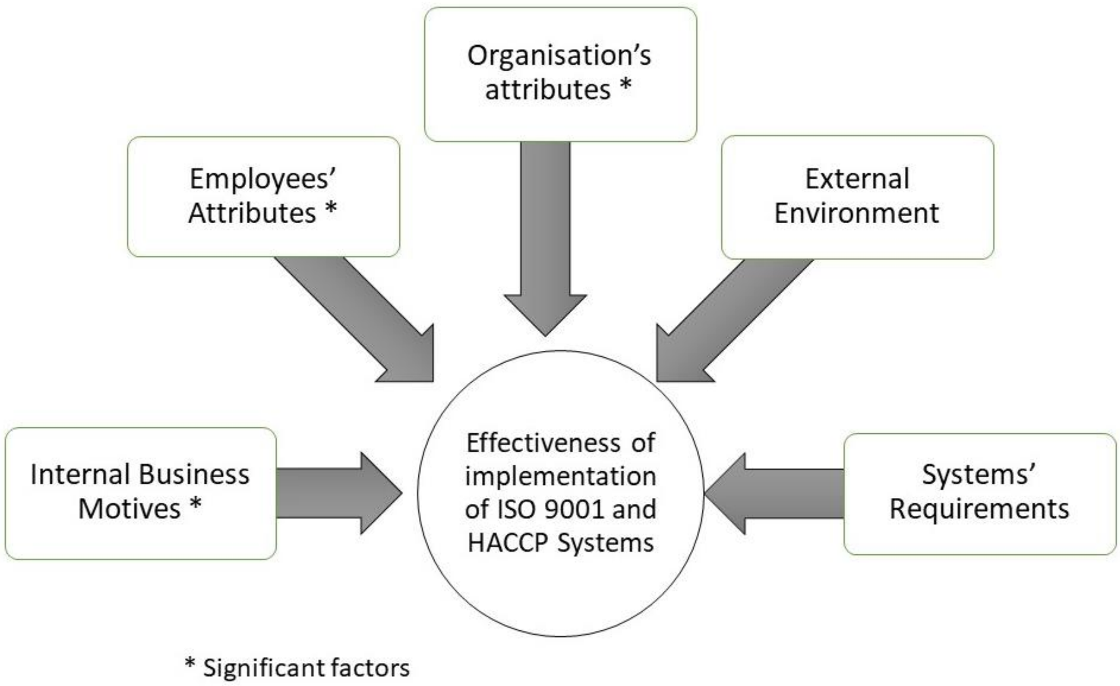
Through a survey of Greek FBOs that had implemented both ISO 9001 and an FSMS (HACCP or ISO 22000), Kafetzopoulos and Gotzamani (2014) aimed to measure the effectiveness of these systems; investigate the CFEI (critical factors for effective implementation) of the systems and finally assess the degree to which the effective implementation of the systems influences company performance. It is the second of these objectives which is relevant to this literature review.

The survey was conducted predominately by email and fax, with structured questionnaires being sent to 840 FBOs, from which 347 responded (a 42.3% response rate), split across the nutrition (59%), agricultural (23%) and beverages (18%) sectors. 91% of the respondents were SMEs.

A preliminary model is presented in which five CFEI are hypothesised for ISO 9001 and HACCP: internal business motives, employees' attributes, organisation's attributes, external environment and systems' requirements. These factors were derived from the authors' previous work in this area (Fotopoulos et al., 2011; Fotopoulos, Kafetzopoulos, & Psomas, 2009; Psomas, Fotopoulos, & Kafetzopoulos, 2010) with the latent constructs confirmed by a first level of exploratory factor analysis of the survey data (see Figure 3.6). A second level of critical factor analysis determined however that only three of the CFEI – employee's attributes, the organisation's attributes and internal business motives – made a significant contribution to the effective implementation of the systems in this study.

One concern arising from this research relates to the hypotheses tested: all five CFEI are hypothesised to have a positive relationship with ISO 9001 and HACCP systems. However, considering the associated items which make up each factor, it is clear that from previous research (e.g. Azanza & Zamora-Luna, 2005; Gilling et al., 2001) there should be an expectation of a negative relationship between some items and HACCP implementation. This is particularly marked for the factor of systems requirements, where all three associated items - the required time and cost of implementation and the volume of paperwork - are recognised as barriers to the implementation of HACCP, rather than positive factors encouraging successful implementation (Azanza & Zamora-Luna, 2005; Gilling et al., 2001). This aspect of the study therefore requires further consideration.

Figure 3.6: CFEI for QMS and FSMS (Adapted from Kafetzopoulos & Gotzamani, 2014)

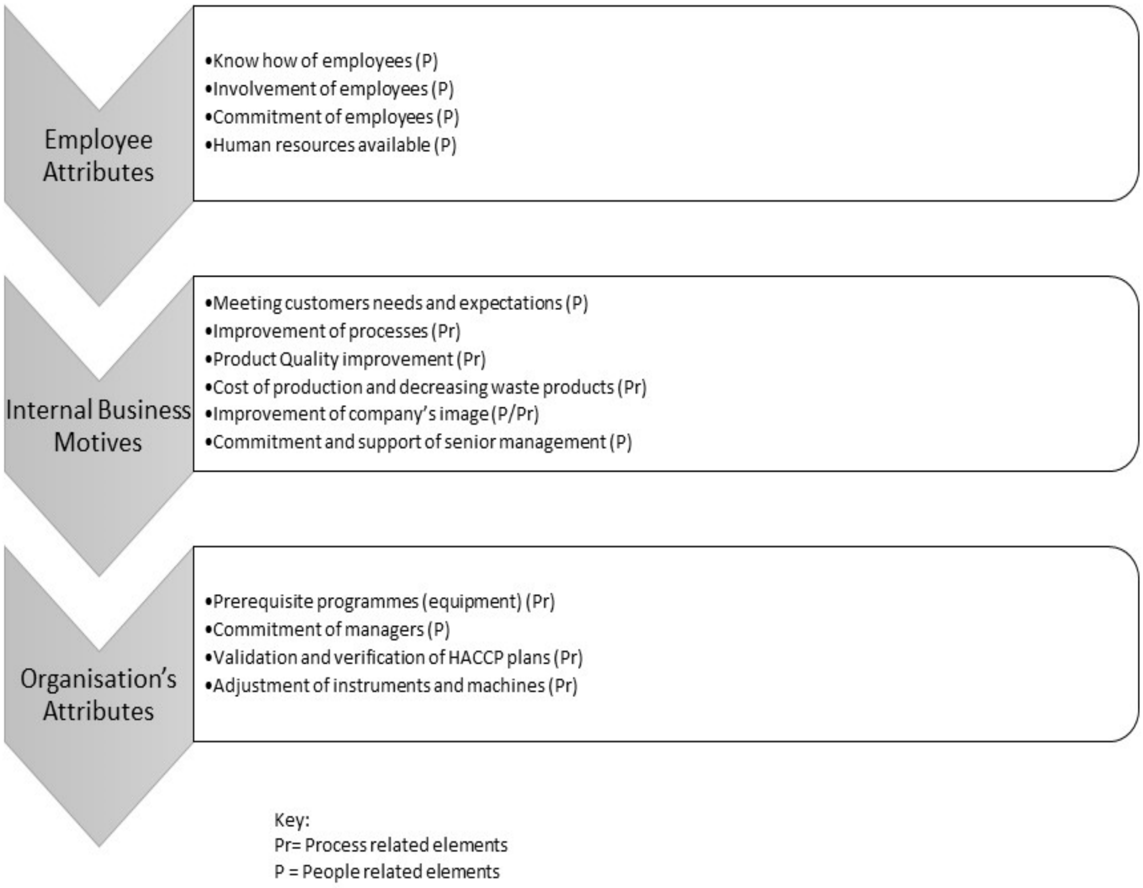


Overall, as with the work of Arpanutud et al. (2009), the quantitative, deductive approach is key to the strength of this paper. However, whilst the study had a high response rate, and indeed a relatively large number of respondents (n= 347) in comparison to other work in this area, no information is given in the paper as to whether the original study population of 840 companies comprises the total population of Greek FBOs who have implemented both ISO 9001 and HACCP / ISO 22000, how these were identified, and / or whether a sampling technique was used to identify these organisations from a larger population. Likewise, no consideration is stated as to whether the study is sufficiently powered to test the model hypotheses.

The authors also recognise some potential limitations of their work, namely that the hands-off nature of the survey may hide bias in the participants' responses. This concern fits with those previously raised for the model of Arpanutud et al. (2009), i.e. that an organisations' assessment of its success in terms of food safety is known to differ from that of independent assessors (Yapp & Fairman, 2005). This might therefore impact on the reliability with which respondents' answer questions relating to the success of FSMSs and QMSs.

To determine whether this study helps answer the question of whether people or process issues are the key limitations for HACCP implementation, it is necessary to assess the individual items associated with each of the CFEI. As shown in Figure 3.7, both people and process issues are represented. However, concentrating on the three factors shown in this study to significantly contribute to effective implementation, shows that people related elements predominate.

Figure 3.7: CFEI and Associated Items (Adapted from Kafetzopoulos & Gotzamani, 2014)



3.2.2 Comparison of Models

All the models reviewed present a range of barriers to the successful implementation of FSMSs. The most common barriers identified across all of the models are people related issues: the knowledge and skills of the workforce, their attitude towards FSMSs (i.e. whether they perceive them to be necessary and / or effective) and the commitment of implementing and using FSMSs by both management and staff. Process (technical and operational) barriers are also seen across all of the models, particularly relating to the complexity of FSMSs, the time and resources required for implementation and maintenance of the systems.

A key difference between the models lies in how they interlink and prioritise the barriers identified. Panisello and Quantick (2001) prioritise their pillars of HACCP, putting commitment as the underpinning step. In contrast, Gilling et al. (2001) and Azanza and Zamora-Luna (2005) differ in their prioritisation, building from awareness (of the FSMS) as the initial step, through knowledge and onto acceptance / commitment, before behaviour change (implementation of an effective FSMS) is achieved. Whilst this prioritisation appears logical, Rennie (1995) has challenged the model of knowledge – attitude – change in practice / behaviour (the KAP model) as being overly simplistic for the field of food safety education, as it takes insufficient account of the environment and of the preconceived ideas and current practices of people involved. Admittedly, the models of Gilling et al. (2001) and Azanza and Zamora-Luna (2005) are more complex than the basic KAP model, but concerns remain. For example, in a study of food handlers' beliefs and self-reported practices, over 60% of people trained in food safety practices admitted to not following them on all occasions (Clayton, Griffith, Price, & Peters, 2002). This suggests that knowledge without commitment is insufficient to ensure the implementation of FSMSs, and that as Panisello and Quantick (2001) suggest, addressing commitment to food safety must underpin any successful system implementation.

The model of Arpanutud et al. (2009) differs again, in that all three groups of factors influencing FSMS implementation are treated equally. A key difference with this model is the grouping of a number of "motivational" factors – drivers for the implementation of FSMSs. The work of Kafetzopoulos and Gotzamani (2014) supports this approach, also identifying internal business motives which drive FSMS/QMS implementation and further support can be found in a number of studies. These include FSMSs as a customer requirement (e.g. Henchion & McIntyre, 2005), FSMSs as a pre-requisite for export (e.g. Cobanoglu, 2012; Williams, 2012) and belief that implementation of an FSMS will improve not only food safety but also profit margins (e.g. Jin, Zhou, & Ye, 2008).

Some of these drivers, such as FSMSs being required as a pre-requisite for exports, are particularly pertinent for FBOs based in countries with less developed legislation on food safety management. However, even in jurisdictions with comprehensive food safety and hygiene laws, such as the EU, government and regulatory bodies also believe that FSMSs such as HACCP bring benefits to FBOs and society in general. The role of such systems in preventing foodborne disease, reducing costs (primarily by avoiding the costs associated with foodborne illness), improving legal protection (i.e. allowing businesses to demonstrate "due diligence") and better managing risks within the business are identified as key benefits of HACCP-based systems (Kane, 2011). Communicating such benefits to FBOs may aid in gaining commitment to the implementation of FSMSs, as the benefits can help to off-set some of the perceived barriers to FSMS implementation.

Of the models reviewed, that of Ball et al. (2009) can be considered the most sophisticated, not so much in terms of the number of individual barriers identified, but in the connections between the categories of barriers. As previously discussed, these inter-relationships lead to the conclusion that process related barriers (physical / operational issues) must be addressed before or in parallel with addressing barriers related to employee characteristics. i.e., people related barriers.

However, in addition to highlighting the differences between the models and their points in common, it is important to consider if data from other research supports or refutes any of the models in particular. This is explored in the next section.

3.2.3 Additional Empirical Research – Does it Support or Refute the Models?

The majority of research into the implementation of FSMSs has not been directed at testing any specific model but rather has endeavoured to identify and comment on barriers and drivers identified in different parts of the food industry, across a wide range of countries. For example, Baş, Yüksel and Çavuşoğlu (2007) studied barriers to HACCP implementation in Turkey; Violaris, Bridges and Bridges (2008) studied HACCP implementation in the hospitality and manufacturing industries in Cyprus; Mensah and Julien (2011) researched the implementation of FSMS in food manufacturers in the UK; Le, Bazager, Hill and Wilcock (2014) studied perceptions of food safety management systems in the artisan cheese industry in Canada; Dzwolak (2014) studied HACCP implementation in Poland in small food businesses; Jin et al., (2008) studied HACCP adoption in food enterprises in China whilst Grover, Chopra and Mosher (2016) studied factors influencing the adoption of food safety controls required under the US Food Safety Modernisation Act.

The exception to this trend is work carried out by researchers at Salford University, who have explored and expanded the awareness to adherence model of Gilling et al., (2001). They also used the expanded model as a tool to develop and implement amended HACCP systems, primarily for the hospitality sector (E. A. Taylor, 2008a, 2008b; E. A. Taylor & Kane, 2005; E. A. Taylor & J.Z. Taylor, 2004, 2008; J. Z. Taylor, 2008a, 2008b; J.Z. Taylor & Forte, 2008). Two further studies by other research groups (Fielding, Ellis, Clayton, & Peters, 2011; Worsfold, 2006) have been identified which look at the implementation of HACCP-like systems akin to that developed by the Salford team. Together these studies can be seen as providing evidence as to whether the awareness to adherence model forms a useful platform from which to develop targeted FSMSs; this research is considered below.

From the Salford team, E. A. Taylor and J. Z. Taylor (2008) describe the research carried out under the auspices of the UK FSA to develop tailored HACCP methods for the hospitality industry. "Menu-Safe" comprises 40 documented and validated safe methods, whilst "Safer Food, Better Business" comprises 25 shortened methods modified specifically for very small businesses. Both systems use a daily diary to manage the HACCP principles of monitoring, corrective action and documentation. In the research trial, Menu-Safe was implemented using a "hands-on" approach involving experienced chefs working directly with owner/managers of the subject catering operations (E. A. Taylor, 2008a).

The success of the initial trial version of Menu-Safe was evaluated using a qualitative methodology (J. Z. Taylor, 2008a, 2008b). In-depth narrative interviews were conducted in small hospitality businesses (n=22) in Greater Manchester and the findings were used to further develop the awareness to adherence model expanding it to 21 barriers to HACCP / FSMS implementation. After implementation of the Menu-Safe system, follow–up interviews were carried out at 6 months (n=12) and 3 years (n=5) to ascertain changes in knowledge, behaviour and attitude and to understand if changes were maintained between 6 months and 3 years without contact during this period. FSMS documentation and records were also examined to assess whether the system had been fully implemented and maintained. J.Z. Taylor (2008a, 2008b) concluded in this research that Menu-Safe could be viewed as a success, reducing or eliminating the 21 barriers to FSMS implementation identified at the start of the research.

However, the limitations of this research must be recognised. First, the research focussed only on hospitality; there is no evidence in these studies as to whether this approach would work in other sectors of the food industry. Second, there was a high drop-out rate in the study; only 54% of businesses completed the 6 month follow up and only 12% the 3 year follow up. Despite recognising the high turnover of staff in the hospitality sector, the study was designed such that follow up interviews were only conducted with the same managers as participated at the start of the study (Taylor, 2008a). An alternative study design, allowing follow up interviews with other staff / management and / or utilising the documentation review in all businesses, might have elucidated different results.

The work of Worsfold (2006) forms another implementation study of Menu-Safe, conducted separately to the Salford group. She reports on a workshop format designed to deliver the trial Menu-Safe pack to 42 small fast food businesses. These businesses were recruited via trade directories and with the assistance of local authority environmental health officers (EHOs). Knowledge, behaviour and attitudes were assessed before training using a questionnaire. At the end of the course a second questionnaire was used to assess relevance and overall satisfaction with the course and the level of confidence to proceed with using the knowledge gained, i.e., a measure of intention to implement the Menu-Safe system.

Analysis of the pre-course questionnaires demonstrated that businesses were confident that they were operating food safe businesses, but in reality, there was a gap between this confidence level and the participants' understanding of risks and actual behaviours. Also of note was the challenge in recruiting study participants; even with the involvement of EHOs, there was a great reluctance on the part of businesses to participate, which in itself can be seen as a measure of attitude towards FSMSs. Whilst Worsfold (2006) reports success in terms of basic quantitative data for measures of satisfaction and relevance of the workshops, there was no follow up on actual implementation in the businesses and no independent verification to ascertain if appropriate changes in food safety practices took place. It is thus impossible to judge from this work if the tailored HACCP method was successfully implemented without direct support and intervention in the individual businesses as provided in the original work of the Salford team (J.Z. Taylor, 2008a, 2008b).

Despite these limitations, these studies suggest that the awareness to adherence model has been successfully used as a basis for the development and implementation of modified HACCP-like systems, primarily for SMEs in the hospitality industry. More recent work (Lowe & J.Z. Taylor, 2013) has also utilised the framework to identify barriers to HACCP amongst primary producers (farmers and growers), and of course the model of Azanza and Zamora-Luna (2005) previously discussed, is an extension of the original Gilling et al. (2001) work. In addition, the qualitative research approach and fundamental principle of developing a tailored HACCP-like system for a specific industry sector, received the endorsement of the FAO/WHO in their guidance report on the application of HACCP in small and /or less-developed food businesses (Food and Agriculture Organization of the United Nations, 2006).

However, another study evaluating the implementation of a tailored HACCP-like system (Fielding et al., 2011) echoes concerns discussed earlier, i.e. that the prioritisation of barriers, putting awareness / knowledge before commitment, will not necessarily lead to behaviour change.

Fielding et al. (2011) present a quantitative study set up to evaluate the success of implementation of an FSMS pack developed with the backing of the FSA. The pack comprised a written information resource tailored to manufacturers of fresh chilled or frozen soups and sauces (or producers of ready meals containing these sauces). The initiative was designed on a similar basis to Menu-Safe in that it was industry / product specific and aimed at breaking down previously identified barriers to FSMS implementation, such as the lack of technical resource in companies.

The study was designed to assess the effect of intervention (resource delivery) versus control (no resource), and to assess the impact of business size on the success of the intervention. Implementation of the FSMS pack was assessed by questionnaires and check lists administered during assessment visits 4 months after the intervention point, using trained and validated assessors.

Unfortunately Fielding et al. (2011) experienced great difficulties in recruiting subjects into the study. Only 123 out of 3000 companies agreed initially to participate - a 4.1% response rate. This was reduced by the withdrawal of 81 companies prior to the assessment visit. Even the response rate of local authorities was low, with only 56% responding to a request for participation (including a letter from the FSA).

The study was therefore greatly underpowered and unbalanced in terms of both intervention and control groups and business size in each group. A trend was reported for higher attitude scores in the intervention group, particularly in SMEs (rather than microbusinesses) but no significant difference could be seen between intervention and control groups to indicate that the resource was effective in improving the knowledge, behaviour or attitude of the participants. A small survey of non-responders (n=14, 50% control, 50% intervention) was also conducted to ascertain any differences between participants and non-responders. These indicated that non-responders may have lower knowledge but a more positive attitude towards food safety, i.e. they may falsely believe that they have an appropriate FSMS in place.

The small sample size and lack of power of the study makes it difficult to draw firm conclusions, but the results indicate that providing information / improving knowledge and changing the FSMS process alone does not necessarily lead to improvements in attitude and behaviour and adequate FSMS implementation.

3.2.4 Summary of Identified Barriers and Benefits.

One of the challenges in comparing different studies on FSMS implementation is the lack of consistency in the naming and description of barriers (Jevšnik et al., 2006).

Despite this challenge two review papers have been identified which endeavour to consolidate the information on barriers and benefits to HACCP implementation and from there to prioritise these factors. Jevšnik et al. (2006) identified 12 scientific papers with empirical research findings and 7 technical studies, with data presented on practical experience and reviews of other literature. Based on this work, they classified elements into 21 categories and ranked them by frequency of occurrence in each published paper reviewed. Fotopoulos et al. (2011) conducted a similar exercise, reviewing 31 papers and identified 32 factors, positive and negative, related to HACCP implementation. Using Pareto analysis, they identified 11 "critical" factors, (one positive and ten negative) which when taken together accounted for over 78% of all mentions of elements influencing HACCP implementation in the literature reviewed.

Figure 3.8 overleaf shows the factors identified by Jevšnik et al. (2006) presented in rank order and Fotopoulos et al. (2011), again, presented in rank order. In addition, the elements have been classified as primarily related to the FSMS process (process, technical or operational areas) or to people (staff and management) related areas.

Figure 3.8: Factors Related to the Success of HACCP Implementation and Classification into People or Process Areas

Classification of elements & ranking the influence of a specific element on HACCP efficiency, Jevsnik et al. (2006)		Critical factors for effective HACCP, Fotopoulos et al. (2011)	
1	Training (P)	1	Limited knowledge & skills for HACCP implementation (P)
2	Human Resources (Pr)	2	Lack of commitment to food safety by employees (P)
3	Planning (Pr)	3	Resistance to change & attitudes of employees (P)
4	Knowledge & competence (P)	4	Increased financial resources – cost (Pr)
5	Documentation (Pr)	5	Lack of employee training (P)
6	Resources (Pr)	6	Length of time to develop & implement HACCP (Pr)
7	Management commitment (P)	7	Lack of technical expertise & support (P)
8	Credibility (P)	8	Need to satisfy stakeholders / customers (P)
9	Hazard analysis (Pr)	9	Low availability of human resources (Pr)
10	Organisational design (Pr)	10	Excessive paperwork & documentation of HACCP (Pr)
11	Personal hygiene (P)	11	Improper organisational structure & PRPs (Pr)
12	Food handling (P)		
13	Customer (P)		
14	Food safety policy (Pr)		
15	Communication (P)		
16	Responsibility & authority (P)		
17	Organisational control (Pr)		
18	Transportation (Pr)		
19	Maintenance & sanitation (Pr)		
20	Food legislation, food standards (Pr)		
21	Infrastructure (Pr)		

P	People related elements	Pr	Process related elements

As might be expected, there are clear similarities between the barriers identified in the two reviews. From a people perspective, knowledge and skills – or the training to develop these – rank as key barriers, as do commitment by both staff and management. From a process perspective, resources appear to be a commonly quoted critical barrier, as does the complexity of HACCP, as evidenced by barriers of documentation, excessive paperwork and the time required to develop and implement HACCP. Overall however, there are roughly equal numbers of people and process related barriers, which appears to leave the debate open as whether process or people change is required for effective FSMS implementation.

However, returning to the empirical studies of the Salford group, these utilise a form of process change to elicit improvements in FSMS implementation. This is demonstrated by the descriptions of “Menu-Safe” and “Safer Food, Better Business”, with the creation and use of an industry tailored approach, simplifying the HACCP system through the introduction of the safe methods and daily diary etc. (E. A. Taylor & J.Z. Taylor, 2008).

Whilst the studies in the hospitality sector were deemed to be largely successful, the relative failure of this approach in the manufacturing sector (Fielding et al., 2011) suggests that changing the FSMS process alone is insufficient. The low recruitment and high dropout rates in the study (Fielding et al., 2011) can be seen as indicators of significant issues with people related barriers such as commitment and attitude to food safety.

Indeed, the challenges organisations face in implementing FSMS may even increase negative attitudes towards these systems, as was seen in a longitudinal study of SMEs in Cyprus tracking HACCP and ISO 22000 implementation and compliance over 30 months (Charalambous, Fryer, Panayides, & Smith, 2015). In this study cost and complexity were postulated as the main concerns, leading to a change from a positive attitude and intention at the start of the study to negative attitudes after 30 months. Similarly, Qijun and Batt (2016) found when studying barriers and benefits to the implementation of third party certified FSMSs in Shanghai, that the perception of barriers and constraints by food processors escalated as they progressed in developing quality assurance certification.

Also, whilst the Salford group changed the FSMS process in their work, they implemented the new system in a person-centred way, using experienced chefs to work directly with the study participants (E. A. Taylor, 2008a). This was in direct contrast to Fielding et al. (2011), who used a hands-off approach to disseminate their targeted FSMS.

Overall, the research findings demonstrate the complex and inter-related nature of the barriers to effective FSMS implementation. From the models discussed, the supporting empirical research, and the summary of barriers collated in the review papers, it is clear that people factors, such as knowledge, skills and motivation, are key to FSMS implementation, but they are impacted by process factors such as complexity, cost and time for system implementation, as well as fundamentals of the food production business itself (e.g. complexity of food production process; facilities available).

Having reviewed the barriers to and drivers for the implementation of FSMSs, the next stage of the literature review considers the literature on reported food safety incidents, in order to determine if these give any further indications on the balance between process and people related issues with FSMS implementation and maintenance.

3.3 Food Safety Incidents: People or Process Failure?

The pervasive nature of reported food safety incidents was presented in Chapter 2, with Figure 2.1 showing the relative number of hazards by type for food incidents investigated by the UK FSA in 2016/17[14]. Incident reports published in the UK and EU are next considered, to ascertain if this published data gives further insight to the

[14] As noted in Chapter 2, the FSA classifies incidents as "an event where, based on the information available, there are concerns about actual or suspected threats to the safety or quality of food and/or feed that could require intervention to protect consumers' interests" (Food Standards Agency, 2017a), although FBOS are only obliged to report to notify the authorities of any products placed on the market which they believe may be "injurious to health" (Regulation (EC) No 178/ 2002, Article 19).

causes (people or process) of incidents, particularly food safety incidents (as opposed to those incidents where there is no risk to human health), which can be postulated to be caused by FSMS failures.

Both UK FSA (Food Standards Agency, 2017b) and EU RASFF annual reports (European Commission Directorate-General for Health and Food Safety, 2017) contain a wealth of detail enabling analysis of incidents by hazard type[15], food type, origin of product or reporting country. However, neither report gives robust information about specific safety system failures. The RASFF report for 2016 (European Commission Directorate-General for Health and Food Safety, 2017) presented more specific descriptions of four specific cases of cross-border outbreaks of foodborne illness. Whilst affected countries, bacterial strains and food vehicles were presented in these case descriptions, there was no information as to how or why the relevant food safety systems had failed. Likewise, there is insufficient detail in the on-line RASFF or FSA databases to determine the root cause of incidents and understand, in relevant incidents, why safety systems have failed. For example, a report of risk of *Clostridium botulinum* in flavoured oils due to inadequate processing could result from a breakdown in processing equipment and a failure in an alert system to notify production staff of inadequate time / temperature treatment (a failure in an FSMnS) or be a more fundamental problem in that the original HACCP plan failed to identify this part of the process as a CCP and adequate monitoring was not put in place (a failure in knowledge or skills of the individual completing the HACCP plan and thus in the overall FSMS).

In the USA, data is available on inter-state outbreaks of foodborne illness[16] from three main sources: the Department of Agriculture (USDA) who have responsibility for meat,

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[15] 27 different hazard types, are identified and reported upon, covering the spectrum of microbiological, chemical and physical hazards in specific subsets (e.g. for chemical hazards, separating allergens, food additives, heavy metals etc.) plus additional hazards such as adulteration / fraud, packaging defects and labelling issues.

[16] An outbreak of foodborne illness is defined by the CDC as "an incident in which two or more persons experience a similar illness resulting from the ingestion of a common food" (Centers for Disease Control and Prevention, 2017). Thus, all outbreaks result from an incident (as previously defined) but not all incidents cause actual illness or indeed an outbreak of foodborne illness.

poultry, certain fish and processed egg products; the FDA who cover all other foodstuffs and the CDC, who report on outbreaks in general.

The CDC National Outbreak Reporting System database for 2016 (Centers for Disease Control, 2018) lists 841 food related outbreaks for 2016, the majority of which (77%) resulted from microbiological contamination. The aetiology was not reported for 21% of cases, whilst the remaining 2% (17 cases) were due to chemical toxins, all but one case being of natural origin (ciguatoxin or scombroid toxin) related to fish consumption. The vast majority of outbreaks (97%) concerned food prepared and served out-of-home (restaurants, institutional catering etc.). Whilst some data is available on the implicated food vehicles and contaminated ingredients (e.g. beef as a contaminated ingredient in a taco meal which acted as the food vehicle), no data is available through this site to distinguish how or why the contamination occurred, thus it is impossible to judge how FSMSs failed, and whether people or process related elements lie at the root of these failures.

In contrast, data is available from the FDA on a smaller number of outbreaks which were investigated by them. Looking at the same time period (2016), the FDA report investigating 22 multistate outbreaks, although more detail is available on only 16 outbreaks via the FDA website (US Food and Drug Administration, 2018a). As with the FSA and RASFF databases, the main purpose of the FDA information is to alert consumers and the food industry of concerns and the actions they should take to avoid illness. In only four of the 16 detailed outbreaks listed for 2016 is more information given on the reasons for contamination, and in only one of these cases are FDA inspection reports (redacted to remove commercially sensitive material) available. For these four cases, inadequate hygiene measures appears as a common thread (e.g. lack of handwashing facilities; inadequate pest control), although a lack of a preventive plan to guard against *Salmonella* contamination and poor record keeping was noted in one case, which suggests failures in developing and managing a FSMS. However, again, there is an overall lack of specific data across the data set to make a more detailed assessment of FSMS failures and causes.

In addition to data on outbreaks, both the FDA and the Food Safety and Inspection Service (FSIS) of the USDA report data on recalls, with the USDA reporting 122 recalls in 2016 (USDA Food Safety and Inspection Service, 2018) and the FDA reporting 484 recalls pertaining to food and dietary supplements (US Food and Drug Administration, 2018b). Again, the focus is on providing information to alert consumers and the industry about products which are possibly injurious to health and there is a lack of systematic analysis of this data available through the enforcement authorities.

Both the FSIS and FDA identify three classes of recalls based on the severity of potential outcomes of consuming products. There are slight differences between these classifications (as shown in Table 3.1) and also in the availability of this data; all FSIS USDA notifications contain this data, whilst it is not immediately available for FDA recalls. The classification systems do not help to determine the reasons for FSMS failures underpinning the need for product recalls.

Table 3.1: USA Recall Classification Systems

	FSIS of the USDA	**FDA**
Class I	A health hazard situation in which there is a *reasonable* probability that eating the food will cause health problems or death.	Dangerous or defective products that predictably could cause serious health problems or death.
Class II	A potential health hazard situation in which there is a *remote* probability of adverse health consequences from eating the food.	Products that might cause a temporary health problem, or pose only a slight threat of a serious nature.
Class III	A situation in which eating the food will not cause adverse health consequences.	Products that are unlikely to cause any adverse health reaction, but that violate FDA labelling or manufacturing laws.

As the level of detail required to investigate causes of FSMS failure is not available through the routine publications of the enforcement authorities, additional literature searches were conducted to identify reviews of food safety incidents / foodborne illness outbreaks published in the academic literature since 2010. 18 papers and edited book chapters were identified, with one paper analysing violations reported in enforcement official inspections of FBOs, six publications focussing on reported food safety incidents / product recalls and ten analysing reported cases of foodborne illness or outbreaks. One paper (Zhang & Xue, 2016) specifically considers food fraud / economically motivated adulteration of food, but was included in this analysis as much of the adulteration discussed in the paper has food safety implications (e.g. the presence of forbidden additives or medicinal products). Indeed, food fraud cases are covered in other papers (e.g. Vemula, Kumar & Polasa, 2012; Wright, 2016; Manning, Wallace & Soon, 2016; Potter, Murray, Lawson & Graham, 2012) alongside "traditional" food safety incidents resulting from microbiological contamination etc.[17] This reflects the recent interest in food fraud and perfectly illustrates the inter-relationship between food quality, food safety and food fraud, which was discussed in Chapter 2.

The reviews cover both highly developed countries with comprehensive food safety regulations such as the USA and UK, and those with developing legislation and systems such as India and China and consider the full range of products from agricultural crops, to highly processed foods and provision from food service outlets. Appendix A provides more detail, tabulating the main findings of each paper with a short discussion as to whether there is a specific link to process or people factors as a root cause of incidents reported.

Overall, these reviews have focussed predominantly on outbreaks involving the microbiological contamination of foods, rather than the full range of incidents

[17] Whilst food fraud is frequently classified as such due to the intentional nature of product adulteration / substitution (Spink & Moyer, 2011), it bears highlighting that there is no intent on the part of the fraudster to impact food safety or public health. Indeed, the "successful fraudster" aims to remain undetected so they can repeat the product adulteration etc., and so gain further financial benefits.

(physical, chemical, microbiological etc.) reported by enforcement authorities in their annual reports. Of note is that in developing countries there appear to be specific concerns with the adulteration of products. Accidental contamination from natural (e.g. toxins produced by mouldy grain) or chemical sources (e.g. pesticide residues) and deliberate, fraudulent contamination (e.g. use of illegal food colourings) are identified as concerns (e.g. Vemula, Kumar & Polasa, 2012), with the lower educational level (particularly in rural areas) and less advanced legislative and enforcement environments being implicated as causative factors. The work of Potter et al. (2012) is also of note. The authors have attempted to systematically review hazards within the agri-food industry by considering recalls in the UK, the Republic of Ireland and the USA between 2004 and 2010. They created three main recall categories: chemical, biological and operational. This last category encompasses a wide range of issues, from "production contamination" (with glass, metal, plastic etc.) through to the use of unauthorised ingredients, incorrect labelling and product spoilage and accounted for 55% of the recalls studied. Potter et al. (2012) claim that "operational product recalls are largely caused by preventable human errors", however, they present no evidence to substantiate this claim. Interestingly, they recommend future research should investigate how HACCP, statistical quality control, traceability and supply chain risk management – i.e. processes – can be used to prevent operational hazards, implying that improving FSMS processes can overcome human errors which might be thought to relate more to people factors such as training and behaviour.

Given the range of study methodologies, countries and products of interest, few firm conclusions can be drawn from this literature. However, whilst both process and people related causes of incidents can be determined from the information presented, an increasing focus on people as the causative factor in food safety failures is apparent, with the construct of FSC being identified in some papers (e.g. Wright, 2016).

Finally, returning to the classification or typology of incidents, a new classification of food safety scares (a food safety incident which impacts consumer demand) has been proposed by Whitworth, Druckman and Woodward (2016). This combines both the hazard (physical, biological or chemical contamination) with, where appropriate, the mechanism through which it arises (wilful deception, transparency and awareness issues), aiming to provide FBOs and enforcement authorities with better information to manage and prevent food scares. However, even with this classification the root cause of FSMS/ FSMnS failure is not necessarily captured and this classification would not aid in the determination of whether people or process issues underpin FSMS failures.

The relative lack of comprehensive analysis of food safety incidents and food scares therefore forms a gap that potentially inhibits FBOs and enforcement authorities from gaining the optimum learning of how to prevent future incidents. To fully address this gap and identify if there is any systematic failure of specific elements of FSMS or FSMnS in reported cases of food safety incidents, secondary analysis of both published and in-company data would be required, which falls outside of the scope of this literature review.

However, with this gap in the literature identified, two objectives for the current research study are proposed: to determine whether reported food safety incidents can be related to specific people or process elements of FSMS failure; and to determine the extent to which the barriers to the implementation and maintenance of FSMSs (particularly HACCP) found in the literature can be used to account for failures in FSMSs[18].

Before moving forward to address these objectives, a further consideration of the people side of the barriers to FSMS implementation and maintenance is required. As noted above, a number of the papers reviewed in this section have touched on the topic of FSC, to encompass the organisational attributes of staff (and management) knowledge, attitudes and behaviour around food safety. However, this terminology is less common in the work on barriers to and drivers of FSMS implementation. The

[18] Whilst the gap identified in the literature pertains to reported food safety incidents, it was not possible to recruit organisations to the research who had reported such incidents, and the research objectives were modified accordingly. This is discussed in Chapter 4, section 4.4.1.

concept of FSC is therefore explored further in section 3. 4 to understand if and how it complements the work on FSMS implementation, maintenance and failure.

3.4 People and the Role of Food Safety Culture (FSC)

3.4.1 Introduction

Previous sections have identified and discussed the range of factors identified as barriers to and drivers for the successful implementation of FSMS. After an early focus on operational and knowledge based barriers, Gilling et al. (2001) transformed the field with the identification of underlying psychological barriers to successful FSMS implementation. Subsequent work has confirmed the importance of these factors, such as confidence in the application of systems and perception of the benefits of FSMS (e.g. Lowe & J.Z. Taylor, 2013; J. Z. Taylor, 2008b). Such barriers can be related not only to the beliefs and attitudes of individuals but also to those of the organisation as a whole, i.e. they can be seen as part of the organisation's culture, specifically its FSC.

Recognition of the importance of FSC and its subsequent study started after one of the major food safety incidents in the UK in 2005. In this incident (the John Tudor & Son case) the provision of cooked meat products contaminated with *E. coli* O157 in South Wales led to 157 reported cases of food poisoning and the death of a five-year-old boy (Powell et al., 2011). In the public enquiry on this case, the culture of the FBO responsible for providing the contaminated meat was highlighted as one of the key causes of the food poisoning outbreak (Pennington, 2009).

Subsequently it has been proposed that a good or strong FSC "gives employees a sense of purpose in maintaining food safety standards" (MacAuslan, 2013), with programmes designed to address FSC being positioned as PRPs (Mortimore & Warren, 2014). However, to develop programmes to address FSC, it is important to first define FSC and understand its position vis-à-vis organisational culture.

This section therefore defines FSC and examines the relationship between FSC and the general field of organisational culture. Models of FSC are critiqued, examining the assessment or measurement of FSC and considering if FSC can act as a construct to bring together the people related elements of the barriers to FSMS implementation.

3.4.2 FSC vs. Organisational Culture

FSC has been defined as "the aggregation of the prevailing, relatively constant, learned, shared attitudes, values and beliefs contributing to the hygiene behaviours used within a particular food handling environment" (Griffith, 2008, 2009 cited by Griffith, Livesey, & Clayton, 2010a). Whilst this definition is specific to FSC, it shares many common elements with well-known definitions of organisational culture.

Deal and Kennedy popularised the definition of organisational culture as "the way we do things around here" (Bower, 1966 cited by Deal & Kennedy, 1982, p 4). Although this is a simplistic definition of a complex phenomenon, it has merit due to the emphasis placed on actions which can be observed, rather than simply purported values and beliefs. This perspective therefore fits with the definition of FSC given above, as this puts an emphasis on "… behaviours *used* within a particular food handling environment" (my emphasis, Griffith, 2008, 2009, cited by Griffith et al., 2010a).

According to Schein (2004, p 26) there are three levels to organisational culture:

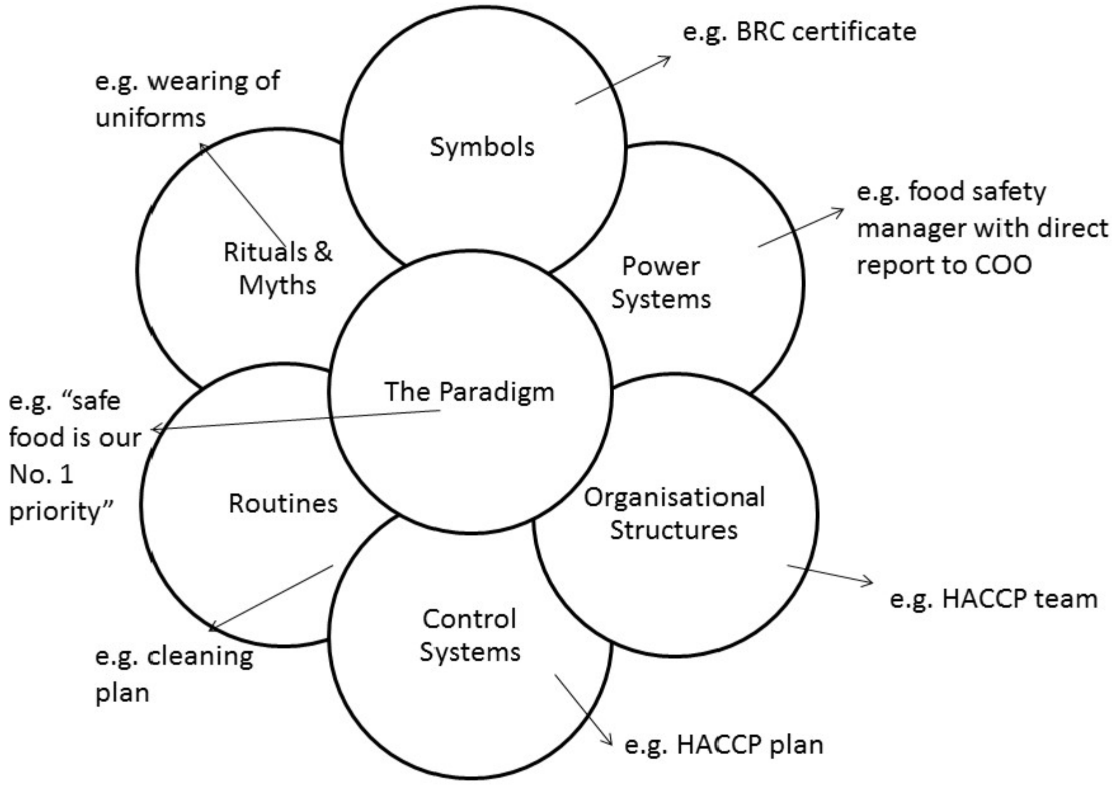
- artifacts - the visible symbols of culture such as structures and procedures;
- espoused beliefs and values – the strategies, goals and philosophies of an organisation;
- basic underlying assumptions – the unconscious, taken for granted beliefs, thoughts and perceptions which act as the sources of values and actions.

Going back to the definition of FSC (Griffith, 2008, 2009, cited by Griffith et al., 2010a), it is implied that FSC relates to the middle and bottom layers of Schein's (2004, p 26) organisational culture model, rather than the top-level elements which could comprise items such as a written food safety policy.

We can also compare the elements of an FSC to the overall elements of organisational culture described by Johnson (1988) as a "cultural web". Johnson (1988) argues that the organisational paradigm, which he defines as "the set of beliefs and assumptions, held relatively common through the organisation ..." is influenced by many aspects of the organisations work, including routine, power structures and rituals and myths. Aspects of organisational culture which make up elements of FSC can be mapped against the cultural web, as shown in Figure 3.9.

In summary, FSC can be considered as a sub-set of the total organisational culture. It might therefore be reasonable to assume that the strength of an organisation's FSC depends not only on the elements contributing to the FSC, but on the relative visibility and emphasis put on these elements versus other aspects of the overall organisational culture.

Figure 3.9: How Elements Making up FSC Map against the Cultural Web (adapted from G. Johnson, 1988)



3.4.3 Models of FSC

FSC has been proposed as an "emerging risk factor" for food safety (Griffith et al., 2010a), with the recommendation that the FSC of a business should be evaluated in the same way that other risk factors, such as raw materials, food handler behaviour, and microbiological hazards, are assessed (Griffith, 2010b). Such evaluation may be useful not only for FBOs but could also form part of commercial food safety standard requirements and official inspections by enforcement officers. However, to undertake these evaluations a deeper understanding of FSC is required, to which end a number of conceptual models of FSC have been developed. Seven of these models are presented and critiqued below.

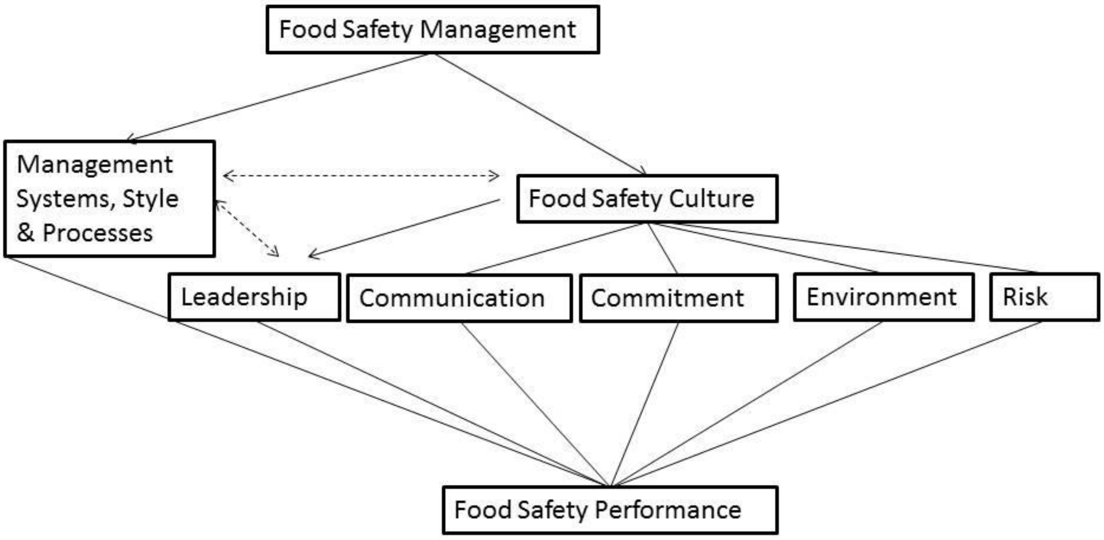
3.4.3.1 Factors Affecting Food Safety Performance (Griffith et al., 2010b)

Griffith et al. (2010b) propose a model of factors affecting food safety performance. As shown in Figure 3.10, this model positions FSC as a determinant of five key factors which impact food safety performance: leadership, communication, commitment, environment and risk. FSC is also seen as having a relationship to the organisation's management systems, style and processes, which directly impact food safety performance.

Griffith et al. (2010b) support this model with reference to the broad published literature on organisational culture and more specifically organisational safety culture. There is a large degree of cognitive consonance between this model and the work previously reviewed on barriers to FSMS in section 3.2, as the elements identified here as key factors affecting food safety performance have been noted previously as barriers to FSMS implementation, in particular commitment, of management and / or staff was seen as a requirement for effective FSMS implementation in five of the six models presented in Section 3.2.1 (Kafetzopoulos & Gotzamani, 2014; Ball et al., 2009; Arpanutud et al., 2009; Azanza and Zamora-Luna, 2005; Panisello & Quantick, 2001) as well as the two review papers cited in Section 3.2.4 (Jevšnik et al, 2016; Fotopoulos et al., 2011). Communication was also noted as a key concern by Jevšnik et al, 2016, and of course is a critical first step in creating knowledge and awareness of FSMSs, which forms a critical barrier in the models Gilling et al., 2001 and Azanza & Zamora-Luna, 2005.

Griffith et al. (2010b) recognise that a continuum of FSC, from negative to positive, can be identified. They also acknowledge that a range of measures should be used to assess FSC, ranging from quantitative surveys of food safety climate, individual or group interviews and audits, including observation of working practices. Throughout their paper they give more detail on each of the key factors identified which could be used to create measures or assessment criteria for FSC.

Figure 3.10: Factors Influencing Food Safety Performance (Griffith et al., 2010b)



However, Griffith et al. (2010b) present no new empirical data within this paper to illustrate the use of the model for the assessment or categorisation of FSC or to demonstrate how such measurement could be used to change an organisation’s FSC. In conclusion therefore, this model links with the previously discussed work on barriers to the implementation of FSMS and provides a theoretical framework on which to build criteria for the assessment of FSC, but it lacks the detail required for FBOs or enforcement officers to utilise as a practical tool.

3.4.3.2 The Food Safety Culture Excellence Model (J. Z. Taylor et al., 2015; J. Z. Taylor, 2011)

This model was originally developed by J. Z. Taylor (2011) as a theoretical framework, combining her previous work on behavioural barriers to FSMS implementation (J. Z. Taylor, 2008b) with an understanding of a number of major psychological theories including social norms, self-efficacy, planned behaviour and reinforcement (see Figure

3.11). As well as illustrating how each of the psychological theories relates to food safety behaviour (e.g. the impact of social norms on the likelihood of a food handler to wash their hands), J.Z. Taylor (2011) referenced her previous work to substantiate the model framework. The original model (Figure 3.11) therefore clearly demonstrates how the people related elements of barriers to FSMS implementation can be encompassed by the construct of FSC.

J.Z. Taylor has since further developed the model into the FSC excellence model (J. Z. Taylor et al., 2015), see Figure 3.12, creating an on-line survey tool which is made available via a commercial relationship between Taylor Shannon International and Campden BRI (Campden BRI, 2017). Whilst the original model focussed on understanding the factors which make up FSC, the culture excellence model and tools are designed to assess an organisation's current FSC, and gives numerical scores on a 1 to 5 scale where 3 equates to "good" and 5 to "excellent". In contrast to other models e.g. that of NSF International Ltd. (2014), no attempt is made to create a descriptive typology of the different levels of FSC represented by the overall model scores.

Given its commercial nature, full details of the survey tool and scoring method used to apply the model are not available in the academic literature. However, it is clear that scores are obtained for each of the four model categories (people, process, purpose and productivity) together with individual scores for the dimensions which underpin each category, with the aim of producing information which an FBO can use to target improvement efforts, i.e. there is an explicit expectation that organisations can improve their FSC. It is interesting to note that whilst the model is set up to measure FSC, one of the categories assessed relates to process, i.e. there is an implication that controls and systems used for food safety management affect FSC.

Overall the framework has evolved from one which endeavours to understand the factors which influence FSC, to one that can be used by consultants to assess FSC and through that enable organisations to effect change. The proprietary nature of the tool used to apply the model limits the detail available to fully critique it. Similarly, whilst Taylor et al. (2015) report a single case study applying the model and related tools, a more comprehensive analysis of the use of the model is required to ascertain if its use meets the aim of assisting FBOs to effect cultural change within their organisations.

Figure 3.11: A Theoretical Framework for Food Safety Culture (J. Z. Taylor, 2011)

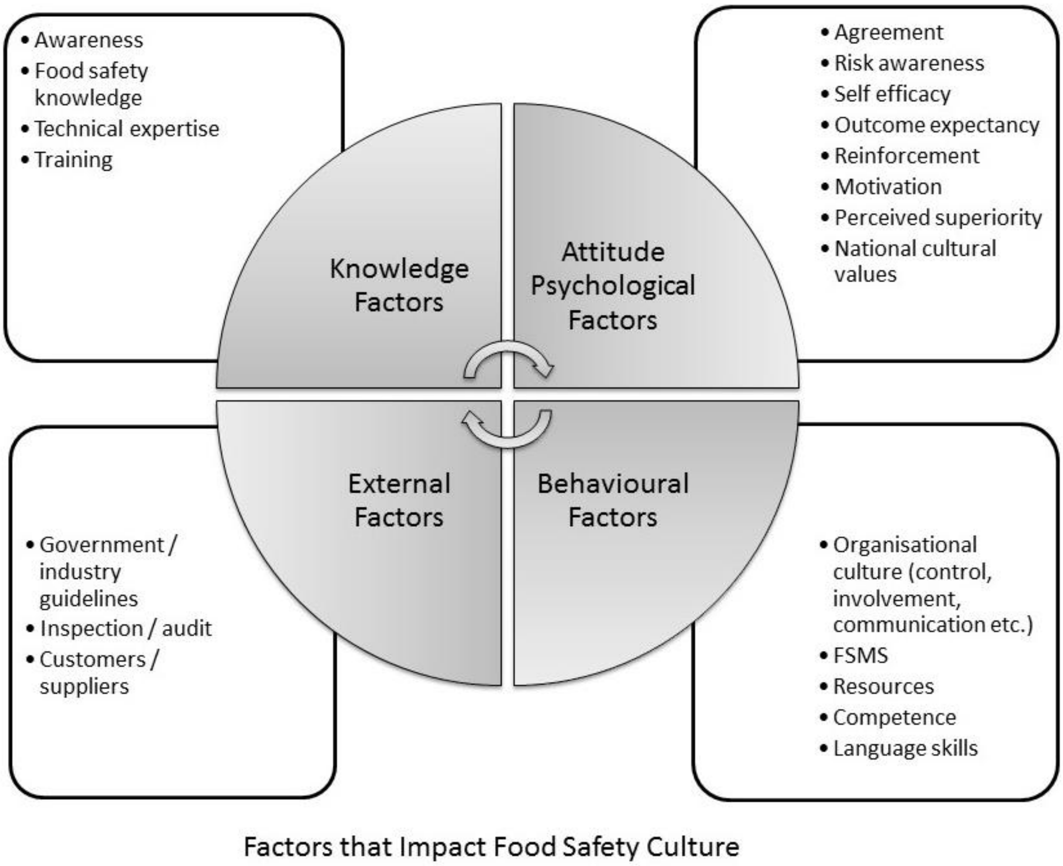
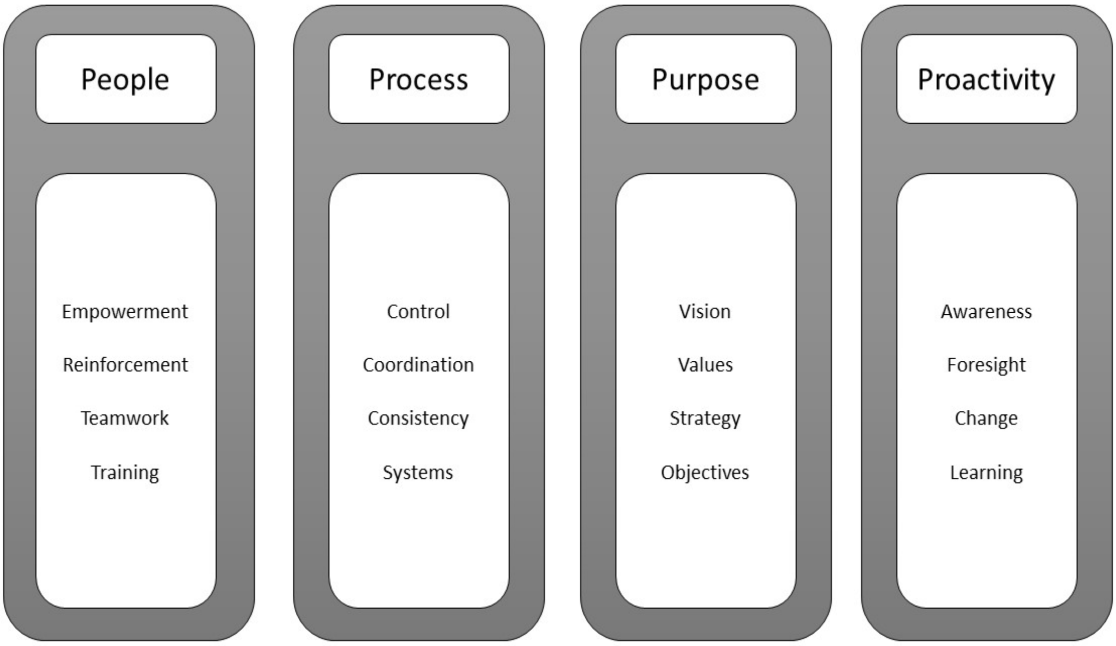


Figure 3.12: The Food Safety Culture Excellence Model (J. Z. Taylor et al., 2015)



3.4.3.3 The FSA/ Greenstreet Berman Ltd Model (Wright, Leach & Palmer, 2012a, 2012b)

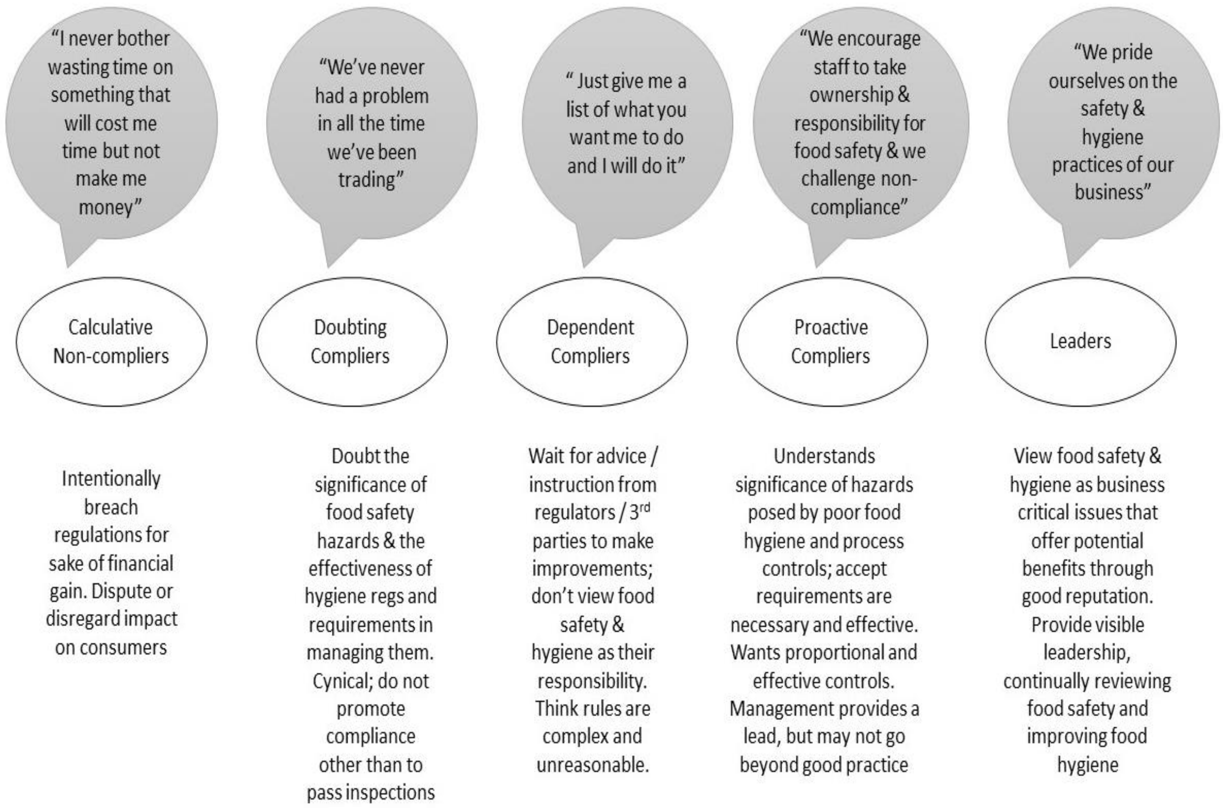
In 2012 the UK FSA commissioned a risk consultancy agency, Greenstreet Berman Ltd, to review the status and effectiveness of safety culture diagnostic tools and develop a tool for identifying aspects of good / poorer FSCs in FBOs, specifically aimed at SMEs (Wright, Leach & Palmer, 2012a). As a result of this work, the FSA published a Food Safety Culture Diagnostic Toolkit for Inspectors (Wright, Leach & Palmer, 2012b).

The model was developed after an extensive review of the literature on FSC and a review of nine existing tools on safety culture and climate, not specific to the food industry (Wright et al., 2012a). No empirical data on the use of the model to assess FSC is presented by Wright et al. (2012a). However, a degree of validation of the model was achieved through the development process, as the initial model was reviewed by FBOs and EHOs in two workshops and modified according to their feedback.

Five of the tools identified in the report were based on a typology, or category approach, where different types of culture can be described and businesses categorised against them (Wright et al., 2012a). Additionally, three of the tools reviewed were based on the theory of cultural maturity, which implies that businesses move through sequential stages of development as their maturity grows. The authors' state that whilst there is research to indicate that different typologies of FSC can be identified, there is inadequate research to demonstrate that FBOs move through sequential levels of maturity, hence a maturity based model was rejected.

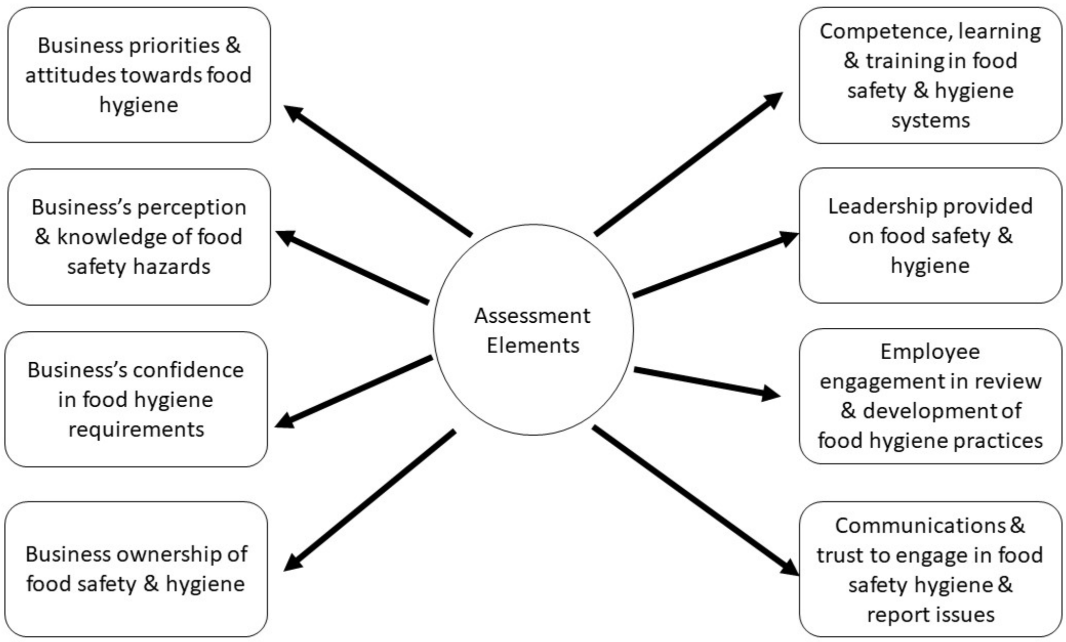
The finalised FSA / Greenstreet Berman model identifies five typologies or categories of food business, as shown in Figure 3.13

Figure 3.13: The FSA/ Greenstreet Berman Ltd Model: Model Categories or Typologies (Wright et al., 2012a, 2012b)



Eight elements of FSC are also identified (see Figure 3.14) and in the final toolkit, a set of questions pertaining to these elements is given, enabling enforcement officers to assess and categorise the FSC of FBOs. These assessment elements of FSC (Figure 3.14) link with the previously presented work on barriers to and drivers of FSMS implementation, e.g. knowledge (Gilling et al., 2001; Ball et al., 2009) and training in food safety (Jevšnik et al., 2006; Fotopoulos et al., 2011).

Figure 3.14: The FSA/ Greenstreet Berman Ltd Model: Assessment Elements of FSC (Wright et al., 2012a, 2012b)



Advice and guidance for each element in each category is then given to aid the enforcement officer in working with FBOs to develop their FSC. The tool kit also allows for two levels of analysis, depending on the time and resources available to the inspector, with analysis being based upon qualitative and quantitative data including documentation of, for example, the current FSMS and training logs, observation of working practice during the inspection and interviews / discussions with management and staff. As such, the practical application of the tool complies with recommendations given by Griffith et al. (2010b) that the assessment of FSC should vary with the needs of the investigation. The method also fits with the tri-component reciprocal safety culture model (Cooper, 2000), which is based on assessment of subjective internal psychological factors, observable safety related behaviours and objective situational features, and which Cooper proposes as a framework to assess and benchmark safety culture in organisations.

Some concerns with this model need to be highlighted. As described above, the published model includes not only an assessment model and method, but standardised ways in which inspectors can use the assessment to guide the FBO on FSC development. This lies in contradiction with the authors' statement that there is insufficient research to justify a maturity development model of FSC. From a practitioners' perspective, it is critical to understand if the approach offered in the FSA toolkit (Wright et al., 2012b) can enable an FBO to alter its FSC, and if this progression is, or should be, sequential in order to build steady improvements or if larger progressions can be made with certain cultural typologies missed out in the development process. Whilst subsequent work by Wright and Leach (2013) has proposed the application of the model alongside a simple framework to identify FSC changes required and to assess progress, further empirical work is required to ascertain the success of this approach.

Other concerns about the practical use of the toolkit (complexity, length, repetition, fit with existing food safety evaluation schemes) were identified by Nayak and Waterson (2017) who conducted semi-structured interviews with EHOs, academics and FBO managers.

One particular concern about the model relates to the number and descriptions of the culture types, especially with category 1, which describes a culture where the organisation consciously ignores or breaks food safety rules and laws. Whilst there is evidence of the existence of "calculative non-complier" FBOs (Powell et al., 2011) there is little evidence to date to quantify the number of businesses which could be determined as non-compliant due to this specific culture versus those businesses which are non-compliant due to ignorance. Indeed, it could be argued that the description of "calculative non-compliers" describes businesses who are perpetrating food fraud (intentional non-compliance, for economic gain) in some fashion, and the inclusion of this category conflates food safety and food fraud concerns.

In Nayak and Waterson's (2017) study, participants recommended that only three categories of FSC be used: non-compliers, pro-active compliers and leaders, due to concerns of reliability and complexity of the full model. Putting this aside, before the category of "calculative non-compliers" is utilised, further research is needed to determine if the "rule breaking" culture described in this typology can be seen as a state of (im)maturity and that organisations can develop better FSCs, or whether organisations possessing such cultural attitudes fit better with other change models.

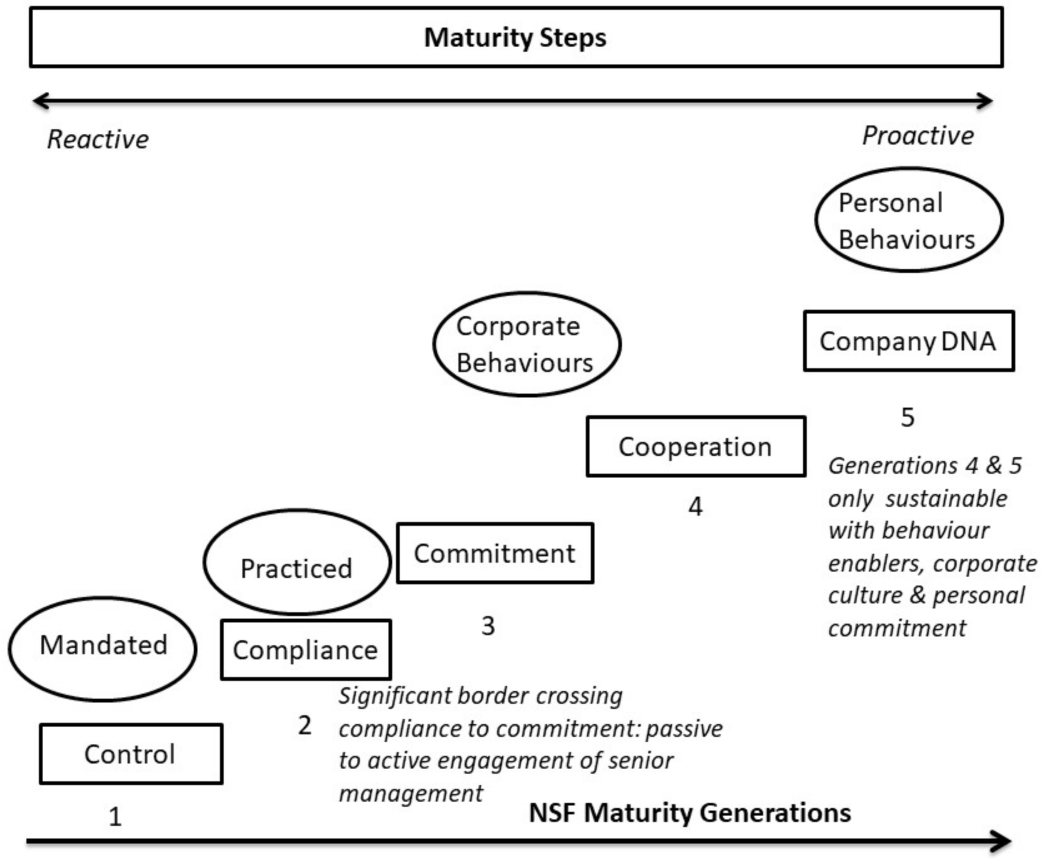
3.4.3.4 The NSF International Maturity Model (NSF International Ltd., 2014)

NSF International Ltd, an organisation which works across the world as consultants, auditors and certifiers for the food industry, has developed a corporate food safety maturity model (NSF International Ltd., 2014). It is proposed as part of a strategic tool to benchmark an organisation's internal FSMS, enabling management to identify strengths and weaknesses in the current system and so plan appropriate actions for further growth and development of the organisation's FSC (NSF International Ltd., 2014).

The NSF International tool kit also maps an organisation's perception of its current status versus an independent audit of actual status.   NSF International Ltd. (2014) set out that this enables organisations to more accurately prioritise areas for improvement.

The model is based upon a philosophy that organisational FSC progresses through different levels of sophistication or maturity, described in the model as "generations", as shown in Figure 3.15 below. The model also gives descriptions of each category or generation.

Figure 3.15: The Maturity Model Generations (NSF International Ltd., 2014)

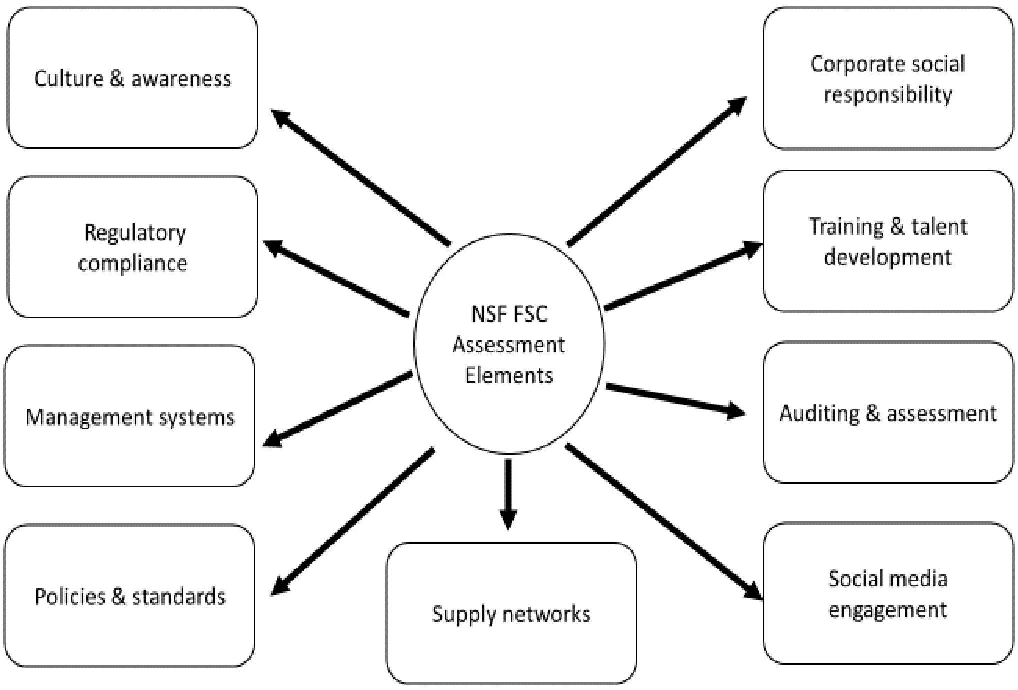


The tool is applied via a benchmarking exercise to assess perceived and audited food safety maturity status and is carried out using both qualitative and quantitative methods, including reviewing policies and procedures, assessment of plants and facilities, observation of operations, sampling (of products and / or raw materials), structured interviews with staff from front line to senior management, and on-line psychological assessments. The aim is to scrutinise the business on nine key dimensions or markers of food safety maturity, shown in Figure 3.16, across an FBOs operations.

Although it is possible to see some links between these dimensions and the barriers / drivers of FSMS implementation previously identified in Section 3.2 (e.g. training and development), the dimensions are far more general than the assessment criteria set out in the FSA / Greenstreet Berman model (Wright et al., 2012a, 2012b).

Similarly, whilst Wright et al. (2012a, 2012b) set out specific questions to be used by enforcement officers utilising the FSA / Greenstreet Berman model, the NSF International Ltd (2014) model is more generic. Specific questions for each assessment area are not set, rather areas of the business are identified for data collection, with the process requiring comprehensive auditing and staff interviews (NSF International Ltd., 2014). Despite this contrasting approach, this model also complies with the recommendations of Griffith et al. (2010b) and fits with the tri-component safety model (Cooper, 2000).

Figure 3.16: Assessment Elements for FSC in the Maturity Model (NSF International Ltd., 2014)



Looking at the typologies described in the NSF International Ltd. model, there is considerable overlap with the FSA / Greenstreet Berman model (Wright et al., 2012a, 2012b), key differences being in the lowest and highest categories.

For the highest category, NSF International Ltd. (2014) recognise a generation 5 category of excellence in industry leadership, which appears to go beyond the level of leadership envisioned by Wright et al. (2012a, 2012b). At generation 5, FSC is described as part of the "company DNA", being second nature to everyone in the organisation at all levels. In contrast, the leadership category described by Wright et al. (2012a, 2012b) fits more closely with the description of senior management commitment in the NSF model.

At the lowest level, both models describe organisations where foods safety is seen as being outside of the companies' priorities, is not budgeted for and where no or few policies and procedures exist. The key difference is that the FSA / Greenstreet Berman model describes a culture where the organisation consciously ignores or breaks food safety rules and laws. The NSF model does not imply such a criminal or immoral mind-set, but implies a neutral culture due to an ignorant or uninformed management and / or workforce.

The NSF International Ltd. (2014) model appears well suited to its intended use as a tool for use by consultants in assessing and developing culture in FBOs. The main drawback to this model is the lack of a clear description of the theoretical background and development of the NSF International Ltd. model, which perhaps results from the proprietary nature of the tool and its use by the organisation in their consultancy work. It might also be reasonable to assume that a large database of evidence exists within NSF due to the large number of FBO audits which will have been conducted over many years, and that this evidence informs the development of the maturity model.

However, the model is also more generic in nature than those already considered in this section of the thesis. Whilst set out as a maturity model of FSC, it might be equally applicable to evaluate and describe an organisation's health and safety culture or innovation culture, or any such subset of overall organisational culture. Taking this into account, together with the limited theoretical underpinning, and lack of transparency of evidence of empirical support, from an academic perspective, it appears necessary for the model to be subjected to rigorous testing and review before it can be determined as suitable as a theoretical framework for future research on FSC.

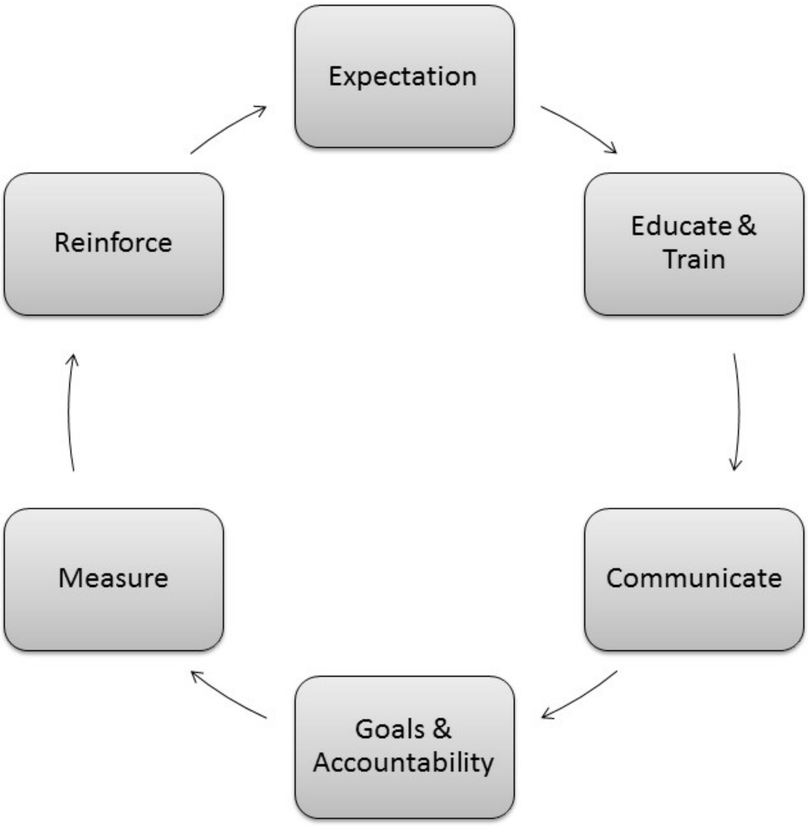
3.4.3.5 The Behaviour-Based Food Safety Management System Continuous Improvement Model (Yiannis, 2009)

Yiannis's (2009) book on FSC presents a view that FSC is critical to making the behavioural changes required in the food industry in order to improve the delivery of safe food. FSC is presented as being "owned" by the leaders of an organisation and, in a similar fashion to that proposed by Schein (2004, p23) with respect to general organisational culture, FSC is seen as an aspect of an organisation which can be changed and developed by the organisation's leaders.

Yiannis (2009) presents a behaviour-based continuous improvement model which he proposes as a systematic way to create or strengthen the FSC of an FBO. This is shown in Figure 3.17.

As a food safety practitioner, Yiannis does not present any specific empirical data to substantiate his model, rather presenting it as the result of his long career in the field. Despite the practitioner development of the model, its theoretical basis is presented, with Yiannis referencing a plethora of behaviour change theories and models, ranging from Skinner's work on operant conditioning (Skinner, 1953), through to social cognitive theory (McAlister, Perry, & Parcel, 2008).

Figure 3.17: The Behaviour-Based Food Safety Management System Continuous Improvement Model (Yiannis, 2009)



Whilst measurement is one of the elements of the model, no framework is presented to assess or categorise an organisation in terms of FSC. Therefore, Yiannis's (2009) model represents a tool which FBOs can use to change (and hopefully improve) their FSC, rather than a tool to assess or categorise the current cultural status. It might therefore be better viewed as an adjunct to other models, as a way of enabling an FBO to progress up the maturity generations (NSF International Ltd., 2014) or through the FSA / Greenstreet Berman typologies (Wright et al., 2012a, 2012b).

Likewise, as a change model, there is little specific overlap between this model and the specific barriers / drivers of FSMS implementation addressed in Section 3.2. However, this model could, in theory be used to address not only change in FSC but also in process barriers to FSMS implementation (for example, addressing specific concerns about completion of HACCP documentation, or the process of hazard analysis). From an academic perspective, research is required to demonstrate the effectiveness of the model as a tool to drive change before it can be used as a standalone framework for future research on FSC specifically or the improvement of FSMS implementation in general.

3.4.3.6 Food Safety Culture Model (De Boeck, Jacxsens, Bollaerts & Vlerick., 2015)

In contrast with the previous models reviewed, De Boeck et al. (2015) endeavour to develop a model which differentiates between overall FSC and food safety climate. They define FSC as "the interplay of the food safety climate as perceived by the employees and the managers of a company (so called *'human route'*) and the context in which a company is operating, the current implemented FSMS, consisting of control and assurance activities (so called *'techno-managerial route[19]'*) resulting in a certain (microbiological) output" (De Boeck et al., 2015). This is illustrated in Figure 3.18 overleaf.

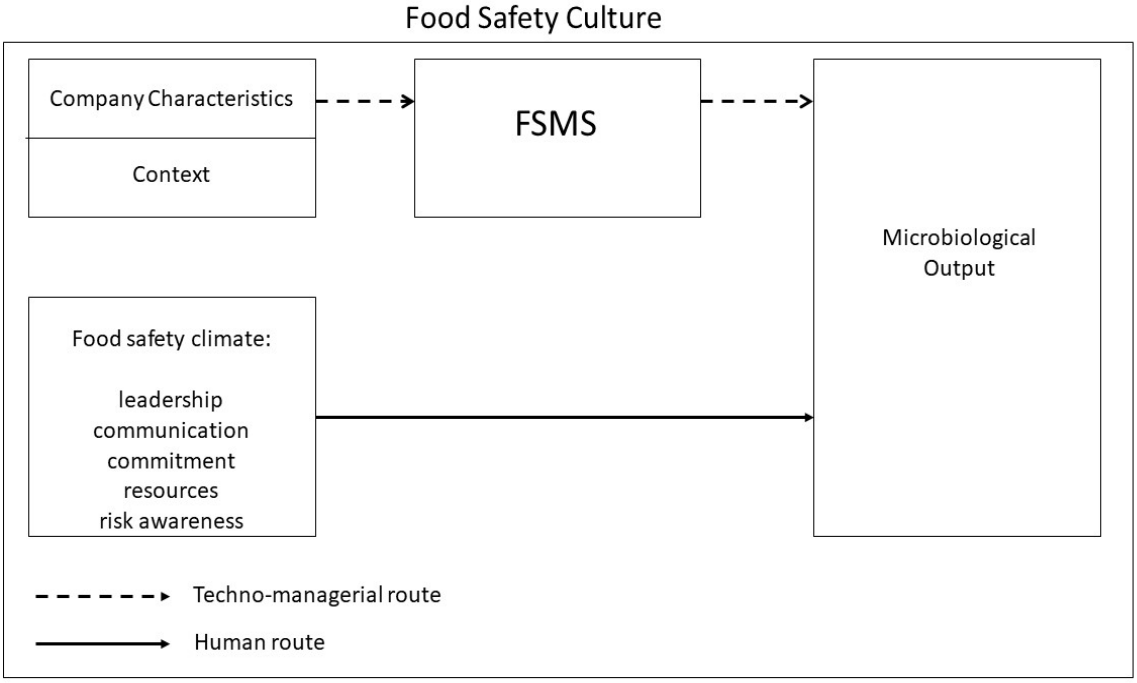
Whilst De Boeck et al. make the distinction between FSC and food safety climate, they acknowledge that confusion exists between the two terms. Indeed, in developing their model they not only reference previous work on FSC by Yiannis (2009), J.Z. Taylor (2011) and others, but draw heavily on the FSC model of Griffith et al. (2010b), who themselves recognised the confusion between FSC and climate.

Again, there is coherence between the factors which De Boeck et al. (2015) set out as components of food safety climate and barriers / drivers to FSMS implementation. Of particular note is the inclusion of "resources" as a component. Although J.Z. Taylor (2011) also included resources as one of the underlying components of her framework for FSC, it was not specifically included in her later FSC Excellence model (J.Z. Taylor et al., 2015). However, a lack of resources – both financial and human – are recognised as

[19] The techno-managerial route is based on previous work by the research group including Luning et al. (2011) and Luning et al. (2015)

barriers to FSMS implementation (Jevšnik et al., 2006; Fotopoulos et al., 2011) and can be seen as "process" related barriers. Therefore, similarly to J.Z. Taylor et al. (2015) there is an implication that process elements impact FSC.

Figure 3.18: Food Safety Culture Model (De Boeck et al., 2015)



De Boeck et al. (2015) also present a number of questions for each component of the food safety climate element of their model, which together comprise a tool to assess food safety climate through the means of a survey. This tool was first assessed by a number of experts from regulatory agencies, certification bodies and FBOs, before being utilised in a pilot study to assess food safety climate in eight affiliates of a large meat processing company, where the results of staff and management were elaborated and compared. A benefit of the tool appears to be its ease of use (taking only five minutes to complete) and the ability to compare management and staff findings pictorially, although the authors note that further research and refinement of the tool is required.

One puzzling point about this model is the restriction of the proposed impact of FSC / climate to that of a microbiological output. The control of microbiological contamination is certainly key to food safety, but is by no means the only food safety hazard which results in food incidents and recalls, or in foodborne illness (as discussed in Section 3.3) and that could be expected to be impacted by FSC or climate. This restriction perhaps mirrors the research groups' previous areas of specific interest (e.g. Jacxsens et al., 2015), although more recent developments of the model have expanded the outputs to a more general target of "food safety; food quality and hygiene" (De Boeck, Mortier, Jacxsens, Dequidt, & Vlerick, 2017).

This recent publication (De Boeck et al., 2017) also expanded the model, by splitting the "human route" into an organisational and a personal level, with food safety climate impacting individual behaviours (compliance and participation), which then lead to the output of the system. Job burnout and stress were postulated as moderators of the system, as were knowledge and motivation. This revised model was tested in two Belgian vegetable processing companies, with the authors concluding that a better FSC / food safety climate was indeed positively associated with food safety behaviour, with knowledge and motivation acting as partial mediators of the effect. However, neither job burnout nor stress appeared to have a mediating effect (De Boeck et al., 2017).

Overall, the studies demonstrate that the model and survey tool can be utilised to understand and assess FSC / climate and confirm the importance of human factors in the context of food safety.

3.4.2.7 Food Safety Culture Dimensional Framework (Jespersen, Griffiths & Wallace., 2017)

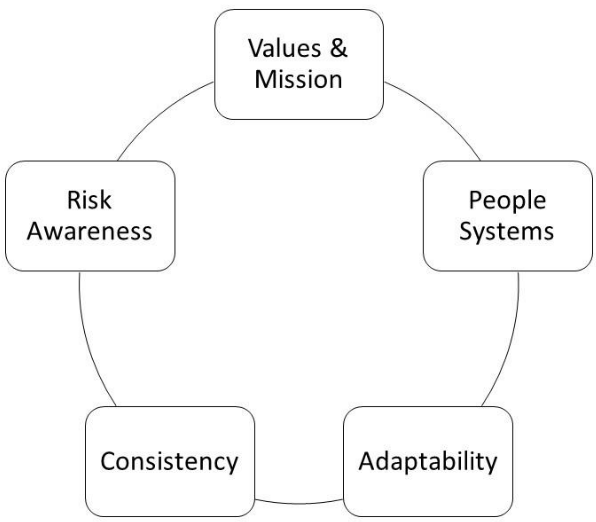
Having previously developed a model of food safety capability areas and maturity (Jespersen, Griffiths, Maclaurin, Chapman, & Wallace, 2016), Jespersen et al. (2017) now present a dimensional framework, based upon their own work, other models of

FSC (De Boeck et al., 2015; NSF International Ltd., 2014; J. Z. Taylor et al., 2015; Wright et al., 2012a, 2012b) and the work of Ball et al. (Ball et al., 2009; Wilcock, Ball, & Fajumo, 2011) on FSMS implementation, together with one model of quality culture and one of safety culture.

Jespersen et al. (2017) applied a systematic framework to evaluate the models, carrying out a content analysis of each of the other models. They identified five affinity groupings of FSC dimensions which form their framework, as shown in Figure 3.19.

Given that the dimensional framework has been developed from other models of FSC and models of barriers to / drivers of FSMS implementation, there is obvious synergy between the components which make up each dimension and the barrier to / drivers of FSMS discussed in Section 3.2. For example, the dimension of people systems includes components such as training and communication.

Figure 3.19: Food Safety Culture – Dimensional Framework (Jespersen et al., 2017)



Whilst no details are given within this paper about the measurement of FSC, previous work by the group has utilised a survey tool to assess FSC maturity (Jespersen et al., 2016). Subsequently Jespersen and Wallace (2017) have utilised the dimensional framework to assess the FSC of five multi-national food companies, utilising a self-assessment questionnaire sent to employees; analysis of food safety documentation (audit reports, food safety meeting minutes, inspection reports, GMP records) and semi-structured interviews with senior production plant and food safety staff. The researchers concluded that using the three different methods to triangulate the results was critical to ensure that the FSC maturity of each plant was correctly classified, as relying on a single method gave different results (Jespersen & Wallace, 2017).

The strength of this model is that it not only synthesizes work in the field of FSC, but that it has already been demonstrated as an effective tool for use in the research of FSC. However, further details of the assessment methods, and work demonstrating the successful application of the model in a range of FBOs, and by other researchers, practitioners and enforcement officers, is required before the model can be adopted as a standard across the industry.

3.4.5 Summary

Seven models of FSC have been reviewed in this section. As work has progressed in the area of FSC, models have developed, from frameworks setting out an understanding of FSC (e.g. Griffith et al., 2010b) and practice models to improve FSC within businesses (e.g. Yiannis, 2009), to more complex models which attempt to combine a descriptive framework of FSC with categorisation or measurement of FSC using a variety of methods.

The theoretical underpinning of the models varies, with reference to theories of general organizational culture, organizational safety culture and theories of behaviour change. In addition, the relationship between barriers to the implementation of FSMS reviewed in section 3.2 can also be clearly seen in many of the models, in the description of elements which make up FSC and / or in the descriptions of different FSC typologies. Primarily the FSC models show coherence with barriers / drivers previously categorised as “people” related elements of FSMS implementation, such as training, commitment and communication. However, the models of J.Z. Taylor et al (2015) and De Boeck et al. (2015) imply that process related factors (resources, systems) directly impact FSC.

Of all the models reviewed, those available as commercial packages for FSC assessment (NSF International Ltd., 2014; J. Taylor et al., 2015) have been most extensively used. However, little of this data has been made available for peer review and publication and so the robustness and reliability of these models cannot be fully ascertained. There is growing empirical data to support the models of De Boeck et al. (2015) and Jespersen et al. (2017), demonstrating that not only has FSC become an increasingly important topic for food safety professionals but a key area for researchers in food safety. The model of Jespersen et al. (2017) shows particular promise as a synthesis of key work in FSC.

One important area to consider is that of the assessment or measurement of FSC. Whilst J. Z. Taylor et al. (2015) and De Boeck et al. (2015) have focussed on developing quantitative survey tools which can be quickly and easily used by organisations, the other models appear to require a combination of measurement methods, combining audit methods (examination of documents, observation etc.) with qualitative interviews and staff questionnaires. Indeed, Jespersen & Wallace (2017) recommend this approach as having greater reliability than using a single method.

However, a challenge faces industry, enforcement officials and researchers in utilising a “mixed methods” approach to assessing FSC. Many of these methods (interviews, questionnaires, reviews of policies and procedures) take considerable time and effort to apply. They do not easily form part of an on-going, day in, day out, performance monitoring system within an FBO, being more suited for use on an intermittent basis. Even short, quantitative surveys (such as utilised by J. Z. Taylor et al., 2015) can only be used periodically if their integrity is to be maintained. Other measures which can be used more frequently or even daily, such as a review of customer complaints or observation of staff working practices, can be related to some assessment elements, but would require organisations to develop appropriate structures to capture, report and review such data. Whether such measures are being considered or used by FBOs as a measure or proxy measure of FSC is a gap in the literature. Likewise, while FSC was introduced as a factor in some of the food safety incidents discussed in Section 3.3 (e.g. Wright (2016); see Appendix A for details), there is a relative paucity of empirically based studies on FSMS failures and FSC. This therefore leads to the third research objective, to evaluate the relationship of FSC to failures in FSMSs.

In summary, FSC can be considered a useful construct to bring together the people related barriers to the implementation of successful FSMSs, but challenges remain in the assessment of FSC particularly as part of standard practice by FBOs and enforcement officials. Returning to the question of whether people or process are the cause for failure of FSMS implementation (R. T. Mitchell, 1998), the balance of opinion from this work appears to be that a strong FSC is seen as a pre-requisite for ensuring that the process (the FSMS) can be applied correctly within an organisation.

Before concluding this literature review, the issue of finance and the cost of resourcing food safety should be considered. Cost has been recognised as a common barrier to FSMS implementation (e.g. Ehiri et al, 1995; Gilling et al., 2001). However, it has been suggested by some authors that implementing FSMSs will not only reduce costs to society through reduction of foodborne illness, (Kane, 2011), but may also improve business profitability (e.g. Jin et al., 2008). The following section briefly looks at the concept of Quality Costing and considers its use to understand the costs and benefits of HACCP and related systems in the food industry.

3.5 Quality Costing in the Food Industry

Quality costing is seen as one of the tools or techniques which organisations should employ in their pursuit of an organisation wide total quality management programme

(Dale & Plunkett, 1999, p 3).   Feigenbaum (1956) was one of the pioneers of this work, identifying the high cost of quality. Whilst Feigenbaum (1956) quotes anecdotal reports of quality-cost expenditures of 7 to 10% of the cost of sales, other authors suggest that properly measured costs can be much higher. Giakatis, Enkawa and Washitani (2001) report costs between 5 and 30%, whilst Dale, Reid & Bamford (2016) suggest that expenditure on quality can range from 5 to 25% of annual sales turnover.

In order to ascertain such figures, it is critical to define what is meant by the "cost of quality". In his publication on quality management for the food industry, Early (1995, p 33) summarised the cost of quality as "the cost of getting things right plus the cost of getting things wrong" or, put another way, the sum of the cost of conformance (to required standards) plus the cost of non-conformance. This fits with Feigenbaum's (1956) suggestion that costs can be attributed into three areas: failure (F) costs, appraisal (A) costs and prevention (P) costs, the so called PAF model.   This general classification was elaborated by the British Standards Institute in BS 6143 Part 2 (1990) splitting failure costs into internal and external failures costs.   Definitions of these categories are shown in Table 3.2.

The four-category version of PAF continues to be the most widely accepted model for quality costing (Chatzipetrou & Moschidis, 2017). However, there are criticisms of the PAF model, for example, Gryna (1999) suggests that this view is too limited, and that the cost of lost sales due to poor quality (generally a hidden cost to the business) and the cost of inefficient processes should also be included. Yang (2008) also proposes an extension to the traditional four-category PAF model, splitting hidden costs into extra resultant costs (items caused by failures or errors which can be trace and counted, such as increased engineering time or premium freight costs) and estimated hidden costs (cost items which are difficult to analyse and quantify such as loss of sales which can be estimated on the basis of lost market share, for example).

There is also debate in the literature as to whether costs should be termed “quality costs” / “cost of quality” or alternatively the “cost of poor quality” (Yang, 2008). Whilst Yang (2008) suggests that the terms are essentially synonymous, this potentially contradicts one of Feigenbaum’s (1956) original assertions, that quality can be improved – and the total cost of quality reduced – by increasing spending on preventative activities, i.e. that some costs are associated with meeting the necessary quality standards, rather than being a cost of poor quality. Feigenbaum (1956) further explains that allocating expenditure to preventative actions should reduce defects and hence failure costs, and, with more effective inspection and audit practices, also reduce appraisal costs.

As previously discussed, HACCP-based FSMSs are preventative systems, aiming to control food production to ensure that safe food is produced, rather than relying on the detection of “unsafe” foods. It might therefore be expected that in implementing HACCP-like systems, FBOS will see an increase in the “prevention” costs and a concomitant decrease in “failure” costs.

The use of the PAF model to measure the cost of quality in the food industry has been challenged. Dale and Wan (2002) evaluated four different quality cost systems in a food flavourings manufacturer and found that the lack of quality cost data recorded in the accounting team and the relative complexity of the process were barriers to the effective use of PAF by the organisation. However, most research on the cost of quality with FBOs continues to be based around the PAF framework.

Indeed, there has been a focus on using the PAF model to study and explain the costs of FSMSs (GMP and HACCP) either exclusively (Romano, Cavicchi, Rocchi & Stefani, 2004; Zugarramurdi, Parin, Gadaleta and Lupin, 2007; Lupin, Parin & Zugarramurdi, 2010; Waisarayutt and Wongwiwat, 2015) or alongside standards QMSs such as ISO9001 (Chayzipetrou & Moschidis, 2017; Moschidis, Chatzipetrou & Tsiotras, 2018). In contrast Omurgonulsen (2009) studied quality costs in the Turkish food industry, but did not specify what types of QMS or FSMS were employed by the participating FBOs.

The work of Lupin et al. (2010) is of particular interest. They are the only researchers to explicitly discuss and justify the study of the economic benefits of HACCP implementation through quality costing, identifying and categorising the costs of HACCP implementation and maintenance (and the costs of failures of HACCP) against the PAF model, as shown in Table 3.2, overleaf.

Moreover, Lupin et al. (2010) demonstrate that over a three-year period, the application of HACCP reduced the total cost of quality in three case study FBOs. As expected, with the implementation of HACCP, failure costs fell, while prevention costs rose. A somewhat unexpected finding was that appraisal costs stayed relatively constant, when it might be expected that appraisal costs would fall with a reduction in final product testing. Indeed, Feigenbaum (1957) suggests that appraisal costs should fall as product quality improves through spend on prevention of defects. However, Lupin et al. (2010) found that the fall in costs associated with final product testing was counter-balanced by an increase in monitoring costs at CCPs, together with the costs of record keeping etc.

Table 3.2 The PAF Model Categories and Examples Relating to HACCP (British Standards Institute, 1990; Lupin et al., 2010)

Prevention costs	The cost of actions taken to investigate, prevent or reduce the risk of non-conformity or defect. e.g. costs of HACCP plan development; training and communication on HACCP; design and development of measurements for CCPs; costs to implement and validate the HACCP plan; calibration and maintenance of equipment to test and measure compliance at CCPs; initial assessment, subsequent audit and surveillance of suppliers to ensure they meet required safety levels; cost of formal HACCP training; HACCP system auditing; analysis and reporting of safety data; safety improvement programmes.
Appraisal costs	The cost of evaluating the achievement of quality requirements including, including the costs of verification and control. e.g. pre-production verification of HACCP plan; inspection and testing of raw materials; initial and ongoing monitoring of CCPs and hygiene plans; materials consumed during analysis and testing; any intermediate or final product analysis; mandatory inspections by authorities; storage and filing of HACCP plans, test results etc.
Internal failure costs	Internal costs due to non-conformities or defects. e.g. Scrap (intermediate materials or final products that cannot be reworked for safety reasons), including labour and overhead costs; replacement of defective materials; rework and repair when possible; corrective actions following departure from critical limits at CCPs; testing, monitoring and verification of re-worked materials; downtime: cost of personnel and idle facilities due to product failures.
External failure costs	Costs arising after delivery to a customer, due to non-conformities or defects. e.g. complaints – cost of research and compensation; warranty claims related to safety issues' products rejected and returned; cost of concessions to retain customers (e.g. discounts following non-compliance situation); recall and withdrawal costs; product liability (cost of claims, plus cost of insurance premiums etc.)

Rather than looking at the impact of a FSMS / QMS on the cost of quality, the aim of Chatzipetrou and Moschidis (2017) was to understand if and how quality costing is used in the food industry in Greece and whether it helps to drive quality improvement and reduce production costs. Using a questionnaire approach (n=250) they found that quality costing plays a limited role in the industry. Their work supports the findings of Lupin et al. (2010) that FBOs spend more on prevention and appraisal costs than on failure costs. However, several limitations to the study were highlighted. Not only was the data self-reported but accounting systems used by FBOs did not record data in the specific categories utilised in the PAF method, and some costs could not be allocated using this model. This echoes the earlier work of Dale and Wan (2002) in that cost allocation against the PAF categories can be problematic.

In Turkey, Omurgonulsen (2009) studied the cost of quality using data from large food manufacturers (n=7) over the time period 2000 – 2005, and demonstrated the expected trade-off between conformance and non-conformance costs. However, whilst external non-conformance costs were shown to be reduced with higher conformance costs (prevention and appraisal), no relationship was seen with internal failure costs. Omurgonulsen (2009) suggests that with quality-based learning, non-conformance costs should decline over time, without a corresponding increase in spend on conformance, which might explain this finding. However, looking at the data on costs provided in the research paper, internal failure costs rose over the course of the study in five of the seven companies, with two companies seeing massive increases (over 8,000%). Without further information it is impossible to understand the cause of such increases, but they may have skewed the results of the study. There is also no indication in this work as to the QMSs / FSMSs employed by the participating companies. Although HACCP-based systems have been required under Turkish law since 2000 (Karaman, 2012), a number of studies have demonstrated poor uptake of HACCP (Bas et al., 2007; Karaman, 2012). It can therefore be postulated that at the time of the study the FBOS were not using HACCP-based preventative approaches and might therefore have been reliant on end product testing, with the concomitant expected higher cost of internal failures.

In summary, quality costing approaches appear to have some relevance in quantifying the potential financial benefits of implementing preventative based QMSs and FSMSs, and support the financial drivers for FSMS implementation identified earlier (Jin et al., 2008; Kane, 2011). However, work to date in the food industry supports more general findings (Williams, van der Wiele and Dale, 1999) of the challenges faced in attempting to use a traditional four category PAF costing method, particularly in terms of the availability of the required financial data. Given the preponderance of SMEs in the food industry, alternative costing approaches, as presented by Dale and Wan (2002) may be more practical to implement.

3.6 Conclusion

The aim of this literature review was to determine whether the extant literature could answer the question of whether failure to implement or maintain FSMSs was primarily due a failure with the systems or with the people implementing them, and from this to develop the central research question and objectives of the study.

To address this question, a number of models setting out barriers to, and drivers of, FSMSs have been presented and critiqued, then further challenged using published empirical research data and review papers. The barriers most commonly identified in the models examined concern people attributes: the knowledge, attitudes and behaviours demonstrated by staff and management towards FSMSs. However, process related barriers, particularly those relating to the complexity of systems and the time and resources (human and financial) to implement and maintain systems are also common across the models reviewed. Two of the models (Arpanutud et al, 2009; Kafetzopoulos& Gotzamani, 2014) also identify drivers or motivational factors for the implementation of FSMSs, such as a gain in social legitimacy, improved product quality and financial benefits. The key differences between the models lies in the links between and prioritisation of identified barriers. Staff and management commitment to food safety (and the implementation of systems to manage it), as identified by

Panisello and Quantick (2001), has been postulated as a fundamental requirement for successful FSMS implementation.

There are numerous studies examining barriers to / benefits of FSMS implementation in different countries and areas of the food industry, e.g. Jin et al. (2008) studied HACCP adoption in China whereas Dzwolak (2014) address HACCP implementation is small businesses in Poland. However, only a limited number of studies have directly considered work to address the barriers identified in the specific models of barriers to FSMS implementation. Of these studies, the work of the Salford research group (E.A. Taylor, 2008a, J.Z. Taylor, 20081a, 2008b etc.) is of particular interest as it concerns the application of the Gilling et al. (2001) HACCP awareness to adherence model to develop amended HACCP systems for application in the catering industry, i.e. work has focussed on modifying the FSMS "process" in order to reduce the barriers to FSMS implementation. Whilst J.Z. Taylor (2008a, 2008b) has claimed success in developing and implementing a modified HACCP-like process – and indeed this has been adopted by the FSA as the resource tool "Safer Food, Better Business" for SME food service outlets – limitations of the evidence base have been identified, primarily the limited nature of follow up with businesses implementing the modified system. It has also been noted that work by Fielding et al. (2011) to design and implement a similar system in a manufacturing setting was less successful and it is clear that the people and process factors are highly inter-related and that both sets of factors need to be addressed for successful FSMS implementation.

The concept of FSC was identified as possibly representing the people related factors impacting FSMS implementation and to be under-represented in this field of research to date, hence literature on FSC was also reviewed. Whilst a number of models of FSC are now available, there is a paucity of published, peer-reviewed empirical data on the application of these models demonstrating success in using the models to measure and / or improve FSC, the work of De Boeck et al. (2017) and Jespersen and Wallace (2017) being the exceptions. Thus whilst the construct of FSC is now well established, more research is required to further develop the area. In terms of FSMS implementation however, the conclusion can be drawn that FSC acts as a pre-requisite for ensuring the application of FSMS processes in an organisation.

Published reports of investigations into the causes of food incidents were also examined, in order to understand whether known system failures have been related to the FSMS process or the people utilising the systems. Data published by enforcement authorities in the US, EU and UK has been examined, together with reviews of the area published in the academic literature. In general, data published by enforcement authorities is targeted at establishing the food vehicle and / or hazard (e.g. specific microbiological contaminant) responsible for causing, or at risk of causing, foodborne illness and in aiding the effective withdrawal or recall of affected products from the market. Little data is available to ascertain the underlying causes of FSMS failures which have resulted in foodborne illness and / or product recalls. Within the academic literature there is a wide variation in study design and methodology, and it is not possible to draw any firm conclusion from this literature on detailed relationships between FSMS failure and food incidents. A detailed, comprehensive analysis of food incidents would require access to both company and enforcement official data and remains a gap in the literature.

This literature search has also identified a lack of research on FSMSs from the perspective of management control. However, given the focus of accounting and cost control as a form of management control, a brief review of the field of quality costing in the food industry was also undertaken. The majority of work uses the PAF model of quality costing (Feigenbaum, 1956) with Lupin et al. (2010) specifically studying the economic benefits of HACCP implementation through the PAF model of quality costing.

Returning to the question of whether people or process drive the success or failure of any FSMS, the literature reviewed fails to give a clear cut answer. Whilst people related elements are commonly identified, and a strong FSC can be considered a pre-requisite for FSMS implementation, most work on improving FSMS implementation has focussed on process change. It might therefore be concluded that to date, the argument is fairly evenly balanced as to whether the key to the success or failure of any FSMS lies with the people or the system itself.

Against the background established in the previous chapter of food safety governance and management control, a number of gaps in the literature have been identified, from which three objectives are identified for this research study[20]:

1. To determine whether food incidents can be related to specific people or process elements of FSMS failure.

2. To determine the extent to which the barriers to the implementation and maintenance of FSMSs (particularly HACCP) found in the literature can be used to explain failures in FSMSs.

3. To evaluate the relationship of FSC to failures in FSMSs.

Finally, the literature search has identified that whilst FSMSs can be considered as a form of management control system, there is a lack of research in the field using this outlook. This leads to the fourth and final objective[21]:

4. To investigate food safety management from the perspective of management control.

Taken together, these objectives will enable answers to be developed to address the overall research question for the study:

> "Why do food safety systems fail and how does this relate to the governance and management control of food safety in food manufacturers?"

[20] Although these research objectives and central research question are pertinent to all FBOs, the majority of reported food safety incidents refer to processed foods, hence a focus on food manufacturers is relevant to this research study.

[21] Although Quality Costing has been identified as a potential construct through which to explore food safety systems, there is no intention to conduct a costing exercise as part of the current research and no specific objective relating to quality costing is developed.

Having established the research question and objectives the following chapter will consider the philosophical underpinning and methodology of the study.

Pragmatic Constructivism (PC), a management control paradigm, is identified as fitting with the ontological and epistemological requirements of the study and its key concepts are presented and critiqued with reference to the management control literature. A multiple case study design, using food incidents[22] as embedded cases, is developed and the selection of two large food manufacturers, with well-developed FSMSs and QMSs and good food safety track records is explained. This enables the interplay between the generally effective, successful organisation and the failures of the food incidents to be examined and the data collection and analysis methods are presented in detail.

[22] The original intent for the research was to recruit organisations which had experienced food incidents requiring official notification and withdrawal / recall of products. Due to challenges in recruitment, the design was changed to study two organisations which had experienced non-reportable food incidents. This is explained further in Chapter 4, section 4.4.1.

4.0 Philosophical Underpinning and Research Methodology

Chapters 1 to 3 set out the background to the thesis, establishing that whilst FSMS can be considered as a specialist form of MCS, there is a lack of literature on food safety management and failures in FSMSs from this perspective. This chapter sets out the research methodology which incorporates the use of a management control paradigm – Pragmatic Constructivism (PC) - to inform both data collection and data analysis.

The chapter is structured as follows. First, the ontological, epistemological and axiological frameworks underpinning the mainstream food safety literature reviewed in Chapter 3 are considered, which helps inform the development of the pragmatic, constructivist philosophical stance used in this research.

Next, PC is identified and critiqued as a specific philosophical framework within the field of management control. A theoretical "roadmap" for the research is developed by combining PC with the concepts of people and process barriers to FSMS implementation, as presented in Chapter 3.

This leads to the third section of this chapter, which sets out the research design – a multiple case study with embedded critical cases of non-reportable food incidents[23] and presents the ethical considerations of the research. This is followed by a detailed description of the methods used for data collection and analysis, together with a discussion of how the quality of the research has been assured. A short conclusion completes the chapter.

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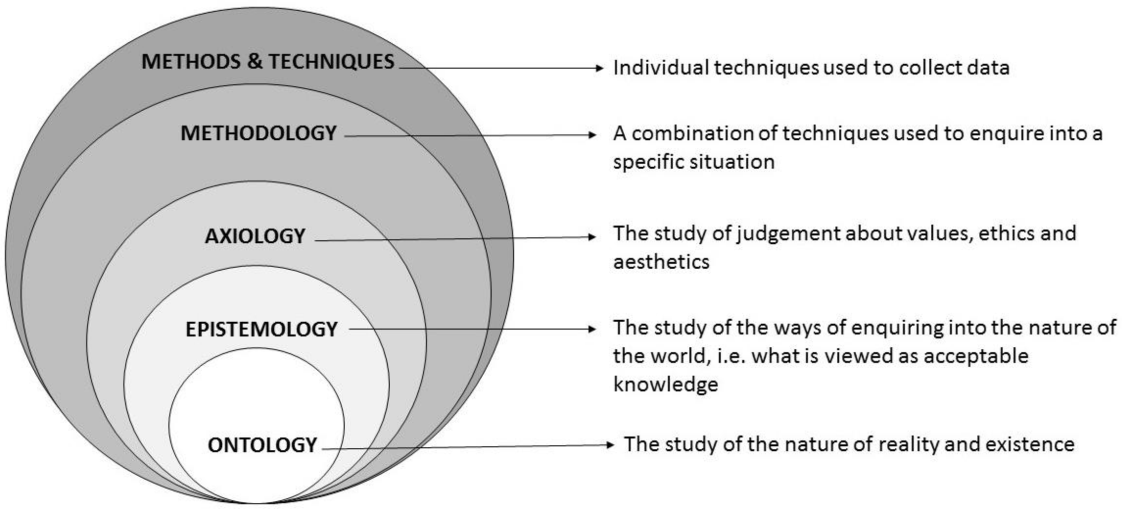
[23] The initial research design was developed with reported food incidents – i.e. failures of food safety – as the embedded critical cases. However, as discussed in Section 4.4.1, it proved impossible to recruit organisations to the study who had experienced such incidents. The study design was therefore modified such that non-reportable food incidents (internally managed food safety or quality issues) acted as the critical, embedded case studies.

4.1 Ontological, Epistemological and Axiological Frameworks within the Mainstream Research Field

Easterby-Smith, Thorpe and Jackson (2012, p 17) state three reasons for researchers to understand the philosophical issues underpinning management research: to clarify research design; to ensure that the chosen research design will “work” and to identify and create new research designs. The key areas of research philosophy which need to be considered are described in Figure 4.1.

Figure 4.1: Key Areas of Research Philosophy (adapted from Easterby-Smith et al., 2012, p 18)



In Chapter 3, a number of models of barriers to and drivers of the implementation of FSMSs and of FSC were identified. Whilst not explicitly declared by the authors, the research philosophy underpinning each model can be deduced through examination of the research methods and data analysis techniques used. Table 4.1 shows the range of ontological, epistemological and axiological perspectives used in these studies. The theoretical and quantitative based studies on FSMS models sit at the realist, positivist end of the spectrum. In contrast, qualitative studies, considering psychological barriers to FSMS implementation, appear to be framed against a relativist, constructionist/ constructivist paradigm[24]. The models on FSC show a similar range, with those looking at categorisation or typologies of culture appearing positivist and realist, whilst the more theoretically based tend to be relativist and constructivist in nature.

Axiologically, some researchers, such as Azanza and Zamora-Luna (2005), make clear attempts to position themselves so that their values do not impact their research. However, all the researchers show an inherent bias towards the subject in that FSMSs, particularly HACCP based systems, are seen as appropriate for assuring food safety, and a highly developed, or strong FSC is seen as desirable for all FBOs to attain.

Some FSC models have been developed from the broader field of organisational health and safety culture. Guldenmund (2010) reviewed work in this field, creating three categories of research on safety culture:

- The academic approach, giving "thick descriptions", predominately based on qualitative insight into the nature of an organisation's safety culture and historical in outlook.
- The analytical approach, based on survey research, which is quantitative in nature and considers the present nature of the safety culture in an organisation.
- The pragmatic approach, which rather than being based on empirical research is based on experience and expert judgement, and aims to improve an organisation's safety culture, i.e. it describes a desirable future state.

This categorisation gives another way to understand the dominant research philosophies in the field of FSC and FSMSs, particularly as the time horizon of research is another factor to be considered in determining appropriate research methodology (Saunders, Lewis, & Thornhill, 2012, p 128). Table 4.1 therefore also includes an analysis of models against Goldenmund's (2010) categorisation.

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[24] Constructionism / constructivism are used interchangeably across the literature. For the remainder of this thesis constructivism will be used as the preferred term.

The analysis shows that research on models of barriers to and drivers of FSMSs encompasses the spectrum of academic, analytical and pragmatic research traditions. A similar split is seen with the models on FSC, but inherent in all of these models is, to a greater or lesser degree, the pragmatic approach of a drive towards a future desirable state of a strong FSC.

Table 4.1: A Classification of FSMS / FSC Models by Philosophical Approach

FSMS Models	Summary	Philosophical Approach
Model to prioritise the HACCP plan (Panisello & Quantick, 2001).	This paper presents a theoretical model of barriers to the implementation of FSMS, derived from earlier published empirical work.	The authors present the model as the "one true way" to prioritise HACCP pillars, which was determined by study of previous work. They also state that the pillars (commitment, education and training etc.) can be difficult to measure. They therefore appear to be taking an ontological position of "internal realism" (truth exists but is obscure; facts are concrete but cannot be accessed directly) and an epistemological stance of positivism, i.e. the social world exists externally and can be assessed objectively (Easterby-Smith et al., 2012, p 22) The prioritisation of HACCP pillars within the model implies an axiology where the values of the researchers (a belief that HACCP is an appropriate system) have impacted upon the development of the model, which may be at odds with the positivist epistemological stance. *Guldenmund*: pragmatic approach.
HACCP awareness to adherence model (Gilling, et al., 2001).	This paper builds upon models of adherence to medical guidelines, utilising a predominately qualitative approach to analyse the results of 200 telephone and 5 in-depth face-to-face	The predominately psychological approach used to develop the model implies an ontology of relativism (i.e. there are many "truths" and facts depend on the viewpoint of the observer) together with an epistemological approach of constructivism (i.e. reality is constructed and given meaning by people) (Easterby-Smith et al., 2012, p 23). When considered with later work

	interviews.	by the same group (e.g. J. Z. Taylor, 2008b), the axiology of the research can be identified as "value laden", i.e. the researcher becomes part of the research. Indeed, in later studies emphasis is placed on minimising the impact of the researcher on the results by choosing a young, female, psychology graduate to conduct in-depth qualitative interviews. *Guldenmund:* academic approach.
Cognitive and behaviour model to HACCP principle adherence (Azanza & Zamora-Luna, 2005).	This paper sets out a hypothetical model of barriers to HACCP adherence based on concepts from models of physician adherence to medical guidelines and the work of Gilling et. al. (2001). The model was tested through quantitative analysis of a survey of HACCP team members in 4 food processors in the Philippines.	The authors present the model as a hypothesis to be tested using predominately quantitative methods, i.e. they present their research within an ontological framework of realism / internal realism and an epistemological approach of positivism. From an axiological perspective, the methods used endeavour to separate the researcher from the subject i.e. they purport a value-free stance. *Guldenmund:* analytical approach.
A model of food safety management system adoption (a tested model)	This paper sets out a number of hypotheses of factors that affect the adoption of FSMS, which are investigated using a survey	The natural sciences approach (hypothesis proposal; quantitative survey methods; randomised sampling; use of descriptive statistics and regression analysis to test the hypotheses), is strongly indicative of an ontology of realism, a positivistic epistemology and an axiology of value-free research.

(Arpanutud et al., 2009).	questionnaire, with a stratified random sample of Thai food manufacturing firms.	*Guldenmund:* analytical approach.
Factors influencing the implementation of food safety systems (Ball et al., 2009)	The researchers utilised qualitative methods: 13 semi-structured interviews with workers at 5 meat processing plants (purposive sampling) plus 2 focus groups with industry and government representatives, with analysis using NVivo 7 qualitative data analysis software.	Ball et. al. (2009) state that they "set out to gain insight into different views about factors that influence the adoption or implementation of FSMS", i.e. they adopt an ontological perspective of relativism. They also demonstrate a constructivist epistemological approach through their use of a combination of deductive and inductive data analysis. The authors accept that there may be some bias in data collection, due to both the subject selection and previous relationships between the researchers and focus group participants, i.e. they accept that axiologically, the research cannot be value free. *Guldenmund:* academic approach.
Critical factors for the effective implementation (CFEI) of ISO 9001 and HACCP (Kafetzopoulos & Gotzamani, 2014).	The authors set out a hypothetical model of CFEI for HACCP and ISO 9001 based on their previous research. Empirical data from an email / telephone survey of 347 Greek FBOs who have implemented both ISO 9001 and either HACCP or ISO 22000, is	This research uses a natural sciences approach, developing multiple hypotheses, using a quantitative survey and factor analysis to identify statistically significant CFEI. This indicates an ontology of internal realism and a positivist epistemology. Whilst the research methods indicate an axiology of value-free research, there is evidence that due to their previous work, the authors place a positive value on HACCP and related systems. *Guldenmund:* analytical approach.

	subjected to two levels of factor analysis, from which three of the CFEI are determined to make a significant contribution to the effective implementation of the systems.	
FSC Models	**Summary**	**Philosophical Approach**
Factors influencing food safety performance (Griffith et al., 2010b).	This paper presents a theoretical model of factors influencing food safety performance, including FSC, derived from studies of organisational safety culture in other highly regulated environments.	FSC is presented as an element of organisational culture, which by definition pertains to the work, values and beliefs of a group of people. Hence, the philosophical perspective of work on FSC by default accepts an ontological background of relativism or nominalism (that facts are human creations, with no recognised truth) (Easterby-Smith et al., 2012, p 19). This paper generates a theory, based on related work on organisation safety culture, and therefore fits an epistemological perspective of constructivism. The axiological basis of the researchers is not clear as no empirical research is presented. However, the researchers discuss the differences between positive and negative FSCs, implying a value laden position. *Guldenmund:* academic / pragmatic approach.

The Food Safety Culture Excellence Model (J. Z. Taylor et al., 2015; J. Z. Taylor, 2011).	This paper sets out a model of FSC, amended from that first proposed by J.Z. Taylor (2011), developed from a range of classical psychological and organisational culture theories, and presents an empirical case study applying the model in a large catering organisation in Abu Dhabi.	In proposing the original model, with its underpinning of psychological and organisational culture theories, Taylor (2011) appeared to demonstrate an ontological and epistemological approach of relativism and constructivism. However, the original qualitative assessment method for FSC has been modified to a survey for completion by groups of people, generating a numerical score in four FSC categories. As such, the authors appear to have shifted ontologically towards internal realism, and epistemologically towards positivism. There is a clearly value-laden axiological approach, evident in the title of the model (FSC excellence) and in the scoring system (1 to 5, with 5 seen as high or good). *Guldenmund:* analytical / pragmatic approach.
The FSA/ Greenstreet Berman Ltd model: model categories or typologies (Wright et al., 2012a, 2012b).	This work presents a typology of FSC derived from earlier work on organisational safety culture across a range of industries.	The typology is presented as a tool for use by safety inspectors, i.e. the authors give the model a realist and positivist perspective of the best or correct way to assess FSC. From an axiological perspective, the tool is presented as a “scientific” style tool (i.e. value free), however the typology is value driven, distinguishing and judging organisations in terms of attitude, behaviours and performance. *Guldenmund:* academic / pragmatic approach.

The NSF International maturity model (NSF International Ltd., 2014).	The paper presents a model of cultural maturity as a framework for organisational mapping and development.	NSF International Ltd. (2014) present this as a “best practice” model to be used with organisations to assess and improve FSC. As such they present the model within a realist and positivist framework. Axiologically, the method is set out as being independent of the assessors; however, the framework itself is not value free, as the higher levels of FSC are set as desirable for all FBOs. *Guldenmund:* academic / pragmatic approach.
The behaviour-based food safety management system continuous improvement model (Yiannis, 2009).	The paper presents a model of FSC development, based on a number of psychological and marketing theories and developed from the author’s experiences in the food industry.	Whilst recognising organisational culture and hence FSC as being based on group belief, values etc. (i.e. inherently relativist and constructionist), Yiannis (2009) presents the continuous improvement model as a systematic way to assess and improve FSC, i.e. he takes a realist and positivist approach to utilising the model. No empirical research is presented, so the axiological approach cannot be directly determined, but would appear to be value-laden as influencing change to improve FSC is the core purpose of the model. *Guldenmund:* pragmatic approach.
Food safety climate self-assessment tool (De Boeck et al., 2015).	De Boeck and colleagues present the development of a self-assessment tool for food safety climate (the “human route” for microbiological food safety) within a broader definition of FSC	Food safety climate and FSC are again presented as group phenomena, so a relativist, constructivist approach would be expected. However, similarly to J. Z. Taylor et al. (2015), the authors create a structured questionnaire which is scored, and basic statistical techniques are used to compare the results

	which also encompasses a "techno-managerial route". It is based on the five factors of FSC set out by Griffith et al. (2010b).	from staff and management respondents in a small pilot study, i.e. there is a shift towards a realist / internal realist and positivist approach. *Guldenmund:* analytical / pragmatic approach.
Food Safety Culture Dimensional Framework (Jespersen et al., 2017).	This paper presents a framework of FSC, developed as a collation of 6 existing models of FSC, one model of organisational culture and one of quality culture. A systematic, qualitative comparative analysis of the models was conducted, from which the dimensional framework was developed.	FSC is presented as a subset of organisational culture, and recognised as a group phenomenon based on values, beliefs and shared behaviours, i.e. relativist and constructivist. In axiological terms, the research is value laden, not only in the presentation of FSC, but in the methods used to develop the dimensions model, where each of the pre-existing models were critiqued for quality against National Research Council guidelines and for trustworthiness against a four-step validation strategy. *Guldenmund:* academic / pragmatic approach.

4.2 The Philosophical Approach of the Current Research Study

As demonstrated in the previous section, research on FSMSs and FSC covers the breadth of ontological and epistemological approaches from realist and positivist, to relativist and constructivist. The research generally takes an axiological stance of accepting FSMSs (including HACCP) as the appropriate means to assure food safety, believing that FBOs should strive to exhibit a strong FSC.

It was established through the literature review that FSC is a useful construct for further study into the people related elements affecting the implementation of FSMSs. Therefore, a philosophical perspective which encompasses the nature of FSC as a phenomenon generated by group understandings, beliefs and values is critical for the integrity of the research. The chosen philosophical perspective also needs to reflect the viewpoint established in Chapter 2 of food safety being socially constructed, rather than absolute.

From a philosophical perspective it is therefore difficult to justify a realist ontological approach, which would attempt to view FSC as "one truth", understood and acted upon in an identical manner by all people in an FBO. However, a relativist position, which would set out multiple "truths" or understandings of FSC may be too broad, as the essence of organisational culture and hence FSC is that of some common beliefs, values and understanding between organisational actors. Easterby-Smith et al. (2012, p 31) describe pragmatism as a philosophical approach which offers a compromise between (internal) realism and relativism, allowing for the creation of structures from the lived experiences of people.

In common parlance, pragmatic is often used as a synonym for practical, realistic or sensible, particularly when applied to problem solving. However, as a philosophy, pragmatism is far more complex and has undergone many transitions and modifications since the founding fathers, Charles Saunders Pierce (1839 – 1914), William James (1842 – 1910) and John Dewey (1859 – 1952) first developed pragmatism as a philosophy in the USA in second half of the 19th Century. Even at this time, there were differences in detail and approach, as Depew (1995, p 13) explains when he describes classical pragmatism as a “patchwork bricolage”, and the revival of interest, led by Richard Rorty (1931 – 2007) and Hilary Putnam (1926 – 2016) has further developed thinking in the area (Malachowski, 2004, *p xviii*). Putting differences aside, the notion of practical consequences is central to pragmatism, (Malachowski, 2004, *p xx*), but as Morgan (2014) emphasises, as a philosophy pragmatism goes beyond problem solving and beyond simply considering “what works”. Indeed, Rutherford (2013) explains that from a philosophical perspective “what works” must be thought of in terms of large scale, consistent and systematic application over time and across society. Morgan (2014) also demonstrates how pragmatism encompasses the circular relationship between actions and beliefs and how both actions and beliefs are socially shaped. Taken together these elements suggest a fit between the pragmatic philosophy and the concepts of FSC and organisational culture presented in Chapter 3.

Similarly, the research question and objectives fit with an epistemological perspective of constructivism, which focuses on understanding and appreciating the experiences of people (rather than relying on fundamental laws) and allows for the study of complex, whole situations, rather than taking a reductionist approach (Easterby-Smith et al., 2012, p 24).

At this point it is worth returning briefly to the question of whether truth is considered as absolute (there is one truth) or relative (there are multiple truths) in terms of food safety, particularly given the previously established perspective of food safety as being socially constructed. Generally, within social constructivism truth is viewed as relative; individuals, with their different world views, may perceive different truths or realities – as P. Berger and Luckman (1966, p 15) put it in their classic text, “what is ‘real’ to a Tibetan monk may not be ‘real’ to an American businessman”. However, some theorists within the field of social constructionism also accept that there are facts (or truths) which are independent of human perception, so called “brute” facts (Anscombe, 1958 in Searle, 1995). With regards to the current research it is clear that there are certain aspects of food safety which can be considered as “brute” facts, e.g.

the pathogenic nature of *Campylobacter jejuni* for humans is independent of perceptions of reality. Therefore, a philosophical approach which avoids the extremes of social constructivism, acknowledges "brute" facts and encompasses a group as well as an individual approach in knowledge creation and recognition, is required to fit with the subject area.

In considering the fit of ontology and epistemology against the research area, the philosophical framework or paradigm of Pragmatic Constructivism (PC)[25] was identified. Positioned primarily in the study of accounting as a management control practice (e.g. H. Nørreklit et al., 2010), PC does not simply blend pragmatism and constructivism, but is rooted across a number of epistemological perspectives: positivism, rationalism, constructivism and functionalism (Guven-Uslu, 2017). PC is used as a paradigm for understanding and conducting research on actors' construction of valid practice (H. Nørreklit et al., 2017), i.e. at its heart is a pragmatic perspective of sound and effective practice. Offering a middle ground between social constructivism and a realist, scientific approach (H. Nørreklit et al., 2017), PC fits with the philosophical needs of this research project and offers a suitable management control paradigm through which to study food safety management. The PC framework and some key concepts which are used in this research study are described in more detail below.

4.2.1 Pragmatic Constructivism and the Actor-Reality Construction

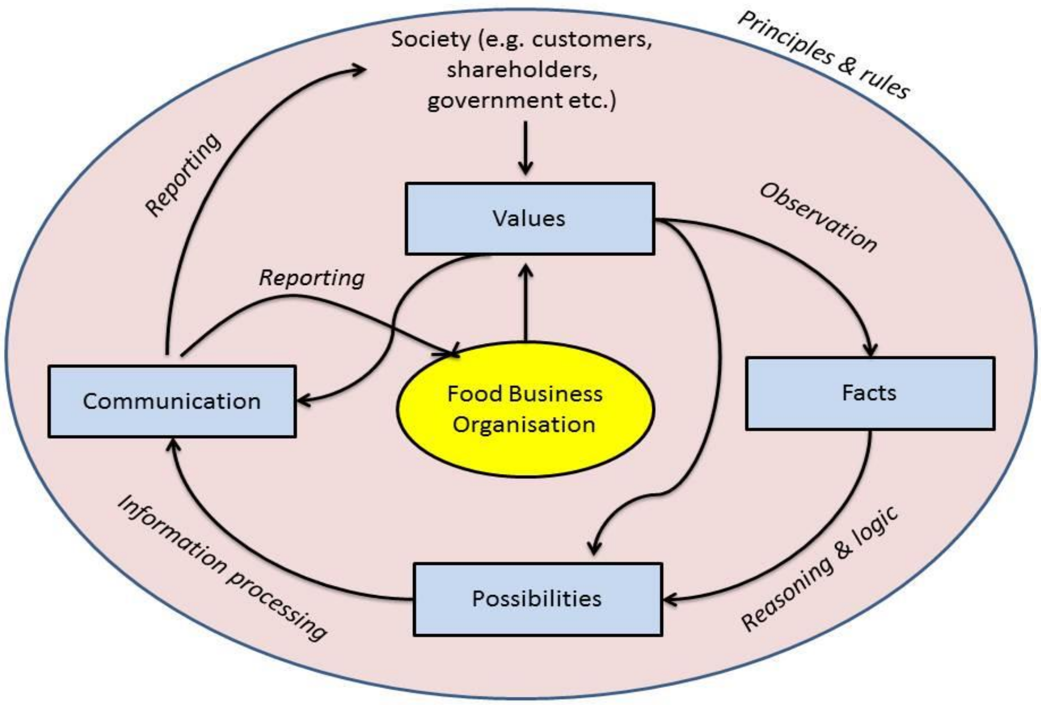
As outlined in the introduction to this thesis, there is wide variation in the definitions of management control and the conceptualisation of MCSs. Many definitions are "based on the assumption that someone (senior manager / top management team / dominant coalition) is seeking to control the behaviours of others (middle management, employees)" (Malmi & Brown, 2008). This approach can be considered

[25] Pragmatic Constructivism has also been used by Avenier and Thomas (2015) as another term for radical constructivism or teleological constructivism. However, in this thesis, PC refers exclusively to the framework as described and used within the Actor-Reality Construction as described by Nørreklit and collaborators.

a form of mechanical governance: rules and prescriptions are formed at the managerial level and used to control the activities performed by employees (L. Nørreklit, 2011; L. Nørreklit, 2017a).

In contrast to this approach, PC is positioned as a framework of actor-based governance, or "actor-reality construction". PC considers management control as an activity set in a social context, i.e. it considers that business and processes do not run "automatically", rather that organisational leaders' co-author the activities of the firm with other staff, treating them as inherently creative actors. The role of leadership is to create a set of business specific guidelines or concepts – a functioning and successful business reality - to encompass and inspire the co-authorship of actions. In the PC framework this reality is termed the organisational topos[26] and is achieved by the integration of four dimensions of reality: facts, possibilities, values and communication (H. Nørreklit et al., 2017; L. Nørreklit, 2017a), as shown in Figure 4.2.

Figure 4.2: A Framework for PC (adapted from H. Nørreklit et. al., 2010)



[26] Topos (singular) / topoi (plural) comes from the Greek, referring to a specific place or space. As L. Nørreklit (2017a, p68) explains "whereas a utopia is a non-existent place, an unattainable ideal, the topos is an existing place, the place of practice it controls".

As stated above, the topos should inspire and guide actors' actions to give success. This can also be expressed from an alternative perspective, in that only actions that integrate all four dimensions to form a coherent topos will ensure the relevant effect and bring about the intended causality (H. Nørreklit et al., 2017). That is, integration of facts, values, possibilities and communication is required for "construct causality" or to give the required cause and effect of any action or set of actions.

With its basis of the actor-reality construction, PC therefore offers an inclusive paradigm for understanding and researching the functioning of MCSs and one which fits with the concept of organisational culture / FSC as it encompasses the idea of collective involvement.

PC has been used in different ways by the research community: as a theory to be tested (e.g. Seal & Mattimoe, 2016), as a normative guide (F. Mitchell, Nielsen, Nørreklit, & Nørreklit, 2013), to guide the research process itself (e.g. H. Nørreklit, 2014) and to interpret and explain empirical data (e.g. Guven-Uslu, 2017; Jakobsen, 2017). For the current study, the intention is to use PC to develop a "theoretical roadmap", by combining the PC framework with insights from the "technical" literature reviewed in Chapter 3. This theoretical roadmap will then be used both to guide aspects of the research process (the development of theoretical themes, theoretical questions and interview questions) and in data analysis. These processes are explained in more detail in Sections 4.3.2 and 4.4.4 respectively.

Whilst the four dimensions and integration (leading to construct causality) form the core of PC, other related concepts - namely those of pro-active truth, pragmatic truth and the truth gap[27] - form a useful analytical tool. Pro-active truth is the expected outcome based on facts and analysis at the point of decision making, but before

[27] In common with constructivist epistemology, in the PC framework truth is generally considered to be relative (from individual or group perspectives), rather than absolute, with the exception of "brute" facts (Anscombe, 1958 in Searle, 1995). However, relative and absolute truth are not commonly discussed in PC, the emphasis instead being placed on potential differences between pro-active and pragmatic truth as two of the relative perspectives of truth and the analysis of the case studies using PC constructs in Chapter 7 will focus on pro-active and pragmatic truth and the truth gap, rather than absolute and relative truth.

actions have occurred, whilst pragmatic truth is an ex-post evaluation of the actual outcome. If pragmatic truth does not equal pro-active truth, then a truth gap exists (H. Nørreklit et al., 2017). This concept is used in studying whether there are differences in pro-active truth (the FSMS works) and the pragmatic truth (the experience of a serious, non-reportable food incident) in the case studies which form the basis of this research study.

This last section has focussed on setting out and explaining PC, demonstrating its attractiveness for the current research study in terms of its inclusivity driven by the actor centred approach, its fit in the philisophical middle ground between constructivism and realism and its pragmatic heart, where integration of the four dimensions leads to a functioning reality. Before considering limitations and challenges to the use of PC, it is also worthwhile to review it in light of Guldenmund's (2010) safety culture classifications. The nature of the four dimensions, where facts, values and communication sit in the present / past, and possibilities sit in the future, means that PC can, with the appropriate research methods, straddle Guldenmund's three approaches. For the current research study, which combines analysis of the organisation "today" (i.e. at the point of data collection) and analysis of an historical (albeit relatively recent) non-reportable food incident , the academic and analytical approaches dominate. However, as with other FSMS / FSC work, an element of the pragmatic approach is seen, particularly as the case study companies describe the activities undertaken to address the quality failures and improve working practices.

Returning to PC itself, there are, as with any philisophical approach, limitations and challenges in using it. The main critique of PC as a paradigm comes from Laughlin (2010), who was specifically addressing H Norrreklit et al.'s (2010) theoretical paper positioning PC as a pragmatic foundation for accounting practice. Laughlin challenged whether PC should be considered as a paradigm or a methodology. Indeed, the variation in terminology and classification of PC is one of the challenges faced in using it, and is specifically adddressed in the Researcher's reflections in Chapter 8. PC is relatively new and it is perhaps inevitable that terminology and concepts evolve and change as they are put into practice.

The second key limitation set out by Laughlin (2010) concerns generalisability; he suggests that PC is limited to characterising (an organisation) at a specific space and time, whereas for PC to act as a paradigm for accounting practice, generalisation from the specific to the global sense would be required. Whilst this might be a valid criticism and limitation of PC as a paradigm for accounting practice, this does not invalidate the use of PC to guide data collection, analysis and interpretation within a case study setting. Indeed, this is the way that PC has predominately been used to date (e.g. Guven-Uslu, 2017). Of course, the generalisability of findings is a limitation of case study research itself; this is addressed in section 4.4 and Chapter 8.

Other challenges to the use of PC relate to its primary use in studying different aspects of mainstream accounting and management control practices. Although PC has been used to study issues such as the strategic performance of organisations (F. Mitchell, et al., 2013; Seal & Mattimoe, 2014), there is no track record to demonstrate that PC can be successfully applied to study FSMSs. However, this challenge creates an ideal opportunity to contribute to the field by demonstrating the applicability, or not, of PC to the study of non-financial MCSs.

As might be expected, given the focus of topos creation to direct successful actions, PC has been primarily used in the study of functional (successful) MCSs, the study by Beusch (2011) perhaps being an exception. The use of PC to study specific failures, such as the quality failures acting as embedded cases in the current research, is therefore largely untested, but again offers an opportunity to contribute to the development of research in the field.

In conclusion therefore, PC presents as a framework which fits with the philosophical requirements of the current research. Whilst having a relatively limited track record of use, this in itself means that the current research will offer opportunities to make significant contributions to academic knowledge.

The following section moves on from the philosophical underpinnings of the research study to considerations of study design, the development of a "roadmap" to guide data collection and analysis in the current study, and ethical considerations.

4.3 Research Design, the Research "Roadmap" and Ethical Considerations

4.3.1 Research Design

A qualitative, case study approach was selected for this research study as it enabled the use of a real-world context to investigate the research question in depth (Yin, 2014, p 16). Case studies are frequently used to generate theory (Eisenhardt & Graebner, 2007), but can also be used to explore existing theory (Saunders, Lewis, & Thornhill, 2012, p 180). This approach therefore fits with the research objective of investigating food safety management from a management control perspective, and specifically using the PC framework within this.

By using two different FBOs as cases - with an internally managed, non-reportable food incident in each organisation acting as an embedded, critical case - both within and cross-case comparisons have been completed. The use of the critical cases also allows the research question to be framed against a potential failure of food safety governance offering the required insights to address research objectives one and two.

The overall research question set out for this research study is particularly suited to examination using an in-depth qualitative approach. Whilst qualitative methods cannot determine results which are generalisable to the entire food industry, these methods are well established in research of organisational culture / FSC and in researching barriers to the implementation of FSMSs, as discussed in Chapter 3. Qualitative methods also appear to offer advantages over quantitative methods in the study of FSMSs and food safety. Published research indicates a low degree of success in engagement with FBOs for large scale, randomised surveys in the area of food safety management (e.g. Fielding et al., 2011). Furthermore, quantitative methods have been criticised as inappropriate for work on food safety, as FBOs and enforcement officers have been shown to give opposing views of the success of FSMS implementation and food safety status within organisations (Yapp & Fairman, 2005). It is also notable that qualitative methods are rising in prominence within management control research (Spekle & Kruis, 2014), hence the use of qualitative methods fits with the fourth objective of this research study to consider food safety from this perspective.

4.3.2 Development of a Roadmap to Guide Data Collection and Analysis

Yin (2014, p17) asserts the use of a theoretical framework to guide both the data collection and analytical phases of case study research. It was not the intention of this research study to develop and test a new conceptual framework, but a “roadmap”, combining the PC framework with insights from the mainstream technical literature on barriers to and drivers of FSMS and FSC, was created to guide data collection and analysis. It became immediately evident that the complexity of FSMS / FSC models posed a hindrance to developing such a roadmap. Consequently, this work was simplified by simply referencing “FBO people” and “FSMS Process” as the two clusters of barriers to and drivers for FSMS implementation and maintenance. At a basic level FSC can be viewed as combining some of the people related elements affecting FSMS implementation, and hence is captured here in the “people” cluster. The resulting roadmap is shown in Figure 4.3 overleaf.

The theoretical roadmap can thus be considered as combining a “technical level”, based on the mainstream extant literature on FSMSs and FSC, with the framework of PC. This roadmap was then used to inform the development of theoretical themes, theoretical questions and interview questions, in an approach adapted from Wengraf (2001, p 63), as shown in Figure 4.4.

Figure 4.3: A Theoretical Roadmap to Study Food Safety Governance

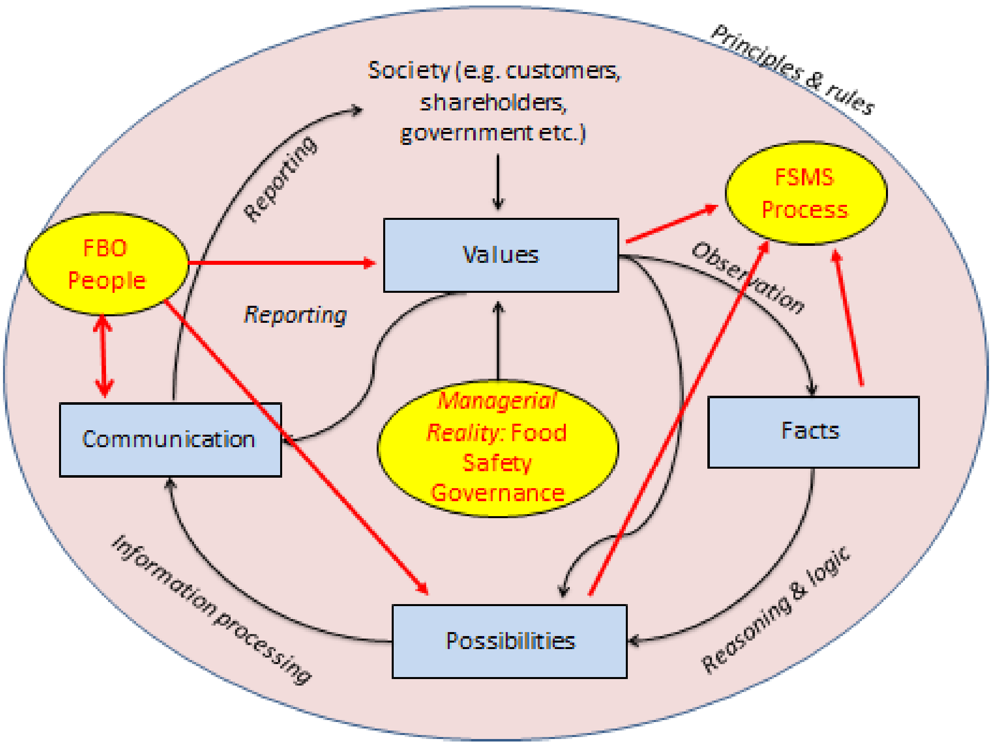
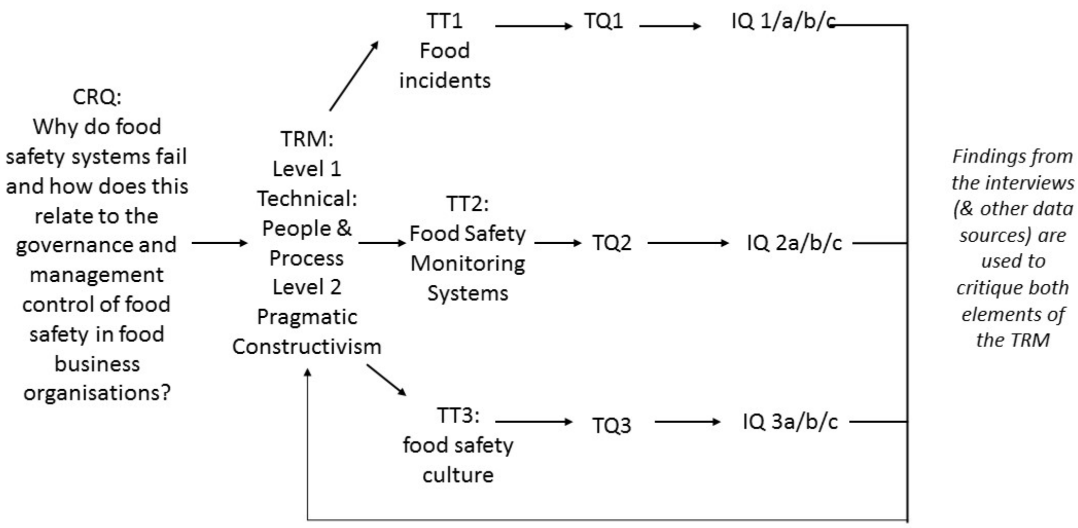


Figure 4.4: From CRQ to IQ, an Abductive Approach (adapted from Wengraf, 2001).



CRQ: critical research question; TRM: theoretical roadmap; TT: theoretical theme; TQ: theoretical question; IQ: Interview question.

An abductive approach was taken to the research, in that the theoretical roadmap not only informed the data collection, but was used to frame the data analysis. The research findings were used to explore the applicability of the roadmap (the people – process clusters from the mainstream literature and the PC framework and concepts) to the research on FSMSs and food incidents and to critique the underlying PC paradigm and concepts.

The case study approach allowed for the collection of data using several formats: observation during site visits, analysis of documents ranging from process plans to signage displayed in the production environment, and interviews. This allows for the process of triangulation, so that findings from interviews can be further substantiated, or challenged, by reference to other data sources, a process which increases the robustness of data analysis and strengthens the construct validity of the research findings (Yin, 2014, p 121).

Whilst Yin (2014, p 110) proposes the use of unstructured interviews to collect case study evidence, a semi-structured approach was decided upon using a standardised interview guide. In this way the three theoretical themes could be approached in a consistent manner, whilst also allowing some freedom to explore other relevant areas arising during the interviews (Bryman & Bell, 2015, p 213). The interview guide was developed and tested with five food industry experts (three senior quality / regulatory managers; one new product development director and one independent consultant in food safety / health & safety), all of whom had been involved in investigating and resolving food safety and quality incidents. In each case the theoretical themes, theoretical questions and interview questions (including prompts / follow up questions) were shared by email with the experts. Feedback was taken by telephone (3 experts), email (1 expert) or face-to-face conversation (1 expert) on whether the interview questions reflected the intended theoretical themes and questions, the clarity of the interview questions and suggestions for improvement. The experts were also consulted about the type of documents which would be useful to access to complement the information obtained in the interviews and enable triangulation of the interview data.

Finally, the interview guide was piloted by conducting an interview with the previous owner of a small dairy company. The final interview guide is given in Appendix G for information.

4.3.3 Ethical Considerations

In line with the University of Portsmouth Ethics Policy (Kolstoe, 2017), the research study was submitted for review and approval by the ethics committee of Portsmouth Business School (see Appendix H for confirmation of ethical approval). A number of key ethical considerations were identified and the approach taken to assure the ethical conduct of this research study is shown in Table 4.2.

4.3.4 Interim Summary

Having reviewed the philosophical background to the extant literature on barriers / drivers of FSMS and FSC, PC was identified as an appropriate management control paradigm with which to research FSMSs and food incidents and a theoretical roadmap was developed to frame both data collection and analysis.

A multiple case study design was developed, using non-reportable food incidents (internally managed failures in food safety or quality) as embedded critical cases, allowing for within- and cross-case comparisons, with data to be collected using interviews, observation and through studying existing documentation. A semi-structured interview guide was developed, with reference to the theoretical roadmap, reviewed by a number of industry experts and piloted. A number of ethical considerations for the research study have also been identified and outlined.

The next section of this chapter provides more detail on the methods of data collection and analysis (including the selection of case study organisations and individual participants), together with thoughts on the evaluation and assurance of the quality of the research study.

Table 4.2: Ethical Considerations for the Research Study

Ethical Consideration	Approach taken
Informed consent.	Informed consent was sought at both organisational and individual participant level; data collection commenced only after organisational consent had been obtained[28]. Information sheets and consent forms were developed for both organisations and individual participants (see Appendices E and F). Information sheets and consent forms were circulated to all individual participants by company gatekeepers prior to interview sessions being arranged. As all interviews / group discussions were recorded, with participants reminded of the study aims at the start of each session, verbal consent was also sought and recorded.
Anonymisation of data.	Companies and individual participants were assigned specific codes, used in place of names to identify recordings / transcripts etc. During transcription data was anonymised to remove references to individual and company names, products, locations of food business facilities etc. To facilitate the security of companies and individuals, electronic and physical copies of consent forms (giving both codes and identifying data) were stored in separate secure locations to recordings and transcriptions.

[28] In addition to the informed consent procedures approved by the ethics committee, LiquiComp UK required that the University of Portsmouth, on behalf of the University and the Researcher, enter into a Non-Disclosure Agreement which set down additional constraints on anonymity and data disclosure.

Data security.	All data (raw and analysed) has been stored securely on the university secured networked drive and / or in a secure, locked location (e.g. paper copies of consent forms, coding journal, case study logs etc.). Specifically, all interview recordings were made using a digital voice recorder (Olympus WS-852); interviews were then downloaded and stored securely on the university secure networked drive and deleted from the voice recorder. All transcription was completed by the Researcher, with transcripts stored on the secured networked drive. All data will be stored until publications (PhD thesis and academic publications including journal articles, book chapters and conference presentations) are finalised; this formed part of the organisational and individual consent obtained from participants. Due to the potential commercial sensitivity of the research, it has been determined that it is inappropriate for data to be available for open access, but anonymised data will be stored on the university data repository at the end of the research study.
Sensitivity of topic area.	Given the sensitivity of food safety and quality, it was anticipated that companies would perceive the data obtained as commercially sensitive and perceive there to be a reputational risk should data be inappropriately disclosed. This risk was managed by anonymisation and appropriate secure storage of all data.

Disclosure of food safety concerns.	Although the research was clearly positioned as exploring and understanding an historic food incident and current business practices from a management systems perspective (i.e. not an audit or food safety inspection of either the incident or current working practices) it was anticipated that during interviews participants might disclose concerns about the food safety of current working practices. To mitigate any concerns of exposure of the individual participant, or concerns about the wider safety of consumers, a protocol was established with each organisation giving a secure and confidential way for participants to report any safety concerns without involving their line manager or the gatekeeper (e.g. utilising company "whistle blower" hot lines). In fact, this protocol was not required when working with participants in either case study organisation.

4.4 Data Collection and Analysis

4.4.1 Case Study Selection

A purposive sampling approach (Bryman & Bell, 2015, p 429) was taken to select the case studies for this research, the intention being for the organisations to be "typical cases", and the incidents themselves to act as embedded "critical cases". Initially, a data base was constructed listing all UK business who had reported food safety incidents to the UK FSA between January 2013 and January 2015, with the intention that this form the population of possible case study organisations.

Due to the sensitive nature of the research, contacts were initially made with FBOs in the database through company employees (mainly senior technical and quality staff) known to the Researcher or supervisory team. Unfortunately, after a number of detailed conversations it became apparent that gaining access to study a reported food incident entailing a failure in food safety, was highly unlikely to be successful. Not only was the nature of the research challenging, but the fast-moving nature of the UK food industry acted as a barrier to access: brands had been sold, manufacturing facilities had been changed (particularly for contract manufactured brands) and contacts within organisations had changed.

An alternative study design, requiring access to study company QMSs/FSMSs in general and a past non-reportable, internally managed food incident was therefore developed[29]. Such incidents could therefore result from failures in FSMSs or QMSs or a combination of both. As discussed in Chapter 2, FSMSs are considered a sub-set of QMSs, so a close relationship between failures in both systems could be expected. Indeed, this is supported by the conflation of QMSs and FSMSs in some of the literature (e.g. Kafetzopoulos & Gotzamani, 2014; Mensah & Julien, 2011). With this modification to the study design, a snowball sampling approach was taken (Bryman &

[29] The change in focus to study non-reportable, internally managed food incidents, rather than reportable food safety incidents, reduced the risks inherent in the study, from an ethical perspective. Resubmission and re-approval by the ethics committee was therefore not required.

Bell, 2015, p 435), and a large number of UK FBOs were contacted (by email, telephone, at face-to-face meetings or via LinkedIn) with requests to participate in the study and / or place the Researcher in contact with other possible study participants.

After extensive discussions two large, well-established food manufacturers[30] agreed to act as research case studies. Both companies produce shelf stable products for sale in the UK and export markets and have long-standing QMSs and FSMSs, and both identified a recent (in the previous 6 months at the start of data collection) non-reportable food incident which had a high impact in the organisation and which could act as the embedded critical case. To preserve the anonymity of the organisations they are named as PowderCo UK and LiquiComp UK within this thesis. A full description of each is given in the presentation of research findings in Chapter 5 (PowderCo UK) and Chapter 6 (LiquiComp UK).

4.4.2 Participant Selection

Once organisational consent had been obtained, the Researcher worked with a designated gatekeeper to identify and contact potential study participants. Again, a purposive sampling technique was used, selecting participants who had been involved in the identified incident (incident investigation or resolution) and/ or whom were regular users of the organisational FSMSs / QMSs. An invitation letter, information sheet and consent form were supplied by email to the gatekeepers, with the request to pass these to every potential participant prior to setting up interviews. As detailed previously, verbal consent was also sought from individual participants at the start of each interview.

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[30] Whilst the majority of work on barriers to and drivers of FSMS implementation has been conducted with SMEs, the implications of failures in food safety / quality in large FBOs are potentially greater, given the volume of goods produced and the breadth of distribution of products both nationally and internationally. Similarly, whilst SMEs are recognised as facing specific challenges in implementing FSMSs (Food and Agriculture Organization of the United Nations, 2006), the investigation into failures of food safety / quality might be more enlightening in companies with established systems, rather than where systems are less developed. Thus, the use of large food manufacturers as case studies potentially strengthens, rather than weakens the robustness and relevance of the research study.

At PowderCo UK seven members of staff and management were initially interviewed, encompassing quality and production teams. During the initial data collection, the central role that the engineering team played in identifying and resolving the incident became obvious. Therefore, an additional interview was arranged with a senior engineer who had participated in the incident investigation and resolution. Details of the participants are given in Chapter 5.

At LiquiComp UK, a total of 17 staff and management were interviewed, from both head office and production sites. Details of the study participants are given in Chapter 6.

4.4.3 Methods of Data Collection

Semi-structured interviews were used as the primary method of data collection. In PowderCo UK interviews were held at the manufacturing site, with three individual interviews and one group interview (with five members of the site HACCP team) completed. In LiquiComp UK interviews were held at the head office (including one group interview, with one participant joining by telephone conference call) and at a manufacturing site; two individual interviews were also conducted by telephone. Interviews typically lasted just under an hour (range 33 minutes to 3 hours).

The use of a combination of individual and group interviews (and, indeed, the combination of face-to-face and telephone interviews) was driven by the availability of participants and access given to the Researcher by the case study organisations. A concern in using group interviews is the possibility of "group effects" (Bryman & Bell, 2011, p. 526), where interviews may be dominated by more voluble participants and other group members may feel unable to express alternative views. This may be of particular concern if certain participants are perceived to have greater authority or power than others. In order to minimise the impact of such effects, care was taken in facilitating group interviews, setting out ground rules at the start of the session (explaining that all views were welcome and that there were no right or wrong answers to the questions). All participants were encouraged to participate in the discussions, with the Researcher asking for specific input on the basis of job role, experience in other organisations etc. Despite this, it is of course impossible to ensure that that there is no bias in group interviews, or indeed in individual interviews. Therefore, in addition to interviews, in both case studies manufacturing site tours were undertaken and access was also given to a range of documents regarding general food safety and quality management practices and the specific incidents[31]. Triangulating information between interviews and with the observational and documentary data helped to assure the quality of data collection and interpretation.

Full details of the data collected are given for PowderCo UK in Chapter 5 and LiquiComp UK in Chapter 6.

4.4.4 Methods of Data Analysis

Before starting data collection, a decision was required about the intended method of analysis. This was important to set out prior to data collection, as it might influence both the collection and handling of data. For example, a method such as conversation analysis would require production of detailed transcripts from all interviews, complete with notation for pauses, timing of periods of silence etc. (Bryman & Bell, 2015, p 533). Indeed, Bryman and Bell (2015, p 579) neatly describe the challenge facing any researcher who undertakes qualitative research: “Because qualitative data deriving from interviews or participant observation typically take the form of a large corpus of unstructured material, they are not straightforward to analyse. Moreover, unlike quantitative data analysis, clear cut rules about how qualitative data analysis should be carried out have not been developed.”

[31] As discussed in Section 4.3.2, a target list of documents was developed with the input of industry experts prior to data collection. However, the exact documents reviewed in the case studies varied. In some instances, additional documents were made freely available, e.g. in PowderCo UK, the Researcher was able to observe and document data on posters displayed around the site. The Researcher also requested additional documents where they were required to explain aspects of the cases, e.g. in PowderCo UK the Researcher requested additional information about the practice of “Gembas” and was provided with a PowerPoint presentation explaining this.

This lack of clear cut rules is evident when prior research on benefits of and barriers to FSMS is considered. As shown in Table 4.1, much of this research is qualitative in nature, but only sparse details of the analytical methods used are given in publications. For example, Gilling et al. (2001) describe constructing "pen portraits" from the five narrative interviews they conducted as part of their research, whilst Ball et al. (2009) state they used NVivo 7 qualitative data analysis software to "identify patterns and themes" using a combination of deductive and inductive analysis.

For case study research, such as the current research project, Yin (2014, p. 136) suggests four general analytical strategies: relying on theoretical propositions; working your data from the "ground up"; developing a case description or examining plausible rival explanations. As the intention was already established with this project to use the theoretical roadmap set out in section 4.3 to inform the data analysis, using only an inductive from the "ground up" approach was deemed inappropriate. However, with the abductive nature of the study in mind, it was also necessary to allow new insights to be generated from the data to critique the roadmap and its underlying components, so a relatively flexible approach was deemed desirable. It was also judged important that case descriptions be generated, to allow both within and cross-case comparisons.

Thematic analysis is considered one of the most common approaches to qualitative data analysis, but one that has been criticised as lacking in specificity (Braun & Clarke, 2006; Bryman & Bell, 2015, p 599). Nonetheless, the basic approach of "identifying, analysing and reporting patterns (themes) within data" and describing the data set in "rich detail" (Braun & Clarke, 2006) fits with at least some of the requirements to build a case description. It is also possible to incorporate concepts or theories of interest into the theme identification process (Ryan & Bernard, 2003), hence this method allows incorporation of the desired abductive approach.

An analytical plan (shown in Table 4.3) was therefore developed utilising the six phases of thematic analysis developed by Braun and Clarke (2006) combined with the work of Guest et al. (2012, p 21 - 48) on applied thematic analysis. The theoretical roadmap was applied in two stages with the people / process clusters being considered in the initial thematic analysis, and the PC paradigm being incorporated in a separate stage of analysis as step 7. The coding and analysis was completed by the Researcher and discussed in detail with the Supervisory team, to sense check and verify both the inductively generated codes and themes and the second stage of analysis against the four PC dimensions.

Given the nature of the multiple case study design and this multi-step analysis, the report writing stage was also divided, with the production of single case study reports using the thematic analysis (Chapters 5 and 6) as step 8, followed by a separate report comparing the case studies to each other, the extant literature and the PC paradigm, presented in the thesis as the Discussion in Chapter 7. As a final step, respondent validation was completed by sharing the reports and seeking feedback from the gatekeeper contacts in each company.

Table 4.3: Thematic Analysis Phases and Description

Number	Phase	Description of process	PowderCo UK	LiquiComp UK
1	Write analysis plan	Preparation of analysis plan.	Plan created for each case study, including within and between case comparisons.	
2	Data familiarisation	Transcription of data; reading / re-reading data, noting initial ideas.	All transcription carried out by the Researcher using "Transcribe" (https://transcribe.wreally.com/) software to give an "intelligent verbatim" account of all individual and group interviews. This enabled both familiarisation with the data and enabled appropriate anonymisation of the data to be completed. Quality control was undertaken by completing a full playback and check of each script against the recordings.	
3	Generation of initial codes.	Coding interesting features of the data in a systematic fashion across the entire data set, collating data to each relevant code.	Codebook developed. Initial structural coding based on the theoretical themes which informed the creation of the semi-structured interview guide. Subsequent inductive coding. 53 codes created.	Initial structural coding not used, due to the more varied nature of the interviews (e.g. head office participants not able to discuss manufacturing plant FSMnS). Transcripts coded against codes created in PowderCo UK case, with

			All initial coding completed by hand; coding then transferred into NVivo (version 10; upgraded to version 11), for ease of data management.	51 of the original 53 codes used; an additional 30 codes created through inductive process, giving 81 codes in total. See Appendix B for the code book with examples, and Appendix C for an extract of a coded transcript.
4	Searching for themes.	Collating codes into potential themes and gathering all relevant data into each potential theme.	Themes created inductively using a clustering approach; 13 initial themes generated.	Each new code considered for categorisation against existing themes; no new themes created. Thematic maps created, clustering of codes to sub- and final themes and to the people / process clusters (Figure 6.6).
5	Reviewing themes.	Level 1 check: do the themes work against the coded extracts? Level 2 check: do the themes work against the entire data set? Generate a thematic map of the analysis.	Themes cross checked against coded extracts and entire data set. Several themes merged and 9 final themes generated. Thematic map created showing codes clustered to sub- and final themes and to the people /	

			process clusters of the theoretical roadmap (Figure 5.6).	
6	Defining and naming themes.	Refine the specifics of each theme and overall story. Generate clear definitions and names for each theme.	Specifics of themes reviewed; coherence also checked by mapping themes to show relevance to the embedded case (the incident) and overall organisational case (Figures 5.3. and 6.2 for PowderCo UK and LiquiComp UK respectively). Although the codes and themes were created primarily from the interview data, other data sources (documents, observations) are combined to triangulate the findings, verifying the themes and their impact on the overall case studies.	
7.	Analysis against theoretical roadmap.	Analyse the inductively generated themes against the analytical framework.	The 9 themes were mapped against the 4 PC dimensions. To check validity, the individual codes were separately mapped against the PC dimensions, and a comparison made of the locations of code to dimension when mapped at the theme level, and code to dimension when	The activity was re-run using the additional codes identified in the LiquiComp case study. No changes were made in the overall mapping of themes to PC dimensions.

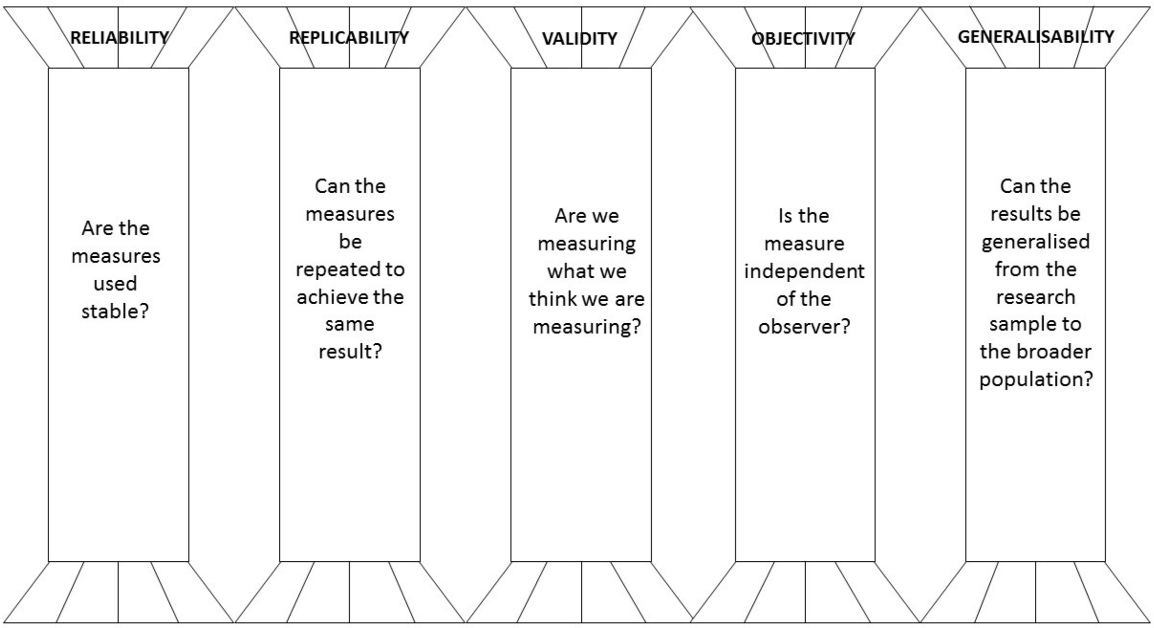
			mapped at the individual code level. Colour coded maps were created showing the relationship of the themes to PC dimensions, and codes and themes to PC dimensions.	
8.	Producing the reports: part 1 individual case studies.	Relate analysis back to research questions; selection of vivid, compelling extract examples; producing scholarly report.	An initial report was created of the PowderCo UK case (Chapter 5). This used the themes to describe and analyse the (i) embedded case (ii) organisational case and (iii) the relationship of the embedded case to the organisation. The “process” vs “people” clusters were also addressed in the findings.	A second report was produced using the findings of the LiquiComp UK case (see Chapter 6) as per the first case study.
9	Producing the reports: part 2, cross	Relate analysis back to research questions; selection of vivid,	Part 2 of the report is presented as the Discussion (Chapter 7), which entails a cross-case comparison for both the embedded and	

	case comparison; comparison with the literature and review against the theoretical framework.	compelling extract examples; producing scholarly report.	organisational cases; a comparison to the extant literature on FSMS and FSC, and finally a presentation and discussion of the results using the PC paradigm (including the four PC dimensions, integration for construct causality and the concepts of pro-active and pragmatic truth and the truth gap).
10.	Respondent validation.	Sharing of the research findings and analysis to ensure good correspondence between the findings and the perspectives of the participants.	It was not feasible to seek feedback from every individual study participant to validate the transcript of their interview (the Researcher was not provided with direct email access, for example). However, the relevant individual case studies and the cross-case comparison and discussion were shared with the gatekeepers from LiquiComp UK and PowderCo UK. This enabled assurance of anonymisation etc. for the organisations themselves and allowed the Researcher to ensure that there was good correspondence between the reported findings and the perspectives of the organisations. Minor amendments were requested, and in the case of LiquiComp UK, additional data supplied to support some of the research findings.

4.4.5 Evaluation of Research Quality

Understanding the quality and standard of research is of importance not only when considering the publication of research, but also to ensure that research is conducted ethically, for funding institutions to make or assess decisions on spend and, of course, for researchers themselves to evaluate the standing of their own work (Flick, 2007, p3). Quantitative research is traditionally evaluated using the criteria set out in Figure 4.5, but the applicability of this criteria to qualitative research has been questioned (Bryman & Bell, 2015, p 400; Flick, 2007, p15), given the differences in ontological and epistemological perspectives which often exist between researchers conducting quantitative and qualitative work. As Bryman and Bell (2015, p 400-401) explain, such criteria "presuppose that a single absolute account of social reality is feasible". However, this presupposition does not fit with the pragmatic and constructivist approach taken for the current research study.

Figure 4.5: Traditional Quality Criteria for Scientific Research



Nevertheless, ensuring that qualitative research is conducted with appropriate rigour and standards remains important (Anderson, 2017). To that end alternative criteria for qualitative research quality have been proposed (Anderson, 2017; Bryman & Bell, 2015, p 400; Tracy, 2010). The application of such criteria not only influenced the research design and methods used, but is evident in the production of this thesis. For example:

- the "worthiness" of the topic is set out in the introduction and background;
- the transparency of methods and challenges in undertaking the research is evident in this chapter and through the findings and discussion in Chapters 5, 6 and 7;
- the paradigmatic positioning of the research is set out here and forms a pillar of the discussion in Chapter 7;
- the resonance and credibility of the findings is evidenced by the "thick description" of the case studies given in Chapters 5, 6 and 7;
- the credibility and consistency of findings has also been supported by the triangulation of the findings from the semi-structured interviews with other data sources (observation and documentation) and the use of respondent validation with the company gatekeepers.

4.5 Conclusion

This chapter started with a review of the philosophical approaches taken in key papers on FSMSs and FSC. From this, a pragmatic and constructivist perspective was identified as an appropriate fit with the field. The specific paradigm of PC, developed in the management control literature, was identified and used to build a theoretical roadmap to inform the current research study.

The selection of PC as a management control paradigm for this research study leads to a modification of the fourth objective of the research, as follows:

4a. To investigate food safety management from the perspective of management control, utilising PC, in order to ascertain the utility of PC for studying control systems outside of the mainstream of accounting.

4b. To gain insight on the use of PC in cases of management system failure, as well as management systems under control.

With the overall research question of “why do food safety systems fail ...” and the objective of studying past food incidents to examine this, a qualitative case study methodology was selected, to enable the in-depth investigation of food safety failures in a real-world context. However, as discussed, it proved impossible to engage any FBOs who had reported food incidents (due to food safety failures) as research participants. Hence, an alternative approach was taken, using non-reportable, internally managed food incidents (resulting from failures in FSMSs and / or QMSs) as the embedded cases, and the cooperation of two large UK based food manufacturers was obtained through purposive, snowball sampling.

With the collection of data primarily through semi-structured interviews (informed by the theoretical roadmap), along with documentary evidence and observations, a systematised form of thematic analysis was developed (Braun & Clarke, 2006; Guest et al., 2012, p 21 - 48). Lastly, ethical and quality considerations of the research have been presented, both of which are critical in the research process.

The next three chapters of this thesis present and discuss the results of the research. Chapters 5 and 6 present PowderCo UK and LiquiComp UK respectively, considering the embedded and overall organisational cases. The comparison of the two cases – again looking at the embedded critical cases and overall organisations – is discussed in Chapter 7. The study findings are also considered in light of the extant literature on FSMSs and FSC and then against PC as the management control paradigm underpinning the study.

5.0 Case Study 1: PowderCo UK

Having set out the philosophical background to this research study and detailed the methodological approach taken, we now turn to the case study investigations themselves.

This chapter details the results of the first case study. PowderCo UK is a long-standing food manufacturer, which operates a comprehensive QMS and FSMS, both of which are accredited to external standards. Despite this, in the summer of 2015, PowderCo UK experienced a food incident: a defect arose in some manufacturing equipment, resulting in the formation of very fine metal shards which contaminated a powdered food product. Although upon investigation the incident was deemed not to require reporting to the FSA, the incident was discovered to result from failures in the QMS and FSMS and had a large impact on the organisation. This incident therefore forms a suitable critical case for the current research.

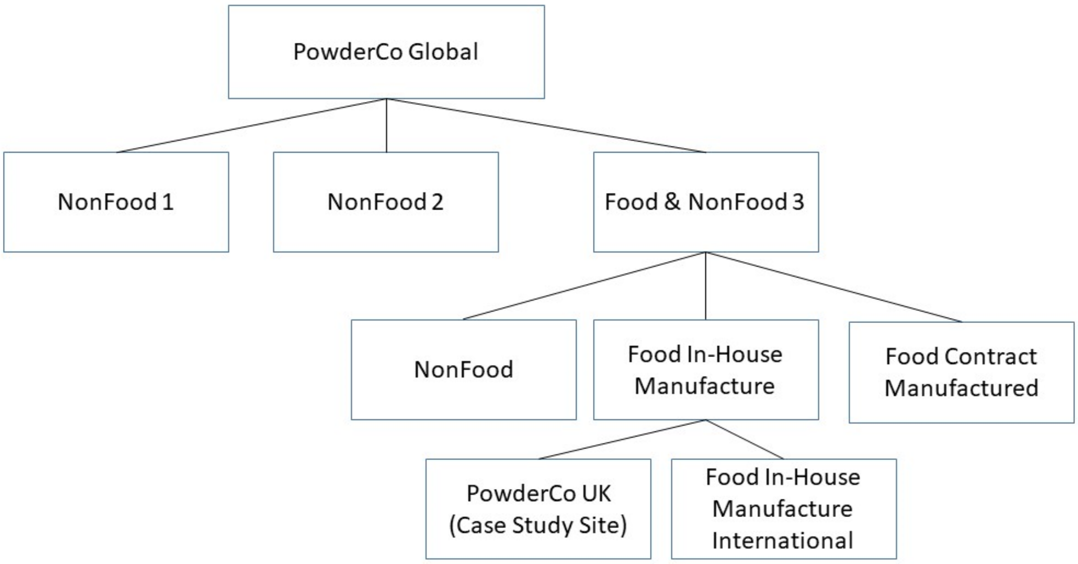
The chapter is organised as follows: section 5.1 gives a brief background to the organisation; section 5.2 describes the specifics of data collection and analysis related to this case, whilst section 5.3 discusses the findings of the thematic analysis, split into an initial examination of the incident, followed by broader findings related to the overall organisation. Finally, section 5.4 addresses the relationship between the embedded critical case and the overall organisation, with a view to answering the question of whether people, process or a combination of the two are to blame when FSMSs or QMSs fail.

5.1 Company Background

PowderCo UK is a manufacturing plant for powdered food products. It is part of a large multi-national organisation which develops, manufactures and markets food and non-food products in over 150 countries. For 2015, PowderCo Global reported a turnover of over £20 billion across all product sectors. PowderCo UK is the only UK based food manufacturing plant in the organisation; other food products are manufactured in company factories internationally or by third party suppliers (see Figure 5.1).

The role of PowderCo UK is the manufacture and onward supply of finished products (in bulk) to the next step of the supply chain (contract packers in the UK and overseas). Manufacturing is supported by a range of functions including product quality, health and safety, engineering and human resources. Other aspects of the business, such as central purchasing, sales, marketing and research and development (R&D), are located separately to the PowderCo UK site, and do not form a direct part of this study.

Figure 5.1: PowderCo Global Organisation Chart



Food products have been made on site at PowderCo UK for over a century and the core manufacturing processes have changed little over time. The site manufactures a base powder product which is blended with other dry ingredients to produce a range of finished products which are packed into bulk containers. These are then shipped to contract packers in the UK, Africa and East Asia, where the products are packed into consumer units for transportation to UK and international customers.

The site operates seven days a week with two, twelve-hour production shifts daily (7am to 7pm; 7pm to 7am) although production line supervisors often arrive earlier to allow for efficient handovers between shifts. Manufacturing staff are organised into "cells" of three or four production staff, each with responsibility for a particular area of production. There is a further level of production management for each shift team, whilst the overall direction of the site is provided by a senior management team led by the site director who reports into the manufacturing division of PowderCo Global. Each batch of product takes around 12 hours to produce from start to finish and the site operates on a 10-day operation schedule (referred to as a "campaign") after which there is a 2-day break for deep cleaning and regular maintenance. (In process cleaning, such as cleaning floors, caustic flushing of tanks and pipes etc. is carried out during the regular production and in production intervals between batches). There are two longer shut down periods each year (in the summer and at Christmas) to allow for more complex maintenance and any production upgrades. At the time of the incident the site had recently re-started production after an additional shut down period for specific upgrade work.

5.2 Data Collection and Analysis

The primary method of gathering data for the case study was through semi-structured interviews, which were held between November 2015 and January 2016. The development and validation of the semi-structured interview guide, and the interview method are presented in detail in Chapter 4.

The study participants were selected with the aid of a gatekeeper (participant P003) and comprised management and staff from the PowderCo UK site. All participants were selected to meet the study inclusion criteria of having an involvement in the investigation or management of the quality incident and / or having a working knowledge of the site FSMS.

The participants varied in job role (quality, production and engineering) and level of responsibility, ranging from junior supervisory positions in manufacturing (cell team leaders) through to middle management (senior quality personnel). The participants also had a wide range of experience within the organisation ranging from less than six months (P001) to over 25 years (P008), with the majority of the study participants having been employed at the site for between three and eight years. In total eight members of staff were interviewed, with three individual interviews and one group interview with five members of the site HACCP team as shown in Table 5.1.

Table 5.1: Description of Study Participants (PowderCo UK)

Participant Number	Job Role	FSMS / Incident experience	Interview Type and Duration
P001	Quality Supervisor	FSMS user	1-to-1, 55 minutes
P002	Production Cell Team Leader	FSMS user	1-to-1, 55 minutes
P003	Quality Manager, responsible for HACCP throughout the site	FSMS lead. Lead investigator of the incident.	Group, 1 hour 35 minutes
P004	Production Shift Supervisor	FSMS user. HACCP team member.	
P005	Production Cell Team Leader	FSMS user. HACCP team member.	
P006	Quality Laboratory Manager.	FSMS user. HACCP team member.	
P007	Quality Manager (Production).	FSMS user. HACCP team member.	
P008	Senior Engineer.	Lead engineer involved in quality investigation. FSMS aware.	1-to-1, 58 minutes

Data was also collected through observation of working practices and examination of a range of documents as listed in Figure 5.2. The Researcher was not given permission to copy documents, so comprehensive notes were taken for later review and analysis. Additionally, information was gathered from publicly available sources, such as brand and company websites.

Although interviews and observation were completed at the PowderCo UK site only, a number of the documents shared with the Researcher concerned the broader organisation. For example, the site quality policy statement made reference to the PowderCo Global quality policy; the supply chain review board referenced in the list of site actions is responsible for both food and non-food supply chain globally; the brand history leaflet referenced sales and marketing information for the products. In this way, it was possible to place information about PowderCo UK and the quality incident within the wider global organisation.

Both the escorted tour of the production facility and attendance at the morning site production meeting (referred to as an accountability meeting) allowed the Researcher to observe staff working practices and behaviours, see the QMS, FSMS and FSMnSs in use and examine and discuss the QMS, FSMS and FSMnS failure points in the metal contamination incident.

Figure 5.2: Documents Examined and Observation Points, PowderCo UK

Documents General
Brand history leaflet
Site quality policy statement
Site quality plan 2015
Personal hygiene policy
Site hygiene procedure
Personal Development Plan for 2015 for head of site quality team
Presentation on "GEMBA" process
Serious incident and investigation handling procedure
Incident report instruction
HACCP manual including charter, annual plan, documents on all PRPs (e.g. change control, pest control); process flow charts.

Documents related to specific incident
Completed form for reporting serious incidents
Storyboard of incident
Report on metal contamination
Contamination report
Serious quality incident decision log
List of site actions from minutes of supply chain review board
Risk template for actions with third party overseas co-packer
Proposal document for dealing with bulk inspection testing
Concession forms detailing increased checking of magnets; corrective/ preventative action for related product line
Diagram of in process magnets and sieves

Observations
Site museum
Staff coffee break areas and canteen
Office space and meeting rooms
Escorted tour of production plant
Morning production "accountability" meeting

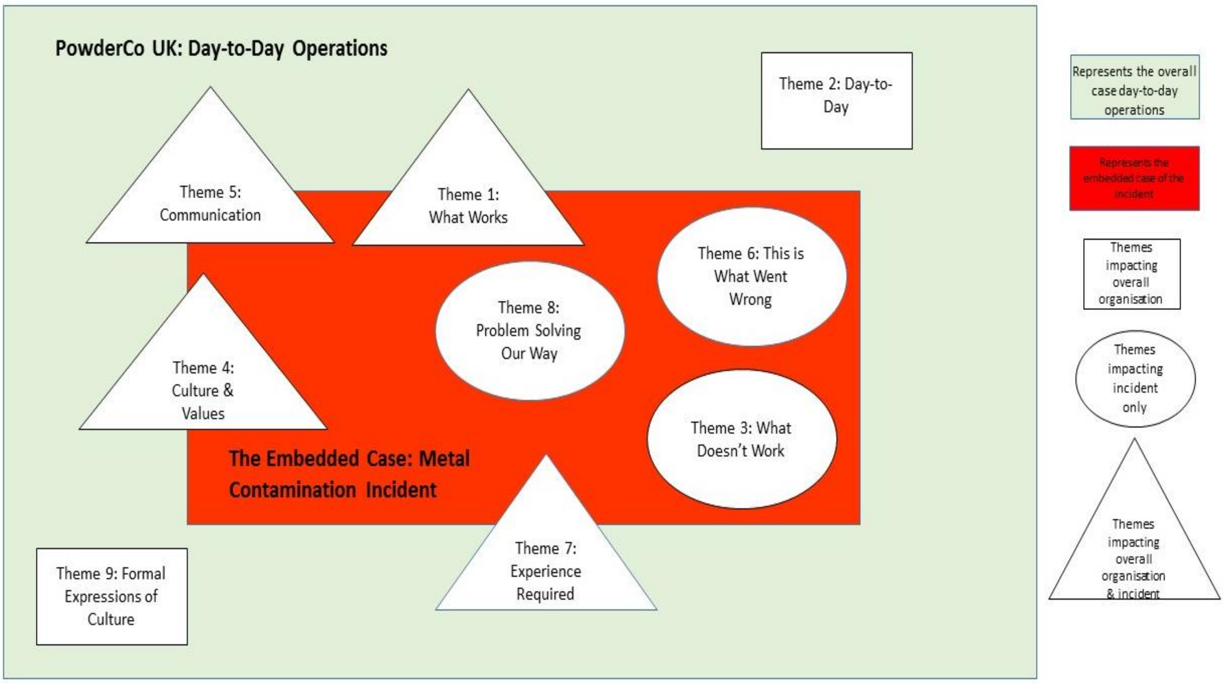
In accordance with the analytical plan detailed in Chapter 4, all interviews were recorded digitally, then transcribed and checked by the Researcher. The transcripts were coded inductively, with 53 codes being created (the code book, with definitions of each code and examples is given in Appendix B). Codes were then categorised into themes using a clustering approach. After several rounds of cross-checking, nine separate themes were developed, which are listed in Table 5.2 below.

Table 5.2: Themes Developed in the PowderCo UK Case Study

	Theme
1	What Works
2	Day-to-day
3	What Doesn't Work
4	Culture & Values
5	Communication
6	This Is What Went Wrong
7	Experience Required
8	Problem Solving Our Way
9	Formal Expressions of Culture

Figure 5.3 shows the relationship between the themes, the main case and the embedded case. As can be seen in Figure 5.3, three of the themes pertain only to the incident and two only to the organisational level of the case, whilst the remaining four themes apply to both.

Figure 5.3: The Relationship of Themes to the Organisational Case and the Embedded Case (PowderCo UK)



The following sections of this chapter describe the research findings in terms of these themes, firstly considering the embedded Incident and then the overall case. A consideration of these findings against the literature presented in Chapter 3, the theoretical "roadmap" developed from PC (described in Chapter 4) and the second case study organisation (LiquiComp UK, described in Chapter 6) is given in Chapter 7.

5.3 Findings

5.3.1 The Embedded Case: An Incident of Metal Contamination

One day, in the early summer of 2015, PowderCo UK was contacted by its UK based contract packer with information that a batch of product had tested positive for "metal firings"[32]. The packer had already carried out additional testing of the product and had identified very small, thin shards of metal (approximately 1 to 2 mm by 4 to 5 mm) mixed in with the product. Scanned photographs of the metal shards were emailed to PowderCo UK by the contract packer, with physical samples being delivered by courier a short time thereafter. The site quality team immediately sprang into action and set about following the company processes and procedures to investigate and manage potential food safety incidents.

As illustrated in Figure 5.3, seven of the nine themes developed from the qualitative data identified pertain to this incident[33]. These themes are: "Communication"; "This is What Went Wrong"; "What Doesn't Work"; "Culture and Values"; "Problem Solving Our Way", "Experience Required" and "What Works". The discovery, investigation and management of the incident, from the perspective of PowderCo UK, is described and discussed below.

"Communication"

As the starting point for each interview, participants were asked to describe how they first found out about the incident and how it was investigated and managed. Although the exact sequence of events and level of detail given varied between participants (depending on their technical role and involvement with the incident investigation), the overall picture of the incident given by participants was remarkably consistent:

> "… we found out about it to a certain extent second hand, because the incident was raised through a reporting of metal findings from our co-packer …." (P007, Quality Manager)
>
> "…I think it was reported to us that the third-party packaging company informed us that they'd had some firings on their metal detector …" (P008, Senior Engineer)

[32] "Metal firings" refers to the alert given by the metal detection system at the contract packers when packed product was scanned prior to releasing it for sale.

[33] As will be made apparent through the case study findings, the incident was investigated by Powder Co UK as a potentially reportable food safety incident. However, as all of the affected product remained in the control of the company, there was no requirement to report the incident to the authorities, and it was managed internally by the company.

> "… so they informed us they had found metal shards, four metal shards, they sent us the picture …" (P001, Quality Supervisor)

All of the staff - even the newest member, P001, who had not been working in PowderCo UK when the incident came to light - were able to relate the main aspects of the incident investigation, describe the technical causes of the incident and the changes that PowderCo UK had made in terms of quality and food safety processes and checks to reduce the risk of such an incident reoccurring.

The participants were also clear about the immediate actions taken on receipt of the notification from the contract packer about the finding of the metal contamination. Communication had been swift and followed the company documented processes and procedures:

> "As soon as that complaint came to us and those pictures came to us …we informed everyone, that's head of site, head of quality ….." (P001, Quality Supervisor)

Indeed, communication about the incident throughout the course of the investigation and during implementation of corrective actions had been regular and open:

> "the majority [of communication] was done through briefings, there was lots of RCA [root cause analysis] investigations going on and where were we at particular times, then it was getting broadcasted through the accountability meetings and via briefings to see where we were and what the next steps were" (P004, Shift Supervisor).

This transparency in communication appeared to play a significant role in fostering a shared understanding of the problems and in consolidating a common set of values (this is described further in "Culture and Values"). The apparent contrast in communication style between PowderCo UK and the second case study, LiquiComp UK, and the impact of this on the development of a cohesive organisational reality or "topos" (as per the PC framework), is discussed in Chapter 7.

In many ways, by the time of the data collection interviews, some six months after the start of the quality incident, the events had already passed into company folklore as a “war story”, telling of a difficult time for the organisation which had been overcome successfully.

Another example of such a narrative was uncovered when the participants discussed other elements of the FSMnS in the factory. In a quality incident which happened more than a decade before, product had been overdosed with a vitamin blend: “the yellow bag incident”. Outcomes of the “yellow bag incident” were improved monitoring and control of vitamin addition to the products and to specific reviews of relevant control points as part of the FSMS.

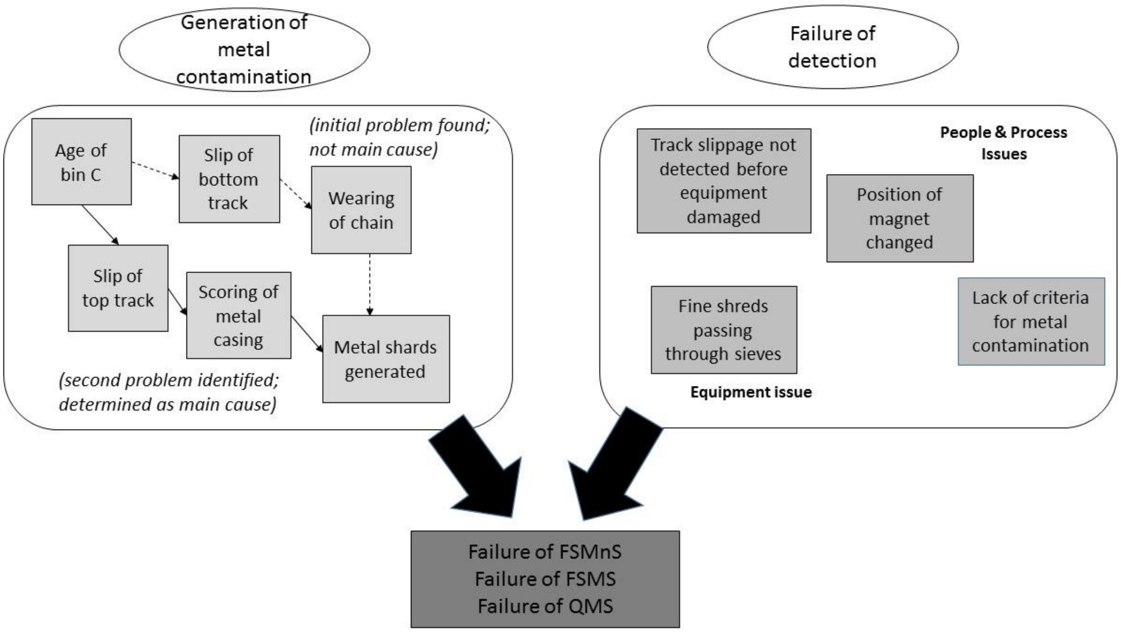
> “Oh yes, I remember the yellow bag incident…… we'd managed to get the vitamin premix screw running on its own, so it just pumped raw vitamin premix and that went through to the bag …… But now there’s monitoring going on, there's alarms on the system which basically if one of the screws stops the other screws should all stop as well, so they're all linked in together.” (P007, Quality Manager).

The importance of communication in allowing narratives about good practice to build from failures can therefore be seen as an underlying capability in PowderCo UK which links to the organisational behaviour of learning from failure and the practice of Continuous Improvement (CI), both of which are discussed under the theme of “What Works”.

“This Is What Went Wrong”

In discussing the quality incident, (and through reference to the documentation supplied on the incident, as noted in Figure 5.2) a picture emerged of a complex series of events, involving failures in both production equipment and in detection of the problem, as illustrated in Figure 5.4.

Figure 5.4: An Overview of the Non-Reportable Food Incident at PowderCo UK



As outlined earlier in section 5.1, the PowderCo UK production site has been operational since the early 20th Century. Over this time, the production plant has been modified and upgraded, to take into account changes in ingredients and technology. However, certain sections of the manufacturing plant have been virtually unchanged for decades and it was in one of these older areas of the plant that the metal contamination was generated. Across the plant, most of the powdered product is now moved under vacuum transfer. However, in some areas the powder is still transferred between processing stages using chain-driven equipment, which leads to the generation of a fine metal powder:

> "We know where we routinely generate metal as a fine powder 'cos we've got a lot of chain-driven material…" (P007, Quality Manager)

The PowderCo UK site operates with a comprehensive QMS and FSMS, including a HACCP plan which is linked to a PRP and the site maintenance plan. A detailed risk assessment for physical hazards (ferrous and non-ferrous metal and other foreign bodies) is included as part of the site HACCP plan. Under the HACCP and QMS, the site controls for potential metal contamination by using a number of magnets placed through the production line to attract and remove ferrous metal. Fine mesh (2mm) sieves are also used to screen out metal (ferrous and non-ferrous) and other extraneous materials at a number of control points through the production process. The magnets and sieves act as control points (CPs), with those located immediately prior to bagging of the finished powder being designated as CCPs. The use of magnets and sieves as CPs should ensure that any physical contamination with ferrous metal is detected as early as possible in the production process, whilst the final CCPs are in place to ensure the safety of the product before it is bagged and leaves the site for transport to co-packers. (As highlighted in this case, further controls for physical contamination are in place in the co-packers. These are in place primarily to guard against any contamination of the product during the packing into consumer units and hence ensure the safety of the product for the end consumer).

In this particular incident, small, very fine shards of metal were generated due to a breakdown of part of the powder transfer equipment: a long, enclosed, chain-driven belt referred to on site as “Bin C”. This equipment, custom made for the site many years ago, has chains running along upper and lower tracks. During routine operation the inside of the Bin is only visible through small observation windows. Running maintenance is carried out on site by the engineering team (e.g. replacement of shear pins, which is discussed under the next theme, “What Doesn’t Work”). More extensive work is conducted at approximately 12-week intervals by an outside contractor, who partially disassembles the bin allowing for deep cleaning and maintenance.

When PowderCo UK was first informed of the finding of metal contamination a Local Incident Committee (LIC) was formed to investigate and report on the incident. Set up by the Head of Site Quality, and composed of an incident manager plus representatives from quality, manufacturing, engineering and logistics, the outputs of the LIC are reported back to the site Senior Leadership Team, and also into the PowderCo Global manufacturing division.

The immediate actions of the LIC were to shut down manufacture whilst the source of metal contamination was established and to place on hold any product still within the factory. This not only demonstrates the importance of food safety to PowderCo UK, but also highlights the potentially high quality costs to the organisation of managing such an incident, with not only the cost of staff and management time in investigating and resolving the incident, but the opportunity costs of lost production and potentially lost sales.

An important step in the management of the incident was the production of a time line to identify what product was potentially affected and where it was in the supply chain, enabling product to be placed into quarantine if held at the co-packers or within warehouses prior to shipment to the retail trade:

> "… so pretty much (the) first thing we did was a timeline to see when the incident started occurring, once we'd identified that timeline then we could see what product was affected and also understand what product wouldn't be affected…" (P003, Quality Manager)

Additionally, as per the company incident management processes (described by participants and as documented in the "Serious incident and investigation handling procedure"), an RCA was started to undertake the technical incident investigations. Given the nature of the metal contamination, and the traceability information for the affected product (the date of manufacture and the Lot codes), Bin C was identified quickly as the most likely cause of the metal generation. The earliest point of contamination was also straightforward to establish, given that the site had re-opened after an extended shutdown only two days prior to the date of manufacture of the contaminated product.

An inspection of Bin C by engineering and the outside maintenance contractor identified that a bearing had come loose in the gearing of the bottom chain. This resulted in the chain itself loosening so that it was being worn by the gears, resulting in the potential to generate metal shards.

This failure mode was new to the site, and totally unexpected:

> "…. he [the contractor] said in all the years that he's been coming to the site he's never seen it [the chain] come loose before…" (P008, Senior Engineer)

Having established Bin C as the site of the contamination, production with the second, smaller bin (Bin B) was restarted. Refinements to the list of products on hold and in quarantine were also possible, so the supply of known unaffected products (those manufactured prior to the shut down and / or manufactured using Bin B) to the market was possible. However, a large amount of product remained in quarantine and full production needed to be re-established.

To re-establish full production, the engineering team and contractors rectified the fault with the bottom chain. Bin C was put back into use and product started to run again on a concession basis, i.e. there was a temporary approval of use of the bin, with a requirement for additional quality checks for metal contamination and a full inspection of the bin after one or two campaigns[34] (as described in the concession documents reviewed and listed in Figure 5.2). However, the additional checks quickly picked up ongoing metal contamination, another unexpected or unforeseen aspect of the incident:

> "…we were still seeing signs of metal so that threw us a little bit ..." (P008, Senior Engineer)

So, Bin C was taken out of commission again and a further inspection showed that the top chain in the bin had also moved. It was rubbing against the side of the bin, which showed bad scoring of the metal casing. As the senior site engineer (P008) explained, "basically we had two problems".

[34] Increased surveillance of key magnets and sieves was retained on an ongoing basis following the resolution of the incident as part of the learnings from failure (detailed in documentation on in-process magnets and sieves, listed in Figure 5.2).

In reality, looking at the system overall there were more than two problems: the failure of the equipment causing the generation of the metal had been compounded by a failure to detect the damage to the inside of the Bin and to screen out the metal shards, as shown in Figure 5.4. So why was the metal contamination not detected? This investigation formed a key part of the activities of the RCA team.

First, the damage to the inside of the Bin had not been picked up during its routine operation, despite the fact that both the bottom and top tracks had slipped. As the Bin is a covered unit, the inside is not visible to operators during production. However, opportunities were missed to detect the equipment failure earlier. These are covered in detail under the next theme “What Doesn’t Work”.

Considering the detection of the fine metal shards themselves, as explained previously, a number of magnets of varying sizes and sensitivities are located along the production line as CPs and a final CCP for metal contamination. Under the HACCP process operated by PowderCo UK, an annual review and verification of the plan is conducted. Additional reviews are required if there are any significant changes in production e.g. the introduction of new products, changes of process etc., and these are linked to steps in PowderCo UK’s change control process.

The RCA investigation of the quality incident uncovered the fact that some time ago, as part of an engineering change, one of the magnets located in the Bin C area had been removed and replaced with a different magnet, just a few feet away:

> “… during that process one magnet had been removed, and it had been replaced by another magnet in a different place...” (P007, Quality Manager) “Further down, yes, only a few feet away to be honest but … “(P003, Quality Manager) “… but I think the effectiveness of that magnet was gone …” (P007) “… there must have been an effect, yes… “(P003).

Thus, despite PowderCo UK’s change control process requiring a HACCP review, and this review having been undertaken, it appeared that this seemingly small change in the metal detection system had an unforeseen, adverse effect. In fact, as part of the

RCA, the site called in the suppliers of the magnets to undertake a full review of that element of the HACCP system (see theme "Experience Required") and the change in this magnet was identified as one of the factors contributing to the failure of the detection of the metal shards.

Another aspect of this issue identified by the RCA team was a lack of clear criteria for the line operators in what constituted problematic metal contamination. As fine powder metal was seen and cleared from the magnets on a regular basis, it was challenging for the operators to distinguish what had been risk assessed as "acceptable" (i.e. "safe") from "unacceptable" (i.e. "unsafe") levels of metal cleared from the magnets:

> "…we did not have a clear understanding of how much is normal …" (P002, Cell Team Leader)
>
> "There also wasn't a standard of what we should be looking for as far as when we checked or inspected for metal…" (P004, Shift Supervisor)

To address this aspect of the problem and help prevent similar failures in the future, clear guides were produced of acceptable and unacceptable levels and types of metal contamination, which are now kept with the standard operating procedures (SOPs) and quality check sheets at the production line side.

Finally, the RCA considered how the metal pieces had been able to escape filtering out by the sieves placed at intervals in the production line. Investigations had not uncovered any failures in the system of checking and cleaning sieves, nor any failures to replace a damaged sieve. It was therefore concluded that the nature of the metal shards, being of a very fine diameter (less than the 2mm mesh size) had enabled these shards to pass through the mesh – yet another unexpected and unforeseen event.

> "…so the material we were looking at, even though it was very long, obviously you put it side on end and it would still go through a sieve." (P007, Quality Manager).

It can therefore be concluded that the failures in the CPs, CCPs and FSMnS and the subsequent failure in the FSMS resulted from a whole series of small events, which by themselves were not problematic, but which, when combined led to this non-reportable food incident. A key finding for this incident is that many of failures were deemed “unexpected” or “unforeseen” and hence had not been adequately controlled for by the existing HACCP plan and supporting PRPs, either as individual events or as a combination of events. The relationship between these “unexpected” or “unforeseen” events and the identification of “factual possibilities” using the PC framework, will be considered in detail in Chapter 7.

“What Doesn’t Work”

The last theme, “This is What Went Wrong”, was developed from a cluster of codes which describe the investigation of the incident and identification of the technical causes of the incident. This next theme, “What Doesn’t Work”, consolidates a series of codes which cast more light onto the factors underlying working practices and behaviours in PowderCo UK and which form a background to the incident.

In fact, on reflecting upon the incident, the study participants themselves identified areas of weakness in the company’s operations. A number of examples were given where the acceptance by the organisation of differing decisions, behaviours and working practices by various staff members resulted in the company missing opportunities to either prevent the incident from occurring or to detect the failure earlier.

The first example concerns the working practices of the engineering team in maintaining the shear pins in the chain drive system in Bin C. These pins snap if an extra load is put onto the system, e.g. if the chain is dragging. The replacement of snapped shear pins is a reasonably routine event, but looking back, P008 said:

> “I suppose the alarms bell should have rung a little bit when we had we had a couple of shear pins snap on it [Bin C] and when the guys just changed the pins, you know, and then and it went on for a couple of days and then it went again. So I suppose really we should have thought about why it snapped then, but

> some of the engineers will just say "oh well I changed the pins", you know, they just change them...." (P008, Senior Engineer)

Whilst the breaking shear pins were not directly related to the generation of the metal shards in the bin, an investigation of the gearing mechanism and chains at that time could have uncovered the slippages to the chains and the start of the damage to the bin. In other words, a more curious attitude, or a more rigorous investigation of why the shear pins had snapped twice in a short time, potentially could have prevented the quality incident from occurring, i.e. an opportunity was missed to prevent the incident.

Underlying this missed opportunity is also an acceptance of variations in working practices in the engineering team, in that different team members appear to respond to the same event - a broken shear pin - in different ways. Some engineers simply replace the pin to enable production to carry on with minimal disruption, whilst others appear to question the event more deeply and search for why the pins break. This last behaviour fits well with the general approach identified in PowderCo UK of learning from failure, (which is covered further in section 5.3.2, under "What Works"), but it is obvious from this example that not all staff embrace that attitude equally, or at least not all of the time.

This same scenario can also be considered from a quality cost perspective. The engineers who simply replace a broken shear pin might be considered to be acting promptly to minimise internal failure costs. In contrast, an engineer who takes the time to consider the reasons for failure is spending time (and hence money) on prevention costs, with, presumably an aim of reducing future problems and so reducing spend on future internal failure costs.

Another example of a missed opportunity was given during the group discussion when the site HACCP lead (P003), reflected on age of the site and equipment and the HACCP team's failure to fully account for that in the HACCP process:

> "I think a lot of it came down to, really when you've got your hazard analysis in there for the food safety management system, is that, over time, the risks change and I don't think we've captured that very well, that the risk from the bin could increase over time as things get older." (P003, Quality Manager).

The need to consider the passage of time / age during HACCP plan reviews arises again in the second case study and will be discussed in more detail in Chapter 7.

The missed opportunities created by variations in working practices were also seen in two other areas. It has already been highlighted that line operators lacked an objective standard to distinguish "acceptable" (i.e. "safe") from "unacceptable" (i.e. "unsafe") levels of fine metal collected on the detection magnets. This indicates that line operators must have been using individual judgement about what actions to take when they found such deposits and when to alert management to a problem with the metal detection system, i.e. there was a variation in practice across the production operatives in this respect.

Likewise, in other interviews, participants identified variations in working practices in the line operators working with Bin C which could have increased the risk of damage occurring to the bin. In normal production, as the powdered product passes through the bins, the food product itself acts as a partial barrier or lubricant, reducing metal to metal contact. Best practice, as per the site SOPs, is therefore to avoid running the bins empty as this conversely increases the risk of metal-to-metal contact and hence the risk of damage to the equipment. However, not all staff adhered to this practice, and such variation in practice appeared to be tolerated:

> "Well according to the SOP if the bins are empty you're supposed to stop. But it depends upon when different operators, different operators take different ways." (P002, Cell Team Leader)

Overall therefore, a number of areas were identified where opportunities had been missed to prevent the occurrence of the quality incident or to identify it sooner. Importantly, many of these missed opportunities resulted from small differences in working practices between different staff. The next theme therefore considers whether the culture and values of the organisation can account for these differences in behaviour (working practice) between different staff members.

“Culture and Values”

Given the focus of this research on food safety and FSC, the data gathered was interrogated to gain an understanding of PowderCo UK’s attitude to food safety, both in terms of the embedded case and at the organisational level. In the embedded case a “safety first” attitude was evident, as exemplified by the actions taken when Bin C was identified as the source of the metal contamination:

> “We immediately stop all the plant, we stop using C Bin, whatever was produced on site from C Bin, we put it on hold.” (P001, Quality Supervisor).

In fact, Bin C was out of action for many weeks while the incident was investigated and new parts for it were being manufactured, which left the site running with reduced capacity and so behind on production targets, i.e. there was an ongoing cost of poor quality to the organisation. This, however, was viewed as secondary to protecting consumer safety:

> “We did stop using one of the bins, we used the second bin which limited our production a little bit, but you know that's not the issue, it's a side effect.” (P007, Senior Quality Manager).

The same degree of concern for food safety was demonstrated in other aspects of the incident investigation, for example in tracing potentially affected products[35]:

> “…we had to find out if there was product anywhere else, like at docks, or in transit, or anything made it actually onto the shelf ...yes, so we did the traceability twice …we did a verification of that traceability effectively and went through all of it again, just to make sure every single pack was accounted for.” (P003, Quality Manager).

[35] In fact, the traceability exercise confirmed that all of the potentially affected product remained under the control of the company, at site or with company or third party co-packers. Hence the incident was classified as a non-reportable food incident under EU and UK legislation.

The fact that undertaking the traceability exercise twice would have doubled the quality costs (an internal failure cost) for this activity was not seen as an issue by the team – assuring that they had full and accurate traceability for the products was far more important.

Another aspect of organisational culture and values illustrated by the embedded case was the commitment of senior management to the investigation and management of the quality incident.

As previously mentioned under the theme of "Communication", when PowderCo UK were first notified of the incident by the contract packer, senior management were immediately informed and were highly involved in managing the incident.

> "A local incident committee is pulled together which is managed by senior management." (P003, Quality Manager). "OK. And who's normally involved in that? (Researcher). "That'd be the quality head, the site director, well, all of the senior leadership team, and then you have inputs from quality, engineering and production. There would also be our logistics department involved as well, to see what the effects on supply might be." (P003). "And how quickly did that happen? How quickly did they get together?" (Researcher). "On the same day [that the site was informed]." (P003).

The involvement of the site management team in the incident investigation is clear from the above quote. From the examination of documents pertaining to the incident, the involvement and concern of the broader organisation in PowderCo Global was also apparent. For example, the site reported several times on the incident to a "Supply Chain Review Board", a senior management team who look at supply chain issues across the entire corporation.

Going back to the description of the formation of the LIC, this involvement and prompt action by PowderCo UK management not only illustrates the value of product safety to the company but also the value placed on systems and processes by the organisation, as the organisation reacted to the notification of the quality incident by implementing standardised, documented procedures. The reliance on and trust in processes and systems was particularly seen in data clustered under the next theme, "Problem Solving Our Way".

"Problem Solving Our Way"

The examination of both the embedded case and the broader organisation revealed the central role that routines, processes and systems play in PowderCo UK. Of particular note were the comprehensive processes used by the company to investigate and manage the incident.

The setup of a LIC was obviously a routine matter, as was the choice of RCA to investigate the quality incident.

> "It's like we've got a standard template in place, and for any major or critical incidents we follow that template, which is called a problem-solving template, a root cause analysis template." (P001, Quality Supervisor)

In fact, RCA as a technique was so embedded within the site there was a room named the "RCA Room" specifically set aside for teams to work on problems (including aspects such as production challenges, not just quality or safety issues).

For the incident in question, as shown in Figure 5.2, a number of documents were examined by the Researcher. Many of these documents demonstrated the standardised processes used by the business to deal with quality and safety issues, e.g. the concessions process which gives temporary approval for production to occur under non-standard conditions, or which allows for the release of product which is out of specification in some way. In the embedded case, the concessions process was used to enable production to restart using Bin C after the initial fault had been identified with the gearing of the bottom chain and it was through the additional quality checks put in place as part of this concession approval that the ongoing problem with metal contamination was identified.

PowderCo UK's reliance on systems and processes will be discussed further in Section 5.3.2, but it can already be seen as one of the elements which the organisation itself would consider a strength or an asset to the business, and one of the reasons that the company is generally successful. However, given the failure of the systems and processes which underlie this incident, this reliance might be called into question. In the terminology of PC, the pro-active truth of “the systems are effective” and the pragmatic truth of “the systems failed” appear not to have been recognised, i.e. there is a truth gap. This aspect of the case will be discussed further in Chapter 7.

It was also possible to identify other elements of the organisation’s practices and customs which can be considered as part of its success, and these are presented next, under the theme “What Works”.

“What Works”

As described earlier, the story of the management and resolution of the metal contamination incident had already been established in the organisation as an historical (albeit recent history) “war story”, where the workers overcame challenge and adversity to attain success.

A part of this success was considered to be learning lessons from this non-reportable food incident with the aim of preventing similar failures in the future. This was illustrated perfectly by one of the key actions taken to resolve the metal contamination incident and get the manufacturing plant back up to full production. To enable this, an upgrade was made to the design of Bin C. PowderCo UK went one step further than a simple repair to the gearing and chain system in the Bin; they went back to the original equipment manufacturers to commission a new conveyor, where the chain sits on a manganese strip, so that should a slippage occur again, the metal of the Bin would not be worn by the chain:

> “We looked at the age of it and things like that and called in the company that actually built the machine and who still had the drawings and we asked them to build us a new conveyor, a totally new conveyor. With a redesign in it; we put a different design to it so that if the chain ever moved again, it wouldn't shred any metal. So it's now got manganese strips. 'Cos the chain sits on a manganese strip and it glides on it. So we put manganese strips on the side so when the chain moves over it won't wear it.” (P008, Senior Engineer)

From a quality cost perspective, this point also illustrates that PowderCo UK was prepared to invest in the future safety and quality of the product (i.e. a spend in the category of preventative costs) to avoid future failure costs.

Further evidence of learning lessons from failure came in the plans put in place to upgrade the second, smaller bin on site so as to guard against future problems of chain wear on that bin as well (another preventative quality cost).

Other lessons learned from the quality incident resulted in upgrades in controls and monitoring on site. For example, the "gouges" in the interior of Bin C had been painted to increase their visibility. This enabled any new wear to the bin, should it happen, to be easily identified during routine maintenance inspections.

Another upgrade to the FSMnS was the increase in inspections for some of the magnets, for example:

> "Yes, we have changed the system from before. We had a system to check the Bin magnets at the end of the campaign only. Now we check every shift." (P002, Cell Team Leader).

From a quality costing perspective, such upgrades to the FSMnS would be classified as an appraisal cost, and again demonstrates that PowderCo UK was prepared to invest in such spend to avoid future failure costs.

From these examples it is clear that learning from mistakes can be considered as a strength of PowderCo UK. This ties in with the site's long-established use of CI practices. This and other elements of the organisational level findings of the case study are considered later in section 5.3.2.

One final element of practice that can be considered to be integral to PowderCo UK's successful resolution of the quality incident was in the organisation's reliance on experience and expertise, both internal and external to the company. This is presented as the final theme for the embedded case.

“Experience Required”

As the study participants told the story of the metal contamination incident the important role played by experienced staff, and particularly by external consultants and suppliers, became clear. External suppliers / contractors were crucial in the determination of the cause of the incident. The roles of the magnet suppliers who undertook a full audit of the site system, and that of the maintenance contractor for the bins, who worked with engineering and discovered the faults in Bin C, have already been detailed.

In addition to these experts, PowderCo UK employed an external food safety expert to undertake a full audit of the FSMS and FSMnS for metal contamination:

> “Did you make any changes to the HACCP plan or the pre-requisites to try and address this [failure in FSMS]? (Researcher). “Yes, so we first of all needed the consultant, we did a sort of broader review really, using the external consultant 'cos the external consultant is a food safety expert.” (P003, Quality Manager).

These clear examples demonstrate again the prioritisation of food safety within the business as well as the trust placed by the companies on guidance and support from external experts. (The use of external consultants to undertake additional audits and reviews is also another example of an internal failure cost which resulted from the incident).

Whilst internal expertise was also clearly valued by PowderCo UK (as showed for example, by the makeup of the LIC, involving experienced staff members and management), there was also some evidence that the value placed on experience may limit the engagement and participation of some staff. For example, when discussing involvement in the RCA team, P002 explained that he had not been involved because he had not been working in the company for very long when the incident came to light.

> “No, we were not involved … and also I believe that because I was quite new … I think it’s because of my lack of understanding they did not involve me” (P002, Cell Team Leader).

Whilst it is true that P002 did not have much experience in PowderCo UK’s operation, he had been working in food manufacturing for some years and therefore might have been able to provide relevant insights to assist the work of the RCA team. This contrasts somewhat with the approach taken in LiquiComp UK, where the incident investigation involved managers who were new into the business, and from whom insights into ways of improving practice were sought.

Conclusion

This thematic analysis of the embedded case shows that the metal contamination incident which took place at Power Co UK was complex, both in its origination and in its investigation. Whilst the organisation had a well-established QMS, FSMS and FSMnS in place, the controls for metal contamination proved inadequate to prevent this incident.

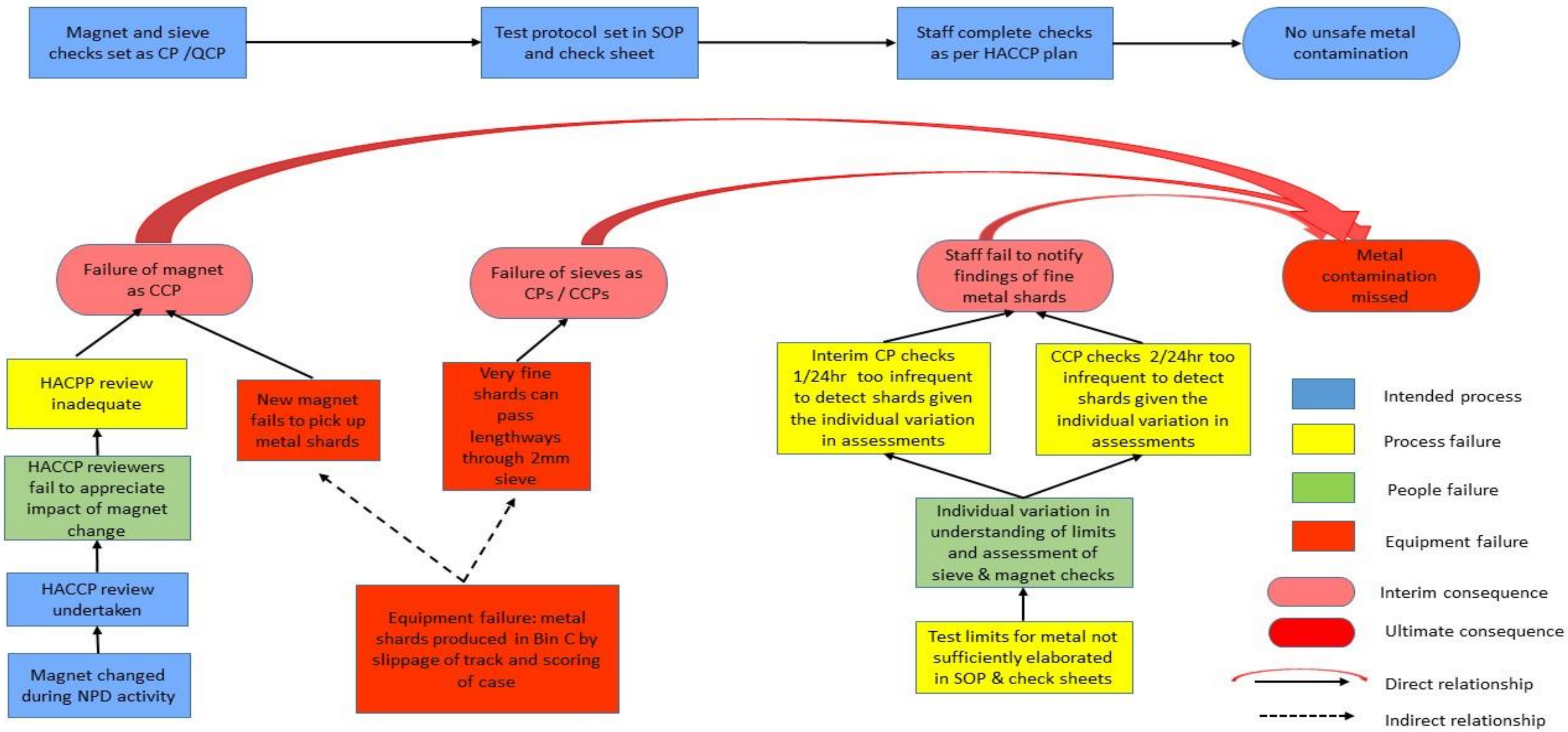
Both the generation of the metal fragments, and the failure of the control measures, were “unexpected” by the company, a finding which will be discussed in Section 5.4 and in more detail in Chapter 7.

The analysis of the incident uncovered both strengths and weaknesses of the organisation. Clear strengths were demonstrated in the processes and systems used to investigate and manage the incident; in the importance with which food safety is held by the organisation, and in its ability to learn from mistakes, particularly through the creation of narratives or “war stories” about such challenging times. These stories form a key part of communication in the company, which throughout the incident was open and timely, helping to foster a shared understanding of the events surrounding the incident and a shared understanding of the company values, particularly in respect to food safety. No data was collected on the cost to the business of this specific incident, however it is evident that the business prioritised the safety of consumers over minimising the internal failure costs associated with shut down of facilities, product tracking and traceability activity and the engineering work to repair Bin C. Indeed, this incident also demonstrated the willingness of PowderCo UK to incur prevention costs to reduce the risk of future failings by instigating the same engineering improvements to Bin B as well as improving the working of Bin C and by investing in improved surveillance and testing (as evidenced through increased magnet and sieve checks, put in place initially as part of the concessions process to restart production after the first finding of metal shards).

The weaknesses identified through the thematic analysis relate predominately to the missed opportunities to prevent the incident, many of which were underpinned by small variances in ways of working. This is illustrated by mapping out the points underlying the failure of the sieves and magnets as CPs and CCPs, as shown in Figure 5.5 overleaf. Whilst both people and process issues (as well as equipment failures) are demonstrated, it is the underlying variance in working practices – a people characteristic - which the standard processes cannot accommodate successfully. This forms an important feature of the case which will be discussed in Chapter 7 in relation to PC and the dimension of possibilities. The "truth gap" seen between the reliance on systems and processes to manage food safety and quality, and the failure of these systems, will also be further discussed in Chapter 7.

Having examined the embedded case, we now turn to examine the organisational level, to consider the study findings pertaining to the day-to-day operations of PowderCo UK.

Figure 5.5: Magnet & Sieve Checks – People or Process Failures?



5.3.2 The Organisational Level

The previous section presented a thematic analysis of the embedded case of the metal contamination incident. Whilst this incident offers insights into the workings of PowderCo UK at a time of QMS / FSMS failure, such events have been, thankfully, a rarity for the organisation – it has after all been a successful food producer for over a century. As such, it is important to consider the general operations of the company. These are presented in this section in a similar fashion to the embedded case, though six of the themes developed in the inductive analysis: "Day-to-Day"; "What Works"; "Experience Required"; "Formal Expressions of Culture"; "Culture and Values" and "Communication".

"Day-to-Day"

This first theme for the overall organisation brings together codes pertaining to the everyday running of the manufacturing plant. Given the nature and focus of the research, much of this information concerned the FSMS, but much of the general philosophy and approach of the organisation can be understood by considering the quality and food safety systems.

First, it is clear from the information collected, that both the QMS and FSMS used on site are well organised and fully documented, with appropriate reviews conducted on time by the relevant personnel. Concentrating on the FSMS, in addition to the documentation provided to the Researcher, all of the participants were able to describe aspects of the system, the CCPs and the FSMnS used in the plant (with the level of detail given depending on experience and job function but appropriate within those limitations). During the factory tour the CCPs were pointed out to the Researcher: they were indicated by specific "skull and cross bones" signs on the manufacturing line and information on the controls was readily available for consultation by production line operatives.

As previously discussed in the embedded case, under "Problem Solving Our Way", processes and systems are central to the ways of working at PowderCo UK. Looking at the broader workings of the company, there were clear demonstrations of the links made between different systems and processes. One example given was the link between new product development, when production trials are conducted in the factory, and the FSMS:

> "…. even for trials we still do a HACCP; there's a HACCP review even if it [the product] doesn't go to the consumer…" (P003, Quality Manager).

Another element of the day-to-day use of systems and processes was the mix of simple and more sophisticated controls used across the production process. For example, automated controls are in place to manage a CCP related to microbiological safety (time and temperature controls). This contrasts with the simple, physical checks made of magnets and sieves as CPs/ CCPs for metal and other physical contaminants.

Recording of checks of the control points likewise ranged from "pen and paper" systems (e.g. recording of the results of magnet checks) to the "IP21" in-house computerised system which monitors and records micronutrient addition to some products.

This blend of simple and complex systems is not unique to PowderCo UK and fits with the Researcher's prior experiences in the food industry. However, it demonstrates the relative complexity of PowderCo UK's quality and safety systems and the need to ensure that changes in one part of the system do not impact on other parts of the system in unforeseen ways, simply because of the mix of systems and recording processes in use.

Another clear take out from the analysis of the case study data is the importance of CI activities in PowderCo UK. CI, and associated tools such as RCA, appear firmly embedded as a way of working as described for metal contamination incident under "This Is What Went Wrong". CI also fits with the site-wide targets of "zero accidents, zero defects and zero waste", which are further discussed under the theme "Formal Expressions of Culture".

Overall, systems and processes are seen as critical for the day-to-day operations within PowderCo UK, just as they were to manage the quality incident. The use of CI and associated tools also fits with the learning from failure approach identified in the embedded quality failure case.

So, if processes and systems are part of what makes PowderCo UK tick, what else can be seen as contributing to the overall success of the organisation? This is the topic of the next theme, “What Works”.

“What Works”

In examining this theme for the embedded case, PowderCo UK’s ability to learn from failure was highlighted as an organisational strength. Related to this is a capability that was coded as “creative thinking”. For example, in a discussion of the efficacy of the control system for metal and other physical contaminants used across the site, P008 related work he instigated some time ago to improve the system:

> “I always said that there was a gap there [in the controls for physical contamination], and I actually got back to the manufacturers, and asked them. Because our guys do a sieve check, so they take the sieve out and check it for any damage to make sure there's nothing gone through it. But what I always said that is if something was ever in that sieve, when they pull that out, it would actually fall into our product. So what I made them do, what we done we retro fitted some trays. So they do a magnet check, pull the magnet out, put a tray in, pull the screen out, so any debris that's in there will fall onto the tray, and then they inspect the tray, so it wouldn't go into our product.” (P008, Senior Engineer)

This example also offers another demonstration of PowderCo UK’s willingness to invest in preventative measures, in anticipation of reducing future quality failure costs.

Creative thinking, or considering alternative possibilities – and in particular considering them as factual possibilities, using the terminology of PC - is one way that upgrades to controls and prevention of failures can be achieved without the need to experience a failure first. The importance of considering possible system failures as factual possibilities, in order to enhance development of a robust HACCP based FSMSs, will be discussed further in Chapter 7.

Lastly under this theme, the application of rigour or thoroughness in the way that staff undertake tasks, was evident in the operations of PowderCo UK. Examples ranged from ensuring that spare sieves are always available on site (as the final sieving before bulk packing constitutes a CCP for physical contamination, and without this in place the production cannot run), to the double-checking of the traceability exercise conducted in the quality incident (see “Culture and Values” in section 5.3.1). This approach appears central to the generally successful day-to-day operations of PowderCo UK.

Another element of the success of PowderCo UK is the respect with which experts and experience are held. This aspect of the case study findings forms the next theme.

“Experience Required”

In the analysis of the quality incident, the important role played by external experts (consultants and suppliers) and the trust placed in internal staff with in-house experience was examined. A similar level of trust and dependence on expertise is seen in day-to-day operations, particularly from a quality and food safety perspective.

PowderCo UK employs a range of staff with food safety and quality experience and operates a site HACCP team, some of whom took part in the group interview during data collection (as outlined in table 5.1). Emphasis is placed on the importance of staff having appropriate training and holding the appropriate food safety and HACCP qualifications:

> “… going back to what you said about what requirement for health and safety or food safety training is, depending on where you are in, and what you're doing, obviously members of the HACCP team have to have a lot higher level of training, but we have escalation all the way down to make sure even the process guys, the guys out on the plant, the logistics guys, they've all got a at least a basic knowledge of food safety and that's part of our on-going yearly training package …” (P007, Quality Manager)

Indeed, not only are staff expected to undergo and pass this training, all members of the site senior leadership team, including the Site Director, take an externally accredited Food Safety Level 3 Certificate when they take up positions in the management team. Similarly, PowderCo UK recognises the value of independent review of its food safety systems. Two levels of internal audits are undertaken regularly, by PowderCo UK and by PowderCo Global quality staff. In addition, the site uses third party audit and certification to demonstrate the quality of its systems, and is both BRC and ISO 22000 accredited. Both the training and audits equate to prevention costs in the terms of quality costing.

Overall, it is clear that respect for expertise is part of the culture of PowderCo UK. The external quality and food safety certifications can be seen as a formal expression of the prioritisation of food safety by the company. The next theme considers such formal expressions of culture in more detail, and in particular considers the position of food safety and quality within this.

"Formal Expressions of Culture"

Although PowderCo UK has been operating as a manufacturing site since the early 20th Century, the mergers and acquisitions which are common across the food industry means there have been several owners of the site. This, plus the passage of time, has inevitably brought periodic changes in official company mission statements.

The current company mission statement for PowderCo Global has been in place for more than a decade and is highly visible to staff and visitors alike. It sits as the headline on the front page of PowderCo Global's website, is inscribed in large letters on the foyer wall of PowderCo UK's reception area and is even written on the door fingerplates of all the meeting rooms across the site. Likewise, PowderCo Global's corporate values are easily found on their website and form part of the induction process for all new staff. These values are further translated into expected behaviours, which comprise part of the annual review of staff Performance Development Plans (PDPs). Staff are assessed on not only the absolute achievement of objectives in their

PDPs – “what” they achieve – but “how” they achieve these, in terms of fit with the behaviours.

Whilst food safety and quality per se are not specifically mentioned in the corporate mission statement or values, there are corporate and site quality statements. These make the link between the corporate core value of trust (by consumers and broader society) and product quality.

Although the corporate mission statement is prominent across the site, none of the staff directly quoted the mission statement as an expression of the purpose of the organisation. However, staff made the link between the official mission statement, the end consumer and food safety. For example, when asked if or how food safety linked with the corporate mission statement, this was the response of one of the focus group participants:

> “… I think it's thinking of the person at the end of the supply chain, and that can be you and me, or a child in Nigeria or Malaysia, so thinking of them, and ourselves, is directly linked with making sure that the product is safe for consumption …” (P003, Quality Manager)

Another formal expression of culture can be seen in site goals and targets. The manufacturing and supply side of PowderCo Global, including the case study site, have adopted goals or targets of “zero accidents, zero defects and zero waste”. These form a focus of the daily accountability meetings and are communicated on notice boards in staff coffee areas and office corridors. Again, food safety is not directly named in the targets, but the displays around the site show how these targets are linked to safety and quality of the product e.g. cleaning of equipment (part of the PRPs) is linked to producing zero defects in the products.

In conclusion, it appears that as a mature organisation there is a stable and well understood formal organisational culture. Examining this in terms of the organisational culture model of Schein (2004, p 26), it appears that with the passage of time staff have been able to take the artifacts and symbols of the corporation’s culture (mission, targets etc.) and imbue them with the basic underlying assumptions of the local site culture, which, as explained in the next theme, “Culture and Values”, is highly focussed on the staff and product safety.

“Culture and Values”

The “safety first” attitude of PowderCo UK during the management of the quality incident was described under this theme for the embedded case. We now look at how the study participants expressed their general views and understanding of company values, to ascertain where food safety fits in their perception of company priorities outside of the particular focus of a quality incident.

As detailed above, food safety is not named per se in PowderCo Global’s mission statement. However, when participants were asked to describe the purpose of the organisation (PowderCo UK), food safety was the first item listed in all interviews:

> “The main focus for the site is, first is food safety… the first priority for everyone is food safety.” (P001, Quality Supervisor).
>
> “We want to make sure that there is no product which is unsafe for the public can go from here” (P002, Cell Team Leader).
>
> “To make product safely ….” (P005, Cell Team Leader).
>
> “To make product that people would feel comfortable buying, they’d feel assured that this is a product that’s not going to cause any harm...” (P003, Quality Manager).
>
> “Provide a safe product for our customers.” (P008, Senior Engineer).

Doubt could be cast on this finding as an artefact created by the study participants being aware (through the provision of participant information sheets and obtaining informed consent) of the interest of the Researcher in food safety. A particular concern might be raised about these views being expressed during the group discussion, given the presence of the HACCP lead in the group. However, as demonstrated by the quotes, this view was also expressed by staff in individual interviews, not simply during the group discussion.

In addition, the same situation was not encountered in the second case study, LiquiComp UK, suggesting that this finding is not merely caused by the study design (or from any group effect) but is an insight into the true values of the study participants. Indeed, this prioritisation of food safety as the purpose of the organisation fits with the "safety first" attitude discussed earlier in terms of the metal contamination incident.

Participants also expressed pride in the work they carry out and the importance of food safety within PowderCo UK. As one participant put it:

> "… the outside [of the factory] probably looks a bit dirty, but you go inside and the standards that we're actually trying to achieve here are top notch …." (P007, Quality Manager).

Another example of the importance of food hygiene and safety was shown by the pride with which participants spoke of a recent review of long term cleaning programmes carried out by an external contractor:

> "… during the meeting they [the contractor] turned around and said we're actually doing far more here than any other factory they visit to do with long term cleaning, far more robust than anywhere else." (P004, Shift Supervisor).

Another good example of the high standards that the site is aiming for (and the willingness of the company to spend on prevention, in quality costing terms) was found during the production plant tour. The Researcher was shown new flooring being laid in a storage area, where traditional wooden slated floors were being replaced with non-slip linoleum. The wooden flooring had been raised as a potential concern in several BRC inspections; although the site had never been marked down in an audit because of this, management had decided to replace it as a proactive measure to improve hygiene, the new flooring being easier to clean and offering better protection against pest ingress.

The commitment of senior management to food safety was also evident through the required training for food safety and HACCP, which has been described under "Experience Required".

A final point to raise under this theme is the importance to the site of the health and safety of employees and visitors, as well as food safety. As P008 put it when discussing engineering changes and the time taken to achieve these:

> "…. we need to make sure, not only as a safe product, but as a safety to our staff you know, and people around us…" (P008, Senior Engineer)

A focus on accident prevention is seen in the site wide target of "zero accidents", previously mentioned in the theme "Formal Expressions of Culture". Study participants also described a "ZAP" system, which is used across the site to record health and safety "near misses" and put in place remedial actions. Further measures to embed the culture of health and safety across the site are also seen in the objectives set for staff:

> "... I must submit a minimum of 6 safety improvement ideas… I have already achieved that six, so small things make a lot of difference…." (P002, Cell Team Leader).

Although no specific scheme to measure FSC or report on food safety issues (in a similar way to the ZAP reports) was described by study participants, the cross over with health and safety systems and culture was recognised:

> "…. we've got the ZAP process as well which generally uses about safety, but can also cover I guess some food safety stuff if it's deemed to be a risk…" (P007, Quality Manager).

> "… and looking at overall safety we have an assessment, something called living safely which is about understanding behaviours and how the site is actually managing safety, going from we obey the rules sometimes all the way up to we live and breathe safety. But the implication is that if you're doing that for safety, you're probably doing it, almost likely doing it for the other side of things which is the product safety, food safety piece". (P007, Quality Manager).

These examples illustrate a link between the "top down", written directives and policies from senior management (as outlined in the previous theme) and actual working practices in the business. In other words, at PowderCo UK, staff appeared to approach food safety with an attitude of "what we say, we do" and not simply pay lip service to written policies on food safety and quality.

The communication of formal policies, and how these are interpreted and recommunicated in the business, have already been touched upon in these last two themes. Communication forms the final theme under which the overall PowderCo UK case will be described.

"Communication"

Communication during the investigation and management of the metal contamination incident was discussed in section 5.3.1, and the development of "war stories", telling of the organisations successful fight to overcome adversity, was highlighted as an organisational strength.

Storytelling is also evident in more general communications in PowderCo UK. The history of the products, site and company are told in a leaflet and visually through physical artefacts, photographs and maps, in a small museum located near the site reception.

In the organisation, product quality and health and safety messages are also often reinforced via stories. During the Researcher's visit to the PowderCo UK site, one story noted was a health and safety "news flash" poster located at a coffee point in the main office area. This told of fines issued to a laundry firm after a worker fell through a floor and received burns from equipment located below. The key message of the poster was "What can you learn from this?", illustrating that that PowderCo UK use such storytelling to impart knowledge and provoke learning on what could otherwise be perceived as "dry" and uninteresting topics.

This type of visual communication might be considered passive, relying on people to use their own initiative and read the posters, for example, but it is a very transparent form of communication, in that such posters are open to view by anyone walking along corridors or using meeting rooms. Such visual communication is also used by management to focus the organisation on key priorities and objectives. Examples range from team work plans displayed in working areas, to site targets for "zero accidents, zero defects, zero waste" being set out on notice boards in the office corridors.

A more active and directed form of communication comes in the form of the daily site accountability meeting, which is attended by the site director together with management representatives of production and supporting site functions, and which is held just inside the main entrance to the production area. This meeting is supported by a series of meetings held earlier in the morning by individual site production teams and support functions, enabling information to flow up to and cascade back down from the main meeting.

At the accountability meeting issues affecting the site are raised as incident reports (IRs); if these are not quickly resolved, are deemed to be of greater significance or require ongoing work, they are classified as a CAPA (corrective action, preventative action). The meeting attendees also run through the three site targets of zero accidents, zero defects and zero waste and the top three priorities for action are agreed and documented on a series of white boards, placed in the production area and visible to all on-site staff. This format allows IRs and CAPAs to be tracked and monitored easily, as well as longer term plans such as tracking capital spend (which is reviewed periodically). The prioritised actions drive part of the workload of the management team, who are expected to work on resolving IRs and CAPAs at 3pm each day, in order to report progress at the following morning meeting. Thus, the accountability meeting acts as an important vehicle for agreeing priorities, directing effort across the site and communicating both targets and progress.

Another specific communication activity used across PowderCo UK was referred to by the study participants as "Gembas", which are conducted by all levels of management. This is a Japanese term, explained as meaning "go and see", the practice of which forms part of the company Six Sigma process improvement tool kit. The Gemba involves managers engaging with staff on the factory floor to look at work practices and understand issues. It was variously described as:

> "…. a bit like auditing, but with a different slant, so you're just trying to find out what's happening…" (P007, Quality Manager)
>
> "…. going out and looking at things and asking questions to the operators in a very polite way…." (P001, Quality Supervisor)

Documentation provided to the Researcher on the Gemba method as used in PowderCo UK set out two different type of Gemba: problem focussed and safety focussed. The first supports problem solving in a focussed area, in a coaching manner, whilst the second is used to identify sources of risk and identify preventative safety improvements. PowderCo UK managers are expected to conduct four Gemba sessions each week (with some targeted to feed into IRs for the accountability meetings). Gemba appeared to be a longstanding practice which was viewed positively, giving staff an opportunity to communicate freely with management, and for management to get close to the issues that matter to their teams.

Overall therefore, the open, transparent approach to communication seen in the quality incident is echoed in day-to-day communications on the site. The communication methods experienced support story telling as a vehicle for CI, and set communication activities (Gembas and accountability meetings) are used to foster closer ties between management and staff and to focus the whole organisation on key priorities.

Conclusion

This thematic analysis of PowderCo UK from an organisational perspective has elucidated key insights into the attitudes, behaviours and working practices of the business. Processes and systems are key to managing the business; communication is regular and open and there is a common understanding of the overall organisational mission and values which are interpreted at a local level to prioritise the safety of food and people. These values are backed up by a management commitment to food safety evidenced by staff training; by the audit and certification of site quality and food safety systems, and by the proactive approach to improving facilities to ensure good hygiene on site, such as the floor replacement programme. Although a breakdown of quality costs was not obtained as part of the case study, it is clear that the organisation is willing to incur additional spend on prevention and appraisal costs, as evidenced by these examples.

With this overall assessment of the organisation, we now return to the case of the non-reportable food incident, to consider if the organisation behaves and works consistently when comparing normal operations to a time of stress, or if there are any differences. We also return to the first research objective: can the failure of the FSMS / QMS be related to the process itself or is it due to the people implementing and using the systems? These questions are addressed in the next section.

5.4 The Relationship between the Embedded Case and the Organisation

Having analysed both the embedded case of the non-reportable food incident and the broader organisational case, it is important to consider the degree of congruity between the results. Are the organisational values, behaviours and practices related in the narrative of the incident the same as those espoused in formal organisational processes and policies? Do the everyday working practices described by study participants differ from the actions taken by PowderCo UK under a time of stress?

As previously described, common themes have been developed across the embedded and organisational cases. The reliance on, and trust in experts (internal and external to the business) and experience was noteworthy. There was also particularly strong alignment in the importance of processes and systems for the everyday running of the business and for incident management and problem solving. In fact, the company might be seen as having an over-reliance on systems and processes. Indeed, excessive paperwork and documentation are known barriers to the implementation of FSMS (Jevšnik et al., 2006; Fotopoulos et al., 2011). Whilst there were few complaints by study participants about the complexity of systems, gaps in the SOP and checklists for checking magnets and sieves were key in the system failures seen in the incident (as shown in Figures 5.4 and 5.5). The plethora of different systems and processes might result in **"system swamping"**, making it difficult for staff to identify any critical gaps in systems and processes and so acting as a barrier to effective food safety governance.

Another key finding was the synergy between CI in day-to-day operations and learning from failure in the case of the quality incident, which can be considered as two complementary elements of organisational learning.

The fundamental importance of food safety to PowderCo UK was also striking. PowderCo Global's mission statement has been successfully interpreted by staff at the UK manufacturing site to position the key priorities of the business as the safety of the food it produces and the workers who make it. This prioritisation was clearly echoed in the management and resolution of the metal contamination incident.

In Chapter 3, FSC was defined as "the aggregation of the prevailing, relatively constant, learned, shared attitudes, values and beliefs contributing to the hygiene behaviours used within a particular food handling environment" (Griffith 2008, 2009, cited by Griffith et al., 2010a. The prioritisation of food safety, both in terms of systems and processes and the central position that food safety takes when employees discuss the purpose of the organisation, suggests that in terms of Griffith's definition, PowderCo UK could be considered as having a strong FSC. A further analysis of the FSC of Powder Co UK using the model of Jespersen et al. (2017), and a comparison with the FSC of LiquiComp UK is presented in Chapter 7, section 7.2.

One element missing from the description of the incident was any suggestion of a blame culture, with neither individuals nor functions being singled out as being responsible for the failure. Blame could easily have been assigned to the engineering team for a failure to maintain Bin C in appropriate working order – surely they should have recognised that the age of the equipment increased risks of failure? Likewise, blame could have been cast on the line operators who failed to recognise an unacceptable level of metal generation when checking in-process magnets – surely they could see that a problem was occurring? Fault could also have been placed with the engineer who ran the project which moved the magnet in Bin C, and with the individuals who conducted the HACCP review and concluded that there was no risk attached to moving the magnet – surely they should have known better or conducted more tests, rather than just making this assumption?

This avoidance of "naming and shaming" fits well with the open communication described through the course of the incident and for the daily operations of the site and must contribute substantially in allowing workers to voice concerns about food quality or safety without fear of retribution. It also links to PowderCo UK's focus on CI activities and the organisation's demonstrated capability to learn from failure.

So, if PowderCo UK did not blame people for the failures which resulted in the metal contamination, were processes held to fault? Was there any sign that HACCP or other elements of the FSMS had been devalued by the incident, given that it happened despite having processes and systems in place?

In fact, there was no evidence that the incident caused staff at PowderCo UK to mistrust the systems and processes in place; they had pride in their work and expressed faith in the site FSMS. In fact, this misplaced faith in control systems and processes might be seen as part of the **"culture & values"** of the organisation, forming another potential barrier to effective food safety governance.

Rather than people or the process being blamed for the incident, it was seen as being caused by unforeseeable events: the possibility of such a failure happening (the metal generation and the failure of detection systems) had not been considered and controlled for in the QMS and FSMS, i.e., in the terminology of PC, if the possibility was identified at all, it was not considered a factual possibility which needed to be seriously considered in plans. There appeared to be no recognition of the "truth gap" between the pro-active truth of "our FSMS works" and the pragmatic truth of "we've seen a failure in the FSMS".

In many ways, the classification of the incident as unforeseeable is an easy option, avoiding the necessity of searching conversations about the adequacy of actions and decisions made in developing and managing the FSMS and preserving an illusion that food safety is under complete control at PowderCo UK. Again, considering the PC framework, it appears that PowderCo UK has a well-developed and integrated organisational topos; against this background it might not be seen as feasible to admit to significant shortcomings in the QMS and FSMS, as this could fragment the topos. Further consideration of the case in light of the PC framework and other literature is described in Chapter 7. Indeed, categorising incidents as **"unforeseeable"** rather than facing uncomfortable truths about possible inadequacies in processes or people might be viewed as a barrier to effective food safety governance. Additionally, if incidents result from unforeseeable events, this calls into question the suitability of HACCP-based FSMSs. This point will also be explored in detail in Chapter 7.

In summary, it appears that PowderCo UK have blamed neither people or process failures for the metal contamination incident, but before simply accepting this answer to the first research question, a further examination of the themes developed in this case must be considered.

Figure 5.6 sets out a map, showing the relationship of the codes to themes, and additionally maps them (at both code and theme level) against the "people" and "process" clusters of the theoretical roadmap set out in Figure 4.3. Codes and themes considered to be related to the people construct only are written in italics; those related to the process construct only are written in capital letters, and those related to both people and process are in italicised capital letters. As can be seen, three themes (Communication, Experience Required and Culture & Values) are mapped to the people cluster alone, whilst two themes (What Went Wrong and Day-to-Day) are mapped solely to the process cluster, whilst the remaining three themes are mapped to both.

To further clarify this, looking at the theme of "Problem Solving Our Way", this was classified as relating to people and process. Four codes were clustered to form this theme. One code, “problem solving process” is considered to relate to process alone, as it covers aspects of the case such as the use of RCA and the LIC. The remaining three codes, “cultural standard” (covering aspects such as the dominance of the RCA method leading to a specific workspace called the RCA room), “decision making” (a code which captures the actual decisions made during the incident management and resolution) and “rationale for decisions” (a code used when participants explain the reasons for decisions, which cover process and cultural explanations), relate to both the people and process clusters. (Appendix B shows the full code book with examples).

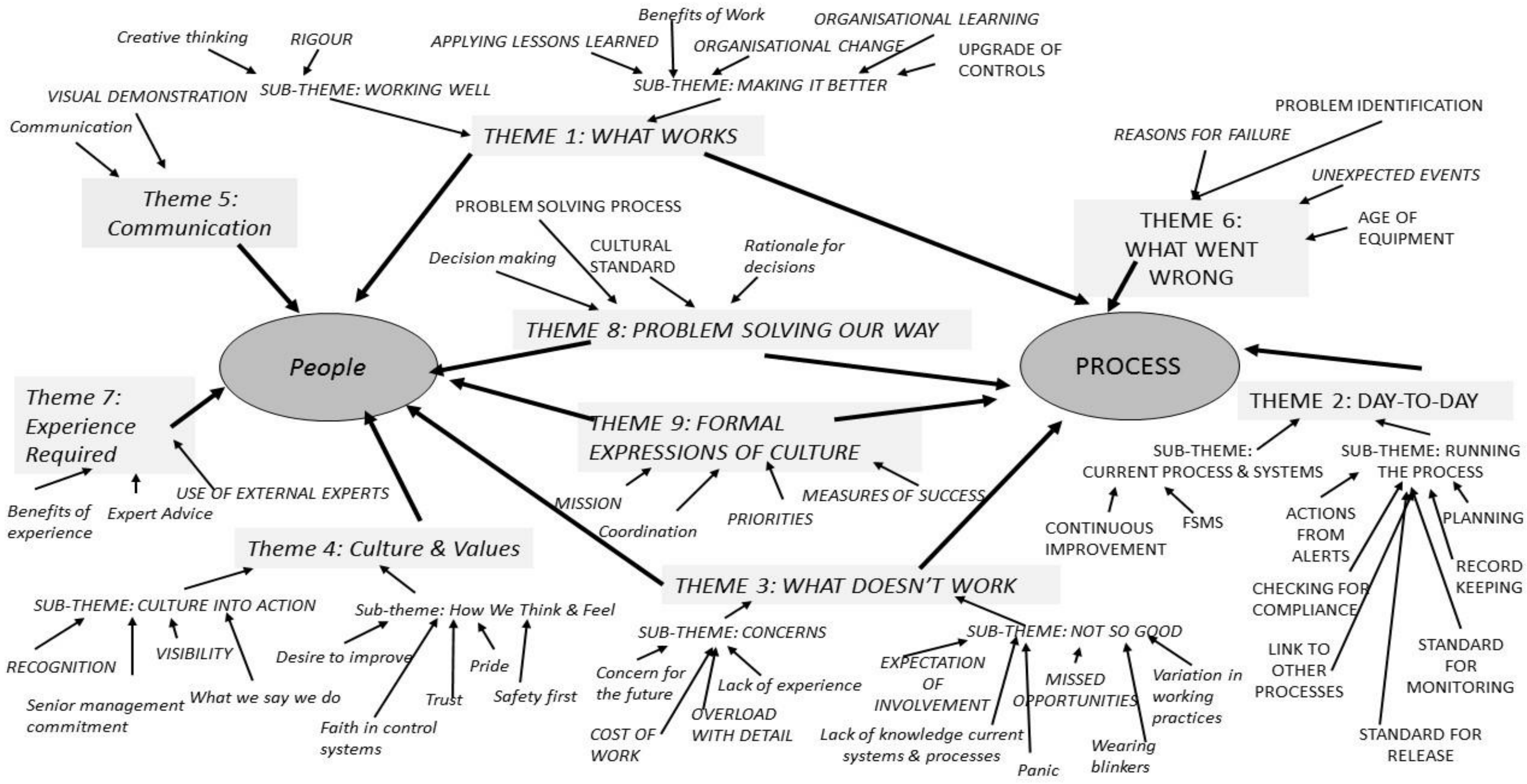
This thematic map shows the interwoven nature of the case and clearly demonstrates the complexity in trying to attribute the underlying cause of the incident – or indeed the generally successful operation of the FSMS – to either the people operating the FSMS or the process itself. This may be another reason why, for staff and management at PowderCo UK, it is easier to consider the failures and the incident itself as unforeseeable, rather than try and ascribe overall responsibility to one aspect of the case or a single individual or group of individuals.

Nevertheless, looking at the thematic map, it can be discerned that there is a strong reliance on processes and systems to manage the day-to-day activities of the business and to solve problems which occur. This is shown for example, in the theme “Day-to-Day”, with codes relating to the FSMS process, planning, standards for monitoring etc. The thematic map also shows that people related aspects of the business constitute much of what makes it generally successful: e.g. under the theme “What Works”, the aspects of rigour and applying lessons learned.

However, whilst aspects of the processes failed in terms of the non-reportable food incident explored as the embedded case (e.g. standards for monitoring, in terms of a standard for metal contamination), people aspects underpin many of the failures demonstrated in the incident, e.g. under the theme “What Doesn’t Work”, the missed opportunities and variation in working practices.

It can therefore be concluded in this case that despite the organisation blaming neither people nor process, failures by people can be seen to dominate the underlying causes of the incident.

Figure 5.6: PowderCo UK Thematic Map



Italics = people related; CAPITALS = process related; *ITALICISED CAPITALS* = people and process related

5.5 Conclusion

This chapter has described the first case study, PowderCo UK, through a thematic analysis of the overall organisation, and the embedded case of metal contamination.

The metal contamination incident perfectly illustrates the complex and interwoven nature of food incidents, involving failures in equipment and monitoring systems, as detailed in Figures 5.4 and 5.5. In fact, the incident happened not because of a lack of quality and food safety systems but despite PowderCo UK having a comprehensive QMS, FSMS and FSMnSs, and indeed against a strong track record of ISO and BRC accreditation for quality and food safety.

The thematic analysis also indicated that the incident happened despite the importance of food safety to both management and staff. Management commitment was illustrated not only by their involvement in the investigation and resolution of the incident itself, but also through their commitment to food safety training and spend on proactive food safety measures, such as more hygienic flooring. Although there was no formal recognition of quality or food safety in the overall global mission statement, all of the study participants voiced a belief that the purpose of PowderCo UK was to produce safe food and made links between the formal mission statement, food safety and the end consumer of their products. Taking Griffith's definition of FSC (Griffith, 2008, 2009, cited by Griffith et al. 2010a), PowderCo UK might be considered to have a strong FSC. A fuller analysis of this is detailed in Chapter 7.

Communication was open and transparent both day-to-day and throughout the incident; even staff not employed at PowderCo UK at the time of the incident (e.g. P001) were able to articulate a clear and consistent narrative about the incident and its resolution. Such narratives or "war stories" enabled PowderCo UK to learn from failures, which linked strongly to their use of CI as everyday practice and can be viewed as a core strength of the organisation.

Systems and processes were fundamental to the ways of working at PowderCo UK, both for day-to-day operations and for incident management and investigation. This was aptly demonstrated by not only the fast set up of the LIC when the company was first informed of the metal contamination, but also by the facilities specifically purposed for certain processes, such as the dedicated "RCA Room".

In fact, the company might be seen as having an over-reliance on and trust in such systems. The plethora and complexity of systems can make it challenging for staff to identify critical gaps in systems, i.e. system swamping might act as a barrier to system effectiveness and hence become a barrier to food safety governance.

Furthermore, the fact that the metal contamination incident can be seen as a failure of the FSMS did not reduce the organisation's faith in the system. In the language of PC, there was a "truth gap" between the pro-active truth of "the system works" and the pragmatic truth of "the system failed this time". This aspect of the case will also be explored further in Chapter 7.

Whilst the thematic map shown in Figure 5.6 illustrates the complex interactions between people and process, it indicates that people concerns underpin the causes of this incident, small – but significant – variations in working practices and missed opportunities being two of the key people related aspects of this case study. These elements relate back to the plethora of, and reliance on, systems and processes, as system swamping may impact on the ability of staff to identify key gaps in processes or to be cognisant with detailed requirements of processes.

However, within PowderCo UK itself, the incident was seen as largely "unexpected" or "unforeseen": neither people nor processes were blamed for the incident. This categorisation of incidents as unforeseen, or even unforeseeable may also act as barrier to food safety governance, as it might impact the ability of the organisation to fully critique its current practices. It also raises questions about the reliability of HACCP as a fully effective FSMS, which will be discussed in more detail in Chapter 7.

With these findings in mind, the next chapter addresses the second cases study LiquiComp UK, and its associated quality failure of cocked / shredded bottle caps, again using a thematic analysis and building upon the codes and themes identified in this case.

6.0 Case Study 2: LiquiComp UK

This chapter moves on to the second case study, which again looks at an established manufacturer who experienced a non-reportable food incident. LiquiComp UK manufactures a range of soft drinks and, just before Christmas 2015, discovered that packs had been produced with a defect where the caps were applied incorrectly to plastic drinks bottles. This resulted in bottles with "cocked" caps (i.e. caps set on bottles at an angle, rather than flat), where the threads of the caps were at times slightly "shredded", so that in some cases fine pieces of plastic were left on the neck of the bottle when opened[36].

This chapter is organised in the same pattern as Chapter 5, i.e. section 6.1 gives a short overview of the organisation; section 6.2 details specifics of the data collection and analysis pertaining to this case; section 6.3 concerns the findings of the case, divided into an examination of the quality incident and those related to the general organisation, whilst section 6.4 considers the relationship between the embedded case and the overall organisation, again with a view to answering the question of whether process, people or elements of both are to blame when FSMSs or QMSs fail.

6.1 Company Background

LiquiComp UK is the UK subsidiary of a multi-national food and drink company. LiquiComp Group was established over a century ago and trades globally, with a turnover in billions of US dollars. LiquiComp UK's organisation is split between its head office (where corporate functions, sales, marketing, and R&D teams are based) and production sites.

[36] It should be noted that the plastic "swarf" was seen on the outside of the neck of the bottle; no pieces of plastic went into the liquid inside the bottle.

LiquiComp UK manufactures both still and carbonated soft drinks. The production facility at the heart of this case has been upgraded and expanded many times over its lifetime.

At this plant specific product blends, other ingredients (such as carbohydrates, acids and sweeteners) are combined and packed on site into a range of different packs and sizes. The finished products are then moved to a warehouse from where they are transported to UK and international customers.

The site operates 24 hours a day, seven days a week. Daily production breaks (1 hour in every 24) are scheduled for cleaning on each line to maintain safety and optimum performance in the factory. A weekly shutdown, after 168 production hours, ensures appropriate cleaning between the manufacture and packing of different products. The site also has two annual shut down periods for general maintenance, at Christmas and during the summer.

Within the production area manufacturing staff are organised into teams, each with responsibility for a different production line. The management of each team has a degree of autonomy and by default the teams compete, e.g. to achieve the best production figures. Production is supported by a range of specialist functions, including health and safety, engineering, quality and logistics. The factory is led by a site director supported by a senior management team. The site director is also a member of the leadership team of LiquiComp UK.

As is not unusual within the food industry, at the time of the data collection for this case study, the organisation was undergoing an operational restructure to meet developing business needs.

6.2 Data Collection and Analysis

Semi-structured interviews were used as the main data collection method. (Chapter 4 details the interview guide development).

Study participants were recruited from the head office and manufacturing sites. Those based in the head office represented a range of central functions who were members of the Incident Review Committee (IRC). The role of the IRC is to review quality and safety incidents and make recommendations of action to the senior management committee in the business (the SMC). These participants had been involved in the review of the "cocked / shredded cap" quality incident which forms the embedded case and were recruited via a gatekeeper (participant L001). An additional participant who was not a member of the IRC, but a junior member of the quality team, also participated in interviews at the head office.

Manufacturing site participants were selected for either their involvement in the investigation and management of the quality incident and / or their knowledge of, and responsibility for, aspects of the site FSMS. These participants were recruited via a member of the quality team, who was a direct report of participant L014.

Across the sites the participants were predominately middle and senior managers or technical specialists. At head office, the majority of study participants had been in the business a relatively short time. In contrast, at the manufacturing plant most of the participants had worked at the site for over 10 years. In total 17 members of staff were interviewed, with 12 individual face-to-face interviews, two individual telephone interviews and one group interview, which was a mixture of face-to-face and phone conference participation, as shown in Table 6.1. Subsequent to the main interviews, an additional informal telephone interview was held with L001, the Researcher's main contact for the study.

Table 6.1: Description of Study Participants (LiquiComp UK)

Participant Number	Job Role	FSMS / Incident experience	Interview Type and Duration
L001	Business Quality Director	Ran IIC and IRC. Author of SOP for product incident management.	Group interview, including phone conference participation by L002, 3 hours. A follow up conversation lasting around 1 hour was held with L001 subsequent to the main data collection.
L002	Head of Risk	Member of IIC and IRC teams.	
L003	Quality Technician	Works for L001 on central quality tasks and incident management activities.	
L004	Consumer Manager	IRC team member.	1-to-1, 54 minutes.
L005	Regulatory Manager	IRC team member.	1-to-1, 54 minutes.
L006	Lawyer	LIC and IRC team member.	1-to-1, 43 minutes.
L007	Corporate Affairs	IRC team member.	1-to-1, phone interview, 36 minutes.
L008	Head of Supply Chain Planning	IRC team member.	1-to-1, phone interview, 51 minutes.
L009	Food Quality and Safety Manager	IIC and IRC team member. Member of RCA team at factory. Member of the HACCP team.	1-to-1, 1 hour 21 minutes.

L010	Line Operator Manager	User of FSMS. Member of the HACCP team.	1-to-1, 29 minutes.
L011	Factory Leadership Team Member	Member of RCA team at factory	1-to-1, 44 minutes.
L012	Technical Team Member	User of FSMS	1-to-1, 33 minutes.
L013	Packaging Manager	Involved in incident investigation	1-to-1, 24 minutes.
L014	Director of Technical and Quality, Manufacturing Site	Owns FSMS on production site.	1-to-1, 1 hour 5 minutes.
L015	Manager, Third Party Manufacturing	FSMS user	1-to-1, 35 minutes.
L016	Manufacturing Site Continuous Improvement Manager	Led RCA on failure of detection methods	1-to-1, 34 minutes.
L017	Site Engineer	Led RCA on failure of production equipment	1-to-1, 1 hour.

Data was also collected through observation of working practices and document examination. Some documents were made available to take away, whilst others (such as HACCP plans and the SOP for product incident management) were only made available for review on site, in which case notes were taken for later review and analysis. These are detailed in Figure 6.1, which also lists the different observation points of the study. The escorted tours of the head office and manufacturing plant, plus attendance at the morning operations and quality meetings, allowed the Researcher to observe staff behaviours and working practices. At the production site, it was also possible to observe the FSMS and FSMnSs in use and discuss the failure points in the FSMS / FSMnS pertaining to the quality incident. Information gathered from observation and document review was used to triangulate findings from the semi-structured interviews in developing the codes and themes which are used to discuss and analyse this case study.

Figure 6.1: Documents Examined and Observation Points, LiquiComp UK

Documents
SOP: LiquiComp UK corporate procedure for management of product related incidents
LiquiComp UK Quality Policy Statement
LiquiComp UK Quality Strategy Proposal for 2016
LiquiComp Europe Quality Mission, Vision and Action plan
LiquiComp UK 2016 Strategy Board
LiquiComp Europe Staff Brochure
LiquiComp UK Quality and Food Safety Update for the SMC, Jan 2016 (including details of the "cocked cap" issue)
LiquiComp UK Manufacturing Site Food Safety and Quality Manual
LiquiComp UK HACCP Study for bottling lines C1 and C2

Observations
Staff coffee break rooms and canteens (head office and manufacturing site)
Office space and meeting rooms (head office and manufacturing site)
Escorted tour of production plant
Escorted tour of head office facilities
Morning accountability meetings for Line C1 and Quality team.

All of the interviews were transcribed in accordance with the analytical plan shown in Chapter 4. Coding was completed using the a priori codes developed in the analysis of the first case study (PowderCo UK), with additional codes created inductively. As described in Chapter 5, 53 codes were created for the PowderCo UK case study. 51 of these codes were judged to apply to this second case and 30 new codes were created.

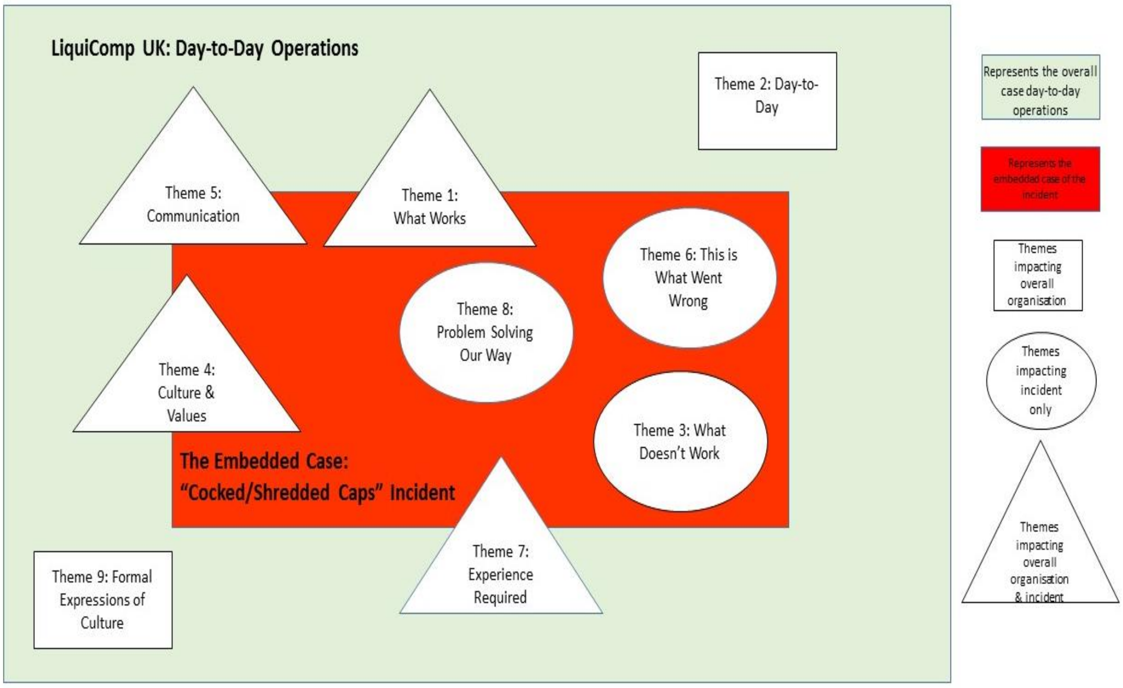
Each new code was considered for categorisation into new themes or into the nine themes created in the first case study. After cross-checking, no new themes were generated and all codes were categorised into existing themes. These are listed in Table 6.2 below.

Table 6.2: Themes Pertaining to the LiquiComp UK Case Study

	Theme
1	What Works
2	Day-to-day
3	What Doesn't Work
4	Culture & Values
5	Communication
6	This Is What Went Wrong
7	Experience Required
8	Problem Solving Our Way
9	Formal Expressions of Culture

As in the first case study, there is an overlap between the themes which describe the embedded case and the overall organisational case (repeated here as Figure 6.2).

Figure 6.2: The Relationship of Themes to the Organisational Case and the Embedded Case (LiquiComp UK)



In the rest of this chapter the research findings are presented primarily in terms of these themes, with a particular view to consider the "FBO People" and "FSMS Process" clusters set out in the theoretical roadmap in Chapter 4. A comparison of this case to that of PowderCo UK, and a discussion of the results in terms of the PC elements of the theoretical roadmap, and further PC constructs, is set out in Chapter 7.

6.3 Findings

6.3.1 The Embedded Case: "Cocked / Shredded Caps"

One Friday afternoon, a week before Christmas 2015, the Head of Manufacturing Site Quality at LiquiComp UK was informed by his microbiology team of a potential quality or food safety incident.

Each day, at two hourly intervals, product samples are taken from the production lines across the sites and held for microbiological testing as part of the manufacturing quality procedures.   On three consecutive days, samples with “cocked” caps had been found at one site; these were noted by the microbiology team because the incorrect sealing of these bottles meant that the samples were not fit for microbiological testing. More worryingly, the cocked cap itself could be a quality or even a food safety issue and, with packs found three days in a row, alarm bells started to ring.

The Head of Manufacturing Site Quality immediately quarantined stock and over that weekend conducted further checks to determine the nature and extent of the issue. On checking bottles with cocked caps, he noted that fine shreds or tails of plastic from the inside of the cap were often left on the neck of the bottle when the cap was removed. These shreds of plastic could potentially be inhaled or swallowed. So, these bottles were not just of poor quality but potentially might be a food safety hazard. The issue was therefore flagged to the Business Quality Director of LiquiComp UK and the formal incident investigation process was immediately kicked off. In fact, the Business Quality Director cancelled a planned foreign business trip to enable him to go to the manufacturing site on the Monday morning and begin the formal processes.

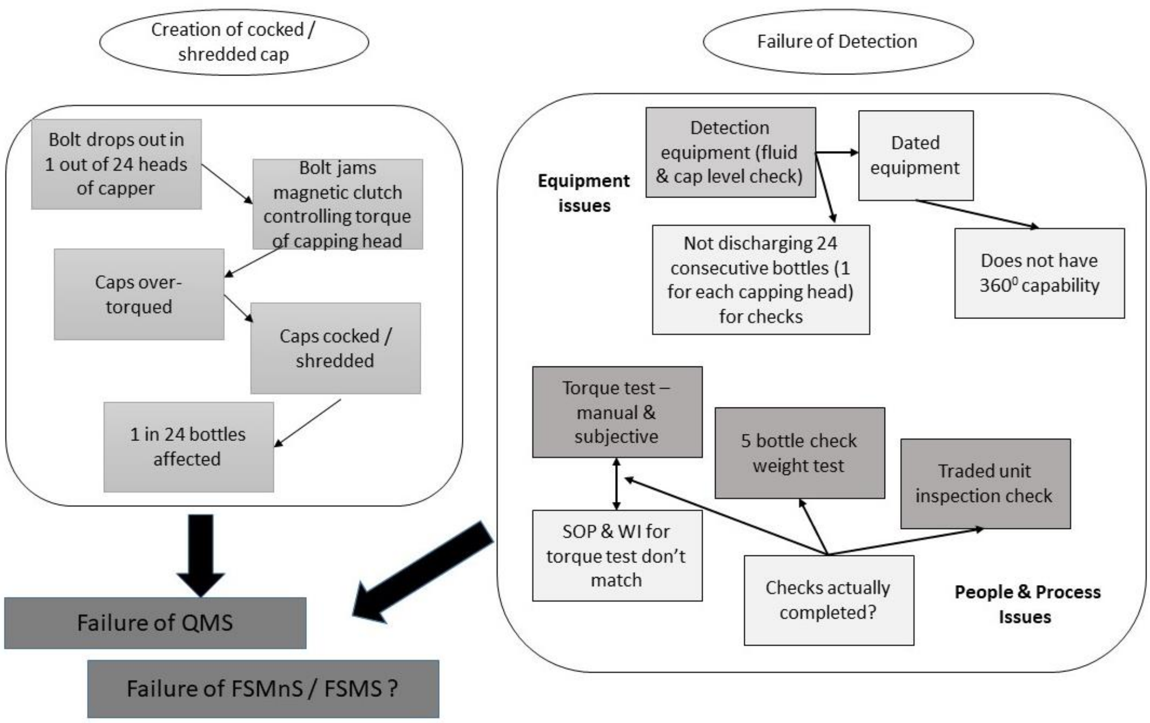
In this section the history of the embedded case - that is the identification and management of the incident as narrated by the study participants - is described and interpreted via the themes developed from the qualitative data. Seven of the nine themes are used in this analysis, namely: “This is What Went Wrong”; “Communication”; “What Doesn’t Work”; “Culture and Values”; “Problem Solving Our Way”, “What Works” and “Experience Required”.

“This Is What Went Wrong”

> “… so there was a whole sequence of little errors which gradually rolled and grew, and rolled and grew” (L014, Director of Technical and Quality, Manufacturing Site).

This quote illustrates a key finding about this non-reportable food incident, in that the cocked / shredded caps had not occurred because of one major problem in the manufacture of the product, but rather as the outcome of a complex series of connected events. The incident involved not only the equipment failure which generated the cocked / shredded caps but also a failure to detect the fault with the caps. This is summarised pictorially in Figure 6.3.

Figure 6.3: An Overview of the Non-Reportable Food Incident at LiquiComp UK



LiquiComp UK has a comprehensive FSMS (including a detailed HACCP plan, with linked PRPs and maintenance schedules) and a QMS for the manufacturing site. In addition to CPs and CCPs set out in the HACCP plan, the production process has numerous QCPs. In terms of CPs, these include intermediate checks during production prior to a final CCP e.g. checks of filters prior to the last filter before bottling. A failure of this type of CP enables issues to be addressed early, but as a CCP follows later in the process, unsafe product should not result from a failure of this type of control.

In addition, QCPs are set as part of the QMS, for example to check the amount of liquid fill and the tightness of the cap on the bottle. Failures in this type of QCP could result in quality issues and possibly regulatory or legal issues (leaking bottles; selling under volume product) but no impact on product safety is expected.

In this incident, failures in QCPs, rather than CPs or CCPs, were evident. However, the nature of the pack damage– the production of fine shreds of plastic from the cap, sticking to the rim of the bottles – could easily have posed a food safety hazard. Understanding the nature of the hazard and answering the question of whether it constituted a FSMS failure which necessitated a product recall and notification to the authorities was part of the incident management process, which is described later in "Problem Solving Our Way". This question also illustrates the interaction in food manufacturing between quality and safety and the challenges of developing an appropriate FSMS.

So, at the start of Christmas week, the incident investigation kicked off with the establishment of an Initial Incident Committee (IIC) and initial investigations at the manufacturing plant. By looking at the affected products and pack sizes, it was established that manufacturing line C was involved. It was also determined quickly that the problem with the bottle caps was due to them being applied too tightly, or "over-torqued":

> "… that example with the shredded caps was fairly obvious, you know we completed that in half an hour, that it was an over-torqueing thing …" (L001, Business Quality Director)

The over-torqueing could only have been caused by some failure in the capping equipment. Therefore, an RCA specifically to investigate the capping equipment, led by a member of the production site engineering team, was started in parallel with the set-up of the IIC. This RCA established that on the Line C, in just one of over 20 heads of the capping machine, a bolt had dropped out and jammed a magnetic clutch. This caused the over-torqueing of the caps, resulting in a 4% failure rate in the packed products. This fault was viewed as novel, both to LiquiComp and their equipment and packaging suppliers:

> "… I've not come across this particular issue previously, and the manufacturers of the magnet head, or the filler or the capper, likewise, they'd not seen this type of failure mode" (L017, Site Engineer).

In some ways, this part of the investigation and the subsequent corrective actions, were seen as relatively straightforward:

> "There was a big work stream happening from the engineering perspective, not detracting away from the engineers, but for me that was an easier one, 'cos they knew what the fault was…." (L009, Food Quality and Safety Manager).
>
> "… the engineering one was fairly open and shut. The capper was you know, not fit for purpose effectively…" (L014, Director of Technical and Quality Manufacturing Site).

What was not immediately apparent was why this the capping head had failed. This, together with developing preventative measures for the future, became the focus of the engineering RCA work stream.

One of the first areas to be considered was equipment maintenance, as regular checks (daily, weekly, monthly and quarterly) by the site engineering team are scheduled. The RCA found that all maintenance had been completed as per the schedules. However, in none of the documentation supplied by the original equipment manufacturers, or in training received from these suppliers, were checks of the bolts in the capping head identified as on-site maintenance points:

> "So we were interested to learn why we didn't have this as a risk factor, and it wasn't in any of the documentation to say you need to inspect or check … we didn't perceive this as a potential risk to food or reliability of the equipment." (L017, Site Engineer).

In essence, the failure of the bolt in the capping head came to be regarded as an "unforeseen" design flaw, just waiting to manifest. As L001 explained:

> "You can reasonably expect that if you buy an off the shelf piece of kit, the supplier has done their homework in terms of assuring that it's fit for purpose …. we are not [manufacturing equipment] designers, we have to trust that they know what they are doing." (L001, Business Quality Director)

This "unexpected" risk of equipment failure due to a design fault gave rise to another key feature of the embedded case – should LiquiComp UK take legal action against the original manufacturers of the equipment to recover costs arising from the incident (withdrawal of product; rework of product; factory opening over Christmas period; potential loss of goodwill etc., i.e. a mixture of internal and external costs of failure from a quality costing perspective)? In "Problem Solving Our Way" it is shown that the legal team play a major role in the management of all product related incidents, but with this possibility of legal action, their role became even more prominent. Communications were routed through and / or approved by the legal team to give the protection of legal privilege in the event of any legal action. The impact of this on the incident investigation process and management is presented in detail in the themes "Communication" and "Culture and Values".

So, the equipment failure was understood. But, as shown in Figure 6.2, this equipment fault was exacerbated by a failure to detect the over-torqued caps, which also involved the failure of multiple control points. As one participant described it (perhaps in reference to the well-known work of James Reason (1997) on accident causation):

> "…it's the old Swiss cheese where the particles can get through all the gaps 'cos it happened to align in the right direction, at the same time, so it was just a perfect storm." (L014, Director of Technical and Quality, Manufacturing Site).

One of the initial consequences of the failure to detect the capping problem was the challenge of assessing the size of the issue, i.e. how many bottles were affected.   The last day of production of the affected bottles was known, as the discovery of cocked caps happened on the last production day of the year before the Christmas shut down.

Only after detailed investigations, taking impounded products and stripping pallets of bottles to look at failure rates, was it determined that 10 days was worth of production from Line C was potentially affected. With a 4% failure rate, this amounted to potentially 8,500 affected bottles or approximately 220 pallets of product. (From a quality cost perspective, this work highlights several internal costs of failure including the storage of impounded product, the staff costs to physically strip down pallets and check for damaged packs and the costs of managing this activity as well as the cost of the affected product packs).

With that volume of stock potentially affected, even though it was of course spread throughout the total production of over 200,000 bottles, LiquiComp UK management were highly sceptical that staff had carried out the required quality checks correctly:

> "… by pure chance alone, given the amount of affected stock, you would have come across a defective one in your hands at some point, you know it's almost incalculable that you wouldn't have got one of those 8,500 in your hand at some point when you're supposed to be doing these [quality checks] every few hours." (L001, Business Quality Director)

This aspect of the case is discussed further in "Culture and Values".

So how were all these cocked caps missed? A second RCA stream was set up in January 2016 to investigate this and looked at the QCPs which should have identified the damaged caps. The first QCP implicated was an in-line check system with an "electronic eye" which scanned the bottles, checking for both cap placement and product fill. This detection equipment had limitations that seem to have been overlooked in the day-to-day operations of the plant. This equipment had a limited angle of sight (i.e. not 360^{o}) so it was possible that bottles with cocked caps had escaped detection:

> "… given that a cocked cap is cocked in one direction, depending on if you're the electric eye looking at it, in a certain direction it has one profile, if you spin the bottle around – and they are spinning – it changes profile, so that's another

> learning really that the equipment isn't 100% fool proof..." (L001, Business Quality Director)

In fact, this detection system had recently been identified by the engineering department as dated and an application had been submitted for system upgrade:

> "...the quality detection system which looks at the cap, it was dated and an old design … it wouldn't have been picking this particular issue up, so we had put it in for the next 3 years to upgrade..." (L017, Site Engineer).

An added complication, which came to light as more of the stock was checked, was that not all of the over-torqued caps were cocked, i.e. some caps still appeared straight on the top of the bottles, and so would never be picked up by this type of check, even with a 360^0 angle of sight. Hence, for this particular manufacturing defect, this QCP was by itself insufficient and affected product could be expected to get through to the second control point.

A second issue with the detection system fed into the failure of the second QCP, a physical check of the bottles called a "torque check". The QMS required the line operative to use this detection system to reject bottles (the same number of bottles as filling heads) from the production line every 2 hours. Although not explicitly written in the procedure, the actual need was for bottles to be taken off the line sequentially, to ensure that one bottle from each filling head was tested. However, it transpired that the equipment was not systematically rejecting one bottle from each filling head. Hence it was, in theory, possible that bottles with damaged caps from the one damaged filling head were not picked up for the "torque check".

The "torque check" itself was the next failure point. This test examined "how much tension you put on the cap to actually align it on the bottle" (L009, Food Quality and Safety Manager). Yet again, the method was, in hindsight, viewed as dated and potentially problematic. The "torque check" was somewhat subjective: the amount of pressure exerted and measured by the line operative varied with their physical strength and familiarity with the test.

> "… again on reading up more and more on it, obviously it can be quite subjective where the dial goes when you turn that cap … it depends on their strength as well … and the resting time between coming off the capper to conducing the test, it slackens off obviously over time as well." (L009, Food Quality and Safety Manager)

Additionally, the full "torque check" was a destructive test: after measuring the force required to remove the cap, each cap was supposed to be completely removed to check the integrity of the bottle neck and cap. Significant doubts were raised about whether staff had completed checks correctly, or even at all:

> "…one of the real smoking gun aspects was the fact that there were, supposedly, line checks where an individual would take a bottle periodically off the line, they would open it up and they were supposed to check and see there was no damage. The check sheets that had been filled out for that affected time period all had a beautiful row of ticks saying 'acceptable, acceptable, acceptable', so you can come to very little other conclusion that to say that was a fabrication…" (L001, Business Quality Director)

During the post-incident RCA investigations, staff who worked on Line C were asked to demonstrate how they completed these tests. These observations showed that staff were completing the tests correctly, but this finding was also questioned:

> "…we should have had the process in place to check the capping heads. You know, hand on heart, I don't know what the people on the line were doing when they were checking the torque. So when we'd gone down in the first three weeks of January to just randomly observe people doing the check, they were all doing it completely perfectly. But that's after the event isn't it, and they knew something had gone on …" (L016, CI Manager)

Another factor uncovered during this RCA work stream was that discrepancies were found between the SOP setting out the test procedure and the check sheet completed at the line side:

> "The SOP and the check sheets didn't match up, so one's telling you to do a destructive test, but it's a satisfactory check …." (L009 Food Quality and Safety Manager)

This may have confused line operatives and as such it was impossible to hold staff accountable for any failure to complete tests:

> "…you can't hold somebody to something you know is already fundamentally flawed… you need to be doing this check, you're saying it's filled in here, wait a minute, your SOP doesn't tell you to do that. You can't hold them accountable. Even though they're writing 'sat, sat, sat', you wouldn't have a leg to stand on …" (L009, Food Quality and Safety Manager)

This mismatch in the documentation meant not only that line operatives were receiving inconsistent instructions on the test procedure, but also that the processes to ensure that the Quality team reviewed all changes to documentation on test procedures had not been followed. This point will be further explored under "What Doesn't Work" later in this section.

Two further physical quality checks of product should also have been completed: a five-bottle check for weights (pack fill) and a traded unit inspection check, where a case of product (a film wrapped tray of bottles) was checked for traceability coding and overall integrity of the wrap. In both checks packs were supposed to be physically handled and cocked caps should have been spotted. Indeed, the traded unit check requires that the case of product is laid on its side, and leaks from products with damaged caps should have been observed. It appears that there were multiple "missed opportunities" to identify the issue earlier. This aspect of the LiquiComp operations will also be discussed further in "What Doesn't Work".

So, should this particular issue have been foreseen? Only one study participant suggested that this was the case:

> "… the cap incident that you mentioned earlier, that is a foreseeable control … you can get damage to closures as a result of applying them ..." (L015, Manager, Third Party Manufacturing)

Even this study participant recognised that elements of the incident were less predictable:

> "… whether it was foreseeable you'd get stripped threads is a different question..." (L015, Manager, Third Party Manufacturing)

Overall therefore the incident was viewed as complex, messy and generally unexpected with multiple causes, which had not been adequately controlled with the current systems. If we put this into the language of PC, there was a "truth gap" between some of the elements which LiquiComp UK relied on as "pro-active truth" to operate its production – the suitability of equipment and the adequacy of tests, evidenced through completion of check sheets – and the "pragmatic truth" that not all elements of the processes and systems were robust and reliable. This aspect of the case will be explored further in Chapter 7.

With this understanding of the incident, the actual processes of investigation and management of the incident will be presented in the next theme "Problem Solving Our Way".

"Problem Solving Our Way"

The analysis and management of the cocked / shredded cap incident at LiquiComp UK can be split into two phases. First, the company set up an IIC to determine the extent and severity of the incident. With initial investigations indicating that the incident was potentially serious – there were many affected packs and a possible food safety hazard - the chair of the IIC (in this case L001) called together the IRC. The IIC and the IRC act as a two-tier assessment process; the IIC giving a provisional assessment followed by a deeper questioning and assessment through the IRC.

The IRC is composed of middle to senior managers representing all relevant areas of the business (quality, legal, marketing, logistics, communications, regulatory etc.). Its role is to further investigate the incident and make a recommendation to the overall head of the UK business, the Chief Executive Officer (CEO) and the SMC about actions required to protect consumers and the business, i.e. they can recommend no action, product withdrawal (of stock from the supply chain and /or trade) or product recall (from consumers)[37]. For this incident, this phase of the activity was completed in under a week, culminating with a final decision at 5pm on Christmas Eve.

Importantly, neither the IIC nor the IRC determine the cause of any incident or put in place remedial actions for the underlying cause, although there appears to be some element of establishing plans to address product supply concerns. This "single-minded" approach was described by L005, the Regulatory Manager:

> "…at the early stages I'm not particularly interested in kind of how it happened, I'm kind of interested in how it presents itself. Because from my perspective I'm only interested in whether or not, fundamentally, it's a technical breach of the Regulation 178 that I need to notify the Food Standards Agency about …." (L005, Regulatory Manager).

Being single-minded helps keep the process focussed and helps the business reach decisions in a speedy manner, which is critical when potential food safety issues are concerned:

> "…. L001 kept us to a specific agenda so we didn't go off, he kind of shuffled us back in, which was very good …" (L004, Consumer Manager)

Whilst more experienced IRC team members do take a broader approach, an element of "single-mindedness" may be required to ensure that IIC and IRC team members take accountability for their specific functional areas. However, this single-minded approach can limit some individuals' overall understanding of the entire incident, which was evident when communication about the incident was explored, and potentially limits organisational learning. This will be considered further under "Communication" later in this section and under "What Works" for LiquiComp UK overall in section 6.3.2.

[37] The Regulatory and Legal teams also review whether official notification of any food incident should be made, depending on where any affected product is located (within or outside of company control) and whether the product has been assessed as potentially injurious to health and hence if an official trade withdrawal or consumer recall is required.

LiquiComp UK has an established and documented incident management processes, with a variety of SOPs for different incident types, including product incidents. The process of investigating and managing incidents though the setup of an IIC and then, if required, an IRC, was generally well understood by head office staff, although it was commented upon that some newer members of staff did not appreciate the seriousness of the situation:

> " …. so, certain people were not at all familiar with what the IRC was, or what the IIC was at that stage, for instance we had somebody in marketing for the brand that was affected come in. And they're quite senior, and but they were tapping away really loudly on their laptop on the conference call, um and that meant that it was very difficult for people to hear. They weren't at all aware of the gravitas of the situation ……." (L006, Lawyer)

Similarly, in the affected manufacturing site, not all individuals involved in the IIC and IRC were familiar with the processes, partly because of the timing of the incident, immediately before the Christmas break, when some senior staff were on holiday:

> "….. the initial incident committee, I don't think people on site knew what they were. I think from a site point of view, um, the people round the table left at that Christmas period, (name - head of site) had only been in the role a couple of months, he had done obviously recalls before but not in this particular way; we had (name) who was the new engineering manager, again, relatively new to position and post, um, myself, [and] um, (name) who's been on site but from a planning perspective, so you didn't necessarily have the expertise that you'd had before to know what the staging is …" (L009 Food Quality and Safety Manager)

Subsequent to the main data collection phase of this study, the Researcher understands that a communication and training programme to upgrade awareness and capability on the incident management processes has been completed. This included a company-wide communication event, five smaller training sessions and a mock incident training exercise.

The second phase of the investigation involved the establishment of teams based at the affected manufacturing site to conduct an RCA. In fact, three RCA streams were established. The first stream focussed on determining the cause of the equipment failure and putting in place required corrective actions. This work stream commenced in parallel with the IIC and IRC. The second stream was set up to look at why the affected packs were not detected. This work started after the Christmas break, with a core team of three people focussing on this task for six weeks. The third RCA stream was established to look at filling the shortfall in product supply caused by impounding stock and withdrawing stock from the market.

Overall, RCA as a problem-solving method was well understood at the manufacturing site. It appeared that staff were confident in choosing the techniques to use to ensure that an appropriately robust problem-solving approach was taken and that conclusions could be reached within an appropriate timeframe:

> “The root cause investigation, is that how problems are normally tackled around here?” (Researcher). “It depends on the scale of the problems, so in my role, I’m the Continuous Improvement Manager, so I’ve developed some sort of tiers of root cause problem solving from a simple decision matric of 4 squares … and then through to a six-step root case process … and then we’ve got a 10-step Kaizen-like process on site which is quite detailed and thorough. So, ‘cos I’ve got a bit of knowledge of all the processes, I’d sort of mix two elements together, our 6-step root cause, pull some elements of the 10-step process in, some tools and techniques to try and help steer the group that I was leading to the outcomes.” (L016, CI Manager)
>
> “…you said you used a 6-step process in this one and not the 10-step?” (Researcher). “…a 10-step may be an item whereby you’re looking at items over a longer period, it could be potentially 2 or 3 months …. clearly this was an escalation to (CEO) and the SMC team … so it’s a very intense, deep dive, so a lot of data but in a much more condensed period of time.” (L017, Site Engineer).

In talking about the problem-solving process with the study participants, it became clear that an important requirement of this process was the need to ensure impartiality. To this end an independent medical advisor was used during the IRC review, both to provide expertise not available internally in LiquiComp UK, and to demonstrate appropriate due diligence should the company’s actions ever be scrutinised by regulatory authorities. More detail on the use of experts is given in the theme “Experience Required”.

Impartiality was also a concern in the second RCA work stream, where the investigation team was selected to encourage co-operation by production staff and management:

> "… we decided to create the robust team, a little separate from the [production line] management team … we had better have a third-party opinion, analysis, regarding this big incident. We had already understood that was driven by the management people, so if management people were involved in this team we might have accused or blame some people, and then management people might have been defensive … so to avoid any negative aspects we had better create another team, a third-party team." (L011, Factory Leadership Team Member)

With the processes to resolve the problems understood, the results of these activities can be considered. For this embedded case, the results of the problem-solving processes can be expressed at two levels: the immediate response of the business to the incident following the IRC, and the technical level, as explored through the RCA streams.

The initial recommendation of the IRC to the CEO and SMC was to recall the batches of affected products. This appears to have been primarily driven by the view expressed by one dominant IRC team member that the plastic shreds generated inside the cocked caps could pose a choking hazard (i.e. it was perceived initially by this manager as a food safety issue):

> "… he was explaining about how when he personally sampled a bottle it was like a fish bone, the swarf in his mouth could be like a fish bone and that was actually quite emotive, because a fish bone is pretty sharp, hard, quite long, and as we all probably know, someone we know or we may have had one stuck a bit in our throats." (L006, Lawyer)

However, some team members expressed concern that this recommendation was subjective and made on insufficient evidence, and indeed the CEO and SMC challenged this conclusion:

> "…we made our recommendation on the Wednesday to the SMC, which was pushed back …" (L001, Business Quality Director)

The IRC team was directed to re-evaluate the incident, to look again at the volume of affected stock (as data on this had been questioned) and to gather further input from the external medical advisor who was entrusted with making an objective, educated assessment as to whether the plastic swarf was a food safety hazard or not.

When the first recommendation was made the external medical advisor had seen only pictures of the damaged caps. After the push back from the SMC he was furnished with actual samples of the damaged products and on examining these concluded that the products were not injurious to health. Hence after discussions with the full IRC team, the recommended action was changed to a "soft" trade withdrawal (i.e. one not requiring official notification to the FSA or recall from consumers):

> "…after further consideration and interaction with our medical expert, we were satisfied, and he was satisfied, that it wouldn't pose a risk to human health such that we should recall the product." (L006, Lawyer)

> "…we substantiated it more, we re-presented it [recommendation of action to the SMC] and it was accepted and then we went with the trade withdrawal…" (L001, Business Quality Director)

Also critical to the final decision was the revised data on the amount of affected stock. As L001 explained, "understanding the scale of an issue can be pivotal in ensuring that the company takes a proportionate response". In this incident, between the first and second IRC recommendations the logistics and operations team confirmed that much less stock was impacted than originally believed, which played a role in revising the recommended action to a "soft" trade withdrawal. (This decision is explored in more detail from a cultural perspective under the theme Culture & Values).

This dialogue and reconsideration of recommendations illustrates the dynamic nature of the problem-solving process in LiquiComp UK. It also clearly shows the challenge of making decisions in the absence of a complete data set – a challenge faced in most incident investigations when organisations are under time pressure. It also illustrates the importance of expert opinion to LiquiComp UK, which is discussed further under "Experience Required".

The second level of results of the problem-solving process pertains to the work of the RCA teams, who produced action plans for the business to address their specific areas of concern (capping equipment failure, failure of detection of the cocked caps and actions to restock the supply chain).

In fact, the RCA studying the failure to identify the defective products presented an extraordinary number of corrective actions to the business:

> "…we came up with, I think it was 90 plus corrective actions…" (L009, Food Quality and Safety Manager)

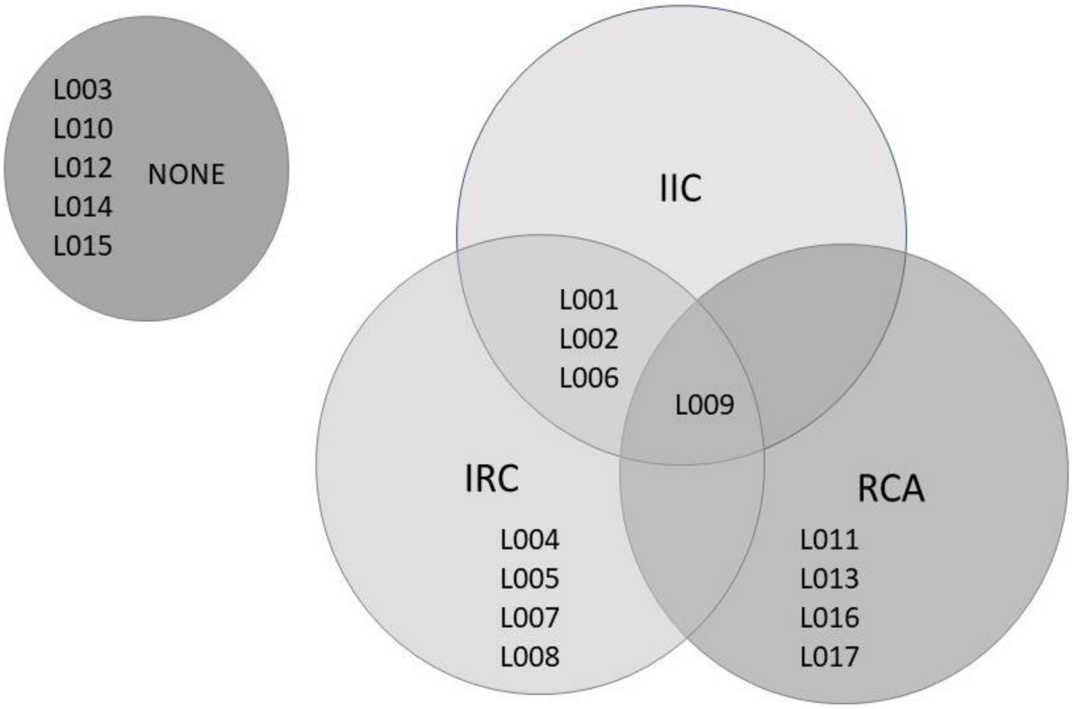
This once again illustrates the size and complexity of the incident and can also be viewed as "unexpected". With the business appearing to operate soundly on a day-to-day basis, meeting production targets and with a good food safety record, this number of corrective actions, covering not just Line C but stretching across the production site operations, could never have been anticipated.

Before moving on to consider some of the areas identified as corrective actions under the theme of "What Doesn't Work", consideration needs to be made of the communications made about the quality incident, and to return to the protection of information under legal privilege.

"Communication"

Of the seventeen study participants, twelve were directly involved in aspects of the cocked cap incident, as shown in Figure 6.4. Everyone's level of involvement in the incident might be expected to impact the way that they understood it and how they described it to the Researcher during the interview process, which needs to be considered in this case study analysis.

Figure 6.4: Participant Involvement with the Cocked/Shredded Cap Incident



Four participants were not questioned directly about the product incident, as they made it clear that they had not been directly involved and were not able or willing to discuss it[38]. With most of the remaining participants, the core of their stories about the incident were essentially similar, but there were also instances where narratives differed, often in quite significant ways. For example, both the outcome of the IRC (that the damaged caps did not pose a safety hazard) and the action taken by LiquiComp UK (a soft withdrawal of product from the trade) were not always described in that way, even by participants who were closely involved in the IIC/ IRC teams. This is illustrated in the following quotes:

> "…because he [the external medical advisor] had received the samples … he confirmed that it could be a food safety risk …" (L009, Food Quality and Safety Manager)

[38] Whilst L003 had not been directly involved in the investigation or management of the incident, he was involved with L001 and L002 in the group interview which included discussions about the incident.

> "… then after further consideration and interaction with our medical expert, we were satisfied, and he was satisfied, that it wouldn't pose a risk to human health …" (L006, Lawyer)

> "… so when we came back in after that period [Christmas holiday], we had then gone to recall, the information packs had gone out, there was a lot of testing" (L009, Food Quality and Safety Manager). "So that was a customer recall?" (Researcher). "Yes, yes, so like a warehouse, well, to main end user customers…" (L009, Food Quality and Safety Manager)

> "… And we made our decision to do a trade withdrawal on that day." (L001, Business Quality Manager)

Few staff outside of regulatory and quality functions might be expected to understand the nuances of calling the resulting action of an incident a "recall" versus a "withdrawal", but as the quotes reveal, the terminology was not used consistently even within these functions. Differences in description - even if staff mean the same thing - could be highly significant for the business, e.g. if a member of staff was asked to explain the incident during a quality audit or official inspection. These different descriptions suggest a lack of clear communication on the outcome of events.

Some of the differences noted might also be explained by the differing responsibilities of the study participants. As described earlier, the role of the IRC is to examine the immediate incident and determine the appropriate business response, not to necessarily understand or solve the underlying case of the incident.

> "…people always want to know well, how did it happen, what have you been doing, and so on and pointing fingers. L001 is pretty good at saying well it's not really [a topic for the IRC] and I'm not interested at all." (L005, Regulatory Manager)

However, given the size and impact of the incident on the business, it was perhaps surprising that individuals were not concerned or curious about how the incident was initially detected or its underlying causes.

> "I must say I wasn't involved in the actual how it was identified, so I don't know if it was identified here or whether it was identified at a customer, I don't really know …" (L014, Director of Technical and Quality, Manufacturing Site)

Whilst this single-minded approach appears to be a strength in keeping the problem-solving process focussed (as discussed in "Problem Solving Our Way"), it might also indicate a degree of silo-mentality. This can impede communication, prevent the organisation developing a comprehensive understanding of events and even hinder them from making the most of opportunities to learn from failures.

Concern was also expressed that communications by some staff and management during the incident investigation were guarded, potentially impacting the understanding and resolution of the incident:

> "…I suppose from my perspective, being sat on the outside periphery of it, it was obvious that people here [at the manufacturing site] were playing their cards close to their chests at times, not necessarily being as open and honest as they could have been, and information flow wasn't always as seamless as you would hope it would be in a major issue." (L014, Director of Technical and Quality, Manufacturing Site).

A lack of transparency and openness in communications could impact the time taken to investigate incidents and indeed influence the outcomes of investigations if all pertinent data is not shared.

The most significant influence on communication about the quality incident was the use of the legal team to filter and route communications to ensure that information – and hence LiquiComp UK - was protected by legal privilege.

During any incident, sensitive information must be managed appropriately, and the routine use of social media has exacerbated concerns:

> "…we do limit who knows what. We have a social media policy and buried in the SOP it states that anybody involved [in the incident investigation and management process] is not to disclose it outside of the confines of the meeting, and we need to keep it tight..." (L001, Business Quality Director)

Relevant, timely communication was nevertheless important to gain the co-operation of production staff in the RCA investigations:

> "…we did an initial team brief to all the operators, all the shift managers and area managers … to say look, we're investigating and we need your help … we were very clear 'cos we had the communications with legal about this, that we informed everyone at the start of the brief that what we were telling them was under legal privilege and was strictly confidential, so they weren't to go home and post it on social media or discuss it in public places or things like that." (L016, CI Manager)

There was a recognition however, that it became confusing about who could be told what:

> "I think on the communication bit, because we'd not come across the same legally privileged information before … It was a bit of blocker for us … and then we were starting not to be sure who we could tell what to who, and who's given what out …" (L009, Food Quality and Safety Manager)

In reality, staff in the manufacturing plant knew that something significant had occurred:

> "But the fact is they [factory operatives] knew something was going on, they were affected by it. They were having to do rework, there were people crawling all over the capper and parts of the machine to find out what had gone wrong, so they knew." (L016, CI Manager)

At the end of the RCA process concerning the failure to detect the cocked caps, open meetings were held with production staff to share the findings, but the communication delays were recognised as causing some frustrations:

> "…. We gave multiple presentations, to multiple people … we went through all the information warts and all, so everything was in front of the guys and they could see it… There were the standard things that came up … the standard questions, and if they think you need to answer those, they want an answer. And I understand the frustrations because I think we were feeling it: we waited a long time to get the comms out, you know we were holed up in that room for quite a while and it was a bit should we, shouldn't we, can we do this, can we not do it …" (L009, Food Quality and Safety Manager).

Managing sensitive communications, such as those for a product incident, is always a balancing act. Organisations have to weigh up the need to communicate sufficient information to enable investigations to take place with the need to ensure that confidentiality is maintained where necessary, and to ensure that the information shared is not misunderstood, taken out of context or miscommunicated onwards in the style of “Chinese whispers”. Overall, LiquiComp UK seems aware of the importance of open and timely communication in ensuring that the incident management process can be conducted in a timely and accurate fashion. However, changes in society, particularly the use of social media and a more litigious culture (which is discussed further in the theme of “Culture and Values”), have brought even more risks to the business, which are impacting communications in these situations.

The imperfect flow of information, and the strict compartmentalisation by individuals only being interested in “what I need to know, right now, to do my job”, potentially impacts the overall organisational reality or topos, in the terms of PC, fragmenting this into two or more co-existing topoi. This will also be discussed in more detail in Chapter 7.

“What Doesn’t Work”

As mentioned previously, the RCA conducted on the failure to detect the damaged caps identified over 90 corrective actions, which covered not only the operation of the affected packaging line but more general operations across the manufacturing site. In this way, the incident had already been used by LiquiComp UK to identify areas of weakness in their current operations, where opportunities to prevent the incident from occurring had been missed.

The specific failure of detection of the damaged caps has already been discussed in detail. Here, two specific areas of challenge, which might be viewed as drivers of these failures, or elements of “What Doesn’t Work”, will be presented.

The first relates to the management of production line C where the cap failures occurred. At the time of the incident, all line managers operated semi-autonomously, organising their staff as they felt suitable to meet the company standards and production targets for their area of responsibility. As explained by L009:

> "I've been in the business a long time, and I've seen how lines operate, and generally they [staff] are on a rotation basis, you'll go from one task to another. It didn't happen on this line. They were basically fixed to tasks and they didn't have the skills to transfer them around." (L009, Food Quality and Safety Manager)

There were also suggestions of a higher than expected sickness absence rate for staff on the line, causing some staffing pressures. This, together with the relative lack of skills, and lack of flexibility in the way the work force on the line could be utilised, appears to have helped create the environment in which the incident occurred.

Indeed, prior to the cocked / shredded cap incident, there had been intermittent production problems on Line C, where small "tails" of plastic were formed at the junction of the cap and bottle. These "tails", caused by over-pressuring, were described by L009 as "not the best quality, but on times it's acceptable". This problem was not directly related to the cocked/shredded cap incident and was the subject of separate quality investigations. However, a total lack of acceptance of the "tails" may have triggered more in-depth examinations of the management and working practices on the line and so, potentially, could have prevented the more serious incident from occurring.

The second area of challenge pertains to the differences discovered during the RCA investigations between SOPs and check sheets for the cap and pack integrity checks. It was discovered that just one member of staff had responsibility for updating all of the manufacturing site's SOPs, work instructions and check sheets and that this documentation had not been kept up to date due to staff overload:

> "...at this site a very particular person has to change the SOP, has to change the check sheet. Shift managers, operators, shop floor people are not required to change the check sheet and SOP, one particular person needs to amend the SOP. But if he was very, very busy, that person was not available to handle all the information, what happened would be just amend the tiny piece, just the check

> sheet, but amending the SOP would be lower priority." (L011, Factory Leadership Team Member)

Rather than blaming the individual concerned for failing in their responsibilities, the RCA team suggested that responsibility lay with management:

> "…from that person's point of view, it was very difficult to have everything done. That could be a management issue I think, managers should handle the things, whether the person can handle all the SOPs and all the check sheet amendments, or not so. If he was very, very busy, if his work overflowed, in that case the manager needs to handle, needs to prioritise what is necessary, but in reality it didn't happen." (L011, Factory Leadership Team Member).

Closely related to this situation was the sheer number of SOPs and work instructions in existence. The QMS was described by L001 as a "bureaucratic nightmare", and he suggested that staff were suffering from "SOP paralysis", where the culture demanded this documentation and did not allow staff to think for themselves. In a similar vein L014 expressed his concern that it was impossible to judge which of the multitude of documents (over 2,500 in the QMS) was critical:

> "…you open up a manual of SOPs and you can't tell in there which is the ones that are really critical to you and your process. I remember looking at one once, and there was an SOP on how to stock the fridges for the offices! You know, is that a critical one to our business succeeding or failing, and making the consumers get good, fit, safe product to consume?" (L014, Director of Technical and Quality, Manufacturing Site)

The "overload with detail" created by excessive documentation did not directly cause the cocked cap incident. However, it undoubtedly made it very difficult for the staff member concerned to prioritise their work effectively, so contributing to the documentation miss-matches seen in the incident.

The size and complexity of the QMS also links to another finding from the RCA investigations, mentioned in "What Went Wrong", in that the changes made to the torque test check sheet should have, but had not, been reviewed by the Quality team, i.e. the correct processes for review of documentation changes had not been followed.

Additionally, the internal audit team, when reviewing this area of the factory, should have picked up on the misalignment of the documentation. Any critical review of the testing process could also have picked up on the previously noted issues of the non-sequential discharge by the detection equipment of bottles for testing and any issues with staff not completing the torque check correctly. It was not possible to identify in this study whether the audit team had not conducted a review of this area of the factory or whether an audit had taken place but was ineffective in identifying the issues which subsequently contributed to the cocked / shredded cap issue. However, it is clear that the sheer magnitude of the QMS meant that not only would production staff have challenges in identifying quality priorities, so too would the audit team, i.e. system swamping appears to be hindering the organisation from working effectively and efficiently.

This triggers the question of why the staff at LiquiComp UK felt the need to create so much formal documentation. Operating a modern manufacturing system, to internationally recognised quality and food safety standards of course necessitates "process thinking" and the recording of this through documentation. However, none of this explains a situation where SOPs proliferated for seemingly non-essential, non-quality related activities and suggests that the use of a fixed process for everything is part of the culture and values of LiquiComp UK. This will be explored later in this chapter.

It is also worth noting that from a quality costing perspective, production of this formal documentation is a relatively costly exercise. Such an expenditure on prevention costs would, in theory, be expected to improve systems and reduce failure costs (Feigenbaum, 1956); however as shown here, this is not necessarily true.

"Culture and Values"

We now turn to the organisational culture and values of LiquiComp UK and reflect on what the embedded case illustrates about these. Given the focus of this thesis, how the organisation feels about food safety is the first aspect of values to be considered.

A belief that the company puts food safety, and so the safety of consumers, as a key priority was expressed by participants:

> "…clearly everybody in the business is aligned to the quality agenda and making sure that our food safety it's just, not a given, given's the wrong word, it implies it's passive, it's something we all actively support." (L008 Head of Supply Chain Planning).

Without a doubt, the amount of resource dedicated to the resolution of the cocked cap incident, the speed with which the incident was tackled and the involvement of senior management in the investigation and decision making processes indicates a high commitment to product quality and safety. (The time and resources dedicated to the investigation and resolution of the incident also illustrate the high cost of quality failure, in terms of quality costing principles.)

> "…so in the end (CEO) was involved, so you know we had the big man, his decision. It's his company, his brands' reputation and the safety of the consumer is paramount." (L004, Consumer Manager)

However, other participants expressed a belief that at the manufacturing site, delivery of production targets was seen as more important than product quality, and hence safety. For example, when talking about the role that line operators play in performing QC checks, L009 explained:

> "…theirs is a dual function. So that probably if you asked them is it quality first or manufacturing, they'd probably say, I think that was the biggest one coming out [of the RCA investigation], that it's more manufacturing driven, it's trying to get the pop out the door" (L009, Food Quality and Safety Manager)

Similarly, L014 expressed concerns about the lack of understanding of line operatives about the quality tests they perform, and indeed the prioritisation of both food safety and quality in the manufacturing site management team:

> "So you've got people who are manufacturing, I test something but I don't understand why I'm testing it, I don't know what that means, what to do if it

> gives me a wrong result, and a management that was focussed on getting the pop out the door." (L014, Director of Technical and Quality, Manufacturing Site).

Another core value identified from the operation of the IIC, IRC and RCAs was the desire to "protect the company", i.e. to safeguard the company's reputation and protect it against possible legal threats. This was demonstrated by the prominent role of the legal team in the investigation and the use of legal privilege, as discussed under "Communication". Concerns about the spread of information via social media was identified as one driver of the use of legal privilege. Another, which reinforces the desire to protect the organisation from harm, is the risk of litigation:

> "…one thing you've got a real challenge on now is this whole legally privileged element. You know, if we're taking our contemporaneous notes, what happens to those notes, how are they referred to …. I think it's a looming problem ... I think that's something that's going to vex a lot of organisations, because we are increasingly being bogged down in the litigious society that is emanating across the Atlantic, if not already here. So that is a real challenge, that's been a massive learning point for me and how I think about this concept of incident management." (L002, Head of Risk)

LiquiComp UK appears to be trying to strike a delicate balance in the incident management process between the need to assure the safety of consumers and the need to protect the organisation from legal, financial and reputational damage.

The value that LiquiComp places on process, systems and documentation has already been highlighted. Another example of this in action during the incident was where L016 was instructed by his managers to collect evidence in the RCA investigation as follows:

> "So there was quite a clear steer from my line manager and the site director of, don't take something on face value, if somebody said it, go and find the paperwork. If somebody says they've been trained, go and get their training record, find out when it was." (L016, CI Manager)

Discrepancies between documentation, or supposed "hard facts", and what the study participants' believed to have actually happened to cause the cocked / shredded cap incident, manifested themselves as a lack of trust, particularly between line operatives and management. For example, management expressed disbelief that staff carried out cap and pack integrity tests correctly – or even at all - when the quality control check sheets were completed showing all packs were correct, and yet faulty product was known to have been shipped to the warehouse.

This lack of trust contrasts with the faith placed by management in the incident investigation teams and the determination to uncover the real causes of the incident so that improvements could be made:

> "There wasn't a time pressure put on it [the RCA investigation]. The main focus was to get to the issue, keep digging no matter what you need to do …. Do what you need to do to get to the facts, don't risk it and miss something." (L016, CI Manager)

One last element of culture illustrated by the incident, was the power of senior management. As previously mentioned, the commitment of senior management to address the quality incident was clearly expressed by study participants. It was also obvious in the construction of the IRC team which involved senior, experienced staff:

> "… when it goes to an IRC in LiquiComp UK the most senior person is involved in each of the functions concerned, whether that's sales, manufacturing, quality or whatever they need to be involved … because to go to an IRC is an issue of such seriousness you want the most qualified people to advise." (L006, Lawyer)

There was however, also evidence that people in positions of power could dominate discussions and perhaps overly influence decisions. For example, it was earlier described how a dominant individual on the IRC influenced the original view that the plastic swarf deposited on the bottle necks might be a safety hazard.

Likewise, the ability of the CEO and the SMC to push back the original recommendation for product recall from the IRC, could also be perceived as the exercise of positional power. Indeed, it could be suggested that the SMC was "repositioning" the incident from one where product was considered to be a food safety hazard to one where it was seen as a quality issue only, i.e. there was a trade-off between food safety and quality. However, this does not appear to have been the case. In fact, the interviewees were clear that the final decision to progress with a soft trade withdrawal (which did not necessitate reporting to the authorities) was driven primarily by the expert assessment and advice offered by the external medical adviser, as described earlier by L006:

> "… then after further consideration and interaction with our medical expert, we were satisfied, and he was satisfied, that it wouldn't pose a risk to human health …" (L006, Lawyer)

Thus whilst the legal responsibility for the decisions made by LiquiComp UK on whether to instigate a product withdrawal or recall rests with the senior managers, they were dependent on the expertise of the IRC and the medical adviser to make the appropriate decision. In fact, the close involvement of the senior team in decision making can be seen as an appropriate use of power and the practice of good food safety governance by the business.

With this in mind we need to consider how the quality incident illustrates positive areas for LiquiComp UK, and this is discussed next, in the theme "What Works".

"What Works"

Individuals and teams get many opportunities to demonstrate skills and commitment in times of crisis and this proved to be the case during this incident. From the site Quality Director, who worked over the weekend following the discovery of the affected packs to analyse stock, through to the IRC and SMC team members who worked right up to 5pm on Christmas Eve, the commitment of LiquiComp UK staff to resolve the incident in a robust and timely fashion was clear.

Another successful element in the resolution of the incident was the level of co-operation and team work seen between staff and external partners. For example, L004 described the work she undertook with the external digital agency who look after the LiquiComp UK brand websites. It was decided to prepare a "banner" for the website, alerting consumers to the pack defects, in case the company decided to progress to a product recall.

> "… because it's Christmas Eve and they were closing at 1 o'clock, and no decision had been made by 1 o'clock, they said 'look, everything is built, all we need is words, and just let us know. Give us a ring and we can do it for you.' So I mean they bent over backwards for us..." (L004 Consumer Manager).

Similarly, productive working relationships were described with the capping machine manufacturers, the third-party logistics suppliers and the external medical advisor, all of whom were instrumental in supporting LiquiComp UK through the incident investigation and resolution.

The examination of the processes undertaken to investigate and resolve the quality issue also demonstrated a high level of rigour in the company's activities (as well as illustrating the high internal failure costs). For example, L009 described the product testing undertaken to determine the timeline of the quality failure (i.e. to establish the starting point of the capping failure):

> "…we made sure a full layer of a pallet, so the very top layer was stripped and looked at, so a destructive test. Initially we were looking for cocked caps, they were opening those caps and then finding the damage. This was a fully destructive test and trying to get the information back as quickly as possible to build the timeline." (L009, Food Quality and Safety Manager)

There was also clear evidence that LiquiComp UK was not just gathering evidence on what went wrong but was proactively putting corrective actions in place across the organisation.

Improvements in quality procedures had already been instigated in the manufacturing plant at the time of the Researcher's site visit. For example, a new test for "closure angle" was being trialled to replace the subjective "torque check" test, not only on the impacted production line (C) but on the sister line, D, and further across the site:

> “So what we are going to do from now, we are going to install the closure angle test. And we’ve already installed the closure angle test for C and D and the next step is to extend our experience across the site” (L011, Factory Leadership Team Member)

Improvements had also been put in place quickly in the capping machine itself. At first, a temporary fix was made through the disassembly of the machines and the application of a food grade chemical thread lock to all the bolts to keep them firmly in place. This was followed by a permanent improvement through a change in product design:

> “So we worked quickly with the supplier to re-design the heads [of the capper] … both machines now have a different head design. So still a magnetic head, but instead of fastening bolts, they are epoxy bonded, so effectively now there’s none of the bolts across the two machines, C and D. And it probably took us about 3 to 6 months; 3 months to get a design agreed, installed and trialled, and then a full set manufactured for C. And D has recently been done as well”. (L017, Site Engineer)

Within the constraints formed by working under legal privilege, the engineering team had also sent out an engineering alert across LiquiComp Group to alert other sites to the potential technical problem with the capping heads and aid proactive action in other manufacturing sites.

Outside of the manufacturing environment, IRC team members also took the opportunity to review the performance and capability of their teams, and to address identified improvement areas. For example, L004 discussed the ability of her team to manage a product recall:

> “There has been the fact that if we were to have a product recall my team of 5 couldn’t cope with it. So we don’t have the capability to have an outsourced call centre that could manage on our behalf, so now I’m working with [L007, Corporate Affairs] and the procurement team to get a facility set ready for us to press the button should we have another issue.” (L004, Consumer Manager).

Improvements to the incident investigation itself were also identified. A key learning was the need to ensure that key players in the process – be that members of the IRC, the external medical advisor, or members of the SMC – see and handle actual products with the known defects. For example, in discussing how the IRC obtained a more detailed opinion from the external medical advisor:

> "…there was a dawning realisation that if we wanted to make that a more substantial experience for him [than just seeing pictures of the defects], upon which he could give us a better-informed answer, we should get some product under his nose, so we actually did that on Christmas Eve…" (L001, Business Quality Director)

Recognising mistakes and learning from them, and the creative thinking required to improve processes and practices, can be considered as an important asset of LiquiComp UK which correlates with the long history of CI in the business, and this will be discussed further in section 5.3.2, under the theme "Day-to-Day".

"Experience Required"

The importance of experience and expertise, both internal and external, has already been highlighted in this analysis. The external medical advisor was the key player in determining the final IRC recommendation to undertake a soft trade withdrawal of product, rather than a consumer recall. Likewise, the expertise of the packaging suppliers and the manufacturers of the original capping equipment was critical in determining the underlying cause of the equipment failure:

> "And actually I got the cap supplier in when we knew we'd got the problem, 'cos it was so important and those guys, together with our engineers and the machinery manufacturers, I think all three of them got together in the engineering stores and literally took apart one of the capping heads and found the sheared bolts…." (L013, Packaging Manager).

There was also recognition that the prior experience of IRC team members relatively new to LiquiComp UK could bring benefits to the incident management process. This was described to the researcher by L008, who had only been with LiquiComp UK a few months when the incident occurred:

> "…the question asked by L001 and the group was, 'L008 have you any insights from your previous organisations that can help us manage this situation better?' They were directly asking for that, just trying to make their approach the best it could be." (L008, Head of Supply Chain Planning).

The important role that experts played in resolving the incident was, however, undermined at some points by the dominant voices of senior staff involved in the IRC. It has been previously discussed that one senior manager drove an initial decision on the safety of the affected products by talking about his experience of the plastic shards feeling like fish bones. L005 described this as the IRC team basing their initial discussions on incomplete information and "unofficial medical" opinions:

> "I think there was a certain amount of gathering of sort of informal opinions from doctors and paediatricians, which I don't think we should have considered under the banner of medical opinions … [we should have] just concentrated on the processes we have within the business." (L005, Regulatory Manager).

Subsequently, the team sought further opinion from the external medical advisor and the recommendation to recall product was changed to one to enact a trade withdrawal. It can therefore be seen that the use of experts, particularly external, independent experts, was used by LiquiComp UK to balance strong opinions and ensure that a robust decision-making process was followed.

Conclusion

In conclusion, this analysis of the cocked / shredded cap incident has not only shown the complex, messy and generally unexpected nature of the issue, but, through the themes developed, gives an insight into the processes and systems which LiquiComp UK used to manage and resolve the incident. The themes also allow an insight into the behaviours exhibited by staff, management, external suppliers and consultants leading up to the occurrence of the incident and during its investigation and resolution.

This embedded case shows an organisation which has well developed processes and systems for incident investigation and management. Staff involved in managing the incident showed a high level of dedication and commitment and through this demonstrated the importance of food safety and quality to the company.

However, the underlying picture was complicated. Whilst equipment failures and limitations were evident in the failure of some of the QCPs (e.g. the limitations of the detection system), management expressed the view that manufacturing line operators had failed to undertake and record quality checks correctly. The company drew short of officially "blaming" staff for the failure to detect the cocked caps due to the failure of another part of the quality system, as relevant SOPs and check sheets had not been kept up to date or correctly reviewed and there was a question about the conduct of relevant internal audits.

Thus the two barriers to food safety governance identified in the first case study are also implicated in this case. **System swamping** appears to be hindering the ability of the business to operate quality and safety systems effectively and efficiently and the simultaneous failure of multiple aspects of the quality systems was viewed as **unforeseeable**.

Two other aspects of the findings must also be highlighted. LiquiComp UK clearly places a high value on experience and expertise, as demonstrated by the significant role played by the external medical adviser in the IRC recommendations, and by the role played by packaging and equipment manufacturers in the manufacturing RCA. However, the relative power of senior management to influence decisions was also clear, in both the initial recommendation for product recall (driven by the strong opinions of one senior manager) and the push back on this recommendation by the CEO and SMC. On a positive note, this exemplifies the close involvement of senior management in such issues, the importance that LiquiComp places on fast and accurate resolution of such events, and senior management's commitment to good food safety governance. Of greater concern was the "single-minded" approach taken by some members of the IRC– the view that people need to stick to their own areas of expertise and not think or advise more broadly – which could potentially inhibit a full and open dialogue in a situation where senior management challenge the view of a lone expert.

The second area to highlight is the impact of the use of legal privilege on communications about the incident across the business. As previously discussed, the desire to "protect the company" may have unforeseen consequences in limiting dissemination of a comprehensive understanding of the incident and so limit organisational learning.

Taken together the "single-minded" focus and desire to "protect the company" resulted in **"constrained communication"** which could also be viewed as acting as a barrier to food safety governance.

Moving on, in the next section a thematic analysis is again used, this time to examine the general, day-to-day operations of LiquiComp UK, before concluding this chapter with a comparison of the embedded and overall organisational case.

6.3.2 The Organisational Level

This section, covers findings related to LiquiComp UK's general operations. It is presented in relation to the following themes: "Day-to-Day"; "What Works"; "Experience Required"; "Formal Expressions of Culture"; "Culture and Values" and "Communication".

"Day-to-Day"

As previously discussed in the analysis of the cocked cap incident, under "Problem Solving Our Way", LiquiComp UK sets high store by processes and systems to manage its business.

This was most clearly demonstrated in the incident management process used, which was well organised and documented. Indeed, this process forms a specific SOP that, as discussed previously, was generally well understood at head office although somewhat less so at the manufacturing site.

The factory QMS and HACCP systems have also previously been outlined. In addition to the manufacturing site systems, LiquiComp UK has a comprehensive QMS for its head office, primarily because the company's R&D facilities, including a small, but busy, development laboratory are situated there. This QMS is based on a BRC framework and has "the intent of being able to design safe, good quality and legal products" (L001, Business Quality Director). Thus, the importance of safety and quality, and the use of structured processes to control this, is set as a standard right from the start of the life of any product, way before it becomes a recipe to be produced in volume for supply to consumers.

At the manufacturing plant, staff readily described the elements of the QMS and FSMS (HACCP, PRPs and maintenance plans) which related to their job responsibilities, be that approval of packaging materials or new ingredients, or the HACCP and PRPs for a designated area of the manufacturing plant.

During the factory tour undertaken as part of the case study, the embedded nature of the PRPs was particularly clear. For example, the Researcher was clearly briefed before entering the manufacturing area and asked to sign a health declaration. There was also routine compliance with personal hygiene requirements, e.g. changing footwear before entering the aseptic filling hall (where still drinks without added preservatives are produced, these recipe constrictions demanding production in a 'clean' environment). In terms of HACCP, the CCPs were marked in the relevant areas with large red signs. However, for staff to get further information on these CCPs, they were instructed to consult a manual, which is available on the site computer system, but not directly available at the production line side. The implications of this will be discussed further under "Communication" later in this section.

As with other production sites, both simple and sophisticated controls are used. The syrup room, where drinks are mixed and processed prior to packaging into individual packs, is highly automated and has a dedicated computer control room. In contrast, many of the quality and safety control checks for the packed products rely on less sophisticated technology and use manual recording of test results with paper and pen:

> "The metal detector is a CCP for us and we do a challenge test on that every 4 hours, where we put a test stick through, and then all that data then for the test stick calibration is recorded on a check sheet." (L010, Line Operator Manager).

CI activities and tools are also well embedded within the manufacturing site having been used for many years as part of routine practice. This fits with the manufacturing site practice of daily "Accountability Meetings". These are held for each production area to identify challenges and concerns within the last 24 hours. Similar morning meetings are held by production support teams, such as quality. Representatives from each of these meetings then attend a mid-morning meeting with the Site Director and site management team to addresses quality, production and health and safety concerns. CI processes are routinely used to address points raised, particularly where there are recurring issues.

Overall therefore, it can be shown that LiquiComp relies on a system of inter-related systems, processes, checks and documentation to manage its routine day-to-day work – as well as less routine events such as product quality and safety incident investigations. These processes appear to be treated very matter-of-factly as simply the way things happen at LiquiComp UK.

So, if processes and systems are "the way we (LiquiComp UK) work", what specifically does work well on an organisational basis? This is the topic of the next theme.

"What Works"

One element of "What Works", which stood out in the embedded case as a strength for LiquiComp UK, was the commitment demonstrated by the staff involved in investigating and resolving the cocked cap issue. So, is there similar evidence of commitment to the organisation on a broader basis?

In considering this question, it is pertinent to reflect on the history of the organisation and its environment at the time of the research study. Many staff at the production plant had worked there for a long time:

> "…we've got quite an aged workforce now, so there's a lot of people been here 20, 30, 40 years, which generally you don't get in companies anymore …" (L009, Food Quality and Safety Manager).

At the time of the data collection, an operational restructuring programme was underway at the manufacturing site. This, combined with the impact of the non-reportable food incident, was recognised as creating a challenging work environment for staff and management:

> "…because we're in this restructure at the moment the management team is probably less visible than it has been for a while, because it's been absorbed in the restructure…" (L014, Director of Technical and Quality, Manufacturing Site).
>
> "…the incident which occurred back here in December, you know, the morale, and how that impacted the site, from an engineering operational team, it was a difficult place to be." (L017, Site Engineer).

Despite this, staff were recognised as continuing to undertake their responsibilities to a high standard, demonstrating their commitment to the organisation:

> "It's a bit of risk to us now, because we're saying to these people, 'sorry, you don't have a job' … and you've got to keep them on board … you've still got to keep the day-to-day ticking over. And, credit to them, the professionalism of the people is absolutely superb, they're just carrying on doing the job they're being asked to do.…" (L014, Director of Technical and Quality, Manufacturing Site).

It is therefore fair to conclude that even in the relatively turbulent times of an operational restructure, staff continue to demonstrate their commitment to the organisation, suggesting that this is a deeply rooted strength for LiquiComp UK.

Another strength identified in the embedded case was the rigour demonstrated in undertaking the incident investigation. In terms of everyday operations in the factory, the FSMS and FSMnS also had a high degree of care and thoroughness – in other words, rigour - built in. For example, L010 described the monitoring process for checking the fillers after cleaning:

> "…and then we would swab the filler into production, using a quick swabbing technique, electronic swabbing. So if anything fails, we take recovery swabs as well and we re-clean until it passes effectively." (L010, Line Operator Manager).

Although the cocked cap incident would appear to cast doubt on the actual rigour of the company's quality and safety processes, the overall rigorous approach to quality and food safety appears to have greatly contributed to the successful operations of the business over many years.

"Experience Required"

In the embedded case it was shown how LiquiComp UK placed a great value on the experience and expertise of staff and consultants to investigate and resolve the cocked / shredded cap incident. We now consider whether a similar value is placed on experience and expertise, particularly in terms of food safety and quality, outside of a "crisis" situation.

LiquiComp UK employs a number of highly experienced staff to develop, manage and monitor food safety and quality. In addition to the manufacturing site HACCP team, senior members of the quality community co-ordinate activities with their European counterparts to develop common standards and approaches across LiquiComp Global.

At the time of this research, the LiquiComp UK manufacturing site had held ISO 9001 accreditation for its QMS for many years. However, it does not hold external certification for food safety against a scheme recognised by GFSI. Rather, the site relies on internal audits by quality and food safety audit teams from its own business, from other parts of the global organisation, customer audits, and, of course, inspections by enforcement authorities. However, a goal is stated in the LiquiComp UK Quality Strategy proposal for 2016 to progress to FSSC 22000 certification.

In summary, therefore, specifically in terms of expertise and experience in food safety and quality audit, LiquiComp UK appears to value "internal" expertise (be that from the UK organisation or from other parts of LiquiComp), rather than independent, third party expertise. Whilst this approach is changing, as evidenced by the intent to gain FSSC 22000 accreditation, this contrasts with the respect for, and reliance on, external experts in the management of the cocked cap incident.

"Formal Expressions of Culture"

Before looking at the culture and values generally expressed across the organisation, it is valuable to consider the more formal expressions of culture set out by LiquiComp UK. As might be expected, LiquiComp UK has developed a corporate identity and strategy. It has a specific vision, mission and ambition cycle, combining elements of the global corporation's core values with that of the UK specific brands. This corporate identity is highly visible in the head office and on the front page of the corporate website. However, both product branding and the company identity are far less visible at the manufacturing site impacted by the non-reportable food incident.

There also appear to be significant differences in the recognition and use of the corporate mission statement between the head office and this manufacturing site. When organisational purpose, mission and values were raised in the semi-structured interviews, all the head office based staff talked at some point about the corporate mission (even if it was only to express a personal dislike of the statement), whereas only two of the eight participants from the manufacturing site mentioned it at all. The need to bring together staff across the different locations and build a new organisational identity has already been recognised by the senior management team. Indeed, the business held a one-day, off-site conference for all staff earlier in the year to start this process:

> "…We had a big meeting ... it was the first time that they'd shut [the manufacturing sites] and got everybody that works for company in one room, so it was hundreds of us, so nobody was making any [brands] that day … and it was sharing the values for the company, what our objectives are for the year..." (L004, Consumer Manager).

Another key consideration is the prioritisation of food safety within the official values and strategy. Although food safety is not specifically mentioned in the LiquiComp UK overall strategy, quality and consumers are placed centrally. The organisation also shares a common quality charter with other European arms of the organisation, which has as an aim the creation of centres of excellence for food safety (i.e. within the LiquiComp Group quality and food safety are embedded in the same strategy). Some concern was expressed that the official quality strategy needed to be more tailored for the needs of the LiquiComp manufacturing site:

> "… he's [Head of Quality for LiquiComp Europe] starting to set out a new quality strategy for the business…. I understand what they're trying to drive to and it fits exactly with what we need to do here. We just need to reorder it slightly for what we need to do, to match our own personal circumstances … because in some respects they're trying to put racing wheels on when you've not even got an axle at the moment." (L014, Director of Technical and Quality).

In conclusion, it appears that LiquiComp UK still has work to do to make the formal aspects of organisation vision, mission etc. visible, particularly within manufacturing sites, and then to create an appropriately tailored quality and food safety strategy.

"Culture and Values"

Moving on from official statements, this theme evaluates how the study participants expressed their understanding of the organisation's culture and values.

There was a degree of coherence with the official company strategy, as both quality and consumers are central to this, and many participants expressed the purpose of LiquiComp UK in these terms:

> "…to provide our consumers with delicious tasting products..." (L004, Consumer Manager).
>
> "…to manufacture prime brand quality…" (L012, Technical Team Member).
>
> "...to provide relevant products for the consumer, at the right quality and at the right value." (L008, Head of Supply Chain Planning).

"… to make high quality soft drinks …" (L005, Regulatory Manager).

"… to deliver very good, tasty, healthy food to consumers…" (L011, Factory Leadership Team Member).

Interestingly, although all participants were aware that food safety was the main interest of the Researcher (through the provision of participant information sheets and the informed consent process), only 2 out of 17 participants mentioned the safety of products in their initial description of the organisational purpose:

"... to provide consumers with a safe, enjoyable product and experience..." (L015, Manager, Third Party Manufacturing).

"... to make a drink that people want to buy, safely, … that people want to go out and drink and buy, but to do it in a way that it's not going to hurt them, you know…" (L013, Packaging Manager).

So, whilst food safety was described as a key priority by participants in the context of the cocked / shredded cap incident, this was not reflected in their descriptions of the overall organisational priorities.

One possible explanation for this was given by L006, who expressed the opinion that head office based staff would see the commercial aims of the organisation as more pertinent to them than food safety:

" … if you go to [affected manufacturing site] it's much more prominent, because I guess it's the site where the product's being made, whereas here [head office] we are more, um, especially on this side of the office, the marketing, design teams, are much more about being creative and coming up with ideas and powering the brands forwards rather than the nuts and bolts of safety and quality, so perhaps it's just the natural organic split that means that here food safety culture is not as prominent…." (L006, Lawyer).

Another explanation for participants not expressing food safety as an organisational purpose might be the overall perception that soft drinks are fundamentally safe products:

> "Quite often within the soft drinks industry the risks are seen as lower, so you will see more focus on culture in companies that are dealing with higher risk products like milks..." (L015, Manager, Third Party Manufacturing).

> "Here, personal opinion, it's kind of taken as a given [by other people] that we make pretty bomb proof products, and for the most part therefore it [food safety] doesn't worry people day to day…" (L001, Business Quality Director).

There was however recognition in the quality community that this "don't worry" attitude can result in complacency and that work is required to build an FSC in the organisation:

> "... so the complacency is a potential to catch us out … [it] means we occupy our days with lots of other stuff and it's [safety] really only brought to the attention of our business when it cocks up. It's not so obviously part of the DNA, I would say." (L001 Business Quality Director).

> "…to me it's absolutely critical that we get that [FSC] embedded and that's the first one. 'Cos ultimately, the people on the line, I want them to think that their kid could drink this product that's coming off the line, and get that connection, to say well, my actions will drive whether somebody drinks and enjoys that or drinks and gets sick off it, and actually get that connection, because that's something we've lost." (L014, Director of Technical and Quality).

In fact, other study participants expressed the view that the predominant culture could be described as a "compliance culture", where, for example, internal audit teams were trained and expected to audit for compliance to the QMS, rather than to specific food safety or quality standards. This suggests that significant change is required to re-focus the day-to-day approach to food safety. In line with this, at the time of the data collection, LiquiComp UK had appointed a new Site Director for this manufacturing plant, who had already expressed a vision for improvement in quality and food safety on the site. This, together with the organisational changes in progress[39], was expected to change the focus on quality and hence food safety across the manufacturing community.

[39] This organisational change might also be expected to have an impact on both the total cost of quality and the distribution of these costs, for example, moving responsibility for routine operations from a specific QA staff member to a production team might result in a reduction in appraisal costs.

The Researcher also understands that since the main data collection phase of the study the central quality team has worked with non-manufacturing departments to strengthen the understanding of food safety throughout the business. For example, the quality team has worked with R&D to articulate and agree what "safety by design" means for new product development. Such activities build accountability for food safety across business disciplines and help to foster FSC across the wider organisation.

Another notable finding was that three of the 17 study participants, all technical and quality staff at the production site, mentioned the safety or well-being of staff in their description of organisational purpose; L013 (above), L014 and L009:

> "…we're here to provide products that the consumers want; you know [to] meet or exceed their expectations. And for me the ethos is that we do that in a safe way, that doesn't harm the environment, and enriches the people who work here, gives them opportunity to grow." (L014, Director of Technical and Quality).

> "I think the purpose of our organisation is obviously the health and safety and well-being of the guys on the line, the quality of products as well, then it goes to cost, delivery etc." (L009, Food Quality and Safety Manager).

This fits with the prioritisation of health and safety at the manufacturing site over recent years, which has seen significant improvements in the site safety record:

> "…. we've gone from having one of the worst safety records to having one of the best, in fact the best in LiquiComp Global, with over a million hours with no accidents. So it shows that cultural change can happen." (L014, Director of Technical and Quality).

As L014 expressed in the last quote, the change in the health and safety culture of the organisation demonstrates that organisational culture change is possible.

Looking at health and safety, the focus at the manufacturing site was easy to see. On entering the factory grounds, the first interactions any visitor has are with site security and reception. All visitors are informed about walking safely around the site (to avoid accidents with delivery vehicles) and are given clear instructions about fire alarms and assembly points. Thus, the importance of health and safety on site is immediately apparent.

Another example of health and safety practices was demonstrated when the Researcher attended a line side accountability meeting. These meetings take place in a noisy environment, where wearing ear protection is mandatory. To enable the meetings to take place safely in that location all staff are issued with radio linked ear defenders, enabling them to hear all the meeting participants clearly, whilst still protecting their hearing.

Finally, the health and safety statistics for the site (days since last lost time accident etc.) are given on a prominent sign at the site entrance, demonstrating transparency in the data and pride in the site health and safety record.

The measurement of FSC was a key topic of conversation in the semi-structured interviews. No specific scheme is currently in place in the organisation to assess this. From a health and safety perspective, the organisation records "near misses", now called "ZAPs" (zero accidents), and the Director of Technical and Quality is already considering how to build a similar system for food safety and quality:

> "… health and safety have their safety triangle and they started by setting up what they call 'near misses' or more recently called 'ZAPs', so steal with pride, and use the same sort of thing, looking at quality improvement activities that we can launch and use the same sort of vehicle and mechanism to do that…" (L014, Director of Technical and Quality).

One challenge to building a stronger FSC in the organisation also came from L014. He related that the management team have, in the past, failed to embed initiatives, leading to scepticism amongst the work force:

> "… unfortunately we tend to have a focus on something, and then, we move on to something else and it just lapses, the jaws of culture grind up some initiatives very, very quickly. So, one thing, and this has been a discussion in the management team, is we need to be absolutely relentless on, if we do put something in, supporting it and making sure it gains the traction until it gets

> really embedded into the place. Because the culture here is, 'oh, it's another management imitative. Give it 6 weeks and then it'll be gone it'll be onto the next one', and you've got to change that. And now having more new people into the management team, we are starting to see there is much more focus on actual long term delivery, rather than 'oh yes, got to do something, let's do something', then it sort of fizzles out. So it is getting better." (L014, Director of Technical and Quality).

This suggests that a firm commitment to improving FSC, with targets set across the organisation and not just for the quality team, will be critical to achieve long term improvements. As concluded in "Formal Expressions of Culture", more work is required to build the top-level strategy for quality and food safety to act as a foundation for organisation wide targets and commitments.

Finally, we need to consider a theme which underpins and influences most of the themes already discussed – "Communication".

"Communication"

In the discussion on communication during the investigation and management of the cocked / shredded cap incident it was noted that concerns about the use of social media and litigation relating to product incidents is driving the use of legal privilege and the closer involvement of the legal team in managing communications.

More generally, a wide range of communication tools were used across LiquiComp UK to focus the organisation on objectives and priorities and to celebrate personal and organisational success. For example, updates on product launches are communicated by email, over the company intranet and using "Yammer", a Microsoft system used to create social networks for businesses. One concern expressed at the affected manufacturing site was that the reliance on IT based communications might create a barrier in communicating effectively with staff who are less comfortable with technology. The example was used of requesting feedback from staff, which required the completion of an on-line form:

> "Everything we get is via email or on the plasmas and the interaction, it's all on line. Some people are really good with it and'll come along with that, others don't, you know, so it's making sure that you're resonating with your audience. To measure your success, 'cos you might have actually been successful, but if they don't fill in an online form, it doesn't mean that it's not [successful]" (L009, Food Quality and Safety Manager).

Another area where the use of technology might constrain communication is the information available at the production line on CCPs. As noted previously, CCPs are marked by large, red signs along the production line, but more detailed information is only available in on-line manuals. This contrasts with health and safety information, where key information is available in paper copy at each piece of equipment. This point was discussed with L014, who conflated this with a lack of staff's understanding and connection to QCPs[40]:

> "But you know, where's the document that says this machine does this, and this is how you check the quality of what it's doing, and this is what you do if it goes wrong? That's not there, but it's allowed for a lack of that connection." (L014, Director of Technical and Quality).

Formal communication between functional teams and senior management frequently takes the form of reports. These are sent as pre-reads for senior management team meetings. For example, L001 shared a copy of the Quality and Food Safety update prepared for the SMC. This report gives information on product incidents, investigations into alleged illnesses and the progress of the quality team against key strategic actions. Similar reports are prepared by other areas of the business e.g. L008 discusses the regular updates on stock status for the company at the commercial review meeting.

At the manufacturing site, daily communication between the site teams (production and supporting functions) and the site director takes place in the form of a mid-morning accountability meeting, as outlined in "Day-to-Day". Teams for each production area, and for the support functions, hold preliminary meetings earlier in

[40] This again demonstrates the intertwined nature and understanding of food safety and quality at LiquiComp UK.

the morning, enabling information to flow up to and cascade back down from the main meeting. The production team meetings take place at the line side (as described in "Culture and Values"). Large whiteboards are used to record actions, incidents to be raised to the main accountability meeting, and to track progress of outstanding work, e.g. to tackle quality or production concerns. Keeping the information at the production line helps to keep issues in focus and ensure that teams are working on agreed priorities.

One of the study participants also spoke about the practice of conducting "Gembas" across the manufacturing site. This practice was widely used by PowderCo UK and described in the previous case study. In LiquiComp UK, "Gemba" appears to have been introduced as part of a raft of CI practices, but is now less used, having been one of the initiatives which failed to become embedded long term within the site:

> "And I go and do GEMBAs on a regular basis. So you go out into the factory, and you know, from years of experience I suppose, but you get a gut feel as well?" (L014, Director of Technical and Quality). "Do you do those round here? I haven't heard anybody else mention them?" (Researcher). "Yes, we do GEMBAs. It's not as embedded as it should be… I do it religiously myself …" (L014).

Overall, the major constraints on communication described in the embedded case did not appear to affect day-to-day operations, and initiatives such as the company wide meeting to present objectives etc. (see "Formal Expressions of Culture") could be expected to improve inter-site and inter-departmental relationships and communication. Nevertheless, further improvements in relevant communications on quality and safety on the manufacturing line were believed to be required. Initiatives such as better signposting of CCPs, access to relevant information and the use of pictures to communicate safety and quality standards were brought up by senior members of the quality community as potential improvement ideas for the site.

Conclusion

The thematic analysis of the main case has elucidated several aspects of the working practices and behaviours of LiquiComp UK. The overall picture is of an organisation which puts trust in processes and systems for all aspects of its business. There is recognition within the quality community that the current QMS is overly complex and burdensome so that a cultural change is required to reposition activities away from compliance to the system, towards a proactive quality and food safety approach. It was also clearly evident that staff - both relatively new and those who have worked for the company for many years - are committed to the organisation.

However, this analysis raises some key concerns in terms of the prioritisation of food safety in the organisation at the time of the study. Whilst many study participants put product quality as a key purpose of the organisation, the key manufacturing priority was judged to be "getting the pop out of the door". At the manufacturing site the HACCP system is established and PRPs such as personal hygiene are well embedded; however overall in the organisation there is an element of complacency towards food quality and safety. LiquiComp UK's core products are viewed as "pretty bomb proof". Indeed, acidified, sugar containing, carbonated products generally have a low risk of contamination with pathogenic organisms, but as the embedded case demonstrates, even these products can suffer from other quality and safety related failures.

The culture and values of the company are developing and not yet fully shared right across the organisation. Senior management appear committed to making the changes required to ensure the future of the brands, the manufacturing sites and the overall organisation. They also recognise that culture change requires a consistent approach and ongoing prioritisation by the senior management team. Whilst this was positively demonstrated by the improvements in health and safety at the manufacturing site considered in this case study, it was also recognised that the site management team have previously failed to embed other initiatives and that a consistent approach will be required to improve FSC.

Following this analysis of both the embedded and organisational cases, a comparison is between them is required. Consideration will be made as to whether the organisation works and behaves in a similar fashion when under the pressures of managing a quality incident as it does during day-to-day operations and if not, look for possible reasons for the differences elucidated.

6.4 The Relationship between the Embedded Case and the Organisation

Overall, the findings of the thematic analysis show that LiquiComp UK demonstrates many consistent behaviours and attitudes across times of normal operations and times of heightened pressure.

There is clear alignment between the importance of processes, systems and routines for the day-to-day running of business and the use of well-structured processes for incident investigation and management. CI tools and techniques are embedded in everyday work and were used for problem solving during the incident which forms the embedded case.

The use of CI illustrates an organisational appetite for learning. This was also clearly seen in the cocked/ shredded cap issue, where a key lesson for the incident investigation process itself was the importance of having physical samples of affected products for all parties to examine. Members of the IRC also used the opportunity to evaluate how well prepared their own areas were for implementing a product recall and had begun to put in place plans to address any shortcomings. These examples come on top of the numerous corrective actions identified as part of the RCAs at the manufacturing site.

However, an unanticipated side effect of the wholesale adoption of processes and systems to run every part of the business was seen in the non-reportable food incident, with the mismatch between SOPs and check sheets for the "torque test". The plethora of processes and documents with its combination of paper based and networked systems could be termed system swamping**,** and poses challenges for the company and its employees, namely:

- How do staff know which are the critical procedures for the safe and efficient running of the business are when there are so many “important” ones?

- How do staff access the information they need at the time when they need it, when it’s spread across different systems and formats – and if they do access it, can they be certain they’ve got the right information?

- How does the company keep all these documents up-to-date, whilst also retaining the right level of control?

An excess of complex documentation has been identified as one of the barriers to the successful implementation of FSMS, particularly HACCP (Fotopoulos et al., 2011; Jevšnik et al., 2006). Although the volume and complexity of documentation has not prevented LiquiComp UK from implementing both a QMS and an FSMS, **“system swamping”**, does appear to be somewhat of a barrier to the successful maintenance and on-going use of the QMS and FSMS and so to food safety governance. At the time of the data collection, LiquiComp UK was in the process of implementing an SAP quality module and a complementary software system to collect and trend quality data, with the aim of streamlining both data collection and analysis, to enable staff to focus attention on key information. Whilst this should help to address the some of the concerns about documentation management and data collection, it will be critical to ensure that the ability to collect and hold more data does not lead to more complexity, rather than the intended simplification and prioritisation.

Another point of difference noted between the embedded and organisational cases, and one which can also be seen as a barrier to effective food safety governance, relates to the style of communication. On an everyday basis, communications appear generally open, timely and inclusive. However, during the quality incident a key concern was to keep a tight hold on information with anxieties expressed about the use of social media and the increasingly litigious nature of society. Whilst such concern is understandable, this **"constrained communication"** appears to have led to tensions with front line manufacturing staff who were, reportedly, frustrated about the lack of information. Even amongst technical staff and management there was a lack of knowledge of, or a misunderstanding of, the complete incident which has the potential to cause miscommunications in the future. It might also prevent the wider dissemination of lessons learned from the incident, as there was a lack of a fully coherent "story" about the incident which was understood across the business.

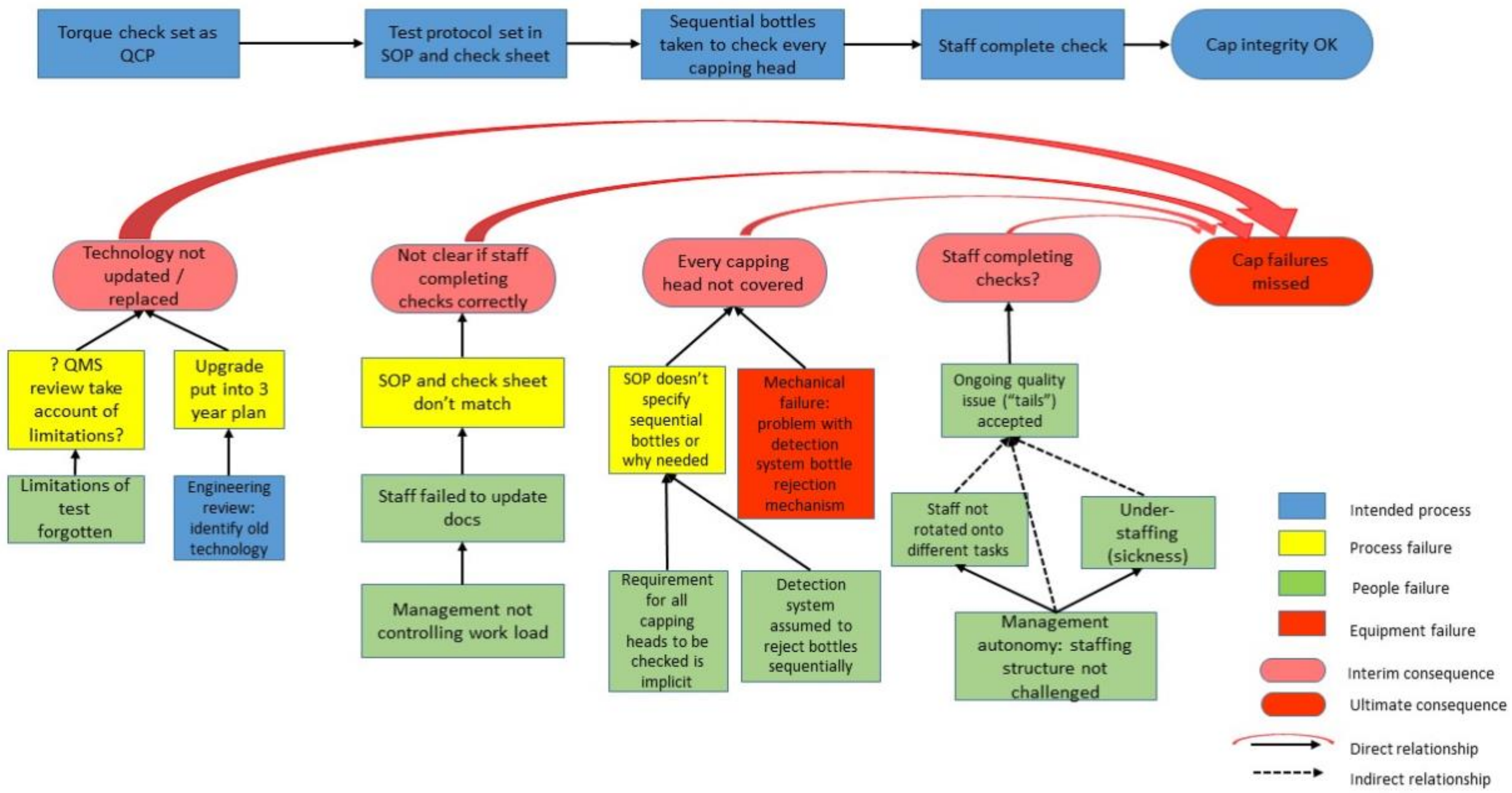
Another element of disparity was seen in culture and values. Concern for food safety came to the fore in dealing with the incident but appears to be of a lower priority in routine operations. "Getting the pop out of the door" – albeit good tasting, high quality products – seemed to be the usual priority at the manufacturing site and many study participants at head office recognised that they did not have front line roles to play in assuring food safety. As discussed in Chapter 3, Griffith (2008, 2009 cited by Griffith et al., 2010a) defines FSC as "the aggregation of the prevailing, relatively constant, learned, shared attitudes, values and beliefs contributing to the hygiene behaviours used within a particular food handling environment". This infers that the day-to-day values and priorities of LiquiComp UK would indicate the true FSC of the organisation – being more prevalent and constant – rather than behaviours and attitudes demonstrated only at a time of crisis, when food safety was a high priority. (A more comprehensive analysis of the FSC of LiquiComp UK is given in Chapter 7, Section 7.2). In fact, the tight control of communication about the incident means that staff may not even be aware that food safety was the key priority at this time. These findings substantiate the concerns raised by some study participants of the amount of work required within LiquiComp UK to improve the FSC of the company and suggest that **"culture and values"** may form another barrier to effective food safety governance.

This case study also suggests that the broader **"organisational culture"** can act as a barrier to effective food safety governance. Whilst all participants based at head office made at least some reference to the official company mission statement, very few of those based at the affected manufacturing site did. In every corner of the head office there were visible displays of company symbols, from brand history displays to samples of new products in coolers, with copies of the mission statement and objectives on poster displays and leaflets. In contrast, the company identity was far less visible at the manufacturing site; in the words of L014, "… so a meeting room like this, we could be anywhere". Taken together, this suggests that the three levels of organisational culture defined by Schein (2004) - artifacts, espoused beliefs and values, and basic underlying assumptions – differ between the head office and manufacturing sites. In terms of the construct of PC, this indicates that there are several organisational topoi in LiquiComp UK (head office; manufacturing site; staff; senior management etc.) and that there is a lack of integration into one overarching topos. This will also be considered in more detail in Chapter 7.

Before moving on, it is important to address the question of whether in this case the people, processes or both underlie the failure in the FSMS / QMS, i.e., how does this case fit with these constructs in the theoretical roadmap set out in Chapter 4 (Figure 4.3)? In fact, a convoluted mixture of people and process issues underlie the failures uncovered. For example, the mechanical failure which set off the quality incident, i.e., the bolt dropping out of the capping head, can be traced back to two underlying issues: poor design (as the bolts could work loose) and a failure to recognise the need for regular inspection and maintenance of the bolts. Whilst the gap in inspection and maintenance programmes are process failures, it can be argued that the actions – or lack of actions - of people underlie both of these gaps. The possibility of a failure of the bolts does not appear to have been considered and hence was not managed by either the equipment manufacturers, or of course by LiquiComp UK. This limitation on possibilities fits with the paradigm of PC and will be addressed in the next chapter.

A further example - the "torque check" QCP - has been mapped out to illustrate the multiple failure points and the underlying causes of people and process failures and is shown in Figure 6.5 overleaf. Overall, it might be concluded that whilst the embedded case illustrates that both process and people failures caused the quality incident, it is the shortcomings of the people who develop, implement and manage the processes which underlie the majority of these failure points.

Figure 6.5: The “Torque Check” – A People or Process Failure?

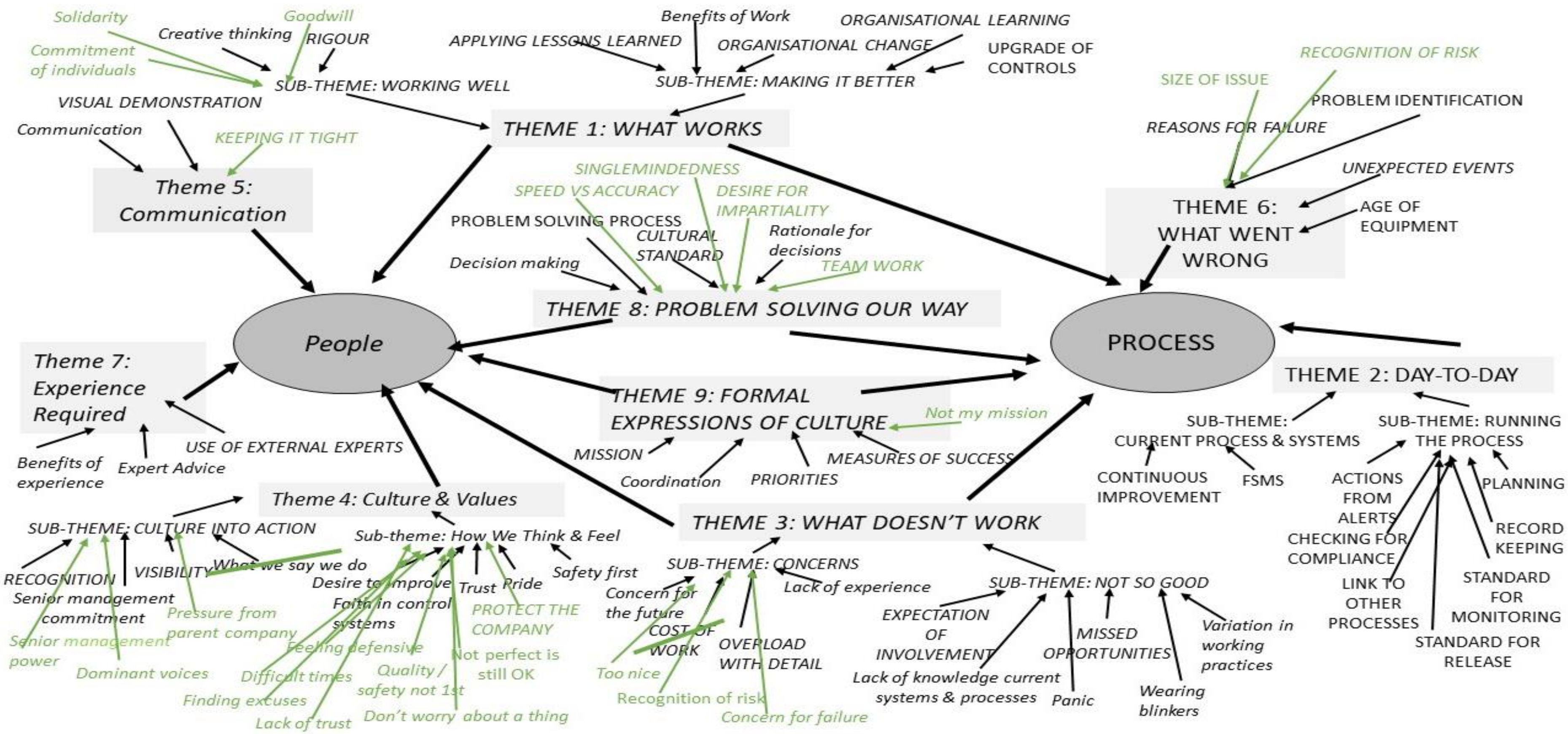


The people Vs process debate should also be considered from the perspective of the overall thematic analysis. As was set out in Chapter 4, no new themes were developed for this case over and above those created for the PowderCo UK case study. Figure 6.6. overleaf is therefore adapted from the thematic map developed for the PowderCo UK case study, with new codes added in green typeface, and again categorised as people related (in italics), process related (in capitals) or both (italicised capitals)[41]. The thematic map reinforces the conclusion of the inter-related nature of people and process elements, in both the routine operations of the organisation and in the analysis of the non-reportable food incident, but with people elements underpinning the majority of themes.

One last point must be re-visited, the perception by the organisation that the non-reportable food incident was unforeseeable, at least to some degree. This echoes an element of the PowderCo UK case, although the drivers of why the organisations take this view are somewhat different. In PowderCo UK it was postulated that individuals might be reluctant to voice concerns about the weaknesses in the organisation (be they people or process weaknesses) as they are constrained by the strong, overarching organisational topos. In contrast, it appears that LiquiComp UK lacks an overarching topos. In this case, individuals may be reluctant to apportion blame on processes or people as do not want to highlight the fragmented nature of the topoi between different departments and sites. Whatever the underlying reasons, classifying the incident as **"unforeseeable"** can be viewed as a barrier to effective food safety governance, as it impacts on the ability of the organisation to fully recognise the need for changes and take full learning from failures.

[41] The two codes which do not relate to the LiquiComp UK case are shown for completeness, but struck out with a green line.

Figure 6.6 LiquiComp UK Thematic Map



Italics = people related; CAPITALS = process related; *ITALICISED CAPITALS* = people & process related;
Codes found in LiquiComp UK case only; ~~codes not found in LiquiComp UK case~~

6.5 Conclusion

This chapter has described the second case study, LiquiComp UK, again using a thematic analysis to explore both the embedded, critical case of a non-reportable food incident – the cocked / shredded caps – and the overall organisation.

As with the PowderCo UK case, the incident itself was complex and unexpected (see Figures 6.3 and 6.5) and occurred despite the company having a comprehensive QMS and FSMS in place. As elucidated by the thematic analysis, LiquiComp UK placed great trust in and reliance on such systems. Processes and systems were seen as the basis for day-today operations and indeed were critical in allowing LiquiComp UK to investigate and resolve the quality incident in a robust and timely manner. However, the sheer volume and complexity of systems – system swamping - was one of the underpinning issues which contributed to delays in the cocked caps being detected by staff earlier. This barrier to effective food safety governance links with findings from the extant literature presented in Chapter 3, that the complexity of HACCP based FSMSs can act as a barrier to FSMS implementation, and this point will be discussed further in the next chapter.

Contrasting communication styles were identified in the embedded and overall organisational cases. In general, communication was regular, open and inclusive, however, constrained communication was a key feature of the embedded case, due to the use of legal privilege to safeguard the organisation from legal, financial and reputational damage. Constrained communication may act as a break on organisational learning from failure and act as a barrier to effective food safety governance.

Whilst LiquiComp UK clearly prioritised food safety during the quality incident, the importance of food safety versus other demands, in particular the drive to “get the pop out of the factory” has been identified and discussed as a potential cause for concern. If one considers that FSC is represented by “prevailing, relatively constant, learned, shared attitudes, values and beliefs ….” (Griffith, 2008, 2009, cited by Griffith et al., 2010a), then the everyday beliefs and actions of staff are a better indicator of the organisation's FSC than the attitudes and behaviours exhibited during the incident investigation and resolution. This suggests that the FSC of LiquiComp UK is underdeveloped and culture and values have also been identified as a barrier to food safety governance in this case. Further analysis of the FSC of LiquiComp UK is given in Chapter 7.

Furthermore, it was apparent that LiquiComp UK continues to develop its organisational culture and strategy. Significant differences in the visibility and understanding of the organisational culture between the head office and manufacturing sites and this somewhat fragmented organisational culture appears to form another barrier to effective food safety governance.

A key aim of this thematic analysis was to explore whether food incidents can be related to specific people or process elements of a failure in FSMSs. The thematic map set out in Figure 6.6 highlights the interactions between people and process in this case, both in terms of the functional day-to-day operations of the organisation and the food incident. However, as with the PowderCo UK case, people related elements - variations in working practices, missed opportunities and unforeseen possibilities –are primary contributors to the root cause of the product incident.

There were several unforeseen, or even unforeseeable, elements to the non-reportable food incident, including not only the primary failure of the capping machine but also the simultaneous failure of multiple control points. As previously noted in the PowderCo UK case, this finding will be used to question the reliability of HACCP-based FSMSs in Chapter 7.

Having considered the thematic analysis of both case study organisations, Chapter 7 presents a detailed comparison and discussion of the cases. First, the results of the thematic analyses are compared and contrasted, before the findings are considered in light of the extant literature on barriers to and drivers for FSMSs and FSC. Finally, the case studies are re-analysed using the concepts of PC, which enables both the determination of the utility of PC to investigate non-financial MCSs and cases of organisational failure, whilst also offering new insights into the cases themselves.

7.0 Discussion

The last two chapters have presented the findings of the thematic analysis of the case studies, PowderCo UK and LiquiComp UK. This analysis has given insights into what happened in the embedded cases of the non-reportable food incidents, how the cases were investigated and resolved and who was involved. The analysis also started to uncover some of the underlying reasons as to why the incidents happened, including failures in manufacturing and test equipment, mismatch of SOPs and check lists for product quality tests, and failures to take account of the consequences of small process changes. A comparison was also made between the generally successful day-to-day operations of the organisations and the incidents, giving further insights into how and why these occurred and what underpins the generally successful operations of the two food manufacturers.

In both cases, the non-reportable food incidents happened despite the companies having comprehensive QMSs and FSMSs; both organisations were process driven not only in using these systems to manage the quality and safety of food production, but also in the way that they used processes and systems to investigate and resolve the incidents. Most strikingly, in both cases the quality incidents were viewed as unexpected or unforeseeable: the possibility of failures happening in this way had not been anticipated or completely controlled for in either organisation. The classification (by the organisations) of the incidents as unforeseeable has been identified as a potential barrier to food safety governance, along with system swamping**.** In the case of LiquiComp UK three other potential barriers were identified: constrained communication and two aspects of culture, both the overarching organisational culture and the everyday culture and values exhibited by staff and management.
To understand these and other findings in more detail, the cases are first directly compared (section 7.1) then reconsidered against the theoretical roadmap. The elements of “FBO People” and “FSMS Process” are further explored by considering the case studies against the extant literature on FSMS and FSC (section 7.2). Then the findings are further analysed and considered against the main constructs of PC (section

7.3), before conclusions are presented in section 7.4. First though a detailed comparison of the cases is made (section 7.1).

7.1 Cross-Case Comparison: PowderCo UK vs. LiquiComp UK

Both LiquiComp UK and PowderCo UK are UK based food manufacturing arms of multi-national organisations. Both companies own highly respected, long established brands and operate from manufacturing facilities which, whilst they have been updated over time, have been in operation for many years, in fact in the case of PowderCo UK, for over 100 years. Neither company produces products which would be considered as specifically “high risk” within the food industry (e.g. chilled, ready-to-eat foods, or a product such as infant formula which is designed for a highly vulnerable population).

From an incident perspective, both organisations suffered from a potential physical contamination issue, although the source of this potential contamination was different. In the case of PowderCo UK the fine metal shards came from processing equipment, whilst in LiquiComp UK, the issue concerned damage to plastic bottle caps. In neither case was formal notification of the incident deemed necessary. In the case of PowderCo UK all potentially affected stock remained within the control of the company, whilst in the case of LiquiComp UK the pack defect was, after expert review, not considered to pose a health risk to consumers. Formal product recalls due to physical contamination of foodstuffs are still relatively rare, representing just 5% of food incidents in the UK in 2016/17 (Food Standards Agency, 2017b). However, this category of incidents has been associated with some of the largest and most costly product recalls in recent years. For example, the 2016 recall by Mars Inc. of chocolate potentially contaminated by plastic, affected 55 countries and was estimated to cost tens of millions of dollars (Quinn, Butler, & Smithers, 2016).

To understand other similarities and differences between the cases, a cross-case comparison is presented under the nine themes developed in the inductive analysis.

Table 7.1 considers the incidents themselves whilst Table 7.2 examines the overall organisational cases. The most striking similarities and differences are then discussed in more detail, before moving on to considering the cases in terms of the primary literature on food safety management, FSC and the cost of quality.

Table 7.1: Cross-Case Comparison - the Embedded Cases

Theme	PowderCo UK	LiquiComp UK
This is What Went Wrong	• A case of physical contamination: fine metal shreds[42]. • Generation of metal shreds due to equipment failure. • Problem compounded due to failure of CPs and final CCP (magnets and sieves). • Problem detected by off-site contract packer. • Root cause of the incident (problem with the equipment) was complex to diagnose – initial findings were not correct. • Change in magnet location partially blamed for failure of detection: move had been checked and approved by HACCP team / process.	• A case of potential physical contamination: cocked/shredded caps[43]. • Mechanical failure in capping equipment resulting in pack damage. • Problem compounded by multiple failures in QCPs (cap integrity not identified as a CCP). • Problem detected during unrelated quality check. • Root case of the incident (problem with the equipment) was easy to identify. • Failure of detection related to: limitations with detection system; pack reject system not working correctly; failures in physical pack checks by staff. • SOP and work sheet for "torque check" not matching, so physical pack checks unreliable.

[42] All product remained within the control of PowderCo UK, hence no formal notification as a food incident was required

[43] After expert review, the decision was reached that the products did not pose a risk to health (plastic swarf only found on cap rim, not inside bottle; swarf was not of a nature to be injurious to health), hence no formal notification as a food incident was required.

	• Lack of visible standard for “normal” amounts of metal powder vs unacceptable “shreds” also identified in RCA. • No blame attached to staff for failure to detect the metal contamination. • Failure seen as unexpected, even unforeseeable – equipment never failed in this way before.	• Staff not directly blamed for failure – but management highly sceptical that checks completed correctly. • Failure of capping equipment seen as unexpected – a design flaw waiting to happen – and capping head bolts not identified as requiring maintenance by original equipment manufacturers. • Failure of multiple checks seen as unexpected / unforeseeable – “Swiss cheese” effect.
Communication	• Consistent narrative describing the incident amongst all participants. • Communication was swift at the start; regular and open throughout the investigation and management of the incident. • Incidents used as “war stories”, allowing narratives about lessons learned from failures to circulate around the organisation.	• Narrative about incident not completely consistent – product recall or withdrawal? • Communication swift at the start (factory quality head to Business Quality Director and then other senior management), but constrained during incident investigation by use of “legal privilege”. • Some concerns that guarded communication impeded incident investigation and resolution.

		• Single minded approach to keep communication highly focussed during initial incident investigation to focus on immediate concerns and decision, i.e. is product safety affected, should product be recalled or withdrawn. • Apparent lack of curiosity amongst study participants about root cause of incident. • Legal privilege resulted in confusion about what could be communicated, when and to whom; delays in communication caused some degree of frustration for staff.
What Doesn't Work	• Opportunities missed to prevent incident occurrence, e.g. breaking shear pins not investigated. • Increasing age of equipment not factored into HACCP reviews as a potential hazard. • Individual judgement being used by workforce to determine "acceptable" vs "unacceptable" metal	• Management of production line semi-autonomous; staff not trained on all equipment; staff not rotating across jobs as per other production lines. • Minor quality defects in packaging viewed as "acceptable" – missed opportunities to examine management of line and working practices.

	contamination, rather than an objective, consistent standard being used.	• Increasing age of test methods not triggered in HACCP review. • Documentation management (SOPs and work sheets) inadequate. • Sheer number of SOPs meant that staff could not prioritise work on documentation, or potentially understand key activities in daily production.
Culture and Values	• “Safety First” attitude and values clearly demonstrated. • Thorough, rigorous approach to incident investigation and resolution. • Senior management commitment evident through involvement in incident management. • Use of systems and processes to manage incident demonstrates value PowderCo UK places on these.	• Beliefs expressed that safety of consumers is the highest priority, but views also expressed that “getting the pop out of the door” is highest priority at manufacturing site. • Incident investigation and resolution approach was comprehensive and thorough. • Core value is to “protect the company” (from legal, financial, reputational damage).

	• Expert advice respected, e.g. role that magnet suppliers, maintenance engineers and equipment manufacturers played in RCA and solving equipment failure.	• Systems, processes and documentary evidence prized above what people say has happened, i.e. hard facts highly valued. • Lack of trust between management and line operators (questioning whether they carried out the tests properly), contrasting with high trust placed in RCA teams. • Power and responsibility of senior management evident – high involvement in incident; had ability to dispute results and push for re-evaluation to ensure they trusted outcome of IRC.
Problem Solving Our Way	• Routines, processes and systems play a central role in everyday work and incident management and investigation. • Root Case Analysis embedded as a way of working, to the extent that an "RCA Room" is dedicated to this approach.	• Highly systematised – IIC, IRC, RCAs. • Clear focus of each part of the process – overlap not condoned. This kept focus and speed during the investigation, but potentially limits overall understanding and potential learnings.

		• Staff are confident in using the RCA process and tools, adapting these as required to meet their needs. • Impartiality of the investigation was an important concern, which correlates with the with trust issues identified in “Culture and Values”. • The role of the IRC is to recommend action, but they are not the final decision makers. In this incident the SMC and CEO pushed back on the IRC recommendation and demanded re-evaluation of both volume of stock affected and safety impact. • Over 90 corrective actions identified in RCAs, covering many areas, not only the affected production line. Is it possible for the business to effectively address all of these corrective actions at the same time?

What Works	• Stories of the organisation overcoming adversity ("war stories") are used to communicate lessons learned. • Rigour and thoroughness was evident e.g. commissioning original equipment suppliers to manufacture new conveyor, with an upgraded system to prevent future defects of the same kind. • Proactive work on second Bin to prevent the same equipment failure shows planning, learning from failures and a "safety first" attitude (prioritising safety over costs, time equipment is out of commission etc.).	• Commitment of individuals was highly evident (weekend working; finishing on Christmas Eve at 5pm). • Good co-operation seen between staff and external partners and suppliers. • There was a proactive approach to putting in place corrective actions and upgrading systems to prevent future failures. • Cross-company communication was seen, within the limits imposed by the use of legal privilege. • Evidence was seen of individual team learning lessons from the incident e.g. customer care team capability to manage recall. • Key learning identified as requiring that all decision makers see failed product / pack to ensure that correct conclusions can be drawn.

Experience Required	• External experts and partner companies were key to the detection, investigation and resolution of the quality incident. • On-site experience valued in investigation team; some newer team members were not included in the initial investigation, despite previous industry experience, potentially limiting PowderCo UK from benefiting from other insights and best practices.	• External exerts key to investigation and decision making (e.g. medic; packaging suppliers). • Recognition of previous experience to ensure processes used were robust and best in class. • However, seniority and the dominance of some senior managers seen as over-riding – at least initially – the views of true experts. Use of valid, impartial experts was required to counterbalance this.

Table 7.2: Cross-Case Comparison - the Organisational Cases

Theme	PowderCo UK	LiquiComp UK
Day-to-Day	• CI is embedded as way of working. • The use of systems and processes is highly embedded. • There are well organised and documented FSMS and QMS. • The formal recognition of the importance of food safety is clear. • CCPs are clearly signposted in the factory, and information on the controls is readily available. • A mixture of simple (manual checks and paper records) and sophisticated (automated checks and recording) controls are used in the manufacturing site.	• CI is embedded as a way of working. • A high store is set in systems and processes. • Both the QMS and FSMS are extensive and well documented. • The embedded nature of PRPs is evident. • CCPs are marked, but staff need to access the IT system to get further information on the controls. • A mixture of simple (manual checks and paper documentation) and sophisticated (automated systems in syrup room) controls are present across the manufacturing site.

What Works	• Creative thinking was evident, to envisage things that can go wrong and put in place adequate controls. • Rigour and thoroughness of approach in managing day to day operations and controls was clear, e.g. upgrade of flooring for better hygiene.	• Staff loyalty and commitment was evident, even at a time of organisational restructuring. • General rigour and thoroughness in manufacturing processes was demonstrated, e.g. PRPs for cleaning.
Experience Required	• HACCP and Food Hygiene certification required not just for line operatives and quality but all management team, demonstrating that training used to build skills and experience. • The PowderCo UK site uses 3rd party audit and certification to demonstrate its quality, and is BRC and ISO 22000 accredited for food safety. • However, the value placed on experience may limit the participation of staff who have experience elsewhere.	• Experienced staff are valued. Evidence of coordination with experts in other parts of the company (e.g. visits from head office team). • Site holds ISO 9001, but does not currently hold certification against scheme recognised by GFSI. However, implementation of FSSC 22000 planned. • Internal expertise seems to be valued more than external for day-to-day activities.

Formal Expressions of Culture	• The official corporate mission statement is highly visible, e.g. on the company website, foyer wall, door fingerplates. • Values are expressed on the website, explained as part of the induction process and incorporated into the "success" measures of the annual review process (success is measured by behaviours as well as outcomes of objectives). • Food safety and quality not specifically mentioned in corporate mission, but corporate and site quality statements make the link between quality and consumer trust, which is a corporate value. • "Zero accidents, zero defects, zero waste" are goals for the site. Food safety is not specified, but posters and displays around the site show	• The corporate identity, vision, mission etc. are highly visible on the website, and in head office. In contrast, there is little visibility at the case study manufacturing site. • The need to build common identity recognised by senior management. • Food safety is not specifically stated as part of the corporate mission / values. • Quality and consumers are part of official company strategy. • There is a common quality charter with European business, but concern expressed that this needs to be better tailored for the LiquiComp UK manufacturing sites (which are currently not at same level of sophistication as some of the other LiquiComp businesses).

	how these goals / targets link to product quality and safety.	
Culture and Values	• All participants put food safety as the main focus or priority for the site. • Participants expressed pride in their work, high standards and the quality of the site (despite outward appearances of the building). • Senior management commitment to food safety as evidenced by the requirement for training and certification of individuals and the site. • The importance of Health and Safety of staff and visitors also highly evident – the site uses a ZAP system to record "near misses". • Some possibility of using ZAP system to record food safety near misses was mentioned.	• Many participants expressed the purpose of LiquiComp UK in terms of providing quality products for customers. • Only 2/17 participants specifically mentioned food safety as the main purpose for general operations. • At head office, it is thought that food safety is more important for manufacturing, but the overall idea that products are inherently safe might mean that people don't worry about food safety day-to-day. • There is some recognition that inherent microbiological safety of soft drinks may lead to complacency and that work is required to build a food safety culture.

		• The Health and Safety of staff and visitors is a high priority at the manufacturing site, with large improvements in health and safety culture change in recent times. • ZAP system in pace for health and safety; participants mentioned "stealing with pride" from this to introduce a specific scheme for food safety. • Recognition given that in the past management at the production site have introduced many ideas which haven't gained traction, causing scepticism in workforce.
Communication	• History of site and products is evident and a source of pride. • Product quality and safety messages often reinforced with stories – not just site ones, but more general (e.g. health and safety notices near office coffee point).	• Wide range of communication tools used, particularly using email, new technology etc. • Concern expressed that use of technology can constrain communications in the manufacturing site – access is not as easy; older workforce who are not IT savvy etc.

	• Notice boards in corridors and team areas used to communicate objectives, results, company values etc. • Daily "accountability meeting" – drives bottom up and top down communication. The site director runs the main meeting. Meeting process gives focus and prioritisation of key activities for the site. • "Gembas" – management tool to engage with line operatives to look at work practices and understand issues. Participants viewed these positively.	• Communication of CCPs also potentially constrained by technology (have to look up on IT system; full details physically available not on the production line). This contrasts with health and safety information which is available lineside in folders kept with each piece of manufacturing equipment. • Formal communication processes are used to ensure that senior management are fully informed of issues etc. • At the production sites daily "accountability meetings" are used within teams and with site management. Keeping information at production line side drives focus and priorities. • Some mention of Gembas, but this was used as an example of a management tool which did not really last.

As well as the organisational and incident similarities touched upon earlier, it is evident from the summary of findings shown in Tables 7.1 and 7.2 that there are many other similarities between LiquiComp UK and PowderCo UK. Both organisations prize the use of systems and processes; CI is well established as a way of working; problem solving through RCA and associated tools is highly embedded and both organisations have well established QMSs and FSMSs. When the incidents occurred, both companies took a similar process-based approach to the investigation and management of the incident. Indeed, both companies might be considered to demonstrate an over-reliance on systems and processes, resulting in system swamping where individuals found it difficult to identify key gaps and weaknesses in the systems, impacting the organisations' governance of food safety.

From a cultural perspective, in both cases the overall safety of the end consumer was of primary importance in making the decisions about how to manage the incidents. Both organisations relied on expertise, and particularly the use of external experts, to identify and resolve the incidents they experienced. Likewise, in keeping with the CI practices used across the organisations, both LiquiComp UK and PowderCo UK demonstrated an ability to learn from failure, with the identification of corrective actions arising from the incident investigations and the application of these learnings not just to the affected manufacturing areas, but more widely across the organisations.

There were also many commonalities between the incidents themselves. In both cases the incidents occurred despite the comprehensive QMSs and FSMSs, not because of a lack of these. In both, the incidents were complex and messy, with equipment failure being compounded by a failure to detect the affected product or packs. In both cases multiple control points failed, rather than the incidents resulting from the failure of only one major control point. As such, both incidents fit with the description given by Reason, Carthy and de Leval (2001) of incidents in well defended but complex systems, where an element of chance or bad luck is involved in bringing about "the precise conjunction of defensive gaps and weaknesses necessary to permit an adverse event". Indeed, this element of chance fits with the belief by both organisations that the incidents were largely unexpected or unforeseeable.

However, despite this element of chance or bad luck driving failures in complex systems, the perception that the incidents were unexpected and unforeseeable is perhaps itself unexpected. Whilst there is a relative paucity of detailed research on FSMS failures from a management control perspective, some work has been undertaken to analyse food safety failures from a systems perspective, for example the work of Nayak and Waterson (2016) who constructed Accimaps of the UK *E. coli* 0157 outbreaks in 1996 and 2005. In this paper the authors noted that a limitation of their research, which sought to identify similarities and differences in human and organisational factors leading up to these incidents, was hindsight bias (Fessel, Epstude, & Roese, 2009), where predictive judgements are distorted by knowledge of the outcome of events. Indeed, Fischhoff and Beyth (1975) report that the perceived inevitability of past events increases significantly. In other words, in the current study it might have been expected that participants would believe that the quality incidents experienced were failures "waiting to happen", not that they were unforeseeable.

Classifying such incidents as unforeseeable can be considered another barrier to effective food safety governance. This element of the cases, along with another common thread between both incidents, that of the failure to take full account of the age of equipment - the conveyor Bin for PowderCo UK; the detection equipment for LiquiComp UK - will be discussed later in this chapter in relation to the framework of PC, the identification of "factual possibilities" and the truth gap between proactive and pragmatic truth.

Whilst there were many similarities between the cases, some significant differences, both overall and specifically in the investigation and management of the incidents, can also be seen. The first difference noted was in the style and nature of communications. In day-to-day operations both organisations prided themselves on having regular, open communication with all staff. At the manufacturing sites, both organisations ran similar accountability meetings, with this bottom up and top down communication enabling the organisations to focus on key priorities to manage their operations efficiently and effectively. However, during the quality incidents significant differences were seen between the companies in communication style and processes.

At LiquiComp UK communication was tightly managed by the legal team and the use of legal privilege to help guard the company against legal, reputational and financial harm. This was driven by a concern about the possible impact of the incident being discussed on social media and the litigious nature of society in general. Whilst these concerns are understandable, the impact was to restrict communications, leading to challenges in knowing what could be communicated, to whom, and when. Some study participants recognised that this led to some frustrations for staff at the manufacturing plant, who knew that an incident had occurred but who had to wait a long time to get information about this. Constrained communication has been identified as another potential barrier to food safety governance from this case.

In contrast, in PowderCo UK the incident seemed to be common knowledge. Participants described regular briefings about the incident to the manufacturing teams. Even staff who had not been employed at the site when the incident first occurred had a thorough grasp of it. There appeared to be a practice in the company of turning such events into “war stories”, where the key elements of the incident and how it was successfully overcome, were used to communicate key lessons from failures. This fitted well with the practice of CI in the organisation.

The outcome of these differences in communication could be seen in the coherence of the descriptions of the incident. All participants at PowderCo UK gave similar descriptions of the incident, whereas in LiquiComp UK, although the core of the story (the cocked / shredded cap) was always present, there were often large gaps in what participants knew and how they described the outcome of events. Differences in knowledge were to some degree understandable, given the range of staff interviewed and their differing responsibilities. The “single-minded” approach to the working of the IIC and the IRC (to make a recommendation on the impact of the event on the safety of the products and whether or not product should be recalled or withdrawn) also meant that staff might not have a full understanding of the root cause of the problem and subsequent corrective actions at the manufacturing plant. However, it was notable that even at the manufacturing site some middle and senior management lacked a complete understanding of the issue and / or used inconsistent terminology to describe the outcomes of the IRC. For example, some participants referred to a product recall rather than a withdrawal, which has a different meaning and implications from a regulatory perspective, and which could potentially cause confusion in future communications. The lack of a widespread, common narrative about the incident might also inhibit full organisational learning from the event. A further consideration of communication, in the context of PC, is given in section 7.3.

The second major difference between the organisations was seen in the area of FSC. Both organisations expressed consumer safety as their highest priority in dealing with the quality incidents. At PowderCo UK this focus was also evident in daily working, with all participants describing the key purpose of the organisation as the production of safe food. In contrast, at LiquiComp UK, the majority of participants expressed the organisation's purpose in terms of making tasty and good quality drinks for consumers. The inherent microbiological safety of soft drinks (versus, for example, dairy based products) appears to lead to a more complacent attitude to food safety, with an overall belief that such products are always safe. In addition, there were indications that even the quality of products takes a back seat in comparison to hitting production targets, e.g. with the acceptance of “tails” on the caps of packs produced on Line C prior to the cocked cap incident.

The value of food safety and quality to the organisations was also evident in the approach taken to audit and accreditation. It is certainly true that food safety and quality audits have many limitations (Powell et al., 2013). However, in a recent study of the audit process and management of this, Bradford-Knox (2017) identified that auditors consider audits as part of a CI process, where food safety and quality are managed and improved rather than policed. This appears to be the philosophy with which PowderCo UK approach audit and certification. Being accredited to both BRC and ISO 22000, PowderCo UK took pride in the feedback from external audits, and indeed took a proactive approach, e.g. making the decision to replace flooring in the manufacturing plant, as this was always raised during audits, even though it had never caused an audit failure.

In contrast, whilst LiquiComp UK was accredited to ISO 9001, they have to date not pursued third party certification for food safety but have relied solely on internal audits (including audits from the parent company). This approach was described as the manufacturing site having more of a “compliance culture” than a proactive, quality culture. The need to build a stronger FSC has been recognised by the quality team at LiquiComp UK and the operational restructuring occurring at the manufacturing site at the time of the data collection was partially designed to address the prioritisation of quality and food safety. In addition, the quality team were setting up structures across the business to reinforce the importance of product safety and quality (e.g. introducing “safety by design” criteria and processes for R&D) and had also put in place an objective to obtain FSSC 22000 accreditation for the manufacturing sites. Nevertheless, at the time of the incident, both overall organisational culture and the day-to-day culture and values expressed and demonstrated by staff and management have been identified as potential barriers to food safety governance, particularly in the LiquiComp UK case.

The final point of difference between the cases to highlight at this stage is that of a “blame culture”, which also fits with the proposed barrier of organisational culture. As discussed in the conclusion to Chapter 5, it would have been very easy for management at PowderCo UK to have blamed staff for failing to anticipate the failure in equipment, for failing to detect the metal contamination, and for failing to draw the correct conclusions in the HACCP review after one of the in-line magnets was moved. Instead the organisation took the approach of openly discussing the incident, recognising the shortfalls and operating a positive attitude to putting in place improvements.

In contrast the LiquiComp UK management team were openly sceptical about whether line staff had conducted quality checks correctly, or even whether they had completed checks at all. Although individual production line staff were not blamed, this was ascribed to a recognised shortfall in the management of the production line, gaps between the SOPs and process check sheets and the recognition that the member of staff responsible for updating the documentation was extremely over-worked.

Nevertheless, during participant interviews this inability to "blame" staff appeared to be a source of frustration for some of the management team, i.e. they appeared to take this approach reluctantly, rather than the lack of blame being a positive choice of the management team. Reason et al. (2001) identify a blame culture, specifically the blame of front line operators, as one of the characteristics of "vulnerable system syndrome", which makes organisational systems more liable to adverse events. They also show how blaming individuals can lead to a vicious cycle, where real opportunities to learn from failures and make improvements are overlooked. In the case of LiquiComp UK, the underlying scepticism and lack of trust in front line staff could have contributed to the somewhat less positive and productive framing of the quality incident observed in LiquiComp UK in comparison to PowderCo UK and suggests that learning from the incident may be impacted.

Having directly compared the two case studies on the basis of the thematic analysis and discussed some key characteristics of them, the following sections examine the cases in the light of the theoretical roadmap. First, the existing literature on barriers to and drivers for FSMSs and on models of FSC is used to look at the dimensions of "FBO People" and "FSMS Process" in the roadmap, to evaluate whether the findings of the cases support or refute this existing literature. A short evaluation of the cases in terms of the literature on quality costing completes this section.

7.2 FBO People & FSMS Process: Comparison of Cases to the Literature

With this understanding of the similarities and differences between PowderCo UK and LiquiComp UK and their respective quality incidents, based on the thematic analysis, the question now needs to be asked about how or whether these cases fit with previous research. This specifically addresses the second research objective, i.e. whether the barriers to the implementation and maintenance of FSMSs (especially HACCP) which had been found in the literature can be used to account for failures in FSMSs in the case studies.

In Chapter 3, models of barriers to and drivers for the implementation and maintenance of FSMSs were reviewed, along with literature on FSC. Several points must be addressed before considering the case studies in terms of this body of literature.

First, the incidents investigated as embedded cases are classified as non-reportable food incidents. The thematic analysis of the case studies demonstrated that in both organisations the incidents occurred despite FSMSs and QMSs having been implemented, not because of a lack of such systems, and in both cases failures of CPs, CCPs and /or QCPs were seen, i.e. there was involvement of both QMSs and FSMSs.

As established in Chapter 2, whilst some authors draw a distinction between food safety and quality (e.g. Spink and Moyer, 2011), many others consider food safety as an aspect of food quality (e.g. Röhr, Lüddecke, Drusch, Müller, & Alvensleben, 2005; Caswell, 1998). From an audit perspective food safety and quality attributes are frequently assessed together (Mensah & Julien, 2011), and recent work studying critical factors for the implementation of FSMSs has combined these systems with ISO quality systems (Kafetzopoulos & Gotzamani, 2014). With this understanding, plus the conflation of food safety and food quality seen in the case study companies, it is therefore reasonable to consider these incidents in the light of the body of literature on the implementation and maintenance of FSMSs.

Finally, the nature of the cases themselves justifies their examination in the light of the literature on FSMSs and FSC. As previously shown, both embedded cases were flagged up to the organisations as potential food safety failures, and indeed could have been reportable food safety incidents but for certain elements. In the case of PowderCo UK, all of the potentially affected product was within the control of the company, whilst in the case of LiquiComp UK it was determined that the plastic swarf generated by the over-torqued caps was not a specific health hazard. Thus, the cases might be considered to be “near misses” in terms of reportable food incidents, and hence interpretation under this field of literature is of value.

The first area to be considered is the extensive literature examining the barriers to and drivers for the implementation of FSMSs. One common criticism which can be levelled at the models of barriers and drivers identified and critiqued in Chapter 3, is the limitations of the research base, with studies generally being restricted in geographic area, industry scope and size, and / or the number of participants. Therefore, in order to take a broader view, the two review papers identified and presented in Chapter 3 (Fotopoulos et al., 2011; Jevšnik et al., 2006) are used as the main focus of the comparison of the cases to the FSMS literature. Each of these review papers set out a number of factors acting as barriers to, or drivers for, HACCP implementation and effectiveness and these factors were further classified in Chapter 3 into those related to people (management and staff) and those related to the FSMS process (process, technical and operational areas). These factors are re-presented in Figure 7.1.

It is not the purpose of this analysis to identify new barriers (or benefits) for the implementation of FSMSs / HACCP, but rather to determine the extent to which the previously reported barriers can explain the non-reportable food incidents at PowderCo UK and LiquiComp UK (as per research objective 2). Each incident is considered in turn below.

Figure 7.1: Factors Related to the Success of HACCP Implementation and Classification into People or Process Areas.

Classification of elements & ranking the influence of a specific element on HACCP efficiency, Jevsnik et al. (2006)		Critical factors for effective HACCP, Fotopoulos et al. (2011)	
1	Training (P)	1	Limited knowledge & skills for HACCP implementation (P)
2	Human Resources (Pr)	2	Lack of commitment to food safety by employees (P)
3	Planning (Pr)	3	Resistance to change & attitudes of employees (P)
4	Knowledge & competence (P)	4	Increased financial resources – cost (Pr)
5	Documentation (Pr)	5	Lack of employee training (P)
6	Resources (Pr)	6	Length of time to develop & implement HACCP (Pr)
7	Management commitment (P)	7	Lack of technical expertise & support (P)
8	Credibility (P)	8	Need to satisfy stakeholders / customers (P)
9	Hazard analysis (Pr)	9	Low availability of human resources (Pr)
10	Organisational design (Pr)	10	Excessive paperwork & documentation of HACCP (Pr)
11	Personal hygiene (P)	11	Improper organisational structure & PRPs (Pr)
12	Food handling (P)		
13	Customer (P)		
14	Food safety policy (Pr)		
15	Communication (P)		
16	Responsibility & authority (P)		
17	Organisational control (Pr)		
18	Transportation (Pr)		
19	Maintenance & sanitation (Pr)		
20	Food legislation, food standards (Pr)		
21	Infrastructure (Pr)		

P	People related elements
Pr	Process related elements

For PowderCo UK, many of the barriers to FSMS implementation in the literature can conversely be seen as strengths of the organisation. For example, rather than a "lack of commitment to food safety by employees" (Factor 2, Fotopoulos et al., 2011) being seen, a high level of commitment and a "safety first" attitude was demonstrated.

Likewise, training on food hygiene and HACCP (Element 1, Jevšnik et al., 2006 and Factor 5, Fotopoulos et al., 2011), management commitment (Element 7, Jevšnik et al., 2006), technical skills (Element 4 Jevšnik et al., 2006, Factors 1 and 7, Fotopoulos et al., 2011) and communication (Element 15, Jevšnik et al., 2006) could all also be viewed as strengths of the organisation.

Nevertheless, there are some aspects of the case which can be explained by these previously identified barriers. For example, an element of faulty hazard analysis (subsequent to the change of an in-line process check magnet during a planned engineering change) was found during the root cause investigation of the incident (Element 9, Jevšnik et al., 2006). Likewise, the issue of the age of equipment can be classified under the factor of infrastructure (Element 21, Jevšnik et al., 2006). Similarly, the lack of a clear standard for metal contamination, identified as one of the root causes of the incident, might be classified as a communication issue (Element 15, Jevšnik et al., 2006), or indeed a training issue (Element 1, Jevšnik et al., 2006 and Factor 5, Fotopoulos et al., 2011), as line staff were not trained to identify acceptable / unacceptable levels of metal powder. There are also clear links between system swamping as a proposed barrier to food safety governance, and the excessive paperwork and documentation identified as Factor 10 by Fotopoulos et al. (2011) and Element 5 by Jevšnik et al. (2006).

Overall however, it is clear that the complexities of the quality failure in PowderCo UK cannot be explained fully by the key barriers to FSMS implementation and maintenance identified in previous studies. First, rather than the FSMS lacking credibility (Element 8, Jevšnik et al., 2006) PowderCo UK displayed a high level of trust in and commitment to systems and processes, including their FSMS. Indeed, as identified in Chapter 5, this level of trust appears somewhat misplaced given that the metal contamination incident occurred despite the comprehensive systems in place. This aspect of the company's culture & values may even be viewed as a barrier to effective food safety governance. Second, the classification of the incident as unforeseeable stands apart from this previous work on barriers to FSMS implementation. In general, lack of knowledge, skills and competence might hinder the development of an effective FSMSs and lead to a perception that failures of such inadequate systems were unexpected and unforeseeable. However, in the case of PowderCo UK a high degree of training and competence was evident in the organisation. The failure to foresee the possibility of this particular incident cannot be explained simply by a lack of training and knowledge and this aspect of the case is considered further using the constructs of PC in section 7.3.

The same overall findings hold true for the incident studied at LiquiComp UK. Again, there were many demonstrations in the general operation of the business where potential barriers to FSMS implementation from the literature were organisational strengths for this company, e.g. personal hygiene (Element 11, Jevšnik et al., 2006); maintenance and sanitation (Element 19, Jevšnik et al., 2006); technical expertise and support (Factor 7, Fotopoulos et al., 2011). However, in considering the embedded case, some of the barriers identified in the literature can be mapped against the underlying causes of the incident. For instance, one of the factors in the cocked / shredded cap incident was the mismatch between an SOP and check sheets for the torque check of bottle cap integrity. This failure to keep the paperwork up to date had been blamed on an excessive workload for the responsible staff member, i.e. an issue with resources (Element 6, Jevšnik et al., 2006; Factor 9, Fotopoulos et al., 2011). Furthermore this failure in documentation was itself due at least in part to the volume and complexity of documentation used at the manufacturing site - system swamping - which clearly links to the identification of excessive paperwork and documentation as a factor for HACCP failure or inefficiency (Factor 10, Fotopoulos et al. 2011; Element 5, Jevšnik et al., 2006).

Lack of training is another factor implicated in the failure of FSMS implementation in the literature (Element 1, Jevšnik et al., 2006 and Factor 5, Fotopoulos et al., 2011). In the case of LiquiComp UK, a lack of employee training for staff on Line C (where the quality failure occurred) was noted. This training gap was not specifically related to food safety, but more broadly to the operation of all the equipment and tests on the production line. This training gap did however reduce the availability of staff to undertake the correct quality checks, which links back to the resource squeeze previously identified.

The LiquiComp UK case study also identified that whilst the safety of consumers was the key priority for the business when investigating and managing the incident, during normal operations the need to meet production targets was viewed as a higher priority. This suggests that some doubt may be cast on staff and management commitment to food safety, two other barriers noted in the literature summarised in Figure 7.1 (Element 7, Jevšnik et al., 2006; Factor 2, Fotopoulos et al., 2011). This links with the potential barriers to food safety governance identified in this case, namely organisational culture and culture and values.

Constrained communication was also identified as a barrier to food safety governance in the LiquiComp UK case and clearly links to the identification of communication as a barrier to effective FSMS implementation (Element 15, Jevšnik et al., 2006). However, as in the PowderCo UK case, the unforeseeable aspects of the case study (the failure in the capping head; the simultaneous failure of multiple QCPs; the identification of so many corrective actions) cannot be explained by the barriers to FSMS implementation noted in the extant literature.

Before moving on to consider the literature on FSC, there are two specific models of the barriers and drivers of FSMS implementation which are worthy of specific comparison against both case study findings. The model of Ball et al. (2009) was developed from research in small and medium meat processing plants in Ontario and is the only one of those reviewed which specifically sets out production system factors which influence the implementation of FSMSs, namely facilities and equipment, process characteristics and product characteristics. The case studies here differ significantly from Ball et al.'s (2009) sample, being large companies and both manufacturing products with a lower risk profile than meat. Nevertheless, in both cases issues with facilities and equipment and process characteristics were related to the root cause of the quality incidents. In LiquiComp UK the perceived inherent safety of the product, i.e. a product characteristic, was also related to the lower prioritisation of food safety versus product output at the production site. These cases therefore support the merit of Ball et al.'s (2009) approach in food manufacturing settings.

The second model which requires specific consideration against the case study findings is that of Kafetzopoulos and Gotzamani (2014) as this work specifically considered CFEI of both QMSs and FSMSs and studied FBOs with externally accredited systems. Of note is the identification of process improvement as a driver for effective QMS/FSMS implementation. Whilst CI / learning from failure is a notable element of the current cases, both LiquiComp UK and PowderCo UK experienced the incidents despite demonstrating this organisational characteristic. Similarly, adjustment of instruments and machines is identified as a CFEI; the failures in monitoring equipment and processes seen in the current cases might be considered as fitting with this CFEI.

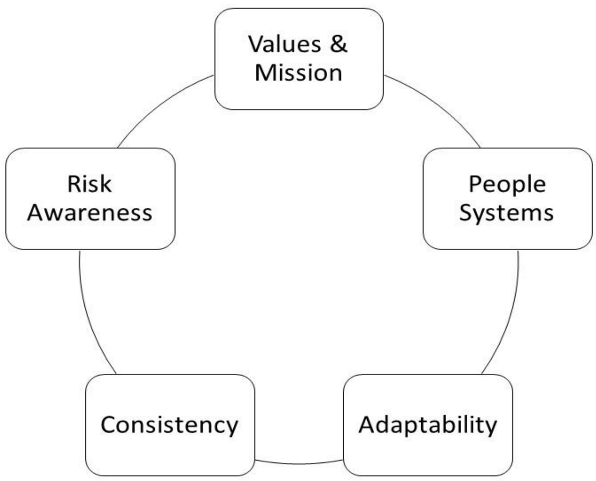
On balance, whilst some elements of the non-reportable food incidents can be explained by the literature on barriers to FSMS implementation and maintenance, key features of the cases - that the incidents occurred despite having FSMS and QMS systems in place; the unexpected or unforeseeable nature of the incidents and an organisational culture which fosters an over-reliance on formal systems and processes to assure food quality and safety - cannot. In addition, whilst communication is identified as a factor in the literature, the influence of organisational values on communication timing, style and content, is not fully captured within this. This is particularly clear in the LiquiComp UK case where the nature and timing of communications during the cocked/shredded cap incident was strongly impacted by a non-food safety value of the organisation, i.e. the requirement to "protect the company" from financial, reputational and legal risk. Therefore, the conclusion must be drawn that the factors identified to date in the literature as barriers to successful FSMS implementation and maintenance only partially explain these specific incidents and fail to address their true complexity.

In light of this conclusion, and before progressing to examine the cases against the second part of the theoretical roadmap, i.e. the constructs of PC, a consideration must therefore be made of the other main thread of literature reviewed in Chapter 3, namely the role of FSC to evaluate whether this literature better explains the case study findings.

As previously discussed in the literature review, FSC has been identified as an emerging risk factor for food safety (Griffith et al., 2010a), and a poor FSC can perhaps be viewed as the summation of the people related barriers to successful FSMS implementation and maintenance. It is therefore highly pertinent to consider the case study findings on culture, and specifically FSC, in terms of the literature in this area.

A number of models of FSC, both academic and commercial, have been developed in recent years and were reviewed in Chapter 3. As the framework developed by Jespersen et al. (2017) represents a collation of the major work on FSC, the case study findings are specifically considered against this model, which is re-presented here as Figure 7.2

Figure 7.2: Food Safety Culture Dimensions Framework (Jespersen et al., 2017)



In Chapter 5 a brief assessment of PowderCo UK's FSC was made, by comparing the case study findings to the definition of FSC set out by Griffith (2008, 2009, cited by

Griffith et al., 2010), with the Researcher concluding that the company exhibited a strong FSC. This was evidenced by practices during the investigation and management of the quality incident, together with overall organisational behaviours and practices. A more detailed analysis of FSC is achieved by mapping the case study findings against Jespersen et al.'s (2017) framework, as shown in Figure 7.3. As can be seen, in three of the five dimensions, PowderCo UK demonstrates attributes which support the previous statement that the company exhibits a strong FSC. There is clear evidence of food safety as a priority in terms of people systems, e.g. the requirements for staff and managerial training and the clear and consistent communications to staff on a routine basis and during the incident investigation and resolution. Adaptability is also self-evident in the case analysis, with the emphasis on RCA, CI and learning from failure. In terms of value and mission, the "safety first" attitudes and beliefs of the organisation were demonstrated not only in discussing the purpose of the organisation, but through the company's painstaking approach to resolving the metal contamination incident.

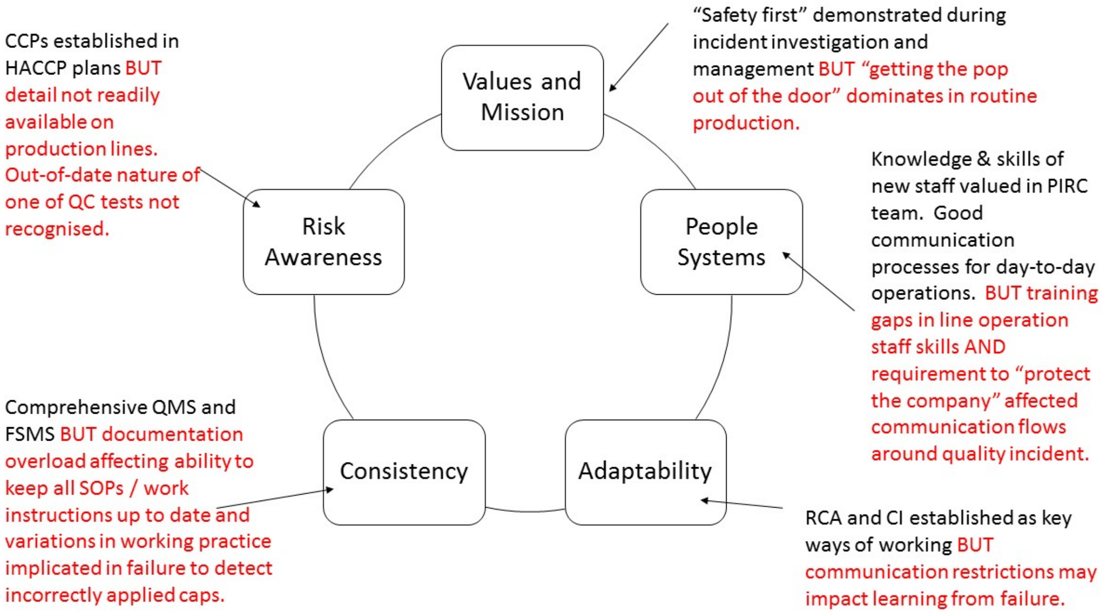
However, this more detailed analysis of FSC also demonstrates potential areas of weakness for PowderCo UK. First, in terms of risk awareness, as despite the comprehensive FSMS and highly visible communication on CCPs, the incident highlighted concerns in that the age of equipment had not been factored into HACCP assessments. In addition, the impact on the robustness of the FSMS of changing the strength / location of a magnet during an engineering change was not appreciated, despite a subsequent review of safety controls as required under the HACCP plan. Likewise, the factor of consistency raises concerns. The company has a documented quality policy; both their QMS and FSMS are documented and third party accredited and comprehensive FSMnSs are in place throughout the factory (e.g. the IP21 system for micronutrient addition). However, the incident highlighted small variations in working practices, which were implicated in the failure to detect the metal contamination and missed opportunities to resolve the incident faster (e.g. the investigation of breaking shear pins).

Overall, using this model supports the previous conclusion that PowderCo UK has a robust FSC, whilst highlighting some areas for improvement. The model also explains further elements of the non-reportable food incident at PowderCo UK which were not mapped onto the barriers to FSMS implementation set out in Figure 7.1.

Figure 7.3: FSC of PowderCo UK Using the Dimensions Framework (adapted from Jespersen et al., 2017)

Moving on to consider the LiquiComp UK case, the picture of the FSC was far less consistent, as shown in Figure 7.4. Although during the cocked / shredded cap incident the company was clear in its determination to protect the end consumer and provide safe products, during routine operations meeting production targets was perceived as a higher priority than food quality and safety. As non-alcoholic drinks are, from a microbiological perspective, inherently robust, there were indications that the safety of the products was taken for granted and so not expressed as a top priority or concern in routine operations. Likewise, looking at other elements of the dimensions framework, there are similarly mixed indicators for FSC, with the framework once again offering support for the importance of variations in working practice and issues with the age of equipment / tests as underlying causes of the incident. The FSC analysis against the framework also supports the conclusions drawn in Chapter 6 that the FSC of LiquiComp UK requires improvement.

Figure 7.4: FSC of LiquiComp UK Using the Dimensions Framework (adapted from Jespersen et al., 2017)



Overall, the FSC dimensions framework captures many of the people related elements of the barriers to the successful implementation and maintenance of FSMS seen in the LiquiComp UK and PowderCo UK cases, and can be seen to explain specific elements of the cases (variations in working practices, related to consistency and age of equipment / tests related to risk awareness) which were not explained by the literature on barriers to FSMS implementation and maintenance. The current cases also demonstrate that this model can be effectively used to assess the FSC of an organisation (using qualitative data) and to compare and contrast the FSCs of different organisations.

However, just as elements of the quality incidents were not encompassed by the literature on barriers to FSMS implementation, important aspects of the cases are not reflected by this FSC model. Again, the perception that the incidents were unforeseeable cannot be explained by this model. Neither does it clearly capture the nuances of constrained communication, nor the impact of the unshakable trust in systems and processes which forms a fundamental part of the culture in both case study organisations.

In part, the limitations of these two streams of literature is due to their focus, as they concentrate solely on FSMSs / FSC, rather than looking at the organisations and their control systems in a more holistic manner. In the research cases, aspects such as the economic climate, the impact of new product development and technology change might be seen as related to the root cause of the quality incidents and the overall successful (or not) implementation and maintenance of FSMSs. However, none of these aspects of the environment are clearly flagged as potential issues or causative factors in the literature considered so far.

In summary therefore, the extant literature on barriers to and drivers for FSMS implementation and maintenance, together with the literature on FSC, explains some, but not all, of the identified causes of the quality incidents under examination. This leads to the conclusion that the cases require examination through a more holistic research perspective, which leads to the use in this research to the management control paradigm of PC which forms the second part of the study's theoretical roadmap.

As presented in Chapter 4, PC is an integrative framework which, through consideration of organisational actors and their relationship to the world, enables evaluation of the organisations' topoi or realities. In the Section 7.3 the inductively developed codes and themes are mapped against the four PC dimensions, in order to evaluate whether this offers different insights into why the quality incidents occurred and whether we can better understand the reasons for the differences seen between the two case study organisations.

However, before moving on to consider the cases against the PC dimensions and concepts, we must return briefly to the topic of the cost of quality. Whilst financial information was not collected as part of this research, insights into different aspects of quality costs were gathered as part of the case studies. These can be split into costs generated routinely by the companies, and those which arose because of the non-reportable food incidents; both are summarised in Table 7.3. Even without financial data, the scale of internal and external failure costs arising from these incidents is readily apparent. Equally apparent is the increased spend post-incident to prevent reoccurrence of similar issues, exemplified by refurbishment of equipment not directly affected by the incident (upgrade / refurbishment of Bin B in PowderCo UK and repairs to other capping machines in LiquiComp UK). It is however, impossible to judge whether this spend on preventative costs will result in decreased failure costs in the future, as proposed by Feigenbaum (1956), without collecting indicative financial data over time.

One interesting contrast between the cases arises in that of appraisal costs after the incident. Both organisations implemented new test procedures so incurring development and verification costs which fit into the appraisal costs category. For PowderCo UK this process appeared to be relatively simple - the development of additional visual criteria for metal contamination and an increased frequency of testing. Costs for the development and verification of these tests might be relatively small, but the increased frequency of testing leads to higher ongoing appraisal costs. In comparison, in LiquiComp UK the replacement of the torque closure tests with a new closure angle test was time-consuming and costly, with new equipment required and the new tests being implemented in parallel to the existing test regime whilst verification was undertaken. Thus implementation of the tests was likely to be far costlier than that experienced by PowderCo UK. However, post-verification the old torque test should be discontinued, hence ongoing appraisal costs would reduce to similar levels prior to the incident (assuming the tests take approximately equal time to perform).

Another facet of quality costing is apparent from the case studies, in that costs may be seen as a driver for decisions made by staff (and management) in both cases to investigate and resolve manufacturing issues which arose prior to the non-reportable food incidents which formed the embedded cases.

In the case of PowderCo UK, the Senior Engineer (P008) described the actions of other members of the engineering team who responded to broken shear pins on Bin C prior to the metal contamination incident: "… the guys just changed the pins, you know, and then and it went on for a couple of days and then it went again …. ". Whilst this issue was not directly related to the gear and chain slippage which resulted in the formation of metal shards, the decision to simply replace the pins rather than conduct further investigations was a missed opportunity to uncover these problems with the Bin. Although costs were not directly explored as a rationale for this decision, it can be postulated that there was an underlying drive to get production back up and running, i.e. to minimise the internal failure costs of production downtime. In contrast P008 spoke about more experienced staff taking the time to investigate engineering problems; this would result in higher internal failure costs and indeed also form a prevention cost, but in the metal contamination incident such costs would potentially have been much lower than the internal failure costs incurred by the incident.

Similarly, in LiquiComp UK, a long-standing quality issue on Line C, with "tails" formed on the bottle caps, was raised. Again, whilst this quality problem was not directly related to the cocked / shredded cap incident, it formed a missed opportunity to identify issues with the work environment on the line. Financial drivers for the business continuing to accept reduced quality packs were not explored in the case study, but it can be postulated that a drive to minimise internal failure costs and prevention costs were factors in the decision to continue production and allow the release of these packs. The potential costs incurred in more fully investigating and resolving the "tails" issue might have identified the shortfalls in the tests for cap integrity. Whilst this would not have prevented the failure of the capping head, it could have led to faster identification of the problem, and so reduced the costs to LiquiComp UK in resolving the more serious incident.

From this brief analysis, it appears that application of the PAF quality costing model, even in the absence of financial data, may explain some of the factors of the case studies and is worthy of further detailed investigation in future research. With that in mind, we now return to the consideration of the cases from a holistic perspective, using the second element of the theoretical roadmap, i.e. the constructs of PC.

Table 7.3: Cross-Case Comparison of Quality Costs

Category of Quality Costs	PowderCo UK	LiquiComp UK
Prevention Costs	Overall organisation: development and implementation of QMS and FSMS; holding of critical parts for safe manufacture (e.g. spare sieves); proactive upgrade of flooring; internal audits; third party audit and accreditation; training of staff and management. Incident: staff re-training on metal contamination checks; site audit by magnet suppliers and food safety consultant; upgrade of Bin B.	Overall organisation: development and implementation of QMS and FSMS; calibration and validation of test equipment; training; internal audits. Plans to upgrade production site to accreditation to FSSC 22000. Development of "safety by design" plans. Incident: staff re-training; proactive repair and replacement of capping heads using similar equipment to line C; costs of communication to other sites.
Appraisal Costs	Overall organisation: costs of routine inspection and testing (e.g. staff time for magnet and sieve checks; IP21 system). Incident: development and verification of revised checks for metal contamination. Increased inspection costs for additional magnet and sieve checks.	Overall organisation: routine inspection and testing costs. Incident: purchase of equipment and verification of new closure angle test.

Internal failure costs	Incident: staff and management time to investigate and resolve incident; traceability costs; product inspection and testing (on-site and at contract packers); external consultants; initial repair of Bin C; re-design and re-manufacture of Bin C; line downtime during incident investigation and resolution; rework of products (re-testing and re-packing); scrap of high risk products; staff and management time to develop production concession plan; development of improved metal check procedures.	Incident: staff and management time for incident investigation and resolution; traceability costs; product inspection (stripping pallets to check for defects); external consultants; repair of affected capping head; replacement of capping head on line C; line downtime during incident investigation and resolution; staff over-time (holiday period) for production on other lines to meet sales commitments; scrap of affected products; development of new test procedures.
External failure costs	Not applicable as all product within PowderCo control.	Costs of soft product withdrawal (communication; transportation; storage; rework; scrap).

7.3 Review of the cases using Pragmatic Constructivism.

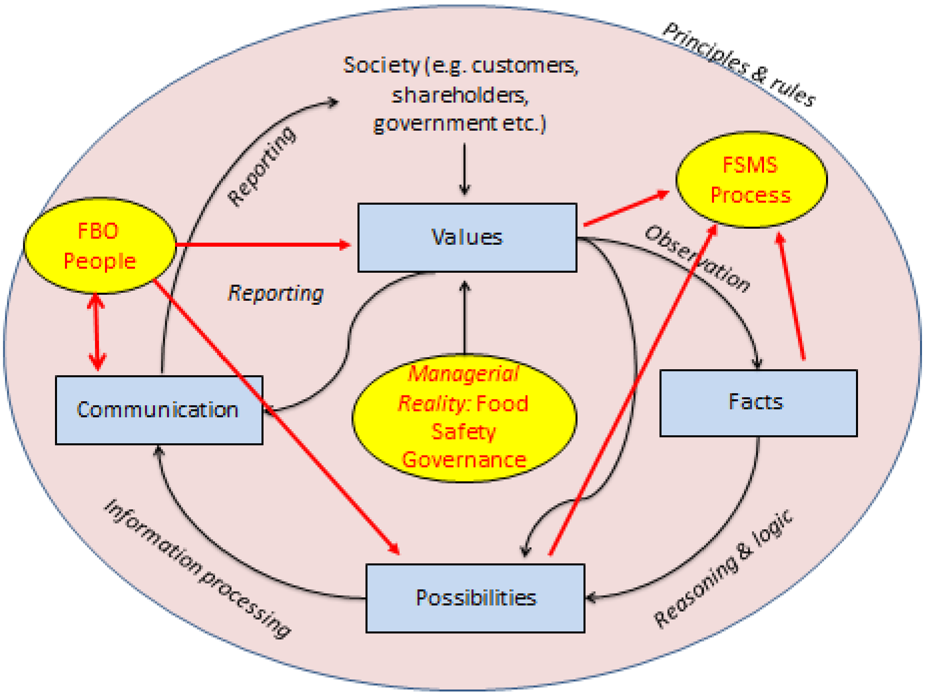
As discussed in Chapter 4, PC can act as a paradigm to explore and understand an organisation's functioning management control systems as constructed through the activities of the actors involved. PC considers four dimensions of reality – values, facts, possibilities and communication – and their integration to form the basis of effective functioning actions (H Nørreklit et al., 2010).

The use of PC in the current study offers two aspects of reality. At an organisational level both PowderCo UK and LiquiComp UK can be viewed as successful organisations with effective FSMSs and QMSs. The PC dimensions can therefore be used to understand how and why the systems are effective. However, the embedded cases might be viewed as times when the FSMS / QMS were ineffective, thus this section also examines whether PC can be used to explore and understand how and why the systems were ineffective at these times. This presents a new approach to the use of the PC framework, as whilst previous research has identified dysfunctional systems and topoi (Beusch, 2011) and studied a failing industry sector (Jakobsen, 2017), the Researcher is not aware of any previous work using PC to study specific system failures or incidents.

Inductively developed codes, themes and fit with Pragmatic Constructivism

Whilst the inductive analysis of the qualitative interview data generated insights into the two case study organisations and their respective quality incidents, reflection on these themes within the structure of the PC framework reveals more of the underlying reasons for the findings. This is accomplished by mapping the inductively generated codes and themes against the four dimensions of the PC framework, shown in the theoretical roadmap in Figure 4.3 and re-presented here as Figure 7.5

Figure 7.5: A Theoretical Roadmap to Study Food Safety Governance



The mapping was undertaken at two levels to give the final working map, which is shown in Figure 7.6. Firstly, the nine themes were mapped against the framework. As a check of validity for the decisions made in this exercise, each individual code was then separately mapped against the four PC dimensions. The exercise was conducted for both case studies, as additional codes were generated in the second case. Next, a comparison was made at the code level, between the location (PC dimension) each code was mapped to at the theme level and the location when the individual codes were directly mapped to the PC dimensions. In many cases, it was clear that whilst an overall theme might fit best under a certain dimension, some of the codes making up that theme exhibited a better fit with one of the other dimensions. An example of this is shown in Figure 7.7 for the theme "Day-to-Day". The "Day-to-Day" theme was mapped against the PC dimension of facts, but it also crosses with the PC dimension of possibilities, as two of the codes clustered under the theme of "Day-to-Day" - "continuous improvement" and "actions from alerts" - were judged to fit more closely with the possibility dimension in the code mapping exercise. Similar diagrams for each of the nine inductively developed themes are given in Appendix D.

As is clear in Figure 7.5, the four PC dimensions are inter-related and influence each other, hence the overlap of inductively developed themes across more than one dimension could be reasonably anticipated. The two-stage mapping process adds complexity to the data analysis, and indeed appears to differ from the approach taken in other studies where data has been coded against a priori codes and then the PC dimensions (e.g. Cinquini, Campanale, Pianezzi, & Tenucci, 2017), coded against a mix of interview topic areas and the PC dimensions directly (e.g. Laine, Korhonen, Suomala, & Tervala, 2017), or simply analysed using the four dimensions and the integration of these (Jakobsen, 2017). However, it is through this two-stage analytical process that the interactions between the PC dimensions in the case studies becomes clear. The overlap of themes and dimensions has been expressed in Figures 7.6 and 7.7 by colour coding. In Figure 7.6 the themes are located under the dominant dimension from the thematic mapping exercise, with the colours showing any split across other relevant PC dimensions.

Figure 7.6: Themes Mapped Against the Four PC Dimensions

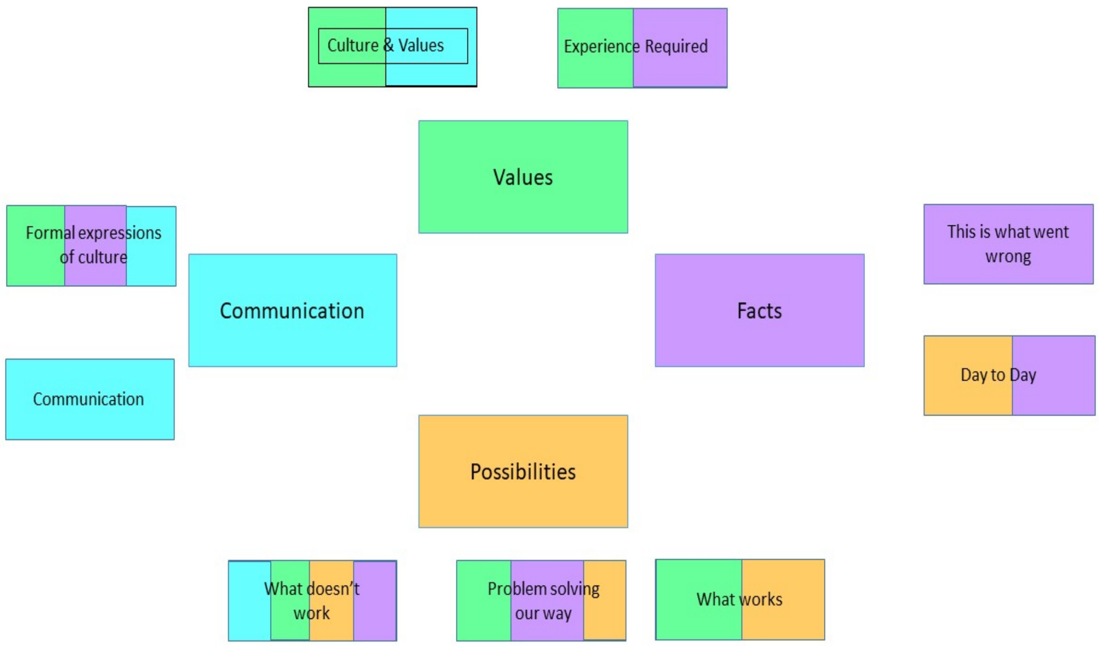
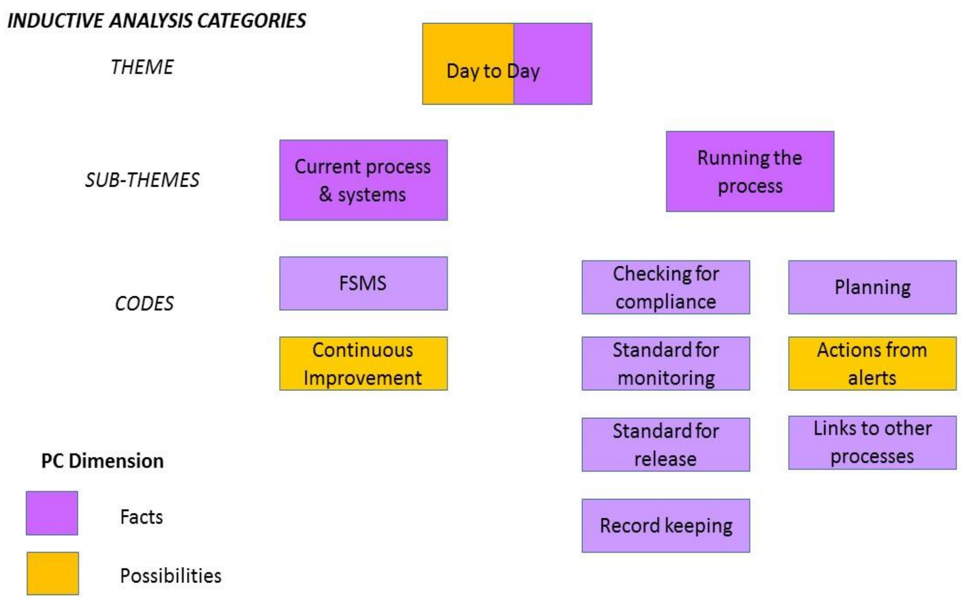


Figure 7.7: An Example of the Mapping of Codes and Themes to PC Dimensions



Clustering the inductively developed codes and themes into the PC dimensions therefore offers an alternative viewpoint of the case studies, and illustrates how the two aspects of each organisation – the "effective" overall organisation and the "ineffective" organisation experienced in the non-reportable food incident – interact. For example, the dimension of facts covers two themes. The first, "Day-to-Day", sets out much of the basis of the generally successful nature of the businesses, whilst the second, "This is What Went Wrong", conversely, looks at the problems encoutered by the organisations in the quality incidents investigated.

Both themes have been presented comprehensively in Chapters 5 and 6, but directly comparing and contrasting these two themes using the constructs of PC confirms patterns of behaviour which offer deeper insight into how and why the incidents occurred.

Both LiquiComp UK and PowderCo UK operate with established and comprehensive business systems and processes, including QMSs and FSMSs, which underpin much of the operational success of their businesses. In both cases, the organisations could be seen as relying on the fact that they had FSMSs and QMSs in place which were validated and verified as appropriate through review and audit, i.e. they trusted the systems in place and relied on the data generated by the use of these systems to make business decisions. In previous work using PC, it has been suggested that accounting (as an MCS) acts as a coordinating system, to facilitate the creation of a shared reality or topos, enabling cooperation between different organisational actors to address complex issues (Cinquini et al., 2017). In the current cases, the FSMSs and QMSs appear to play a similar role, i.e. they act as a core fact which shapes the organisational reality and enables business issues to be addressed.

We have seen however that in both of these cases the quality incidents occurred despite having these systems and processes in place; the fact of having a trusted system in place did not protect either organisation from costly non-reportable food incidents.

In the paradigm of PC, an organisation's values impact what an organisation understands as, relies on and, indeed, values as facts. Neither PowderCo UK nor LiquiComp UK ascribed the incidents solely to failures in systems and processes; in contrast the failures were seen as complex, unexpected and largely unforseeable events. Whilst both organisations implemented corrective actions to improve aspects of their respective FSMSs and QMSs (and LiquiComp UK in particular had begun to review their systems to reduce their complexity), the bulk of each company's systems remained unchanged. Therefore both organisations could be said to have continued to trust and rely on these systems to manage their operations. The incidents experienced did not fundamentally shake either organisations' belief in and dependance on the facts obtained from these systems – both organisations continued to value these systems. This suggests an over-reliance on these process and systems within the organisations; despite the evidence to the contrary, there is still faith that the systems will protect the organisations from future quality and food safety failures.

This insight can be further explored using the concepts of pro-active truth (what is believed will work, based on analysis of current data) and pragmatic truth (an ex-post evaluation of actual experience), which are closely related to the PC framework (L. Nørreklit, 2017b). Where the expectations of pro-active truth are not borne out by actual events, this is termed a truth gap (H. Nørreklit et al., 2017). For both case study organisations the pro-active truth can be expressed as an expectation that FSMSs and QMSs will guard against food incidents, whilst the pragmatic truth is that for both companies incidents occurred, hence in both cases a truth gap is seen. F. Mitchell, Nørreklit and Nørreklit (2017) state that the truth gap should become a basis for organisational learning and improvement. Although both case study companies have CI well embedded as organisational practice, the failure to recognise the truth gap in terms of the overall efficacy of their QMSs and FSMSs, suggests that organisational learning from the incidents might be inadvertantly limited.

The themes under the dimensions of values and communication have also been discussed in depth in chapters 5 and 6, but using PC highlights the relationship between these dimensions. The communication styles used by the two case study organisations during their repsective quality incidents were markedly different. PowderCo UK communicated to staff and management in an open and transparent manner, with the incident appearing to be well known and well understood across the organisation. In contrast, in LiquiComp UK, there was a concern to keep a tight control over information, using legal privilege; i.e. the previously discussed barrier, constrained communication, can be seen. As already discussed, these contrasting styles of communication appeared to be driven by different values. The open communication in PowderCo UK was driven by values such as “safety first”, “desire to improve” and “visibility”, whilst the tight control in LiquiComp UK was driven by an underpinning value of “protecting the company” from financial, legal and reputational harm. This latter value appeared to take precedence over other values held by staff and management in LiquiComp UK, so having the greatest impact on communication during the management of the quality incident. Any factors which negatively impact communication are likely to impact the integration of the four PC dimensions, as communication can be seen as the driver which integrates the actors’ facts, possibilities and values in the PC framework (L. Nørreklit, 2017a). This will be further discussed below.

The final PC dimension, possibilities, and the interaction of the dimensions of facts and values with this dimension, also drives new insights into the case studies. Three themes are placed under the possibilities dimension: “what works”, “problem solving our way” and “what doesn’t work”. Looking across these three themes the first impression reinforces the conclusion that the systematic use of processes and tools, such as RCA, enabled both case study companies to investigate and manage their respective non-reportable food incidents in an efficient and effective manner. This fits well with the use of systems and processes in every day operations and the high value placed on systems and processes in both organisations. However, part of the underlying cause of both incidents was a breakdown in processes: the “variation in working practices” seen under the theme “what doesn’t work”. This was exhibitied in LiquiComp UK in the conduct of the bottle cap torque test, and in PowderCo UK in the assessment of metal contamination.

H. Nørreklit et al. (2010) state that “possibilities create room for choice”. In the incidents under discussion, one could argue that there were gaps in the processes and control systems which left too much room for the line operatives to make choices, and hence the “variation in working practices” occurred which were causal elements in the incidents. Alternatively, looking at the interconnections between the PC dimensions, it can be argued that the issue underlying the “variation in working practices” is not that alternative choices were possible, but that line operatives did not make the right choices.

In the case of PowderCo UK, inappropriate choices were made by operatives who were responsible for checking the sieves and magnets because of a lack of factual knowledge on the acceptable (i.e. safe) level of fine metal powder cleared from the magnets. In other words, the operatives were not able to make the right choice from the possibilities available because they had inadequate facts on which to base their decisions.

In the case of LiquiComp UK, the possibilities to choose from were whether to complete the torque tests correctly, or not. Whilst the lack of agreement between the SOP and work instructions might suggest that here too the choices were made because of inadequate facts (a lack of knowledge on how to conduct the tests properly), I contend that this was not the case. Observations carried out by the LiquiComp UK RCA team after the incident showed that line operatives were conducting the torque tests properly. This indicates that the possibility of conducting the torque tests wrongly was not chosen because of a lack of knowledge, but rather that values drove this choice; that meeting production targets was more valued within the manufacturing team than food safety and quality. This reinforces the finding that organisational culture can act as a barrier to effective food safety governance and that there was an inadequate FSC in LiquiComp UK at the time of the incident.

Another common element across both incidents was the belief that the incidents were, at least in part, unforseeable. Under the PC framework, possibilities for action need to be factual possibilities, i.e. facts and possibilities must be integrated (L. Nørreklit, 2017a). In both case studies it can be seen that the different failure points were not considered as factual possibilities by the organisations during the development of their QMSs and FSMSs.

For example, in the case of PowderCo UK, the chain-driven conveyors in Bins B and C had been working successfully for many decades and the highly experienced staff and contract maintenance personnel had never seen a similar failure ("… he [the contractor] said in all the years that he's been coming to the site he's never seen it [the chain] come loose before…" (P008, Senior Engineer)). Likewise, the bolt that failed in the capping machine in the LiquiComp UK site was totally unexpected ("… I've not come across this particular issue previously, and the manufacturers of the magnet head, or the filler or the capper, likewise, they'd not seen this type of failure mode" (L017, Site Engineer)). Therefore, in both cases, even if such equipment failures had been considered as possibilities which needed to be controlled and monitored within the QMSs and FSMSs, it is highly likely that they would have been rejected by the teams responsible for developing and reviewing the systems as unrealistic possibilities, not factual possibilities which could actually occur.

One factor which may be influencing the determination of possibilities as either unrealistic or factual, is the value which both organisations place on experts and expertise. The literature on barriers to the implementation of FSMS indicates that a lack of knowledge, experience and skills in HACCP is a demonstrable barrier to successful implementation of such systems (e.g. Fotopoulos et al., 2011; Jevšnik et al., 2006). However, the use of experts may itself bring limitations to the development of FSMSs and QMSs. Experts' views may be limited by what education and experience has taught them should and can occur; non-routine possibilities might be automatically discounted. In other words, were the incidents truly unforeseeable or simply unforeseen because the experts did not consider these failures as factual possibilities?

Additionally, by categorising the incident as unforeseeable, PowderCo UK were able to shy away from blaming either the people producing the product and running the FSMS and QMS, or the processes and systems themselves. As discussed in Chapter 5, the avoidance of a blame culture appears helpful, as it allowed PowderCo UK to discuss the incident with their staff and foster a culture of learning from failure. However, by deeming the incident unforseeable the QMS and FSMS are being considered as sacrosanct and the superiority of HACCP to assure food safety treated as an inviolable fact, despite the fact that the metal contamination incident occurred.

Similarly, in LiquiComp UK, the initial failure of the capping head was also seen as unforseeable. In this case some gaps were recognised in the processes (e.g. the limitations in detection system) and the people related element of the failure was also recognised (the failures to keep documents up to date; the failures in the quality checks). Despite this, the fundamentals of the QMS and FSMS were not challenged at that time, although subsequent to the incident work has commenced to streamline and prioritise the food safety and quality documentation (suggesting that the previously discussed barrier of system swampling has been recognised in part).

Another underlying challenge for LiquiComp UK lies in the general perception that their products are “virtually bomb proof”, as this belief is again likely to constrain thinking about possible failures and their classification as factual possibilities rather than unrealistic possibilities.

The systematic and rigorous nature of HACCP underlies its strengths and indeed the whole proactive approach to managing food safety. However the case studies suggest that this systematic approach has limitations. Firstly, HACCP plans are built on the ability to understand and control known variables. If, as in these case studies, a hazard is not foreseen (e.g. the failure of the capping head bolt in the LiquiComp UK case) and/or the failure of a CCP in a novel way is not foreseen (e.g. the fine slivers of metal passing lengthwise through the sieve mesh in the PowderCo UK case), then adequate controls cannot be put in place, and HACCP-based FSMSs may not be a foolproof way of preventing food incidents.

Secondly, in both case studies, age related failures of equipment occurred. During the annual review of HACCP plans the question is asked “has anything changed which would impact the hazard analysis?” If nothing obvious has changed (no new products, ingredients, regulatory requirements etc.) the HACCP plan is re-ratified. However, time has moved on; even if nothing else has changed, equipment is older and monitoring systems may become outdated. As both cases demonstrate, the passage of time and age of equipment did not trigger any re-evaluation during the annual HACCP reviews. That is not to say that no consideration of age/time was made, as in both organisations the engineering departments had flagged up the relevant equipment/tests as requiring updating. However, in neither case had the HACCP team identified immediate safety concerns, so upgrading of equipment and tests was put into a medium- to long-term plan and not addressed promptly.

The age and outdated design of equipment and facilities was identfied as a contributory factor to the listeria outbreak at Maple Leaf Foods Inc in 2008 (Jespersen & Huffman, 2014), indicating that consideration of age and time is indeed a missing element in the annual revalidation and reverification of HACCP plans . Whilst it would be relatively easy to amend the annual HACCP reviews to prompt HACCP teams to consider these factors, this would merely address one specific gap in the review process, or, in the terminology of PC, make one more item a factual possibility to be considered by the HACCP teams. However, no checklist can be exhaustive, and other possibility gaps might still exist.

Taken together, the systematic approach of HACCP and the explicit and implict trust displayed by the case study organisations in both FSMSs and QMSs, might be limiting what possibilities the organisations consider as factual possibilities and so what possibilities get actioned in the safety and quality management systems. From a broader perspective, the current research suggests that traditional risk assessment based management systems, such as HACCP, may be inadequate to prevent less common or emerging hazards.

Set against this concern are some examples in the theme "what works", where outside of the formal systems and processes, creative thinking has been used to put in place additional pre-emptive controls or to improve the incident investigation process. For example, in PowderCo UK, P008 (Senior Engineer) worked with equipment manufacturers to develop and retrofit trays underneath the control point sieves. P008 considered it a factual possibility that material collected on the magnets / sieves could fall into the product when the control points were being checked and so turned this possibility into action to strengthen the product safety controls.

Although additional insights to the cases have been identified by reflection on the four PC dimensions, the true strength of this paradigm lies in the integration of the dimensions to give the organisational topos. Integration is required for construct causality, i.e. for organisational actors to construct cause and effect enabling them to produce successful actions. Hence the degree of integration in each organisation is now considered.

In the case of PowderCo UK, there is clear integration of the four dimensions; all of the actors interviewed appeared to share a common worldview of the organisation's purpose and the incident under investigation. A common language was used in describing the incident and the general working practices and routines of the site. Values, facts and possibilities for action were consistently communicated across the organisation. In other words, the communication fostered the integration of the facts, possibillites and values and a coherent topos for the PowderCo UK site was displayed. There was also evidence that the local site topos was integrated with that of the parent company, for example in the interpretation of the PowerCo Global vision and mission to incorporate food safety.

This presentation of a strong, coherent topos should, under the theory of PC, be the hallmark of a successful organisation that works and, as previously described, PowderCo UK has a long history as a successful organisation producing safe food products. Nevertheless, the embedded case of the metal contamination incident demonstrates that elements of the organisation did not, in this instance, work.

As discussed above, one of the elements identified through the PC framework in this case was a failure to consider potential hazards as factual possibilities, which allowed the eventual breakdowns and the incident to be viewed as unforeseeable by the organisational actors. I propose that the close integration of the dimensions and the strength of the organisational topos might in itself be one of the factors constraining the consideration of different possibilities, i.e that “over-integration” of the dimensions leads to a failure in construct causality and a disfunctional topos in much the same way that a lack of integration of the dimensions can. This finding differs from previous research using PC, which has, in the main, proposed a lack of integration as a block to organisational performance and success (e.g. Cinquini et al., 2017).

Re-examining the PC literature with the question of “over-integration” in mind, uncovers potential support for this proposal. Firstly, in work by Jakobsen (2017) the strong, coherent topos of the Danish family farming community is described as illusory, given that the industry measure of success – production volume / growth – is inconsistent with the financial realities of the sector. Jakobsen (2017) suggests a lack of external communication or perspective as an issue, restricting the identification of alternate possibilities. However, it is clear from the research that individual farmers do receive some external input from consultants and banks. Alternatively, it can be postulated that the "over-integration" of the PC dimensions inhibits the farmers from recognising alternate communications and possibilites, impeding construct causality and so preventing successful actions from occurring. From an alternate perspective, Seal and Mattimoe (2014) have examined the role of dialectics in purposfully identifying and utilising difference between the topoi of different functional areas to create a strong organisational meta-topos and effective buisness strategy. This supports the idea that in an organisation with a very close or "over- integrated" topos the possibilities created by dialectic debate will be missing, resulting in a poorer organisational performance.

In the case of PowderCo UK, recognition of the truth gap - the difference between the proactive truth of successful, safe production, 100% of the time, and the pragmatic truth of the metal contamination incident – could be one way for actors to break through barriers created by the over-integration of the PC dimensions. If actors are trained and conditioned to think in certain ways to fit within the organisation, they may feel uncomfortable in thinking differently and identifying different potential problems outside of the norm, akin perhaps to a form of groupthink, as propounded over 40 years ago by Irving Janis (1973). However, recognising the fact of the truth gap may enable actors to engage in dialectic debate, to think of alternate possibilities without threatening the overall organisational topos, and so to construct the conditions for successful actions.

Turning to LiquiComp UK, different levels of integration and the presentation of several topoi within the case could have been expected, given the split of study participants between different sites and functional groups. This indeed was the case; however, the different world views presented did not split clearly along the expected lines. For example it might have been expected that all actors from the quality function, whether based at head office or at the manufacturing site, and whatever their grade, would present a fairly coherent topos. In actuality, actors within this one function presented somewhat differing views, giving different descriptions and having differing understandings of the incident, suggesting a lack of integration of the four dimensions even at the functional level.

It was also clear that in LiquiComp UK, in comparison to PowderCo UK, there was less successful integration of the different functional and site topoi into an overall organisational topos for the UK business, or into the meta-topos of the global company. That said, there was clear evidence that senior management were working to develop organisational values, strategies and plans which would drive the creation of an overarching, integrated UK entity topos e.g. through the large, business-wide meeting, which was the first time that all UK staff had been gathered in one place.

The LiquiComp UK case study offers additional insights towards building a coherent organisational topos. Firstly, there was a high level of trust placed in the systems and processes used by the organisation including those used to investigate the manage the quality incident. One element of the process used to manage the incident was that it encouraged people to be “single-minded”in their approach, i.e. to keep within their own expertise, which showed synergy with the value placed on experience and expertise by the organisation. Additionally, a culture to “protect the company” was also identified , and the constraining effect of this on communication during and surrounding the quality incident has been explored. L. Nørreklit (2017a) describes communication as the glue that connects people, enabling them to cooperate and to integrate the four dimenions of PC into a working reality construction. Thus together, these cultural and process factors identified in the LiquiComp UK case appeared to, albeit unintentionally, disrupt communication and so impede the cooperation of the actors and the integration of the PC dimensions. Improving cooperation and reducing functional boundaries could build commonalities between the individual functional/site topoi seen in the case study and so encourage the development of a more coherent overarching organisational topos.

Improved cooperation and communication, leading to improved integration, is not proposed simply for its own sake. As previously explained, under the PC framework integration is required for construct causality, enabling actors to act and succeed.

Previous research on organisational change has demonstrated that restricting participation and communication adds risks to change plans and casts doubt on whether any integration of the dimensions under these circumstances will produce lasting results (Guven-Uslu, 2017). As incident investigation and resolution inevitably involve change, similar concerns can be raised for the LiquiComp UK case: changes put in place as a result of the incident may not be embedded and effective long term without broader participation of actors across the organisation allowing for true integration of the dimensions and an effective construct causality.

7.4 Conclusion

This chapter has discussed the findings of the case studies in comparision with each other and against the theoretical roadmap, first by considering the literature on FSC and FSMSs, and then by exploring findings in light of the PC paradigm. The cases have also been considered in light of the PAF dimensions of quality costing. However due to a lack of financial information on the cases, limited conclusions can be drawn from this field of work and future research should explore this area in more detail.

A key finding is the determination that the current literature on barriers to the implementation of FSMSs does not adequately explain the causes of the incidents examined in this research. Whilst issues with training, communication, faulty hazard analysis and excessive paperwork and documentation are common to both cases and the literature, other factors identified in the literature as barriers to FSMS implementation can be seen as organisational strengths, for example, management and staff commitment in PowderCo UK; personal hygiene, technical expertise and support in LiquiComp UK.

In terms of the literature on FSC, analysis of the organisations against the Dimensions Framework (Jespersen et al, 2017) gave, as might be expected, a more nuanced appreciation of the FSC in each company, whilst confirming the findings of the thematic analysis that PowderCo UK demonstrates a more developed FSC than LiquiComp UK. However, the consideration of the cases also highlighted some limitations of this model, and FSC models in general, in that they consider FSC in isolation, with little account of the wider environmental context within which companies operated and as such also do not fully account for the occurrence of the non-reportable food incidents studied here. In particular the PowderCo UK case highlights the fact that even FBOs with relatively robust FSCs can experience food incidents and that a focus on FSC alone is unlikely to be sufficient protection against FSMS failure in any organisation.

Of the potential barriers to food safety governance identified in the thematic analysis, there are some clear links with this literature, with system swamping linking with the known barriers of excessive paperwork and documentation; constrained communication with communication as a barrier, and culture and values and organisational culture linking with staff and management commitment to food safety, a key element of FSC.

However, neither the literature on FSC nor that on barriers to FSMS implementation help explain the barrier to food safety governance created by incidents being viewed as unforseeable. Likewise, the unshakeable trust in systems and processes displayed by both companies – a key aspect of their culture and values – runs contrary to the literature, where a view that FSMSs lack credibility is seen as a barrier.

In contrast to the focussed nature of the analysis against FSMS barriers and FSC, PC offers a broader perspective and brings new insights to the cases. An important insight concerns the recognition that the quality incidents represented a truth gap, between the pro-active truth believed by the case study organisations - our QMS and FSMS are strong and effective - and the pragmatic truth that the incidents represented failures in the quality and food safety processes and systems, be they due to the processes themsleves or the actions, or lack of actions, of the organisational actors. Neither organisation fully recognised this truth gap. Although PowderCo UK had undertaken extensive expert reviews of their system for identifying and removing any metal contamination, only minor adjustments were made to the system – in principle the systems and processes were still believed to be robust, comprehensive and reliable. The situation at LiquiComp UK was a lttle different, as work had commenced to simplify and streamline some of the systems and processes (in recognition of the impact of system swamping). Nevertheless, the organisation retained an unshakable faith that overall their QMS and FSMS were robust, comprehensive and reliable if somewhat overly complex.

Consideration of the possibilities dimension also brought specific insights in terms of the potential classification of the incidents as largely unforeseeable. It can be argued that the incidents were simply unforeseen, rather than unforeseeable, however using the constructs of PC it is suggested that the failures were both unforeseen and considered unforeseeable because organisational actors did not recognise, even after the incidents, the potential problems in the systems as factual possibilities.

The reliance on experts, both internal and external consultants to the business, has been related to the failure to recognise potential problems as factual possibilities. Whilst sufficient knowledge and skills in food safety and quality are critical to develop QMS and FSMS systems, it is proposed that experts may be overly focussed on more routine and well-established hazards and overlook the importance of lesser known or emerging hazards. In turn this means that HACCP-based FSMSs may not be a fail safe way of preventing food incidents if potential hazards can not be, or are simply not foreseen.

Another key finding of the analysis concerns the integration of the four dimensions to create the organisational topoi. The suggestion is posed that for LiquiComp UK closer integration of the four dimensions is required to build a coherent overarching organisational topos, enable effective construct causality and thus allow actors to take successful actions, i.e. closer integration will better allow the identification of factual possibilities and counteract the tendency for failures to be perceived as unforeseeable.

In contrast, the topos of PowderCo UK was highly integrated. In this case it is postulated that this close integration might itself be constraining the ability of actors to construct a full range of factual possibilities, necessary to identify potential problems outside of the norm of the standard QMS and FSMS control points (i.e. those currently perceived as unforeseeable). To my knowledge, previous research using the PC framework has not explored the impact of "over-integration" on construct causality and this offers a contribution to the theory of PC and the actor-reality construction.

Another aspect of the cases, namely the aspect of age and time as a contributory factor to the quality incidents, is also worthy of particular consideration, in that it highlights a possible constraint of the current PC framework. Just as a HACCP plan considers organisational conditions at a set point in time, so does an analysis of organisational topos, and just as the current study illustrates that in the absence of any other change time must be considered as a change factor in HACCP reviews, the impact of the passage of time on the topos must be considered. An appreciation of time is implicit in the PC framework, given that facts reflect the past / immediate present (point of analysis), values and communication sit in the present, and possibilities give alternatives for the future (L. Nørreklit, 2017a). However, every action that is taken and every possibility that is realised changes the nature of the facts available; they can also influence values and be a topic of communication, hence the topos evolves constantly. Whilst the nature of case study research is that it takes place over a period of time (e.g. Cinquini et al. (2017) conducted interviews over a 16 month period), the impact of time and the evolving nature of the topos is under explored in the literature and the current research illustrates the importance of further development of the PC framework in this respect.

It is also important to step back from considering the general PC constructs and to revisit the theoretical roadmap developed in Chapter 4 which also incorporated the people versus process debate underlying this research, i.e., when food safety systems go wrong, is it the fault of the people or the process itself? The interwoven aspects of people and process in contributing to the food incidents was shown in the thematic analysis of each case (Chapters 5 and 6), with the conclusion that people issues underpin these failures. In both case studies the underlying trigger for the non-reportable food incident was an equipment issue. Therefore in both cases it might be considered that the FSMS and QMS processes had failed as the processes had not enabled the organisations to envisage the exact failures and put in place adequate controls. On the other hand, the construction of the processes relies on the skills and judgement of the actors involved, and so the shortfalls in the processes are actually a result of people failures, not process failures per se. The analysis using PC underpins this conclusion, as this shows the importance of people, particularly in determining factual possibilities on which to base decisions and actions.

Overall, this research illustrates the benefit of positioning future studies on food safety and quality within the area of management control and in utilising PC as a management control theory, as it enables both process and people elements of FSMS / QMS failure to be addressed.

This research makes contributions to literature on food safety and quality. By using the case study approach to consider the causes of non-reportable food incidents in generally successful organisations with well established QMSs and FSMSs, rather than investigating the barriers to implementation of such systems, it was established that, at least for these case studies, the absence of barriers for FSMS implementation did not protect the organisations from experiencing these incidents. Indeed, some of the barriers to FSMS implementation identified in previous research (e.g. Jevšnik et al., 2006) could be viewed as strengths for the case study companies. In addition, rather than the incidents being viewed in hindsight as inevitable, they were seen by the case study organisations as unforseeable, and so were uncontrolled by their current FSMSs and FSMnSs.

A contribution is also made to the literature on PC by utilising the framework in the novel management control setting of quality and food safety management. The current research also demonstrates the use of the PC framework in cases of organisational failure, which contrasts with the main use of the framework which was developed to explain and understand effective practice. Finally, the research raises the question of “over-integration” of the four dimensions as a block for the identification of alternate factual possibilities, and so of the creation of an effective construct causality. This contrasts with the literature to date, which has focused on a lack of integration of the four dimensions as the underlying reason for failures in construct causality and poor performance (e.g. Cinquini et al., 2017).

These areas, together with limitations of the research and recommendations for future studies will be presented in the final chapter of this thesis.

8.0 Conclusion

Food and drink are necessities for life. Unfortunately, despite legislation, best practice and scientific expertise, the safety of the food supply chain all too often fails and high numbers of food safety incidents are reported every year (e.g. European Commission Directorate-General for Health and Food Safety, 2017). Instead of supporting life, health and well-being, all too often food and drink bring foodborne illness, and consumers' trust in the industrialised, global food supply chain has been damaged (Yamoah & Yawson, 2014).

This project was designed to address one aspect of this complex issue through the research question "Why do food safety systems fail and how does this relate to the governance and management control of food safety in food manufacturers?"

The first three chapters of this thesis presented the rationale for this research, set out the background to food safety governance and management control and reviewed the literature, examining barriers to and drivers for the implementation of FSMSs, published data on food safety failures and FSC. The use of quality costing in the food industry was also considered. From this the research question and objectives for this research were developed. This was followed in Chapter 4 by an exploration of the philosophical background of the research field, with the elaboration of PC as a management control paradigm, which was used as the basis of a theoretical roadmap to guide both the research design and data analysis.

Chapters 5 and 6 presented the results of the two organisational case studies – PowderCo UK and LiquiComp UK - together with their respective embedded cases of non-reportable food incidents. This was followed in Chapter 7 by a discussion of the research findings, comparing and contrasting results from the case studies with each other and, in the context of the theoretical roadmap, to the extant literature on FSMSs and FSC and the constructs of PC.

This final chapter concludes the thesis by reconsidering the research question and objectives (section 8.1); presenting the contributions made to knowledge, theory and industry practice and policy on the management of food safety (section 8.2); eliciting the limitations of this work (section 8.3) and offering recommendations for future research (section 8.4). The chapter closes with a personal reflection on the research process (section 8.5).

8.1 Research Questions and Objectives

Research Objective One

The first research objective stemmed from the question posed by R.T. Mitchell (1998): "When HACCP appears to fail, is it the fault of the HACCP system itself or does the real failure lie with the people who are trying to implement it?" The objective was therefore to determine whether reported food safety incidents can be related to specific people or process elements of FSMS failure.

As previously discussed, the case studies presented in this thesis concern non-reportable food incidents, rather than ones which had required reporting to the authorities. Nevertheless, as each case was investigated as a potential reportable food safety incident and involved failures in CPs / CCPs / QCPs, they were determined as relevant examples to study in order meet this objective, particularly given the practical challenges of gathering information on reported food incidents.

As discussed in Chapters 5, 6 and 7, both cases exhibited failures in people and process elements of their QMSs and FSMSs. However, where process elements were determined (e.g. in LiquiComp UK, the excessive complexity of the QMS, and in PowderCo UK, the lack of an appropriate standard for metal contamination) these can be ascribed to failures by the people implementing and maintaining the systems. In conclusion therefore, the fundamental failures in

FSMS can be regarded as failures by the people implementing and maintaining FSMSs and QMSs.

Despite this conclusion, this research indicates a potential challenge with the underlying precept of HACCP (which forms the core of modern FSMSs) in that as a preventative system, HACCP relies on the identification and control of known hazards. Common to both cases was the belief that the incidents were largely unforeseeable in the way that the original equipment failure happened and / or in the failure of control systems. The hazards which presented were therefore not adequately controlled, as the possibility of such failures had not been considered. This factor has been discussed in Chapter 7 through the lens of PC, where the shortfall in identifying potential hazards as "factual possibilities" was presented. Again, it is a people failure to insufficiently explore potential hazards and recognise them as "factual possibilities", but nonetheless this finding indicates a weakness in the HACCP process. The implications of this for industry practice and future research will be addressed in sections 8.2 and 8.4 respectively.

Research Objective Two

The second research objective was to determine the extent to which the barriers to the implementation and maintenance of FSMSs (particularly HACCP) found in the literature can be used to account for failures in FSMSs, and hence to a subsequent food incident.

Five potential barriers to food safety governance were identified in the thematic analysis of the case studies, and, as presented in Chapter 7, links between four of these – constrained communication, system swamping, organisational culture and culture and values –and the extant literature were established. However, neither case could be adequately explained by the previously identified barriers to FSMS implementation. Indeed, in both cases, some of the identified barriers to FSMS implementation could, conversely, be seen as strengths of the case study companies. In particular, the fifth barrier to food safety governance, that the incidents were viewed as unforeseeable**,** stands apart from the previous literature, as does the explicit and implicit trust placed in food safety and quality systems and processes by both case study organisations.

This finding highlights that just as audits and inspections can not necessarily predict that a company will not suffer from a food safety or quality failure (Mullen et al., 2002; Powell et al., 2013), neither will the absence of the barriers to FSMS implementation and maintenance.

Research Objective Three

The third research objective was to evaluate the relationship of FSC to failures in FSMSs. The research therefore evaluated the FSC of each organisation, seeking to understand whether a consistent approach to food safety was demonstrated during the investigation and resolution of the quality incidents and during normal operations.

In the period since this research project commenced there has been a significant increase in communication about FSC right across the food industry, with models of FSC being refined (e.g. J. Z. Taylor et al., 2015), new models being developed (e.g. Jespersen et al., 2017) and FSC being a core topic at industry focussed food safety conferences (such as Food Manufacturer's Food Safety Conference, June 2017). It might therefore be expected that there was good awareness of FSC within at least the quality communities of the case study organisations, as indeed was found. The value placed on food safety by the broader organisations was also seen in the case studies (e.g. by supply chain, regulatory and manufacturing teams). The research methodology used proved suitable to make this determination and to offer a qualitative assessment of the FSC of both companies with PowderCo UK being assessed as having a relatively strong FSC, whilst the FSC at LiquiComp UK appeared to be less well developed.

In neither case study was FSC being formally measured by the organisation, but the quality teams in both companies had given consideration of how to improve

FSC and both were interested in building on existing tools and practices on health and safety culture to develop proxy measures of change in FSC.

As discussed previously, the research findings support the importance of people – their knowledge, values and behaviours – in ensuring the correct development and implementation of FSMSs. That is, this research study provides support for the premise that a good or strong FSC is important for appropriate food safety management. However, this study also highlights that having a relatively strong FSC does not necessarily prevent failures in food safety management, as evidenced by the incident which occurred at PowderCo UK. This indicates that FSC should be viewed as only one element of food safety management and that a holistic approach, addressing both people and process is required for optimum performance.

Research Objective Four

The fourth research objective was set out in two parts. The first part of the objective was to address the research of food safety management from the perspective of management control, utilising PC, in order to ascertain the utility of PC for studying control systems outside of the accounting mainstream. The second part of this objective was to gain insight on the use of PC in cases of management system failure as well as management systems under control.

As discussed in Chapter 4, a theoretical roadmap was developed by combining the constructs of PC with the two clusters of barriers to FSMS implementation (FBO People and FSMS Process). This roadmap was used in the development of the semi-structured interview guide used for data collection. This approach was particularly valuable in ensuring consistency across the interviews, not just in the initial interview questions, but during probing follow up questions by using the four PC dimensions of values, facts, possibilities and communication to frame these questions. Using the PC dimensions was also of practical help in steering both the Researcher and the study participants away from concentrating solely on technical and scientific points, thus enabling a broader conversation about food safety management from a management control perspective. PC was also used to further interrogate and explain the findings of the thematic analysis of the case study data, as set out in Chapter 7, and new insights to the cases were developed in this way. The contributions arising from this analysis will be covered later in this chapter.

As discussed in Chapter 4, PC posits the integration of the four dimensions of fact, possibilities, values and communication to form a functional organisational topos. Although studies utilising PC have identified dysfunctional topoi and systems (e.g. Beusch, 2011), this study took the relatively novel approach of setting out to deliberately explore a system failure. The research has successfully demonstrated the value of using PC to investigate the embedded cases of system failure, and compare these with the workings of the generally successful organisational cases.

The Research Question

Having considered the four research objectives, we now return to the overall research question and specifically the relationship of failures in food safety to the governance and management control of food safety. The multifactorial nature of food safety governance was established in Chapter 2, where it was determined that FBOs play a key role in assuring food safety, having a requirement to set in place appropriate FSMSs in order to comply with the law.

The current research demonstrates that even FBOs apparently working in compliance with the law and using comprehensive FSMSs, can experience food incidents, albeit non-reportable food incidents in these case studies. Both case study organisations used a primarily technical approach to food safety governance in that they placed great emphasis on systems and processes for both day-to-day management of food safety and for the investigation and resolution of the incidents they experienced. This is not an unexpected finding, given the emphasis under UK and EU law to manage food safety using HACCP-like systems, i.e. to take a technical approach to food safety.

However, the case studies illustrate the interwoven nature of people and processes in the control of food safety and quality. Considering the barriers to food safety governance identified in this research, system swamping may appear initially to be technical in nature, with the technical systems approach requiring a plethora of systems, processes and paperwork. However, this barrier is really a social construction, with the case study organisations interpreting the legal requirements for documented HACCP-like systems to mean the construction and documentation of detailed processes for every aspect of food safety management. The other proposed barriers – constrained communication, culture and values, organisational culture and the unforeseeable nature of food incidents – are also clearly people oriented. This indicates that in FBOs food safety governance actually relies on a socio-technical approach, and that a higher emphasis on the social aspects of food safety governance is required to address these barriers.

8.2 Contributions

In addressing the research question and objectives, this thesis offers contributions to academic knowledge, to theory, and to industry practice and policy on food safety management, which will now be presented.

Academic Knowledge

The first contribution from this research is to the literature on food safety and quality and the determination that known barriers to FSMS (particularly HACCP) implementation do not fully explain the non-reportable food incidents experienced by the case study companies.

As set out in Chapter 3, much of the current literature seeks to understand the challenges for the implementation and maintenance of FSMSs. This research differs in that it studies cases of generally successful organisations, with established QMSs and FSMSs, and examines serious, but non-reportable, food incidents. The comparison of the causes of the incidents and system failures with the barriers to FSMS implemetation is, to the Researcher's knowledge, a novel contribution to the field of food safety management research.

A further contribution to knowledge lies in the investigation of the first research objective, i.e. to answer the people versus process question related to the causes of HACCP failure posed by R.T. Mitchell (1998). Whilst people issues have been identified as underpinning the failures to monitor food safety / quality and detect product failures at an earlier stage, a key contribution of this work lies in the identification of a weakness in HACCP-based FSMSs, which are built on the premise that food safety hazards can be foreseen and controlled.

The unexpected or unforeseeable nature of the incidents investigated as embedded cases demonstrate that a traditional hazard identification and risk assessment based process, as used in HACCP, was inadequate to identify and control for the equipment and system failures seen. Indeed, the classification of the incidents as unforeseeable or unexpected is a contribution in itself, and as discussed contrasts with the expectation that incidents are likely to be viewed as events "waiting to happen" due to the effects of hindsight bias (Fessel et al., 2009).

This finding might therefore be of particular interest to academics in the field of food safety as it suggests that HACCP based systems may not be adequate to anticipate and control for the full range of hazards – particularly less well known or emerging hazards - which can result in food incidents. New processes and systems for hazard identification and risk analysis should be explored to complement traditional risk assessment based systems and improve food safety governance within the food industry.

Theory

The food industry is the largest manufacturing sector in the EU, employing 4.25 million people with a combined turnover of €1.089 billion (FoodDrinkEurope, 2016a) and can be considered a complex socio-technical system (Nayak & Waterson, 2016). Control systems to manage food safety are legally mandated in the EU and many other legal jurisdictions. As such, a FSMS forms a cornerstone of the required MCSs for any food business. Whilst there is a body of literature on FSMSs, particularly HACCP, and quality management (e.g. Grover et al., 2016; Ren, He, & Luning, 2016), there is remarkably little published on FSMSs in the management control literature. The case study presented by Di Cimbrini and Migliori (2016) forms a notable exception, and even that paper considers HACCP from a quality management, rather than a management control, perspective.

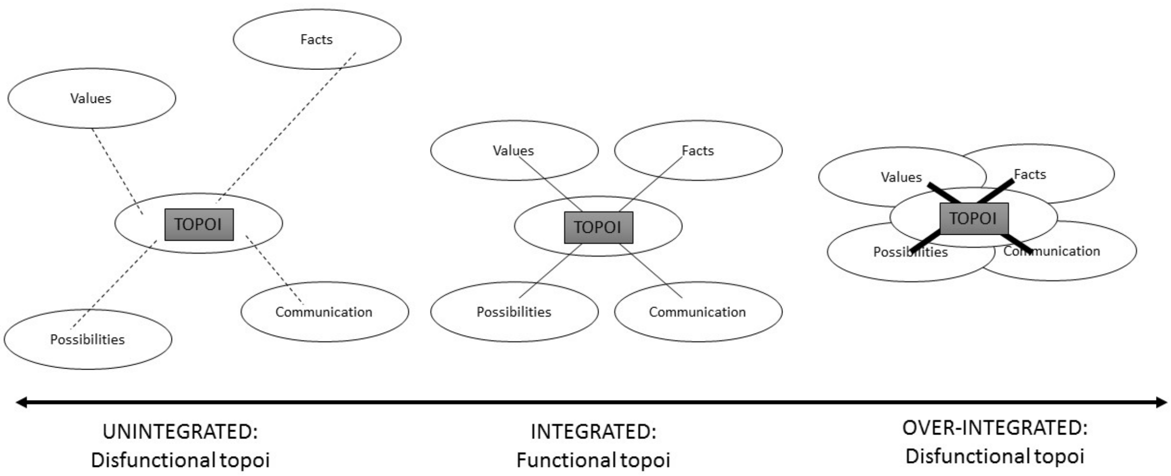
The present study therefore makes a significant contribution to the management control literature by using management control theory to study a non-financial system which is pertinent to a major industrial sector.

Not only is the study of food safety management as an MCS a contribution to theory, so too is the use of PC to frame the research. Although PC is gaining traction within the management control research environment it is relatively new and to date the majority of research using PC has focussed on accounts, accounting or accountants. Using PC to explore quality and food safety MCSs helps to develop and enrich the academic community's understanding of PC itself. Similarly, a contribution is made by the use of PC in the current study to understand and explain a situation of organisational failure. This contrasts with the predominant use of the framework, which was developed to explain and understand effective, rather than ineffective, practice.

Furthermore, as discussed in Chapter 7, central to PC is a requirement for the integration of the four dimensions of communication, possibilities, values and fact. Through this integration a coherent and functional organisational topos is formed and without adequate integration there is a fragmented topos and a lack of construct causality to enable actors to take effective actions. Put simply, integration of the four dimensions is required for a functioning and effective organisation. As discussed in Chapter 7, this pattern of inadequate integration was demonstrated in the LiquiComp UK case study. However, in the other case, PowderCo UK, very close integration of the dimensions was seen. The Researcher has therefore postulated that PowderCo UK may offer an example where "over-integration" of the dimensions, rather than a lack of integration, is constraining construct causality, i.e. resulting in a dysfunctional or ineffective organisation. This is, to the Researcher's knowledge, a new contribution to the theory of PC.

This contribution is important as it suggests that rather than functioning topoi existing at a point of integration, which forms the end of a simple scale from unintegrated to integrated dimensions, there is a wider scale from unintegrated to over-integrated, with functional topoi sitting at the mid-point, as illustrated in Figure 8.1.

Figure 8.1: Functioning Topoi on a Spectrum of Dimension Integration



This scale of the integration of PC dimensions enriches the PC framework, offering the opportunity for finer grained analysis and interpretation of organisational topoi. By offering an alternative explanation for failures in construct causality – over-integration as well as a lack of integration – this should enable PC to better reflect the complexities seen in real life situations.

Food Safety Practice and Policy

The first contribution to food safety practice and policy from this research relates to the consideration of the passage of time within QMS and FSMS reviews. For example, best practice for HACCP requires at least an annual review and revalidation of the plan, part of which requires the review team to question whether any changes to the product, ingredients, process etc. have occurred. In both case studies the age of equipment (production and / or monitoring equipment) was related to the root cause of the incidents experienced, yet in neither organisation was time, or age, considered as a "change" during annual process re-validation activities. The current research highlights the importance of adding a consideration of time / age as an element of re-validation activities.

A second contribution to food safety practice and policy from this research is the insight that the unexpected or unforeseeable nature of the incidents potentially relates to such failures not being identified as factual possibilities through QMS and HACCP reviews. In particular, the reliance on expert opinion (which by definition might be considered to be deep, but potentially narrow, and to concentrate on known hazards which are likely to occur) was suggested as one reason that the possibility of the failures happening was not identified. Previous research has concluded that poor HACCP plans include too many CCPs (e.g. Fielding et al., 2011) and also that a lack of expertise is a factor when FBOs fail to successfully implement HACCP (e.g. Lowe & Taylor, 2013). The current research does not contradict these findings, but suggests that FBOs need to balance concentration on known hazards with identification of potential new hazards and to better consider the impact of seemingly unlikely failures as well as highly likely failures. The involvement of staff who are knowledgeable and curious, but not necessarily expert, may play an important role by allowing teams to explore more possible failure points in FSMS as potential factual possibilities and so encourage the development of HACCP plans with greater breadth as well as depth of insight. The research also makes a contribution to the practices of, and policies on, communication on food safety and quality incidents within FBOs. The case studies illustrate the positive role that open communication on incidents can play by fostering the development of a strong FSC (as seen in PowderCo UK). The cases also illustrate the challenges faced by organisations who are striving to do the right thing in terms of food safety, but are concerned with the financial, legal and reputational costs of inappropriate communication (as illustrated by the LiquiComp UK case) which can be seen to constrain communication.

Given the prominence of social media and the increasing risks of litigation where food safety and quality issues arise, the concerns noted by LiquiComp UK are likely to become more prevalent in the food industry. A contribution of this research is therefore to highlight the need for companies to consider their policies and practices on communication at the time of any food incident, to ensure that management of communication does not adversely affect the understanding of company values on food safety and from that the FSC of the organisation.

A final contribution to industry practice and policy also relates to communication on food safety and quality issues, but in this case, concerns communication across the industry and with other stakeholders such as enforcement officers. The research findings highlight the role of learning lessons from failures, particularly those previously considered unforeseeable. Sharing the knowledge that such failures not only can happen, but have happened, would enable other organisations to reassess and improve their own practices. However, a vehicle to facilitate such communication, in an anonymised form, is likely to be required. Present communications on food incidents by authorities, such as the UK FSA, prioritise consumer safety at the time of the incident. They therefore concentrate on identifying affected products to allow for their prompt withdrawal or recall from the market. Information on exactly what happened, how or why, is less available. Few organisations volunteer detailed information or discuss incidents widely, the paper published on Maple Leaf Foods in Canada being a notable exception (Jespersen & Huffman, 2014). Whilst information pertaining to incidents is viewed as highly sensitive, this research study adds weight to the need to review practice and policy in this area for the good of the industry as a whole and, from that, for consumers. The concept of sharing sensitive information by the food industry is already established to some degree in the UK in terms of communications with the National Food Crime Unit / Food Standards Scotland re food crime (Food Standards Agency, 2017c; Food Standards Scotland, 2017) and appropriate practices could be developed from these existing schemes. A failure to address the need for better information sharing runs the risk that opportunities to improve practices, improve food safety and reduce the incidence of foodborne disease will be missed.

8.3 Limitations of the Research

All research designs and methods have recognised limitations. Criteria such as reliability and validity are hotly debated as to their applicability for qualitative, case study research (Bryman & Bell, 2015, p 400). Nevertheless, the specific study design and methodological approach described in Chapter 4 was undertaken to address such issues. For example, data triangulation using interviews, observation and documentation as data points, was used to address concerns of data consistency. The robustness of data analysis was also addressed, as thematic analysis has been criticised as an imprecise method (Braun & Clarke, 2006). However, by combining the method of Braun and Clarke (2006) with that of Guest et al. (2012, p 21 - 48), as described in Chapter 4, this limitation of the method has been addressed in the current research.

There are however other limitations to the research which must be acknowledged. These are predominately concerned with the generalisability of the findings of this research and the possibility of response bias.

Firstly, the research comprises qualitative case studies of two large, UK based food manufacturing businesses, conducted between November 2015 and August 2016, and it does not claim to be representative of a wider population of food manufacturers or other types of FBO. In particular, given the importance of SMEs to the sector (being responsible for over 60% of employment and 49.5% of turnover in the sector (FoodDrinkEurope, 2016a) it is clear that the case study organisations cannot be considered as representative of all food manufacturers, let alone all FBOs. That being said, the case study organisations are typical of large manufacturing companies, and insights on this part of the industry are critical when one considers that a food safety or quality error made by a large manufacturing company has the potential to affect many consumers and has much higher cost implications than one made by a small producer with limited local trade. For example, the 2016 recall by Mars of chocolate bars potentially contaminated with plastic was estimated to cost the company tens of millions of dollars and affected products in 55 countries (Quinn et al., 2016). More recently, Lactalis has recalled 12 million boxes of baby milk potentially affected by *Salmonella* from 83 countries (BBC News, 2018).

A second limitation of the ability to generalise from the findings of the current research is the use of non-reportable food incidents as the embedded cases, rather than reported incidents. The applicability of using these incidents has been justified previously. Whilst the incidents investigated were not classified by the case study organisations as one's requiring reporting to the authorities, this was determined in both cases as a result of the company investigations. Had the product reached the end consumer in the case of PowderCo UK, or the nature of the plastic shreds (or the profile of the end consumers) been slightly different in the LiquiComp UK case, both could have been considered as reportable food incidents. Indeed, contamination by foreign bodies and packaging defects accounted for a total of 125 reported food incidents in the UK in 2016/17 (Food Standards Agency, 2017b). Whilst further research on reported food incidents is desirable, the practical limitations of accessing organisations willing to share such data must be recognised.

In conclusion, whilst there are limitations to the extent to which the findings of the current study can be generalised to other incidents, or other types of FBO, it is well recognised that the purpose of case study research is not to enable generalisation from specific cases to other settings. Rather the purpose of such research is to enable generalisation to theory (Bryman & Bell, 2015, p 414), which has been accomplished in this research through the use of the theoretical roadmap.

Moving on to response bias, some concerns must be acknowledged in this regard to the data collected in both organisations. In PowderCo UK, the boundary of the case study was set at the manufacturing plant. Whilst some information pertaining to other parts of the global organisation was obtained (through document analysis, for example), in contrast to the access provided by LiquiComp UK, at PowderCo UK no access was provided to senior management, commercial or legal personnel involved with the incident. This may have impacted the breadth of information gathered, with the organisation presenting a stronger FSC and a more integrated topos than exhibited by LiquiComp UK because of the more limited access given within the business. Having said that, it was clear from the data collected that neither the FSC of LiquiComp UK, nor the degree of integration of the topos, significantly changed if only the manufacturing site was considered, so it can be concluded that the differences in case study boundaries had a limited impact on the research findings.

A second aspect to response bias comes about as not all study participants could offer a detailed, first hand, insight into the embedded cases of the non-reportable food incidents. In the case of PowderCo UK, for example, P001 had not been employed by the company at the time of the incident, whilst in

LiquiComp UK, no direct access was given to line operatives or supervisors due to the operational restructuring which was taking place at the time of the data collection. Whilst knowledge of the incidents was one recruitment criteria for participant selection, a second criteria was knowledge of (through design, management or daily work) the organisations’ FSMSs, as this was critical to gain an overall understanding of the normal working practices of the businesses and allow comparison between generally effective practice and the incident. Thus whilst some participants were not directly involved with the management or resolution of the incidents, all offered insights into the day-to-day running of the operations. Similarly, whilst access to line operatives working on Line C at the time of the incident was restricted in LiquiComp UK, access was granted to the new supervisor of the line, who had in-depth knowledge of the processes and systems used and the changes put in place, which supported the data obtained from a number of staff and management involved in the incident investigation and resolution.

Finally, the sensitive nature of food safety and food incidents as a topic may be seen as potentially biasing the information obtained, particularly during group interviews, where the presence of more senior staff might be seen as constraining input from other participants. As set out in Chapter 4, the issue of topic sensitivity was anticipated when designing the research study, and managed through anonymisation and data security. In addition, a non-disclosure agreement was put in place with LiquiComp UK, to further give assurances to participants and the company overall of the integrity of the research and the Researcher and to encourage frank and full disclosure of pertinent information, given the anonymisation of the research results. From a group perspective, the possible impact of “group effects” (Bryman & Bell, 2011, p. 526) in such interviews was also raised in Chapter 4. Careful facilitation of the group interviews, plus triangulation of data between interviews and with data from document analysis and direct observation, was used to minimise any such group effects.

Overall therefore, whilst some response bias cannot be ruled out, stringent efforts were made to minimise this. However, response bias remains a possible limitation of this work as with any qualitative, interview based research.

Other common criticisms of qualitative research, namely those of subjectivity and reproducibility, particularly the influence of the Researchers previous experience on these issues, are the subject of the personal refection in section 8.5. Some of the specific challenges of using PC, a relatively new and still developing research paradigm, are also addressed in section 8.5.

A final specific limitation of this research pertains to the lack of specific financial data gathered on the cases. This limits the use of the PAF quality costing model and the conclusions which can be drawn in this area. Both additional qualitative data on quality costing (e.g. from interviews with members of the finance team) and costing data would be required to fully develop insights in this area and this remains an area for future research.

8.4 Areas for Future Research

Based on the contributions and limitations of this research, a number of areas for future research have been identified.

Given the limited number of cases and incidents in this research, further study of food incidents, both reported and non-reportable, should take place. By examining further cases it would be possible to explore whether the key findings and conclusions of this work – the unforeseeable nature of incidents and the importance of identifying factual possibilities in hazard analysis – hold true in other cases. Studying cases in smaller, less established manufacturing companies, in companies with both high and low levels of resource, in other areas of the food industry (companies in other countries; the hospitality industry or food retailers; producers of higher microbiological risk foods) would offer further insights.

Further study of FSC and its relationship to the PC framework would also be insightful. A number of additional studies on FSC have been published since the start of this work (e.g. J.Z. Taylor et al., 2015). Research using PC to assess the organisational topoi (overall and for a quality / food safety incident) with organisations who have utilised one of the off-the-shelf methods to assess FSC would enable a critique of the FSC models and measurement systems. Additionally, both case study organisations were considering the use of in-house proxy measures of FSC, based on existing programmes to encourage a good health and safety culture. Longitudinal research to assess the implementation and effectiveness of such an introduction would be of benefit to researchers and practitioners.

As detailed in Section 8.2, the current study contributes to the body of literature using PC by assessing its utility to explain a case of failure in a management control system, rather than explaining effective practice. Further research using PC to explain and understand “failed” management control systems is required to firmly establish its use in this way. Similarly, further work to explore the concept of a scale of integration and over-integration as an explanation for ineffective construct causality is also required, be that in the context of management control in the food industry or other areas.

As previously discussed the results of this research have indicated a potential flaw in the use of HACCP to manage food safety with the traditional risk assessment process (risk versus likelihood) depending on hazards being recognised and assessed, whilst this research indicates that incidents result from unforeseeable, or at least unforeseen, circumstances. In addition to further research to understand if this finding can be substantiated in other food incident cases (be that non-reportable or reported incidents), research is needed to address the potential application of these findings in other risk assessment based processes in the food industry.

Following well-publicised cases of food fraud (particularly economically motivated food adulteration) such as the horsemeat scandal in Europe in 2012 and the risk of ideologically motivated food contamination, standards and guidelines have evolved to address these concerns (e.g. British Standards Institute, 2014). TACCP (Threat Assessment Critical Control Point) and VACCP (Vulnerability Assessment Critical Control Point) have been developed from the HACCP approach. Research is required to understand if the same challenges of identifying factual possibilities, and classifying events as unforeseeable, pertain to TACCP and VACCP as well as HACCP based FSMSs. The teams charged with developing TACCP and VACCP plans are often not experts in "thinking like a criminal" and in developing comprehensive defence plans. Understanding whether this relative lack of expertise inhibits or encourages the identification of factual possibilities is therefore highly pertinent for the food industry and regulators as well as being of academic interest.

Finally, two other areas of research are pertinent from a theoretical perspective. First, additional research is required to develop more comprehensive insights into the use of and contribution of quality costing in the food industry pertaining to the management of food incidents. Second, further research is required to develop time as a dimension within the PC framework and the evolving nature of organisational topoi with time.

8.5 A Personal Reflection on the Research Process

A PhD is often compared to an apprenticeship, where the student acquires the skills and knowledge to undertake independent research in a specialist field

(Phillips & Pugh, 2010). As such, a short reflection on my growth towards this outcome is pertinent.

Through my own studies I have compared the PhD process to riding in the Grand National: every stage is like a fence, which appears – and indeed is – enormous. However, once jumped the fence retreats into the distance, you look back and think "why was that so hard?" Then the next fence looms up looking larger and harder than anything you've faced before, until that too, is successfully cleared. Of all the fences jumped, I have chosen two which I feel are particularly worthy of sharing my reflections on.

The first area concerns the possible influences of my previous work experience on my PhD studies. I graduated in 1987 with a degree in nutrition and worked as a dietitian in the National Health Service before moving into the food industry, where I held a variety of nutrition science and food regulatory positions for over 20 years. Whilst I did not directly work on food safety and quality, I worked closely with quality and safety teams, and have experience in investigating and resolving food incidents. Indeed, this was why the subject area for my PhD initially appealed: I know how much effort FBOs put into making food safe and of high quality, yet I've also seen that things can go wrong, so I was keen to understand more about why that happens.

As discussed in Chapter 4, I decided to use a qualitative approach for my research. As I progressed with the study, the challenges of ensuring the high quality of the work became apparent. I vividly remember a meeting with one of my supervisors (who most often uses a quantitative approach in his work) when he asked "if someone else did this work would they get the same results as you?" and I responded "no". So, had I unwittingly sabotaged the quality of my own work?

As a scientist, my aim in research was to be an objective, unbiased observer. With a positivist philosophical approach (although I had not appreciated at the time that this was what it was), research quality entailed concerns with random sampling, the reproducibility of results and the validity of conclusions based on statistical probabilities. Yet here I was undertaking qualitative work, which by its very nature means that the researcher becomes an intrinsic part of the work. As Bryman and Bell (2015, p 416) express it "The qualitative researcher seeks close involvement with the people being investigated, so that he or she can genuinely understand the world through their eyes." What was the impact of my experience and knowledge of the food industry on my research and was my instinctive answer of "no" to the question on reproducibility a real issue?

This one simple question set off a period of work to critique and demonstrate the quality of my research methodology, the results of which formed a key part of my work in Chapter 4. And what did this give me as an answer to my supervisor's question? Well, no, another researcher would not necessarily get the same results that I have, unless they too had similar background knowledge and experience in the food industry. My background aided me in gaining access to the case study companies. Rather than being a random PhD student asking for access to discuss a sensitive topic, I had a reputation and track record which helped my initial contacts justify and legitimise my work and so gain approval from senior managers to participate in the research. Likewise, my background helped me to build a rapport with participants when conducting interviews, so that they felt able to share information about sensitive areas. After all, admitting that you and your organisation have potentially made mistakes is not an easy or comfortable experience. By showing my understanding of the challenges of working in the food industry, I was able to probe and get fuller and richer answers to my questions. Benefits of access, relationship building and the nuanced understanding that comes from shared experiences have been recognised as possible advantages in "studying the familiar" (R. Berger, 2015).

However, the challenge of over-familiarity between the research and the researched, must also be recognised (R. Berger, 2015). Whilst my prior work experience helped me dig deeper during the interview process, I also reflected that I had simultaneously taken care to avoid making assumptions during data collections, which would bias my findings. From the construction of the semi-structured interview guide (which I validated through review with industry experts) to ensuring the clarification of acronyms, I had actively sought to avoid making assumptions about the questions to ask, or the answers to the questions, because of my experience.

So overall, whilst I still believe that my answer to "would someone else get the same results as you?" is "no", a more complete answer is "no, I've got better insights into this area than someone else might get, because of my background and experience", which from a qualitative research perspective gives an improvement in the quality of the study.

These considerations were formed as part of my reflexive practice through the course of my PhD study, to understand and account for, explicitly, my positionality (versus the case study organisations and participants) and the impact of this on both the research process and results. As expressed by R. Berger (2015) "the idea of reflexivity challenges the view of knowledge production as independent of the researcher producing it and of knowledge as objective", nevertheless through the act of reflexivity my aim has been to maintain the independence and objectivity of my research. I have previously described the steps taken to avoid introducing bias in data collection through making assumptions based on my knowledge of the food industry. Likewise, through the development of a detailed analytical strategy, by repeated reflection on the thematic analysis and discussion of findings with my supervisors and other researchers at doctoral colloquia and other research conferences, I have sought to ensure transparency in the research process and to achieve the required degree of independence and objectivity required for high quality research.

In reflecting on research quality and reflexivity, I touched on the second challenge I faced as a novice researcher: getting to grips with different philosophical approaches in research. More specifically, this second challenge concerns that of working with a research paradigm, the actor-reality construct and PC, which is relatively new and still evolving.

When my first supervisor initially suggested that I consider PC as a basis for developing a theoretical roadmap for my research, she shared an article published in Financial Management which sets out PC as a conceptual framework for management accounting (H. Nørreklit, L. Nørreklit, & Mitchell, 2013). As I explored PC and the actor-reality construction more, I realised that this starting point was deceptively simple and that using PC within my research presented challenges and opportunities. The first challenge is how to categorise PC. Although my initial introduction to PC described it as a conceptual framework, other papers refer to it as a paradigm (H. Nørreklit, L. Nørreklit, & Mitchell, 2010), an ontology (Seal, 2012), a performance measurement framework (F. Mitchell et al., 2013), both an epistemology and an ontology together (Pianezzi & Cinquini, 2016), a meta-theory (Seal & Mattimoe, 2016) and a conceptual methodology (Jack, 2017). This became the first challenge in using PC: in what way was I using it and how would I describe its use?

Similar challenges arose from other parts of the PC vocabulary. For example, the concept of the organisational topoi is used in much of the research, but there is inconsistency in the use of the singular "topos" and the plural "topoi" across the literature to describe the reality of an organisation, when considering a single organisational unit versus the over-arching top level of an organisation.

Whilst this variation in descriptors comes from evolving nature of PC, the central tenants of its four dimensions and the importance of the integration of these dimensions has not altered. Thus, the terminology has posed a challenge in understanding and describing PC in my written work and presentations, rather than a challenge in using PC to inform the development of the theoretical roadmap for my own research, and its application in data analysis and interpretation.

Leaving aside the challenges of classification and terminology, my main reflection on using PC has been on whether it has added value to my work. As explained in Chapters 4 and 7, I utilised PC firstly to inform the development of my main research tool (the semi-structured questionnaire) and then in the analysis and interpretation of results. In this analysis I took the codes and themes developed from the inductive analysis of the data, mapped these against the dimensions of PC and then interpreted the results in light of the PC constructs. This additional layer of analysis added complexity to my work, not least in how to present and explain these differing levels of analysis. However, I believe that the use of PC has added value. The thematic analysis was very useful to set out and explain the what, when, where, who and how questions about the case study companies and the quality incidents. It also began to give insights into the underlying question of why the incidents happened, and why certain behaviours and actions had occurred, for example, the insight into the role of experts in each organisation. However, adding PC enabled greater insights to be developed. For example, adding the PC constructs to the combination of the incidents being "unforeseen" and the value placed on experts and processes in both organisations, led to my positing the gap in identification of factual possibilities as an underlying cause of the incidents.

For future work however, I believe that rather than completing a full thematic analysis before applying the PC framework, it might be more straightforward and equally insightful to inductively develop codes and then map these against the PC dimensions without the intermediate step of developing themes from the codes. Whilst this breaks from accepted practice in thematic analysis, it fits well with an abductive approach informed by PC and that used by other academics working with PC, as previously described.

Further debate on the best practice of data analysis when using PC could be usefully undertaken with the community of researchers who use PC and the actor-reality construction. This community has welcomed my participation in annual conferences on the actor-reality construction where I have not only been able to see how the use and theory of PC is developing but, through the network's support and feedback, have been also able to develop my skills as a researcher in management control and my ideas for this thesis.

This neatly takes me back to the start of this section, and the apprenticeship nature of the PhD. Choosing PC as the basis for my theoretical roadmap introduced some unexpected fences into my gallop around the PhD Grand National, but has given me experiences that have enabled me to develop key skills towards becoming an effective academic researcher. As a developing field of work, the use of PC offers me opportunities for further research, as I move on, hopefully, from my apprenticeship and take my next steps as an early career researcher.

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Appendix A: Summary of Literature on Food Safety Violations, Incidents or Outbreaks of Foodborne Illness and FSMS / FSMnS Failures

#	Authors	Area of concern	Method	Findings	Process / People issues identified
1	Kwon, Roberts, Shanklin, Liu and Yen (2010)	Health inspection violations in ethnic restaurants in Kansas USA	Review of 500 randomly selected Kansas Department of Health and Environment inspection reports (250 ethnic and 250 non-ethnic restaurants). Data coded re violation type, critical / non-critical, date of inspection etc. and statistically analysed.	Ethnic restaurants had higher numbers of total and critical violations. Time / temperature violations were most common, followed by violations relating to personal hygiene and equipment cleanliness. Ethnic restaurants demonstrated a higher failure rate (25.2% vs 10%) for knowledge of foodborne illness prevention and application of HACCP than non-ethnic restaurants.	The violations noted demonstrate that process and people related elements e.g. time and temperature control can be a failure to have an appropriate system in place (process) or a failure to follow the correct process (people). The authors stress the need for food safety training to improve food handling etc., i.e. they see changing the behaviour of people as key to improving food safety in this environment.

2	Gormley et al. (2011)	Review of foodborne outbreaks in England and Wales 1992 -2008	2429 foodborne outbreaks recorded in the Health Protection Agency surveillance database were analysed.	Overall rates of foodborne illness are declining. Outbreaks are most likely to occur in food service establishments (52.6% of cases). Poultry meat was the most commonly implicated food vehicle. Contributory factors in outbreaks were cross-contamination, inadequate heat treatment, inappropriate food storage and infected food handlers.	Both processes and people are implicated as the causative agents of foodborne illness.
3	Soon, Singh and Baines (2011)	A review of foodborne disease in Malaysia.	Review of foodborne disease surveillance data from Ministry of Health in Malaysia from 1990 to 2009. Detailed analysis of a snapshot of 30 cases in Jan 2008	The majority of foodborne related diseases are associated with outbreaks in institutions (schools, academic institutions, community gatherings). Unhygienic	In addition to increased surveillance and monitoring, increased training and education is highlighted as a need, i.e. addressing people aspects of the issue. Also recognised that knowledge alone is insufficient –

			is shown to illustrate key causes of food contamination.	handling of food and lack of cleanliness in food preparation establishments – i.e. insanitary food handling procedures – identified as key contributing factor.	authors identify FSC as a key concern.
4	Hall et al. (2012)	Epidemiology of foodborne norovirus outbreaks in USA 2001 – 2008	Analysis of 2,922 foodborne norovirus outbreaks, allowing identification of key vehicles of transmission (food type), location and probable causes of transmission.	Leafy vegetables, nuts and fruit, and molluscs identified as primary food groups associated with norovirus infection. Restaurants, delicatessens and other commercial settings identified as locations of infection. Infected food handlers implicated in 82% of outbreaks.	Key interventions for reduction in incidence of infection were hand washing, compliance with policies on sickness and the presence of a certified kitchen manager. These are primarily people issues.

5	Potter, Murray, Lawson and Graham (2012)	Trends in product recalls in agri-food in UK, Ireland and USA.	Compilation of a database of product recalls between 2004 and 2011 using US FDA, USDA Food Safety & Inspection Service, UK FSA and the Republic of Ireland Food Safety Authority of Ireland information. Recalls were classified under RASFF headings, with additional new codes created as required.	2070 product recalls were identified, 74% in the USA. The frequency of recalls was found to be increasing over the time period analysed; partly explained by three large scale US recalls in this time period. 24% of all recalls were associated with processed foods, followed by meat (13%) and fruit, vegetables and salads (10%). Recalls were further split into 3 categories: biological product recalls (36%), with *Salmonela, Listeria* and *E. coli* being the most common hazards; chemical product recalls (9%), which encompassed dyes, irradiation,	The authors suggest that "operational product recalls" are "largely caused by preventable human errors", i.e. people related shortcomings in food safety management. However, the authors present no data to substantiate this assertion and the wide range of sub-categories under this category could have very different root causes. The classification of different recalls can also be challenged. For example, Sudan 1, Sudan 4 and Para Red Dye recalls in 2005, along with melamine, are classified as chemical product recalls. Whilst these elements are, of course chemicals, the use of such chemicals is strongly associated with food fraud.

				food additives, food contact materials and pesticides etc.. The largest category pertained to “operational product recalls” (55%) which included incorrect labelling, packaging defects, unauthorised ingredients, and food fraud.	Likewise, the Peanut Corporation of America Salmonella case has been identified as one of food fraud, rather than a “simple” case of biological contamination. Despite suggesting that human error – people – underlie a large proportion of product recalls, the authors suggest that further research to investigate how to reduce such incidents might consider practices such as HACCP, traceability and statistical process control, i.e. processes, illustrating the intertwined nature of people and process in FSMS success and failure.

6	Vemula, Kumar and Polasa (2012)	A review of foodborne diseases in India from 1980 to 2009	Review of the scientific reports of 37 reported outbreaks.	Compared with other papers reviewed, the outbreaks reported here were more varied, with adulteration (e.g. with illegal food colouring), chemical contamination (e.g. pesticides), and illness caused by toxins in foods (e.g. from consumption of mouldy sorghum) as well as illness resulting from microbiological contamination of food being presented. Much of this is likely to be due to India being a developing country with a high population of rural poor. However, as India is increasingly involved in international food trade, the	The discussion in this paper focuses on the need to improve surveillance of foodborne illness in India, and to improve awareness of the risks of food spoilage etc. There is no discussion about the implications for the Indian food industry, particularly for companies who export products to other markets. No clear picture can be ascertained as to whether process or people issues would be most important to address in the local food industry.

				cases of deliberate adulteration of products are particularly concerning.	
7	Soon, Manning, Davies and Baines (2012)	Investigation of food safety breakdowns at farm level (primary producers) and possible role of HACCP	A desktop study of outbreaks and recalls of fresh produce in US A and EU.	The outbreaks discussed are focussed on microbiological contamination of produce. Agricultural practices (e.g. source of irrigation water, presence of domestic or wild animals) and the actions of workers highlighted as potential sources of contamination.	The authors' research involves the assessment of whether the HACCP process can be applied in primary production. It is suggested that process implementation (guidelines, manuals) is insufficient by itself to improve produce microbiological safety. This suggests that whilst process development (a modified form of HACCP) might be beneficial, addressing people aspects (education, culture) will be key for success.
8	Painter et al. (2013)	Categorisation of foodborne illnesses against	Review of all outbreaks reported to the CDC, categorising against food groups	4,589 outbreaks with an implicated food vehicle and a single aetiological agent	The study was not designed to examine system failures. However, the importance of complex foods

		food categories in the USA, 1998 - 2008	and identifying key causative agents.	examined. Norovirus responsible for most outbreaks; 49% of outbreaks associated with complex (rather than single ingredient) foods. Produce (fruits, nuts, vegetables) and poultry were the food groups most often implicated.	and norovirus indicate cross-contamination by food handlers as a cause for concern, i.e. people related issues. Additionally, the authors stress the need to prevent contamination of poultry and produce, i.e. this indicates process concerns.
9	Xue & Zhang (2013)	An analysis of 2387 incidents of acute foodborne illness in China.	Foodborne illness reports identified in professional Chinese journals, from 1999 – early 2010.	Data identified 99,487 illnesses and 380 deaths: much less than official Government figures for the same period (possibly due to focus in journals on metropolitan areas and requirement for professional evidence). Microorganisms linked to 57.8% incidents and 36.3%	In common with the study of Vemula et al. (2012), this report also highlights that the rural population are at risk of foodborne illnesses from chemicals and toxins to a higher degree than typically reported in Western societies. The authors stress that human factors - negligence, intentional behaviour, weak regulatory

				deaths. Chemicals (food additives, pesticides, rodenticides, veterinary medicines) linked to less illness but higher percentage of deaths. Detailed information also given on location and type of foods involved. Detailed information also given on human causes, ranging from unhygienic practices, to ingestion of decayed food, overuse of additives, illegal use of feed additives etc.	enforcement and lack of knowledge - were largely accountable for the food safety problems analysed.
10	Van Doren et al. (2013)	Investigation of foodborne illness from microbial contamination of	Literature search and investigation of CDC database to identify and describe foodborne illness attributed to spice	Multiple causes of infection noted, including inappropriate: growing conditions (using manure as a fertiliser); treatment of spices – "steam	The causes identified indicate failures in the process of food safety management, e.g. inappropriate heat treatment. However, it seems likely that a lack of knowledge (a

		spices, 1973 - 2010	consumption (including in processed foods).	washing" which cleans spice but which does not effectively reduce pathogens; sampling for testing to verify safety of spices; addition of spices to ready-to-eat products after the main pathogen reduction step (i.e. spices not subject to this); vendor control (e.g. use of unregistered suppliers).	people issue) lies at the heart of many of these issues.
11	Callejón et al. (2015)	Reported outbreaks due to fresh produce (fruits and vegetables) in the USA and EU, trends and causes.	An analysis of reported food outbreaks in fresh fruit and vegetables, confirmed by laboratory detection of a suspected causative agent, in the EU and USA between 2004 and 2010. Data is taken from USA CDC reports and EU RASFF reports.	In this time period the USA reported 377 outbreaks, the EU 198. No clear trend in the number of outbreaks was seen in either region, with numbers per year varying between 23 and 60 reported outbreaks in the USA and 10 and 42 in the EU. Norovirus was the main	This study shows both the strengths and limitations of the information available in CDC and RASFF reports. Detailed information is available about type of contamination, affected products, place of outbreak etc., but limited data is available to ascertain the underlying cause of any outbreaks. Given the

				pathogen identified, followed by *Salmonella* spp. and *Escherichia coli*. Salad vegetables were most commonly affected, along with sprouts (alfalfa, mung etc.) in both regions. In the EU a high number of norovirus outbreaks were also associated with berries, whilst in the USA melon was the fruit most implicated in outbreaks (predominately *Salmonella* contamination). From this data, produce-associated outbreaks were more likely to take place in food-service establishments (particularly restaurants), and	predominance of norovirus outbreaks, the expectation is that contamination results from poor food handling practices. The expectation appears to be that such failures result from people factors - the actions, or lack of actions of food workers (e.g. handwashing). However, process related failures (e.g. on farm washing of produce with contaminated water) might also be implicated, but cannot be fully ascertained from the data available.

				private homes, although other outbreaks had been described at hospitals, nursing homes etc.	
12	Manning, Wallace and Soon (2016)	An analysis of four major foodborne disease outbreaks related to complex food manufacturing environments.	A narrative analysis is presented of four well known cases of foodborne disease related to microbiological contamination of food products.	Case 1 relates to a typhoid outbreak in Aberdeen in 1964 which affected 507 people, causing 3 deaths. The incident was caused by contamination of corned beef with *Salmonella* Typhi, due to use of unchlorinated cooling water in the canning plant in Argentina, with subsequent cross-contamination during meat slicing in the UK. Case 2 concerns a UK outbreak of botulism in 1989. Changes in the recipe of a hazelnut	The four cases are used to highlight the complexity of designing adequate FSMS in food manufacturing. Cases 1 and 2 demonstrate the importance of PRPs for hygiene and cleaning. Case 2 also demonstrates the requirement for food safety to be considered during new product development. Cases 2, 3 and 4 all demonstrate the need to establish appropriate corrective actions if CCPs fail, or routine testing indicates issues with product safety and quality.

				puree (replacement of sugar with sweetener) used to flavour a yogurt resulted in the growth of Clostridium botulinum in the puree and subsequent toxin production, which was carried over into the yogurt. This resulted in 27 cases of botulism, including 1 death. Case 3 concerns the outbreak of *Salmonella* Typhimurium in peanut products manufactured by the Peanut Corporation of America (PCA) in 2008. 715 cases presented across 48 US states, with 166 hospitalisations and 9 deaths. 3918 products were recalled	Although the authors concentrate on the technological aspects of the food safety failures, two of the cases have been directly related to people related aspects. The PCA case has been recognised as an example of food fraud (R. Johnson, 2014), with company executives being prosecuted for knowingly shipping contaminated products on falsified certificates of analysis. The former president of PCA was sentenced to 28 years in prison (Wagner, 2015). In Maple Leaf Foods, whilst a combination of technical and behavioural deficiencies and assumptions were identified as the root causes of the incident, much of the organisation's efforts have

				and PCA closed and filed for bankruptcy in 2009. Multiple failures in the FSMS were found. Case 4 concerns the *Listeria monocytogens* outbreak in Maple Leaf Foods products in Canada in 2008. 57 people suffered from listeriosis, with 22 deaths, following consumption of contaminated cooked meats. The outbreak was traced to a failure in cleaning / sanitisation protocols for certain meat slicing equipment, with a conflict between demands to increase production output and the plant time required for	concerned the transformation of their FSC – i.e. the people elements of the FSMS (Jespersen & Huffman, 2014).

				dismantling and deep cleaning of the equipment.	
13	Wright (2016)	An analysis of three well known food safety incidents, which Wright attributes to failures in FSC.	A short presentation of three food safety incidents, followed by a detailed description and discussion of FSC, including how to analyse, categorise and improve FSC, building on Wright's previous work for the FSA (Wright et al., 2012a, 2012b)	The three cases presented are: 1) The 2007 *Salmonella* Motevideo outbreak at Cadbury, caused by waste water dripping onto milk chocolate crumb. Three people were hospitalised, many more made ill, and Cadbury was fined over £1 million. 2) The 2008 PCA case (discussed above by Manning at al. (2016). 3) The 2010 Harles and Jentzsch GmBH case of dioxin contamination of animal feed	Wright presents all three cases as those where, amongst other causes (e.g. in the case of Cadbury a leaking waste pipe), food safety outbreaks resulted from intentional noncompliance with procedures, be that systematic breaches of safety procedures and testing regimes, the failure to notify the appropriate authorities of food safety failures and / or the failure to recall products. As such, it is clear that poor decisions made by people were central to the placement on the market of unsafe products. What is less clear from these cases is

				which resulted in the closure of thousands of farms, the slaughter of thousands of animals and company losses of around €100 million, with the eventual bankruptcy of the company.	whether / how the actions and decisions of people related at all to the original failures. For example, in the Cadbury case, the court found clear evidence of a change in policy on product testing for *Salmonella* and release. What is not clear here is whether there was a human element involved in the root cause of the waste water contamination or were process failures seen, e.g. was a decision made to reduce plant maintenance which impacted on the equipment failure?
14	Zhang and Xue (2016)	An analysis of media reports of food scandals or incidents related to food fraud /	A manual search of media reports of food scandals identified 1553 reports for 2004 – 2014. Reports were analysed by EMA database category for	Although this paper concerns food fraud / economically motivated adulteration, much of the “contamination” identified and reported affects	As this report relates specifically to food fraud it is self-evident that people related factors underlie the identified safety issues, food fraud being a deliberate choice to

		economically motivated adulteration in China and Hong Kong.	specific types of food fraud plus food type, source or location (farm, supermarket, street vendor etc.) and "adulteration" type (e.g. contaminant (chemical, microbiological, physical), counterfeit foods etc.).	food safety e.g. the presence of forbidden additives; presence of human or animal medicines; microbiological contamination; physical contamination (Insects, metal, cigarette ends etc.). The results indicate that most cases involve legitimate food businesses (25.69% of cases concerned products sourced from illegal food shops), although it is not possible to ascertain from this data whether or not products sold in supermarkets / restaurants etc. were obtained through legitimate supply chains.	adulterate / mislabel products etc. for economic gain (Spink & Moyer, 2011). However, it appears from the results that many of the cases concern legitimate food businesses (e.g. 12.3% of cases involving supermarkets / groceries), hence there may also be elements of process failure (such as inadequate processes for supplier checks).

15	Nayak and Waterson (2016)	A socio-technical systems analysis of two major UK outbreaks of *E. coli* 0157, from 1996 in Lanarkshire and 2005 in South Wales.	The authors present an Accimap analysis of each outbreak. This is a control theory-based systems approach for accident analysis, considering 6 “organisational levels”.	For the purpose of this review, results at the company level are most pertinent. The Accimaps presented identify a number of inter-related causes (direct and indirect) which resulted in the *E. coli* outbreaks under consideration. These included factors such as the lack of documented FSMSs; complexity of regulations; untrained helpers and staff serving meals; no cleaning protocols and negligence in providing training for staff.	Both process and people failures are presented as causes of the food safety failures, however the authors particularly comment on “complacency failures” and safety culture within the businesses concerned i.e. a people focus.
16	Djekic, Jankovic and Rajkovic (2017)	Analysis of foreign bodies in	The RASFF database for 1/1/1988 to 31/12/2015 was examined to extract hazard	1446 foreign body notifications were reported with 185 notifications prior to	The violations noted suggest issues with control systems. For example, pest contamination suggests failures

		European food using RASFF data.	notifications under the category of “foreign body”. Results were analysed statistically to test for relationships between European regions, types of foreign body and food industries. Results were reported in two time-frames, prior to 2006 (the introduction of EU food hygiene law) and the subsequent period.	2006, and 88 – 213 (typically 100 – 120) notifications each year since. The top 3 food categories associated with foreign body contamination were fruits and vegetables; nuts and seeds; bakery and confectionery products. The top 3 contaminants were pests (insects, faeces, larvae etc.), glass and metal. Glass and metal contamination was reported most often in Western European countries, pests in Eastern European countries and plastic, rubber and wood in the Northern European region.	in pest control (basic PRPs), whilst metal contamination suggests a failure in FSMnSs for metal, which the authors relate to failures to implement appropriate systems and / or to adequately verify or validate the FSMnSs. Whilst recognising the limitations of the research, the authors put emphasis on people related aspects of FSMS implementation and maintenance, particularly training to improve food safety knowledge.

17	Park, Kim and Bahk (2017)	An analysis of food safety incidents in South Korea, 1998 - 2016	In the absence of an existing database of reported food safety incidents, the authors collected data on incidents from public institutions, food safety professionals (e.g. FBOs, food society journals) and mainstream media (newspapers, TV, websites etc.). After excluding overlapping reports, the results were collated and analysed by time (incident report date), food category, stage of the food chain in which the incident occurred and hazard type.	Reports from 975 cases were examined (average 51.3 cases per year). Fruits and vegetables (19.8%) and fish and fish products (10.2%) represented the top 2 food categories for reported safety issues, with 63.1% being related to the first stage of food production, described as "food material production". In terms of hazards, chemicals represented 41.6% of reported incidents, followed by biological (22.7%) and physical contamination (20.4%).	Whilst details are not given in the paper, and so the conclusions cannot be verified, the authors claim to have gone "beyond an analysis of specific chemical or biological factors … to determine a deeper cause". They claim "that human error during the production and processing stage underlies most of the food safety incidents". Also of note is that the authors propose the introduction of GMP and HACCP to improve food safety, along with general education of the general public i.e. a mixture of process and behaviour change is recommended to reduce the occurrence of future food safety incidents.

18	Aguiar et al. (2018)	An analysis of the incidence of physical hazards in dairy products in Brazil, as reported via a consumer complaint website (*Reclame Aqui*).	Data collected directly from the *Reclame Aqui* website for all September 2012 – December 2016, covering 11 dairy industries. Data classified by product type (e.g. UHT milk, Parmesan cheese), physical contaminant (hair, metal etc.). Chi-square test used to analyse complaints by product type and year.	515 incidents relating to physical contamination were identified (2% of total complaints), with 37% of these related to yogurt / milk drinks and 14.6% relating to UHT milk. 42.6% of complaints pertained to "foreign objects", demonstrating the difficulties consumers have in describing the actual hazard type. As the data relates to consumer reports of contamination, only limited conclusions can be drawn.	This paper suggests contamination results from failures in food processing (to protect against physical contamination) and food inspection (labels of dairy products in Brazil carry a seal signifying that manufacturing has been inspected by official authorities). The recommendations for improvements made by the authors include both people (training) and process (reviewing CCPs) elements.

Appendix B: Description of Codes with Examples

#	Code	Description	Example
1	Communication	Discussion / description of communication e.g. who is involved in an activity; types of communication used between parties e.g. email, daily meeting reports	"… as soon as that complaint came to us and those pictures came to us, as a senior management, we informed everyone, that's head of site, head of quality, quality compliance manager, engineering manager, production manager …." (P001)
2	Problem solving process	Discussion / description of problem solving processes e.g. root cause analysis, risk analysis.	"… what we also had to do was back track and identify well, if this material was being identified at our co-packer here, when was it made, where's the gap, have we been making material on an on-going basis, and then try to put together not only a mechanism, for tracking the problem and fixing it, but looking back historically ad identifying which is the highest risk product, what was the risk, is there anything we needed to do for a recall …" (P007)
3	FSMS	Discussion / description of specific types of food safety system e.g. description of critical control points or elements of PRPs	"Obviously we've got a pre-requisite programme, which we manage from a hygiene point of view, glass and hard plastics, wood policy, all those sort of thigs, plus we have a maintenance strategy based on top of that which links into the food safety plan as well and the pre-requisite programme. So rather than maintenance becoming a CCP point, it's more a pre-requisite programme". (L010)

4	Cultural standard	Discussion / description of element which form cultural standards or expectations in the organisation e.g. when a process is routinized so that it has a specific physical location named after it.	(Participant discussing food packaging materials and recycling) "... as part of any development of a food contact material we won't do anything until the supplier has proved to us that those materials pass all of the relevant EU legislation on food contact materials. And to be honest, it's routine for everybody now. A supplier, well a reputable supplier, wouldn't even think of giving you something that didn't match but we need all of that documents, we need all of the proof, so yes, you know we wouldn't even think of doing anything, we wouldn't even do a trial before we got all of that information." (L013)
5	Upgrade of controls	Description of upgrade of controls used vs current FSMS / FSMnS	"… so we brought in new procedures, which is the closure angle check. The traded unit, they moved where the check was being conducted, and ensured that it was a fully destructive test, that the caps were being taken off the bottles and the same with the torque check as well." (L009)
6	Use of external experts	Discussion / description of use of external experts / consultants e.g. pest control specialists	"… so if you think about our cleaning programme, we've got 2 tiers, we've got the operators and then we employ Sodexo as line based facility cleaners …" (L010)
7	Applying lessons learned	Discussion / description of activities to improve systems / processes which results from the conclusion of problem solving work e.g. refurb of Bin B based on failing of bin C	"But the root cause threw out a whole load of other things around quality culture and some systems and processes on site that needed to be adapted, 'cos they're generic things like change control, documentation

			management systems, and they're not just by line C, they're used by every line, every function on site and we spotted gaps in those. So, it's escalating them up." (L016)
8	Decision making	Discussion / description of decisions made during incident management (embedded case) or in similar incidents in the past	"… we immediately stop all the plant, we stop using Bin C, whatever was produced on site from Bin C we put on hold" (P001).
9	Reasons for failure	Discussion / description of detailed reasons for failure e.g. age of equipment, belts slipping	"… not detracting from the engineers, but I would, for me that was an easier one, 'cos they knew what the fault was. They, you know, it was like some ball bearings that had come out of a fixing and jammed it (the capper) basically …" (L009)
10	Faith in control systems	Discussion / description of positive faith in organisation's control systems (especially FSMS)	"… we're probably doing more than most food companies would be expected to do, let alone actually do … in that BRC audits, we don't normally have a problem with, ISO audits we don't normally have a problem with. Our own internal auditing structure are much more stringent for looking at the quality side, but also the safety side …" (P007)
11	Expectation of involvement	Discussion / description of participants' expectations of their involvement in problem solving process / communications or of who else is involved in aspects of incident management	(Discussing the makeup of the IIC and IRC teams) "So we keep it flexible, according to which location's got the biggest vested interest, (head office), (manufacturing site), co-packers, and which kind of function's got the biggest vested interest ..." (L001). "So the composition of

			the team will depend on the nature of the incident?" (Interviewer). "Absolutely does" (L001).
12	Panic	Discussion / description of a state of "panic" or extreme concern	"I think the fact that it had got through all the processes and got to the co-packer was a significant cause of concern for us and the risk going forwards was that obviously material had gone to (export market), so that was where it became immediately apparent that it was a relatively major issue compared to what we'd normally deal with on a daily basis…" (P001)
13	Variation in working practices	Discussion / description of a variation in practice between different staff members	"… and I think there was the human element that certain checks that should have been performed were not always being performed …" (L006)
14	Continuous improvement	Discussion / description of CI activity ongoing prior to the specific quality incident (embedded case)	"we know we routinely generate metal as a fine powder 'cos we've got a lot of chain driven material, we've had an ongoing process of removing it as much as possible to transfer to vacuum transfer …" (P007)
15	Age of equipment	Discussion / description of age of factory / equipment /process etc.	"I think a lot of it came down to, when you've got your hazard analysis in therefore the food safety management system, is that, over time, the risks change, and I don't think we've captured that very well, that the risk from the bin could increase over time as things get older ..." (P003)

16	Rigour	Discussion / description of additional effort / care in the processes of determining cause of failure or in making new processes better, or in applying experience & skills for benefit of the organisation	"The main focus was to get to the issue, keep digging no matter what you need to do, so if you need people, bring them in. If you need people who were on shift, you need them to come in on their day off, get them, or if you need to stay late to speak to somebody, it was kind of, do what you need to do to get to the facts, don't rush it." (L016)
17	Lack of knowledge of current controls / process	Discussion / description of a lack of knowledge of current controls (prior to incident) or process	(focus group, talking about review of site magnets by external consultants) "… so they came in and did a complete review of all of our magnets and made recommendations that maybe some of the magnets that we had in place weren't quite the best design for the places that we got … we even managed to find some magnets we hadn't recognised we'd got!" (P007) (laugher) "we found two magnets that we didn't know we had" (P003)
18	Missed opportunities	Discussion / description of actions not taken / decisions not made which could have prevented the incident or altered the course of the incident	"So there was a failure there, where people were doing the test, [number of] bottles, no one had linked that actually we have to do one per filler head, capper head. That aspect is in place in places that really understand what purpose that test is." (L015)
19	Unexpected events / results	Discussion / description of an event or result which is unexpected, not anticipated, or unforeseen e.g. no history of equipment failure in this way	" … and then they ran some product and were still getting the metal shavings …" (P008)

20	Wearing blinkers	Discussion / description of "wearing blinkers" / missing things when going through the problem solving process or when making changes to production system which affect FSMS	" it's quite ways to within engineering to wear blinkers, and think you've found something, you've found the problem, but obviously there was two issues …" (P008)
21	Creative thinking	Discussion / description of developing new standards, new ideas e.g. trays under magnets	"…because one of the things I did was challenge the design of the head (of the capping machine). So we worked quickly with the supplier to re-design the heads …" (L017)
22	Problem identification	Discussion / description of identifying the problem, finding a gap in current processes / systems / controls etc. May be part of problem solving process or separate from it.	".. that example with the shredded cap was fairly obvious, you know we completed that within half an hour…" (L001)
23	Rationale for decision making	When a rationale is given by participants for particular decisions	"… So we asked ourselves, and this was part of the push back from SMC, we asked ourselves, who really is the target market here, who were we worrying about?" (L001)
24	Safety first	Use when participants describe an action / decision which put safety concerns above products volume / costs etc.	"I mean the first thing is, if the product had been considered to be injurious to health it would have been recalled. There's no grey area, that's white … we identified that it wasn't injurious to health and therefore we didn't do a recall; if it had been, we would have." (L008) "… so the senior management director, from senior director to the operative who is working on the factory

			shop floor, everyone knows like food safety is the main concern ...” (P001)
25	Standard for monitoring	Discussion / description of a standard or routinized part of the FSMnS e.g. checking magnets at the end of shift	“We check the magnets twice a shift, um, I’m sorry, twice a day, that’s once a shift, and then um sieves as well, so we check the sieves …” (P001)
26	Standard for release	Standards used to gain release / approval of product to the market e.g. micro testing of finished product	“.. we have the packers that are protecting the consumer with their metal detection ....” (P003)
27	Visual demonstration	Description of visual demonstration of monitoring in FSMnS / FSMS or in the depiction of standards e.g. use of real product samples in problem solving sessions	(Describing visual displays of incidents and management of them). “There are timelines that have been produced around specific IICs that have gone on for 6 months or almost a year in some cases, where you have a timeline, that, there is a bigger timeline which takes account of all of the IICs and IRCs that have occurred over the last 3 to 4 months …” (L003)
28	Actions from alerts	Description of actions taken when alerts are raised by monitoring systems in factory	(Participant describing the discovery of the quality issue of cocked caps and immediate actions) “We just didn’t know where it [the capping problem] had started, so day by day, from the Sunday, (Quality Manager) had put some into hold on quarantine …” (L009)
29	Expert advice	Description of getting expert advice (internal – other departments, or external – consultants etc.)	“… for example, for the physical removal, which is sieve and magnets, we, with the consultant ….” (P003)

30	Record keeping	Description of how records are kept by the business, including during incident management process and in production (in process QCPs and CCPs)	(focus group discussing CCPs in the factory) "… How's that monitored?" (Interviewer) "It's recorded on record sheets, production record sheets" (P004) "it's holding times critical …" (P007)
31	Link to other processes	Descriptions of cross-process links e.g. FSMS / FSMnS to technical change process.	(Focus group discussion of engineering changes which impacted the detection of the metal fragments). " … and again an assessment of our change control process which basically allowed us to remove a magnet that shouldn't have been removed and replace it with a magnet that was not equivalent or suitable" (P007) "that was another part of it, defect and change control" (P003).
32	Checking for compliance	Description of instances of compliance checks e.g. managers checking handwashing; checking of control systems such as sieve integrity.	(Discussing delivery of raw materials) "… it comes up by tanker load for pumping off into our cold store and it comes up with a certificate of analysis from (supplier) and then it gets tested again before it goes down the cold store." (L012)
33	Desire to improve	Description by participants of desires and plans for self-improvement or where they wish for organisational improvement	"And actually, myself and (colleague) we have a plan where we're going to revamp the system and make it encapture general sort of improvements not just safety improvements, but quality improvements and also efficiency improvements as well." (L016)

34	Concern for the future	Description / discussion of situations which pose a risk or problem in the immediate or longer future e.g. detection of stainless steel	(Discussing the issue of need for protecting data and issues of litigation etc.) "So that really I think is a looming problem and I would suggest for the purposes of your research and study, I think that something that's going to vex a lot of organisations, because we are increasingly being bogged down in the litigious society that is emanating across the Atlantic, if not here already. So that that is a real challenge that's been sort of a massive learning point for me and how I think about this concept of incident management". (L002)
35	Cost of work	Discussion / description of the costs (money, time people) of undertaking specific activities such as maintenance, including costs of impact of the quality issue.	"… so in the meantime, we were running another Bin, obviously it's a lot smaller, and less capacity and we were struggling in the factory, because the factory will fill that Bin quite quickly ..." (P008)
36	Benefits of work	Discussion / description of the benefits of certain activities e.g. faster production speed	"… we did it this this September just gone, we just had a big shutdown, so we did a lot of work but we've paid benefits, the plant has been running really well." (P008)
37	Lack of experience	Discussion / description of situations where staff lack experience	"… I've got new members of staff that don't really understand the site ..." (P008)

38	Benefits of experience	Discussion / description of situations where there are benefits of staff experience	"… you know I worked in (major retailer) for a long time and did many recalls at (major retailer), and therefore kind of if actually we did a recall here I would actually know what to do, just 'cos I've got experience …" (L005)
39	Planning	Discussion / description of planning operations, activities, day-to-day or within the management of the incident	"… as part of the Customer Care element I got involved to kind of understand the problem a bit more, how much stock was actually out there, because in my head I'm thinking, if this goes to a public recall have I got the correct resource, have I got enough vouchers in the draw, enough letterhead, all of that, and we're near Christmas, holiday period, so I think one of my ladies was on holiday as well, so I was a man down as such …" (L004)
40	Priorities	Description / discussion of priorities for organisation; may be related to organisational values e.g. consumer at the heart.	"… so the senior management director, from senior director to the operative who is working on the factory shop floor, everyone knows like food safety is the main concern ..." (P001)
41	Visibility	Visible demonstrations of values and culture e.g. posters, slogans	"… so it's on the wall, in foot high letters, from all our desks we can see (mission statement strap line) at the top of it" (L008)
42	Mission	Expressions of formal organisation mission statement	"… so it's on the wall, in foot high letters, from all our desks we can see (mission statement strap line) at the top of it" (L008)

43	Targets	Discussion / description of targets set e.g. annual objectives	“We all have a series of objectives for the year and during the course of reviews with our managers we understand how we’re doing with those objectives …” (L008)
44	Measures of success	Discussion / description of organisation’s measures of success; can be related to targets but have more specific values	“We have a company-wide meeting every month, both here (head office) and in (manufacturing sites) and so the managing director did an update on how we’re performing against our 5 business objectives, so it’s very transparent, it’s very clear, it’s very well communicated, it’s baked into our development programme, and obviously our bonuses are based on company performance as well as personal performance, so everyone has a real vested interest in achieving those goals. And everything we do is working towards those objectives” (L007)
45	Co-ordination	Discussion / description of how targets / goals / measures are co-ordinated across the organisation or between teams	(Discussion on cascading goals in focus group) “So this idea we've talked about the zero accidents, zero defects, zero waste, does that get cascaded down to the operators? “(Interviewer) “Pretty much so yes. It gets talked about at every single performance meeting that we have, and every accountability meeting that we have.” (P004) “It’s linked into every part of the business.” (P003) “It runs off the back of that ...” (P004) “Yes, all of our PDPs are off the back of that.” (P003) “So most of this

			would come under the incident managing and zero defects.” (P007)
46	Organisational learning	Description / discussion of formal and informal systems for learning across the organisation	“So we had conducted all the maintenance requirements set out by the makers of the equipment, so we followed that, and we also used their skills, expertise, we looked at our people's competencies, we checked training documentation. We have individuals who do this particular task, and they've been away to Italy where the equipment's made, they've been on the recommended training, so we were quite comfortable with the maintenance we were delivering.” (L017)
47	“What we say, we do”	Discussion / description of putting values / mission / priorities/ targets into action	“… looking at overall safety, we have an assessment, something called living safely, which is about understanding behaviours and how the site is actually managing health and safety, going from we obey the rules sometimes, all the way up to we live and breathe safety. But the implication is that if you’re doing that for safety you’re probably doing it, almost likely you’re doing it for the other side of things, which is the product safety, food safety ...” (P007)
48	Pride	Discussion / description pride in achievement of goals etc.; including pride in tackling difficult situations	“So what I made them do, what we done was retro fitted some trays, so they do a magnet check, pull the magnet out, put a tray in, pull the screen out, so any debris that’s

			there will fall onto the try, and then they inspect the tray, so it wouldn’t go into our product, that was something extra if you like ...” (P008)
49	Recognition	Discussion / description of recognition or rewards given by the organisation	“Um, there's also formal reward and recognition process called the (name) that we have.” (L016) “Yes. I saw one of the boards with photos on as we were going round the factory.” (Interviewer) “But also simple things like people saying thank you, well done, job well done, pat on the back, little things like breakfast, canteen vouchers, free breakfast, staff shop vouchers. So we've got a number of mechanisms on site, how we do that.” (L016)
50	Trust	Description of trust as a value or target	(Joint interview, discussing selection and approval of suppliers and co-packers) “So, we either do that by assessing what they've got for themselves already. So if they have got BRC and they're maintaining it, and it's on an annual review, and it's against an international standard, that's reasonable cause to say well, the fact that you've worked down and got the certificate, means you're probably likely to keep it, and all the while you keep it, you're at least operating at the same level we probably would. You have to put a certain level of trust in those things otherwise the whole fabric of GFSI breaks down.” (L001)

51	Senior management commitment	Discussion / description of the commitment of senior management to values, processes etc.	"...the whole company, and I mean the whole company, we stopped the factories for a day, so if you want an example of the company investing in sharing its way forward with everybody, I mean stopping the factory production is a big investment for the company to get the messages out." (L008)
52	Overload with detail	Use when participants fail to recollect all details of an area and ascribe this as due to excessive information, or where excessive complexity of system causes challenges in daily operations	"… actually the amount of paper we have for quality, the you have all the operational stuff on top of that, all the engineering documentation, and all the safety stuff, no wonder the operators become a bit blasé to it, because literally they're constantly filling in paper ..." (L014)
53	Organisational change	Discussion / description of how organisation has changed over time or is changing and implications of this.	"I couldn't swear to say I actually know of a statement on food safety." (L012) "Is there a site quality mission or anything like that" (Interviewer) "Yes, now then (pause)" (L012). "There might be. I'm just asking, who knows, I don't know whether there is or not, so it's not a right or a wrong answer." (Interviewer) "I'm not so certain there is … but I think that's obviously, other than [strap line of company mission statement] I can't see that there's a site specific quality one." (L012)
54	Senior management power	Description of examples / occasions where senior management over-rule advised actions / enforce their views or opinions	(explaining the IRC process and recommendations) ".... you've only got three options: don't do anything, do a trade withdrawal, do a public recall. And then officially

			(CEO) replies back and says 'yes, I endorse that, get on with it' or 'no, I don't, do something else' …" (L001)
55	Protect the company	Description of actions taken by company to protect the company (legally) rather than putting consumer safety and well-being as #1 priority (linked to legal privilege, due diligence)	(Talking about communication about the incident) "Um, as you can appreciate, releasing documentation on this particular incident, because it was legally privileged, and working with (colleague) and (lawyer) and the team, there wasn't a lot shared at early stages of the process, other than what we could share. The engineering alert was the key part of the early understanding of the issue. So the engineering alert went out in a very summary form of things to check. I'd written the document alongside the legal team …" (L017)
56	Commitment of individuals	Descriptions of actions of individual staff which go beyond the "9 to5" daily job e.g. working weekends, in Xmas holiday	"… but it was a testament to the number of people that right up there to the wire on Christmas Eve, and then subsequently still carrying on pieces through. Add onto that throughout the Christmas period and into the new year." (L002)
57	Pressure from parent company	Description of pressures (implied or actual) from parent company to be given info / get results etc.	"There was a bit of an external timeframe because we're part of a big group, so we had a bit of interest from the Europe level and the international level of somebody will be here in 2 weeks and they'll want a status update …" (L016)

58	Keeping it tight	When participants describe restricting or limiting communications in order to avoid distractions / whispers about the incident.	(talking about knowledge of the incident internally) "I think obviously the brand team are aware, because it's their brand, and you know they have a link with it as well, because they have to. Um, so kind of, the legally privileged minutes were obviously circulated to the chosen few, and then the rest, it was kind of, you know, we've got an issue but it's not a major issue, it's fairly low key, so don't go, you know, oh yes, by the way blah, blah, blah, it's only for those people, that kind of need to know basis kind of thing." (L004)
59	Recognition of risk	Descriptions of "recognition of risk" due to size of organisation, type of products etc.	"… when we make an error it's bigger, because we're a big business …" (L001)
60	Don't worry (about a thing)	Description / discussion of a lack of concern / worry about a situation; a lack of recognition by others of complexity of situation, amount of work required etc.	".. I think the people who were involved from a recall point of it, then forget how much work went into getting us back up as a site, and running …." (L009)
61	Teamwork	When participants describe working together (formal teams or informally), especially for problem solving	" .. we obviously have a risk register, and a risk management process, and (L001) and I are heavily involved in that with (name), our legal advisor, and again, we set up a risk committee, so it's got a core of (number) people …" (L002)
62	Expectation of improvement	When participants express an expectation of improvement in quality systems / processes, but have no actual knowledge of whether this has taken place	(Discussing operational restructure at the manufacturing site) "And it's the first time I've seen the alignment all the

			way from the SMC down, on what they want to achieve ... " (L014)
63	Goodwill	When participants favourably describe interactions with external organisations to aid in problems solving, resolution of the quality incident	(Explaining about preparation work carried out with website agency) "… and because it was Christmas Eve, they were closing at one, and no decision had been made by one o'clock, and they said, 'look, everything is built, all we need is the words, and just let us know, give us a ring and we can do it for you'. So I mean they bent over backwards for us, which was really sweet of them". (L004)
64	Single-mindedness	Description of "single-minded" approach to focus on just an individuals' area of expertise and / or just the issue to hand; and /or where a lack of interest in past or future events is described	"... I must say I wasn't involved in the actual how it was identified, so I don't know if it was identified here or whether it was identified at a customer, I don't really know …" (L014)
65	Not the experts	Description / discussion of a non-expert opinion being used as the basis for decision making , process change etc.	(Discussing the initial IRC meetings) "... you know at that meeting, so we had the meetings, we had certain medical opinions and possibly sort of opinions, claimed to be medical opinions but possibly weren't" (L005) "What do you mean by that?" (Interviewer) "I think people were, I think there was a certain amount of gathering of informal opinions from doctors and paediatricians, which I don't think were, you know, we should have considered under the banner of medical opinions, the proper medical opinions that we got for the purpose of informing our

			decision. You know, a little more conjecture in them …" (L005)
66	Speed vs accuracy	Description / discussion of a conflict between need for speed versus accuracy in decision making, problem solving process etc.	(Explaining about the set-up of the IRC) "… and we probably convened it too soon, really, before we had all the information. So a lot of the conversations that we had, were based on incomplete information." (L005)
67	Lack of trust	Description / discussion of a lack of trust / faith in actions, beliefs, behaviour of colleagues	(Describing communication to staff during incident investigation) "…so I think a lot of it they thought we were just keeping it all to ourselves, and we wanted people not to know about it." (L009)
68	Not my mission	When participants describe scepticism towards corporate mission statement, values etc. or express concern about interpretation of these across the company.	"so there's (Company mission statement strap line), yes, which is just [slightly derogatory term] as far as I'm concerned ..." (L005)
69	Dominant voices	Description / discussion of situations where a senior person dominates, forcing a certain decision / actions, even if they are not best placed in terms of expertise	(Participant discussing the decision as to whether the product needed to be recalled) "So that was the key thing but that actually took quite a long time in the circumstances for us to establish, because we had one really dominant voice, who was a very senior person, who had formed his own view, which kind of scared us ..." (L006)
70	Disconnect	When a description / discussion of disconnect between how different parts of the organisation work or operate	" …and I don't know if some of this goes back … [the] sort of era, where manufacturing made, quality inspected and released, and you had the silo

			compartmentalised, compartments, that resulted in actually having these almost like gulfs between areas…" (L014)
71	Not perfect is still OK	When participants describe / discuss situations where a reduction in product quality is seen as acceptable by the business	"...before this timeline we'd been seeing a bit of scoring, or what are called tails on the bottle. (explanation of what this looks like) .... It's not the best quality but on times it's acceptable." (L009)
72	Systems challenge	Description / discussion of situations when IT or other systems are not fully operationalised and so are 'unreliable' or difficult to use	(describing building a picture and tracing affected stock during quality incident) ""So, then it was looking at a picture on Monday of the time line, 'cos we had to try and build one, which turned out wasn't the easiest. The complications over it, and the biggest major complications was we have a SAP system on site, which we transitioned to (date)… from a financial point of view, but from a production point of view, I would suggest it was still in its infancy." (L009)
73	Feeling uncomfortable	When participants describe feeling uncomfortable or uneasy, having insufficient data or evidence to make decisions	(Describing the IRC and the push back from senior management). "Yes. Well, as I said, I've only been at LiquiComp UK 2 years, and done 3 IRCs, so that was the first time that the recommendation had been challenged enough to go back and then have a review. And a review was always necessary, but in terms of coming to a change of conclusion, that was the first time I've experienced that" (L007) "Right. Did it feel strange? How did everybody react to that?" (interviewer) "I think um, it

			didn't feel strange, I think that hindsight is an amazing thing, but wishing that we'd had more clear evidence would have enabled us to get to the second conclusion the first time round, but that's just the way it is. We didn't have enough evidence at the time and we made the decision based on what we knew on that day, in that room." (L007)
74	Size of issue	Descriptions / discussion of the size or scope of an issue	"so yes, come back in, back to reality, with a big problem to unpick. " (L016)
75	Feeling defensive	Descriptions / discussion of staff feeling defensive (about cause of issue, usual working practices etc.) or blaming others.	"... because if you think about it we weren't monitoring it correctly, the finished product. And then probably, the argument, and there was many of them, well why haven't the engineers not detected it (the equipment failure) when they're doing plant maintenance? Why is not been picked up?" (L009)
76	Quality / safety not first	Description / discussion of attitudes (staff or management) when quality and / or safety are seen as being secondary to other concerns	"So that probably if you asked them [line operatives] is it quality first, or manufacturing, they'd probably say, I think that was the biggest one coming out, that it's more manufacturing driven, it's trying to get the pop out the door, which I do understand, but you need to then shift the mind-set of them doing a target or targeted task, that their job description dictates, to then shifting them into a position that I'm now at a bench and I'm doing a quality check." (L009)

77	Desire for impartiality	Discussion / description of situations when 'impartial' analysis or investigation is required	"... my understanding is (pause), yes, actually, we had better have a third-party opinion, analysis, regarding this big incident. We already understood that was driven by the management people, so if management people were involved in this team we might have accused or blame some people, and then management people might have been defensive. So to avoid any negative aspects we had better create another team, a third-party team. " (L011)
78	Silo mentality	Discussion / description of parts of the organisation working remotely, separately, in silos. (NB Refers to sections / team rather than individuals)	"There is a gulf you know and um, you know a lot of people, I'd probably say there's less than a 100 people on this site who've been to (head office), have even see head office. Some people here probably couldn't even tell you where head office was …" (L014)
79	Competition not cooperation	Discussion / description by participants of parts of the organisation competing rather than cooperating	"… I don't know if some of this goes back … [the] sort of era, where manufacturing made, quality inspected and released, and you had the silo compartments, that resulted in actually having these almost like gulfs between areas. You know, and it creates this sort of very insular approach. And the way that (manufacturing site) was structured again, in my mind, you had 'ambients', with all the carbonate lines, then you had 'asceptics', with all the still lines, and you know they were like competitive cells, as well. So it created almost like a, little fortress mentality in some respects. And you know, there's 2 quite strong characters running each side of the

			business, and I think there was almost like a reluctance to lose face?" (L014)
80	Too nice	Discussion / description by participants of behaviours or attitudes of staff / management as being "too nice" to push for results"	(Discussing gathering information in the run up to and during the quality incident). "And unfortunately I don't think (previous Quality manager) to his credit, didn't necessarily have the strength of character to be able to push through that at times. I think there was a bit too much "nicey, nicey" about it sometimes." (L014)
81	Solidarity	Discussion / description by participants of company management or staff acting together and / or acting / planning for the future in a coordinated way	"You know, and a clear vision. And it's the first time I've seen the alignment all the way from the SMC down, on what they want to achieve …" (L014)
82	Finding excuses	Use this when participants describe or explain away others failures of behaviour; when they find reasons or excuses to accept or understand failure to meet standards etc.	".. maybe people weren't following processes that were there, or they were following part of them but not strictly to the letter of how everything should have been done. But then there's always reasons why people act in those ways you know. As I say, there was a lot of time pressure in that area because of how that area was structured, the number of people operating in the area. The sickness absence in that area as well meant that people were running 2 fillers at once which is, if you go down to line 2, you can see it's quite a busy area …" (L016)
83	Difficult times	Discussion / description of difficult or challenging times, particularly related to the quality incident	"Then you know, the incident which occurred back here in December, you know the morale, and that, how that impacted the site, you know from an engineering

			operational team, you can just, uh, it was a difficult place to be" (L017)
84	Health and Safety First	Discussion / description of health and safety being number one priority of the business (NB not food safety)	"I think the purpose of our organisation is obviously the health and safety and well-being of the guys on the line. The quality of the products as well, and then it goes into the cost, delivery etc." (L009)
85	Concern for failure	Discussion / description by participants of concerns about potential situations which could result in failures	(Describing QMS processes) "…What's not in our favour is the amount of volume we've got to get through, which makes it a very, very busy endeavour. What we don't do, and should be doing more of, is packaging related quality analysis …" (L001)

Appendix C: Example of N-Vivo Coding

Coding example for Participant L005

there's no right or wrong answers, um, you might think I'm slightly mad at some stages, in terms of what I ask

A005: umm

I: but you know what I'm trying to do is get information on the incident and the company from lot's of different view points, because obviously everybody's view point is slightly, you know, it's unique to you. Um, so the first thing I'd like to do, is if you could actually walk me through from your perspective about the incident with the cocked caps. So I'd like to understand what happened and what the organisation did, so, you know, when did you first hear of it, if you can, I know it's casting your mind back a few months now, um, but just you know, tell me the story, in your words.

A005: U I I guess, I guess I heard from from from our Quality Director that um that we may do on it, that's the first I heard about it, and that would usually be the first time that I'd hear about it.

I: OK

A005: Um, I might, you you know, uh, there are els of management. There's the kind of local incident committee we hav and there's th committ have and and I I can sometimes be involved in th I'll always be involved in th So, yes, so, so, (A001) highlighted it to me as potential incident, and um, and um uh explained explained what we'd been finding.

I: yes

A005: not in a great deal of detail, not with any particular cause, so, so, um, at the (clears throat) at the early stages I'm not particularly interested in kind of how it happened, I'm kind of interested in sort of what the, how it presents itself. Because , from from my perspective I'm only interested in whether or not, well fundamentally, whether or not it's it's a technical breach of the Regulation 178 that I need to notify the Food Standards Agency about. Um, it was, it it it ah, so we knew it was a foreign body, so foreign bodies yes, you kind of you kind of, they're sort of difficult ones to judge, foreign bodies, really.

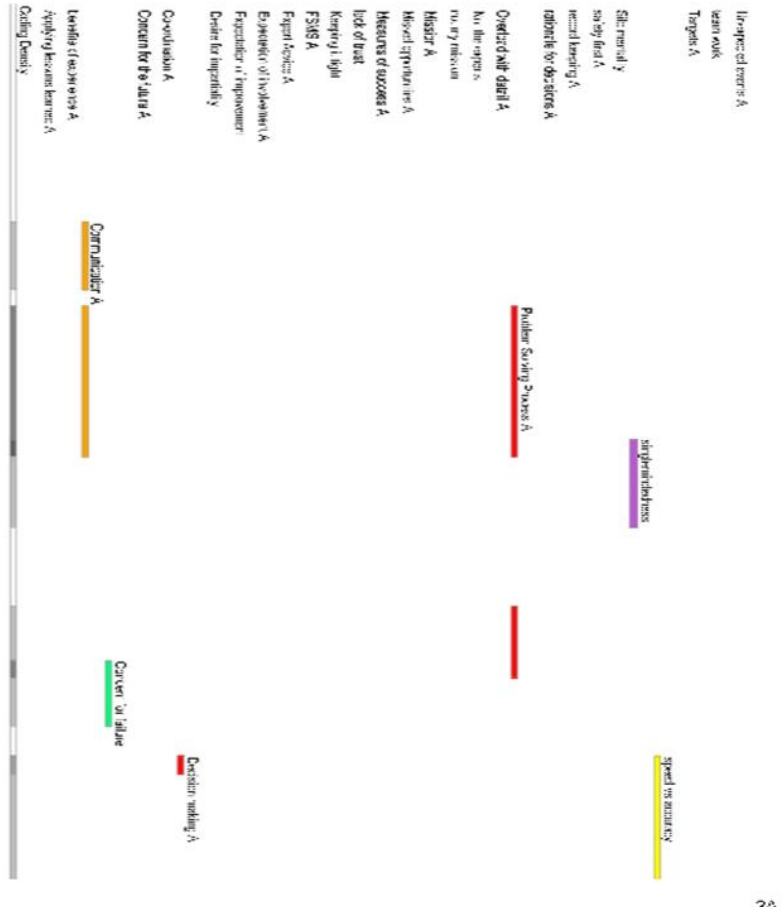
I: yes

A005: Um, yes, you know, some things, bits of glass, you can categorise them fairly simply, but other things you know, whether you know it's undoubtedly, you know, there is that that is an undesirable thing, but the extent to which its its going to cause a a safety issue, a technical breach of the Regulation is harder to judge. Um, I found out about it just before Christmas, what I was, (clears throat) what I was I mean **just** before Christmas, and so what I was worried about was um managing an incident over Christmas

I: yes

A005: so actually I was I was quite keen to make quick decisions, and get people around quickly, just because I could, you know, it's difficult to manage these things over a weekend, but over

I: yes



A005: the Christmas break is just going, it's just going to be a nightmare. So I was pushing quite hard for a bit, so

I: yes

A005: so, so (clears throat)

I: Do you know how the incident was originally found?

A005: no.

I: OK.

A005: um

I: So your first knowledge of it was A001 coming to you and going "(A005) we've got .."

A005: this is what we've got,

I: Houston we've got a problem

A005: yup. This is what we've got, um, so, so I was quite keen to um, I was quite keen to um to have a have uh to complete the firs meeting quickly.

I: yes

A005: which which we did, I think everyone was keen to do that, it wasn't just me. Uh, and we probably convened it too too soon, really before we had all the information. So a lot of the conversations that we had um, um, were were based on sort of incomplete information.

I: OK,

A005: And we had, you know at that meeting, so we had the meetings, we had certain medical opinions and possibly sort of opinions, claimed to be medical opinions, but possibly weren't and, um,

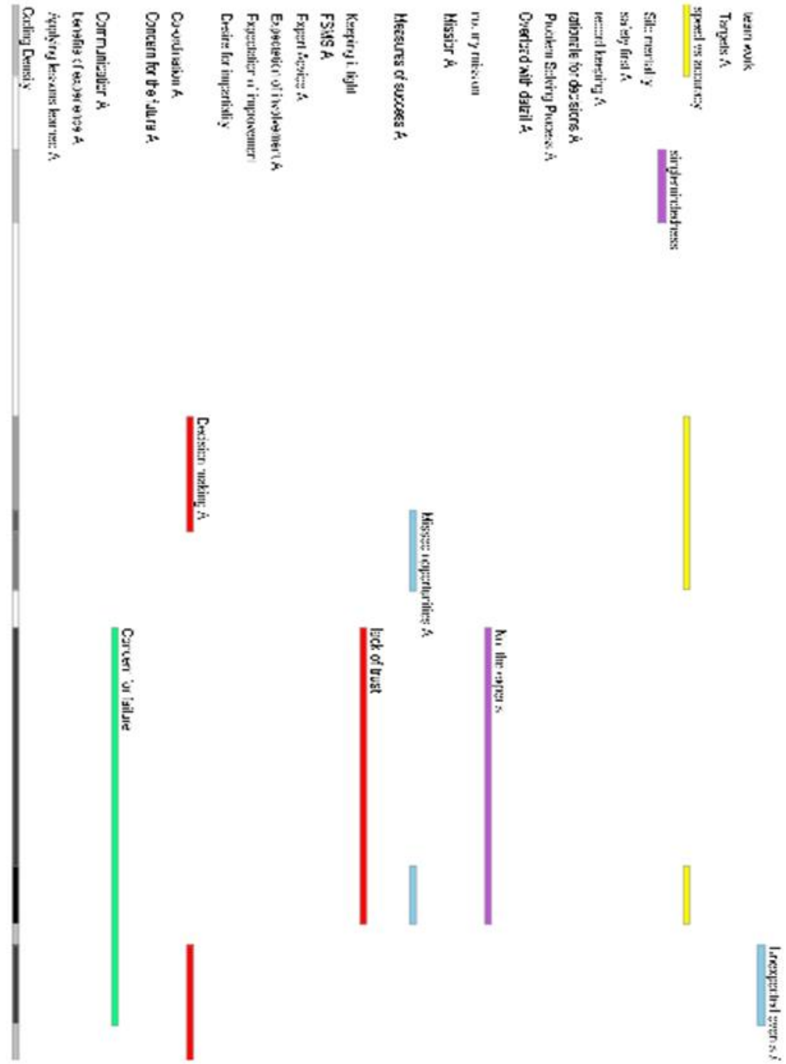
I: what do you mean by that?

A005: Uh I think, I think people were were um, I think there was a certain amount of gathering of sort of informal opinions from doctors and paediaticians, which I don't think were, you know, we should have considered under the under the banner of medical opinions, the proper medical opinions that we we got for the purpose of informing our decision,

I: OK
A005: you know, a little more conjecture in them. Um, and um yes, so, I don't think the quality of the information we had was really good

I: OK
A005: and therefore because we were trying to get to a decision at tha , which was just before Christmas, um, then I think we probably made the wrong recommendation to start with.

I: And what was that?

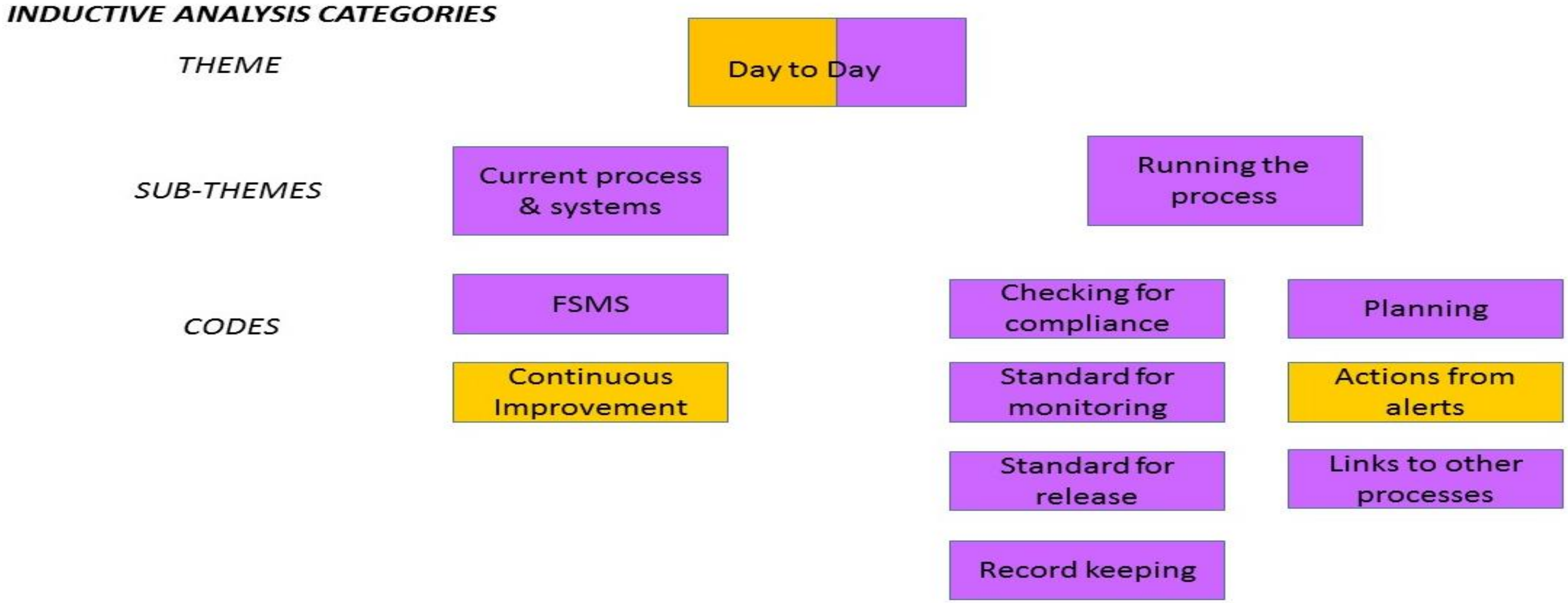


Appendix D: Mapping of Codes and Themes to PC Dimensions

PC Dimension

Facts	Communication	*	Code from LiquiComp UK case only
Values	Possibilities	**	Code from PowderCo UK case only

PC Dimension: Facts



INDUCTIVE ANALYSIS CATEGORIES

THEME

This is what went wrong

CODES

Age of equipment

Problem identification

Reasons for failure

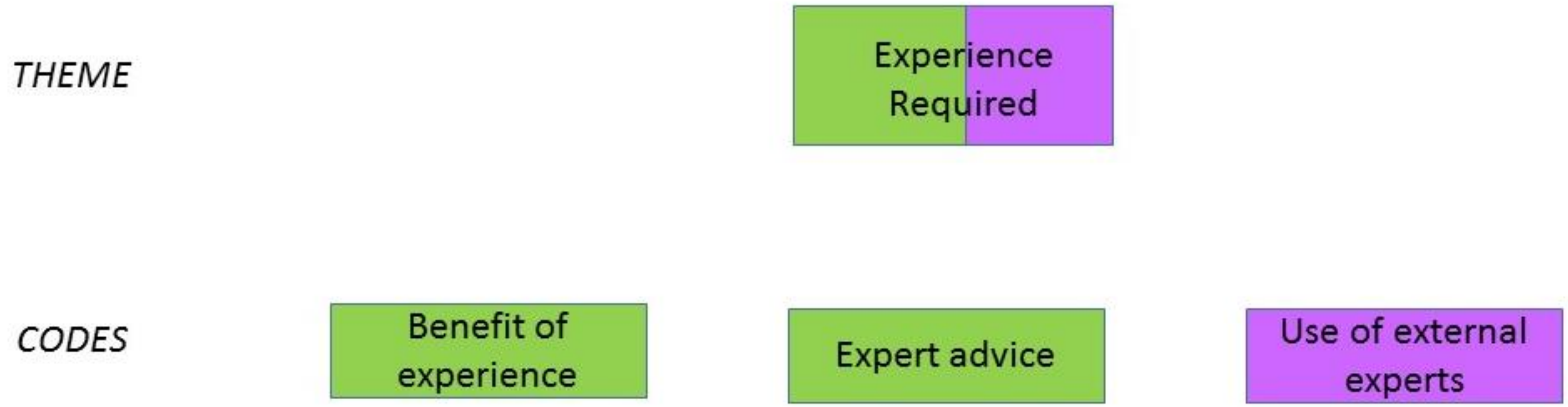
Unexpected events

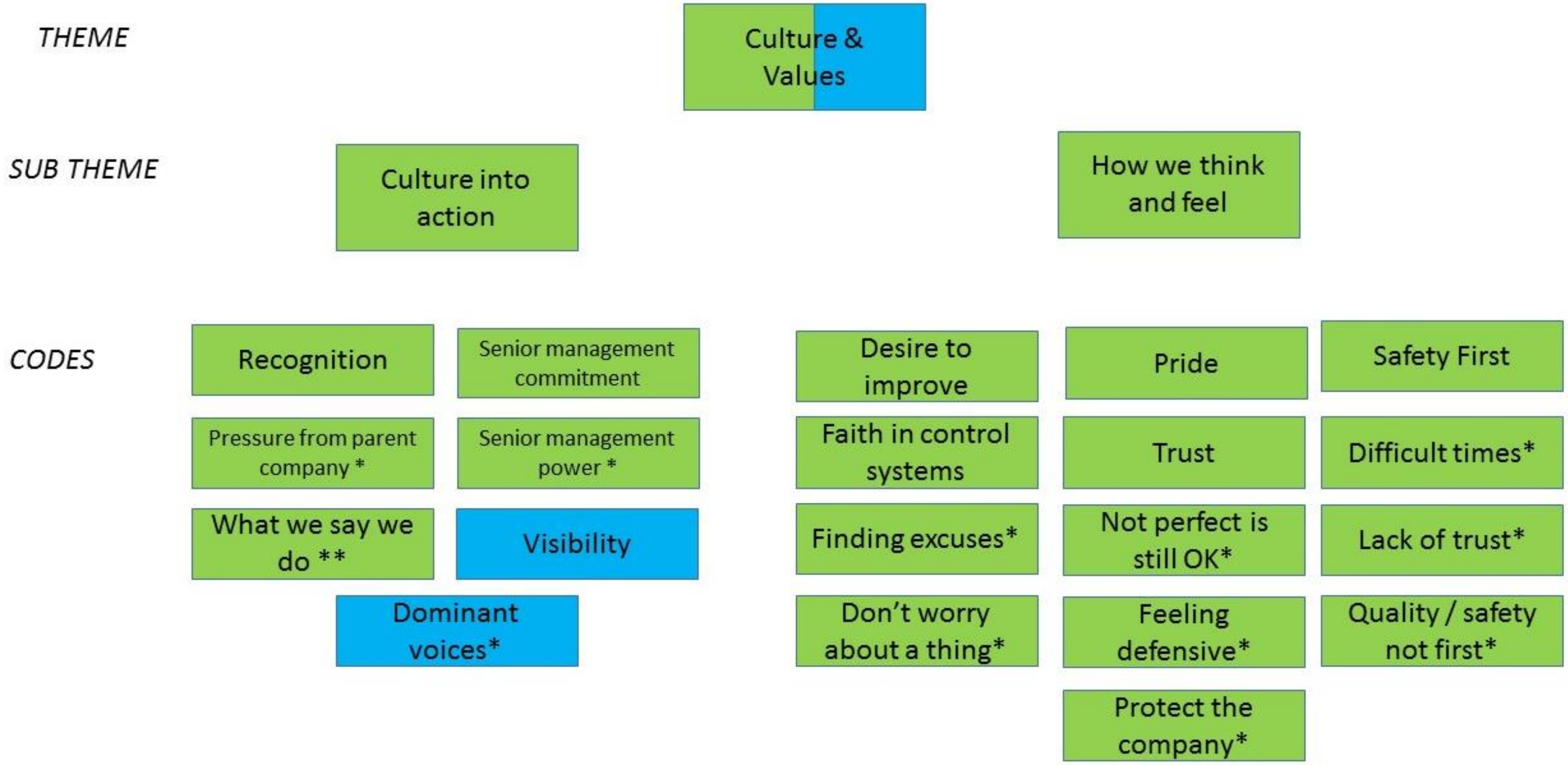
Recognition of risk *

Size of issue *

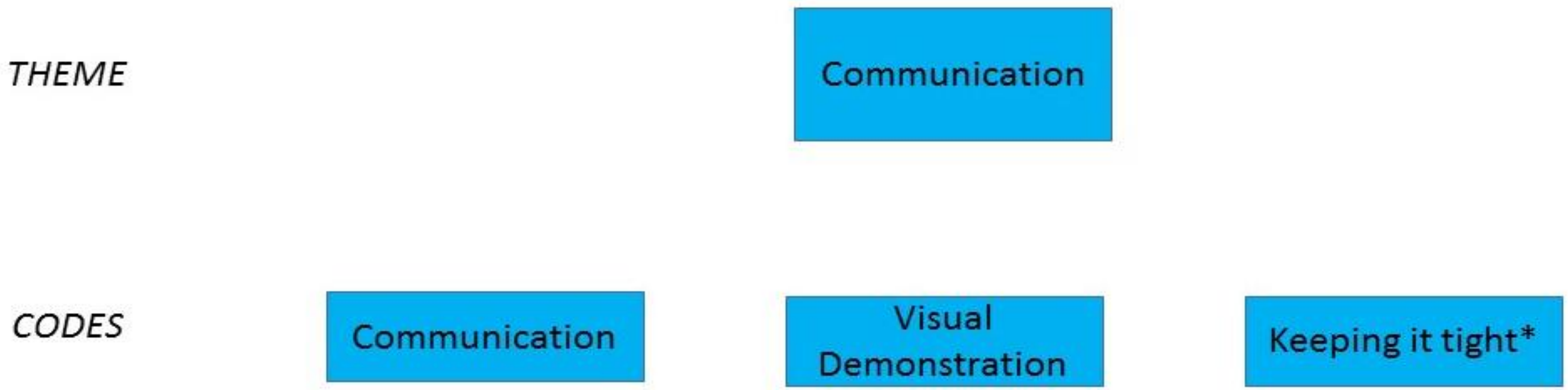
PC Dimension: Values

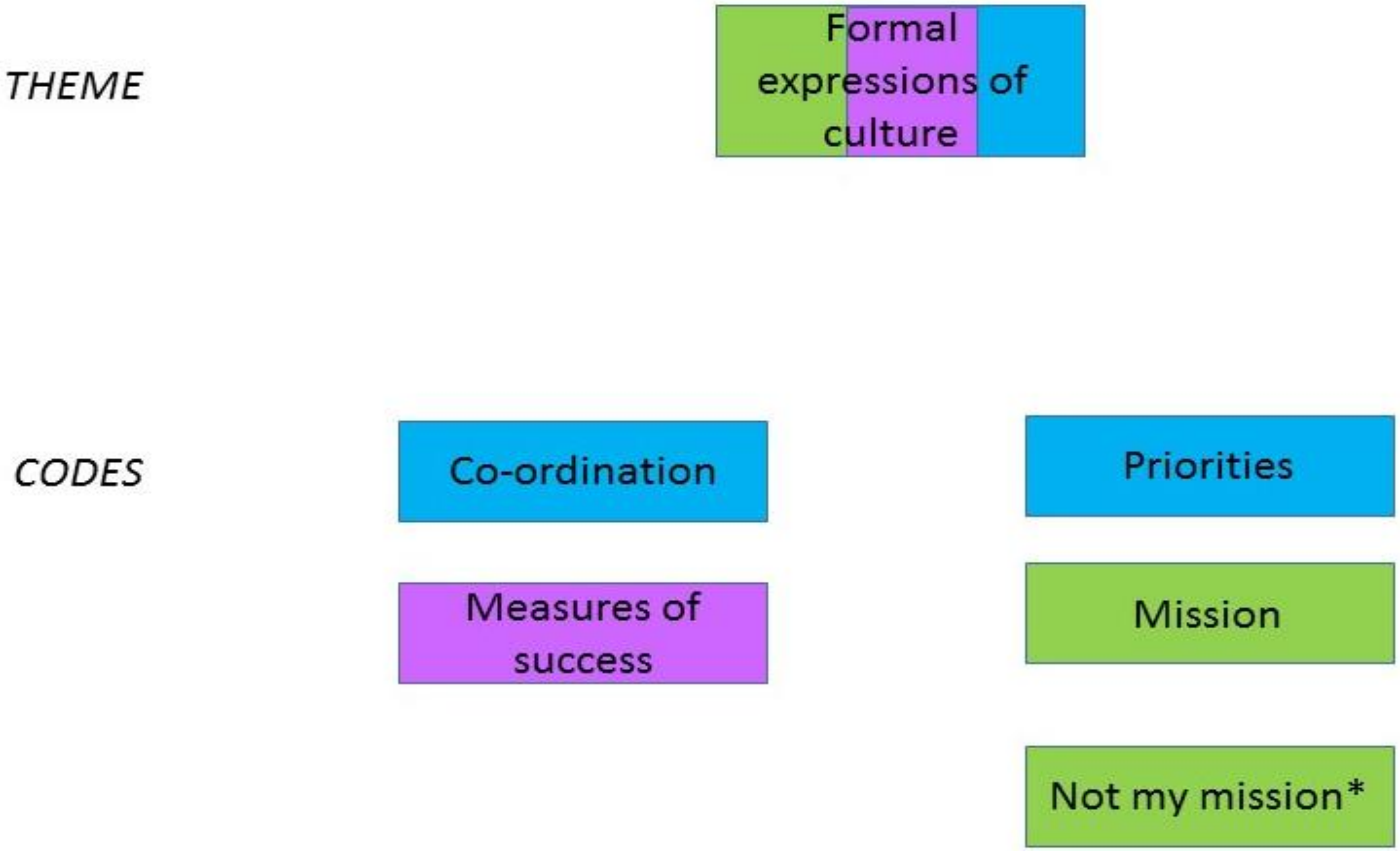
INDUCTIVE ANALYSIS CATEGORIES



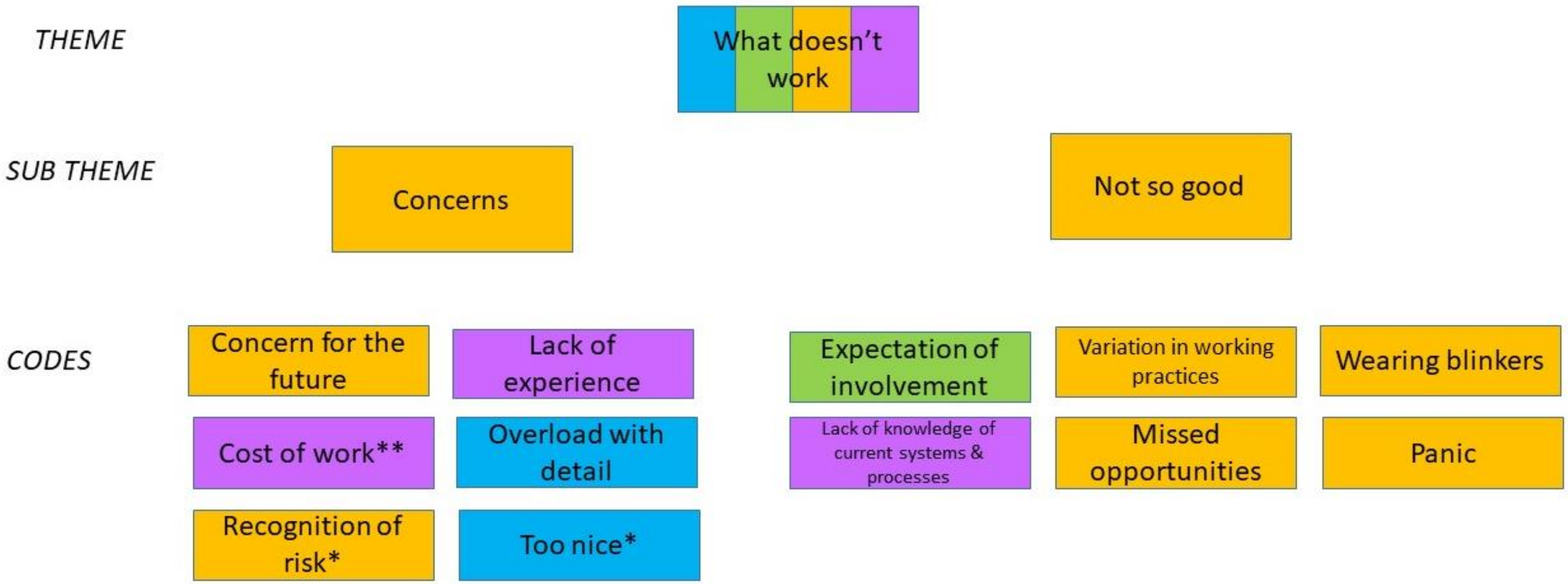

THEME
Culture & Values
SUB THEME
Culture into action
How we think and feel
CODES
Recognition
Senior management commitment
Pressure from parent company *
Senior management power *
What we say we do **
Visibility
Dominant voices*
Desire to improve
Faith in control systems
Finding excuses*
Don't worry about a thing*
Pride
Trust
Not perfect is still OK*
Feeling defensive*
Protect the company*
Safety First
Difficult times*
Lack of trust*
Quality / safety not first*

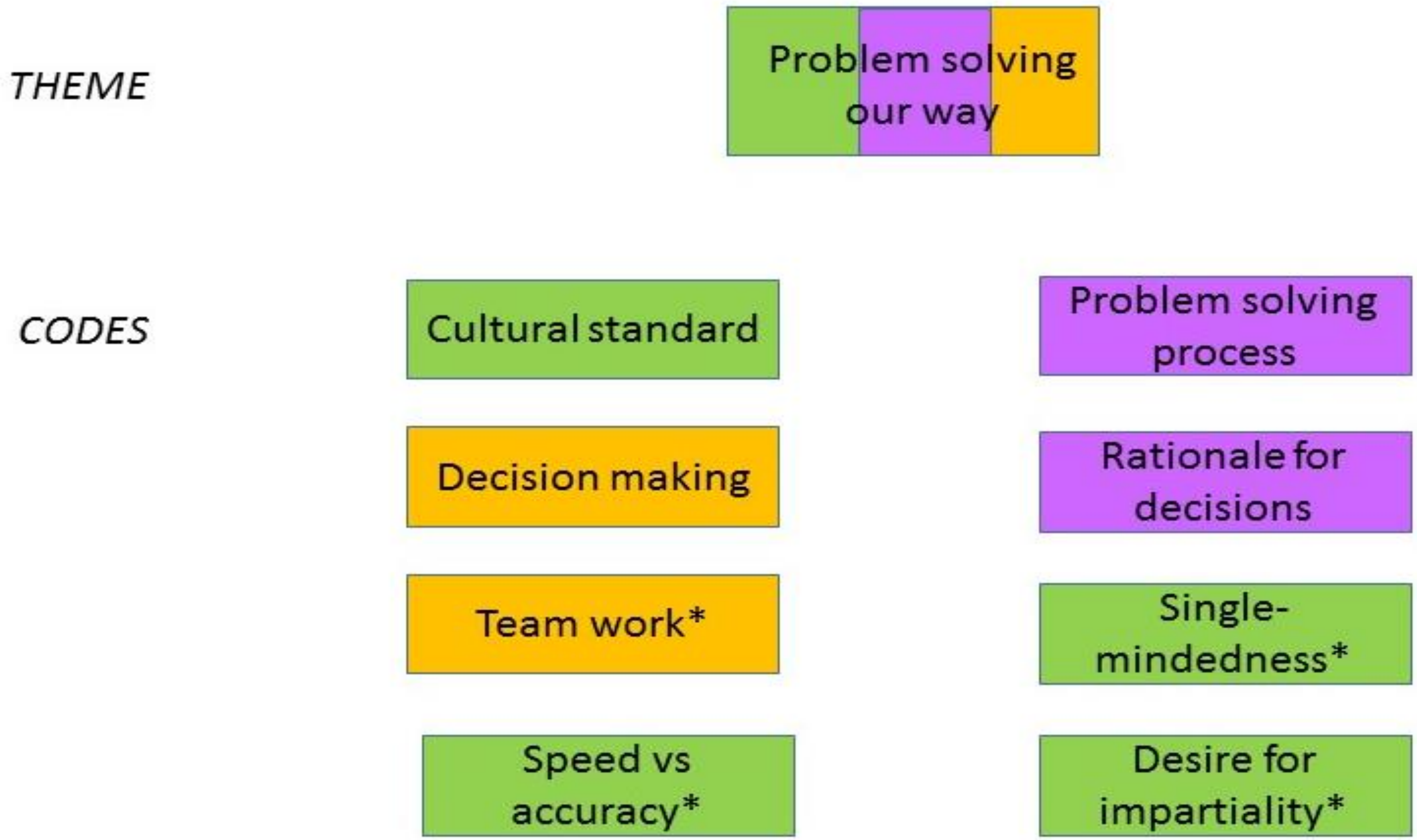
PC Dimension: Communication

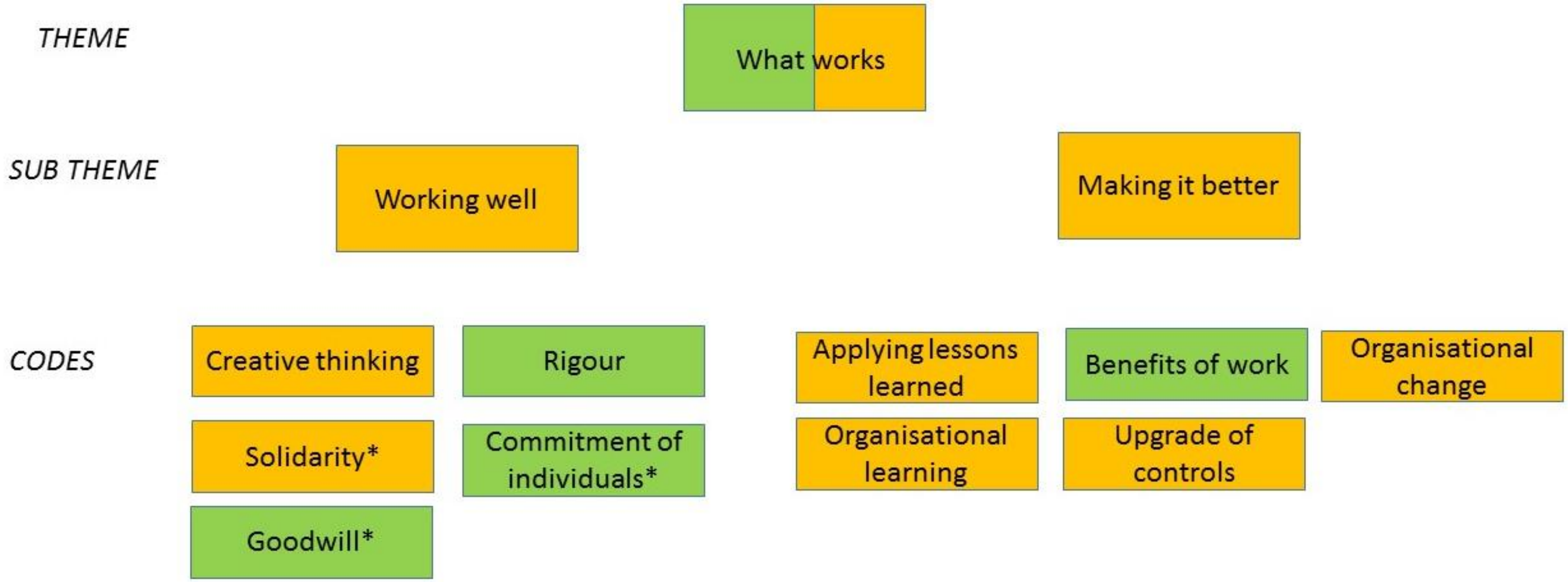



THEME
Formal expressions of culture
CODES
Co-ordination
Priorities
Measures of success
Mission
Not my mission*

PC Dimension: Possibilities




THEME
Problem solving our way
CODES
Cultural standard
Problem solving process
Decision making
Rationale for decisions
Team work*
Single-mindedness*
Speed vs accuracy*
Desire for impartiality*


THEME
What works
SUB THEME
Working well
Making it better
CODES
Creative thinking
Rigour
Solidarity*
Commitment of individuals*
Goodwill*
Applying lessons learned
Benefits of work
Organisational change
Organisational learning
Upgrade of controls

Appendix E: Organisation Invitation Letter, Information Sheet and Consent Form

Research Student: Sally-Ann Krzyzaniak,
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First supervisor: Professor Lisa Jack,
Accounting and Financial Management,
Portsmouth Business School, University of Portsmouth,
Richmond Building, Portland Street,
Portsmouth, PO1 3DE.
Tel: 023 9284 4136
Email: lisa.jack@port.ac.uk.

Date: 14th August 2015

PhD Study: Request for Company Participation

Study Title: Key determinants for the governance of food safety in food business organisations.

REC Ref No: 338

My name is Sally-Ann Krzyzaniak. Following a career working as a nutritionist and regulatory affairs expert in the food industry I am now studying for my PhD at the University of Portsmouth and am conducting research on the management of food safety in the food industry.

I am interested in working with a small number of food and drink companies to conduct case study research examining their food safety management and monitoring processes and practices. If a company has experienced a food safety or quality incident in the past, I am also interested in exploring this past incident. I am interested purely in studying any past incident and current practices from a management perspective – I will not be conducting a quality or food safety audit.

As my research will be undertaken as a case study, it will involve studying a range of published documents (e.g. HACCP plans, food quality charters, incident management meeting minutes), observing current working practices (e.g. through a production site tour) and undertaking a series of semi-structured interviews and / or focus group discussions with members of staff who have relevant responsibilities in the running of the food safety management system today (the exact format will be agreed with yourselves). The interviews / focus group discussion involve a series of questions being asked of the interviewees, which may be modified slightly from one interview to another depending on the responses of the interviewees. All the questions will be related to the systems used to manage and monitor food safety, to the organisational culture of the firm and if appropriate, to any past food safety or quality incidents. The time taken for the research work will vary with the exact access and research method agreed (approx. 1 hour per individual interview) and I am happy to discuss this further.

All information provided to me as part of the study will be held securely. At the end of the study a short report will be provided to company management, but no individual data will be disclosed – participant names and job titles will not be used in any report. In the same way all data will be anonymised so that no reference to individuals' names or job titles, to the company name or product names will appear in any academic publication.

Please contact me if you are interested finding out more about this research (my email address and mobile phone number are given above). Taking part in the research is voluntary so the company and any individual may withdraw consent at any point prior to the data being analysed. Nobody is under any obligation to participate, and there will be no negative consequences should they withdraw from the study.

Thank you for reading this letter. Please feel free to contact me if you have any further questions.

Sally-Ann Krzyzaniak, BSc (Hons) Nutrition, MBA

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First supervisor: Professor Lisa Jack,
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Portsmouth, PO1 3DE.
Tel: 023 9284 4136
Email: lisa.jack@port.ac.uk.

Date: 14th August 2015

Participant Information Sheet: Organisations

Study Title: Key determinants for the governance of food safety in food business organisations.

REC Ref No: 338

I would like to invite your organisation to take part in my PhD research study. Before you decide, I would like you to understand why this research is being done and what it would involve for you and your organisation. Please feel free to discuss this with colleagues and please contact me if there are any points that are not clear.

What is the purpose of this research?

This purpose of this research is to study the management of food safety in the food industry and the management and monitoring systems which companies use to do this.

All food businesses are expected by their customers and by the authorities to produce safe food. However, there are still a high number of food safety incidents reported every year to the Food Standards Agency (FSA) (over 1500 in 2013) and many people continue to become ill because of eating unsafe food.

This research is important as it will study the food safety management and monitoring systems and incident management processes used by a small number of companies, together with gathering an understanding of the culture of the companies – what is important to the company and staff and how is this measured. If the company has experienced a food safety or quality incident in the past, and is willing to discuss this, I would like to understand this incident from a management perspective i.e. what the company did when it discovered the issue and what investigations it undertook.

Why has my organisation been invited?

A number of companies of different sizes and in different sectors of the food industry have been invited to take part in the research.

Does my organisation have to take part?

It is up to the organisation to decide whether to participate in the study. I will describe the study and go through this information sheet. If your organisation agrees to take part, I will ask you to sign a consent form on behalf of the company. I will then ask you to help me to identify and contact relevant people within the company to participate in the research study, and will seek their consent to participate.

Participation in this research is purely voluntary and both the company and individual participants may withdraw at any stage prior to the data being analysed. Participants are under no obligation to participate and there will be no negative consequences if they withdraw.

What will happen to the organisation and our staff if we take part?

I will ask the organisation to help me identify relevant staff and management to participate in the study.

Individuals will be asked to take part in an individual interview or a focus group discussion with other colleagues to express their personal experience and views on this subject matter. A list of questions will be asked to the interviewees, and the questions might be changed slightly from one interview to another depending on the response of the interviewees. The interviews will be audio recorded, and the interviews might take up to an hour. I may request extra time to discuss more issues if required.

I will also be asking the company to provide documents which give additional information on the discussion topics (for example, a copy of the company HACCP plan and incident management policy) and for a short escorted tour of relevant production facilities, so that I can best understand the food safety management and monitoring systems in use. I may therefore require some additional time from some members of staff or management who are participating in the study to help me gather this information. If relevant, I may also ask permission to attend certain regular meetings (e.g. quality briefings), to help familiarise myself with the company, its products and the food safety management and monitoring systems used.

A final part of the study is to work with selected organisations to develop a monitoring system for food safety culture (using direct or proxy measures of food safety culture). This would involve working closely with a relevant member of the quality or food safety team to design and trial any agreed measures, and to review the success of the trial after an agreed period (around 3 months). Individual staff, after giving their informed consent, will be asked to review the success of implementation by means of a short questionnaire.

Both organisation and individual consent forms emphasise that the information collected might be shared with authorised people for academic purposes. Collected data (recorded interviews, copies of documents) will be transferred to a computer. All computer files will be password-protected and the recorded interviews will be immediately erased from the recording device. The consent form will also include that the information collected will be saved securely as it might be needed for future academic publications (PhD thesis, journal articles, book chapters, conference presentations). As soon as the research and the publications are completed all data collected will be erased.

A short report of my results will be provided to the company. Individual participants will not be identified by name or job title in this report or in my PhD thesis and any other academic publications. The organisation's name and its brands will also be disguised in my PhD thesis and any other academic publications.

Expenses and payments

All interviews and other data collection will be scheduled to take place at times and locations convenient participants, within their normal place of work. I am afraid I can offer no expenses to the organisation or to individual participants. However, the organisation will be supplied with two short reports of my findings, one specific to your individual organisation and a second summarising my findings across all participating organisations.

What will the company and staff have to do?

If the company decides to accept this invitation and returns the signed consent form, I will contact you to arrange dates and times to visit relevant facilities to conduct the research.

Once individual participants have been contacted, and have agreed to participate and signed consent forms, I will arrange a convenient time and place to meet with them for the interview / focus group discussions, when I will ask questions relating to the subject matter.

All interviews will be carried out in a quiet environment for recording purposes.

Each interview should take approximately an hour. Additional time will be required with any staff / management who are asked to help me locate certain documents and / or to escort me on a factory tour.

One or two of the companies I am working with will be asked to help set up and evaluate a new food safety measure. The exact time requirements for this may vary depending upon the measures devised. Any staff that are affected may be asked, after giving their informed consent, to complete a short questionnaire to get their views on the new measures, which should take only a short time to complete.

What are the possible disadvantages and risks of taking part?

There are no significant risks of taking part in this research.

Staff involved in the research will be asked to commit a small amount of time to the research study (approximately 1 hour per interview, plus additional time to help with gathering documents etc.). All interviews, factory site visits etc. will be organised to minimise disruption to the work of participants.

The reputation of the company will be protected by ensuring the anonymity of the company, its brands and its staff in all publications. The organisation and its brands will only be identified the company specific report. In all other reports and academic publications, the company and its brands will not be identified. The names and job titles of all participating individuals will not be given in academic publications or in any reports supplied to participating companies. All data collected will be held securely to ensure the confidentiality of the company and its staff.

Although the researcher will not be conducting a quality or food safety audit on current practices, research participants may raise concerns about the food safety of current working practices. Prior to the research commencing, the researcher will work with the management of the organisation to establish a secure and confidential means for participants to report any such concerns. The researcher will ensure that such information is not included in the research in any way.

What are the possible benefits of taking part?

The possible benefits of this research are that we will have a fuller understanding of what companies do when they discover a food safety incident, what food safety monitoring systems are in use in companies and how company culture impacts on food safety. These findings will help inform the food industry and enforcement authorities of best practice so that improvements in food safety can be made by the industry.

As an individual company this work gives you the opportunity to evaluate current food safety management and monitoring systems, incident management policies and the organisational food safety culture. Should a food safety or quality incident be examined, the research would give the opportunity to reflect on actions taken to manage this incident. There may also be the opportunity to develop and evaluate a monitoring system for food safety culture, which can be seen as an advantage in a highly competitive industry sector.

Will our participation be kept confidential?

Input into the research will be kept confidential, both from a company and individual perspective. Collected data (recorded interviews and documents) will be transferred to a computer and all computer files will be password-protected. The recorded interviews will be immediately erased from the recording device. All collected information will be kept in password-protected folders on a secure University computer drive. Any handwritten notes taken during the study will be kept in a secure, locked location. At the end of the study they will be scanned and kept on the secure computer drive with the other data, and all hard copies will be disposed of securely.

The consent form will emphasise that the information might be shared with authorised people for academic purposes. All will have a duty of confidentiality to you as a research participant and will do their best to meet this duty.

The consent form will also state that the information collected will be securely saved as it might be needed for future publications. Once the research and the publications are completed all data collected will be erased.

What will happen if the company or any individual does not want to carry on with this study?

When you give your consent for the company to participate, it is understood that circumstances may change and that you may no longer wish to carry on with the study. You may withdraw your consent for the company to participate at any time prior to the time of results being analysed. You will not be compelled to give a reason for leaving. On leaving the study, all the information you have provided will be deleted.

Likewise, should any individual decide that they no longer with to carry on with the study, they may withdraw their consent at any time prior to the time of results being analysed. They will not be compelled to give a reason for leaving the study and any information they have provided will be deleted.

What if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researcher; Sally-Ann Krzyzaniak (023 9284 4831/ sally-ann.krzyzaniak@myport.ac.uk) or my supervisor Professor Lisa Jack (023 9284 4136/ lisa.jack@port.ac.uk) who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can contact Rd. Judy Rich, Faculty Research Degree Coordinator (023 9284 4048 / judy.rich@port.ac.uk).

What will happen to the results of the research study?

The results of the study will be published in a PhD thesis and available at the University library. It is also hoped that the results will produce journal articles, book chapters and academic conference presentations, which again, will be available via the library electronic resources. Neither the company, its brands nor any individuals working for the company will be identifiable from the results in any document. Once the research and the publications are completed all data collected will be deleted.

Who is organising and funding the study?

This research is sponsored by the University of Portsmouth.

Who has reviewed this study?

Research in the University is looked at by an independent group of people, called the Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the Portsmouth Business School Research Ethics Committee.

If your organisation has its own ethics procedure which would relate to this research, please contact the researcher, Sally-Ann Krzyzaniak, by telephone or email (07890 607932 / sally-ann.krzyzaniak@myport.ac.uk) so that we can discuss how to apply for the appropriate company approvals prior to any research starting.

Further information and contact details

If you would like to know the further details of research in the University, please follow the following link to the University of Portsmouth research website: http://www.port.ac.uk/research/

If you would like details on the research carried out in the Portsmouth Business School, please follow the following link to the Portsmouth Business School research website;

http://www.port.ac.uk/departments/faculties/portsmouthbusinessschool/research/

If you would like further information about this project, please contact the researcher;

Sally-Ann Krzyzaniak, **Tel**: 07890 607932 **Email**: sally-ann.krzyzaniak@myport.ac.uk

Thank you for taking the time to read this document. Hopefully it has answered all of your questions, but if not please get in touch. If the company decides to participate in this research you will be given a copy of this information sheet to keep and you will be asked to sign a consent form.

Research Student: Sally-Ann Krzyzaniak,
Portsmouth Business School Postgraduate Centre,
University of Portsmouth,
Portland Building, Portland Street,
Portsmouth, PO1 3AH.
Tel: 023 9284 4831 / Mobile 07890 607932
Email: sally-ann.krzyzaniak@myport.ac.uk.

First supervisor: Professor Lisa Jack,
Accounting and Financial Management,
Portsmouth Business School, University of Portsmouth,
Richmond Building, Portland Street,
Portsmouth, PO1 3DE.
Tel: 04423 9284 4136
Email: lisa.jack@port.ac.uk.

Company Code:

University of Portsmouth

Consent Form: Organisation

Study Title: Key determinants for the governance of food safety in food business organisations.

REC Ref No: 338

Name of Researcher: Sally-Ann C Krzyzaniak

Please initial box

I confirm that I have read and understood the information sheet dated 14/08/2015 for the above study. I have had opportunity to consider the information, ask questions and have these answered satisfactorily.

I understand participation is voluntary and that I am free to withdraw company consent at any time without giving any reason, up to the point where the data is being analysed.

I agree that the information collected during the study can be shared with authorised people for academic purposes.

I agree to the data I contribute being stored securely, until all academic publications (PhD thesis, journal articles, book chapters and conference presentations) have been completed.

I confirm that I have the authority to give consent for the company to participate in this research.

I agree to the following types of data being collected by the researcher: copies of documents (e.g. site quality and HACCP plans; minutes of meetings; photographs of documents); interviews or focus group discussions with relevant company personnel.

I agree to information on food safety / quality incidents being collected by the researcher

I confirm that I have discussed with the researcher company policies for raising food safety concerns and have agreed a secure and confidential procedure for employees to utilise during the research study.

I agree to working with the researcher to develop, implement and review the success of a monitoring system for food safety culture (using direct or proxy measures of food safety culture).

I agree to the company …………………………..taking part in the above study.

Name of Participant: ....

Signature: ....   **Date**: ....

Name of person taking consent: ....

Signature: ....   **Date**: ....

(When completed, one copy to be retained by participant; 1 copy for researcher's file)

Appendix F: Individual Invitation Letter, Information Sheet and Consent Form

Research Student: Sally-Ann Krzyzaniak,
Portsmouth Business School Postgraduate Centre,
University of Portsmouth,
Portland Building, Portland Street,
Portsmouth, PO1 3AH.
Tel: 023 9284 4831 / Mobile 07890 607932
Email: sally-ann.krzyzaniak@myport.ac.uk.

First supervisor: Professor Lisa Jack,
Accounting and Financial Management,
Portsmouth Business School, University of Portsmouth,
Richmond Building, Portland Street,
Portsmouth, PO1 3DE.
Tel: 04423 9284 4136
Email: lisa.jack@port.ac.uk.

Date: 14th August 2014

Invitation Letter: Request for Participation

Study Title: Key determinants for the governance of food safety in food business organisations.

REC Ref No: 338

Dear Potential Participant

My name is Sally-Ann Krzyzaniak. I am a PhD student and am conducting research on the management of food safety in the food industry and the management and monitoring systems which companies use to do this.

I will be working with a small number of food manufacturing companies to ask questions about their food safety systems and practices and their organisational culture.

It has been identified that you might be a possible key contributor to this research. I would therefore like to invite you to participate in the research study, on which more information is provided in the enclosed information sheet.

During the research I will be undertaking a series of semi-structured interviews and / or focus group discussions. These involve a series of questions being asked of the interviewees, which may be changed slightly from one interview to another depending on the response of the interviewees. All the questions will be related to the systems used to manage and monitor food safety, to report food safety or quality incidents and to the organisational culture of the firm. It is expected that an interview would take around an hour of your time.

All information provided to me as part of the study will be held securely. At the end of the study a short report will be provided to company management, but no individual data will be disclosed – participant names and job titles will not be used in any report. In the same way all data will be anonymised so that no reference to your name or job title, your company name or product names will appear in any academic publication.

Please contact me via email or phone if you are interested in taking part in this research. Taking part in the research is voluntary so you may withdraw your consent at any point prior to the data being analysed. Participants are under no obligation to participate, and there will be no negative consequences if they withdraw from the study.

Thank you for reading this letter. Please feel free to contact me if you have any further questions.

Yours faithfully,

Sally-Ann Krzyzaniak

Research Student: Sally-Ann Krzyzaniak,
Portsmouth Business School Postgraduate Centre,
University of Portsmouth,
Portland Building, Portland Street,
Portsmouth, PO1 3AH.
Tel: 023 9284 4831/ 07890 607932
Email: sally-ann.krzyzaniak@myport.ac.uk.

First supervisor: Professor Lisa Jack,
Accounting and Financial Management,
Portsmouth Business School, University of Portsmouth,
Richmond Building, Portland Street,
Portsmouth, PO1 3DE.
Tel: 023 9284 4136
Email: lisa.jack@port.ac.uk.

University of Portsmouth

Date: 14th August 2015

Participant Information Sheet: Individuals

Study Title: Key determinants for the governance of food safety in food business organisations.

REC Ref No: 338

I would like to invite you to take part in my PhD research study. Before you decide, I would like you to understand why this research is being done and what it would involve for you. Please feel free to discuss this with colleagues, friends or family if you wish and please contact me if there are any points that are not clear.

What is the purpose of this research?

This purpose of this research is to study the management of food safety in the food industry and the management and monitoring systems which companies use to do this.

All food businesses are expected by their customers and by the authorities to produce safe food. However, there are still a high number of food safety incidents reported every year to the Food Standards Agency (FSA) (over 1500 in 2013) and many people continue to become ill because of eating unsafe food.

This research is important as it will study the food safety management and monitoring systems and incident management processes used by a small number of companies. I am also interested in understanding the culture of the company – what is important to the company and staff and how is this measured. If your company has experienced a food safety or quality incident in the past, and the management of the organisation has agreed for me to discuss this, I may also ask you questions on this topic.

Why have I been invited?

You are identified as a possible key contributor in the present research due to your knowledge of and use of the food safety processes used by your company.

Do I have to take part?

It is up to you to decide to participate in the study. I will describe the study and go through this information sheet. If you agree to take part, I will ask you to sign a consent form.

Participation in this research is purely voluntary and you may withdraw at any stage prior to the data being analysed. Participants are under no obligation to participate and there will be no negative consequences if they withdraw.

What will happen to me if I take part?

You will take part in an individual interview or a focus group discussion with other colleagues to express your personal experience and views on this subject matter. A list of questions will be asked to the interviewees, and the questions might be changed slightly from one interview to another depending on the response of the interviewees. The interviews will be audio recorded, and the interviews might take up to an hour (an hour and half for a focus group). I may request extra time to discuss more issues if required. I may also ask you to provide documents which give additional information on the discussion topics (for example, a copy of the company HACCP plan) and / or to escort me on a short tour of the relevant production facilities.

The consent form emphasises that the information might be shared with authorised people for academic purposes. Collected data (recorded interviews, copies of documents) will be transferred to a computer. All computer files will be password-protected and the recorded interviews will be immediately erased from the recording device. The consent form will also include that the information collected will be saved securely as it might be needed for future academic publications (PhD thesis, journal articles, book chapters, conference presentations). As soon as the research and the publications are completed all data collected will be erased.

A short report of my results will be provided to the company. Neither you nor any other participant will be identified by name or job title in this report and none of the responses you provide will be reported in a form that can be used to identify you. The same rules will apply in my PhD thesis and any other academic publications, and additionally the name of the company and its brands will also be disguised.

Expenses and payments

The interview will be take place at a time and location which is convenient to you at your place of work. I am afraid I can offer no expenses for your participation.

What will I have to do?

If you decide to accept this invitation and return the consent form, I will contact you to arrange a convenient time and place to meet with you for the interview / focus group discussion, when you will be asked questions relating to the subject matter.

The interview will be carried out in a quiet environment for recording purposes.

The interview should take approximately an hour of your time (an hour and a half for a focus group). If you are asked to help me locate certain documents and / or to escort me on a factory tour, this may take up to another hour of your time.

One or two of the companies I am working with will be asked to help set up and evaluate a new food safety measure. If you are affected by this, you may be asked to complete a short questionnaire to get your views on the new measures.

What are the possible disadvantages and risks of taking part?

There are no risks of taking part in this research. Your name and job title will not be used in any report of my research findings, either to the company or in any academic publication. Direct quotes of information given in interviews, will only be used in reports and other publications if they cannot be used to identify individual participants, companies or brands.

What are the possible benefits of taking part?

The possible benefits of this research are that we will have a fuller understanding of what companies do when they discover a food safety incident, what food safety monitoring systems are in use in companies and how company culture impacts on food safety. These findings will help inform the food industry and enforcement authorities of best practice so that improvements in food safety can be made by the industry.

Will my participation be kept confidential?

Your input into the research will be kept confidential. Collected data (recorded interviews and documents) will be transferred to a computer and all computer files will be password-protected. The recorded interviews will be immediately erased from the recording device. All collected information will be kept in password-protected folders on a secure University computer drive. Any handwritten notes taken during the study will be kept in a secure, locked location. At the end of the study they will be scanned and kept on the secure computer drive with the other data, and all hard copies will be disposed of securely.

The consent form will emphasise that the information might be shared with authorised people for academic purposes. All will have a duty of confidentiality to you as a research participant and will do their best to meet this duty.

The consent form will also state that the information collected will be securely saved as it might be needed for future publications. Once the research and the publications are completed all data collected will be erased.

What will happen if I don't want to carry on with this study?

When you give your consent, it is understood that your circumstances may change and that you may no longer wish to carry on with the study. You may withdraw your consent to participate at any time prior to the time of results being analysed. You will not be compelled to give a reason for leaving. On leaving the study, all the information you have provided will be deleted.

What if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researcher; Sally-Ann Krzyzaniak (07890 607932 / sally-ann.krzyzaniak@myport.ac.uk) or my supervisor Professor Lisa Jack (023 9284 4136/ lisa.jack@port.ac.uk) who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can contact Dr. Judy Rich, Faculty Research Degree Coordinator (023 9284 4048 / judy.rich@port.ac.uk).

What will happen to the results of the research study?

The results of the study will be published in a PhD thesis and available at the University library. It is also hoped that the results will produce journal articles, book chapters and academic conference presentations, which again, will be available via the library electronic resources. You will not be identifiable from the results in any document. Once the research and the publications are completed all data collected will be deleted.

Who is organising and funding the study?

This research is sponsored by the University of Portsmouth.

Who has reviewed this study?

Research in the University is looked at by an independent group of people, called the Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the Portsmouth Business School Research Ethics Committee.

Further information and contact details

If you would like to know the further details of research in the University, please follow the following link to the University of Portsmouth research website;

http://www.port.ac.uk/research/

If you would like details on the research carried out in the Portsmouth Business School, please follow the following link to the Portsmouth Business School research website;

http://www.port.ac.uk/departments/faculties/portsmouthbusinessschool/research/

If you would like further information about this project, please contact the researcher;

Sally-Ann Krzyzaniak, **Tel**: 07890 607932 **Email**: sally-ann.krzyzaniak@myport.ac.uk

Thank you for taking the time to read this document. Hopefully it has answered all of your questions, but if not please get in touch. If you decide to participate in this research you will be given a copy of this information sheet to keep and you will be asked to sign a consent form.

Research Student: Sally-Ann Krzyzaniak,
Portsmouth Business School Postgraduate Centre,
University of Portsmouth,
Portland Building, Portland Street,
Portsmouth, PO1 3AH.
Tel: 023 9284 4831 / Mobile 07890 607932
Email: sally-ann.krzyzaniak@myport.ac.uk.

First supervisor: Professor Lisa Jack,
Accounting and Financial Management,
Portsmouth Business School, University of Portsmouth,
Richmond Building, Portland Street,
Portsmouth, PO1 3DE.
Tel: 023 9284 4136
Email: lisa.jack@port.ac.uk.

Participant Code : …………………

Consent Form: Individuals

Study Title: Key determinants for the governance of food safety in food business organisations.

REC Ref No: 338

Name of Researcher: Sally-Ann C Krzyzaniak

Please initial box

I confirm that I have read and understood the information sheet dated 14/08/2015 for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	☐
I understand my participation is voluntary and that I am free to withdraw at any time without giving any reason, up to the point where the data is being analysed.	☐
I agree to my interview being audio recorded, and to being quoted, using my original words, in reports of the research.	☐
I agree that the information collected during the study can be shared with authorised people for academic purposes.	☐
I agree to the data I contribute being stored securely, until all academic publications (PhD thesis, journal articles, book chapters and conference presentations) have been completed.	☐

I agree to take part in the above study.

Name of Participant: ....

Signature: ....   **Date**: ....

Name of person taking consent: ....

Signature: ....   **Date**: ....

(When completed, one copy to be retained by participant; 1 copy for researcher’s file)

Appendix G: Semi-Structured Interview Guide

INTERVIEW GUIDE

Research Question: What are the key determinants for the governance of food safety in food business organisations?

Interview preamble

Thank you for giving me some of your time today to have this interview with you. You should have seen the information sheet on my research project, but just as a quick recap, my research is concerned with the management of food safety in the food industry. Just to be completely clear I am not conducting a quality or food safety audit, in the way that an EHO or BRC auditor would do.

I will be asking you questions about the food quality incident X which happened in (date)

I am interested in understanding the incident itself, what the company did when it discovered the issue and what investigations it undertook, that is I am interested in the management of the incident and the processes used by the company when it happened

I am also interested in the management and monitoring systems generally used by the company to look at food safety and in understanding the culture of the company – what is important to the company and staff and how is this measured.

You have also been given a consent form to read and sign. As I explained in the information sent to you, all the information you give me will be anonymised, so neither your name or job title will be used in any reports, either to the company or in any academic publications. For all reports and publications external to the company, I'll also be making sure that company and brand names are not given, and that the product and company can't be easily identified.

So before we start the interview I'd just like to check if you have any other questions, and also check that you are happy for this interview to be recorded.

Question Area	Interview Questions	Notes
TT1 Historical food safety or quality incident (QFSI)/ incident management policy and procedures	IQ1a: Can you tell me about X incident? I'd like to understand what happened and what the organisation did. OR Can you tell me about the company's incident management policy and procedures? I'd like to understand what happens when an incident occurs and what the organisation does (USE IF NOT INVOLVED IN / CAN NOT DISCUSS INCIDENT) Prompts: Facts - who was/is involved, timescales, actions, was a specific company protocol followed?	
Note only relevant where specific incident is discussed. Otherwise ladder to get values and possibilities in IQ1a	IQ1b: Can you explain to me why the organisation acted in this way? Prompts:	

	Facts and values- look at each action identified in Q1 and prompt for “why” – ladder to get full information. Possibilities: were alternative actions considered? What were these? Why were they not chosen?	
	IQ1c: Did the business undertake any analysis of the situation to understand the cause of the incident (Clarify that don’t mean chemical / micro analysis)? Can you tell me about this? What did the organisation decide was the cause of the incident? Prompts: Facts - when was analysis conducted, who was involved, why were these people chosen, what was the result, were the results used to drive the decisions made? Communications - how was the analysis and the results communicated and to whom? Values - If no analysis conducted, why not, who decided this?	

	IQ1d: Did the business make any changes to the Food Safety Management System (FSMS) / Food Safety Monitoring System (FSMnS) after the X incident? Can you describe these to me? Prompts: Facts – what, where, when, how? Values – why? Communications - how communicated? Possibilities – were other changes considered? Why were they not chosen?	
	IQ1e: Do you feel that the incident was related to a specific problem in implementing or maintaining the company FSMS / FSMnS? Can you tell me a bit more about this? Prompts: Problems / barriers related to people or process concerns?	
TT2 Use of FSMnS	IQ2a: I'd like to understand what monitoring systems the company uses to ensure food	

	safety as part of its overall food safety management system. Can you tell me about the monitoring systems (MnS) & measurements used? Prompts: Facts - walk through production or FSMS process flow as a prompt for remembering MnS.	
	IQ2b: Why were these specific monitoring systems chosen? Prompts: Values and possibilities - related to CCPs, standard industry practice, look at automation. Look for considerations of cost, quality, time. Also balance of costs, risk (of problem) and severity (of problem).	
	IQ2c: You've told me about monitoring systems at these places (list). Do these cover the manufacturing / processing / preparation of food only or other areas too? Why is that? Prompts:	

	Values and possibilities - PRPs as well as HACCP, suppliers, related activities e.g. labelling, packing, pilot production, R&D.	
	IQ2d: Do the MnS get reviewed? Who does this and how often does it happen? Prompts: Facts, possibilities - look at HACCP plan for revision dates.	
	IQ2e: How do the results of the different MnS get recorded? Are these reported within the business? Prompts: Possibilities, communication - who reports results, to whom and how, how frequency?	
TT3 Food Safety Culture	IQ3a: How would you describe the purpose of this organisation? Prompts: Values, communication: does the organisation have a mission statement or stated values? Is food safety mentioned in this? Is there a	

	separate food safety mission statement? If so, who has underwritten this and who "owns" it?	
	IQ3b: How is success measured in this business? Prompts: Values, facts, possibilities – financial measures, MBOs, are quality or food safety goals set as success measures, is six sigma or a similar quality system used to measure success? Does senior management look at food safety criteria as a measure of success? Communication – how are the success criteria communicated and by whom?	
	IQ3c: Does the organisation assess or measure food safety culture in any way? What sorts of measures are used? If no measurement is carried out, why do you think this is? Prompts: Facts, communication: audits, questionnaires, EHO assessments.	

Appendix H: E-Mail of Ethical Approval of Study and UPR16

UNIVERSITY OF PORTSMOUTH

Sally-ann Caroline Krzyzaniak <up713085@myport.ac.uk>

Ethics Review application ref. E338 [Sally-ann Krzyzaniak]

3 messages

Sharman Rogers <sharman.rogers@port.ac.uk> 28 April 2015 at 10:25
To: Sally-ann Krzyzaniak <sally-ann.krzyzaniak@myport.ac.uk>
Cc: PBS-Ethics <pbs-ethics-group@port.ac.uk>

Dear Sally

Ethics Committee wishes to thank you for your very detailed submission and is pleased to grant a favourable ethical opinion.

Best wishes

Sharman

--
Sharman Rogers

Business Services & Research Office
Portsmouth Business School
Portland Building, Portland Street
Portsmouth, Hampshire PO1 3AA UK
T: +44 (0)23 9284 4202

What we offer business:
http://www.port.ac.uk/portsmouth-business-school/find-out-more/
Services for Business
Research
Talent Development
Events and Open Evenings

The Value-Added Board - - what you need to know to add value in the Boardroom

Highest ranked modern university in the UK
THE WORLD UNIVERSITY RANKINGS TOP400
Top university for student satisfaction
The National Student Survey

FORM UPR16

Research Ethics Review Checklist

Please include this completed form as an appendix to your thesis (see the Postgraduate Research Student Handbook for more information

Postgraduate Research Student (PGRS) Information		**Student ID:**	UP718085
PGRS Name:	Sally-Ann Caroline Krzyzaniak		
Department:	ACCFM, PBS	**First Supervisor:**	Prof Lisa Jack
Start Date: (or progression date for Prof Doc students)	**1/2/2014**		
Study Mode and Route:	Part-time ☒ Full-time ☐	MPhil ☐ PhD ☐	MD ☐ Professional Doctorate ☐

Title of Thesis:	Key Determinants of Food Safety Governance in Food Manufacturing: A Case Study Investigation
Thesis Word Count: (excluding ancillary data)	79,359

If you are unsure about any of the following, please contact the local representative on your Faculty Ethics Committee for advice. Please note that it is your responsibility to follow the University's Ethics Policy and any relevant University, academic or professional guidelines in the conduct of your study

Although the Ethics Committee may have given your study a favourable opinion, the final responsibility for the ethical conduct of this work lies with the researcher(s).

UKRIO Finished Research Checklist:
(If you would like to know more about the checklist, please see your Faculty or Departmental Ethics Committee rep or see the online version of the full checklist at: http://www.ukrio.org/what-we-do/code-of-practice-for-research/)

a) Have all of your research and findings been reported accurately, honestly and within a reasonable time frame?	YES ☒ NO ☐
b) Have all contributions to knowledge been acknowledged?	YES ☒ NO ☐
c) Have you complied with all agreements relating to intellectual property, publication and authorship?	YES ☒ NO ☐
d) Has your research data been retained in a secure and accessible form and will it remain so for the required duration?	YES ☒ NO ☐
e) Does your research comply with all legal, ethical, and contractual requirements?	YES ☒ NO ☐

Candidate Statement:

I have considered the ethical dimensions of the above named research project, and have successfully obtained the necessary ethical approval(s)

Ethical review number(s) from Faculty Ethics Committee (or from NRES/SCREC):	E338

If you have *not* submitted your work for ethical review, and/or you have answered 'No' to one or more of questions a) to e), please explain below why this is so:

UPR16 – August 2015

Signed *(PGRS)*:	S. C. Krzyzaniak.	**Date:** 29/1/2018