The impact of personnel, training, culture and organisational factors on application of the HACCP system for food safety management in a multinational organisation

Volume 1 of 2

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I declare that while registered as a candidate for the research degree, I have not been a registered candidate or enrolled student for another award of the University or other academic or professional institution. I further declare that no material contained in the thesis has been used in any other submission for an academic award and is solely my own work.

Carol Wallace

Abstract

The Hazard Analysis and Critical Control Point system (HACCP) is the internationally accepted mechanism for control of foodborne disease through food safety assurance. It is a generally held belief that HACCP is best applied by a multidisciplinary team, thus delivering a stronger food safety system than could be developed by individuals working alone. However, the origins and reasons for the use of HACCP teams in the historical record are unclear and there are no studies into the effectiveness of HACCP team decision-making. Similarly, HACCP training is believed to be fundamental to successful HACCP implementation; however there are few objective measures of the standards of training or of the effectiveness of learning. This is compounded by a lack of internationally agreed tools to measure the effectiveness of HACCP systems in practice.

Whilst literature on barriers to HACCP application, particularly in small and less developed businesses, is strong, the reasons for HACCP success or failure in manufacturing companies are less well understood. Multinational manufacturers generally work across, not only national and regional boundaries, but also cultural dimensions, however international projects such as HACCP application may be initiated without consideration of how different cultural factors within the organisation could affect the project's success. Due to the limited literature on HACCP success factors and the absence of previous studies considering the potential impact of national or regional culture, it is important to gain an understanding of and share the experiences of multinational companies that have applied HACCP.

In the setting of a multinational food company, this research has developed new tools, assessed HACCP knowledge levels, investigated HACCP team decision-making processes, assessed the validity of working HACCP Plans and considered how cultural and organisational dimensions impact HACCP application. This multifaceted approach has facilitated deconstruction of HACCP learning and development, leading to an understanding of key factors involved in effective HACCP in a global manufacturing context.

This thesis makes a theoretical contribution by extending the understanding of the HACCP application process in international manufacturing. It provides insights that will underpin future policies for HACCP application and makes practical recommendations for effective HACCP within the diverse cultures of international business.

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Acknowledgements

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This thesis is dedicated to the memory of my Mother,
Helen C MacMillan (1932-2008).

Abbreviations

BSI	British Standards Institute
CCP	Critical Control Point
CIEH	Chartered Institute of Environmental Health Officers (England & Wales)
Codex	Joint FAO/WHO Codex Alimentarius Committee on Food Hygiene
FSA	United Kingdom Food Standards Agency
HACCP	The Hazard Analysis and Critical Control Point System
HPA	UK Health Protection Agency
ICMSF	International Commission on Microbiological Specifications for Foods
ILSI	International Life Sciences Institute
ISO	International Organisation for Standardisation
NACMCF	United States National Advisory Committee on Microbiological Criteria for Foods
QMS	Quality Management System
RIPHH	Royal Institute of Public Health and Hygiene (UK)
RSPH	Royal Society for Public Health (UK)

Chapter 1 HACCP and Effectiveness – an Introduction

1.1 Significance of Foodborne Disease and the Need for Control Systems

Food safety is an increasingly important public health issue. The World Health Organisation (WHO) estimates that in 2005 alone 1.8 million people died from diarrhoeal diseases. A large proportion of these cases can be attributed to consumption of contaminated food and drinking water (WHO 2007 [a]).

In industrialized countries, the percentage of people suffering from foodborne diseases annually has been reported to be up to 30%. For example, it is estimated that around 76 million cases of foodborne disease, resulting in 325,000 hospitalizations and 5,000 deaths, occur each year in the United States of America (USA) (WHO 2007 [a]).

Whilst most foodborne disease cases are sporadic and often not reported (Kaferstein *et al*, 1997), the number of cases involved in foodborne disease outbreaks may be significant (Adak *et al*, 2002; Kaferstein, 2003; Hughes *et al*, 2007). For example, in 1988, an outbreak of hepatitis A, resulting from the consumption of contaminated clams, affected some 300,000 individuals in China and, in 1994, an outbreak of salmonellosis due to contaminated ice cream occurred in the USA, affecting an estimated 224,000 (WHO 2007 [a]). However, data on the extent of foodborne disease outbreaks and related deaths are known to be highly incomplete and to understate the extent of the problem (Rocourt *et al*, 2003).

Food contamination results in significant social and economic burdens on communities and health systems. For example, in the USA, diseases caused by food pathogens are estimated to cost up to US $35 billion annually (1997 figures) in medical costs and lost productivity. The re-emergence of cholera in Peru in 1991 involving contaminated fish products resulted in the loss of US $500 million in fishery exports that year (WHO 2007[a]).

In this context, governments worldwide are intensifying their efforts to improve the safety of the food supply. The work of the WHO Food Safety Programme includes strengthening food safety systems, promoting good manufacturing practices and educating manufacturers, retailers and consumers about appropriate food handling (WHO 2007[a]).

1.2 The Internationally Agreed Approach to Food Safety Control

The hazard analysis and critical control point system (HACCP) is the internationally agreed approach to food safety control (WHO 2007[b]). The reference standard for implementation of HACCP is published by the Codex Alimentarius Commission of the joint United Nations Food and Agriculture Organisation (FAO)/WHO Food Standards Programme (Codex 1993, 1997[a] and 2003). The HACCP approach is also enshrined into legislation in many countries, including the EC Regulation on the Hygiene of Foodstuffs (EC No. 852/2004), that came into force in January 2006 (European Parliament, 2004).

HACCP was developed as part of the USA manned space programme, where NASA collaborated with the US Army Natick Laboratories and the Pillsbury Company to develop an approach that would protect the astronauts from foodborne illness (Ross-Nazzal, 2007). Following its success in the space programme, HACCP was further developed by the Pillsbury Company who applied it to its own operations and launched the system to the food industry in the USA at the first National Conference on Food Protection in 1971 (Ross-Nazzal, 2007). Although the principles of HACCP were further developed to become the internationally agreed approach to food safety management (Codex, 2003), the methods for HACCP principle application using multidisciplinary HACCP teams are still based on the original approach taken by Pillsbury in the USA in the 1970s (Ross-Nazzal, 2007, Sperber, pers. comm., 2007).

1.3 The HACCP System

Hazard Analysis Critical Control Point is a preventative approach to food safety management. It is designed to control significant food safety hazards, i.e. those hazards that are likely to cause an adverse health effect when products are consumed.

Hazard analysis critical control point requires development of the HACCP Plan. This document states how food safety hazards will be controlled in the food production operation. It is developed by a multidisciplinary HACCP team, including representatives from production, quality/technical and engineering.

The HACCP System comprises the HACCP Plan plus associated monitoring and verification records, which demonstrate that the HACCP Plan is working in practice at all times.

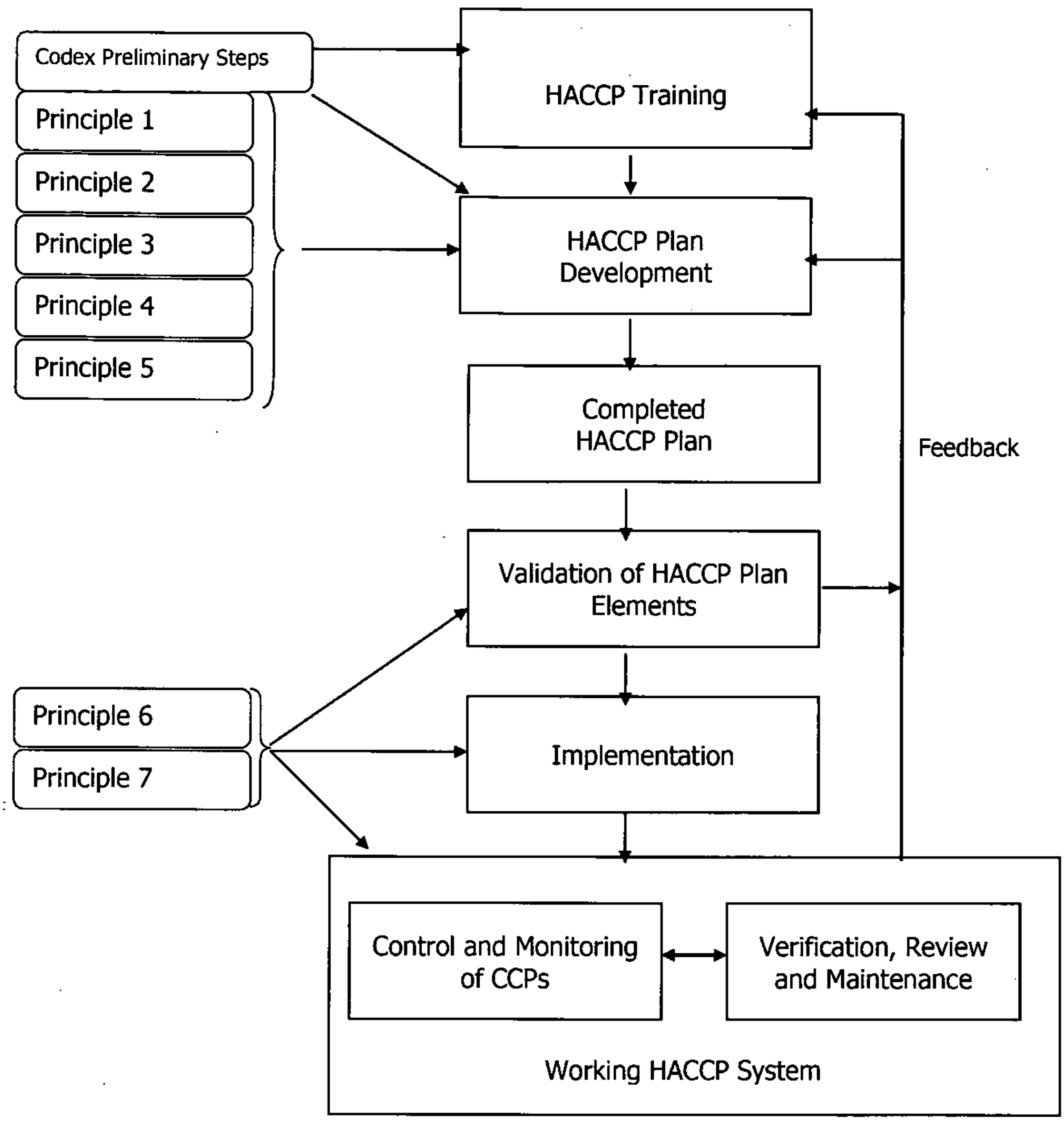
HACCP Systems are developed through the application of the internationally agreed HACCP Principles (Codex, 2003) (Table 1.1).

Table 1.1 The HACCP Principles (Codex 2003)

PRINCIPLE 1 Conduct a hazard analysis. **PRINCIPLE 2** Determine the Critical Control Points (CCPs). **PRINCIPLE 3** Establish critical limit(s). **PRINCIPLE 4** Establish a system to monitor control of the CCP. **PRINCIPLE 5** Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control. **PRINCIPLE 6** Establish procedures for verification to confirm that the HACCP system is working effectively. **PRINCIPLE 7** Establish documentation concerning all procedures and records appropriate to these principles and their application.

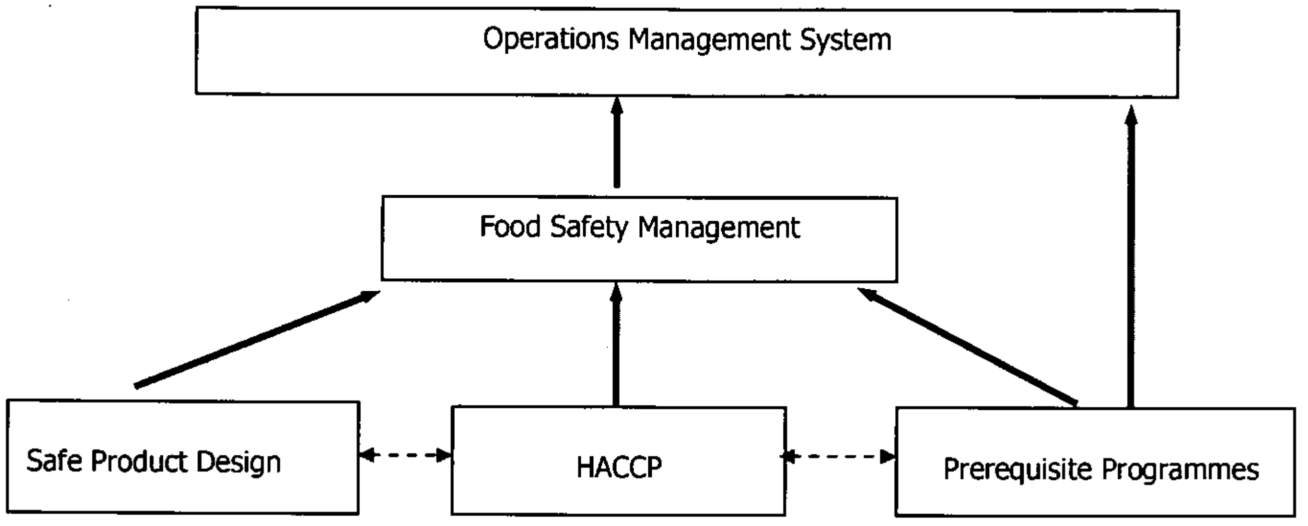
The process of HACCP Plan development and implementation, through the application of the Codex HACCP Principles, involves a number of interlinked stages (Figure 1.1).

Figure 1.1 HACCP Application Process



In order for food safety management to be effective, it is essential that HACCP be supported by Good Manufacturing Practice (GMP) or Prerequisite Programmes (PRPs) that control the general hygiene and environmental conditions in a food processing operation (Sperber, 1998; ILSI, 1999; Wallace & Williams, 2001). In a manufacturing operation, food safety management is achieved through the application of system 'building blocks' – safe product design, prerequisite programmes and HACCP – operating under the framework of the overall operations management system (Figure 1.2).

Figure 1.2 Manufacturing Food Safety Management Model (adapted from Mortimore and Wallace, 2001)



The systems of the HACCP 'building block' are developed through application of the internationally agreed HACCP Principles (Codex, 2003). For effective food safety management, all 3 'building blocks' need to be adequately designed and their implementation be verified. This research focuses on the HACCP 'building block'.

1.4 Effectiveness of HACCP

While considering HACCP effectiveness, Mitchell (1998) questioned whether apparent failures of HACCP are due to weaknesses in the HACCP system or failures associated with the personnel trying to implement it. Arguments (Motarjemi and Kaferstein, 1999; Adams, 2002) have tended to support the view that it is not the HACCP system that is at fault but the approaches and methods of application, including personnel issues, which are likely to be causes of failure. Demortain (2007) suggests that this is because scientific 'experts' involved in the development of HACCP standards and guidelines have tended to defend the properties of their concept and, in doing so, displayed a high level of trust in HACCP principles, however, as a preventative system, the theoretical basis for the effectiveness of a properly implemented HACCP system is strong.

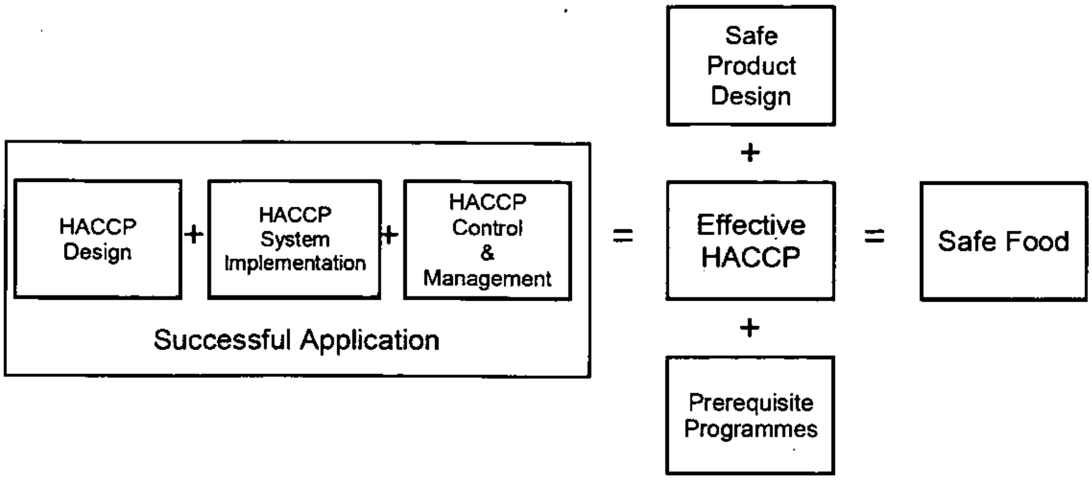
The preventative nature of the HACCP approach to the management of food safety comes through its identification, evaluation and control of hazards that could cause harm to the consumer. HACCP should be effective in that it proactively identifies potential food safety hazards and implements control systems before the hazards are realised. However HACCP cannot guarantee zero tolerance for all food hazards 100% of the time due to variability in materials and processes in conjunction with the potential for control procedure failure and human error, so it should be considered a risk management system that can minimise the likelihood of food safety hazards occurring (Cormier, 2007). A rigorously designed, fully implemented and securely managed and controlled HACCP System – i.e. 'effective HACCP' – should come as close to zero tolerance as technically and operationally feasible in a food operation. However, the promotion of HACCP by government agencies worldwide as the panacea for foodborne disease control is not supported by data (Wallace *et al*, 2005[a]).

The HACCP system will prevent foodborne disease only if it is understood and applied correctly (Motarjemi and Kaferstein, 1999). There are very few records of foodborne disease outbreaks in which a food company operating with full commitment and understanding of the HACCP system has been implicated. Hence when the HACCP system is applied correctly, logic tells us that foodborne disease should not occur. Evidence of foodborne disease outbreaks and their investigation is limited, however in the outbreaks that have been reported involving industries that have implemented the HACCP system, serious flaws could be detected in their HACCP plans or the implementation of HACCP. This reflects a lack of understanding of, or commitment to the HACCP system (Motarjemi and Kaferstein 1999). Untermann (1999, p163) reported that practical application of HACCP was 'unfortunately quite often watered down, leading to a decline in the effectiveness of food safety concepts', and this would suggest that some companies could have weaknesses in HACCP application, which may in turn lead to the presence of uncontrolled hazards and the occurrence of food safety incidents.

Since Motarjemi and Kaferstein and, separately, Untermann reported in 1999, there have been several high profile food safety incidents involving large manufacturers who would have been expected to have HACCP in place (Manning, 2007; Lowe, 2008). Referring back to Mitchell (1998), this has again raised questions about the capability of the HACCP system to manage food safety and/or the capability of food businesses to apply effective HACCP. According to Cormier *et al* (2007), the HACCP System is assumed to have failed if a hazard is found in a food product. Experience with a range of food companies has shown that, although manufacturing sites often consider that they have implemented HACCP, frequently the outcome is an inadequate or poorly implemented HACCP System (Wallace *et al* 2005[a]). Therefore, it is much more likely that the true failure is in the application or operational management of the HACCP system rather than the system itself (Sperber, 2008 pers. comm., Wallace, 2008).

As previously discussed (Figure 1.2), food safety depends on the 'building blocks' of safe product design, prerequisite programmes and HACCP all being applied fully and correctly (Wallace *et al*, 2005[b]). Focussing on HACCP, achievement of effectiveness depends on the design, implementation, control and management of the HACCP system. This framework for effective HACCP should achieve safe food production when accompanied by the other building blocks within the food operation (Figure 1.3). However, there is a need to understand the factors impacting successful HACCP application such that food companies can design, implement and manage systems that will control all relevant food safety hazards, i.e. effective HACCP.

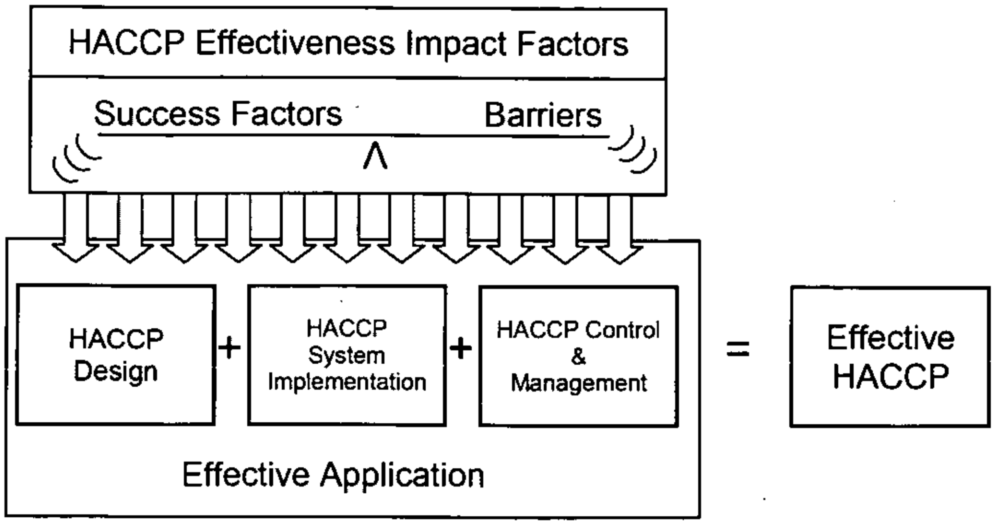
Figure 1.3 HACCP Effectiveness Framework



Barriers to HACCP application have been more widely studied, including investigation of technical barriers (Panisello and Quantick, 2001), concepts of psychological/behavioural barriers (e.g. Gilling *et al*, 2001; Azanza and Zamora-Luna, 2005; Taylor and Taylor 2004[a],) and, in particular, barriers to small and/or regional food businesses (e.g. Taylor, 2001; Taylor and Taylor, 2004[b]; Vela and Fernandez, 2003; Bas *et al*, 2007; Celaya *et al*, 2007;). However, research identifying HACCP success factors is limited.

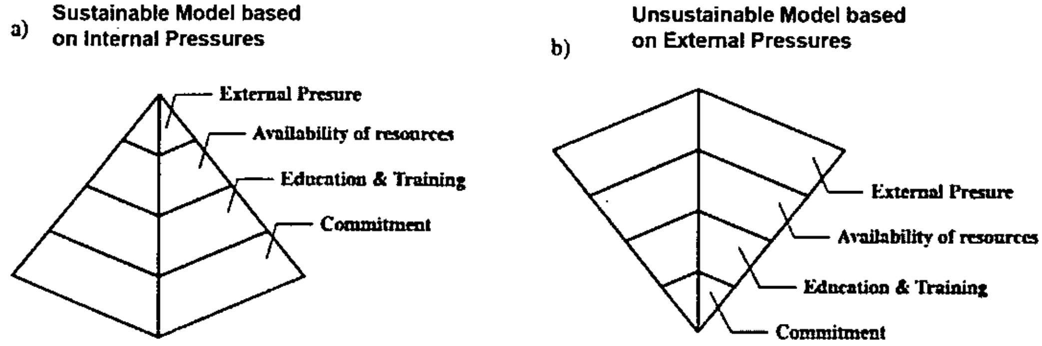
To enable effective application of HACCP it can be postulated that sufficient HACCP success factors must be in place to 'balance out' or overcome the barriers to HACCP application (Figure 1.4). Currently, HACCP success factors are poorly understood and need to be further studied.

Figure 1.4 HACCP Effectiveness Impact Factors



Panisello and Quantick (2001) report that HACCP needs to be built on 4 'Pillars', i.e. management commitment, education and training, availability of resources and external pressures, and that sustainable HACCP can only be built as a result of internal pressure and support (i.e. the decision to apply HACCP is internal to the company and its management), the alternative being an unsustainable model that is the result of external pressure (i.e. the company is pushed into HACCP application by others, e.g. customers or regulators) (Figure 1.5).

Figure 1.5 HACCP Success Factors – Prioritisation of the 4 Support 'Pillars' (source: Panisello and Quantick, 2001)

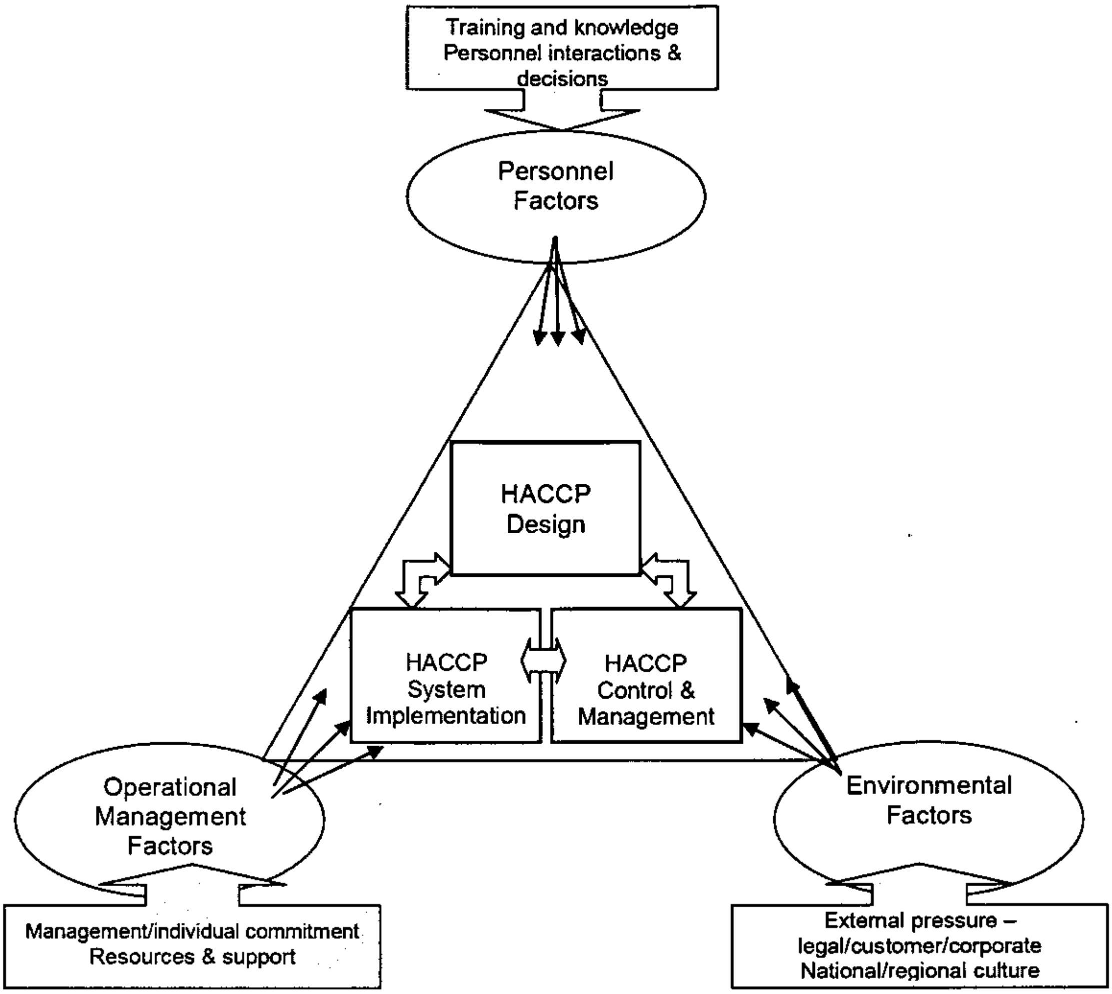


Panisello and Quantick's 'Pillars' (2001) may provide some of the success factors necessary to balance the barriers and provide for effective HACCP application (Figure 1.4), however data gaps mean that this cannot be established. Resource availability is likely to be closely connected with management commitment in that a committed management team is more likely to ensure that the required resources and support for HACCP are available. Widespread support exists for the concepts of both the education and training and external pressures pillars, and for the view that a sustainable HACCP model can only be achieved when the foundations of management commitment and education and training are strongly laid at the start of a HACCP programme, rather than as a response to external requirements (Mortimore and Wallace, 1998; Panisello and Quantick, 2001; Williams *et al* 2003).

However, although these 'Pillars' (Figure 1.5) are expected to be important in the application of HACCP, there are likely to be other factors that contribute to its success in food manufacturing businesses. For example, in addition to the training and education of personnel in HACCP knowledge and skills, the ways that personnel interact and work together are likely to be important, particularly as the HACCP system relies heavily on teamwork (Codex, 2003). Senior management commitment to the HACCP programme and to provision of necessary resources is likely to be important for progress, as will commitment of the entire management team and workforce. External factors such as legislative and customer pressures for HACCP will influence the decision and approaches to HACCP however, in a multinational food manufacturer, additional external factors such as corporate and national policy along with organisational management structure and national/regional culture dimensions may also play a part.

It is postulated, therefore, that factors which impact HACCP effectiveness may fall into 3 main groupings (Figure 1.6): personnel factors, operational management factors and environmental factors.

Figure 1.6 HACCP Impact Factor Groupings



Personnel Factors

Knowledge and understanding of the Principles of HACCP is normally achieved through training, which is believed to be a key aspect of successful HACCP (WHO, 1993 and 1995; Codex, 1997, 2003; Mortimore and Wallace, 1998; Williams *et al* 2003). Many organisations and individuals worldwide offer HACCP training. However, there are few measures of the standards of training being offered or of the effectiveness of learning that takes place (Mortimore and Smith, 1998). In addition, there are no agreed methods to measure HACCP knowledge following training (Wallace *et al*, 2005[a]) or to assess how this knowledge impacts HACCP team decision making. Literature on team interactions and problem solving is well-established in other disciplines (McKenna, 2000; Landy and Conte, 2007), however there are no studies on HACCP team deliberations and decision making. Due to the central role of the HACCP team in developing systems to protect the consumer, this is an important area of study not previously investigated.

Operational Management Factors relating to management commitment, resources and management support for the ongoing functioning of HACCP systems have been widely identified as key requirements for effective HACCP development, implementation and maintenance (Mortimore and Wallace, 1998 and 2001; Panisello and Quantick, 2001), however data to support this are limited. Perception of management commitment and its importance by the workforce along with its potential impact on the HACCP process requires further study.

Environmental factors are the items that may influence the operation from the outside, e.g. legislative requirements for HACCP and other outside pressures such as customer specifications. It is possible that other general factors operating at a local business level, such as dimensions of national and regional culture, might impact the HACCP process and therefore HACCP effectiveness. This has not been studied previously.

1.5 Measuring HACCP Effectiveness

For any assessment programme to generate useful information, criteria to evaluate the effectiveness of the HACCP Plan and its application need to be established and assessment methods need to be identified (Wallace *et al*, 2005[b]). Due to the lack of internationally agreed tools and methods for the measurement of HACCP effectiveness and the factors impacting HACCP success (Wallace *et al*, 2005 [a & b]), it was necessary to develop and validate a variety of tools and methods to progress research in this area, and these will be described in the following chapters.

1.6 Multinational Food Companies and HACCP Approaches

In a multinational organisation there may be a variety of approaches to the application of HACCP at individual sites. This applies in particular where there is a requirement to use HACCP at corporate level but no prescriptive approach to training or the HACCP study process across different sites. It is essential to identify the most effective approach(es) in order to make recommendations on implementation methods and global food safety policy. This requires an understanding of the experiences of companies that have applied HACCP, drawing on the perceived success factors and causes of failure during HACCP application. Whilst the literature on barriers to HACCP application, particularly in small and less developed businesses, is strong (as discussed above), the reasons for success or failure in manufacturing companies that have attempted to apply HACCP are less well understood.

Multinational organisations, through the placement of their manufacturing and/or sales and distribution units within different communities, work across national and regional boundaries and cultural dimensions. This may have a significant impact on the effectiveness of HACCP as there needs to be an understanding of the different ways of thinking in different cultures (Hofstede, 1980). However, international technical projects such as HACCP application may be initiated without considering how different cultural factors within the organisation could affect the project's success.

HACCP was developed in a 'Western[1]' setting as part of the USA manned space programme and the methods for HACCP principle application using multidisciplinary HACCP teams are still based on the original approach taken by Pillsbury in the USA in the 1970s (Ross-Nazzal, 2007, Sperber, pers. comm., 2007). HACCP training is similarly based around 'Western' models from the UK (UK Steering Group on HACCP Training Standards, 1995, 1999; Improve, 2008), the USA (International HACCP Alliance, 1996) and Canada (Canadian Food Inspection Agency, 1995) and there have been no studies to date that consider the potential impact of national or regional culture on the effectiveness of HACCP training or the success of HACCP programmes.

The research reported here is based in a multinational organisation where requirements for HACCP, prerequisite good manufacturing practice (GMP) programmes and Quality Management Systems are mandated at corporate

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[1] For the purposes of this research, 'Western' is taken to mean *Of or pertaining to the Western or European countries or races as distinguished from the Eastern or Oriental* (Oxford English Dictionary, 2009)

level, but responsibility for implementation and decisions on style of approach are at local level.

1.7 The Current HACCP Situation and Need for the Study

This general introduction (1.1-1.6) has highlighted a number of gaps in knowledge about HACCP application and effectiveness:

- Currently, there are no agreed HACCP measurement tools available to measure either HACCP knowledge or system effectiveness. Therefore, not only is the impact of training on HACCP not understood, currently it is not possible to evaluate the impact of HACCP on food safety.
- The potential impact of national and regional culture on HACCP training and the HACCP application process is not known.
- The business factors impacting the success of HACCP application are poorly understood.

These factors need to be established so that recommendations for best-practice HACCP application approaches to multinational food companies and food safety policy makers can be developed.

1.8 Research Aims

In the setting of a multinational food company, this research aims to:

i. Establish strategies for the assessment of HACCP effectiveness;

ii. Evaluate the impact of training on successful HACCP development, implementation and maintenance;

iii. Characterise the relationship between national/cultural issues, business/organisational factors, personnel and training on HACCP effectiveness;

iv. Make recommendations for HACCP training and support strategy in multinational organisations.

This research makes contributions to knowledge in a number of areas:

- Development of new methodology for assessment of HACCP knowledge.
- Development of new methodology for assessment of HACCP system effectiveness.
- Application of models of national/cultural dimensions to a new area of study.
- Reporting of new empirical evidence on HACCP knowledge and HACCP effectiveness.
- Reporting on the impact of training on HACCP effectiveness in a multinational organisation.
- Recommendations for policy based on previously unavailable evidence.

1.9 HACCP Effectiveness – Programme of Work

The organisation being studied is a global food and drink manufacturing company whose products are marketed in approximately 200 countries. The research focuses largely on a division of the company, which consisted of 53 factories in 25 countries at the start of the research and which manufactured a variety of confectionery products. The company's business language is English.

The company's food safety strategy included the mandatory application of HACCP and prerequisite programmes at all manufacturing sites. A corporate HACCP training model was available, and limited central/regional HACCP expertise was also available to help review progress at individual sites. However both responsibility for implementation of HACCP and prerequisite programmes, and decision on style of approach were at local level, which resulted in a number of sites using the corporate model/expertise whilst other sites have utilised existing site expertise or local support. The programme of work included 2 main phases of data collection within the company as follows:

Phase 1 – Preliminary Study

- Methods development and validation
- HACCP Knowledge Testing at 14 sites
- Desktop Audit on HACCP plan validity

Data collection in Phase 1 involved sites that were known to have gone through HACCP training using the corporate training model and thus had HACCP trained personnel available for knowledge testing. The data obtained from phase 1 indicated the need to explore the HACCP initiative in more detail at a smaller number of sites, which was planned and achieved in phase 2. Key findings from phase 1 were published as two articles in a peer-review journal and are reproduced in Appendices 1.1 and 1.2. Phase 1 is discussed in detail in Chapter 2 of this thesis.

Phase 2 – Detailed Examination of HACCP Processes at Case Study Sites

Phase 2 included a detailed study of HACCP knowledge and its application, in conjunction with exploration of other factors that may impact effective HACCP in a multinational manufacturing context as follows:

- HACCP Knowledge Testing – individuals and HACCP teams
- HACCP team decision-making observation
- Semi-structured interview with a range of site personnel
- Administration of National Culture Questionnaire
- HACCP Effectiveness Assessment – audit of HACCP plans and system in practice.

Data collection for phase 2 was completed at manufacturing sites in Australia, India and Singapore. Although it might seem that it would have been more logical to study manufacturing sites in the UK, for company practical reasons at the time of the research the region that was available for study was the Asia Pacific Region. Therefore, sites within this region were chosen to give an expected range of national cultural characteristics (See Chapters 3 and 6).

Ethical Approval was sought for both phases of work from the University of Central Lancashire Psychology Ethics Committee. Approval letters for each phase are reproduced in Appendix 1.3.

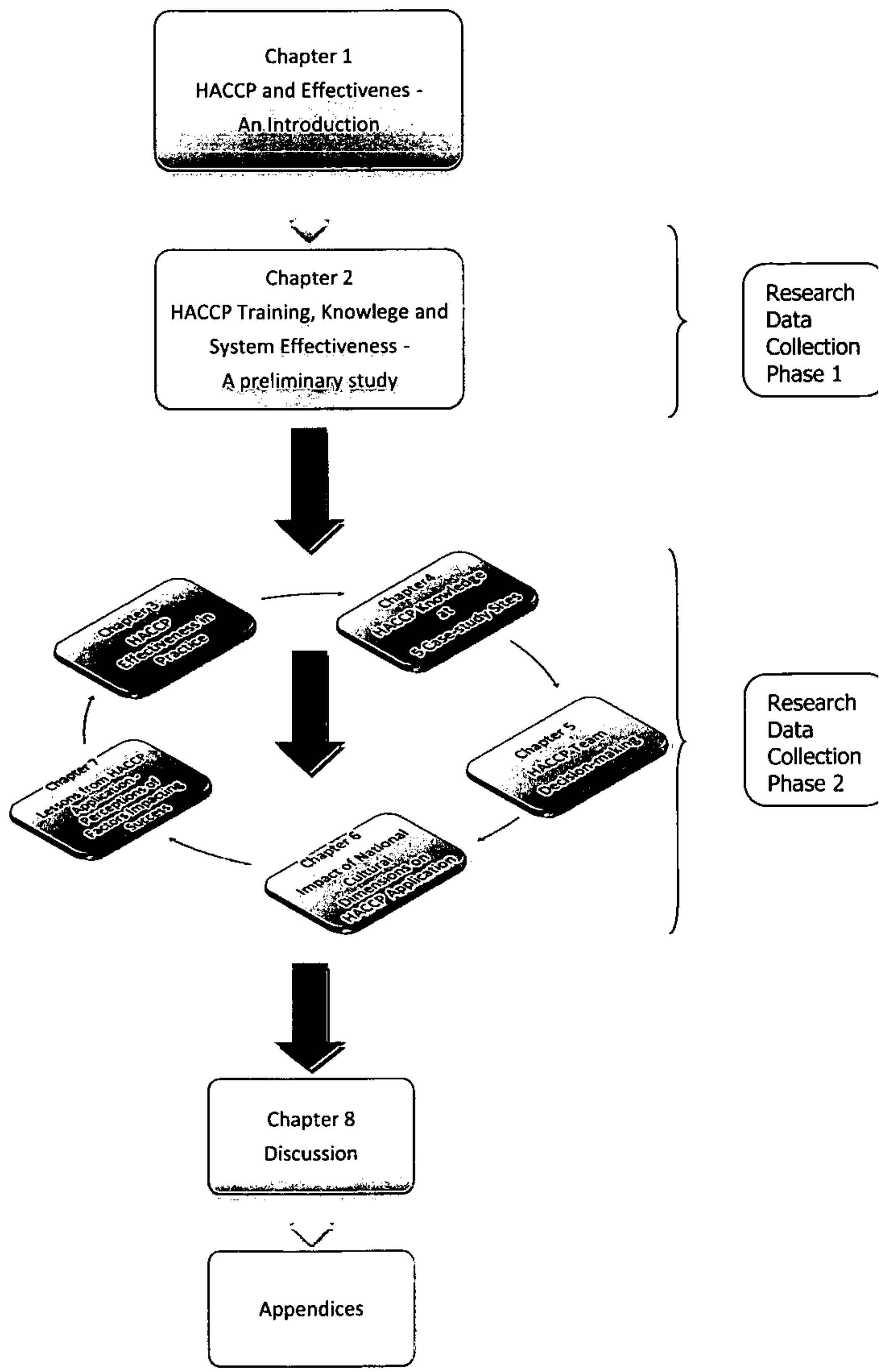
The programme of work was planned such that review and analysis of the results would allow deconstruction of HACCP learning and development, leading to an understanding of the key factors involved in successful HACCP in a manufacturing context. The data presented in the remainder of this thesis will provide the evidence necessary to evaluate the impact of personnel, training, culture and business/organisational factors on application of the HACCP system for food safety management and make to recommendations for support of effective HACCP in multinational organisations.

1.10 Style and Structure of the Thesis

Because this thesis involves a blend of qualitative and quantitative research, the style reflects a combination of the two approaches. There are cases where literature is brought in to make sense of data in line with the iterative nature of blended research and other cases where it is predominantly used in the introduction to chapters, where it is used in support of study design. In addition, due to the length of time involved in this research, further literature has now been published that was not available in the initial stages. This has been referred to in discussion sections where appropriate to this work.

Following this introductory chapter, Chapters 2 to 7 of this thesis describe the different phases and elements of work. Chapter 8 considers the findings of Chapters 2-7 and how these interact within manufacturing sites. Models are proposed illustrating how training, business and cultural dimensions impact the HACCP process and recommendations are made for HACCP training and support strategy in multinational organisations. Figure 1.7 illustrates the structure of this thesis.

Figure 1.7 Structure of the Thesis



Chapter 2

HACCP Training, Knowledge and System Effectiveness – a preliminary study

2.1 Introduction

As highlighted in Chapter 1, a key aspect of successful HACCP implementation is believed to be effective training in the application of HACCP Principles (WHO, 1993 and 1995; Mortimore and Wallace, 1998; Codex, 2003; Williams *et al* 2003). Training of food handlers in safe food handling has been identified as one of the most critical interventions in the prevention of foodborne illnesses (WHO, 2007[a]). As a result, many companies require personnel to complete externally run HACCP training courses or utilise trainers for an on-site programme of similar content for a number of key staff. Many organisations and individuals around the world offer HACCP training, yet there are few measures of the standards of training being offered or of the effectiveness of learning that takes place (Mortimore and Smith, 1998).

2.1.1 HACCP Training Standards

In the UK, attempts to standardise HACCP training began in the early 1990s with the foundation of the Steering Group on HACCP Training Standards (UKSGHTS), initially based at the Royal Institute of Public Health & Hygiene (RIPHH; now known as the Royal Society for Public Health following merger). The UKSGHTS published introductory and advanced level training standards (UKSGHTS, 1995, 1999), which were adopted by a number of key HACCP training providers (Gaze, Palmer, and Sprenger, pers. comms.[2]) but which had no mandatory status. Although validating tests were available from the RIPHH for training courses meeting these standards, a number of competing training specifications of different levels were also in place and, except for customer preference, there was no requirement for HACCP trainers to use any particular standard/specification. In the USA, the International HACCP Alliance (1996) provided a basic course curriculum covering similar topics to the UK, as did the Canadian Food Inspection Agency (1995). More recently in the UK, the owners of competing training specifications were brought together and a new framework of HACCP training levels agreed (Improve, 2008).

A number of training providers and awarding bodies developed their own validation tests for use at the end of courses and this is also true of courses designed to meet the new UK training framework (e.g. RSPH, 2007). However, these generally test the knowledge of individuals at the end of the training intervention and do not consider the impact of this knowledge on multidisciplinary team decision making or the ability of individuals to retain the necessary information until required in the workplace. Concerns have also been raised about whether the validating tests for the new training framework (Improve, 2008) are sufficiently challenging to meet the needs of manufacturing (Palmer, pers. comm.) and, therefore, the effectiveness of this 'standardised' training in terms of food business requirements for the

[2] Personal communications with key individuals in the UK HACCP training business illustrated the adoption of courses meeting HACCP training standards and examinations. The individuals are Robert Gaze, Head of HACCP Training for Campden & Chorleywood Food Research Association; Gill Palmer, Head of Training for Reading Scientific Services Ltd and Chief HACCP Examiner for the RIPHH; Richard Sprenger, Managing Director of Highfield.co.uk Ltd. These businesses were key players in the UK HACCP training market.

development, implementation and maintenance of working HACCP systems, has not been measured.

A typical HACCP training intervention consists of a 2-3 day programme on HACCP Principles and their application. This normally involves lectures/presentations on the background and theory of HACCP interspersed with practical activities on the application of the Principles. This allows the trainees to learn while experiencing the HACCP study process, i.e. the approach used to develop HACCP Plans through the application of HACCP Principles. This meets requirements for HACCP training to be practically based (UK HTSSG, 1995, 1999, Improve, 2008), allowing active learning and practice in knowledge application that is consistent with the process of experiential learning (Kolb, 1974).

Many companies consider that a single training intervention for one or a group of employees is sufficient to achieve development of effective HACCP. However experienced HACCP practitioners consider that this means of training alone is unlikely to lead to effective HACCP (de Winter 1998; Mossel *et al* 1999; Boccas *et al*, 2001; Wallace 2001).

There are no internationally agreed methods to measure HACCP knowledge following training, nor agreement on essential knowledge and skills that HACCP team members require. Hence, there is no evidence that demonstrates the impact of HACCP training on food safety management.

2.1.2 HACCP Assessment

Ongoing assessments are considered to be essential once a HACCP system has been implemented (World Health Organisation, 1995; Sperber, 1998) , including internal assessments carried out by food industry and independent assessments carried out by regulators and third-party bodies. A WHO Consultation in Geneva in 1998 considered 'The Role of Government Agencies in Assessing HACCP' (World Health Organisation 1998) and provided guidance on:

- Government roles and responsibilities
- Principle activities for regulatory assessment
- Organisation and planning of assessments
- The assessment process and its implementation
- Assessor competencies
- Specific problems encountered in assessing HACCP systems

Although aimed primarily at Government Agencies, this document provided valuable guidance on how to approach and manage a HACCP assessment process. However, although the use of a checklist in assessing HACCP was recommended and a list of possible checklist questions included, no standard assessment data collection tool was proposed. This would seem to have been a missed opportunity for standardisation of HACCP assessment processes, at least at government level. Other previous publications have also described the roles and approaches taken by government agencies in different parts of the world in assessing HACCP (Gagnon, McEachern, and Bray, 2000; Kvenberg *et al*, 2000; Merican, 2000; Torres, 2000).

Gagnon *et al* (2000) described the position in Canada where the Food Safety Enhancement Program (FSEP) is voluntary for establishments registered under the Meat Inspection Act, and the Quality Management Program (QMP) is mandatory for federally registered fish processors. Both these initiatives are compatible with Codex HACCP requirements and use similar methods for verification of compliance and adequacy, including the use of Critical, Major and minor non-conformity ratings.

Kvenberg *et al* (2000) described the development of HACCP and regulatory assessment in the USA, including the FDA and USDA HACCP inspection/verification programmes. Although regulators and food processors have the same goal of safe food production, they may have different perspectives on how to measure 'effectiveness'. Therefore, objective and direct measures that have a baseline against which an assessment can be made and/or a change can be calculated need to be developed (Kvenberg *et al*, 2000).

A number of other studies (Ababouch, 2000; Merican, 2000; Torres, 2000) have used frameworks that include checklists and guidance for auditors. However, there is limited consistency and no internationally agreed approach. For any assessment programme to generate useful information, criteria to evaluate the effectiveness of the HACCP Plan and its application need to be established and assessment methods need to be identified.

Building on the recommendations of Mortimore and Wallace (1998) and the International Life Sciences Institute (ILSI, 1999), broad criteria for HACCP effectiveness assessment can be established and an understanding of how these criteria are met can be used to plan the data collection requirements for HACCP effectiveness assessments (Table 2.1).

Table 2.1 HACCP Effectiveness Criteria

The HACCP Plan must be:	Considerations for Assessment Planning
Valid for control of significant food safety hazards that are likely to occur in the type of operation being studied.	Validity of the HACCP Plan depends on the knowledge and skills of the HACCP team in terms of understanding the process, its ingredients and the likely occurrence of hazards and their potential severity; and ability to understand and apply the Codex HACCP principles to develop an effective HACCP Plan.
Implemented into the every-day operation of the food company	This is achieved through a handover process from the HACCP team to operations management and line personnel, where it is important that operations personnel take ownership for day-to-day operation of the HACCP Plan. Implementation is demonstrated through monitoring of critical control points, taking corrective action where necessary and keeping records.
Adequately verified and maintained.	Verification includes audit of the working HACCP system for compliance with the HACCP Plan and review of food safety records. Maintenance involves ongoing update procedures both to evaluate impact of changes in the operation and keep up to date on knowledge of food safety hazards.

2.1.3 The Need for HACCP Assessment Tools

Both the approach taken by government agencies (Kvenberg et al, 2000) and work with multinational companies (Beckett and Bennett, pers. comms.[3]) has identified a need for standardised tools for the assessment of HACCP effectiveness. This is important to allow comparison of progress across a range of sites. Although previous groups (Mortimore and Wallace, 1998; WHO, 1998; ILSI, 1999; Mortimore, 2000) have produced auditing practice guidelines and/or identified key points to cover, few standardised tools have been published.

Sperber (1998) outlined the approach to food safety audit within Cargill Incorporated (a multinational food and agricultural products company), including the provision of a 17-question 'Food Safety Effectiveness Audit Worksheet' for evaluating HACCP procedures on the production floor and a 10-question 'Food Safety Management Worksheet'. Use of these worksheets allows the implementation of HACCP in production to be verified but they do not cover the validity of the HACCP plan, and there appear to be weaknesses in the assessment of corrective action effectiveness at CCPs.

A number of HACCP Audit Checklists and example questions have been published (e.g. Ababouch, 2000; Torres, 2000; Australian Standing Committee on Agriculture and Resource Management, 2003; United States National Conference on Interstate Milk Shipments (NCIMS), 2004), however most look

[3] These personal communications were with Technical Directors operating at regional and global levels of multinational food manufacturers.

for presence or absence of HACCP System elements and do not, as written, challenge the effectiveness of these elements.

Wilkinson and Wheelock (2004) published a checklist of questions used in assessing the effectiveness of HACCP implementation and maintenance in food production plants on the island of Ireland. This checklist is designed to be applied by trained auditors. It is a detailed approach, and includes aspects of food safety management as well as HACCP development, implementation and maintenance. However, the checklist is written as a series of interview questions and therefore must be applied at the manufacturing site with assistance from site personnel. Whilst it is clearly important to verify HACCP implementation and maintenance on-site, it is also possible to assess the validity of HACCP documentation remotely. This has benefits of identifying major flaws in the approach without the time and travel expense of a site visit.

Although all of these approaches contain useful guidance on topics/questions to be covered, it was considered that they do not offer a 'complete' approach to the assessment of HACCP systems. Highly structured sets of interview questions such as those proposed by Wilkinson and Wheelock (2004) also have the potential to limit auditor flexibility and judgment. It is therefore important to obtain a balance, including a structured framework whilst still allowing some subjectivity based on auditor experience. This is consistent with international guidelines for quality and environmental management systems auditing (BSI, 2002) which states that 'the use of checklists and forms should not restrict the extent of audit activities, which can change as a result of information collected during the audit'. Therefore, a checklist framework needs to act as an aide memoir on the essential points to be assessed, while allowing flexibility to the auditor in making expert judgements about HACCP status, and the checklist style is thus important.

Some approaches (Sperber, 1998) use simple scoring systems based on allocating points to 'satisfactory' or 'unsatisfactory' ratings whilst others (NCIMS, 1999; Gagnon et al, 2000; Mortimore, 2000) rely on listing of deficiencies/non-compliances. Cooper and Pronk (1997) describe scoring systems as a topic of contention, indicating that some companies find scoring useful to indicate progress whilst others believe that they are difficult to keep objective. Indeed, this is confirmed by discussions with many food safety professionals who are wary of the use of arbitrary scores, particularly percentages, since a scoring system could be envisaged where a particular HACCP Plan achieves an apparently high score but still has a major food safety flaw (Mortimore, Palmer and Swoffer, pers. comms.[4]). It is therefore crucial that any scoring system is carefully designed and that its limitations are clearly understood.

Recently there has been a growth in 3rd party auditing of food safety and quality systems as part of the 'due diligence' of suppliers, manufacturers and retailers in the food supply chain (BRC, 2008; Manning, 2007). Several privately owned audit schemes have developed in different parts of the world to meet the needs of local and regional industry. At the international level there

[4] Sara Mortimore is a leading author on HACCP and Technical Director of a Multinational Food Manufacturer; Gill Palmer is a HACCP consultant and trainer, Head of Training for Reading Scientific Services Ltd and was Chief HACCP Examiner for the RIPHH; Kevin Swoffer is a former Retail Technical Director who was instrumental in development of the 3rd party food safety and quality audit scheme for the British Retail Consortium.

have been initiatives to establish equivalence of these individual schemes (GFSI, 2007) and most recently the publication of an international standard for food safety management, ISO 22,000 (ISO, 2005[a]), which uses Codex HACCP principles (Codex, 2003) as its base. All of these schemes require assessment by trained auditors and, although the standards outline the requirements that food companies are expected to meet, few audit tools have been published to establish whether the requirements have actually been met.

Therefore, there is no internationally agreed approach to HACCP assessment and it is necessary to establish standard approaches to examine the effectiveness of HACCP Systems.

The aims of this element of the research were to:

- Establish strategies for assessment of HACCP knowledge and HACCP effectiveness
- Develop and validate tools to measure HACCP knowledge and effectiveness
- Determine the levels of HACCP knowledge held by trained HACCP team members
- Determine the validity of HACCP Plans developed by trained HACCP teams
- Evaluate the impact of training on successful HACCP plan development
- Determine the additional research elements required to meet the main research aims.

2.2 Methods – Development of Tools

2.2.1 HACCP Knowledge Assessment Tool

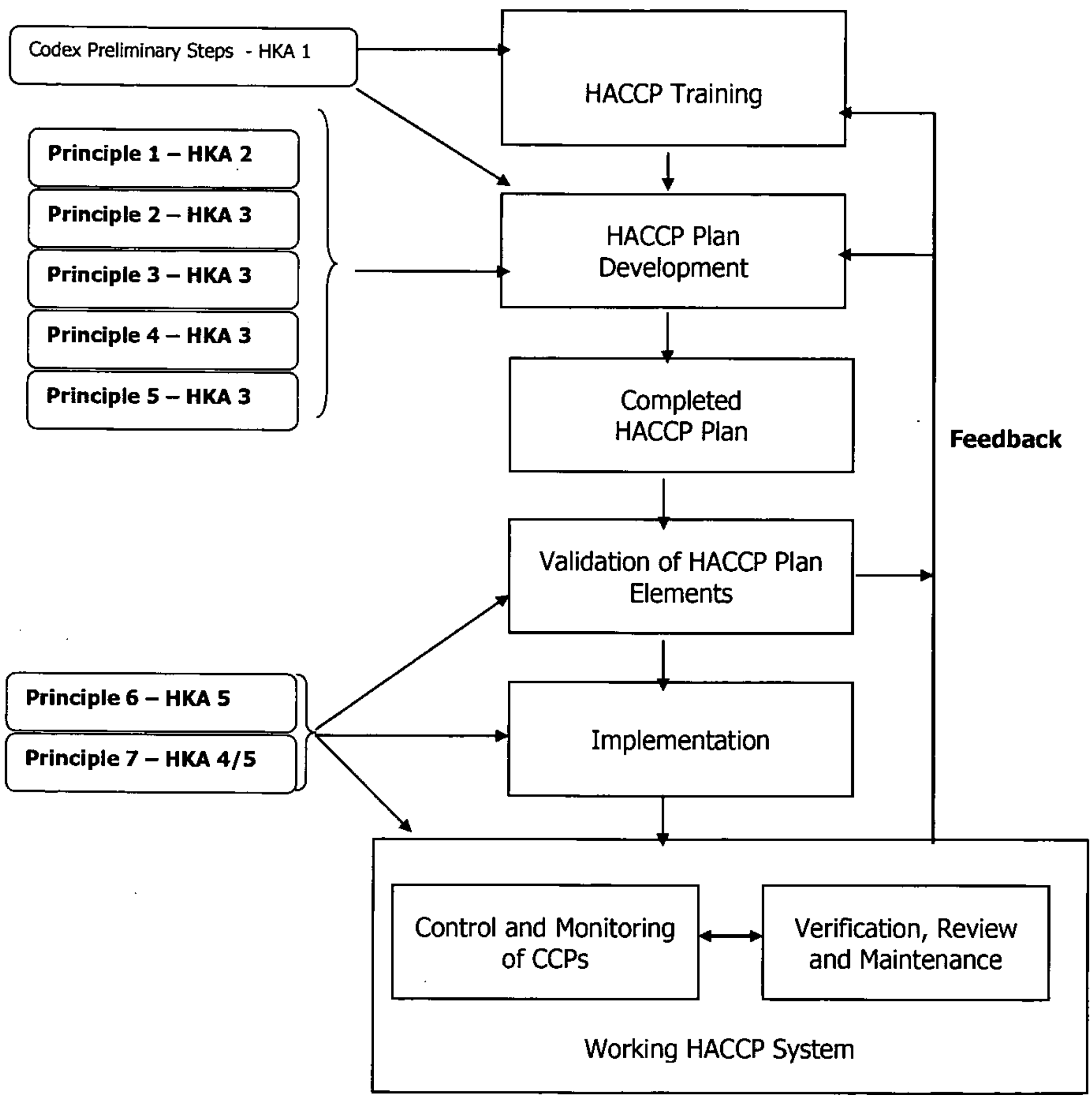
A HACCP questionnaire (Appendix 2.1) was developed to test knowledge of Codex HACCP Principles and their application. The questionnaire was based on short-answer questions using standard Codex HACCP terminology, and the design, development and piloting of the tool is discussed below, and in Wallace *et al* 2005[a] (See appendix 1.2).

Short-answer questions were chosen to overcome the potential problem of recognition memory that can be seen with multiple-choice tests, where the potential answers give candidates clues to the answers that they might not have thought of themselves (Bowling 2002). The questionnaire was piloted with groups of HACCP trainees in the UK and China. In China a translated version was used. The translation was completed by a professional translating company and the translation accuracy was verified by a Chinese speaking HACCP practitioner. This approach to translating is consistent with the approach of Hofstede (2001) where one-shot translation by an able translator and careful checking by a bilingual reader familiar with the content matter is identified as an effective approach that is less costly and time consuming than translation and back translation by two separate translators. On cross-checking of the Chinese translation slight refinements were needed to two questions (wording change to the Chinese version to ensure HACCP sense of words rather than literal translation) before application of the questionnaire to the main test groups.

Questions were split into 5 HACCP Knowledge Areas (HKAs) (Figure 2.1) covering knowledge of HACCP Principles and their application as follows:

HACCP Knowledge Area	Codex Principle(s)
1. Codex Preliminary Steps	Codex Preliminary Steps
2. Hazard Analysis	Principle 1
3. CCP Identification & Control	Principles 2-5
4. HACCP Implementation	Principle 7 plus application of work from 1-6
5. HACCP Maintenance	Principles 6-7

Figure 2.1 Relationship of Codex HACCP Principles and HACCP Knowledge Areas (HKAs) to the HACCP Development Process



a) Marking Scheme

In order to ensure that results were comparable across individuals and sites, a standardised marking scheme was developed. The marks breakdown is summarised in Table 2.2, and the marking guidelines are reproduced in Appendix 2.2. It was also necessary to ensure that the marker was independent from the training to prevent any marking bias through knowledge of the trainees. Therefore, as the researcher had been involved in training at some sites, after data collection the submitted questionnaires were assessed by one independent HACCP specialist marker using the standardised marking scheme.

Table 2.2 HACCP Knowledge Areas, Questions and Marking Breakdown

Q. No.	HACCP Knowledge Area	Question	Marks available	Marking Rationale
1	Hazard Analysis	Explain what is meant by a hazard?	2	Codex HACCP gives precise definition of the term hazard. 2 marks for complete definition or 1 mark for answer that demonstrates knowledge that hazards cause harm or illness.
2	Hazard Analysis	Explain what is meant by a control measure?	2	Codex HACCP gives precise definition of the term control measure. 2 marks for complete definition or 1 mark for answer that demonstrates knowledge that control measures are to do with hazard control.
3	Codex Preliminary Steps	What is the purpose of the process flow diagram in HACCP?	1	Simple answer required – to capture all process steps for consideration in study, therefore 1 mark.
4	Codex Preliminary Steps	Why is it important to validate the process flow diagram?	2	2 points could be made – that it is the basis for a hazard analysis so should be correct and that if any steps are missing then hazards may be missed. Therefore 2 marks.
5	CCPs & their control	What is a critical control point?	2	Codex HACCP gives precise definition of the term critical control point. 2 marks for complete definition or similar answer showing knowledge that it is essential to control hazards here for food safety.

6	CCPs & their control	How can critical control points be identified? List two methods that could be used.	2	2 methods are mentioned in training – CCP decision trees (e.g. Codex) and HACCP team expertise/judgement. 1 mark for each method.
7	CCPs & their control	What is a critical limit?	1	Answer to demonstrate knowledge that this is the boundary between acceptability and unacceptability or safe and unsafe.
8	CCPs & their control	Metal detectors are checked every 30 minutes with metal test pieces. What kind of activity is this?	1	Straightforward answer (monitoring procedure) – 1 mark.
9	Implementation	What records might be found in the production area when a HACCP Plan has been implemented?	2	2 main types of records might be found (monitoring and corrective action records) – 1 mark for each.
10	Implementation	Why is microbiological testing not a good monitoring procedure?	2	Points made here should include time taken to get results is too long for operational food safety control and limits of microbiological sampling due to distribution of microorganisms. 2 marks for complete answer or 1 for either point.
11	CCPs & their control	What should happen if there is a deviation from a critical limit?	1.5	Answer should indicate that defined corrective action should be taken (1 mark). Additional 0.5 mark available for relevant specific actions such as stopping the line or quarantining product.
12	Implementation	Describe the two main types of corrective action.	2	Trainees should be able to state both that there is corrective action to identify and handle (e.g. destroy) potentially contaminated product and corrective action to repair the process fault. 1 mark for each.
13	Codex Preliminary Steps	Why is it important that the HACCP study is done by a multidisciplinary team?	1	Straightforward answer to ensure appropriate blend of expertise is available.
14	Codex Preliminary Steps	List the three main disciplines required in a manufacturing HACCP Team.	3	Disciplines expected are production, quality assurance/technical and engineering/maintenance. 1 mark for each.
15	Implementation	What document is completed at the end of a HACCP study?	1	Straightforward answer – HACCP Plan.
16	Maintenance	List two verification procedures that can be used to determine if the HACCP system is working correctly.	2	Expected answers include audit and records review/analysis (possible record examples include CCP monitoring, deviations, product testing, customer complaints). 1 mark for audit and 1 mark for another suitable procedure.

17	Hazard Analysis	Give an example of a hazard from each of the following groups: Microbiological Chemical Physical	3	Examples should include a pathogenic microorganism, toxic chemical or allergen and true physical hazard (only foreign material that would cause direct harm). Demonstrates knowledge of what the HACCP team should consider. 1 mark for each appropriate answer.
18	Maintenance	When should a HACCP Plan be reviewed?	2	Trainees should be able to state that review should be done periodically (e.g. at least annually) and whenever there is a proposed change to the operation. 1 mark for each point.
19	Implementation	What type of training is important for line operators when a HACCP Plan is implemented in their work area?	2	HACCP awareness training plus monitoring/corrective action training if they are responsible for these activities. 1 mark for each.
20	Hazard Analysis	What should the HACCP team do if they have identified a significant hazard but there is no control measure at that step or any following step?	2	Important question demonstrating knowledge that control is required for all significant hazards identified. Answers should indicate the need to redesign the process, product or equipment to build in control – 1 mark for redesign, 1 mark for need to build in control.
21	Hazard Analysis	Suggest a control measure that could be used for hazards associated with raw materials.	1.5	Demonstrates knowledge of control measures and identifies confusion between control measures and monitoring procedures. Answer should include effective supplier quality assurance programme (1 mark). Additional discretionary 0.5 mark for relevant specific hazard control.
22	Hazard Analysis	Which two factors should be considered when carrying out the hazard analysis?	2	Answers should demonstrate knowledge that it is important to assess both likelihood of occurrence and severity of health outcome to determine the significant hazards. 1 mark for likelihood and 1 for severity.

b) Establishment of Training Background

Before completing the HACCP knowledge questions, candidates were asked to give details of their HACCP training. This included structured and open questions to elicit the approximate date of training, whether it was an in-house or external programme, the type of training (e.g. lectures, practical exercises, etc.), its duration and whether attendance or examination certificates had been received. Although it was known that most candidates had received the same standard, non-assessed company HACCP training, this information was collected to confirm training and to highlight any anomalies, e.g. additional training received.

c) Perception of HACCP Ability following training

Candidates were also asked for their view on their HACCP ability following training, choosing from the following options:

a) I had enough knowledge to develop/participate in the development of a HACCP Plan straight away.

b) I needed more practice in applying HACCP Principles before I was comfortable with developing/participating in the development of a HACCP Plan.

c) I was unsure of where to start, in order to develop/participate in the development of a HACCP Plan.

d) Other, please specify

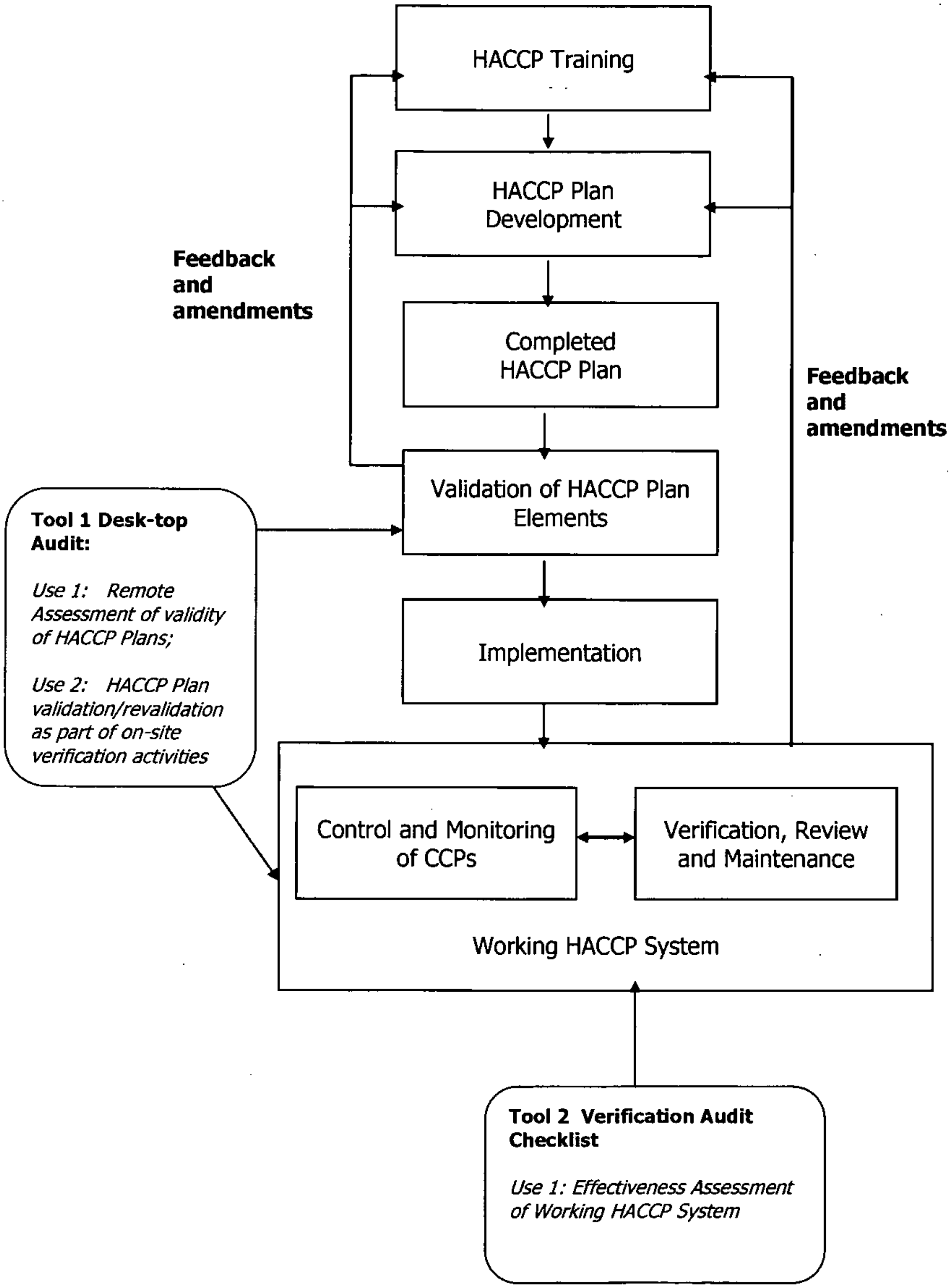
This question was designed to gain information on whether the training had delivered the confidence and ability to develop HACCP plans.

2.2.2 HACCP Assessment Tools

Literature on HACCP audit and assessment was reviewed and existing guidelines and tools were identified as described above (Wallace *et al*, 2005[b]). Due to the limited consistency and lack of an existing internationally agreed approach (Wallace *et al*, 2005[b]), it was concluded that an assessment tool needed to be developed (Kvenberg *et al*, 2000; Wallace *et al* 2005[b])

In order to establish a standardised audit framework that would cover all required aspects of HACCP assessment, two audit checklist tools were developed. These two tools provide a step-wise approach to HACCP Assessment (Figure 2.2). At the same time, it was also necessary within the multinational company, to establish a comparative measure of individual manufacturing site HACCP progress so that priority targets for additional training and HACCP support could be identified. Therefore a scoring system was included both to allow comparison between sites, and to allow comparison with HACCP knowledge data.

Figure 2.2 Use of Audit Tools in HACCP Assessment



This combination of HACCP Audit Tools was designed both to assess the validity of the HACCP Plan (i.e. will the HACCP Plan control all likely hazards?), and to verify the implementation and maintenance of the HACCP system (i.e. is the HACCP Plan working in practice in the factory?). The tools were designed to allow off-site assessment (desk-top audit) of HACCP documentation for validity as well as on-site assessment of implementation and maintenance effectiveness. Use of off-site desk-top audit was also important to allow assessment of a larger sample of sites than could be covered by on-site audit, and thus give an indication of site positioning for HACCP competence throughout the large manufacturing group. On-site assessment would be necessary to provide more rigorous assessment of HACCP at a smaller sample of sites. (Wallace *et al*, 2005[b])

Assessment Tool 1 – A HACCP Desk-top Audit Checklist (Appendix 2.4) was developed by selecting aspects of HACCP audit that focussed on the approach to HACCP Plan development and its validity. Assessment Tool 2 – HACCP Verification Audit Checklist (Appendix 2.5) was developed as a complimentary checklist that would allow verification of implementation and maintenance at the site.

In order to assess the validity of HACCP Plan documentation (Assessment Tool 1), 6 groups of questions were developed, relating to the steps in a HACCP study, as follows:

- Codex Preliminary Steps and Documentation
- Principle 1 – Hazard Analysis

- Principle 2 – Determination of Critical Control Points
- Principle 3 – Critical Limits
- Principle 4 – Monitoring Procedures
- Principle 5 – Corrective Action

Questions assessed not only the completeness of the documentation, but also validity of the content. It was intended that the checklist would be applied by experienced auditors who had known HACCP expertise. Guidance notes were included, where appropriate, to ensure consistency of application. Wording of individual questions was designed to be appropriate to a remote audit of HACCP Plan paperwork without access to further site information.

Questions were not developed for Principles 6 (Verification) and 7 (Documentation) since, although documentation is considered as part of a desk-top audit, these Principles can only be fully assessed during an on-site audit. They are therefore included in Tool 2.

In order to produce comparable data from application of the desk-top audit tool, a scoring system was also developed. Since all the HACCP Principles being assessed and the preparation included in Codex Preliminary steps were deemed equally important to the development of a valid HACCP system, each of the 6 question groups was allocated 20 points. However, weighting of individual questions within each question group was developed by considering their likely relative impact on the development of effective HACCP systems. For example, the relatively minor question: 'Is intended use for product stated?' was allocated 0.5 points while the question: 'Are listed control measures sufficient to prevent, eliminate or reduce each significant hazard to an acceptable level?' was allocated 6 points. All questions were designed to have 'yes' or 'no' answers, denoting whether the information is present and acceptable or not. If the auditor considers that the information demonstrates partial coverage/acceptability for a specific question, the answer would be recorded as 'marginal'. Scoring is given as full marks for an acceptable answer and no marks for an incorrect answer of missing information. Where the answer is 'marginal', proportional marks are given based on auditor judgement.

Assessment Tool 2 – HACCP Verification Audit Checklist (Appendix 2.5), was designed to work at site level in conjunction with the HACCP Desk-top Audit Checklist, thus allowing both validity to be assessed and implementation/maintenance of HACCP to be verified. For verification of HACCP effectiveness, both tools are applied together on-site, requiring the trained auditor(s) to visit the site for 2-3 days to perform the assessment. Assessment Tool 2 consists of 4 sections:

- Overall assessment of HACCP Plans
- Assessment of Process Flow Diagram
- Verification of HACCP Implementation
- Verification of Maintenance procedures

Because Tool 2 was intended to highlight specific anomalies and weaknesses at individual manufacturing sites to give an overall qualitative view of HACCP effectiveness, a numerical scoring system was not included in this case. Rather, it was decided to use the accepted quality systems audit approach of deficiency identification (British Standards Institute, 2002).

Assessment Tools 1 and 2 - Pilot Study

Questionnaire design and wording were discussed with 3 experienced HACCP auditors and tested against 5 sample HACCP Plans. Any difficulties in application and interpretation were highlighted and minor modifications were made to the tools. In the judgement of this group of expert HACCP auditors, the questions were considered appropriate to measure HACCP validity and effectiveness.

2.3 Methods – Data Collection

2.3.1 Sites and Language

This preliminary stage of the research included the administration of the HACCP knowledge questionnaire at a range of manufacturing sites to HACCP team members who had received a known level of in-house HACCP training, and desk-top assessment of HACCP plans developed at the same sites. All respondents to the HACCP knowledge questionnaire had been trained and were members of site HACCP teams and had therefore participated in the development of the HACCP system for that site. Data were collected from individual manufacturing sites as follows (Table 2.3).

Table 2.3 Preliminary Study HACCP Data Collection

Country	No. of Manufacturing Sites	No. of Candidates at each Site	No. of HACCP plans assessed**
India *	4	10	0
		10	2
		10	1
		8	1
Zimbabwe *	1	2	1
Egypt *	3	15 total across 3 sites (collected as one group)	1
New Zealand *	1	1	2
South Africa *	1	5	1
Russia *	2	14 total across 2 sites (collected as one group)	2
Indonesia	1	10	1
China	1	6	1

* Indicates that the English version of the questionnaire was used, following discussion on language ability with factory management where English is not the first language.
In China an updated Chinese version from the pilot test was used and in Indonesia local translation was done with back-translation of answers into English.
**HACCP plans for assessment were all provided in English, the business language of the company.

2.3.2 Administration of the HACCP Knowledge Questionnaires

The questionnaire (Appendix 2.1) was administered either by the researcher or a trained Quality Management Professional within the multinational company. A candidate briefing protocol (Appendix 2.3) was developed to ensure that all candidates were given the same information about the questionnaire, its confidentiality and their ability to decline participation or withdraw. Administrators were trained in the use of the briefing protocol and the questionnaire, and were not permitted to give any guidance relating to the questions to candidates.

Questionnaires were marked by one independent marker using the Marking Guidelines (Appendix 2.2). Marks were checked by the researcher for consistency between participants and application of the marking guide. This included identification of any local wording that might affect marking, e.g. 'asset care' is terminology for 'engineering' personnel at some sites. Any necessary amendments to marking were agreed with the independent marker before analysis.

2.3.3 HACCP Assessment Data Collection

A group of 6 HACCP auditors was trained in the application of Tool 1 and its accompanying scoring system. HACCP Plans were collected from 117 manufacturing sites as part of a larger HACCP progress review within the multinational company, and these were assessed by the trained HACCP auditors. This included ten of the eleven sites where HACCP knowledge was also tested (see section 2.3.1 above) such that comparison of HACCP knowledge and predicted ability could be made with HACCP assessment findings. One site (India-W) was unavailable for HACCP assessment as HACCP plans had yet to be developed.

2.4 Methods – Data Analysis

2.4.1 Classification of HACCP Knowledge Data

In order to evaluate the level of knowledge in each of the HACCP Knowledge Areas (HKAs), the mean scores for each question and each candidate group were assessed. Knowledge was classified as poor where ≤ 29% of candidates answered the question correctly; fair where 30-59% of candidates were correct; good at 60-84%; and excellent at ≥85% correct. These divisions were chosen to reflect the likely ability of the HACCP teams to work together in these HKAs.

For example, a group of 10 candidates completing the questionnaire would normally reflect inclusion of 2 separate HACCP teams (normal practice is to have HACCP teams of 4-6 individuals). Less than 29% correct would reflect less than 3 people in the total group and therefore 1-2 people in each team. The ability of the HACCP team to address this aspect of HACCP satisfactorily would depend on how confident and how vocal these individuals were compared to their colleagues. If one person knows the answer and the remaining team members do not, there may be a better chance of the team acting correctly than if one person is correct and the remaining team members think they know the answer but are incorrect. This is consistent with the work of Soloman Asch on conformity (Asch, 1955) and with the theory of Groupthink (McKenna, 2000).

Similarly in the same group of 10 candidates, an overall level of 30-59% would reflect 2-3 people in each team with the necessary knowledge. In this case it is considered more likely that the team would act correctly. At 60-84% there would be 3-4 personnel in each team and at ≥85% there would be 4-5 personnel in each team with the correct knowledge, with a growing chance of the team making correct decisions in each case.

The precise way that the team acts on the knowledge of individual members depends on team dynamics and the personalities involved in each case. This is not possible to establish from the data collected in the preliminary study but it is the subject of further investigation in Chapter 5.

2.4.2 Development of Predictive Scheme for Impact of Knowledge on HACCP Effectiveness

In order to evaluate the likely impact of team member knowledge on HACCP development, implementation and maintenance at each site, the HKA data were further evaluated. The overall level of knowledge for HACCP teams on the site was categorised as 'appropriate', 'marginal' or 'unsafe' depending on the combined accuracy of answers for the group of questions in each HKA. This judgement included consideration of any specific essential questions within the HKA. The category of overall level of knowledge was used to predict the effectiveness of resulting HACCP Plans, their implementation and maintenance.

2.4.3 HACCP Assessments

Scoring was done by the individual trained auditors according to the scoring system outlined in section 2.2.2 in order to establish a measure of HACCP effectiveness at the sample sites.

2.4.4 Comparison of Predicted HACCP Ability versus Desk-top Audit Findings

In order to determine the accuracy of the predictive outcomes based on HACCP knowledge predictions, it was necessary to compare the outcomes for knowledge levels and HACCP effectiveness. To facilitate this, corresponding levels between the HACCP knowledge and desk-top audit scoring schemes were identified (Table 2.4). Two levels in the desk-top audit scoring system (Good and Excellent) were considered to be equivalent to one level (Appropriate) in the knowledge scoring system. This was because the extra divisions in the desk-top audit scoring system had originally been designed to show progress between sites, whereas the knowledge scoring system was intended to show only that satisfactory knowledge was present or not.

Table 2.4: Comparison of Scoring Schemes – Knowledge Questionnaire vs. Desk-top Audit

	Knowledge Questionnaire	**Desk-top Audit**
Level 3	Appropriate	Excellent
		Good
Level 2	Marginal	Fair
Level 1	Unsafe	Poor

2.5 Results

2.5.1 HACCP Knowledge

a) General Levels of HACCP Knowledge

The HACCP Knowledge scores for the test groups are summarised in Table 2.5. The scores showed considerable variation both within and between groups, with the number of low scores raising concern about the overall level of HACCP knowledge shown by the candidates. For example, the highest score overall (78.9%) was seen in the Indonesian group, which also had a low score of 21.1% and a median of 46.7%. Similarly the scores for India-M ranged from 26.3% to 77.5% with a median of 43.8%. The closest grouped scores were from Russia, ranging from 52.5% to 72.5% and with a median of 57.5%.

Table 2.5 HACCP Knowledge Scores

Country	No. of Manufacturing Sites	No. of Candidates at each Site	HACCP Knowledge Questionnaire - % Scores achieved by individuals within the candidate Group		
			Minimum	Maximum	Median
India *	4	10 (site W)	30	57.5	46.3
		10 (site M)	26.3	77.5	43.8
		10 (site T)	32.5	60.0	41.3
		8 (site I)	15	65.0	46.3
Zimbabwe *	1	2	50	50.0	50
Egypt *	3	15 total across 3 sites (collected as one group)	2.5	20.0	12.5
New Zealand *	1	1	57.5	57.5	57.5
South Africa *	1	5	25	62.5	37.5
Russia *	2	14 total across 2 sites (collected as one group)	52.5	72.5	57.5
Indonesia	1	10	21.1	78.9	46.7
China	1	6	23.7	69.7	50.0

b) Time since Training and Knowledge Levels

The length of time since HACCP training was identified for each manufacturing site. Table 2.6 shows the manufacturing sites and their HACCP knowledge scores in ascending order of time since training.

Table 2.6 Time since Training and HACCP Knowledge

Site (No. candidates)	Time (months) since training	HACCP Knowledge Questionnaire - % Scores achieved by individuals within candidate Group		
		Minimum	Maximum	Median
Russia (14)	1	52.5	72.5	57.5
China (6)	1	23.7	69.7	50.0
Indonesia (10)	3	21.1	78.9	46.7
India – W (10)	6	30	57.5	46.3
South Africa (5)	20	25	62.5	37.5
India – M (10)	22	26.3	77.5	43.8
India – T (10)	38	32.5	60.0	41.3
Egypt (15)	38	2.5	20.0	12.5
India – I (8)	38	15	65.0	46.3
Zimbabwe (2)	44	50	50.0	50
New Zealand (1)	72	57.5	57.5	57.5
Total (91)	N/a	2.5	78.9	46.3

c) Perception of HACCP Knowledge Following Training

Results for candidate perception of their ability following training are given in Table 2.7, together with their HACCP knowledge scores. Data were available for 75 candidates from the total group of 91. Two candidates chose two separate perception statements making the total reported 77. No respondents ticked the 'other' perception statement option. The perception question had not been included in the scripts administered to the remaining candidates as this had not been translated from the original English version. Perception data are therefore not available for the Chinese and Indonesian groups.

Table 2.7 Perception of HACCP Knowledge following Training

Perception Statement	Number of candidates reporting	HACCP Knowledge Questionnaire - % Scores achieved by individuals within candidate Group		
		Maximum Score	Minimum Score	Median Score
Enough knowledge to get going	34	77.5	15	50.7
Need more practice	42	67.5	2.5	36.9
Unsure where to start	1	65	65	65

d) Knowledge in Particular Aspects of HACCP

Mean scores for each question in the 5 HACCP Knowledge areas (HKAs) are given in Table 2.8. This indicates a variety of different knowledge levels both across sites for a particular question and across questions/HKAs for a specific site.

Table 2.8 Scores (% correct within test group) Achieved for Specific Questions within HACCP Knowledge Areas

HACCP Knowledge Area	Question No.	Russia	China	Indonesia	India - W	South Africa	India - M	India - T	Egypt	India - I	Zimbabwe	New Zealand	Totals
Codex Preliminary Steps	3	50	50	85	30	60	70	30	0	50	100	100	54.9
	4	32.1	25	15	0	30	5	5	0	0	25	0	11.5
	13	42.9	16.7	30	60	60	20	70	0	25	50	100	35.2
	14a	85.7	66.7	70	90	100	90	40	0	62.5	50	100	62.6
	14b	100	66.7	60	90	100	100	40	0	62.5	100	0	64.8
	14c	100	50	80	100	100	90	30	0	62.5	100	100	65.9
Hazard Analysis	1	100	100	75	85	40	50	80	20	62.5	50	100	67
	2	92.9	75	65	55	40	55	50	30	75	25	100	59.3
	17a	100	16.7	100	60	40	50	40	20	37.5	100	100	56
	17b	100	100	100	90	80	90	90	73.3	87.5	100	100	90.1
	17c	71.4	100	100	100	80	100	80	93.3	87.5	100	100	90.1
	20	14.3	8.3	15	25	10	30	20	3.3	37.5	25	50	18.1
	21	61.9	16.7	13.3	33.3	6.7	26.7	53.3	20	33.3	33.3	0	33.3
	22a	57.1	*[5]	*[5]	20	0	20	20	0	12.5	0	0	20
	22b	0	*[5]	*[5]	0	0	10	0	0	12.5	0	0	2.7
CCP Identification & Control	5	85.7	66.7	60	75	30	20	50	10	56.3	0	100	49.5
	6a	100	66.7	80	80	40	70	30	0	37.5	0	0	53.8
	6b	100	100	80	70	60	80	100	6.7	12.5	100	100	67.8
	7	92.9	33.3	70	60	20	50	70	40	75	100	100	61.5
	8	35.7	16.7	30	80	20	75	50	0	68.8	100	0	41.6
	11	33.3	66.7	50	13.3	53.3	26.7	20	8.9	33.3	66.7	0	30.4
Implementation	9	42.9	33.3	25	40	30	50	65	0	43.8	50	0	35.2
	10	32.1	25	20	40	50	45	25	6.7	56.3	50	50	31.3
	12a	7.1	33.3	20	20	40	40	30	0	0	50	100	19.8
	12b	14.3	16.7	40	20	60	10	0	0	25	0	0	16.5
	15	78.6	0	20	30	0	40	70	0	12.5	0	100	31.9
	19	35.7	58.3	25	25	10	40	50	0	50	50	50	31.3
Maintenance	16a	78.6	33.3	40	40	60	70	80	20	37.5	100	100	52.7
	16b	57.1	16.7	10	30	40	0	20	0	37.5	50	100	24.2
	18	57.1	0	20	20	50	20	35	3.3	43.8	50	50	28

*[5] Question not included in script submitted to this group.

e) HACCP Knowledge and Predicted Impact on Effective HACCP Systems

Following analysis of the results in each HKA (Table 2.8), a judgement on HACCP team knowledge and its likely impact on effective HACCP systems was formed as depicted in Table 2.9. This shows the considered positioning of each site according to whether their knowledge is considered 'appropriate', 'marginal' or 'unsafe' for effective HACCP development, implementation and maintenance.

Table 2.9 Judgement of Level of HACCP Knowledge at Sites

Predicted Level of Knowledge for : ➔	Effective HACCP Development			Effective HACCP implementation	Effective HACCP Maintenance
Unsafe	Egypt, China, India - T	Egypt, S. Africa	Egypt, S. Africa	All Sites	Egypt, India - W, Indonesia, India - I, China
Marginal	India - I, Zimbabwe, India - W, N. Zealand, S. Africa, India - M	Zimbabwe, India - M, N. Zealand, China, Indonesia, India - T, India - I, India - W, Russia	N. Zealand, China, India - I, India - T, India - M, Zimbabwe, India - W		India - M, India - T, Zimbabwe, N. Zealand, S. Africa, Russia
Appropriate	Russia, Indonesia		Russia, Indonesia		
	Codex Preliminary Steps	**Hazard Analysis**	**CCP Identification and Control**	**HACCP Implementation**	**HACCP Maintenance**
	HACCP Knowledge Area				

2.5.2 HACCP Assessment Findings

Table 2.10 HACCP Desk-top Assessment Scores

Manufacturing Site	Preliminary Steps & Documents	Principle 1	Principle 2	Principle 3	Principle 4	Principle 5	CCP Identification and Control* (Mean of Principles 2-5)	
India-T	Fair (13)	Fair (11)	Fair (10)	Excellent (20)	Excellent (20)	Poor (0)	Fair (12.5)	**Key:**
India-M	Good (16)	Excellent (17)	Fair (11)	Excellent (20)	Excellent (20)	Excellent (20)	Excellent (18)	Poor <10
India-I	Fair (13)	Fair (13)	Fair (11)	Fair (10)	Excellent (20)	Fair (10)	Fair (13)	Fair 10-13.5
Zimbabwe	Fair (11)	Poor (5)	Poor (9)	Poor (0)	Poor (0)	Poor (0)	Poor (2)	Good 14-16.5
Egypt	Good (14)	Poor (3)	Poor (4)	Fair (10)	Fair (12)	Excellent (20)	Fair (11.5)	Excellent ≥17
New Zealand	Excellent (20)	Good (14)	Good (15)	Excellent (20)	Excellent (20)	Excellent (20)	Excellent (19)	
South Africa	Fair (11)	Good (14.5)	Excellent (19)	Excellent (18)	Excellent (18)	Excellent (20)	Excellent (19)	*Mean calculated for comparison with HACCP knowledge areas
Russia	Poor (8.5)	Fair (11)	Good (16)	Excellent (20)	Excellent (20)	Excellent (20)	Excellent (19)	
Indonesia	Good (15)	Fair (11)	Fair (10)	Poor (5)	Excellent (20)	Excellent (20)	Good (14)	
China	Poor (6)	Poor (9)	Poor (6)	Good (15)	Excellent (18)	Excellent (20)	Good (15)	

Table 2.10 shows the findings from the desk-top assessments by the trained auditor group, highlighting the wide variety of ratings and hence HACCP plan effectiveness within the sample sites. All sites had weaknesses in some areas of assessment and, with the exception of Zimbabwe, which was rated 'poor' or 'fair' across all areas of assessment, all sites also achieved 'good' or 'excellent' in other areas of assessment. The strongest results overall were seen for the application of HACCP Principles 3, 4 and 5, with five sites (50%) gaining an 'excellent' rating for Principle 3, eight (80%) for Principle 4 and seven (70%) for Principle 5. Weaknesses in application of Principles 1 and 2 give concern that hazards and/or CCPs might be missed and, therefore be uncontrolled in the food operations.

2.5.3 Comparison of Predicted HACCP Ability and Desk-top Audit Findings

Table 2.11 shows the comparison of predicted HACCP ability (Table 2.9) versus Desk-top Audit findings, using the comparison of scoring schemes described in Table 2.4.

Table 2.11:

Comparison of Predicted HACCP Ability vs. Desk-top Audit Findings

	Codex Preliminary Steps	Hazard Analysis	CCP Identification and Control
Full Agreement	7/10 sites	5/10 sites	4/10 sites
Sites with Full Agreement	• Indonesia • Zimbabwe • S. Africa • India-T • India-M • India-I • China	• Indonesia • Russia • India-T • India-I • Egypt	• Russia • India-T • India-I • Indonesia
Sites Better than prediction	• New Zealand • Egypt	• New Zealand • S. Africa • India-M	• New Zealand • S. Africa • India-M • China • Egypt
Sites worse than prediction	• Russia	• Zimbabwe • China	• Zimbabwe

This shows different levels of agreement for the HACCP knowledge areas of Codex preliminary steps, hazard analysis and CCP identification and control, indicating a mismatch between the predictions and the desk-top audit data.

2.6 Discussion

2.6.1 HACCP Knowledge

a) General Levels of HACCP Knowledge (Table 2.5)

The Egyptian group had low levels of knowledge overall, with a range of scores between 2.5% and 20%. Further review of the background information and answers provided by this group indicated a difficulty with understanding of the English wording, e.g. inability to understand the question 'what was the duration of your HACCP training?' It is, therefore, not possible to establish whether these scores are a measure of HACCP knowledge or of ability to understand the questions. This group had been trained in English, using English materials but with sequential Arabic translation of the spoken material. However, the management team had been confident in using the English questionnaire and indeed English is the business language for the multinational organisation. It would be interesting to revisit this group using an Arabic version of the questionnaire.

The Zimbabwe and New Zealand groups were small, with respectively two and one candidate responses received. Since these sites would both be operating normal sized HACCP teams (4-6 personnel), it is not possible to gain an understanding of the breadth of HACCP knowledge in these HACCP teams from the data received. In both cases it was understood that the low numbers of candidates were not due to reluctance of candidates to take part but to local management issues, e.g. production pressure at the time or change in site Quality Manager, which prevented the questionnaire being administered to a larger group.

Of the remaining groups, the Russian group had consistently higher scores. The median scores for all other sites, with the exception of South Africa, fall between 40 and 50 inclusive. South Africa is a relatively small data set with only 5 candidates completing the questionnaire. It is therefore not possible to establish whether the apparently lower scores are due to lower levels of knowledge or due to the small sample size.

b) Relationship between time of training and knowledge (Table 2.6)

The time between training and completion of the questionnaire was also considered. The ability to retain and recall information is known as memory. Contemporary thinking on memory suggests that concepts pass from perception, through short-term memory to long-term memory (Reece and Walker, 1997). Recall statistics often quoted in training folklore list recall after 3 months as 10%, 32% and 65% depending on whether trainees have been 'told', 'told and shown' and 'told, shown and experienced' respectively (Whitmore, 1992). Reid and Barrington (1999) report that rehearsal is necessary to transfer information from short-term to long-term memory and that understanding meaning assists memory. The practical nature of HACCP training interventions, which give trainees experience in applying HACCP Principles should, therefore, assist in memory.

In this study, although a number of groups had answered the questions <6 months after training and the remainder had longer periods in between training and questionnaire completion (20-72 months), no time-dependent effect on knowledge was apparent. This may be because, whilst trainees who have recently been trained may have good recall from the training, trainees who had been trained earlier are more likely to have participated in practical application of HACCP knowledge during HACCP studies and, therefore, to have reinforced their knowledge.

c) Consideration of HACCP Ability Perception following training

The results for candidate perception of HACCP ability following training are shown in Table 2.7. Seventy-five candidates provided data for this area with option (a) (I had enough knowledge to develop/participate in the development of a HACCP Plan straight away.) and option (b) (I needed more practice in applying HACCP Principles before I was comfortable with developing/participating in the development of a HACCP Plan.) being chosen by most candidates. Two candidates chose 2 perception statements: one who scored 65% picked both option (a) and option (c) (I was unsure of where to start, in order to develop/participate in the development of a HACCP Plan.); the other candidate who scored 67.5 picked both options (a) and (b).

The ranges of individual HACCP knowledge scores for options (a) and (b) were similar, with the median value at approximately the same position in the range. However the minimum and maximum values for option (a) were positioned at slightly higher knowledge scores than for option (b). This may indicate slightly more confidence in HACCP ability from the individuals in the higher scoring group although it is considered that there are insufficient data to confirm this.

Option (b) included all but one of the Egyptian group whose results have already highlighted as problematic due to language difficulties. However it is interesting to note that the one candidate from Egypt who chose option (a) was the second highest scoring in that group with 18.8%.

Perception of confidence in HACCP ability will be further studied in the second phase of the research (Chapter 7).

d) Analysis of Knowledge in Particular Aspects of HACCP

Several questions were identified with low scoring in the 'poor' or 'fair' categories across all sites (Table 2.8). This was generally due to incorrect answers rather than no response and indicates that either there was lack of understanding of this aspect of HACCP or the wording of certain questions is problematic. These questions included:

Q 4. Why is it important to validate the process flow diagram?
Q 10. Why is microbiological testing not a good monitoring procedure?
Q 12. Describe the two main types of corrective action
Q 16. List two verification procedures that can be used to determine if the HACCP system is working correctly.
Q 18. When should a HACCP Plan be reviewed?
Q 19. What type of training is important for line operators when a HACCP Plan is implemented in their work area?
Q 20. What should the HACCP team do if they have identified a significant hazard but there is no control measure at that step or any following step?
Q 22. Which two factors should be considered when carrying out the hazard analysis?

Q 4 (Why is it important to validate the process flow diagram?) was a supplementary question to Q 3 (What is the purpose of the process flow diagram?). Since these questions are linked and a larger proportion of candidates managed to answer Q3 correctly, it is considered that the problem with Q4 is not that the candidates misunderstood the wording of the question but that they did not know the answer. If HACCP Plans are developed from an un-validated process flow diagram then serious flaws can result since it is common for steps to be missed out or process step linkages to have errors in the early process flow drafts. This in turn can cause hazards to be omitted or their significance is misunderstood.

Q 10 covers an area where experience shows that errors are often made by new HACCP teams, who tend to identify microbiological testing as monitoring since this is often already being done in the factory quality control plan. This topic may be more difficult for the non-technical members of the HACCP team who may know that microbiological testing is not normally used but may not understand why.

Q 12 looks at both process and product orientated corrective action. Since more candidates were able to give one example, identifying process corrective action, it is considered that the wording of the question is not problematic. However results indicate that people do not understand the need for product orientated corrective action to protect the consumer from receiving potentially unsafe products.

Q 16 and Q18 both cover maintenance aspects of HACCP, which would not be in practice until the HACCP Plans had been developed and implemented, while Q19 involves implementation practice. These are areas where HACCP team members may not have experience until they have completed their HACCP Plan development, although they are all covered as part of training. Since a number of groups scored 'good' for one example of verification (audit) but could not easily identify another example, it is considered that the wording of this question did not cause misunderstanding. For the review and implementation training questions, a number of candidates gained marks moving 6/11 and 8/11 groups into the 'fair' category respectively. This suggests that the wording of these questions was satisfactory.

Q 20 is considered to score poorly due to lack of knowledge rather than misunderstanding of the wording since more candidates were able to answer the basic questions about hazards and their control (Qs 1,2 and 17). This area is an important knowledge gap since redesign is essential where an uncontrolled significant hazard is identified.

Q 22 covers an area of HACCP that is often poorly understood by HACCP trainees and HACCP team members, however it is not possible to determine whether the 'poor' scores were due to lack of knowledge or misunderstanding the question in this case. The Russian group had higher scores for the likelihood of occurrence part of this question with 57% of the group getting this correct. This indicates that they understood at least part of the judgement required in analysing hazards. All of the trainee groups work in an area of the food industry that would traditionally be considered 'low risk'[6] or 'low concern' in terms of food safety, due

[6] Although the terms low risk and high risk are widely used in conjunction with foods, there are few official definitions available. High risk foods are defined in the Food Law Code of Practice for England (FSA, 2009) as 'foods which support the growth of micro-organisms, and/or are intended for consumption without further treatment that could destroy pathogenic micro-organisms or their toxins'. Low risk foods have no specific definition in this document, however 'foods other than high-risk, such as fruit, vegetables, canned and other ambient shelf stable products' are mentioned. The products manufactured by the multinational company are ambient shelf stable products and are therefore considered to be of lower risk for the consumer if manufactured correctly in line with

to the production of ambient stable products. This may mean that fewer hazards are encountered than in 'higher risk' operations and therefore that all hazards identified are carried through the HACCP study without further evaluation. Where hazards are included without any risk/concern based judgment, the resulting HACCP Plans may have extra Critical Control Points (CCPs) that are not required for product safety (Wallace and Williams, 2001). It is not possible to assess this from the knowledge data of this preliminary study but this outcome will be reviewed as part of the further research elements (Chapter 3).

e) Predicted Impact of knowledge on successful HACCP development, implementation and maintenance.

Three HKAs, Codex Preliminary Steps, Hazard Analysis and CCP Identification and Control, are involved in the development of HACCP Plans. Table 2.9 shows that the majority of sites were judged to have marginal knowledge in each of these areas and it is therefore predicted that there are likely to be weaknesses in the development of HACCP Plans at these sites through the application of HACCP Principles. Russia and Indonesia were rated as having appropriate knowledge for Codex preliminary steps and CCP identification and control. Russia was also considered to be on the borderline between the marginal and appropriate knowledge categories for hazard analysis. It is therefore considered that the

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HACCP principles. Such definitions are still problematic, however, as foods that do not support the growth of microorganisms could still be contaminated with pathogens and, therefore, be a vehicle of infection.

Russian, and to a lesser extent, the Indonesian HACCP teams are likely to be capable of developing effective HACCP Plans.

As previously stated, it is believed that the Egyptian results were affected by difficulty with the questionnaire language and therefore the rating given of unsafe knowledge levels for effective HACCP development may not be accurate. The South African group showed unsafe levels of knowledge for hazard analysis and CCP identification and control, although they showed better knowledge of the requirements of Codex preliminary steps. This indicates that they may know the importance and composition of multidisciplinary teams and why a process flow diagram is required (although not why it needs to be validated) but they may have problems in building on this basic knowledge to identify and assess hazards, identify controls and establish CCPs and their management criteria.

All sites scored poorly or fairly on the majority of questions relating to the HKA for implementation of HACCP Plans. There were a few specific instances where higher scores were seen, e.g. 70, 78.6 and 100% of the groups at India –T, Russia and New Zealand respectively were able to state that the HACCP Plan is the outcome of the HACCP study (Table 2.8, Question 15) and similarly New Zealand was 100% correct on process corrective action (Table 2.8, Question 12a). However this was one individual and therefore may not be representative of the HACCP teams. Of particular concern was the fact that few individuals/HACCP teams, with the exception of South Africa, were capable of identifying the need for corrective action that prevents unsafe product from being released to the consumer. From these findings it is therefore predicted that the transition of the paper HACCP Plans into everyday operation is likely to be a general area of weakness at the sites.

Results were poor in just under half the groups for the questions relating to the HACCP maintenance HKA. The remaining six sites (India – M, India – T, Zimbabwe, New Zealand, South Africa and Russia) were slightly stronger in being able to identify the need for audit as part of HACCP verification. This suggests that these sites should be capable of carrying out at least some basic verification of the HACCP system through audit. The New Zealand candidate was also able to identify an additional method of verification, although the practical application of this knowledge will depend on the position that this candidate holds as well as the knowledge of other HACCP/management team members at that site. Knowledge of when HACCP should be reviewed was again poor or fair, with Russia being the only site with >50% of candidates able to state when review should take place. Review of the HACCP system, at regular intervals and whenever any changes are proposed, is essential to ensure ongoing currency and validity of HACCP. This is likely to be an area of weakness in the application of HACCP knowledge.

2.6.2 HACCP Plan Assessment

The spread of ratings for different aspects of HACCP application is striking, with no sites achieving good or excellent ratings across all assessment elements. Weaknesses in Codex Preliminary Steps (Codex, 2003) and documentation include weaknesses in some of the foundation elements of HACCP, e.g. make-up of multidisciplinary teams or missing elements/lack of validation in process flow diagrams. This could lead to hazards being missed during the HACCP study due to incomplete expertise or incomplete information about products and processes. Even if the application of all other HACCP Principles had been strong, these weaknesses could potentially affect product safety. Weaknesses in the application of HACCP Principle 1: Conduct a Hazard Analysis and Principle 2: Establish Critical Control Points (Codex, 2003) are of major concern as these key areas establish the strength of the HACCP plan. Even if all other HACCP Principles are applied correctly, missing a significant hazard or a required CCP at this stage will inevitably mean that unsafe product could be made. It is only the fact that this company manufactures products that would not be considered 'high risk[7]' that make the likelihood of significant hazards being missed in this way less likely.

It is encouraging that most sites achieved 'good' or 'excellent' ratings for the application of HACCP Principles 3: Establish Critical Limits; 4: Establish a system to monitor control of the CCP; and 5: Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control. This perhaps reflects the fact that food companies often find that control and monitoring requirements for HACCP are similar to existing monitoring systems for quality

[7] High risk foods are defined in the Food Law Code of Practice for England (FSA, 2009) as 'foods which support the growth of micro-organisms, and/or are intended for consumption without further treatment that could destroy pathogenic micro-organisms or their toxins'. Such definitions are still problematic, however, as foods that do not support the growth of microorganisms could still be contaminated with pathogens and, therefore, be a vehicle of infection.

management in many places. It does suggest that, as long as the correct CCPs have been identified, the control and monitoring systems at these sites will be strong, however this can only be determined by on-site evaluation of the working HACCP system.

2.6.3 Comparison of Predicted HACCP Ability and Desk-top Audit Findings

As shown in Table 2.11, the predicted HACCP capability from HACCP team-member knowledge (Table 2.9) did not fully agree with the measured outcome from the desk-top audit (Table 2.10). This is interesting as it indicates that there are likely to be additional factors involved in the development of effective HACCP and that HACCP training and its delivery of knowledge of HACCP Principle application are not the only factors involved in successful HACCP.

It can be seen that some sites did better than expected and some sites worse than expected. At the end of the preliminary study, the reasons for these differences were unclear and therefore required further investigation. Possible explanations were postulated to include:

- Possible extra interventions between knowledge test and desk-top audit.
- Interactions within HACCP teams led to different decisions and actions being taken than those suggested by individual team member knowledge.
- Additional people in HACCP teams who were not tested.

- Incorrect or incomplete information supplied for audit.
- Additional factors, as yet to be established at the time of the preliminary study, are impacting the development of HACCP Systems.

2.6.4 Strengths and Limitations

Although knowledge of HACCP Principle application within HACCP teams is likely to be important in the development of effective HACCP systems, the precise way that the team acts on the knowledge of individual members depends on team dynamics and the personalities involved in each case. Since the preliminary study was designed to evaluate individual knowledge it was not possible to establish team interactions effects at this stage, however it was planned that this would be included in the second phase of the research (Chapter 5).

For the HACCP knowledge testing activity there were differences in numbers of candidates providing answers to the questionnaire at different manufacturing sites. This was due, in part, to local management issues preventing the administration of the questionnaire to a larger group at some sites but it does make comparison between sites and comparison of HACCP knowledge with HACCP Plan development at sites where there were few knowledge respondents potentially problematic. Language was also an issue identified as potentially affecting the outcome of the knowledge questionnaire, particularly at the Egyptian sites. This had not been anticipated since local management had been confident about English language ability on site, however it indicated the need to look carefully at language and translation requirements in the planning of future studies.

The auditor plays a vital role in the assessment of HACCP systems and both his/her HACCP knowledge and audit expertise is crucial to success. In this study it was concluded that training of auditors in the use of the checklist tools is also important to ensure consistency of application, and a strength was the availability of highly skilled and experienced HACCP auditors to assist in the desk-top audits. However this desk-top audit approach is limited in that, as an off-site assessment, it cannot give a complete judgment on the validity of hazard identification but rather an assessment of the approaches taken and likely hazards for the product group. Nevertheless, it is similarly questionable whether on-site assessment by one to two auditors could give a more complete judgement on hazard identification validity if they are independent from the site and unfamiliar with its processes.

Since the desk-top audit, by definition, could not look at implementation and maintenance, these HACCP knowledge areas were not included in the comparison. Assessment of CCP control, therefore, was based on the information stated in the HACCP Plan rather than the active control situation. It was also reliant on the data submitted by the individual sites and so a misunderstanding of data requirements could have led to key information being withheld and the site being marked down for that aspect of HACCP. This is considered to be unlikely for these sites because a detailed checklist of information requirements had been sent to all those involved in the desk-top audits, however in the wider study of all 117 manufacturing sites it was found that further communication with sites was necessary to clarify details of information provided or to obtain missing information in some cases. These issues could be overcome by on-site assessment where all documents are available. It is also possible that the relationships between knowledge and HACCP outcome may be different if the working HACCP System were assessed or if HACCP team knowledge data were available to compare against the HACCP plans produced by that HACCP team. These issues need to be explored in more depth through field study.

2.6.5 The Need for Further Study

The preliminary study was important in developing and testing methodology that could be used in the wider research. It also demonstrated that a HACCP knowledge questionnaire based on short-answer questions can give an indication of the level of HACCP knowledge in trained HACCP team members and highlighted areas of HACCP where knowledge was problematic at the sites tested. Detailed analysis of the data showed that there was a potential predictive element and predictions were made on the likely impact of knowledge levels on effective development, implementation and maintenance of HACCP at site level. However comparison of this predicted HACCP ability with desk-top audit findings showed poor agreement, indicating that there are likely to be additional factors involved in the development of effective HACCP. This is consistent with the prediction that several groups of impact factors are likely to be involved in HACCP success, as discussed in Chapter 1.

The remaining research explores further HACCP knowledge and its application, in conjunction with other factors that may impact effective HACCP. This second phase uses case-study sites to gain deeper information on HACCP application and effectiveness to fully address the research aims via the following approaches:

- retesting the levels of knowledge in trained HACCP team members and HACCP teams at case-study sites;
- observing and analysing HACCP team interactions;
- determining the validity of HACCP Plans developed by trained HACCP teams;
- Evaluating the implementation, verification and maintenance of HACCP Plans;
- Identifying and analysing aspects of national culture and business dimensions, including how these might impact HACCP effectiveness;
- Evaluating the findings to make recommendations for effective HACCP training and implementation in multi-national companies.

The remaining chapters of this thesis describe the application of these approaches in the second phase of the research, commencing with Chapter 3 on HACCP Effectiveness in Practice.

Chapter 3 HACCP Effectiveness in Practice

3.1 Introduction

Results of the preliminary study (Chapter 2) indicated that individual HACCP knowledge was not a good predictor of HACCP development effectiveness and suggested that additional factors are likely to be involved in the overall picture of effective HACCP. Although training has previously been identified as a key factor in successful HACCP (Mortimore and Smith, 1998; Mortimore and Wallace, 1998, 2001; Egan *et al*, 2007), these findings were consistent with the need to consider other factors required to overcome the potential barriers to HACCP application in manufacturing identified by Panisello and Quantick (2001) and others (e.g. Gilling *et al*, 2001).

Therefore, in order to fully understand HACCP effectiveness, it is necessary to establish 'what is going on' at manufacturing sites as they work through the development, implementation and maintenance of HACCP systems. This requires a deeper understanding of the processes at individual manufacturing sites and necessitates a case study approach to evaluate how a range of potential impact factors relate to HACCP at those sites.

In Chapter 1 it was postulated that factors involved in the success or failure of HACCP are likely to fall into 3 main groupings (Figure 1.6) of personnel factors, operational management factors and environmental factors. The remainder of this thesis discusses the work done to investigate key factors potentially impacting HACCP success in each of these 3 areas within a multinational food business. These included:

- Personnel Factors
    - Training and Knowledge
    - HACCP team decision-making and team interactions
- Environmental Factors
    - National culture
    - External pressure for HACCP
- Operational Management Factors
    - Commitment
    - Resources and support

As a baseline for investigation of factors impacting HACCP success, it was important to establish a measure of the actual HACCP effectiveness at any site under study. Effective HACCP is a system that would meet food safety requirements and protect the consumer from harm. This requires that the HACCP plan is both valid, i.e. it will, by design, be effective at controlling all relevant food safety hazards, and that it is fully implemented in practice, i.e. the stated requirements of the HACCP plan can be verified as working as intended in the operation. The specific aim of this element of the research, therefore, was to provide data on the effectiveness of HACCP plans at the case study sites, such that this baseline could be used to achieve the main research aims of:

- Evaluating the impact of training on successful HACCP development, implementation and maintenance; and
- Characterising the relationship between national/cultural issues, business/organisational factors, personnel and training on HACCP effectiveness.

3.2 Identification of Study Sites and Programme of Work

In order to set the scene for the case study field-work that will be discussed in Chapters 3 – 7, the following paragraphs outline the choice of sites and overall programme of work for the data collection in this second phase of research. Detail of methods applied will then follow in the individual chapters.

As the company being studied was a multinational organisation and national culture had been identified as one of the potential impact factors for study, it was necessary to obtain a sample of case study sites that included a range of national cultures. A comparative group of 3 countries was chosen and, where possible, 2 manufacturing sites were identified in each country for detailed study (Table 3.1).

Table 3.1 Case Study Sites for Detailed investigation

Country	No. of Sites
India	2
Australia	2
Singapore	1

As noted in Chapter 1, for company practical reasons the region available for study in the multinational company was Asia Pacific, which was its largest geographical region ranging from the Indian subcontinent east to China and Japan and south as far as New Zealand, with manufacturing sites spread throughout the countries of the region. Australia was identified as an example of a 'Western[8]', 'developed[9]' country and India as an example of a 'developing[10]' country in South Asia. Singapore was chosen as a 3rd country that was expected to differ culturally from the other two, being a 'developed' country with a largely Oriental – 75% Chinese at June 2008 (Singapore Department of Statistics, 2009) – culture.

Data collection was conducted over 5 full days spent at each site, with the exception of the Singapore site which is smaller and where it was possible to complete all activities in 3.5 days. A data collection schedule was used to timetable the activities at each site and ensure that all were completed (Appendix 3.1) and briefing documents and consent forms were produced for management, individual participants and HACCP teams (Appendix 3.2).

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[8] The term 'Western' is both in wide colloquial use and commonly mentioned in cross-cultural and business research, however few definitions are available in the literature. The Oxford English Dictionary online (2009) defines 'Western' as: *Of or pertaining to the Western or European countries or races as distinguished from the Eastern or Oriental*, and 'Western Man' as: *Man as shaped by the culture and civilization of Western Europe and North America.* Although Bhopal and Donaldson (1998) suggest that the value of the term 'Western' has been undermined due to the global spread of 'western' populations, it still has usefulness in referring to businesses and cultures that have their root in the west, as was the case in this global company that originated in the UK, and with the nation of Australia due to its Commonwealth and settlement links to the UK. Western countries and cultures would therefore be expected to show some differences from Oriental and South Asian countries and cultures.

[9] The term 'developed' country is used with reference to the World Bank Data and Statistics on Country Groups (World Bank, 2009)

[10] The term 'developing' country are used with reference to the World Bank Data and Statistics on Country Groups (World Bank, 2009)

This programme of work and findings will be discussed in chapters 3 – 7, with detailed discussion in chapter 8. The remainder of this chapter describes the effectiveness assessment of the working HACCP system at each site.

3.3 Methods – HACCP System Effectiveness Assessment

The HACCP Audit tools (Wallace *et al*, 2005[b], previously discussed in Chapter 2 of this thesis and reproduced in Appendices 2.4 and 2.5) were applied to assess the effectiveness of HACCP Systems in practice at the case study sites. This was achieved by assessing sample HACCP plans that were operating at the case study sites during the data collection site visits. The choice of HACCP plans to assess was made by the researcher in discussion with regional and local management and was based on:

- The range of completed HACCP plans in operation at the site and therefore available for assessment
- Choice of manufacturing processes of similar complexity both within and between sites.

It was the intention to assess at least one operating HACCP plan at each site to establish a measure of effectiveness in practice however, where possible, two

HACCP plans were assessed (3/5 sites) to give a deeper understanding of HACCP competence. This HACCP system assessment was done as the final on-site data collection activity in all cases (Appendix 3.1) to prevent assessment findings from influencing any other activities.

Following the protocol discussed in chapter 2, the documentation, including development paperwork, for each HACCP plan was first assessed using Audit Tool 1 and this gave a rating of 'poor', 'fair', 'good' or 'excellent'[11] for each of the 6 question areas of the HACCP documentation assessment, i.e.

- Codex Preliminary Steps and Documentation
- Principle 1 – Hazard Analysis
- Principle 2 – Determination of Critical Control Points
- Principle 3 – Critical Limits
- Principle 4 – Monitoring Procedures
- Principle 5 – Corrective Action

Effectiveness of HACCP implementation and maintenance systems was then assessed using tool 2, the HACCP verification audit checklist (see Chapter 2). Following the assessments, key findings were summarised for research purposes and were also reported to factory management at the end of the site visit. Fully completed audit checklists were typed up and maintained.

[11] See Chapter 2 for description of ratings and scoring.

3.4 Results

Data were compiled for assessment of the specified HACCP plan's validity, i.e. its potential to be effective if implemented, and also the measured effectiveness of the system in practice. The HACCP plan validity assessment used the same scoring system developed for the preliminary study and findings are listed in section 3.4.1 (Table 3.2). The assessment of effectiveness in practice involved identification of strengths and weaknesses of the system operating in the manufacturing areas and key findings across the sites are described in section 3.4.2 (Tables 3.3 – 3.5).

3.4.1 Validity of HACCP Plan Documents

Table 3.2 HACCP Plan Development Assessment Data

(Each element given as score out of 20 and (%); Assessment rating as per HACCP Desk-top Assessment Checklist (appendix 2.4)

Country and site no.	**India 1**		**India 2**		**Australia 1**	**Australia 2**		**Singapore**
HACCP Plan No.	**Plan 1**	**Plan 2**	**Plan 1**	**Plan 2**	**Plan 1**	**Plan 1**	**Plan 2**	**Plan 1**
Preliminary Steps/ Documentation	19.5 (97.5)	19.5 (97.5)	17 (85)	19 (95)	14 (70)	17 (85)	18 (90)	20 (100)
Assessment rating	Excellent	Excellent	Excellent	Excellent	Good	Excellent	Excellent	Excellent
Site Preliminary Steps Score (%)	**97.5**		**90**		**70**	**87.5**		**100**
Principle 1 Hazard Analysis	18 (90)	17 (85)	13.5 (67.5)	14 (70)	10.5 (52.5)	15 (75)	12 (60)	10 (50)
Assessment rating	Excellent	Excellent	Fair	Good	Fair	Good	Fair	Fair
Site Hazard Analysis Score (%)	**87.5**		**68.8**		**52.5**	**67.5**		**50**
Principle 2 CCP Determination	20 (100)	20 (100)	18 (90)	16 (80)	8 (40)	11.5 (57.5)	14 (70)	18 (90)
Assessment rating	Excellent	Excellent	Excellent	Good	Poor	Fair	Good	Excellent
Principle 3 Critical Limits	20 (100)	20 (100)	15 (75)	20 (100)	14 (70)	20 (100)	15 (75)	15 (75)
Assessment rating	Excellent	Excellent	Good	Excellent	Good	Excellent	Good	Good
Principle 4 Monitoring	13 (65)	17 (85)	13 (65)	13 (65)	17 (85)	20 (100)	16 (80)	17 (85)
Assessment rating	Fair	Excellent	Fair	Fair	Excellent	Excellent	Good	Excellent
Principle 5 Corrective Action	20 (100)	20 (100)	14 (70)	14 (70)	14 (70)	17 (85)	20 (100)	20 (100)
Assessment rating	Excellent	Excellent	Good	Good	Good	Excellent	Excellent	Excellent
Site CCP Identification and Control Score (%)	**93.8**		**76.9**		**66.3**	**83.5**		**87.5**
Site HACCP Development Assessed Competency Score (%)	92.1	94.6	75.4	80		83.8	79.2	
	93.3		**77.7**		**64.6**	**81.5**		**83.3**

From Table 3.2 it can be seen that the majority of HACCP teams (7/8) had achieved the 'excellent' rating for work on preliminary steps (Codex, 2003) and HACCP plan documentation. Only 1 team (Australia, site 1) failed to achieve this level, however it was still rated as 'good' in this area. Ratings for the remainder of the HACCP assessment areas were more variable.

For the **hazard analysis** information detailed in the HACCP plans, only 1 site (India, site 1) was rated 'excellent' for both HACCP plans assessed. Two of the remaining sites (India, site 2 and Australia, site 2) achieved a combination of good and fair ratings for separate HACCP plans and the final 2 sites (Australia, site 1 and Singapore), which both only had one HACCP plan available for assessment, both achieved 'fair' ratings, indicating that there were weaknesses in their hazard identification and analysis process.

For example, at Australia site 1 the hazard identification had been done in a general manner, listing 'micro' rather than considering specific pathogens that could likely be present. This had given the team difficulties with significance assessment and, even though a regionally developed structured method had been used, the lack of clarity about what the hazards actually were had resulted in more issues being raised as significant than necessary. As is standard HACCP practice, these 'significant' hazards should have followed through into CCP identification but had not (see below). At Australia site 2, one HACCP team had listed inappropriate measures, e.g. 'verification checks' as control measures for the identified hazards showing confusion between control and monitoring/verification requirements. However, of more concern was the situation at Singapore and India site 2, where more serious flaws in the hazard analysis were detected. In the Singapore HACCP study no microbiological hazard had been identified in raw cocoa beans, even though these are well known to be at risk of contamination with *Salmonella* spp. (Craven *et al*, 1975; Gill *et al*, 1983; Cordier, 1994). This site had also used a structured method of significance assessment (rating severity as critical, serious, major or minor against low, medium or high risk of occurrence) however not only had the *Salmonella* spp. risk been missed, but metal hazards had been identified and not been considered as significant. Metal is one of the key physical hazards believed to be of significant concern due to its ability to injure the consumer when the product is consumed (Mortimore and Wallace, 1998; Codex, 2003). One of the HACCP teams at India Site 2 had also used a locally developed risk assessment method for determining hazard significance. Although this tool, if used correctly, would be suitable for identifying significant hazards (if anything identifying too many items as significant), a fundamental misunderstanding of severity ratings was discovered: both pathogens and metal contamination had been identified at a number of steps but rated as low severity whereas, by their very nature, these issues should have been considered high severity (Mortimore and Wallace, 1998, 2001). These findings also suggest potential difficulties with the assessment rating system as the rating of 'fair' did not give a true indication of either the importance of these issues or any differentiation between their weighting.

For **CCP determination** excellent ratings were achieved by India site 1 for both HACCP plans and for one HACCP plan at India site 2 and Singapore. One HACCP plan at each of India site 2 and Australia site 2 was rated good, indicating that, although not perfect, the CCP determination by the HACCP teams had been generally acceptable. The second HACCP plan at Australia site 2 achieved a fair rating indicating a number of weaknesses, however the lowest rating in this area was Australia site 1, which gained a 'poor' rating. This gave concern about the ability of the HACCP team to correctly identify CCPs.

Australia site 2 had used the questions of the Codex CCP decision tree (Codex, 2003) to identify CCPs, however the questions were not used in the correct decision tree format but were applied sequentially such that the decision routes were incorrect. Although this was not found to have caused CCPs to be missed in this case, it is possible that incorrect application of methodology in this way could lead to such serious errors.

The 'poor' rating at Australia site 1 was due to several weaknesses in the CCP identification process. It was found that microbiological hazards had not been considered in any CCP decision process such as the Codex decision tree, even though these had been identified as significant in the hazard analysis; their consideration had stopped at the previous stage. Further, no decision process was evident in the HACCP plan and no historical records were available. It was stated that CCP decisions had been taken by the previous HACCP team and that the decisions from the previous HACCP manager had been reviewed against the Codex decision tree but there were no records of this activity or of the historical decision process. Even with these weaknesses, it appeared that the appropriate CCPs had been identified for the processes assessed, however it is possible that failing to follow HACCP procedures in this way could lead to CCPs being missed.

Critical Limit identification was rated as good or excellent at all sites and for all HACCP teams indicating good capability in this area, however the ratings for the **determination of monitoring procedures** were more mixed. India site 2 achieved 'fair' ratings for both HACCP plans and India site 1 achieved 'fair' for one HACCP plan, which were the lowest ratings overall for these factories and indicated weaknesses in documentation of monitoring requirements. The remaining sites/teams achieved good or excellent, including the second HACCP team from India 1, suggesting inconsistency of application within this site.

The weaknesses in monitoring for India site 1 related to a missing aspect of monitoring for one CCP (pasteurisation). Monitoring of the automatic divert system had not been listed as part of the CCP management procedures even though this is generally considered an essential part of the food safety control on plate pack pasteurisers (Dairy UK, 2006). On further questioning, it was stated that divert checks were done daily at start up, a frequency that is questionable due to the potential time lag of up to 24 hours in detecting a problem. At India site 2 an identical problem was found in both HACCP plans assessed: both had metal detection CCPs but neither had any monitoring procedures listed for these CCPs. Because the metal detectors were inline as part of the process, the teams had decided that checking that detection was functioning correctly was verification and not monitoring. In fact this had been due to an Indian corporate QA decision and had also been seen at India site 1 in the second HACCP plan, however correct monitoring procedures for additional CCPs had led to a higher rating in this case.

For the final area of assessment, **determination of corrective action procedures**, all sites/teams again received excellent or good ratings, indicating that this area was well understood.

In summary, weaknesses in the application of HACCP principles in the development of HACCP plans were found in a number of areas, including:

- Missed hazards
- Difficulties with hazard significance assessment
- Errors in CCP identification process
- Lack of evidence of CCP identification process
- Missing elements of monitoring
- Confusion between monitoring and verification procedures

3.4.2 Effectiveness of HACCP Plans in Practice

Table 3.3 Validation of HACCP plan elements

Validation				
India 1	**India 2**	**Australia 1**	**Australia 2**	**Singapore**
Process Flow Diagrams:				
No anomalies found. Flow diagram is accurate representation of process. New trial process equipment also seen on site and this had its own process flow diagram and hazard analysis in place for the duration of the trial.	One HACCP plan had no issues; 2nd HACCP plan had some minor omissions from process flow diagrams, however the steps had been included in separate HACCP plans and so had been assessed.	Very detailed process flow diagrams and sub-diagrams. Some anomalies between diagrams and process re. step order and numbering.	Some anomalies in process steps, reported to be due to lack of process specialist knowledge during process flow diagram development.	Assessment of process area reconfirmed potential uncontrolled cross-contamination risk from contaminated raw material identified during desk-top assessment as full segregation not in place. Missing step – air-blowing of bag before filling.
Critical Limit Validation:				
Calibration records showed that calibration was up to date. However, it was difficult to identify the details for the critical temperature monitoring devices on the plate heat exchanger (PHE) for pasteurisation due to inconsistencies in labelling systems and use of labels that could not tolerate production conditions.	Calibration records were reviewed for the metal detectors and heat sensor – all acceptable for CCP management, however there was no validation information available to demonstrate why a particular time temperature limit had been set for ambient holding of in-process material (batter hold at 18 °C for ≤3 hours).	Validation information not available during assessment.	Validation information not available during assessment.	Validation information not available during assessment.

Table 3.3 shows findings for the on-site process flow diagram validation done during the assessment at each site plus details of critical limit validation by HACCP teams, where this information was available. It can be seen that, with the exception of India site 1, all sites had some errors in process flow diagrams when compared with the actual process on the day. Critical limit validation information was only available for the 2 Indian sites: at site 1 this information indicated

that critical limits were set at valid levels for food safety and were achievable within the limits of process variation, however, inconsistencies in labelling systems made clarification of critical temperature monitoring device calibration difficult; at site 2 all calibration data were acceptable, however it was not possible to demonstrate why a particular time temperature combination had been chosen as a critical limit for holding of in-process material.

Table 3.4 shows the assessed implementation status with regard to CCP monitoring and record keeping at the 5 sites. It can be seen that monitoring procedures were being carried out in all cases and staff questioned understood the requirements of the HACCP plans and were able to explain monitoring procedures correctly.

With regard to the CCP monitoring history, table 3.4 also details key issues identified from assessment of monitoring records for 2 separate months, chosen at random for each implemented HACCP plan.

Table 3.4 HACCP Implementation – Monitoring and Record Keeping Systems

HACCP Implementation				
India 1	**India 2**	**Australia 1**	**Australia 2**	**Singapore**
CCP Monitoring – General				
Operators on the line were found to be knowledgeable about CCPs – they knew what to do and are carrying out procedures effectively.	Operators on the line were seen to be performing checks and recording results	Monitoring – people in the factory responsible for monitoring were able to explain the procedures correctly.	CCPs were being monitored in the factory and records kept.	Operators seen to be monitoring and recording results.
Issues Identified from CCP records (2 months records for each CCP sampled)				
3 occasions where monitoring records were not signed by operator. 5 occasions where supervisors had not signed records to demonstrate their oversight as part of verification - 7 pages of records missing for PHE. Although a separate summary (Manufacturing Quality Index) for the period showed that checks were done, there was no evidence that the results were satisfactory. 3 days records missing for sieve checks on a number of occasions there were no checks but no comment to show whether production was working or not	Very difficult to find CCP record as 18 separate pages of line records from each shift are kept together. These have been bound into books but there is no system of how many records/which dates are kept in each book. Only fragments of the requested month's records were provided, although the team were able to show that they had additional record books after the assessment. For the other HACCP plan, records filed together by calendar month and are therefore easier to review. All requested records we.re presented for inspection 2 occasions no supervisor sign off 1 occasion no temperature checks for 4 hours although 9 batches made during this time **and** no supervisor sign off	- records missing with no indication that production was shut down. In some cases these records had been countersigned by supervisors and the lack of monitoring had not been identified. - inconsistencies in data that is being recorded, e.g. ticks or temperatures for gelatine - temperatures below the stated critical limit recorded for gelatine with no apparent corrective action. Archiving of records was generally satisfactory but some sets of records were mixed up making it difficult to locate data for verification.	Missing records with no comment about why checks have not been done, i.e. impossible to tell if monitoring had been missed or whether production had stopped. Detail being recorded where there is a problem/unusual situation is not sufficient in some places making it impossible to tell exactly what the problem was or whether any corrective action had been taken. Archiving was seen to be good and requested records could be identified easily.	2 occasions the actual batch temperature record was missing from the shift log sheet. It was possible to show that one of these batches had received the intended temperature by going back through process computer records. No defined storage period for process computer records – this should be reviewed along with necessary archiving periods for CCP records.

Table 3.4 HACCP Implementation – Monitoring and Record Keeping Systems - Continued				
India 1	**India 2**	**Australia 1**	**Australia 2**	**Singapore**
Issues Identified from CCP records continued (2 months records for each CCP sampled)				
	1 occasion deviation temperature recorded but no corrective action taken 1 occasion metal detector and belt failure noted and 'No' written in corrective action column. 1 occasion of no records for 3 hours but no comment about line being shut a metal detector failure and corrective action were recorded. However, the record sheet had been filled in as OK and then scored out as not OK. This gives the appearance of records being completed in advance, which must not be done. - dash in column rather than 'no' for sieve check – does this mean that it wasn't checked or that it wasn't damaged? - sieve listed as broken for 2 batches but no corrective action. The supervisor has countersigned with no apparent action being taken.			Although not managed as CCPs, records of metal control through magnets and metal detectors were also sampled. No records of checks were found for a number of occasions. It was stated that checks may not be done if production was down or if the equipment could not be accessed while production was running. However there was no way of telling why the records had not been maintained as no information about process status had been provided, i.e. was the process down, were the checks just not done, etc. Since some checks are only done on one shift, it could be at least another 24 hours before they are done if missed. This area needs to be strengthened

As portrayed in Table 3.4, a number of issues that can be considered deviations from CCP monitoring requirements were identified in all cases, the key problems being:

- Critical limit deviation noted with no apparent corrective action taken and, in some cases, countersigned by supervisor without being identified as a problem
- Missing CCP monitoring checks with no corresponding comment on records to indicate if process working or not
- Missing sets of records
- Records not signed by monitoring personnel
- Records not countersigned by supervisor to show verification of monitoring requirements
- Incomplete monitoring records countersigned by supervisors with missing records apparently not identified
- Insufficient detail being recorded or unclear markings making records difficult to understand
- Poor record archiving making it difficult to identify records
- No defined storage period for process computer records (Singapore).

Table 3.5 shows the assessment of HACCP maintenance status at all sites, with particular reference to verification procedures, document control, HACCP plan review and change management. All sites were carrying out internal HACCP audits and had previously been audited by external bodies, including professional audit companies and regulatory auditors. Internal audit schedules had been allowed to slip at one site (Australia 2) and audit sampling practices were considered insufficient at another site (Singapore). Sites also mentioned use of customer complaints analysis and microbiological testing as additional verification measures.

Table 3.5 HACCP Maintenance

HACCP Maintenance				
India 1	**India 2**	**Australia 1**	**Australia 2**	**Singapore**
Verification Procedures:				
Include audit, complaints analysis and microbiological testing. External 3rd party audit has been done.	Include audit, complaints analysis and microbiological testing. External 3rd party audit has been done.	External HACCP audits are done annually as part of the Food Safety Victoria requirements. The site team was working on items identified in the recent audit during the visit. Additional internal audits are done – reports not seen due to time constraints. There is currently a large HACCP review project ongoing to update and simplify the system. Until this exercise is completed, the HACCP System will remain out of date.	The importance of keeping to audit and review schedules for the HACCP/GMP systems was discussed and it was understood that this was not fully up to date.	The HACCP plans are verified through audit annually, however the sampling only looks at two weeks of records each time. This needs to be expanded for each issue sampled – recommend at least a month of records, preferably 2 separate months in each case as per this HACCP assessment framework. Microbiological testing and customer complaints monitoring are also used as verification procedures.
HACCP Plan Review and Document Control:				
HACCP Plan review is described as 6-monthly with update of documents annually. However documents were dated February 2005 with a few individual pages slightly later. The new HACCP plans with amendments following last year's certification audit were non-approved software copies only. Since it is more than 15 months since the last update and 14 months since the last audit, the HACCP system documentation is **not** current.	- there were 2 copies of the HACCP Plans in the controlled document file (2005 and 2006). Although some of the general HACCP documents are still to be reviewed/updated this year, the 2005 versions of specific HACCP plans are out of date and should have been removed.	Large review project ongoing to update and simplify overall factory system (original HACCP plans had been developed for each product making the system too complex to manage). Until this review is completed there will be out of date documents in place in some areas.	Document control for current documents appears to be satisfactory, however a number of documents require review and update.	HACCP plan review and updating is currently done every 2 years. The effectiveness of the HACCP plan should be reviewed annually and signed off, although the paperwork may be updated less frequently if no issues are found.

Table 3.5 HACCP Maintenance - continued

India 1	India 2	Australia 1	Australia 2	Singapore
Change Management:				
Procedures were discussed and considered to be satisfactory	Procedures were discussed – recommended adding a tick box to the form to demonstrate that food safety/HACCP requirements are being considered it is signed off. The central change management procedure held on site was an out of date copy.	This area has not been well managed due to the HACCP plans being out of date for the factory as a whole (see above). Stated that process changes are discussed and agreed but no evidence seen.	The lack of a formal change control procedure for equipment/process/material changes that might impact food safety was discussed. This had already been identified by site personnel and needs to be addressed asap.	The issue of process/equipment changes was discussed and how they would be assessed for product safety implications. Although there did not seem to be a formal mechanism for reviewing the safety of changes, the small management team would be involved in any changes and would consider safety implications.

HACCP plan review was being done at all sites (Table 3.5), however frequency of review was not in line with recommendations (Mortimore and Wallace, 1998, 2001) at the Australian and Singapore sites. The progress with reviews had led to lapses in document control with certain HACCP plan documents seen to be out of date at both Indian sites and Australia 1.

Change management was also assessed (Table 3.5). Change management procedures were in place at both India factories, although the forms in use at India 2 required clarification to indicate that food safety requirements were being considered during process/equipment/ingredient changes. India 2 also had an out-of-date central change management procedure in place from the Indian corporate office. Formal change management procedures were absent at the 2 Australian sites and the Singapore site and, although it was stated that changes were discussed before implementation, there was no evidence to verify this.

3.5 Discussion

As discussed in Chapter 1, HACCP is a step-wise process and effective HACCP plan development requires that the HACCP team follows the Codex Logic Sequence (Codex, 2003). The combination of HACCP plan validity assessment via the desk-top audit checklist and HACCP implementation assessment via the HACCP verification audit checklist allowed the application of all steps of the Codex logic sequence to be challenged and is therefore considered to be a useful strategy for HACCP effectiveness assessment.

3.5.1 HACCP Plan Validity

The documentation requirements of Codex preliminary steps, i.e. 'Assemble HACCP Team'; 'Describe Product'; 'Identify intended use'; and 'Construct Flow Diagram' (Codex, 2003) were found to be effectively addressed, indicating that this first part of the Codex logic sequence (Codex, 2003) was well understood at all sites. Codex preliminary steps are about documenting existing information in preparation for HACCP principle application and, therefore, might be expected to be relatively straightforward. However it is also possible that the previous in-company desk-top audit (Chapter 2) had also identified any areas where improvements were needed regarding any missing documentation, allowing improvements to be made before this assessment.

Following Codex preliminary steps, the remaining parts of the HACCP study to document the HACCP plan require the application of more expertise and judgement by the HACCP team. Therefore, it might be expected that there would be more potential weaknesses in these areas.

As described in section 3.4.1, several weaknesses were identified in the application of HACCP Principle 1: Conduct a Hazard Analysis, including problems with hazard significance assessment resulting in both under-identification and over-identification of significant hazards, failure to identify likely hazards and confusion between control measures for the identified hazards and monitoring procedures.

Where there is a serious weakness in hazard analysis, e.g. missing significant hazard leading to insufficient CCPs in a HACCP plan, then assessment of whether the documented HACCP plan is working in practice cannot give an 'effective' measure of food safety since the missing hazard/CCP could result in harm to the consumer. For example, if a potential hazard of *Salmonella* spp. contamination in a raw ingredient is likely to occur in that ingredient then, due to the nature of salmonellae as human pathogens (Bell and Kyriakides, 2001), this should automatically be seen as a significant hazard that will require control via a CCP. If no CCP has been identified then an uncontrolled hazard could exist and endanger the consumer. In this example of *Salmonella* spp. in a raw ingredient, it would be important to address both the hazard in the product stream and the potential cross-contamination risk to the factory and other products (Mortimore and Wallace, 1998, Reij *et al*, 2004). If a heat process CCP has been identified to eliminate the hazard then assessment of the monitoring and corrective action systems in practice, along with associated records for that CCP, will give a view on its effectiveness. However, if the cross-contamination risk has not been addressed, then no matter how well managed the heat process CCP, there will still be a risk of salmonella contamination in the product and the HACCP plan cannot be said to be effective. This was the situation found at the Singapore site, which would seem to be at the same level of risk as manufacturing sites previously involved in foodborne disease outbreaks known to be caused by post-process contamination (Reij *et al*, 2004).

Further issues with hazard significance assessment were seen to involve errors in application of, or inappropriate use of, risk assessment tools and fundamental misunderstandings in severity evaluation for potential hazards identified. This suggests that the requirement to analyse hazards in HACCP principle 1 is an area where HACCP teams experience difficulty and this may be because of the lack of guidance provided and/or their limited experience and knowledge. This also ties in with the classification of hazard analysis knowledge as marginal or unsafe for the majority of sites in the preliminary study (Chapter 2) and with the levels of knowledge seen in this HACCP knowledge area at the Australian sites in phase 2 (Chapter 4).

Although Codex HACCP guidelines (Codex, 2003) offer suggested points to consider when applying HACCP principle 1: Conduct a Hazard Analysis (Table

3.6), no specific advice or tools are provided to help in the determination of significant hazards, i.e. those '*hazards (that) are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food*' (Codex, 2003). This is an area which clearly requires substantial judgement and experience to be applied by HACCP team members and it is questionable whether people working in day-to-day factory roles have the ability to, or should be expected to, take these decisions alone, without expert help.

Table 3.6 Codex Guidance on Application of HACCP Principle 1: Conduct a Hazard Analysis (Codex, 2003)

Step 6. **List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards**
The HACCP team should list all of the hazards that may be reasonably expected to occur at each step according to the scope from primary production, processing, manufacture, and distribution until the point of consumption. The HACCP team (see "assemble HACCP team") should next conduct a hazard analysis to identify for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food. In conducting the hazard analysis, wherever possible the following should be included: - the likely occurrence of hazards and severity of their adverse health effects; - the qualitative and/or quantitative evaluation of the presence of hazards; - survival or multiplication of microorganisms of concern; - production or persistence in foods of toxins, chemicals or physical agents; and, - conditions leading to the above. Consideration should be given to what control measures, if any exist, can be applied for each hazard. More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure

In order to overcome the difficulties in identifying significant hazards, some companies use risk assessment frameworks to try and systematise this judgement-based decision (Palmer, Pers. Com.; Ropkins and Beck, 2000). These may be based on published risk assessment tools (e.g. NACMCF, 1989) or may be developed in-house within the company, either at site, regional or corporate level. In fact the case study company had provided such a tool from its corporate technical centre for use by sites, however the sites investigated here had used their own site-specific or regionally developed versions, possibly due to the timing of release of the corporate model (too late). These tools attempt to structure and simplify the process of evaluating severity and likelihood of occurrence by positioning the identified hazards in a range of risk sub-categories. Depending on the sub-categories chosen the tool indicates whether each hazard is significant or not. Although these tools are generally believed to make significance assessment more straightforward by the companies using them (Palmer, pers. comm.), they do still require training in their application and use of judgement to position the identified hazards in the correct sub-categories. From the assessments reported here 2/5 sites made errors in applying these tools and a further site had difficulties due to lack of clarity in the initial hazard identification. Although structured risk assessment tools were used in the earlier application of HACCP (NACMCF, 1989), international guidelines (Codex, 1993, 1997[a], 2003) have never advocated this approach. Current tools appear to have their root in the early publications of the American National Advisory Committee on Microbiological Criteria for Foods (NACMCF) who published 'Hazard Analysis and Assignment of Risk Categories' in its 1989 version of the HACCP system. This approach fell out of favour in the USA and was written out of subsequent versions of the NACMCF HACCP document (NACMCF, 1992, 1997), mainly because the process was not found to be helpful, in fact as much a hindrance as a help (Sperber, pers. comm.), in establishing significant hazards. It is interesting, therefore, that companies still cling to these ideas as a way to facilitate the hazard evaluation process, even though HACCP teams, perhaps unknowingly, continue to make errors in applying their tools. This is likely to be because they do not have enough expertise at a local level and suggests that further assistance is needed by HACCP teams trying to make decisions about hazard severity and likelihood of occurrence. Perhaps there is a role for Codex in providing more guidance in this area, at the very least to recommend that these critical judgements are made by people with the sufficient expertise. Whilst Codex (2003) does highlight that where expertise to form a multidisciplinary team does not exist on site that expert advice should be obtained from other sources, the inference is that this is most likely to be required in "small and/or less developed businesses" rather than the large manufacturing sites of a multinational manufacturer as in this case. In fact the sites investigated here had all managed to form multidisciplinary HACCP teams that would meet the expected scope of team disciplines in a HACCP team (Mortimore and Wallace, 1998) but a key issue discovered was the lack of competence in evaluation of hazards to establish significance to food safety. This is an area that clearly needs more focus from standards and guideline setters as well as HACCP trainers and food companies. In addition, the current version of the Codex HACCP Principles and Guidelines (Codex, 2003) refers to training only in general terms, i.e.

> "The efficacy of any HACCP system will nevertheless rely on management and employees having the appropriate HACCP knowledge

> and skills, therefore ongoing training is necessary for all levels of employees and managers, as appropriate." (Codex 2003)
>
> and
>
> "Training of personnel [...] in HACCP principles and applications [...] are essential elements for the effective implementation of HACCP". (Codex 2003)

More specific guidance from Codex on training needs and syllabus requirements for hazard analysis and other detailed aspects of HACCP Principle application would therefore seem prudent.

Difficulties in the application of tools were also seen at the next stage of the HACCP study process – application of HACCP Principle 2: Identify CCPs. Here the Codex decision tree (Codex, 2003) had generally been used and, although most HACCP teams had applied this correctly, one site (Australia site 2) had used the questions independent of each other such that the links between questions were lost, which could have led to errors in CCP identification. Since the other teams managed to apply this tool well, further training in the use of the decision tree should allow this site to apply the decision tree correctly. It is interesting to note that the Singapore site scored highly in CCP identification, suggesting that the HACCP team knew how to apply this tool and had done so correctly. However, as discussed above, this team had missed a significant hazard of cross-contamination with *Salmonella* spp. and therefore had not considered it in the CCP decision process resulting in no CCP being identified. This illustrates the step-wise additive approach of HACCP and demonstrates the importance of the initial hazard analysis stage in determining the effectiveness of the HACCP plan. It is also suggestive that a limitation of HACCP audit might be that through focussing on the CCPs identified by the HACCP team then the wider picture might be missed. It is therefore crucial that HACCP auditors have sufficient expertise and experience in the product area of the company such that errors and omissions by HACCP teams can be picked up and recommendations for rectification immediately highlighted.

Errors in moving between the steps of the HACCP study were also seen at Australia site 1 where microbiological hazards had not been considered in the CCP identification process and assessment of CCP decision-making was impossible due to lack of records. Records of each stage in the HACCP study process are important to justify the reasoning behind decisions taken and HACCP teams need to ensure that this information is available for validation and verification purposes.

No weaknesses were found associated with the application of HACCP Principle 3: Establish Critical Limits, indicating that this area was well understood. However information to justify the validity of the chosen limits for product safety was only available at 2/5 sites (India site 1 and 2) during the assessment (Table 3.3) and even at these sites it was difficult for the HACCP teams to prove that the food safety processing requirements would be met for one process (India 1) and to justify why a particular time/temperature combination had been chosen for safety (India 2). This illustrates the need for HACCP teams to be clear about the criteria that are governing food safety in their processes and to keep adequate records to demonstrate that critical limits have been validated within the normal operating parameters of the process equipment.

Further weaknesses were identified in the application of HACCP Principle 4: Establish Monitoring Procedures, including missing an element of monitoring required for food safety (India site 1) and no monitoring indicated for a particular CCP (India site 2). In the latter case, this was because monitoring had wrongly been described as 'verification', however the procedures were being applied in practice.

HACCP Principle 5: Establish Corrective Action Procedures was found to be adequately addressed by the HACCP teams at the 5 sites. However, as discussed above, difficulties were seen in the application of 3 out of the 5 HACCP Principles involved in the HACCP study or HACCP plan development phase, i.e.

HACCP Principle 1: Conduct a Hazard Analysis

HACCP Principle 2: Establish Critical Control Points

HACCP Principle 4: Establish Monitoring Procedures

If these manufacturing sites are representative of multinational manufacturers operating throughout the global food supply chain, this raises serious questions about the validity of HACCP plans being developed at manufacturing sites and, therefore, their potential to be effective in practice in order to protect the consumer.

3.5.2 Verification of HACCP Plans in Practice

As stated above, effectiveness assessment of HACCP plan operation in practice relates to the verification of the identified CCPs as operating within the control procedures defined by the HACCP plan. Therefore there may be limitations in system effectiveness if significant hazards, CCPs, critical limits, monitoring or corrective action requirements have been missed or have errors that could reduce food safety protection. These limitations may be compounded by further weaknesses in the day-to-day management of food safety, i.e. in the practical application of the HACCP plan.

Validation of HACCP plan elements involved assessment of critical limit validity, as discussed in 3.5.1 above, and assessment of process flow diagram validity by walking the process and identification of differences and/or missing process steps. Anomalies in process flow diagrams were found at 4/5 sites. This was surprising in that process flow diagram validation is a relatively straightforward part of the HACCP study to carry out, relying only on careful comparison of the prepared diagram against the actual process. Process flow diagram validation is step 5 of the Codex logic sequence (Codex, 2003) and is expected to be done as part of the preliminary steps before HACCP Principle application. This is intended to ensure that any errors in process flow diagrams are corrected before they are used as the basis for the hazard analysis. However process flow diagrams (as part of the entire HACCP plan) also need to be reviewed when there are changes to the operation to ensure that any safety considerations necessitated by the proposed changes can be addressed.

At 4/5 sites the process flow diagrams had indications that validation had been done against the process by HACCP team members and/or process personnel. This suggested that either anomalies had been missed in this initial validation process, or that changes to the processes had developed after validation, with no follow up review of the process flow diagrams. This is significant for food safety since the process flow diagram is key to establishing an effective HACCP plan. Any process activities missed at this stage are unlikely to be considered in the hazard analysis and, therefore, any associated hazards may remain uncontrolled by the resulting HACCP system.

CCP monitoring appeared to be well understood and being carried out as defined on a day-to-day basis (Table 3.4), however detailed investigation of historical monitoring records identified a number of anomalies, as described in section 3.4.2. All of these issues involve weaknesses in the ongoing management of the HACCP system and give concern for its effectiveness. The anomalies can be grouped as:

- personnel and training issues – where further training would be required for CCP monitoring personnel and/or supervisors involved in verification of monitoring requirements, for example:
    - deviation noted by CCP monitor with no apparent corrective action taken and, in some cases, countersigned by supervisor without being identified as a problem
    - Missing CCP monitoring checks with no corresponding comment on records to indicate if process was working or not

- Records not signed by monitoring personnel
- Records not signed by supervisor to show verification of monitoring requirements
- Incomplete monitoring records countersigned by supervisors with missing records apparently not identified
- Insufficient detail being recorded or unclear markings making records difficult to understand

- record maintenance and archiving issues – where more care is required in the maintenance of food safety information, for example:
    - Missing sets of records
    - Poor record archiving making it difficult to identify record
    - No defined storage period for process computer records
    - Use of correcting fluid on production records, which is not good practice.

Such weaknesses could have a real effect on product safety. The most obvious case is where monitoring has identified apparent CCP deviation but no corrective action has been recorded, however missing records or verification countersignatures could also mean that CCP deviation has been missed. Missing records could also mean that a company has no evidence of effective food safety management if challenged, e.g. by regulatory personnel. These lapses in record-keeping and archiving suggest that this area of HACCP management may not be given sufficient importance by company management and so recommendations on further training and increasing the emphasis of records as an essential element of the food safety system should be made.

HACCP maintenance, including verification, review and change management were also assessed (Table 3.5 and section 3.4.2). Although all sites had a range of verification procedures in place, including internal and external audit, these procedures had failed to pick up the weaknesses identified in this assessment. This underlines the need for agreed standard audit approaches and effective training of HACCP auditors, and it is recommended both that food companies question the competency and experience of external HACCP auditors before their engagement, and that standard setters establish effective qualifications, training and experience standards for HACCP auditors. HACCP plan reviews were not being done at recommended frequencies and HACCP plan documents were found to be out of date. In addition, there were deficiencies in change management procedures suggesting that HACCP maintenance was another area needing re-emphasis and retraining at the study sites.

3.5.3 Overall Judgement of HACCP Effectiveness

Due to the number of failings identified in these HACCP assessments, it is evident that the HACCP systems in place at the 5 sites are not fully effective, and that this could have implications for product safety. All sites had deficiencies that would reduce HACCP effectiveness, both in the defined HACCP plan and/or in its implementation and maintenance. The HACCP plans at India site 1 were the strongest performing overall, with Australia site 1 showing the most weaknesses. However, although seen to be competent in the steps of the

HACCP process, the presence of an uncontrolled significant hazard at the Singapore site indicated that having the necessary judgement and experience to identify problems and take decisions about product safety are as important, if not more so, than competence in HACCP techniques. Similar levels of deficiencies in implementation and maintenance of HACCP systems were seen at all five sites, suggesting that day-to-day management needed to be tightened up for HACCP to be fully effective.

HACCP application is covered by guidelines (Codex, 2003) and further detailed assistance is available in practical HACCP textbooks (e.g. Mortimore and Wallace, 1998, 2001). Although areas where HACCP guidance needs to be strengthened have been identified above, the existing guides and textbooks offer detailed advice on HACCP Principle application which, if followed, should have overcome most of the weaknesses identified in these HACCP assessments at the 5 sites. So, although the areas where difficulties were seen are not new, with the breadth of support material and training available, it is, perhaps, surprising to see that HACCP plans operating at manufacturing sites of a multinational manufacturer should have so many flaws in their application. This raises concern about the status of HACCP plans operating in food manufacturing companies throughout the world and indicates that further detailed guidance and support is needed in a number of areas.

The products manufactured by this multinational company were ambient stable, low water activity items that would not support the growth of pathogenic microorganisms. This 'low risk' nature of product area meant that there were generally fewer significant hazards and hence fewer CCPs than could be expected in a more perishable product area. Considering the deficiencies found here, the risk to consumer safety would likely be magnified if similar standards were applied in a higher risk product manufacturer.

3.5.4 Strengths and Limitations

HACCP Assessments or audits are, by their nature, snapshots in time in the operation of a HACCP system. Where deficiencies are identified, these can be addressed to strengthen the HACCP system. However, because assessments are based on sampling, where no deficiencies are identified in the sample it does not follow that no deficiencies exist in the system. This means that differences could have been found if different HACCP plans were assessed at the 5 manufacturing sites, although the similar levels of training and standard documentation approaches used at each site suggest that similar issues could be expected.

A scoring scheme had been developed in the preliminary study (Chapter 2) for the HACCP plan documentation development assessment (desktop audit), in order to allow comparison of large numbers of sites. Application of the scoring system was also done for the documentation assessment in this case. Potential scoring difficulties were found when assessing monitoring requirements (3.4.1) where 2 sites had the same issue identified for metal detection CCPs (India site 1 and 2) but one had gained a 'fair' rating (India 2) and the other had been rated 'excellent' (India 1) due to additional correct monitoring procedures for other CCPs. This suggests that the scoring system did not discriminate enough between sites, necessitating a more detailed review of findings in the detailed audit checklist records (Appendix 3.1) to ensure that all key findings were reported in section 3.4.1. Concerns were also noted at the hazard analysis stage, where it was considered that the 'fair' rating did not give enough emphasis to the severity of issues found, nor discriminate adequately between different issues at different sites. For future work a review of the scoring system would be prudent.

Because the assessment tools had been designed separately, i.e. 2 tools to allow separate assessment of the HACCP plan documentation (tool 1, desktop audit) and the HACCP effectiveness in practice (tool 2, verification audit), this gave the potential for the assessment to be somewhat disjointed. Therefore both tools were combined and used together in the assessments, with tool 1 covering initial stages and running smoothly into use of tool 2. In this way the HACCP assessment strategy developed for this research was considered to work effectively for HACCP assessment, however a review of the tool formats may be beneficial for future work. For example the tools could be combined to make one overall assessment tool or elements could be moved between tools as appropriate, e.g. validation of HACCP plan elements might be better recorded as part of documentation assessment (desktop), although it is recognised that process flow diagram validation can only be done on site. As with any documented form, issues were identified with size of boxes regarding the amount of information needing to be recorded in all cases. Although it is difficult to accommodate this on a printed paper form, the use of an electronic audit recorder, e.g. PDA or tablet PC, might overcome difficulties if larger numbers of assessments need to be done.

3.5.5 Recommendations for Multinational Food Businesses

Based on the findings of this element of the research as discussed above, the following recommendations are made for multinational food businesses:

- Ensure that HACCP team members have the correct blend of training, skills and experience to take decisions about food safety hazard management, in particular the identification of potential hazards and evaluation of their significance to food safety. HACCP team limitations in this aspect need to be identified and external expertise brought in where necessary.

- Caution should be used when applying structured risk assessment tools that are not part of the Codex (2003) HACCP system. Where used, steps should be taken to ensure that the chosen tool works in practice, i.e. it is capable of correctly establishing which hazards are significant for food safety, and that team members are skilled in its application.

- Records of HACCP study process should be kept, including justification of all decisions made so that validity of the HACCP system can be proven.

- The importance of monitoring and corrective action records in food safety management needs to be promoted, with special emphasis given to accuracy and clarity of records, verification sign off by a more senior member of staff and careful archiving.

- There should be increased focus on provision of adequate training on monitoring requirements for CCP monitors, such that they understand exactly what to do for monitoring, recording results and taking corrective action; and to supervisors, such that they understand what they should be looking for when reviewing and countersigning CCP records.

- Reviews of HACCP plan effectiveness should be carried out on a regular basis and at least annually. The HACCP Assessment Strategy and Tools developed in this research could be used to enable this outcome.

- It is strongly recommended both that food companies question the competency and experience of external HACCP auditors before their engagement.

- Change management procedures, identifying the need to review food safety requirements and amend HACCP plans and procedures where necessary, should be applied for all proposed changes to products, processes, equipment, ingredients and facilities.

3.5.6 Recommendations for Standard and Guidelines Setters

- Further detailed guidance on how to approach hazard analysis, i.e. evaluation of severity and likelihood of occurrence, needs to be established to assist food companies in correctly identifying significant hazards, since lack of competence was clearly identified in this area.

- Recommendations on expertise needed to successfully analyse hazards and take critical food safety decisions need to be provided. In particular, a strong reminder to food companies that this area does require technical expertise and judgement would be beneficial, reminding them to recognise HACCP team limitations and seek expert help where necessary.

- Further detailed guidance on specific training needs and syllabus requirements for training in the application of HACCP Principles needs to be provided.

- Standard setters need to establish effective qualifications, training and experience standards for HACCP auditors.

3.5.7 Further Work

Literature in the field of HACCP assessment is limited and there are no comparable studies detailing findings for manufacturing company HACCP assessments. Replication of this work with other companies/manufacturing sites would give additional detailed information about HACCP effectiveness within manufacturing, both confirming these findings and providing lessons to help food businesses improve their food safety systems.

Further minor work on refining the tools and a review of the scoring system would also be beneficial in confirming these as the recommended standardised approach to HACCP assessment.

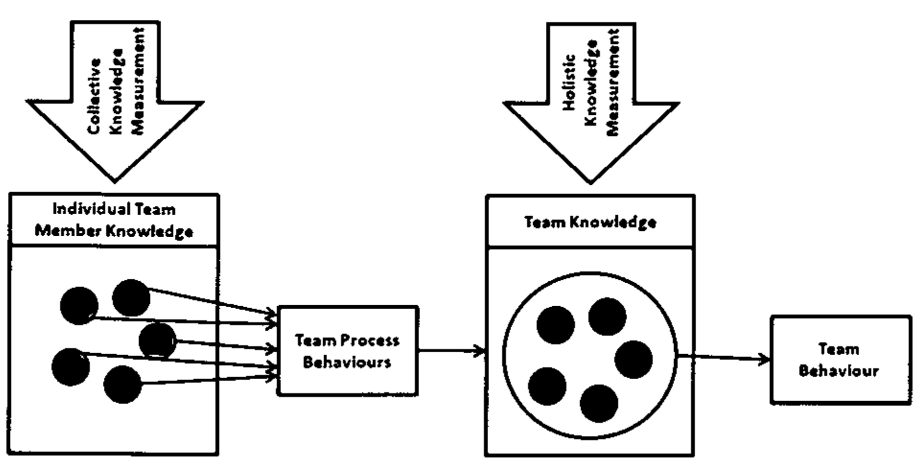
In conclusion, this assessment element of the research has provided a baseline measure of HACCP effectiveness at the five case study sites. The next chapter of this thesis will explore HACCP knowledge in trained HACCP team members and HACCP teams.

Chapter 4 HACCP Knowledge at Five Case Study Sites

4.1 Introduction

Further to the examination of individual HACCP knowledge and prediction of its possible impact on HACCP success in the preliminary study (Chapter 2), it was necessary to establish individual HACCP knowledge again at the in-depth case study sites to provide a baseline for comparison with HACCP team knowledge and decision-making, and HACCP effectiveness data. HACCP team behaviour in terms of decisions about HACCP principle application is dependent on both the collective knowledge of the team members, i.e. the knowledge that each individual member of the team brings and the holistic team knowledge, i.e. the knowledge of the team as a whole (Cooke *et al*, 2000). It is therefore important to measure both individual and team knowledge (Figure 4.1).

Figure 4.1 Measuring Collective and Holistic Team Knowledge (Adapted from Cooke *et al*, 2000)



For a HACCP team to be capable of applying HACCP Principles correctly, it follows that there must be an understanding of HACCP Principles within the team. HACCP team knowledge, therefore is an important consideration in the overall picture of factors with potential to impact HACCP effectiveness.

The aim of this element of the research was to establish the levels of knowledge in trained HACCP team members and operational HACCP teams. This chapter, therefore, describes the evaluation of HACCP knowledge in individuals involved in HACCP teams at the five case-study sites. It also discusses the links between HACCP knowledge and effectiveness, building on the findings of Chapter 3. Further discussion of HACCP team knowledge and decision-making follows in Chapter 5.

4.2 Methods

4.2.1 Choice of Method

The Wallace *et al* (2005[a]) HACCP Knowledge Questionnaire was established in the preliminary study as a useful tool to gather information about individual knowledge of HACCP Principles and their application. Therefore, this questionnaire was the tool of choice to evaluate baseline HACCP knowledge in the individuals making up HACCP teams at these case study sites. The full questionnaire (Appendix 2.1) was used for testing the knowledge of individuals and to provide supplementary data on their training background. For HACCP team knowledge testing only part 2 of the questionnaire was used, i.e. the HACCP knowledge questions without training background questions.

4.2.2 Sites and Data Collection

Rationale for choice of sites in this second phase of research was discussed in Chapter 3. With regard to the numbers of people tested for HACCP knowledge, Table 4.1 outlines the personnel at each site and their HACCP team affiliations. At most sites it was possible to test additional people to the HACCP teams such that a view of the overall background knowledge of HACCP at the sites could be obtained. All personnel gave consent to be involved and their job roles were collected via the consent forms such that the levels of HACCP knowledge throughout the site management structure could be examined.

Table 4.1 Phase 2 HACCP Knowledge Data Collection

Country	No. of Sites	Site No.	Total No. of Candidates at each Site	No. of HACCP Teams at each site	HACCP Team No.	No. of HACCP Team Members
India	2	1	14	2	1	6 (5 tested)
					2	5
		2	24	2	1	7
					2	7
Australia	2	1	10	1	1	5
		2	22	2	1	6
					2	7
Singapore	1	1	5	1	1	5

4.2.3 Administration of the Questionnaires

In this phase of the research, the questionnaire was administered by the researcher at the manufacturing facility to both individual HACCP team members and to HACCP Teams. Individual questionnaires were completed under 'exam conditions' in an appropriate room and were scheduled such that they were concluded before the HACCP team met. HACCP team members were asked to refrain from discussing any questions or answers with colleagues following the individual session and were not told that they would also complete the questionnaire as a team until they gathered together for the team meeting. This approach was designed to prevent individuals having foresight of the questions and/or benefitting individually from their colleague's suggestions and also to prevent the team from benefitting from pre-team discussion of questions and potential answers.

For the team sessions, each HACCP team was asked to meet the researcher in an appropriate room at a set time after the individual knowledge testing had been completed, but on the same day. Seating was arranged for team members to sit in a circle to allow members to see each other during the discussions. A microphone was placed in the centre to record discussions. Once all team members had arrived the task of completing the HACCP knowledge questionnaire as a team was explained, and teams were instructed that they needed to agree on answers and allocate a team member to record their results.

4.2.4 Marking of Completed HACCP Questionnaires

Questionnaires were marked by one independent marker (same independent HACCP specialist involved in marking for the preliminary study) using the 'Marking Guidelines. Marks were checked by the researcher for consistency between participants and application of the marking guide. As previously stated, this included identification of any local wording that might affect marking, e.g. 'asset care' is terminology for 'engineering' personnel at some sites. Any necessary amendments to marking were agreed with the independent marker before analysis.

4.2.5 Data Analysis

Knowledge data were analysed using descriptive statistics as for the preliminary study. Results were examined for each site group as a whole, and also for different management levels and job roles. Analysis of HACCP team results versus individual team member results was also completed and confidence intervals were calculated (http://statpages.org/confint.html#Binomial). In addition, team knowledge scores were plotted against HACCP plan effectiveness scores findings from Chapter 3.

4.3 Results

Results of individual HACCP Knowledge and HACCP team knowledge from the second phase of the research are reported here, firstly the general levels of HACCP knowledge at each site.

4.3.1 General Levels of HACCP Knowledge

Table 4.2 shows the minimum, maximum and median scores achieved by all candidates tested at each manufacturing site. This included the members of the HACCP teams being studied in further detail, plus additional individuals who were involved in separate HACCP teams on site.

Table 4.2 HACCP Knowledge – Candidate Group Scores at Case Study Sites

Country	No. of Manufacturing Sites		No. of Candidates tested at each Site	HACCP Knowledge Questionnaire - % Scores achieved by Total Candidate Group		
				Minimum	Maximum	Median
India	2	Site 1	14	52.5	92.5	73.75
		Site 2	24	23.75	85	48.75
Australia	2	Site 1	10	15	66.25	34.38
		Site 2	22	5	82.5	28.75
Singapore	1	Site 1	5	3.75	61.25	33.75

As had been seen in the preliminary study (Chapter 2), the scores showed considerable variation both within and between groups. The highest levels of HACCP knowledge overall were seen at the Indian sites, in particular India site 1, which also had the tightest spread of results. Although India Site 2 and Australia Site 2 also had individuals gaining high scores of 85% (India) and 82.5% (Australia), both these sites also had low scoring individuals whose knowledge levels would indicate concern about HACCP capability, and the median scores for both these sites were low at 48.75% and 28.75% respectively. The maximum and median scores for Australia Site 1 and Singapore were very close, within the 60s and 30s % levels respectively; both these sites also had very low minimum scores of 15% and 3.75%, the latter score at Singapore being the worst overall HACCP knowledge.

4.3.2 Knowledge in Particular Aspects of HACCP

Mean scores for each question in the 5 HACCP knowledge areas (HKAs) are given in Table 4.3. As seen in the preliminary study, there was a variety of different knowledge levels across sites for particular questions and also across questions/HKAs for each individual site.

Table 4.3 Scores (% correct within test group) Achieved for Specific Questions within HACCP Knowledge Areas – Total Personnel Tested and HACCP Teams

HACCP Knowledge Area	Question No.	India			India			Australia		Australia			Singapore
		Site 1			Site 2			Site 1		Site 2			Site
		Total	Team 1a	Team 1b	Total	Team 2a	Team 2b	Total	Team 3	Total	Team 4a	Team 4b	Total/ Team
Codex Preliminary Steps	3	78.6	70	87.5	66.7	57.1	66.7	65	50	43.2	41.7	28.6	60
	4	58.9	55	50	42.4	50	29.2	25	15	30.7	33.3	25	30
	13	100	100	100	78.3	92.9	83.3	50	60	40.9	41.7	42.9	60
	14a	78.6	60	75	95.8	100	100	50	40	36.4	33.3	42.9	20
	14b	71.4	60	75	95.8	100	100	35	30	34.1	25	42.9	20
	14c	71.4	60	75	95.8	100	100	40	40	31.8	16.7	28.6	20
Hazard Analysis	1	89.3	80	87.5	67.4	60.7	66.7	35	40	26.1	25	25	25
	2	96.4	90	100	59.8	57.1	54.2	32.5	15	27.3	33.3	17.9	20
	17a	92.9	80	100	100	100	100	50	40	43.2	50	35.7	80
	17b	100	100	100	100	100	100	70	60	38.2	33.3	85.7	80
	17c	100	100	100	100	100	100	75	50	59.1	66.7	57.1	80
	20	39.3	30	50	26.1	28.6	8.3	35	50	25	25	21.4	25
	21	71.4	66.7	66.7	43.5	52.4	33.3	40	26.7	27.3	27.8	19	33.3
	22a	64.3	60	25	58.3	57.1	16.7	25	10	31.8	16.7	28.6	0
	22b	53.6	50	25	12.5	14.3	0	30	20	27.3	33.3	14.3	20
CCP Identification & Control	5	82.1	80	75	55.4	71.4	37.5	37.5	40	30.7	25	28.6	15
	6a	100	100	100	39.1	42.9	16.7	0	0	18.2	16.7	14.3	20
	6b	67.9	40	62.5	30.4	42.9	16.7	10	0	13.6	8.3	0	20
	7	78.6	90	75	68.8	57.1	50	40	40	40.9	50	42.9	70
	8	85.7	100	75	50	57.1	16.7	10	10	25	41.7	28.6	40
	11	50	26.7	50	48.6	33.3	50.0	40	33.3	39.4	50	47.6	26.7
Implementation	9	75	60	75	44.6	46.4	33.3	45	50	38.6	50	21.4	20
	10	87.5	80	100	56.5	57.1	41.7	25	20	19.3	29.2	17.9	10
	12a	50	40	50	47.8	42.9	41.7	30	20	31.8	41.7	42.9	20
	12b	85.7	60	100	41.3	21.4	50	50	40	29.5	33.3	42.9	20
	15	50	40	50	39.6	35.7	33.3	20	20	36.4	16.7	14.3	40
	19	53.6	60	62.5	55.2	46.4	50	32.5	25	27.3	41.7	17.9	30
Maintenance	16a	50	40	25	66.7	57.1	50	40	20	36.4	33.3	14.3	20
	16b	60.7	60	75	54.2	57.1	16.7	20	20	34.1	33.3	35.7	20
	18	64.3	70	62.5	47.9	57.1	41.7	75	60	59.1	58.3	57.1	25

India Site 1 showed generally high levels of knowledge across all HACCP knowledge areas, gaining > 60% correct for the majority (73%) of questions, and including a number of questions answered correctly by 90-100% of participants. This group's poorest score overall was for question 20 in the Hazard Analysis knowledge area, which only 39.3% of the group answered correctly. India Site 2 also had high scores for a number of questions, gaining 90-100% correct in parts of the Codex Preliminary Steps and Hazard Analysis knowledge areas, however the group's two worst scores were also in the Hazard Analysis knowledge area: 26.1% correct for question 20 and 12.5% correct for question 22b. Both the Australian sites and the Singapore site were more variable in their achievement of correct answers across the HKAs, however the Singapore personnel were 80% correct for all elements of question 17 (a-c). HACCP teams achieved better or worse scores than the total group on a number of occasions.

4.3.3 HACCP Knowledge by Job Role at each Site

HACCP scores were examined by job role to establish if knowledge was stronger in any particular sub-team within the factory hierarchy. These data are portrayed in Table 4.4.

Table 4.4 HACCP Scores by Job Role at each Site

Country	Site	Job role	(n)	Minimum (%)	Maximum (%)	Median (%)
India	1	QA	(5)	71.25	92.5	81.25
		Engineering	(2)	66.25	67.5	
		Manufacturing	(5)	52.5	82.5	60
		Other	(2)	67.5	82.5	
	2	QA	(6)	43.75	81.25	75.63
		Engineering	(1)	45	45	
		Manufacturing	(15)	23.75	85	45
		Other	(0)	-	-	-
Australia	1	QA	(1)	57.5	57.5	
		Engineering	(2)	60	66.25	
		Manufacturing	(7)	15	38.75	26.25
		Other	(0)	-	-	-
	2	QA	(6)	58.75	82.5	66.25
		Engineering	(1)	62.5	62.5	
		Manufacturing	(14)	5	42.5	12.5
		Other	(1)	27.5	27.5	
Singapore	1	QA	(1)	61.25	61.25	
		Engineering	(1)	3.75	3.75	
		Manufacturing	(2)	33.75	37.5	
		Other	(1)	13.75	13.75	

It can be seen that the highest level of knowledge overall lies with the quality assurance team at India Site 1, however high scoring individuals were also found in the manufacturing and other disciplines at this site. Similarly, a high standard of knowledge was seen in the quality assurance function at India Site 2, and, although there was a wider spread of knowledge within quality assurance at this site, the median score remained high at 75.63%. High scoring individuals were also seen in the manufacturing team at India Site 2. At Australia Site 1 the highest score was with the engineering discipline, however only one member of the quality assurance team was available for testing at this group. It is also interesting to note that neither of these engineers were involved in the HACCP team at this site. At Australia Site 2 and the Singapore site the quality assurance team again provided the highest scores of the disciplines tested on site. These findings are, perhaps, not surprising in that the quality assurance/technical personnel are often given the role of coordinating HACCP activities on site and may, therefore, focus more on HACCP application than some of their colleagues.

4.3.4 HACCP Knowledge by Rank at each Site

It was also possible to investigate HACCP knowledge in the different management or rank levels within the case study sites. These data are listed in Table 4.5. Operators, Supervisors and Managers were tested at all sites, with the exception of India Site 1 and Singapore, where no line operators were involved directly in HACCP teams and so had not been trained to the same level as other personnel on site.

Table 4.5 HACCP Scores by Rank at each Site

Country	Site	Job role (n)	Minimum (%)	Maximum (%)	Median (%)
India	1	Operator (0)	-	-	-
		Supervisor (10)	52.5	82.5	67.5
		Manager (4)	76.25	92.5	85.63
	2	Operator (8)	23.75	51.25	33.13
		Supervisor (11)	43.75	85	77.5
		Manager (3)	73.75	83.75	77.5
Australia	1	Operator (2)	15	38.75	
		Supervisor (5)	22.5	38.75	26.25
		Manager (3)	57.5	66.25	60
	2	Operator (6)	5	62.5[12]	18.75
		Supervisor (11)	5	58.75	21.25
		Manager (5)	62.5	82.5	67.5
Singapore	1	Operator (0)	-	-	-
		Supervisor (1)	13.75	13.75	
		Manager (4)	3.75	61.25	35.63

The highest scores were generally found in the Manager group, with the exception of India Site 2 where the highest score came from the Supervisor

[12] This person trained outside the company

group, and both Managers and Supervisors showed median scores of 77.5%, although the Management group had more tightly grouped scores overall. Operator scores were generally the lowest, with the exception of Australia Site 2 where an Operator had one of the higher scores at 62.5%, however this individual had been trained outside the company and had more experience of applying HACCP principles than colleagues at this level.

4.3.5 Knowledge Scores of HACCP Teams and Individual Team Members

Table 4.6 shows the knowledge scores achieved by HACCP teams and their individual HACCP team members

Table 4.6 HACCP Knowledge – HACCP Teams and Individual Team Members

Country	Site No.	HACCP Team No.	Team HACCP Score %	No. of HACCP Team Members	HACCP Knowledge Questionnaire - % Scores achieved by Individual HACCP Team Members		
					Minimum	Maximum	Median
India	1	1	91.25	6 (5 tested)	52.5	82.5	66.25
		2	82.5	5 (4 tested)	67.5	81.25	69.38
	2	1	77.5	7	23.75	82.5	77.5
		2	73.75	7	32.5	85	45
Australia	3	1	51.25	5	15	57.5	26.25
	4	1	53.75	6	7.5	70	31.88
		2	66.25	7	5	70	21.25
Singapore	5	1	66.25	5	3.75	61.25	33.75

As had been seen for the general site knowledge data described previously, there was again considerable variation for total HACCP knowledge between and within HACCP teams and the Indian sites again performed best, as would be expected from the site data. HACCP teams' total knowledge scores were better than or equal to the median of the individual's total knowledge scores, however the team scores were poorer than those of the best individuals for five out of the eight teams.

4.3.6 HACCP Knowledge – Teams versus Individuals by HACCP Knowledge Area

A comparison of the best individual and team scores for all questions in each HACCP Knowledge Area (HKA) is included in Appendix 4.1, and question scores for individuals and teams at each site are listed in Appendix 4.2. Tables 4.7 and 4.8 below show the comparison of HACCP team scores with median individual and best individual scores respectively for the five HKAs.

Table 4.7 Comparison of HACCP Team Scores with Median Individual Scores* for each HACCP Knowledge Area

HACCP Knowledge Area (HKA)	Team Score < Individuals	Team Score = Individuals	Team Score > Individuals	95% CI for Team > Individuals
Codex Preliminary Steps	2/48 (4.2)	30/48 (62.5)	16/48 (33.3)	20% to 48%
Hazard Analysis	4/72 (5.6)	39/72 (54.2)	29/72 (40.3)	28% to 53%
CCPs and their Control	6/48 (12.5)	23/48 (47.9)	19/48 (39.6)	25% to 55%
Implementation	2/48 (4.2)	16/48 (33.3)	30/48 (62.5)	47% to 76%
Maintenance	2/24 (8.3)	7/24 (29.2)	15/24 (62.5)	40% to 81%
Total (%)	6.7	47.9	45.4	

* reported as frequency/total number of possible occasions (% of possible occasions)

Table 4.8 Comparison of HACCP Team Scores with Best Individual Scores* for each HACCP Knowledge Area

HACCP Knowledge Area (HKA)	Team Score < Individuals	95% CI for Team < Individuals	Team Score = Individuals	Team Score > Individuals
Codex Preliminary Steps	10/48 (20.8)	10% to 35%	38/48 (79.2)	0/48 (0)
Hazard Analysis	11/72 (15.3)	8% to 26%	59/72 (81.9)	2/72 (2.8)
CCPs and their Control	14/48 (29.2)	17% to 44%	34/48 (70.8)	0/48 (0)
Implementation	13/48 (27.1)	15% to 42%	34/48 (70.8)	1/48 (2.1)
Maintenance	5/24 (20.8)	7% to 42%	19/24 (79.2)	0/24 (0)
Total (%)	22		77	1

* reported as frequency/total number of possible occasions (% of possible occasions)

In Table 4.7 it can be seen that, in the majority of cases, the team score was equal to or greater than the median of the individual scores, which might support the concept of the HACCP team being greater than the sum of its parts. However it should also be noted that the team score was lower than the median of the individual scores on a number of occasions, and this was seen in all HKAs, ranging from 4.2% of possible occasions for the Codex Preliminary Steps and Implementation HKAs to 12.5% for the CCPs and their Control HKA. This indicates something happening in the team decision process causing a poorer suggestion to be generated by the team.

Table 4.7 also indicates that the team scores were better than the median individual scores only on between 30-40% of occasions for the first three HACCP knowledge areas (HKAs) of Codex Preliminary Steps, Hazard Analysis and CCPs and their Control, although this improved to 62.5% for each of the Implementation and Maintenance HKAs. Confidence Intervals (CI) for team score better than individual scores are portrayed in column 5 of Table 4.7: for the first three HKAs the upper CI limit is not particularly high, suggesting that the chance of the team being better than the median individual scores is not much more than 50%. For the last two HKAs the upper CI values are higher. This might be because these aspects of HACCP are generally easier to understand, being similar to the requirements to implement and maintain any quality system initiative, however for the Maintenance HKA it may also be because of the small sample size.

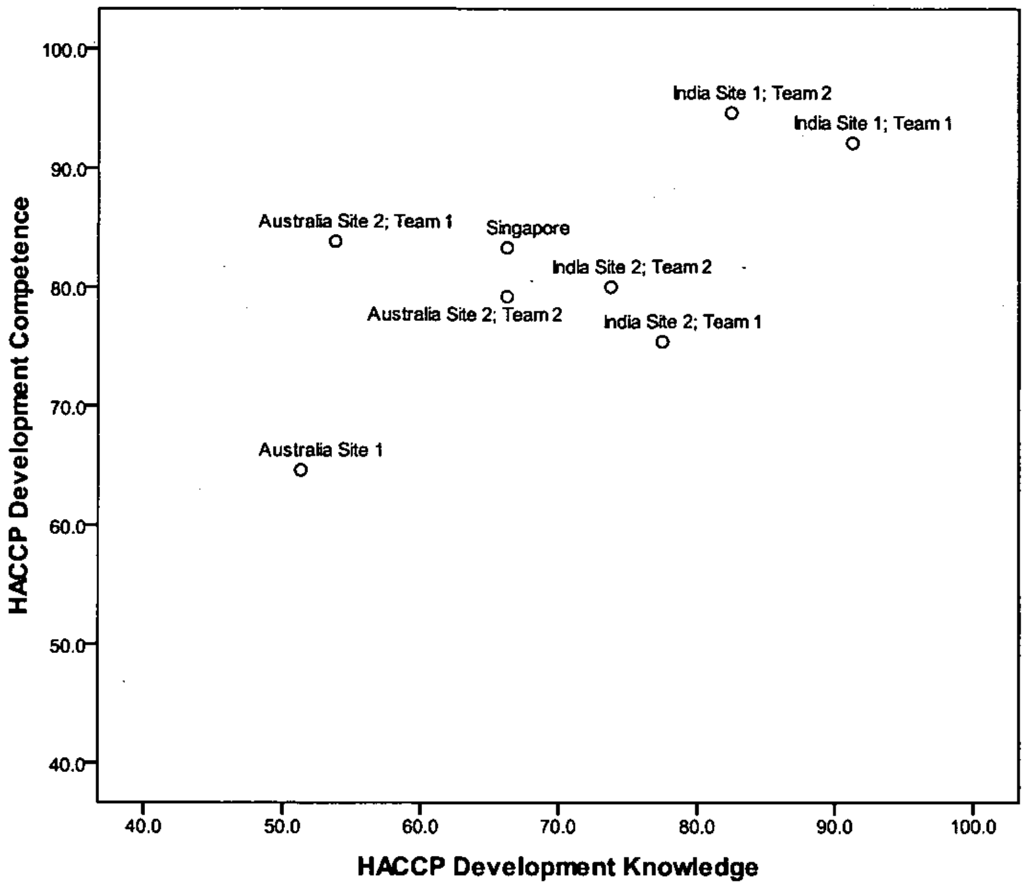
Considering Table 4.8, it can be seen that in the majority of cases (>70% of possible occasions) the team score was equivalent to the score of the best individuals in the team. In a small number of cases the team score was higher than the scores for individuals within the team; this only occurred in the hazard analysis (2.8% of possible occasions) and HACCP implementation (2.1% of possible occasions) knowledge areas, thus three HKAs had 0% of occasions where the team was better than individuals. More worrying is the number of occasions when the team score is actually worse than the best individuals, ranging from 15.3% of possible occasions for the hazard analysis HKA to 29.2% of occasions for the CCPs and their Control HKA. When CIs are calculated for this data (Column 3 of Table 4.8), the best view is that the lower CI limit is 7-

10% for the HKAs of Codex Preliminary Steps, Hazard Analysis and Maintenance, suggesting that teams scoring less than individuals is not a rare event. Similarly the upper CI values range from 26-44% across all HKAs, suggesting that this would not be uncommon.

4.3.7 Comparison of HACCP Knowledge with HACCP Effectiveness Data

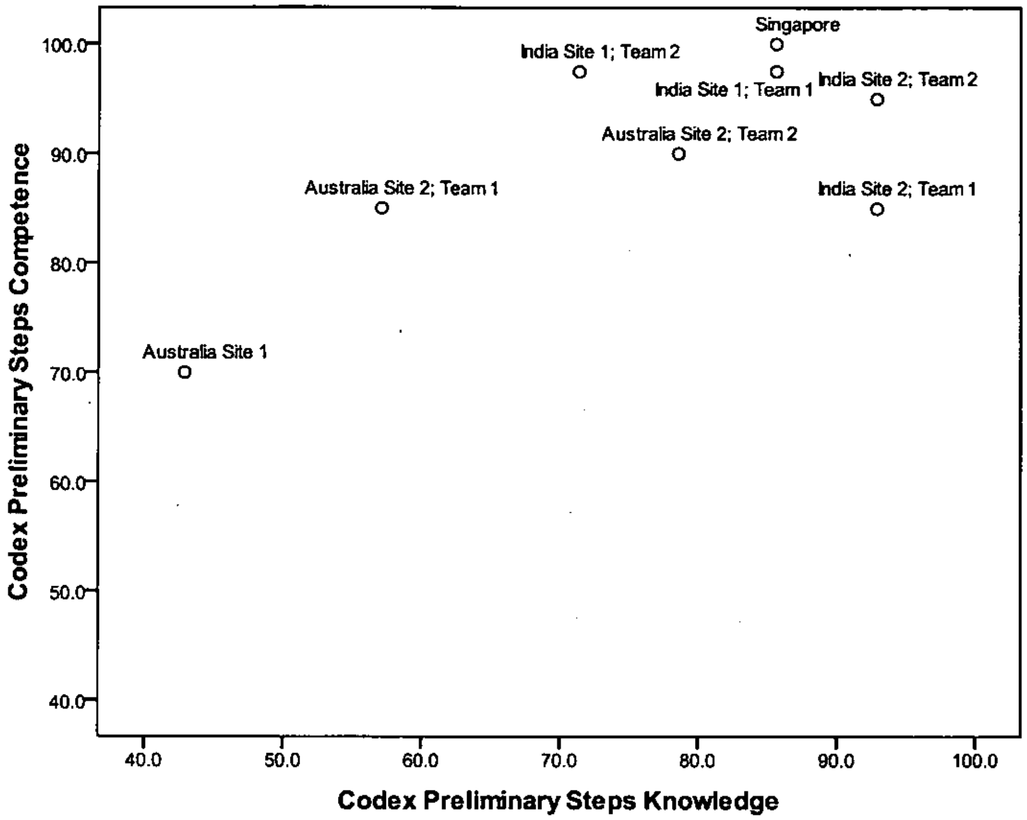
HACCP Knowledge for each team was plotted against the team's overall HACCP Development assessed competency score (Figure 4.2) and, in addition, knowledge was plotted against assessed competency for each of the Codex Preliminary Steps, Hazard Analysis and CCPs and their Control HKAs (Figures 4.3 – 4.5). Competency scores were taken from the desk-top audit element of the HACCP assessment (Chapter 3) in all cases.

Figure 4.2 Comparison of HACCP team Knowledge and HACCP Development Competency



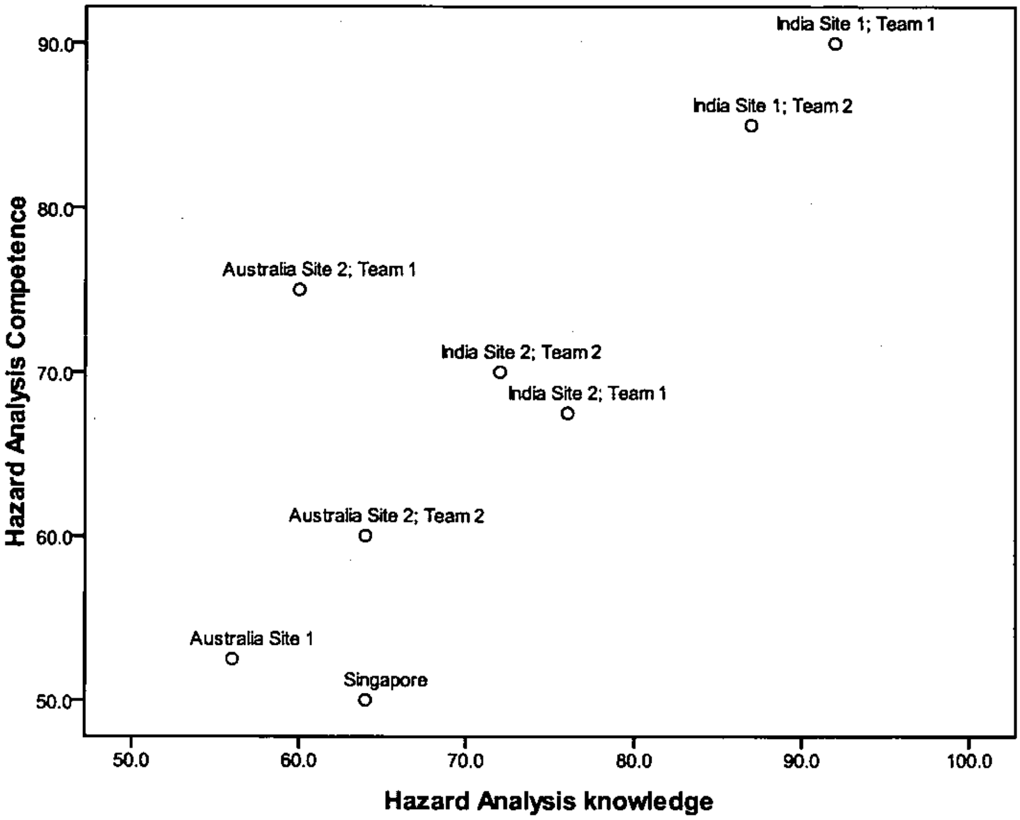
Data are slightly suggestive of a relationship between HACCP knowledge and HACCP development competency at the team level, however additional data points across a wider range of knowledge and competency scores would be needed to confirm this.

Figure 4.3 Comparison of Team Codex Preliminary Steps Knowledge and Assessed Competence



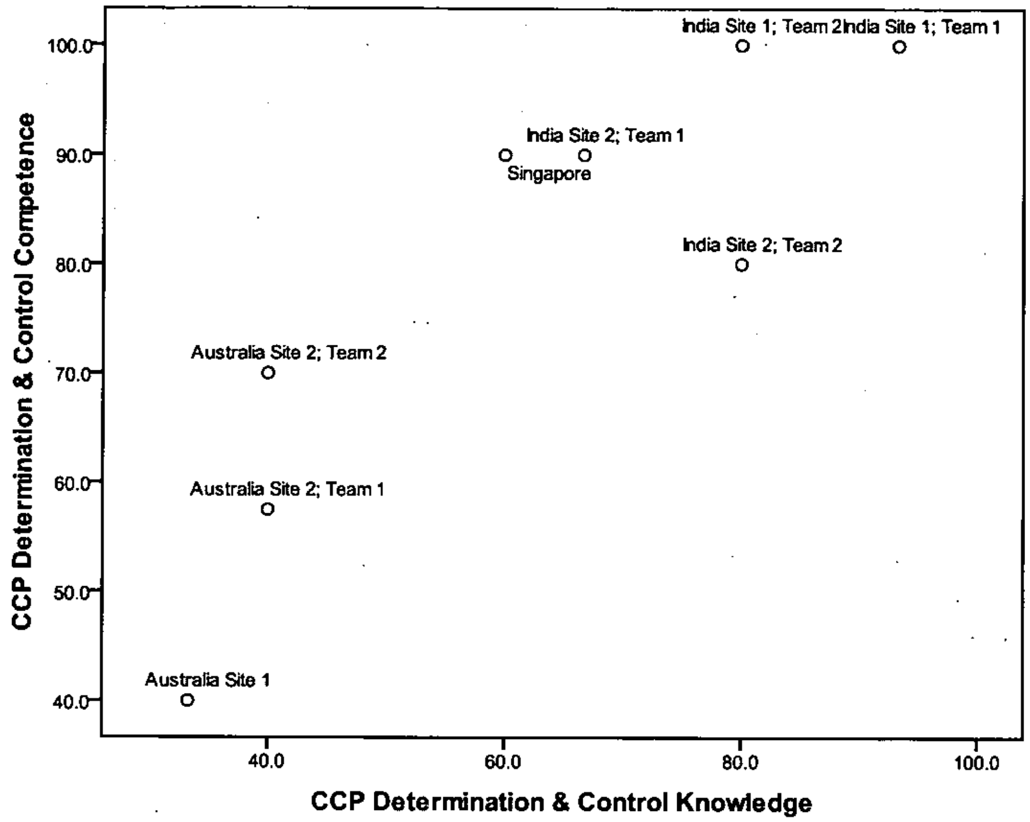
Data are clustered in the top right hand quadrant since this was a relatively high scoring HKA for both knowledge and competence. Further data points would be needed to establish if any relationship exists.

Figure 4.4 Comparison of Team Hazard Analysis Knowledge and Assessed Competence



With the exception of Australia Site 2; Team 1, data are quite strongly suggestive of a relationship between hazard analysis knowledge and hazard analysis competence as part of HACCP plan development, however additional data points would be helpful to confirm this.

Figure 4.5 Comparison of Team CCP Determination and Control Knowledge and Assessed Competence



Again there is a suggestion of a potential relationship between knowledge and competence at the team level for CCP determination and control. This would need to be confirmed by additional data points.

4.4 Discussion

4.4.1 General Levels of Knowledge

The overall levels of candidate HACCP knowledge found at the case study sites (Table 4.2) indicated that there were some individuals with sound HACCP knowledge and other individuals with very low knowledge of HACCP principle application. Knowledge was also spread within sites, suggesting that each site had some people who would be capable of developing HACCP plans and other people who would struggle at this task. This highlighted similar levels of concern about HACCP knowledge at these sites as seen the preliminary study sites.

The Indian sites, in particular India Site 1, had the best knowledge overall. Since the Indian sites had also been involved in the preliminary study, it is possible that some foresight of the questionnaire had given these candidates an advantage. However the fact that this data-collection exercise was completed two years after the preliminary study suggest that memory of the questions is unlikely. It is possible that the findings of the preliminary study had resulted in a focus on HACCP and additional training at these sites, which had in turn led to a higher general level of HACCP knowledge on site however, although it is not possible to determine fully if this was the case, discussion with the site Quality Manager elicited the information that there had been more local focus on HACCP and training following the preliminary study. Taking the median of the HACCP team member scores into account suggests that particular weaknesses might be found in the HACCP plans developed at the Australian and Singapore sites.

4.4.2 Knowledge in different HKAs

HACCP Knowledge Area (HKA) data should show weaknesses in any particular aspects of HACCP Principle application. India Site 1 again showed a high level of HACCP knowledge and this was spread across all HKAs and also reflected by the knowledge within the HACCP teams. The site group's poorest score overall related to question 20 (What should the HACCP team do if they have identified a significant hazard but there is no control measure at that step or any following step?). Examination of the HACCP team data in more detail showed that both HACCP teams at this site had shown weaknesses in different HKAs with HACCP team 1 struggling in particular on question 20 (above), and question 11 (What should happen if there is a deviation from a critical limit?) and HACCP team 2 on question 22 (Which two factors should be considered when carrying out the hazard analysis?). Weaknesses in these three questions were also seen at all the other sites, suggesting that these aspects of HACCP are generally found difficult, however the other sites and their HACCP teams showed weaknesses in a range of areas.

4.4.3 HACCP Knowledge by Job role

Coordination of food safety systems, including HACCP team leadership, often lies with the quality assurance department within food manufacturing operations (Mortimore and Wallace, 1998). As such, it could be expected that QA personnel would show the best HACCP knowledge scores across the sites and this was generally the case (Table 4.4), although some high scores were also seen from individuals working in production at the Indian sites and engineering personnel in India and Australia. In fact the highest scores overall at Australia Site 1 came from engineers, neither of whom were involved in the HACCP team. This would seem to be an oversight in team selection at Australia site 1, however engineers also showed the poorest scores at Singapore and India Site 2, although only one individual was available for testing in both cases. The scores do confirm which job role groups have poorer HACCP knowledge in this data set and thus could be used to make recommendations for targeted HACCP refresher training. However it would not be possible to generalise this finding to other sites/companies since the variation in scores within the job role groups demonstrates that job role is not necessarily related to HACCP knowledge.

4.4.4 HACCP Knowledge by Rank

Scores for HACCP Knowledge by Rank within each case study site showed that managers generally had the best knowledge overall and this would tend to suggest capability to apply HACCP Principles at this level. Supervisors also showed good HACCP knowledge at the Indian sites, although this was more variable, but poorer knowledge at the Australian and Singapore sites. Operators were tested at three sites and had the poorest HACCP knowledge overall, however this may be because operators had lower levels of HACCP training and had may have been recruited to HACCP teams to bring experience of what happens on the line rather than HACCP. It is possible that language and literacy levels may also have impacted operator knowledge scores but this was not tested.

4.4.5 HACCP Knowledge of Teams versus Individuals

Comparing the scores for the HACCP teams with those of the individual team members (Table 4.6) again showed variation within the teams, with some team members scoring considerably higher than others, e.g. the Singapore HACCP team member scores ranged from 3.75% to 61.25%. Commonly held beliefs of HACCP 'folklore' support the view that a multidisciplinary team would provide a better HACCP solution than could be expected from individuals working alone, i.e. HACCP team scores should be better than individual scores. This was supported by the finding that the HACCP team total knowledge scores were better than or equal to the median of the individual team scores, however the team scores were poorer than the best individuals for five out of the eight teams, suggesting a levelling out of knowledge within the group as the individual member's knowledge meets at a 'midpoint' that becomes the team decision.

When HACCP team scores for each HACCP knowledge area (HKA) are compared with the median of the individual team member scores (Table 4.7), a more detailed picture emerges. On the surface, the results again tend to support the view that the team has generally done better than the individuals, albeit with a small number of occasions where the team score was lower. However, comparison of the team and best individual scores data (Table 4.8) suggest a loss of knowledge happening through the team deliberations and does not support the view of the team as greater than the sum of its parts. This is more striking when the Confidence Intervals for the teams better than median individuals and teams worse than best individuals data are calculated (Tables 4.7 and 4.8), as these suggest that teams scoring lower than the best individuals is not a rare event and that the chance of the team being better than the median individual scores is not much more than 50%.

This leads to the conclusion that the potential 'dumbing down' effects as the team comes to its level could be considerable. Since poor knowledge of HACCP Principle application could lead to food safety problems, this suggests that it is important for food companies to understand the levels of HACCP knowledge that different individuals possess prior to team selection. This would either allow balancing of skills within the HACCP team or the assigning of a specialist 'HACCP Process Facilitator role, giving the identified individual(s) the task of keeping the HACCP process on track and correct, and allowing other team members to concentrate on the discipline specialism, e.g. factory processes or engineering, that they bring.

Literature on team membership and composition supports this finding of knowledge loss and knowledge gain as the team performance finds its level. Sundstrom *et al* (1990) discuss research on tank crews where teams made up of high ability personnel performed in excess of what was expected, suggesting a 'synergy' effect due to team composition, but teams of low ability personnel fell short of expectations. Mathieu *et al* (2008) consider that the least or most competent individual team member can have disproportionate influence over team performance, whilst Devine and Philips (2001) note that relationships between cognitive ability and performance at the individual level do not imply relationships at the team level. High, low and mean levels of team cognitive ability have been positively correlated with measures of team performance, however mean cognitive ability was found to be a weaker predictor of team performance in real organisational settings than in laboratory studies (Devine and Philips, 2001). Certainly the findings of this study demonstrate differences in knowledge between the individual and the team level and confirm that different predictions of team ability would be given when comparing the team knowledge with the best member results, median result or indeed the worst member results. The coming together of knowledge from the best performing and worst performing members to meet at a new team level knowledge between the two suggests that it would be beneficial for food companies to make sure that there are enough high performing individuals within HACCP teams to 'balance out' lower performing individuals, rather than automatically expecting the team performance to be better than individual performance. This could be done by testing knowledge levels within the team using the HACCP knowledge questionnaire developed in the preliminary study (Wallace *et al*, 2005[a]).

4.4.6 Comparison of HACCP Knowledge with HACCP Effectiveness Data

Comparing HACCP team knowledge directly with the measured effectiveness of HACCP plans developed by the HACCP team provides further exploration of the impacts of knowledge on HACCP success. Looking at the overall scores for HACCP team knowledge against assessed HACCP development competency

(Figure 4.2), the positioning of points suggests a potential relationship. This potential relationship appears stronger when the team data for hazard analysis knowledge and hazard analysis assessed competence is compared (Figure 4.4) and the possibility of a relationship is again suggested for the team knowledge of CCP determination and control (Figure 4.5). These findings suggest a potential predictive element at the team level between the HACCP knowledge gained through training and the capability to apply HACCP principles in practice. However this finding needs to be treated with caution since potential limitations with the competence scoring element of the HACCP assessment have already been pointed out (Chapter 3), and further data points across the spectrum of HACCP abilities would be useful to confirm whether the potential relationship exists.

In addition, knowledge of how to apply HACCP Principles does not necessarily imply that all potential hazards will be identified nor that an appropriate understanding of severity or likelihood of occurrence will be available on site to enable correct determination of significant hazards. In other words knowledge of the mechanics of how to do HACCP does not necessarily imply suitable knowledge and experience of what needs to be controlled for effective food safety management in a given food operation. HACCP teams, therefore, need an appropriate blend of personnel who have a good theoretical knowledge and practical ability of HACCP Principle application and personnel with sound understanding of food safety hazards and their inherent risk appropriate to the food operation under study.

4.4.7 Conclusions

Knowledge levels both for individuals and for HACCP teams operating at the case study sites showed a wide variation in knowledge in the five HACCP knowledge areas. Knowledge was generally strongest in the Indian factories but variation was also found at these locations. HACCP team knowledge was equal to or greater than the median of individual knowledge scores in the majority of occasions suggesting that the team is greater than the sum of its parts. However comparison of team knowledge with the best individual knowledge in each HACCP knowledge area showed that for between 15.3% and 29.2% of possible occasions the team knowledge was worse than the best individuals in the team and a 'dumbing down' effect had occurred. The numbers of people with good HACCP knowledge in the HACCP team compared to those with poor HACCP knowledge would therefore seem to be important. Comparison of HACCP knowledge and hazard analysis knowledge against assessed HACCP development and hazard analysis competency showed a possible relationship, although more data would be needed to confirm this.

These findings suggest that it would be beneficial for food companies to understand which individuals have the best theoretical and practical knowledge of HACCP Principle application and to give these individuals the role of 'HACCP Process Facilitator' within the HACCP team. Combined with individuals who have sound understanding of food safety hazards and their inherent risk appropriate to the food operation under study, this should enable a strong HACCP performance and the development of effective HACCP plans.

4.4.8 Strengths and Limitations

No previous studies have investigated the knowledge that individuals bring to HACCP teams and how the team acts using this knowledge. A key strength of this element of the research, therefore, is its novelty and this can be built on by gaining understanding of the HACCP team decision processes (Chapter 5).

The Indian sites tested here had been tested previously as part of the preliminary study (Chapter 2) and this may have been reflected in their higher HACCP knowledge scores. However it is considered unlikely that individuals would have remembered the HACCP questions over the two-year period between the data collection exercises. Rather it is possible that the better knowledge was as a result of increased focus on HACCP and HACCP training following the results of the preliminary study, although this cannot be determined.

4.4.9 Further Work

This research provided conflicting findings around the commonly held belief that HACCP teams will provide a better solution than individuals, as the team results were both better than some individuals and poorer than other individuals. Further study of this concept, perhaps in testing application of HACCP Principles by teams and individuals in addition to theoretical knowledge, would be beneficial to understand the potential limitations of individuals and teams in this area.

It would be beneficial to conduct further knowledge testing of HACCP teams in combination of assessment of competency in developing HACCP plans. This would help to confirm the suggested relationship between knowledge and competency seen in these findings.

4.4.10 Recommendations for Multinational Food Businesses

- It is beneficial to have an understanding of the HACCP knowledge within HACCP teams as, although there is evidence that the team should have an outcome that is as good as, or better than, its median level of individual HACCP ability, a 'dumbing down' effect within the team can also be seen, where the team performance is worse than its best members. Thus, as it is impractical to expect all food company personnel likely to be appointed to HACCP teams to have excellent knowledge of HACCP principle application, a balance of abilities ensuring that some personnel have excellent knowledge is beneficial. Knowledge testing of HACCP team members, with retraining as necessary, is therefore recommended.

- Because it is likely that some people will have better knowledge of HACCP Principle application, it is recommended that companies determine who has the best knowledge and give these personnel the role of 'HACCP Process Facilitators' within HACCP teams. This is likely to be more feasible than expecting all HACCP team members to become experts in HACCP principle application. Combining these facilitators with individuals who have sound understanding of food safety hazards and their inherent risk appropriate to the food operation under study, should enable a strong HACCP performance and the development of effective HACCP plans.

This study of HACCP knowledge has discovered findings relating both to individuals and HACCP teams and their differential HACCP ability, and to possible relationships between HACCP team knowledge and HACCP development capability. In order to further explore how HACCP team results differ from individuals and to understand how teams impact the HACCP process it is necessary to explore HACCP team decision-making in more detail. This is considered further in the next chapter – Chapter 5: HACCP Team Decision-Making.

Chapter 5 HACCP Team Decision Making

5.1 Introduction

It is a generally held belief that HACCP is best applied by a multidisciplinary team and that the outcome of this team approach will be a stronger food safety system than could be developed by individuals working alone. This belief has been promulgated by guidance publications (Mortimore and Wallace, 1998; WHO, 1993; Codex, 2003) and training interventions (Royal Society for Public Health, 2007; Palmer, pers. comm..). For example, Codex (2003) lists 'Assemble HACCP team' as the first step in its 'Logic Sequence for Application of HACCP' and suggests that the optimal way to ensure that appropriate knowledge and expertise is available for the development of effective HACCP is to use a multidisciplinary team approach. In a manufacturing operation, this may be partly because the required knowledge to take decisions about food safety – e.g. knowledge about ingredient and product formulations, processes and handling practices, equipment and environment issues – is likely to be spread among several individuals. However, the origins and reasons for the use of HACCP teams in the historical record of HACCP development are unclear.

In the earliest stages of the system that would become HACCP, i.e. the work at NASA on space foods, a multi-agency 'team' approach was used (Bauman, 1993; Ross-Nazzal, 2007), with involvement of parties such as the NASA food/nutrition team under Paul La Chance, the US Army's Natick Laboratories and industry contractors/subcontractors, including the Pillsbury team headed by Howard Bauman. Although the philosophy of analysing hazards and identifying critical control points came out of this work, there was no defined system requiring teams to apply the principles and, in fact, the term HACCP had not been invented at that stage; being later coined by Pillsbury (La Chance, 2006).

The concept of HACCP teams first appears in the HACCP literature in 1992 in the USA National Advisory Committee on Microbiological Criteria for Foods (NACMCF) HACCP guide (NACMCF, 1992). There is no mention of use of teams in the original HACCP publication (The Pillsbury Company, 1973; Bauman, 1990, 1993). However, further investigation has revealed that Pillsbury did use a variant of HACCP teams 'without exception' from 1972 when applying HACCP to their civilian retail food operations (Sperber, 2007, pers. comm.). At this stage, Pillsbury required a food microbiologist, process engineer, product development scientist and regulatory officer to review and approve all new product and process developments or modifications, with additional expertise being sought where necessary (Sperber, 2007, pers. comm.). This process was formalised in 1972 in the Product Systems Safety Office and, as practised, this team function applied only to the corporate technology centres within Pillsbury and not to the individual manufacturing plants: "The plants had no voice in this process, and 'HACCP' was dictated to them" (Sperber, 2007, pers. comm.). The plants operated a system known as 'Physical Systems Hazard Control', which was largely a good manufacturing practice (GMP)/prerequisite programme based system for physical hazards, e.g. metal detection, sieving systems. This was because Pillsbury was largely a milling and bakery products company at this time. As it expanded into vegetables, ice cream and pizzas, etc., i.e. higher risk products[13], the need for more plant involvement became more obvious and, through a formal review of Pillsbury/GrandMet Foods[14] HACCP systems and training in 1992, the concept of HACCP teams involving plant-level personnel was built into Pillsbury HACCP Manuals and Training Programmes (Sperber, Mortimore and Wallace, 1992).

Sperber (2007, pers. comm.) believes that the team concept in HACCP originated at Pillsbury in 1972 and was not the result of later industry trends towards teamwork in many business functions. He acknowledges that there may have been recognition of the team advantage earlier during the NASA work, but states that "Pillsbury passed the HACCP team concept on to the food industry and eventually to the rest of the world...[...]... the team concept was taken for granted until it was finally codified in 1992 (by the National Advisory Committee on Microbiological Criteria for Foods, NACMCF, 1992)" (Sperber, 2007, pers. comm.).

It is also likely that trends towards use of teams within the business environment have played a role in the widespread acceptance of the team approach as being the most appropriate for effective HACCP development. According to McKenna (2000), the growth in the use of teams within organisations has been pronounced since the 1980s. This timing would tie in with the diffusion of the HACCP system innovation (Rogers, 2003) into the international food industry. Reasons for use of teams within business

[13] High risk foods are defined in the Food Law Code of Practice for England (FSA, 2009) as 'foods which support the growth of microorganisms or their toxins'.
[14] The UK-based GrandMet Foods had recently acquired The Pillsbury Company at this time.

organisations include beliefs that team performance will surpass individual performance when the task requires a variety of skills judgement and experience (Mohrman *et al*, 1995), which would tie in with the multidisciplinary expertise sought in HACCP. Evidence of productivity gains and reductions in rejects through use of teamwork has also been reported (Wellins *et al*, 1994, cited by McKenna, 2000), which is again consistent with HACCP as a continuous improvement-based preventative management system. Arnold *et al* (1998) report that decisions made by groups can evoke greater commitment than those made by individuals because more people feel a sense of involvement. Certainly gaining the commitment to take forward the outcome of the HACCP team deliberations, i.e. the HACCP plan, and implement it in the operation is central to an effective food safety system, however this transfer of the HACCP plan from being a paper 'specification' to everyday food safety practice generally also involves additional personnel to the HACCP team.

Whatever the origin of the multidisciplinary HACCP team, it is now a firmly embedded part of the HACCP system (NACMCF, 1997; Codex, 2003). HACCP team members are normally selected for their operational skills and expertise rather than HACCP knowledge, and are normally trained to an equivalent level in HACCP principle application (Mortimore and Wallace, 1998). However if there are weaknesses in the HACCP team's knowledge about how to apply HACCP principles it follows that there could be weaknesses in the system, e.g. incorrect identification of CCPs if there is confusion about how to apply CCP decision trees, or incorrect decisions about which hazards need to be controlled, and how, in a given operation. The basis of these decisions is knowledge about the HACCP Principle application process, along with technical knowledge of likely hazards and possible control options in the food industry sector.

Similarly the way that HACCP team members interact and share knowledge, particularly whose view will prevail when there is a difference of opinion, and whether more junior team members have the confidence to challenge their more senior colleagues, could have an impact on food safety. It is therefore important to understand the way that HACCP teams work together to make decisions about food safety and HACCP.

5.1.1 Makeup of the HACCP Team

The HACCP team is multidisciplinary in its makeup (Codex, 2003) in order to provide a blend of expertise and experience necessary to take decisions about product safety as part of the HACCP development process. Manufacturing HACCP teams normally consist of 4-6 individuals (Mortimore and Wallace, 1998) representing a range of disciplines. Key disciplines are reported to be manufacturing/operations/production, technical/quality assurance and engineering, with additional specialists, e.g. microbiologists, raw material specialists, distribution personnel, toxicologists, product developers, etc., brought in to assist the core team depending on the scope of the HACCP study (Mortimore and Wallace, 1998).

Within the multidisciplinary HACCP team the individual team members are expected to bring appropriate expertise and experience from their discipline to allow the team to complete its task (i.e. develop an effective HACCP plan) and to work in cooperation with their colleagues within the team. In addition to the common role of HACCP team member, it is normal practice for an individual to take on a team coordination or leadership role in order to facilitate teamwork progress (Mortimore and Wallace, 1998). This role may be appointed either externally from, or internally within, the HACCP team. A second team role identified as important to HACCP team work is that of the scribe (Mortimore and Wallace, 2001) or rapporteur (WHO, 1993; Moy *et al*, 1994).

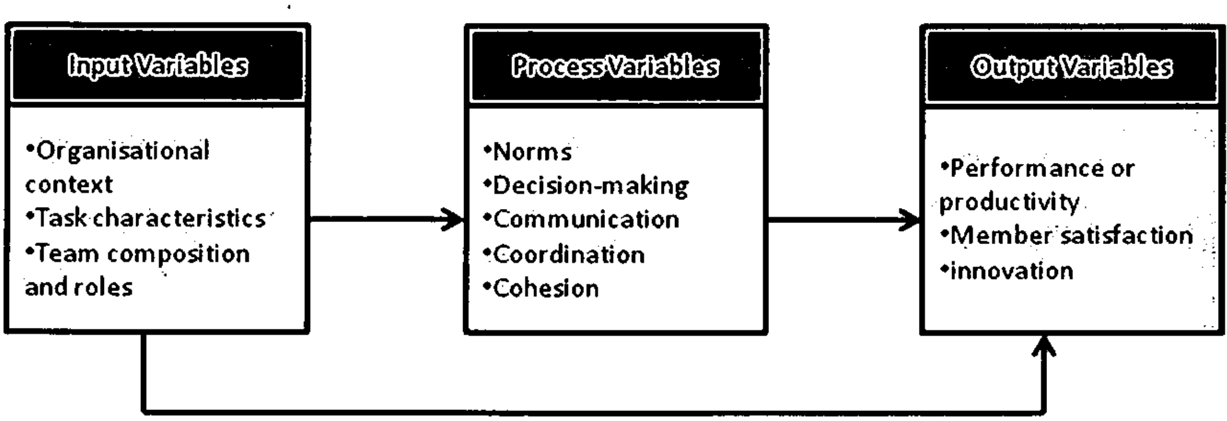
5.1.2 Team-work in Organisations

Much of the work on effectiveness in teams has been published in the last 30 years, reflecting the move to use of team-work in the business environment over this time. Previous work concentrated on the group, including group processes and decision-making (McKenna, 2000). The terms team and group tend to be used interchangeably within the literature (Landy and Conte, 2007), although some proponents identify differences between the two terms. McKenna (2000, p328) defines a team as a "small number of people with complementary skills who are committed to a common purpose, common performance goals and a common approach for which they hold themselves mutually accountable", whilst Landy and Conte (2007, p542) refer to "an interdependent collection of individuals who work together toward a common goal and who share responsibility for specific outcomes for their organisations". This latter definition ties in well with the role of HACCP teams. Where teams are distinguished from groups, size is often identified as the key characteristic differentiating between the two, i.e. teams are generally smaller (Belbin,2000; McKenna, 2000). Teams then could be considered as a special subset of groups, with the main differences being size, i.e. teams are generally smaller, and objective, i.e. teams generally have a defined task to perform, as in HACCP.

5.1.3 The Input-Process-Output Model of Team Effectiveness

The main model used to study team effectiveness is the 'input-process-output' model (Gladstein, 1984; Landy and Conte, 2004, 2007; Salas *et al*, 2008). This model suggests that inputs either directly affect team outputs or indirectly affect team outputs via team processes (Fig. 5.1) and is useful to unpick the potential impact factors in the effectiveness of HACCP team decision-making.

Figure 5.1 The Input-Process-Output Model of Team Effectiveness (adapted from Landy and Conte (2007)



The input-process-output model of team effectiveness stems from organisational psychology and it is accepted as fit for purpose in the study of teams within organisations (Landy and Conte, 2007). A consideration of how the Input-Process-Output Model is likely to apply to HACCP team decision-making now follows.

a) Input Variables

In the context of the study of HACCP team decision making via a specific HACCP task, the key input variables are considered to be the **Task** itself and the **Team Composition and Roles. Organisational context** is likely also to be involved in team effectiveness as part of more general HACCP application, and will link with cultural and other dimensions (Chapters 6-8).

Team Composition in a HACCP study would consist of individuals from a variety of disciplines to give the required blend of skills and expertise for food safety management, generally personnel from the production, quality/technical and engineering work areas (the core team) plus other relevant specialists (Codex, 2003). Team composition will also include the knowledge and skills brought by the individual team members to the team as a whole. If members of the HACCP team do not understand HACCP Principle application it is possible that there will be weaknesses in the HACCP plan that they develop, e.g. CCPs might be missed if the team does not have the capability to apply the Codex (2003) decision tree correctly or process deviation could occur unnoticed if the team has specified inappropriate critical limits and/or monitoring procedures. This could lead to the very real risk of harm to the consumer. As stated in the previous chapter, it is therefore important to understand both the collective knowledge of the team members, i.e. the knowledge that each individual member of the team brings and the holistic team knowledge, i.e. the knowledge of the team as a whole (Cooke, Salas, Cannon-Bowers and Stout, 2000), as this will affect team behaviour (Chapter 4, Figure 4.1).

In order to understand the potential impact of **Team Roles**, it is necessary to consider both the identified key HACCP team roles, i.e. team leader and scribe/rapporteur (WHO, 1993; Moy *et al*, 1994; Mortimore and Wallace, 2001; Codex, 2003) and team-role theory, as used in organisational psychology. Team-role theory was proposed by Meredith Belbin (1993) who identified 9 key team roles that need to be present and balanced in order to maximise team performance (Table 5.1). It was not proposed to test for Belbin's team roles within the teams to prevent adding further complexity to this study, however it is useful to consider how these roles might contribute to the work of HACCP teams and Belbin's team roles can therefore be used as a conceptual lens to illuminate findings.

Table 5.1 Belbin's Team Roles and their Contribution (Belbin, 1993)

Team Role	Description	Contribution
Plant	Creative, imaginative, unorthodox.	Solves difficult problems.
Resource Investigator	Extrovert, enthusiastic, communicative.	Explores opportunities and develops contacts.
Coordinator	Mature, confident, a good chairperson.	Clarifies goals, promotes decision-making and delegates well.
Shaper	Challenging, dynamic, thrives on pressure.	Has drive and courage to overcome obstacles.
Monitor Evaluator	Sober, strategic, discerning.	Sees all options and judges accurately.
Team-worker	Cooperative, mild, perceptive, diplomatic.	Listens, builds, averts friction and calms the waters.
Implementer	Disciplined, reliable, conservative, efficient.	Turns ideas into practical actions.
Completer	Painstaking, conscientious, anxious.	Searches out errors and omissions and delivers on time.
Specialist	Single-minded, self-starting, dedicated.	Provides knowledge and skills in rare supply.

Although there are 9 team roles, team members may exhibit more than one role so a typical HACCP team of 4-6 personnel could still cover all the roles identified by Belbin (1993) as necessary for team effectiveness.

b) Process Variables

Norms are the informal and often unspoken rules that regulate team behaviour and can have an impact on team decision-making and performance (Forsyth, 1999). Examples of Norms include punctuality, productivity, acceptable behaviour and often dress-code, although this latter point would not be relevant as a group norm in the food industry since dress code is specified by industrial and organisational hygiene requirements.

For effective **Decision-making**, the team needs to define the task, gather, discuss and evaluate information and come to a group consensus on the best course of action. Previous work on group decisions has identified the phenomenon of Groupthink, which was first described by Irving Janis (1982) and which can cause faulty decisions. Groupthink is most likely to occur in cohesive groups where members' desire to agree with the group overcomes their motivation to evaluate alternatives. Groupthink is an example of group polarisation, where the group makes more polarised or extreme decisions than would be made by the individuals. In group polarisation, the individuals shift their opinions to go along with what they feel is the group opinion (Forsyth, 1999).

Communication involves the transmission of information from one team member to another in a common language (Landy and Conte, 2007). In addition to any other common terms, HACCP uses specific language that would be taught in HACCP team training and used by team members in the HACCP study. Communication in HACCP teams is generally face-to-face at HACCP team meetings, a situation where everyone can normally hear and see everyone else in the team. This should minimise the likelihood of communication loss, although it is possible that points may be heard but not understood by individual team members. Even when HACCP team members split up to do individual work in HACCP study preparation, e.g. fact finding on a particular hazard, it is most likely that the team will come together to discuss the information in more detail and make appropriate judgements. Therefore the potential problems of loss of information in communication networks (McKenna, 2000), where individuals may only be in touch with some other individuals rather than the whole group, should not occur. However it is possible that team communication and decision-making may be affected by the assertiveness of individuals involved and whether they are willing to speak out in front of more senior or more forceful colleagues, and this might, in turn, be linked to norms about acceptable behaviour on site.

Coordination is important in multidisciplinary teams because individual team members are bringing different skills and experience to collaborate on the team task. Coordination losses occur when team members work against each other, e.g. by working in different directions on sub-tasks (Landy and Conte, 2007). Another phenomenon reported in team-effectiveness studies is social loafing (Landy and Conte, 2007). This occurs when team members assume that other members will perform the task so their own input is not required.

Cohesion is defined as the degree to which team members desire to remain in the team and are committed to the team goal (Forsyth, 1999). Cohesive team members are reported to be good at communication and to respond well to each other, while being heavily involved with the team's activities (Landy and Conte, 2007). Cohesion has been positively related to task performance (Beal *et al*, 2003, cited by Landy and Conte, 2007).

c) Output Variables

Output variables from the input-process-output model of team effectiveness include **Performance or Productivity**, **Member Satisfaction** and **Innovation**. In terms of HACCP effectiveness, the most important output variable is likely to be **Performance**, as this will relate to the HACCP plan developed through the HACCP team's deliberations. Innovation may have some impact, e.g. through the proposal of innovative solutions to control food safety hazards, however productivity and team member satisfaction are likely to be less important to an effective HACCP plan.

Consideration of the Input-Process-Output model of Team Effectiveness applied to HACCP is useful in providing a foundation for exploring how HACCP team decisions are made, and for understanding some of the likely limitations of team-work tasks.

5.1.4 Aims

The aim of this element of the research was to provide an insight into the HACCP team decision-making process, such that this would provide a contribution to understanding the impact of training, knowledge and personnel factors on HACCP effectiveness.

5.2 Methods

5.2.1 HACCP Team Decision-making Observation Method

Since HACCP team deliberations are most frequently held in the development stages of HACCP, it is difficult to observe HACCP team decision making in action in companies with established HACCP systems. This is compounded by a difficulty in comparing data across sites/teams, since HACCP teams are working on their own unique product/process situation, both within and between sites. For example, a large manufacturing site might have several HACCP teams appointed to develop HACCP plans for different process modules within the operation. Although the team members may have had equivalent training in HACCP Principle application, their decision-making process may be impacted by the challenges of the product/process module that they are studying in addition to the potential impact factors around individual and team HACCP knowledge and interactions within the team.

In order to overcome these difficulties, it was necessary to observe HACCP team deliberations and decisions in carrying out a standard task that would not rely on knowledge of a particular process. The Wallace *et al* (2005[a]) HACCP knowledge questionnaire (see Chapter 2 and Appendix 2.1) was chosen as an appropriate tool that could be completed by HACCP teams as a team task, providing that this was done after the individual knowledge testing to prevent individuals having foresight of the questions and/or benefitting individually from their colleagues' suggestions. In this way it would be possible to gain a measure of the collective team knowledge, i.e. the sum of individual team member knowledge, as well as a holistic measure of the team knowledge (Figure 4.1) (Cooke *et al*, 2000), as has been discussed in Chapter 4.

In order to observe and record the process of deliberation and decision-making in the HACCP teams, it was necessary to use 'ad libitum' sampling (Martin & Bateson, 1993) and develop a continuous recording framework to obtain a faithful record of the HACCP team discussions (Martin & Bateson, 1993). A check-sheet (Appendix 5.1) was designed for note-taking such that the types of comments and suggestions being made by individual team members, i.e.

answer suggestions, comments on other's suggestions and group support comments, could be recorded, along with the group reactions and decisions. The check-sheet design was validated by application to group work with a volunteer group of food safety students where inter-rater reliability of the check-sheet recording system was checked by 2 observers using the same check-sheet design and comparison of notes taken, and within-observer reliability was verified through use of a tape recording of the session. Following this pilot, some minor modifications to the check-sheet layout were made for ease of use prior to application to HACCP team observation. However, due to potential difficulties in accurate note taking in a fast-moving situation, it was decided that observation sessions should also be recorded for comparative purposes and permission to record sessions was obtained from HACCP teams in all cases.

5.2.2 Observation Process

Each HACCP team was asked to meet the researcher in an appropriate room at a set time after the individual knowledge testing had been completed, but on the same day. Seating was arranged for team members to sit in a circle to allow members to see each other during the discussions. A microphone was placed in the centre to record discussions. Once all team members had arrived the task of completing the HACCP knowledge questionnaire as a team was explained, and teams were instructed that they needed to agree on answers and allocate a team member to record their results. It was also explained that the researcher would be taking some notes in the background to help clarify data when analysing the results. When the team was ready to start, the researcher commenced the recording and, deliberately taking up an unobtrusive position, to be out of the line of site of as many participants as possible, used the check-sheet (Appendix 5.1) to record the observational process. At the end of the session, the researcher also recorded any further general observational notes, e.g. how the team had interacted, any individuals not participating, etc.

5.2.3 Questionnaire Marking

A previously described in Chapter 2, a marking guide (Appendix 2.2) with expected sample answers was used to mark the scripts provided by HACCP teams. For consistency, all scripts were marked by one independent marker and the marking process was rechecked for accuracy and consistent application of the marking guide.

5.2.4 Data Analysis

a) HACCP Knowledge Data

Team knowledge data were tabulated and compared with knowledge data for the individuals within each team as discussed in Chapter 4. Any anomalies, i.e. where team results were different from the individual results were highlighted for further study via the observational data.

b) Observational Data

Preliminary study of the observational data recorded on the check-sheet and the researcher's general notes suggested three different decision making routes (see 5.3.1 below). To test if these decision routes reflected all the pathways taken, examination of each HACCP team's decision process for all questions was done via the check-sheet, backed up by the recording where necessary. Anomalies found between team and individual knowledge scores were also followed up during this detailed examination of the observational data by examination of the observed decision process for occasions where the team score was better or worse than the individual scores. This data is summarised in Appendix 5.2.

5.3 Results

5.3.1 Observation of Team Decision-making Process

Observation of the team deliberation and decision process to answer the questionnaire established that all team members were participating in the process and offering suggestions, although it appeared that some team members were more prolific in this respect than others. The focus of the teams was on completing the questionnaire and so the majority of suggestions and comments being made were to do with either offering or discussing possible answers, however a number of group support comments were also made by team members, e.g. 'take your time' and 'let him speak', and light-hearted comments or jokes were also made by some individuals, e.g. after a long discussion about a specific question.

A number of team members asked clarification questions of their colleagues, either about the question meaning or about answer suggestions being offered. Individuals who had taken on coordination/leadership and/or scribe roles within the teams were also heard to make checks that everyone was happy with the suggestions and, in some cases, to read back what had been recorded or recite what should be recorded.

In general, when the team had come to agreement about an answer they moved straight on to the next question and proceeded through the questionnaire without delay and without revisiting any items. There was one exception to this where a team member insisted on going back to a question that he had been unhappy about at the end. He then persuaded his colleagues to accept his suggestion and change the answer given, although the team scribe stated "if it's wrong it's your fault" – he was correct.

5.3.2 HACCP Decision-making Routes

Through the general observation process it was established that there were three potential routes to a decision within the HACCP teams (Figure 5.2). These were:

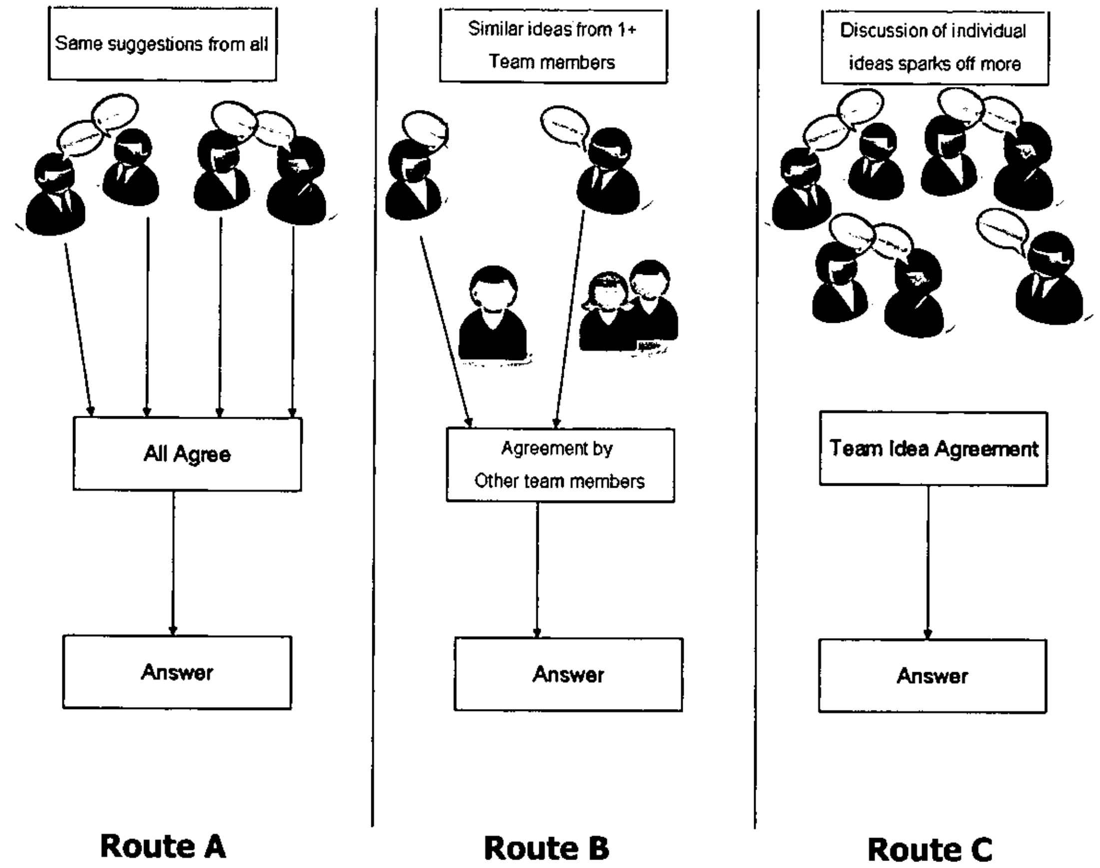
A) Where everyone knew the answer and there was virtually immediate agreement

B) An idea or similar ideas expressed by 1 or more team members, which is accepted by other team members

C) An idea or ideas spark off further discussion within the team leading to final agreement on an answer by the team.

Decision route A), in this research, related to knowing the answers to questions about HACCP from training, but could also apply where, for example, all team members offer the same suggestions about hazards at a particular step during a HACCP study, due to their common knowledge of the processing operations. Decision route B) was seen where a smaller number of team members knew the answer and this was readily accepted by other team members. A subset of this decision route, seen on one occasion at Australia Site 2, was where team members admitted that they did not know the answer and so accepted an answer suggestion from another, more 'learned', colleague. Decision route C) was the most commonly seen pathway in this study, where introductory ideas from individual team members sparked off other ideas and the agreed solution came after ideas had been debated.

Figure 5.2 Potential Decision-making routes within HACCP Teams



Review of all the observation data for each team provided a breakdown of team decisions fitting into each of the three categories above, and this is detailed in Table 5.2.

Table 5.2 HACCP Team Decision Categories and Frequency of Occurrence

			Frequency in each Decision-Making Route		
			A.	B.	C.
Country	Site	HACCP Team	Same suggestions from all, leading to general agreement	Similar ideas from > 1 team member leading to agreement by other team members	Discussion of individual ideas sparks off more ideas leading to team idea agreement.
India	Site 1	Team 1	2	12	8
		Team 2	2	9	11
	Site 2*	Team 1	5	5	12
Australia	Site 1	Team 1	0	10	12
	Site 2	Team 1	0	7	15
		Team 2	0	6	16
Singapore	Site 1	Team 1	0	6	16
Total for each decision route Frequency (%)			9 (5.8%)	55 (35.7%)	90 (58.4%)
*Although a second HACCP team was in place at this site and provided knowledge data, during the observation the team kept lapsing into discussions in Hindi so it was not possible for the researcher to determine which decision-making route was in place in all cases.					

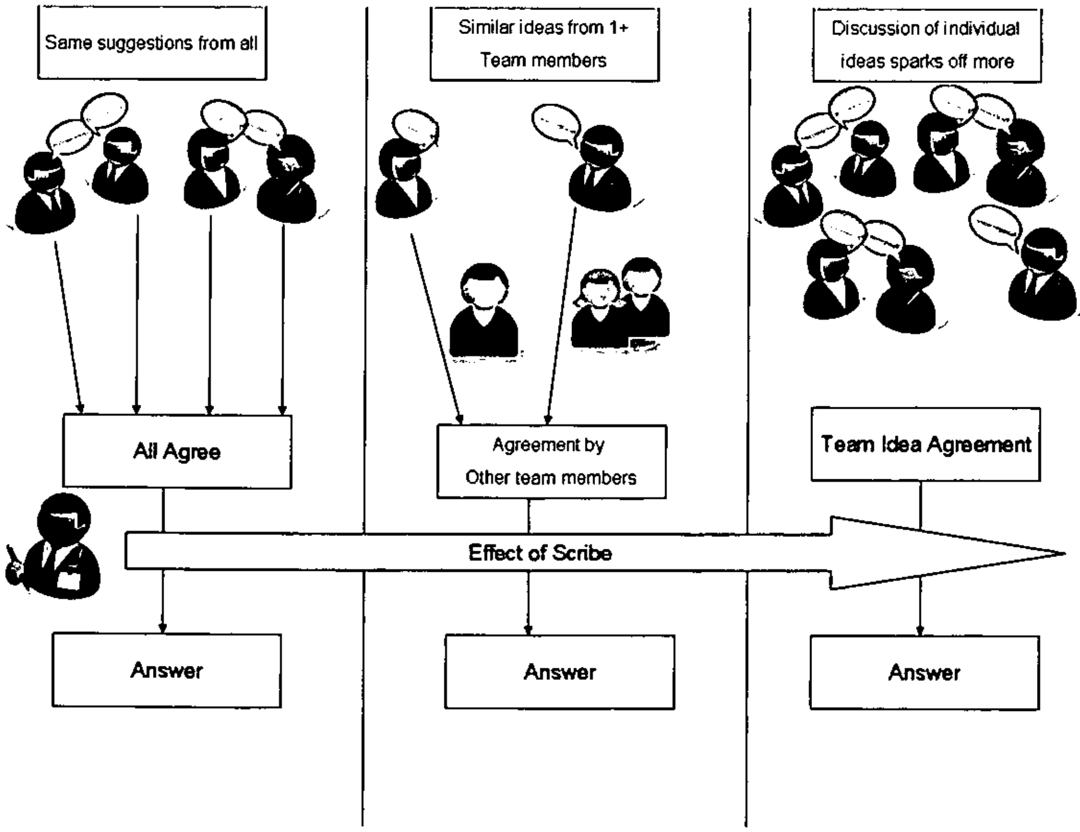
Decision route A) was seen on the least occasions, and only at the Indian sites. This may have reflected the levels and style of training at these sites. Decision route B) was seen on 35.7% of occasions and route C) on 58.4% of occasions, illustrating the tendency towards discussion and debate before the team came to an agreement.

In order analyse the HACCP team decision making process in more detail, it was decided to focus on areas where the team score was different (higher or lower) from the individual scores within the team (source of knowledge data: Chapter 4 and Appendix 4.1). Detailed observational data for these areas are recorded in Appendix 5.2 and the main points emerging are described below.

5.3.3 Effect of Scribe

From this further analysis of the decision-making process an additional factor impacting the final recorded decision was identified: the effect of the scribe. This was seen in several occasions where the team were seen and heard to have agreed on an answer, but the resulting script had a different answer (Figure 5.3).

Figure 5.3 Effect of Scribe on Decision Process



Specific examples of this phenomenon are as follows (Table 5.3), with commentary on each example given within the table:

Table 5.3 Examples of Scribe effect on Team's Answer

Q	Country/ Site/ Team	Score				Observed Decision Process
		Possible	Team Member Range	Team Member Median	Actual Team Score	
Explain what is meant by a hazard	Australia Site 2 Team A	2	0-1.5	0.25	0	2 team members suggest partly correct answer, then 1 team member suggests fully correct answer. Team discuss correct answer but incorrect answer is recorded. **Comment:** Scribe may be using his own language – he has written 'risk to product' rather than identifying that a hazard is a factor that can cause harm to consumer. In his own submission he also mentioned contamination to a product rather than harm from a contaminated product.
Explain what is meant by a control Measure	Australia Site 2 Team A	2	0-1.5	0.75	0.5	Correct answer is suggested by one team member (operator), however quality manager states incorrect; another production person has partly correct and then QAM states correct answer following discussion. However it is incorrectly recorded. **Comment:** In this case the scribe obtained the same score as the team but for a different answer. It appears that a recording error prevented the team from getting full marks here.
Why is microbiological testing not a good monitoring procedure?	India Site 1 Team A	2	2	2	1	Suggestions from production, quality and engineering supervisors; 2nd quality supervisor mentions that it is destructive; Scribe mentions trends; Production supervisor agrees on trends; overall agreement. **Comment:** All individuals got full marks for this question. Correct themes were coming up in discussion but this question appeared to be somewhat hurried in the discussion. Scribe has recorded a very close, although abbreviated, form of his own answer, but in abbreviating has lost the sense of one aspect, i.e. the problem of microorganism distribution in food matrices.

Table 5.3 Continued	Country/ Site/ Team	Score				Observed Decision Process
Q		Possible	Team Member Range	Team Member Median	Actual Team Score	
Suggest a control measure that could be used for hazards associated with raw materials	Australia Site 2 Team A	1.5	0-0.5	0.5	1	Several team members give specific examples (partly correct) then quality manager gives full answer. Group agreement follows further discussion. Scribe records some of the points highlighted. **Comment:** In this case the scribe had a lower mark when completing the questionnaire on his own, however he had not captured all the points made by the team which had prevented them from obtaining full marks.

5.4 Discussion

The aim of this element of the research was to provide an insight into the HACCP team decision-making process, such that this would provide a contribution to understanding the impact of training, knowledge and personnel factors on HACCP effectiveness.

The potential for a HACCP system to manage food safety effectively relies on the predetermined 'strength' of that system as specified by the HACCP plan. Since the HACCP plan is developed by the multidisciplinary HACCP team, it follows that the HACCP team plays a crucial role in food safety effectiveness. Commonly held beliefs of HACCP 'folklore' support the view that a multidisciplinary team would provide a better HACCP solution than could be expected from individuals working alone, i.e. HACCP team scores should be better than individual scores. However, the team and individual scores data from Chapter 4 provided conflicting evidence regarding this expected phenomenon. When team scores were compared with the median of individual scores the team did appear to do better, however when team scores were compared to the best individual scores a number of cases were found, ranging from 15.3% of possible occasions for the hazard analysis knowledge area to 29.2% of occasions for the CCPs and their control knowledge area, where the HACCP team score was lower than the score for individuals within the team, and in only a small number of cases the team score was higher than the scores for the best individuals within the team. This indicated a 'dumbing down' effect of HACCP knowledge within the team and gave further importance to the need for understanding of HACCP team processes via the observational data.

Analysis of the observational data revealed that, in a number of cases where the team result was weaker than that of individuals within the team, although an incorrect or only partially correct answer was given and/or recorded by the team, the correct answer had come up in the team's deliberations. These findings question beliefs about the superiority of HACCP teams to individuals in HACCP plan development and, therefore, it is necessary to explore the potential reasons for these differences.

5.4.1 HACCP Decision-making and the Input-Process-Output Model of Team Effectiveness

The organisational and business psychology literature reveals theoretical frameworks and models of team processes and group decision making that may have impacted the results. As highlighted in the introduction (5.1.3), the main model used to study team effectiveness is the 'input-process-output' model (Gladstein, 1984; Landy and Conte, 2004). In considering the findings of this study in the context of the input-process-output model, the following points can be made:

a) Input Variables

In this study the **task** was to complete a HACCP knowledge questionnaire while working as a HACCP team and full instructions on what to do had been given. All team members had previously completed the same questionnaire as individuals and so could bring their own knowledge and ideas to the team. In this specific task, some of the factors potentially impacting the team's answer decisions may include:

1. Whether all team members know correct answer – if they do then it is highly likely that the team will also get the correct answer, if not then a correct answer from the team will depend on whether correct ideas come from an individual(s) or from discussion and further debate of the individual suggestions.

2. Whether team members are prepared to accept ideas from colleagues who think they know the solution. The likelihood of getting the correct answer will also depend on whether or not these colleagues are correct.

3. Whether team members' ideas spark off further ideas and discussion within the team – likelihood of a correct answer will depend on the discussion process and team member memory of HACCP

principles/training.

4. Whether the scribe is accurately recording decisions of the team – if not, this could be due to carelessness, mishearing or misunderstanding, or because the scribe feels his or her own answer is better than the team's. In this latter case the likelihood that the team's answers will be correct will depend on the scribe's knowledge, and it should be noted that scribes in HACCP teams are often appointed in a quasi-random fashion, e.g. who has the neatest hand-writing, and are unlikely to be the experienced facilitators suggested by the use of the term rapporteur in WHO language (WHO, 1993; Moy *et al*, 1994).

It could be argued that the findings of poorer HACCP knowledge within the HACCP team as a whole rather than the individual team members are not relevant to food safety since team members are expected to contribute their operational, e.g. process, knowledge rather than HACCP knowledge. However, as previously stated, if members of the HACCP team do not understand HACCP principle application it is possible that there will be weaknesses in the HACCP plan that they develop. The common practice of providing HACCP Principles training to all HACCP team members could result in a team made up of individuals who all think they (or who the company thinks) understand HACCP application to the same degree. This could have potentially serious consequences if the more senior or more forceful team members have poorer knowledge but are the people directing the team. In this case it might be more effective to have a limited number of HACCP specialists on the team who are known to have an excellent knowledge of HACCP principle application and who are present to direct the HACCP development process, allowing the team to take in specialist expertise from the other multidisciplinary team members in their food safety decision-making. These would be the 'HACCP Process Facilitators' identified in Chapter 4, whose knowledge levels could be established using the HACCP knowledge questionnaire (Chapter 2, Wallace *et al*, 2005[a]).

Team Composition in this study related to existing HACCP teams, containing personnel from the production, quality/technical and engineering work areas (the core team) plus a number of other specialists. All team members had previously been trained in the application of HACCP principles to the same level[15]. It was therefore considered that the team composition, in terms of subject expertise, was appropriate both to the application of HACCP principles in a real HACCP study and to answering questions about HACCP principle application as in this research, however the knowledge of hazards relevant to the operations was not tested.

In this research, the key HACCP **Team Roles** had been considered to be team leader and scribe/rapporteur. The team leader is believed to be important (Mortimore and Wallace, 1998) because of his/her role in coordinating the HACCP study and the scribe/rapporteur because the accuracy of information recorded by the scribe is crucial to the development of an effective HACCP plan

[15] Although teams had been trained to the same general level in HACCP Principle application, there were differences in the time of training and training providers used by the different sites, however it is not anticipated that this would have affected any differences between HACCP team decisions and individual team member decisions as there was a range of knowledge levels within each team.

(WHO, 1993; Mortimore and Wallace, 2001). This accuracy may be affected by the scribe's own views on the points to be recorded as well as his or her 'carefulness' in recording what the team has agreed. Data collected here suggest that the scribe did sometimes play a role in changing the sense of the answers agreed by the HACCP team. For example, at Australia Site 2 when HACCP team 1 was discussing what was meant by the term 'control measure', the correct answer was suggested by one team member (a line operator) and, although this was followed by an incorrect suggestion from the quality manager and a partly correct suggestion by another production person, the team leader stated the correct answer following discussion, but it was incorrectly recorded. Similarly, at the same site and in the same team, the discussion of what was meant by the term 'hazard' produced the correct answer but an incorrect answer was recorded. In this case the scribe used similar language to his own individual submission – risk to product rather than harm to consumer. A further example was seen when India Site 1, HACCP team 1, was discussing why microbiological testing is not a good monitoring procedure for CCPs – the correct themes came up in discussion and all team members had got this fully correct individually but the answer given was only partly correct. This question also appeared to be somewhat hurried in the discussion which may have affected what the scribe recorded. Whether these examples indicate deliberate actions on behalf of the scribe as someone who felt they knew better than team-mates, or whether it was simply down to inaccuracies in hearing, interpreting or recording what was being said cannot be determined. Whilst the scribe role has been identified as an important one within the HACCP team (Mortimore and Wallace, 2001) this is given little significance in HACCP training

(Palmer, pers. comm.) and there are no previous studies on HACCP scribe accuracy in the literature. This would seem to be an area where further study would be beneficial to support guidance both on scribe selection and training, and on approaches to prevent errors in recording during the HACCP study.

In a real HACCP plan development scenario it may be possible to pick up errors in recording through validation of the HACCP team deliberation records by other team members. This would rely on other team members being able to recall the deliberations and agreed decisions and taking time to read through the records in detail. It is recommended, therefore, that this validation check of records produced at each stage of the HACCP team deliberations is added as an essential stage of the HACCP process, in the same way that process flow diagram validation is an accepted step in the HACCP logic sequence (Codex 2003)

Another facet to consider regarding team composition is that of team-role theory Belbin (1993) as noted in the introduction to this chapter (5.1.2). Because team members may exhibit more than one of the nine team roles established by Belbin (1993), a typical HACCP team of 4-6 personnel could cover all the roles identified for team effectiveness. It can be postulated that for the HACCP team leader role, someone with the characteristics of the 'Coordinator' team role would be most effective whilst for the scribe, a natural 'Completer' is likely to be the best option. It is possible that some of the issues identified with inaccurate recording could have been caused by a scribe who is not a natural 'Completer'. This area would need future research to establish if there is a benefit of selecting people with specific natural team role preferences, either to take on the key HACCP team roles of Team Leader and Scribe, or for the overall makeup of the HACCP team. However the practicalities of selecting HACCP team members on the basis of a combination of Belbin's team roles (Belbin, 1993), HACCP knowledge levels (Wallace *et al*, 2005[a]) and work discipline expertise might make team selection problematic, and it is possible that the gains from a spread of team roles might not outweigh the problems of selecting the right combinations of people in this way.

b) Process Variables

Norms can have an impact on team decision-making and performance (Forsyth, 1999). However, it is considered that this is unlikely to have impacted the data-collection in this case, since this was an artificial situation rather than a normal HACCP team meeting and thus personnel did not know what to expect when entering the session. It is possible that there could be a norm regarding acceptable behaviour operating at some sites, such as not contradicting people of higher rank. However this was not apparent in the observational data and further study would be required to establish any impact of norms on HACCP performance in general.

As highlighted previously, for effective **Decision-making,** the team needs to define the task, gather, discuss and evaluate information and come to a group consensus on the best course of action. This process was exactly the scenario observed in the team decision-making activity, although the outcome was not always the effective (correct) solution with regard to the HACCP questionnaire marking guidelines (Appendix 2.2). It is possible that some of the final HACCP team decisions were affected by the phenomenon of Groupthink (McKenna, 2000; Landy and Conte, 2007), e.g. where team members agreed to incorrect answers even though they had themselves suggested or heard others mention correct answers. However it is also possible that an individual's confidence about their own knowledge compared to the level of knowledge they believed their colleagues had could have played a part, e.g. where they believed their colleagues more likely to be correct than themselves.

As stated in the introduction (section5.1.2 b)) **Communication** is another process variable that can affect team effectiveness. Because all team members had been trained in HACCP, the terminology used should not have caused communication difficulties. In fact the HACCP questionnaire provided an opportunity to test whether this common language of HACCP was understood by the team members. From the observation, in addition to the individual knowledge testing (see Chapter 4), it was noted that some team members understood more and were therefore able to communicate more about HACCP than others. It is possible that the need to communicate in English may have been a factor in reducing suggestions from some individuals where English was a 2nd language, however the main team that this affected (at India Site 2) held discussions in Hindi where necessary. No indication of any other communication difficulty was evident, although this was not directly tested as part of the study. The design of the HACCP team sessions should have minimised communication losses and all members could see and hear each other, although it is possible that points may be heard but not understood by individual team members. It is also possible that team communication and decision-making may be affected by the assertiveness of individuals involved and whether they are willing to speak out in front of more senior or more forceful colleagues. However, from the observation of team members it is considered that this is unlikely to have played a major role, since all team members were seen to offer suggestions and participate in discussions.

As previously stated, **Coordination** is important in multidisciplinary teams because individual team members are bringing different skills and experience to collaborate on the team task. In this observation of HACCP teams all members were seen to contribute ideas. Although coordination losses were not studied directly, none became apparent through the observations as all team members were seen to contribute ideas, suggesting lack of social loafing, and there were limited opportunities for team members to work against each other as the teams did not separate onto sub-tasks. A possible exception to this may be scribe behaviour if a scribe was knowingly over-riding the team's agreed decision because he or she thought they knew the answer better. It is not possible to confirm or reject this from the current data and further study would be required to further inform this area.

Whilst this analysis relates to a one-off data-collection intervention, the HACCP teams were existing teams who had previously worked together in HACCP development and review activities. It is therefore expected that the teams would have developed a degree of **Cohesion**, although this was not measured. With regard to the communication practices that were observed, it was the perception of the researcher that the HACCP team members did appear to communicate well and, in general, were comfortable with working together on the task in hand.

c) Output Variables

As stated in the introduction (section 5.1.2 c)) the most important output variable was postulated to be **Performance**, and this was the key output variable being measured via the HACCP knowledge questionnaire. Differences between individual and team performance were found (Chapter 4) and, considering the Input-Process-Output model of Team Effectiveness as applied to HACCP, the potential reasons for these performance differences include:

- Inappropriate combination of team roles or personnel in key HACCP team roles with inappropriate personal team role characteristics
- Team decisions affected by group polarisation or groupthink
- Individual reluctance to offer suggestions due to lack of confidence in own knowledge/abilities.
- Communication losses within team due to assertiveness issues between more senior/forceful and junior/less forceful team members or possibly through norms of acceptable behaviour preventing challenge of more senior staff.
- Coordination losses, e.g. if scribe over-rides agreed group answer

However, although the input-process-output model is an established approach for considering team effectiveness impact factors, it is recognised that the possible inputs and processes discussed above are likely to be only part of the story and that other impact factors are likely to be involved in the broader macro political context of HACCP application in multinational food businesses. These issues were studied in further detail in other elements of the research and are discussed in Chapters 6-8 of this thesis.

5.4.2 Strengths and Limitations

The fact that this study involved teams and individuals completing a HACCP knowledge questionnaire rather than a real HACCP study might initially seem to HACCP practitioners to be a limitation. However this is actually a strength as it is a controlled situation and HACCP team decision-making is being explored via a quasi-experimental paradigm rather than a case study, where more confounding factors might be seen. Nonetheless, several limitations do need to be taken into account for this study.

All the individuals in the HACCP teams had seen the questions previously since the individual knowledge was tested prior to that of the HACCP team. Although this was only, at most, a few hours previously it is possible that the fact that they had already done the task as individuals made the team members rush to come to a consensus rather than thinking and debating for full agreement. It is not possible to confirm this but the fact that questions were debated thoroughly in many cases would tend to suggest that team members were prepared to take time and discuss suggestions with their colleagues. The Indian groups had also been exposed to the HACCP questionnaire in the preliminary study (2 years before the onsite data collection), which may have affected both the individual and team responses. This may have impacted the occurrence of Decision Route A), where all team members make the same suggestions and automatically agree with each other, as this was only seen in the Indian factories. It is not possible to confirm this but it is considered unlikely that individuals would have remembered the questions over time. Further work with additional HACCP teams could confirm that Decision Route A) is valid.

Observation of one team at India Site 2 was hampered by the HACCP team's deliberations in Hindi, which could not be understood by the researcher. Although the team had been asked to communicate in English, several individuals tended to use Hindi to discuss points in more detail and so observation of the decision process was limited to observation of how many team members were interacting and whether discussion/debate was apparent.

It is possible that being observed may have had an effect on the process, i.e. that the Hawthorne effect occurred. This relates to a change in behaviour that results from researchers paying attention to the subjects and was first described following Elton Mayo's experiments at the Hawthorne plant of the Western Electric Company in 1920s USA (Hsueh, 2002). In the Hawthorne experiments it was found that productivity went up under experimental conditions that were expected to reduce productivity and this was determined to be because of close supervision. The researcher was known to a number of participants due to previous business communications and had to be present during the decision process with each HACCP team, however steps were taken to minimise any potential effect on the outcome, e.g. via explanation of the researcher role to all participants before the observations took place and deliberate positioning of the researcher to be out of the line of site of as many participants as possible. It is considered that the Hawthorne effect was unlikely in this study as it was observed that teams seemed to forget that the researcher was present, however it is not possible to confirm this.

5.4.3 Further Work

This study highlighted a potential effect of the scribe on the outcome of the HACCP team's deliberations. A future study on the impact of scribe accuracy on effective HACCP development would help to confirm these findings and draw out more detailed recommendations on scribe selection and training.

Although Belbin's team roles (1993) were highlighted as possible considerations for team effectiveness, these were not studied in this instance. A future study of Team Roles within HACCP teams linked to HACCP effectiveness data might provide further useful information about HACCP team member selection.

5.4.4 Recommendations to Multinational Food Businesses

- Choose HACCP team scribe carefully – needs to be someone with excellent attention to detail and who will provide a true reflection of the team's discussions and agreement.

- Consider appointing a scribe who has no technical input into the HACCP study and who is there purely to accurately record the proceedings. This person would still need an understanding of the HACCP principles and process to be followed.

- Ensure a validation step is built in for each stage in the HACCP study process, not just for the process flow diagram. Team members should check and sign that they agree each set of documents involved in each stage of the HACCP study, e.g. hazard analysis charts, CCP decision records, etc. This should be done immediately after the HACCP team meeting, as soon as the meeting records can be produced.

This element of the research has provided an insight into HACCP team decision-making process, and identified some potential limitations within HACCP team operation that need to be understood by food companies. Along with the remaining elements of the research on national culture and business/operational factors, this will help to determine the impact of training, knowledge and personnel factors on HACCP effectiveness. The next chapter will consider national culture and its potential impact on HACCP.

Chapter 6

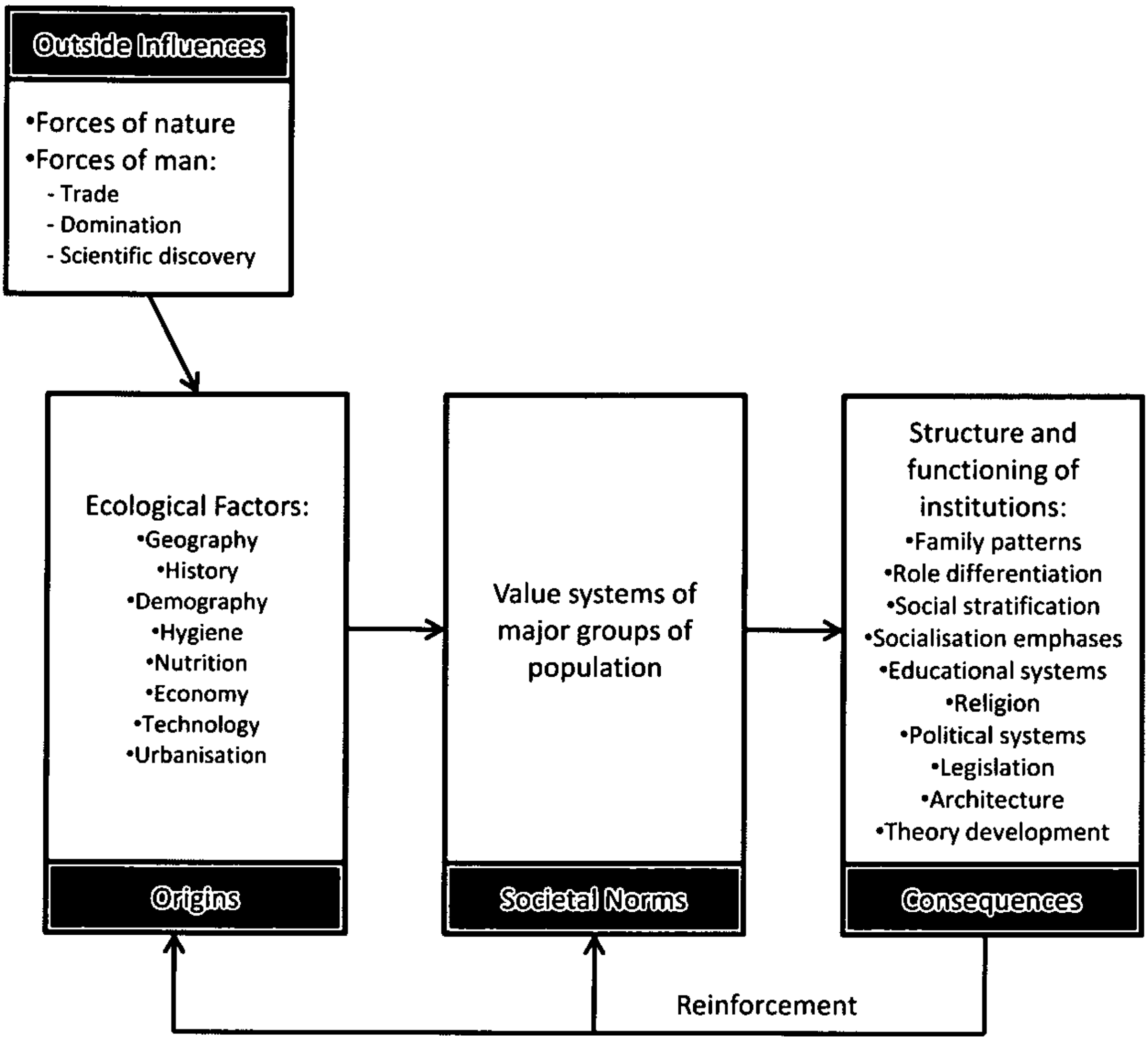
Impact of National Cultural Dimensions on HACCP Application

6.1 Introduction

Multinational organisations generally work across, not only national and regional boundaries, but also cultural dimensions, through the placement of their manufacturing and/or sales and distribution units within different communities. Culture can be defined as a "system in which individuals share meanings and common ways of viewing events and objects" (Ronen, 1997, cited by Landy and Conte, 2004, p22). It influences the values, attitudes and behaviour of individuals and groups (McKenna, 2000) and is in turn influenced by changing patterns of individual and group behaviour (Adler, 2002). Culture can also be considered as a way of distinguishing between members of different groups, i.e. "culture is the collective programming of the mind that distinguishes the members of one group or category of people from another" (Hofstede, 2001, p9).

Culture tends to be relatively stable over time due to self-regulation and reinforcement of value systems and societal norms (Figure 6.1), however it can be impacted by external influences such as developments and shifts in science and technology as well as forces of nature.

Figure 6.1 Stability of Culture Patterns (adapted from Hofstede, 2001)



Multinational organisations rely on business interactions and collaboration across international boundaries, which requires some grasp of how other people in other countries might think differently from ourselves (Hofstede, 2001). However, international technical projects such as HACCP application may be initiated without any consideration of how different cultural factors within the organisation could affect the project's success.

In multinational organisations, culture exhibits both national and organisational dimensions. Whereas national culture relates to the values, attitudes and behaviour of individuals and groups at the country or regional society level, organisational culture is concerned with the way that attitudes and beliefs are expressed within a corporate or company culture (Trompenaars and Hampden-Turner, 1997) and the values and behaviour standards that people working within that organisation are expected to follow (McKenna, 2000). In terms of HACCP application, the decision to use the HACCP system at international manufacturing sites is often a corporate decision that is imposed on all sites, as in the company studied. Whilst it may be in line with shared organisational culture values such as consumer protection, the methods and practices of the HACCP system are derived from its origin in Western[16] settings and there are no previous studies considering the potential impact of national or regional culture on HACCP application. This chapter focuses on dimensions of national culture; aspects of organisational and business cultural dimensions are addressed in Chapter 7.

6.1.1 Dimensions of National Culture

Culture and its impact on workplace behaviours, attitudes and outcomes has been widely studied in the fields of psychology, anthropology and sociology, with a number of tools and models proposed for investigation of different aspects of culture (Kirkman, Lowe and Gibson, 2006). The most

[16] For the purposes of this research, 'Western' is taken to mean *Of or pertaining to the Western or European countries or races as distinguished from the Eastern or Oriental* (Oxford English Dictionary Online, 2009). HACCP was developed in the USA as part of the manned space programme (Ross-Nazzal, 2007)

comprehensive treatment of the topic comes from the work of Geert Hofstede, who studied culture in a multinational organisation from the 1960s to the 2000s (Hofstede, 1980, 2001) and is widely cited (e.g. Kirkman *et al*, 2006; Triandis, 2004; Tayeb, 2001; Chapman, 1997; D'Iribarne, 1997).

Hofstede (2001) identified 5 main dimensions on which country cultures differ (Table 6.1) based on empirical study of national culture in the IBM organisation (Hofstede 1980, 2001) and work with Michael Harris Bond including the results of the Chinese Value Survey Project (Chinese Culture Connection, 1987).

Table 6.1: Dimensions of Country Cultures (Hofstede 2001)

Dimension	Interpretation
Power distance	This looks at degrees of human inequality and the extent to which less powerful members of organisations accept the distribution of power.
Uncertainty avoidance	This considers how members of a culture have been programmed to feel comfortable or uncomfortable in unstructured situations.
Individualism/collectivism	Is the degree to which individuals look after themselves or remain integrated into groups.
Masculinity/femininity	This considers the distribution of emotional roles between the genders.
Long-term/short-term orientation	This looks at the way members of a culture are programmed to accept delayed gratification of their own needs (material, social and emotional).

Hofstede (1980, 2001) conducted a cross-cultural survey with a large number of employees within the IBM Corporation, including participants from over 50 countries who were matched as closely as possible in aspects such as gender, age, and job role to eliminate differences between individuals. The study design and analysis also eliminated differences from policies and practices at the different research locations, such that variations found could be attributed to national culture (Hofstede, 2001).

Hofstede's 5 dimensions (2001) are widely used in cross-cultural studies (Kirkman *et al*, 2006) and each dimension is expressed as a continuum (Bearden, Money and Nevins, 2006) such that a country can be placed as either low or high, or somewhere between on the dimension scale. A more detailed discussion of each cultural dimension now follows.

As indicated in Table 6.1, Power Distance (PDI) is the degree to which the less powerful members of institutions and organisations within a society tolerate the unequal distribution of power and expect to have to do so (Hofstede, 2001). Hofstede (2001, p83) defines power distance as the 'difference between the extent to which a boss can determine the behaviour of a subordinate and the extent to which the subordinate can determine the behaviour of the boss'. Values close to zero indicate a low PDI and at or above 100 a high PDI and unequal distribution of power. For example, Countries that display low PDI tend to have decentralised decision structures with less concentration on authority and subordinates who expect to be consulted whilst those with high PDI tend to have centralised decision structures with more concentration on authority and subordinates who expect to be told what to do.

Individualism in a society means the ties between individuals are loose and people tend to look after themselves and their immediate family only, whereas collectivism is represented by societies in which individuals are integrated into cohesive groups which protect them throughout their lives. The scale of the individualism index runs from 0 (or below), representing strongly collectivist societies, to 100 (or above), representing strongly individualistic societies. Employees in low Individualism-Collectivism (IDV) score countries tend to act best in groups and believe in collective decisions, while those in high IDV countries tend to act best as individuals and believe in individual decisions.

The cultural dimension of masculinity represents a society with clearly distinct gender roles. In masculine societies (index score close to 100), men are likely to be assertive and focussed on material success, whereas women are likely to be concerned with quality of life. At the opposite end of the masculinity index (values close to 0) both men and women are likely to be concerned with the quality of life and to exhibit 'feminine' characteristics such as supportiveness in relationships. As an example of how this dimension fits in the workplace, in countries with a low Masculinity-Femininity (MAS) score, work relations and working conditions are important to workers, whereas in countries with a high MAS score security, pay and interesting work are more important.

Hofstede's Uncertainty Avoidance index (UAI) measures the extent to which individuals in organisations feel comfortable or threatened by events or situations that are uncertain, unstructured or unknown. At values close to 0 there is weak uncertainty avoidance, in other words people are comfortable with uncertainty, whilst at values close to 100 there is a strong tendency to avoid uncertainty. In the workplace, countries with low uncertainty avoidance scores tend to have employees with weak loyalty to their employer and a short average duration of employment, while those with a high UAI score tend to be the opposite (Hofstede, 2001).

The final Dimension in Hofstede's suite of cultural measures is the Long-term Orientation Index (LTO), which was absent from his early work (1982) and came from collaboration with Michael Bond following the results of the Chinese Value Survey Project (Chinese Culture Connection, 1987). According to Hofstede (2001), long-term orientation stands for a society that fosters virtues oriented towards future rewards, in particular perseverance and thrift, whereas short-term orientation implies a society that fosters virtues related to the past and present, in particular respect for tradition, preservation of "face" and fulfilling social obligations. Where there is low LTO quick results are expected, while with high LTO there is persistence and perseverance towards longer term goals (Hofstede, 2001). It could be argued that there is a paradox here, in that past societies, at least in Western Europe, have fostered both the virtues of thrift and perseverance and those of respect for tradition at the same time. However Western[17] countries are generally seen to have low LTO and eastern societies high LTO.

[17] Hofstede does not offer a definition of 'Western', although he does discuss the fact that his original tool was developed by 'Western minds', i.e. American, British, Dutch, French and Norwegian, and how the development of the Long-term Orientation Index (LTO), in collaboration with Michael Bond, introduced an 'Eastern' dimension to the tool. As previously noted, for the purposes of this research, 'Western' is taken to mean *Of or pertaining to the Western or European countries or races as distinguished from the Eastern or Oriental* (Oxford English Dictionary Online, 2009).

6.1.2 Cultural Dimensions and HACCP

In terms of the HACCP system of food safety management, these dimensions of culture may influence HACCP effectiveness to a greater or lesser extent. As discussed in chapter 5, the development and implementation of HACCP is largely carried out by teams of individuals who must work together to provide a system that is capable of controlling food safety hazards. Therefore, position on the Individualism-Collectivism (IDV) scale would seem to be a potential impact factor for HACCP success, i.e. countries with low IDV scores are likely to work well in groups as required for HACCP.

The site senior management must be committed to HACCP from the outset and be seen to actively support the system, through managerial and financial means (Mortimore and Wallace, 1998, 2001; Panisello and Quantick, 2001). This could be possible in organisations at either end of the Power Distance (PDI) scale through their different management styles, however the consultative management and information sharing qualities of low PDI societies are most likely to provide a suitable environment for HACCP. It may also be possible for the more authoritative leadership style in high PDI societies to enable effective HACCP as long as key managers are behind HACCP and closely supervising its progress.

For ongoing effectiveness, individuals have a continuous and crucial role in the monitoring and auditing of the system, and these management and maintenance activities may be thought of as being the responsibilities of site personnel working as a 'team'. Again the IDV score may influence this.

The masculinity-femininity dimension (MAS) may also have an impact on team-work. Sites with a low masculinity score (strongly feminine) are likely to be able to form cohesive and supportive HACCP teams, however sites that are strongly masculine may focus on the outcome, i.e. 'getting the job done'. Positioning at either end of the MAS score may, therefore, have influence on HACCP success but for different reasons.

Sites with a low uncertainty avoidance index (UAI) may be more accepting of the new ideas of HACCP in training situations and be willing to take on these new skills and responsibilities. The long-term orientation index (LTO) may also have an impact: sites with long-term orientation may find it easier to plan, develop and implement a HACCP system since they are looking to the future. However, the fact that HACCP is a company requirement means that both these dimensions are less likely to have an impact on whether or not the HACCP system is applied.

Overall, the individualism-collectivism (IDV) and power distance (PDI) dimensions were considered the most likely to impact HACCP and the following hypotheses relate to the likely impact of these cultural dimensions on HACCP:

- Countries with a tendency towards collectivism are more likely to be able to operate successful HACCP teams than those with a tendency towards individualism, as long as the correct blend of knowledge and skills are available within the identified team members.

- Power distance is likely to have an effect on HACCP effectiveness. Sites with low power distance are more likely to provide a suitable management framework for effective HACCP as their more consultative management style will help in gaining commitment to and progressing the HACCP project. Sites with high power distance may also enable effective HACCP if key managers are committed to and closely involved with the project.

Depending on the positioning on the cultural dimensions scores, comparison of IDV and PDI scores against HACCP knowledge and effectiveness data should give an indication of whether or not these hypotheses can be supported.

6.1.3 Measuring the Dimensions of National Culture

Since work in the area of national/cultural factors is well-established it is appropriate to use existing methodology. Therefore, Hofstede's VSM 94 survey (Appendix 6.1), developed from his original work in IBM, (Hofstede 2001) was determined to be an appropriate method to study cultural dimensions in this research. This tool is a good fit since Hofstede had studied business locations in a multinational organisation and this research is also a comparative study of manufacturing sites of a multinational company applying HACCP in their different country settings. The comprehensive nature of Hofstede's original research meant that all countries within the portfolio of manufacturing sites of the multinational organisation in this research had also been tested by Hofstede and results were available for comparison. Hofstede's values for these countries on the cultural dimensions scales (Hofstede, 2001) and are detailed in Table 6.2.

Table 6.2 Hofstede's Dimension Score for Research Countries

	Country Dimension Score (Hofstede, 2001)		
Cultural Dimension	India	Australia	Singapore
Power Distance	77	36	74
Individualism	48	90	20
Masculinity	56	61	48
Uncertainty Avoidance	40	51	8
Long-term Orientation	61	31	48

From these scores it could be expected that the most marked differences between the countries would be for Individualism-Collectivism, Uncertainty Avoidance and Power Distance, two of which (IDV and PDI) were the dimensions predicted to have most likely impact on HACCP success. Hofstede's data (2001) suggested that the Australian sites were more likely to be working within an individualistic culture, with Singapore being a collectivist culture and India towards the centre of the dimension scale, perhaps slightly more collectivist than individualist. On the Power Distance scale, the lower power distance of Australia predicted a country with less concentration on authority and the higher power distance in both India and Singapore predicted a more hierarchical management structure where subordinates have close supervision and expect to be directed (Hofstede, 2001). For uncertainty avoidance, all countries were at, or lower than, the midpoint of the dimension scale, indicating that people feel generally comfortable with uncertainty and that this was most marked in Singapore. The 3 countries were also fairly close to the midpoint of the masculinity-femininity dimensions, with Australia indicated as the most masculine and therefore material success orientated society, and Singapore very slightly feminine. For the final dimension of Long-term Orientation, India scored as the most long-term orientated with Australia more inclined to shorter term goals and Singapore around the midpoint of the scale.

If collectivist cultures, given the correct blend of knowledge and skills, are more likely to operate successful HACCP teams then Singapore could be predicted as highly successful in this area, followed by India as moderately successful. Australia would not be expected to be naturally successful in this area from a cultural perspective. However, if countries with a lower power distance are more likely to provide a suitable management framework for HACCP effectiveness then Australia would be expected to rank highest above both Singapore and India.

Since Hofstede's data (2001) were based on original studies from the 1960s and 1970s, it was necessary to collect further data as part of this study in order to establish primary data for the sample countries and to identify any indication of changes in cultural dimension scores over the interim period.

Although Hofstede's work has been criticised by a number of workers (Baskerville, 2003; McSweeney, 2002[a]; McSweeney, 2002[b]; Spector *et al*, 2001),often in studies exploring individual level rather than country level phenomena, it is supported by others (Chapman, 1997; Kirkman *et al*, 2006; Smith, 2002; Williamson, 2002). Hofstede has also defended his original work

(Hofstede 1981) and refuted criticism (Hofstede 2001, 2002), with particular reference to the need to apply scores at the country level. This is further supported by Bearden *et al* (2006) who consider application of Hofstede's national culture dimensions at the individual level to be 'misguided' (p 196). As a seminal and widely used method (Bearden *et al*, 2006), it was therefore considered that Hofstede's instrument (1994) was an appropriate method to use in assessing the impact of national cultural factors in this study.

6.1.4 Instrument Validity

Country scores are based on the central tendencies in the answers by the individuals in each country (Hofstede, 2001). This means that correlation is needed at the national level rather than the individual level and so it is inappropriate to challenge scale reliability using traditional calculations such as Cronbach's alpha on the individual scores (Hofstede, 2001). Validation of an instrument at the country level, however, requires data from a sufficiently large sample of countries and Hofstede (2001) recommends at least ten country datasets. Due to the nature of this detailed research investigation into HACCP success factors in three countries, it was not possible to re-validate the instrument here using this dataset. However, because the instrument has been previously validated (Hofstede, 2001) and the five dimensions are considered by researchers to provide a clear framework for country comparisons (Kirkman *et al*, 2006), it was selected as an appropriate, proven instrument for this research.

6.1.5 Aims

The aim of this research pertaining to national culture was to characterise the relationship between national/cultural issues on HACCP effectiveness. Therefore the work described in this chapter focuses on consideration of dimensions of national culture rather than organisational culture. Aspects of business dimensions and organisational culture are discussed separately in Chapter 7.

6.2 Methods

6.2.1 The Research Setting

The research was carried out in 5 manufacturing sites spanning 3 countries within one regional division of a multinational company. The company is a long-established (c. 200 years), traditional producer of food products with a portfolio of global and local brands, and has had several international manufacturing sites since the early 1900s, becoming a true multinational by the 1960s. At the time of the research, it was the market leader in its sector with approximately 10% of the global market.

6.2.2 Choice of Sites

Sites were chosen to give a spread of different national characteristics based on findings of the Hofstede data (2001). As discussed in chapter 3, the region available for study in the multinational company was known internally as Asia Pacific, which was its largest geographical region ranging from the Indian subcontinent east to China and Japan and south as far as New Zealand, with manufacturing sites spread throughout the countries of the region. Following discussion about the research aims with the researcher, regional management offered the opportunity to study three separate countries. Australia was identified as an example of a 'Western[18]', 'developed[19]' country and India as an example of a 'developing[20]' country in South Asia. Singapore was chosen as a third country that was expected to differ culturally from the other two, being a 'developed' country with a largely Oriental – 75% Chinese at June 2008 (Singapore Department of Statistics, 2009) – culture. All 3 countries had been British colonies at some point in their history and are still members of the Commonwealth, therefore English is widely spoken.

6.2.3 Application of the Hofstede Instrument

The most recent version of the instrument, known as the Values Survey Module 1994 (VSM 94) (Hofstede, 1994) was obtained. A recording sheet (Appendix 6.2) was developed to capture responses and the instrument was administered according to the guidelines provided (Hofstede, 1994) at the manufacturing sites during the field data collection visits (see Appendix 3.1 for site visit work plan).

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[18] The term 'Western' is both in wide colloquial use and commonly mentioned in cross-cultural and business research, however few definitions are available in the literature. The Oxford English Dictionary online (2009) defines 'Western' as: *Of or pertaining to the Western or European countries or races as distinguished from the Eastern or Oriental*, and 'Western Man' as: *Man as shaped by the culture and civilization of Western Europe and North America.* Although Bhopal and Donaldson (1998) suggest that the value of the term 'Western' has been undermined due to the global spread of 'western' populations, it still has usefulness in referring to businesses and cultures that have their root in the west, as was the case in this global company that originated in the UK, and with the nation of Australia due to its Commonwealth and settlement links to the UK. Western countries and cultures would therefore be expected to show some differences from Oriental and South Asian countries and cultures.

[19] The term 'developed' country is used with reference to the World Bank Data and Statistics on Country Groups (World Bank, 2009)

[20] The term 'developing' country is used with reference to the World Bank Data and Statistics on Country Groups (World Bank, 2009)

Samples of personnel were chosen to establish the background level for each dimension at the sites, including personnel from management, technical, production and administrative roles, reflecting the roles present within the manufacturing sites. Due to the nature of the manufacturing sites and the numbers and distribution of their staff, it was not possible to match individuals on all criteria used by Hofstede (2001), i.e. age, sex, level of education, job level, and ethnicity. Instead, representatives from the different levels of the management structure were requested in order to give a broad representation of the individuals on site. The samples included both staff who had responsibility for the implementation of HACCP along with colleagues from other departments.

Hofstede (2001) recommends that samples used in replications of the VSM 94 survey are matched in all aspects except culture to ensure that culture traits are the factors that are seen to vary. This is because people of the same gender, age, occupation and occupational level are likely to see things in similar ways (Hofstede, 2001). The practicalities of conducting this survey during fieldwork within each manufacturing site made exact matching of all samples impossible, since it was not possible to know exactly which individuals would be available for testing on the day and the factories did not offer good population matches for various reasons. For example, in India there are very few women working in any roles in the factories and women are extremely rare in production roles, whereas in Australia and Singapore the proportion of women to men is generally higher than in India, and in Australia it is quite common to have women working in production. Hofstede also acknowledges the difficulties in accessing matched samples: "researchers have to accept compromises in order to obtain any data at all" (Hofstede, 2001, p23-24). It was therefore decided to go for a 'best match' at the point in time that the samples were collected by obtaining a spread of job roles and seniority at each location.

To enable production line staff in India to be involved, the questions were translated into the local language by a member of the company's corporate management team and the translation was verified by two bilingual members of local management personnel. This approach to translating is consistent with the approach of Hofstede (2001) where one-shot translation by an able translator and careful checking by a bilingual reader familiar with the content matter was identified as an effective approach that is less costly and time consuming than translation and back translation by two separate translators. The administration of the questionnaire was either in a group setting or individually, depending on the practicalities of approaching the relevant staff samples on site. A briefing was given on how to complete the task and all questionnaires were completed individually.

6.2.4 Data Analysis

Dimension scores for each country and each site were calculated using the formulae provided by Hofstede (1994; Appendix 6.3). Although cultural dimensions have historically been measured at the National level (Hofstede, 2001), HACCP is applied at manufacturing site level. Within the country it was also suggested that culture can be markedly different within different regions of the same country (Apte, Pers. Comm.). For these reasons it was considered important to calculate cultural dimensions both for country and site levels.

Results were also inputted into the Statistical Package for the Social Sciences (SPSS) to allow comparison with HACCP data, and dimension scores were plotted against HACCP plan validation scores and HACCP knowledge scores, from Chapters 3 and 4 respectively, to investigate any potential relationships.

6.3 Results

6.3.1 Site Data Collection

Background data on the participants in the VSM 94 survey are detailed in Tables 6.3 and 6.4 and pictorial presentation of the proportion of participants in different age ranges, education and candidate-selected job categories is given in Figures 6.2, 6.3 and 6.4 respectively.

Table 6.3 Participants' Age, Gender, Education and Job Role Data

		India			Australia			Singapore
		Total	Site 1	Site 2	Total	Site 1	Site 2	Site
Total	Number of participants	68	35	33	63	35	28	20
Job role within company	Operator	27	12	15	21	14	7	6
	Supervisor	30	18	12	20	11	9	5
	Manager	11	5	6	22	10	12	9
Gender	Male	62	32	30	43	22	21	13
	Female	6	3	3	20	13	7	7
Age Band (Two did not state – site 3)	20-24	1	0	1	0	0	0	1
	25-29	8	3	5	3	2	1	1
	30-34	16	6	10	12	6	6	6
	35-39	18	7	11	13	8	5	3
	40-49	19	15	4	19	12	7	6
	50-59	6	4	2	13	4	9	3
	≥ 60	0	0	0	1	1	0	0
Years of formal school education (or their equivalent) completed (starting with primary school)	≤ 10	10	10	0	11	5	6	3
	11	3	3	0	6	3	3	0
	12	3	2	1	12	9	3	3
	13	3	1	2	6	3	3	4
	14	4	1	3	3	2	1	0
	15	9	4	5	3	3	0	4
	16	8	1	7	6	2	4	5
	17	9	4	5	5	2	3	0
	≥ 18	19	9	10	11	6	5	1
Average years of formal education		15	15	16	14	14	14	14

Table 6.3 Participants' Age, Gender, Education and Job Role Data – Continued								
		India			Australia			Singapore
		Total	Site 1	Site 2	Total	Site 1	Site 2	Site
What kind of job do you do?	No paid job	0	0	0	0	0	0	0
	Unskilled or semi-skilled manual worker	13	12	1	12	6	6	2
	Generally trained office worker or secretary	1	0	1	4	4	0	2
	Vocationally trained craftsperson, technician, informatician, nurse, artist or equivalent	15	2	13	10	6	4	3
	Academically trained professional or equivalent (but not a manager of people)	13	7	6	6	2	4	5
	Manager of one or more subordinates (non-managers)	21	11	10	26	15[21]	11[22]	7
	Manager of one or more managers	5	3	2	8	3	5	2

As can be seen in table 6.3, at the country level there were 68 participants in India, 63 participants in Australia and 20 participants in Singapore, and these people had a range of different jobs. The 'job role within the company' recorded is the actual rank of each person's job within the factory structure and was collected separately from the Hofstede VSM 94 data. The ratios of operators to supervisors in each country were approximately 1:1, however the proportion of managers tested varied from country to country. There were

[21] 1 person stated both manager of ≥ 1 subordinates plus vocationally trained
[22] 2 people stated both manager of ≥ 1 subordinates plus vocationally trained or academically trained

approximately 1/3 managers to either supervisors or operators in India, whereas in Australia there were approximately the same number of managers to both supervisors and operators and in Singapore proportion of managers was just under double that of supervisors and 1.5 times that of operators.

In both Australia and Singapore the ratio of women to men in the samples was approximately 1:2, however the low numbers of women available in Indian factories led to the female: male sample ratio of approximately 1:10.

In order to compare the data for age, education levels and self-described job role further, it was necessary to calculate the percentages in each banding within each country. These data are portrayed in Figures 6.2 – 6.4.

Figure 6.2 Age Range of Participants in VSM 94 Survey (%)

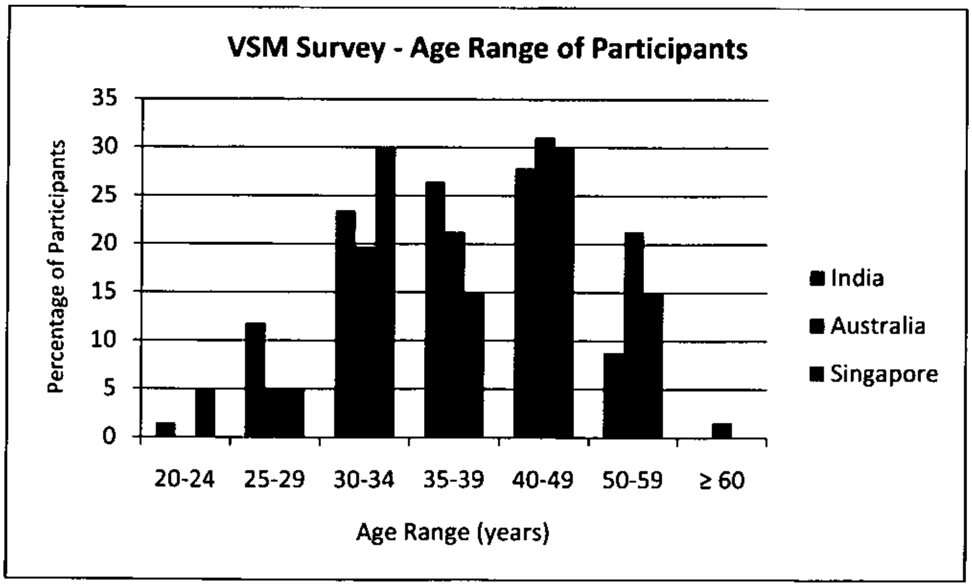
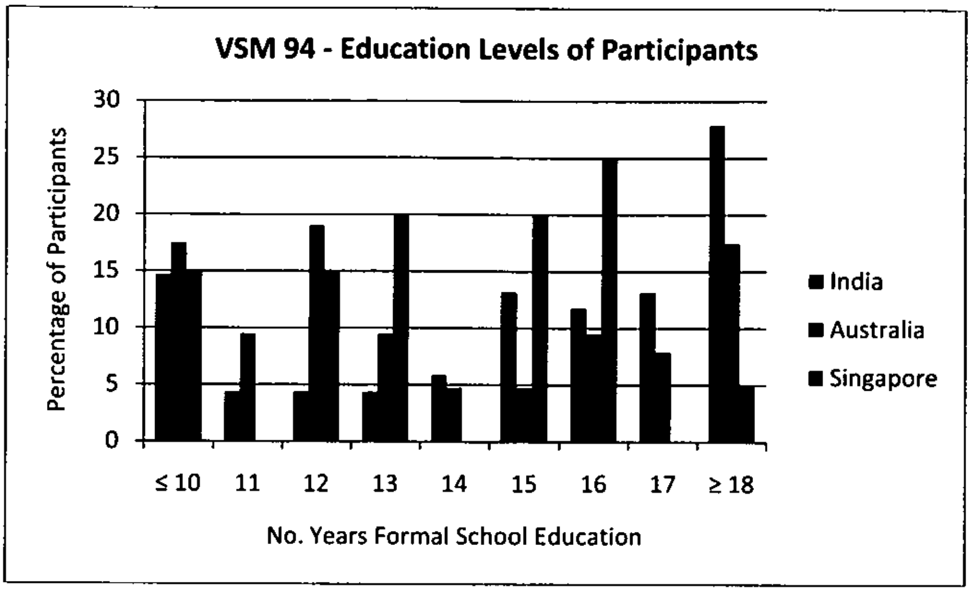


Figure 6.2 shows that the highest proportion of personnel in all three countries (equal highest in Singapore) was in the 40-49 year old age bracket. The Australian sites showed a slightly older age profile overall, with all personnel in

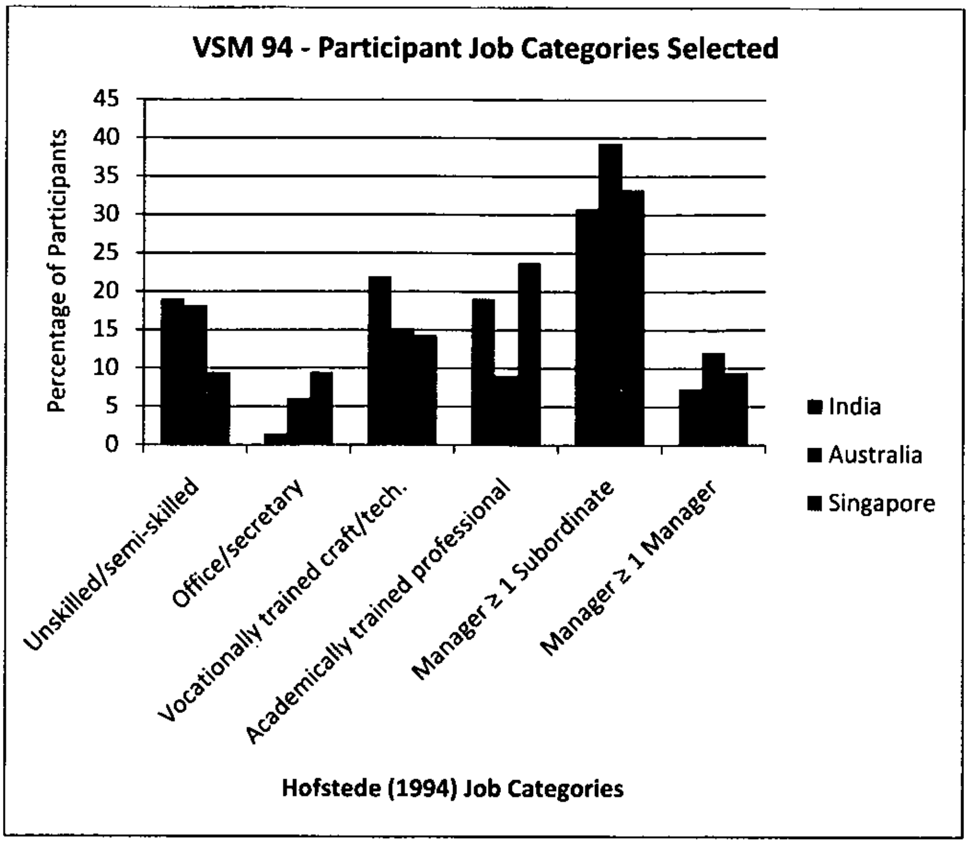
the 25-≥60 age range, whilst all personnel in both India and Singapore were in the 20-59 age bracket.

Figure 6.3 Formal School Education (Years) of VSM 94 Participants (%)



Fewer patterns were seen in the education levels between countries (Figure 6.3). Similar proportions of personnel were found to have ≤ 10 years formal school education at all countries, however all other educational periods were further spread between the countries. India had the most educated group of personnel overall, with 28% reporting ≥ 18 years formal school education.

Figure 6.4 VSM 94 Participants Job Roles Selected (%)



As can be seen from Figure 6.4, the largest number of participants in all three countries described themselves as managers of ≥ 1 subordinate (Australia 39%; Singapore 33%; India 31%). The Indian and Australian sites had approximately the same proportion of unskilled or semi-skilled workers (19% and 18% respectively), both approximately double the proportion labelling themselves part of this group from Singapore (9.5%). Whilst few personnel were in the office worker/secretary group in India (1.5%), there were slightly higher numbers in Australia (6%) and slightly higher again in Singapore (9.5%), however this was the smallest grouping in all three countries. India had the highest proportion of vocationally trained craftspeople/technicians (22%), with Australia and Singapore both reporting close to 15%. Singapore had the highest percentage describing themselves as academically trained professionals (24%), followed by India (19%) and Australia, which at 9% was just over a third of the Singaporean score and just under half of the Indian score. Managers of ≥ 1 manager was a relatively small group at all three countries, being the second lowest reported in India and equal lowest in Singapore. However in Australia there were slightly higher numbers of managers of ≥ 1 manager than academically trained professionals, and both these groups were higher than the office worker/secretary group.

Nationality

The participants' nationality is described in Table 6.4. This shows all the participants at the Indian sites to be of Indian origin, while highlighting some differences in current and birth nationalities in Australia and Singapore. In all cases the majority of participants (100% of Indians, 83% of Australians and 80% of Singaporeans) were nationals of the countries of study and had been nationals since birth (100% of Indians, 75% of Australians and 75% of Singaporeans). Therefore it is considered that, although not perfect, these samples are reasonably well-matched for nationality.

Table 6.4 Participants Nationality Data

Nationality (No.) of Participants in VSM 94 Survey at Case Study Sites									
India				Australia				Singapore	
Site 1		Site 2		Site 1		Site 2		Site	
Current Nationality	**Birth Nationality**	**Current Nationality**	**Birth Nationality**	**Current Nationality**	**Birth Nationality**	**Current Nationality**	**Birth Nationality**	**Current Nationality**	**Birth Nationality**
Indian (35)	Indian (35)	Indian (33)	Indian (33)	Australian (28)	Australian (24) Vietnamese (2) French (1) Filipino (1)	Australian (24)	Australian (23) South African (1)	Singaporean (16)	Singaporean (15) Malaysian (1)
				New Zealand (3)	New Zealand (3)	British/ Australian (2)	British (2)	Malaysian (2)	Malaysian (2)
				Irish (1)	Irish (1)	American/ Australian (1)	American (1)	Australian (1)	Australian (1)
				Italian/ Australian (1)	Australian (1)	Jordanian (1)	Jordanian (1)	Indian (1)	Indian (1)
				Seychellois/ Australian (1)	Seychellois (1)				
				Malaysian/ Chinese (1)	Malaysian/ Chinese (1)				
Total Participants:	35		33		35		28		20

6.3.2 Cultural Dimensions

Data collected through administration of the VSM 94 instrument are listed in Appendix 6.3. Cultural Dimensions scores calculated using Hofstede's formulae for the instrument (see Appendix 6.2) are detailed in Table 6.5.

Table 6.5 Country and Site Level Cultural Dimensions Scores

Country	India			Australia			Singapore
Site	Overall Country Score (Hofstede Score)	Site 1	Site 2	Overall Country Score (Hofstede Score)	Site 1	Site 2	Overall Country & Site Score[23] (Hofstede Score)
Power Distance	10.3 (77)	7.6	10.8	15.3 (36)	16.9	13.8	11.5 (74)
Individualism	73.5 (48)	76.2	70.6	87.4 (90)	83.4	97.1	77.1 (20)
Masculinity	45 (56)	29.9	60.4	-3.4 (61)	25.2	-14.1	23.9 (48)
Uncertainty Avoidance	31.7 (40)	3.7	61.8	62.2 (51)	47.9	73.4	90.8 (8)
Long-term Orientation	48.6 (61)	49.2	48.8	43 (31)	44	42	46.4 (48)

Table 6.5 shows that there were striking differences between the actual scores achieved for these countries and sites and Hofstede's original data. Power Distance had been found to be quite high by Hofstede (2001) in both India (77) and Singapore (74), while at the lower end of the scale in Australia (36). In this study all 3 countries had power distance results at the lower end of the scale and the rank order had also reversed – India 10.3, Singapore 11.5 and Australia 15.3. These results indicate that all 3 countries were likely to have

[23] There was only 1 site in Singapore so the score reflects both that site and the country score.

cultures with consultative decision making styles and acceptance of responsibility throughout the structure (Hofstede, 2001).

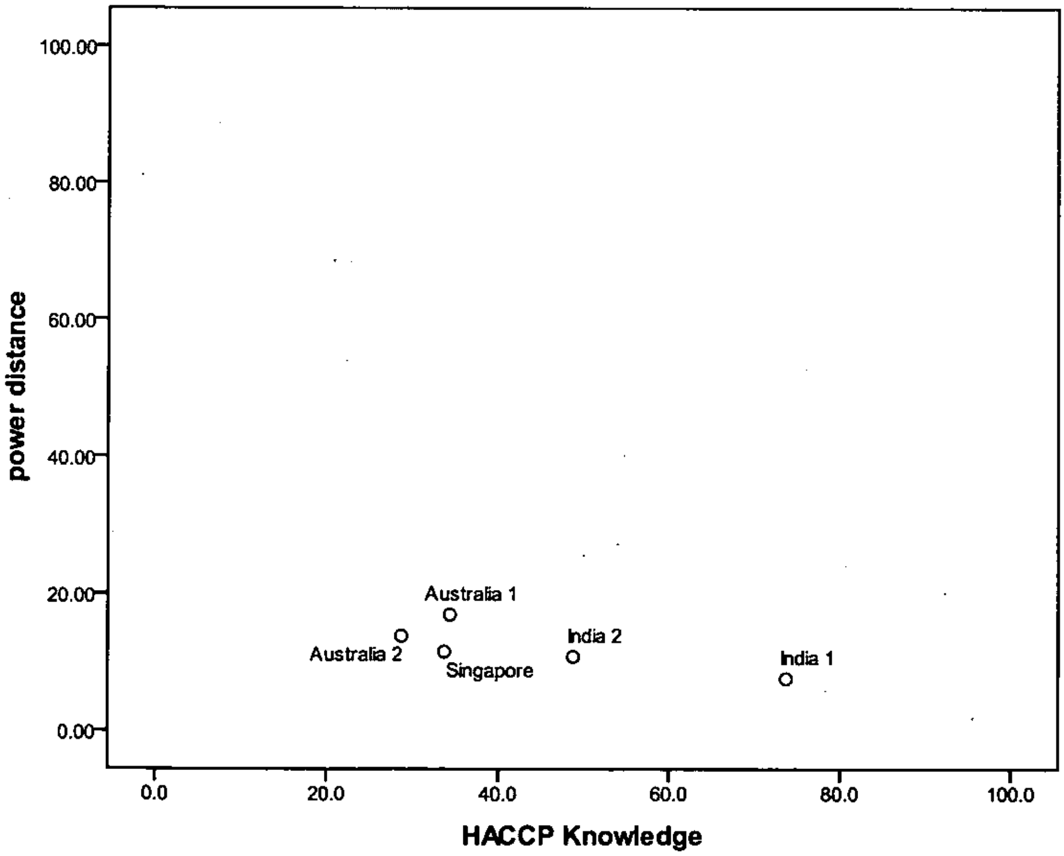
On the individualism-collectivism scale, Hofstede had found Australia (90) to be at the individualistic end of the scale, Singapore (20) to be closer to the collectivist end and India (48) to be close to the centre of the scale, but slightly on the collectivist side. In this study reasonable agreement with Hofstede's results was seen in the calculation for Australia (87.4), however both India and, to a greater extent, Singapore had moved towards the individualistic end of the scale (73.5 and 77.1 respectively). The lack of an apparently collectivist culture made it impossible to further explore the hypothesis that collectivist cultures would be more likely to operate successful HACCP teams.

For the remaining three dimensions, very little agreement was seen between Hofstede's original data and the calculated results from this survey, with the exception of Long term orientation for Singapore (Hofstede 48; calculated 46.4)

6.3.3 Plots of Cultural Dimensions against HACCP Findings

Although there was less difference between the cultural dimensions results for the three countries than expected, the cultural dimensions predicted to have most likely impact on HACCP from the hypotheses in section 6.1.2 were plotted against findings for HACCP knowledge and HACCP effectiveness from Chapters 3 and 4. Figures 6.5 and 6.6 show plots of the cultural dimensions against HACCP knowledge for each of the sites over the power distance and individualism-collectivism dimensions, Figure 6.5 being the plot of power distance against HACCP knowledge.

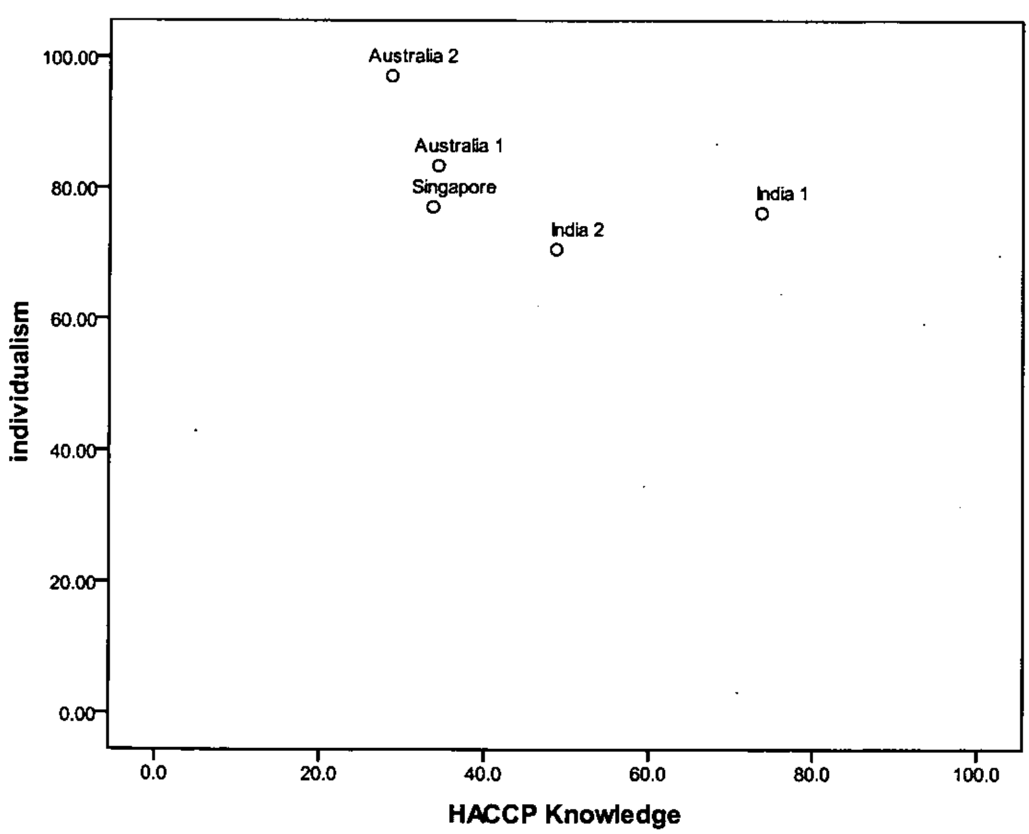
Figure 6.5 Plot of Power Distance against HACCP Knowledge



There is a slight suggestion of a line between power distance and hazard analysis knowledge, however all countries were towards the low power distance end of the scale and extrapolation across the whole scale would not be possible.

Figure 6.6 shows the plot of individualism-collectivism against HACCP knowledge. On this dimension no relationship is apparent. Further data from a range of additional countries would need to be collected to establish if any relationship exists.

Figure 6.6 Plot of Individualism-Collectivism against HACCP Knowledge



Figures 6.7 and 6.8 show plots of cultural dimensions against assessed HACCP development competence, with Figure 6.7 power distance against assessed competence. Again there is the very slight suggestion that there could be a potential relationship, however additional data points would be needed to investigate this further as, again, both power distance and HACCP results are within relatively small ranges. No relationship is apparent between individualism-collectivism and hazard analysis competence (Figure 6.8).

Figure 6.7 Plot of Power Distance against HACCP Development Assessed Competence

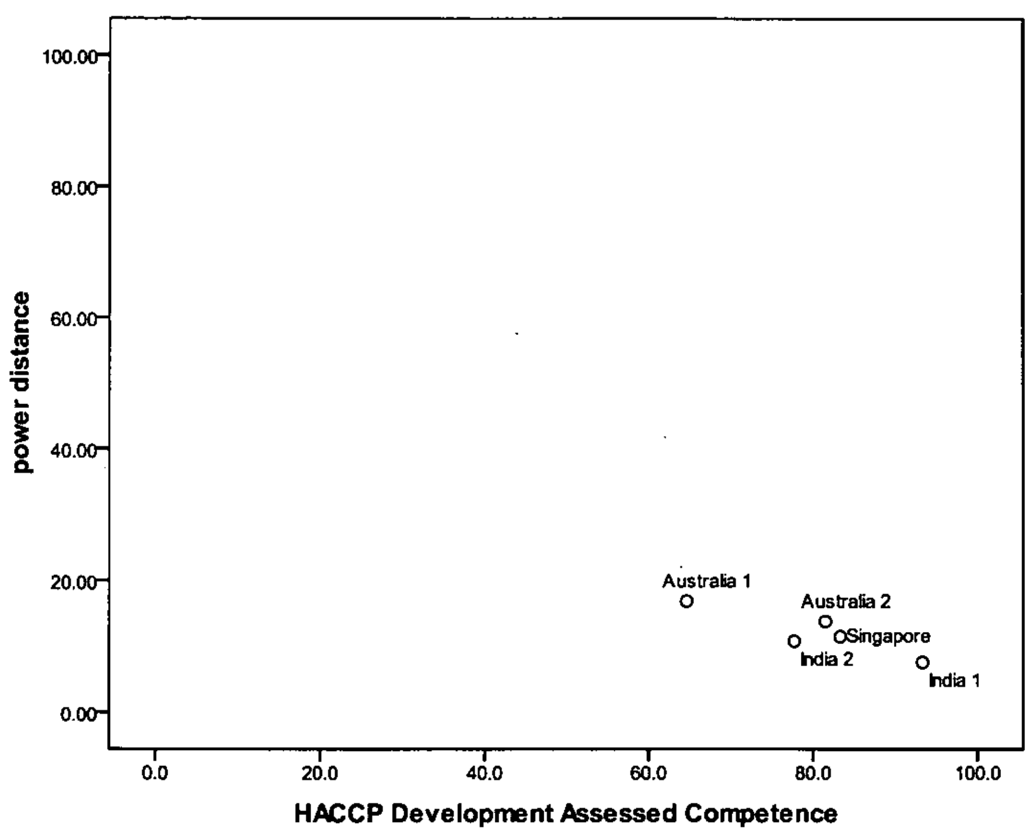
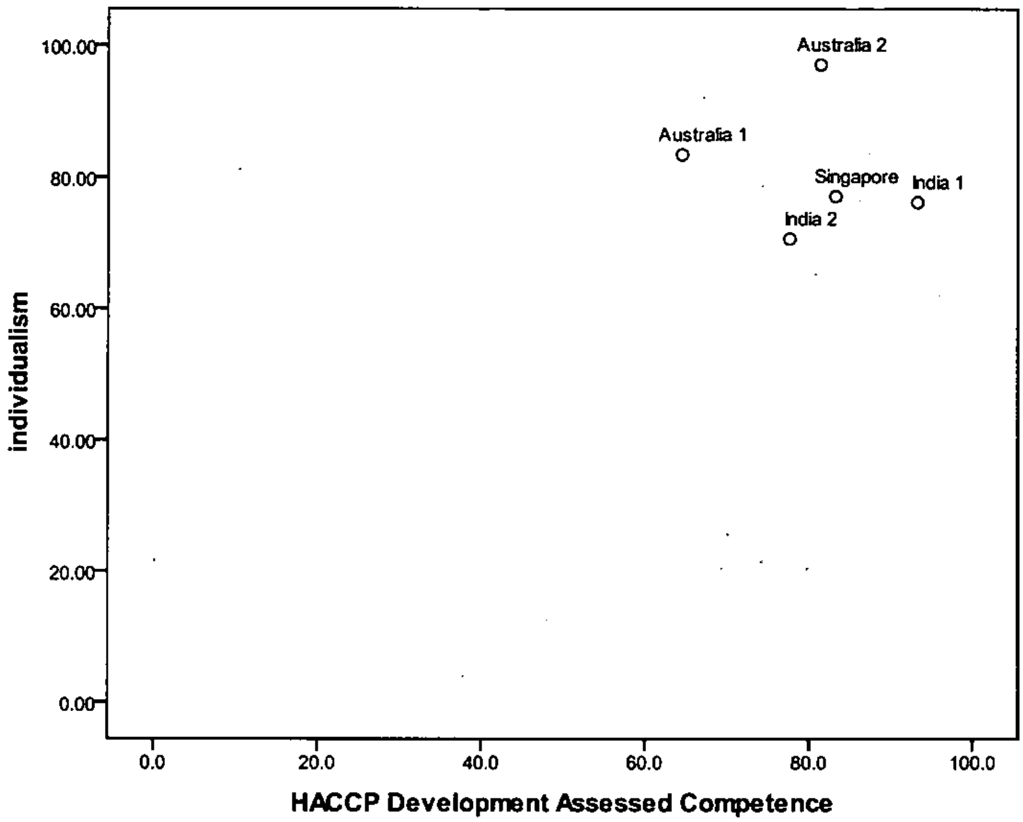


Figure 6.8 Plot of Individualism-Collectivism against HACCP Development Assessed Competence



6.4 Discussion

The aim of this research pertaining to national culture was to characterise the relationship between national/cultural issues on HACCP effectiveness. It was intended that this would be achieved through the choice of three countries that were expected to show different national cultural characteristics based on published data (Hofstede, 2001). However, cultural dimensions testing at the three countries showed markedly different results from those anticipated (Table 6.5), making the comparison of national cultural dimensions and HACCP effectiveness problematic. The following discussion explores the reasons for these findings in the context of the data and outlines further work recommendations to progress this area of research further.

6.4.1 Site Background Demographic Data

a) Participant Numbers

The recommended minimum number of participants in replications of the VSM 94 survey is 20 individuals, with 50 individuals highlighted as being more ideal (Hofstede, 1994). As can be seen from table 6.3, India and Australia had approximately the same numbers of participants (68 and 63 respectively) but Singapore had less than a third of this level at 20 participants. The reason for the lower number in Singapore was because the company had only one manufacturing site in the country and this was a smaller site, both in terms of physical size and in numbers of processes and personnel. It was therefore not possible to match the total numbers of personnel for Singapore, however the minimum recommended level was achieved.

b) Participant Age Ranges

The age range of participants in this survey (Figure 6.2) showed a spread across the possible sub-ranges, however the Indian group was slightly younger overall, having the majority of participants in the 30-49 age group and both the Australian and Singapore groups having the majority spread across the 30-59 age group.

c) Educational Levels

The number of years of formal school education listed by the candidates again varied across the range of year options (Figure 6.3). Although both the Australian and Indian groups both had sizeable blocks (≥ 10 participants) of participants at the lower end of the educational spectrum (≤ 10 years formal education), the Indian group also had the highest level of education overall, with 19 participants (28%) listing ≥ 18 years formal education and 45 (66%) participants with ≥ 15 years formal education. This compares with 11 Australian participants (17%) and 1 Singaporean participant (5%) with ≥ 18 years and 25 Australians (40%) and 10 Singaporeans (50%) with ≥ 15 years formal education. The average number of years formal education was 15 in India (site 1 – 15 years; site 2 – 16 years), 14 in Australia (both sites 14 years) and 14 in Singapore. Although Bosland (1985, cited in Hofstede, 2001) proposed correcting factors for power distance, individualism-collectivism, uncertainty avoidance and masculinity-femininity based on average number of years formal education, these correcting factors were not used to equilibrate the data for educational matching both due to the closeness in education averages in this dataset and since there were differences between the version of the questionnaire studied by Bosland (VSM 82) and the current version (VSM 94) and Bosland's factors did not cover all dimensions.

d) Job Roles

Actual job roles as defined by the company structure were collected on the individual consent forms. The participants also selected their job roles from the list of options provided by Hofstede (1994) in the VSM instrument. Again a spread of roles across the categories was seen (Figure 6.4 and Table 6.3) with the exception of the 'no paid job' category as all participants were employed by the company. These job role categories are somewhat subjective and rely on the individual's judgement of what their role is. This point is illustrated by the personnel in the Indian factories with the company-designated role of Operator. At site 1 the majority of Operators described themselves as unskilled or semi-skilled manual workers whereas at site 2 the majority of personnel in the same role described themselves as vocationally trained craftspeople. Similarly, in the Australian factories, some of the personnel with supervisory roles at site 3 (Team Leaders) described themselves as unskilled or semi-skilled manual workers. Even though they may lead sizeable teams of line operators, they clearly do not see themselves as managers. At the same site several people with the rank of Operator described themselves as managers of ≥ 1 subordinate in the Hofstede categories, whilst at site 4 an Operator described herself as an academically trained professional. These issues were compounded by the fact that personnel at sites 3 (one person) and 4 (two people) chose two separate categories each – all three personnel had picked manager of ≥ 1 subordinate plus either vocationally or academically trained. Similar levels of inconsistency in job choices were seen at site 5 (Singapore) where several supervisors described themselves as vocationally or academically trained professionals rather than managers and some personnel working at operator level described themselves as academically trained.

These inconsistencies question the validity of the Hofstede job categories as a basis of personnel matching between country samples, at least in this study. Hofstede's question is worded as:

"If you have or have had a paid job, what kind of job is it / was it?"

However 3 of the category options given are not only job descriptions but also include description of training:

- Generally trained office worker or secretary
- Vocationally trained craftsperson, technician, informatician, nurse, artist or equivalent
- Academically trained professional or equivalent (but not a manager of people)

This inclusion of training may be confusing to participants as it is referring to their journey towards the current job rather than solely describing the job. It is possible that rewording these options to the following might give a more accurate representation of job roles when the survey instrument is completed:

- Office worker or secretary
- craftsperson, technician, informatician, nurse, artist or equivalent
- professional non-management role

It was not possible to test this theory since the discrepancies in job role descriptions only came to light after the field visits when the data were being analysed, however it would be useful to consider this in future applications. For the benefit of this study, the actual job role/rank data collected separately via consent forms signed by individual participants was considered to be more useful for matching of participants.

e) Nationality

As shown in Table 6.4, all participants at the Indian sites were of Indian origin, however there were some differences highlighted between current and birth nationalities at the Australian and Singapore sites. As a country of immigrants (Castles, 1992), Australia might be expected to show a range of different nationalities and this was borne out by the sample, including a number of personnel who were born elsewhere and had taken on Australian nationality since birth. Similarly, Singapore is made up of a range of different peoples so the presence of other nationalities in addition to Singaporeans is not surprising.

Hofstede makes repeated comments about the necessity to match samples for meaningful replications using the VSM 94 instrument (Hofstede, 1994, 2001, 2002), however he also points to the practical problems of obtaining matched samples, stating that "researchers have to accept compromises in order to obtain [any] data at all" (Hofstede, 2001, p23). As described above there were some differences between the sample groups but overall they were reasonably matched for this study. It was not possible to match these samples to Hofstede's original data (2001) as full background demographics were not published. In addition, the length of time between Hofstede's original data collection (1960s-1970s) and the present study made meaningful comparison difficult, however it was useful to consider Hofstede's results as a 'baseline' of where cultures were in the countries at the time.

As discussed in 6.2.5, it was decided to investigate the cultural dimensions at both country and site level. Taken as individual sites, the Australian and Indian samples are less well-matched than at country level (Tables 6.3 and 6.4). Following Hofstede's arguments about matching of individuals within samples, this indicates the need to treat observed differences at site level with caution.

6.4.2 Cultural Dimensions

It was expected that the values obtained from application of the VSM 94 instrument at the case study sites would be similar to the values obtained in Hofstede's country surveys (Hofstede, 2001). However this was not the case in several dimensions and countries, with movement towards the opposite end of the scale in some cases.

Reasons for differences between the Hofstede data (2001) and the current dataset might suggest movement on the cultural dimensions within these countries during the interim period, however this finding needs to be treated with caution for several reasons. It was not possible to match the current dataset against the original Hofstede data both since demographic data were not available and because the point in time for data collection differs by almost 40 years and therefore they cannot be matched on this criterion. Also, although relatively closely matched overall, the 3 countries in this data set did have demographic differences such as female: male ratio and age of correspondents. These factors may have impacted on their position on the dimension scales. However it is clear that there are major differences between the Hofstede findings and this study, including countries moving to different ends of the dimension scales.

Power Distance had been found to be quite high by Hofstede (2001) in both India (77) and Singapore (74), while at the lower end of the scale in Australia (36). In this study all 3 countries had power distance results at the lower end of the scale and the rank order had also reversed – India 10.3, Singapore 11.5 and Australia 15.3. These results indicate that all three countries were likely to have cultures with consultative decision making styles and acceptance of responsibility throughout the structure (Hofstede, 2001). If the hypothesis of low power distance being linked to successful HACCP via the more suitable consultative management style was correct, then all 3 countries would be expected to have similar success with HACCP application.

On the individualism-collectivism scale, Hofstede had found Australia (90) to be at the individualistic end of the scale, Singapore (20) to be closer to the collectivist end and India (48) to be close to the centre of the scale, but slightly on the collectivist side. In this study reasonable agreement with Hofstede's results was seen in the calculation for Australia (87.4), however both India and, to a greater extent, Singapore had moved towards the individualistic end of the scale (73.5 and 77.1 respectively). The apparent lack of a collectivist culture in the sample made it impossible to further explore the hypothesis that collectivist cultures would be more likely to operate successful HACCP teams. Since all countries showed individualism to be the predominant cultural trait on this dimension, it was concluded that they would have similar levels of success with HACCP teams.

For the remaining 3 dimensions, very little agreement was seen between Hofstede's original data and the calculated results from this survey, with the exception of long term orientation for Singapore (Hofstede 48; calculated 46.4). Masculinity results ranged from -3.4 for Australia through 23.9 for Singapore to 45 for India, contrasting with Hofstede's results (2001) of 61, 48 and 56 respectively, the most marked difference being for Australia, which had moved from the masculine end of the dimension to the extreme of the feminine end. Uncertainty avoidance results showed some similarity with Hofstede's results for India and Australia. The India result was 31.7 whereas Hofstede had found 40 and the Australian result was 62.2, compared with Hofstede's 51. Singapore, however, had moved to completely the other end of this dimension scale, achieving a measure of 90.8 compared with Hofstede's result of 8. Results from this study suggest that the Singapore team would show a strong tendency to avoid uncertainty, whilst the Australian sites may have a slight tendency of avoidance and the Indian sites would be much more comfortable with uncertainty. Long-term orientation results were fairly closely matched for all three countries towards the centre of the dimension scale on 48.6, 43 and 46.4 for India, Australia and Singapore. This contrasts with a wider spread anticipated from Hofstede's original work (2001) of 61, 31 and 48 respectively, suggesting that there would have been more perseverance towards longer term goals in India and more of a propensity towards quick results in Australia. As these additional dimensions were considered to be of less importance to HACCP they will not be considered further here, however it is interesting to note the differences from the predictions based on Hofstede's data (2001), which could be further explored with additional replication and expansion of the study.

If these differences do reflect changes in culture within these countries over the last 40 years, this might be due to globalisation and the increasing conformity of business and lifestyle standards around the world. Within multinational businesses the speed of communication and globalisation of management standards have led to changes over the last few decades, the growth in international quality standards such as ISO 9000 (ISO, 2008) and food safety certification audit schemes such as BRC (BRC, 2008) and the Global Food Safety Initiative (GFSI, 2007) being cases in point . Growth in use of mobile phone and internet technology and the march of Western cultural icons such as McDonald's has led to individual aspiration to similar lifestyles in many areas of the world (Company personnel, pers. comms.) and the globalisation of approaches such as the global public health strategy (Brown and Bell, 2008). Although the cultural consequences of globalisation are complex, these moves may have impacted cultural values such that cultures move towards more standardisation with Western values or incorporate elements of Western culture (Holton, 2000), and this might, for example, lead to naturally collectivist cultures becoming more individualistic and with lower power distance as seen in this case.

Since the country results were at the same ends and in relatively similar positions on the dimension scales that were predicted to impact HACCP it is not possible to establish if these dimensions of national culture have an impact on HACCP with this dataset. A larger sample of countries from different areas of the world would be needed to further explore this, although if globalisation is bringing cultures closer together as suggested above then some convergence of dimensions scores could be expected in any sample of countries. Hofstede (2001) suggests 10 or 15 countries as being a suitable sample size for replication and reliability testing of the survey. The current study was not intended to be an in-depth study of culture in its own right. Rather it was to consider impact of culture as part of a larger study on HACCP application across three countries and five sites.

6.4.3 Cultural Dimensions and HACCP

Since there was still a degree of spread between the three counties, albeit at the same ends of the dimension scales, the cultural data was plotted against the HACCP knowledge and effectiveness data (Figures 6.2 – 6.5). HACCP is applied at the site level rather than the country level and there were expected to be differences in HACCP success between sites rather than just between countries. This also gave 5 potential data points for comparison rather than just 3 for the country level. Potential for differences in culture between sites had also been highlighted (Apte, pers. comm.) which also suggested that it would be useful to compare at this level. Therefore the cultural dimensions were also calculated for site level (Table 6.5) and these data were used to compare with HACCP. However the matching between sites was less reliable than between countries so these results have to be viewed with caution.

Figures 6.5 and 6.6 show plots of the cultural dimensions against HACCP knowledge for each of the sites over the power distance and individualism-collectivism dimensions. There is a slight suggestion of a line between power distance and HACCP knowledge, i.e. that HACCP knowledge is better where the power distance is lower, however all countries and sites were towards the low power distance end of the scale and extrapolation across the whole scale would not be possible. For individualism-collectivism against HACCP knowledge, no relationship is apparent. Further data from a range of additional countries would need to be collected to establish if any relationship exists for either of these dimensions to HACCP knowledge.

Figures 6.7 and 6.8 show plots of cultural dimensions against assessed HACCP competence. Again there is the very slight suggestion that there could be a relationship between power distance and HACCP competence (Figure 6.7), i.e. HACCP competence is higher where there is lower power distance, however the spread of the data points suggest that a substantial number of additional country data would be needed to investigate this further. No relationship is apparent between individualism-collectivism and HACCP competence.

6.4.4 Conclusions

It was not possible to establish the impact of national culture on HACCP from this study due to the similarity of results for the dimensions of national culture across these countries. A larger study of additional countries would be needed to further investigate potential relationships. Compared with Hofstede's original data (2001) this study suggests substantial movements in cultural dimension scores for the countries surveyed. Because of inability to match samples with Hofstede's original work these findings need to be treated with caution, and further work in this area within similar multinational manufacturers is recommended.

6.4.5 Strengths and Limitations

As an enquiry into national culture, this study was small as it only covered three different nationalities. As discussed above, this was only one element of a larger case study on HACCP effectiveness within these three countries and so it was not possible to examine a larger sample of countries for national cultural dimensions, such as the minimum of ten countries suggested by Hofstede (2001). The issues regarding size of study were compounded by the fact that the countries sampled provided similar results in terms of the national culture dimensions expected to be of most importance to HACCP, namely power distance and individualism-collectivism, and this made comparison with HACCP knowledge and effectiveness data problematic.

Hofstede (2001) makes much of the need to ensure closely matched samples in any studies using his tools, however the practicalities of sampling at manufacturing sites during fieldwork made this difficult and so best match possible samples were taken. It is possible that some of the findings, in particular the differences between Hofstede's original data and these findings, were affected by less than ideal sample matching, however it is impossible to verify this due to the lack of demographic data in Hofstede's publications. The fact that the personnel completing the questionnaire in these three countries were reasonably closely matched suggest that the findings should be an accurate picture of current cultural dimensions positioning for this dataset, however the small sample means that these findings cannot be generalised.

Correcting factors were proposed by Bosland (Bosland, 1985, cited by Hofstede, 2001) for comparing sets of data with different average educational levels. However this was established against the previous version of the VSM (VSM 82) and it therefore only corrects for four dimensions since long-term orientation had not been developed at that stage. Further developments of the tool had also been done since Bosland's proposals, including the reversal of some questions in the VSM 94 version (Hofstede, 1994) and the removal of some questions that had previously been used to calculate the formulae. These points combined with the facts that the average years education in this dataset are close anyway (average 14-15 years for countries; 14-16 years for sites) and that the corrections would make minimal difference to the outcome (Power distance would be -1 for all; Individualism-collectivism +13; Masculinity-femininity -5; and Uncertainty avoidance index -9; therefore the overall order would not change) meant that the correction factors were not used in this study.

In order to plot the results on the national cultural dimensions scales against HACCP effectiveness data, it was necessary to use data that had been scored, and this was done for both HACCP assessment data from Chapter 3 and HACCP knowledge data from Chapter 4. However some limitations in use of the scoring system for desk-top HACCP assessments were noted in Chapter 3 and these limitations may therefore have had an effect on the comparison in this Chapter. In any further study it may be better to compare cultural dimensions data with more detailed HACCP assessment data, including the overall qualitative assessment of HACCP effectiveness on site. This will be further explored in Chapter 7, however the closeness of all three countries on the cultural dimensions scales here would make it difficult to draw meaningful conclusions from this dataset.

6.4.6 Further Work

In order to characterise the relationship between national culture and HACCP effectiveness, this study would need to be repeated with a larger sample of countries to establish a wider spread of cultural dimensions. This could then be combined with detailed assessment of HACCP and comparison of HACCP effectiveness findings with national culture dimensions.

In conclusion, this element of the research has provided data on dimensions of national culture in three countries and the five case study sites. Although the closeness of positioning on the cultural dimensions scales made establishment of the impact of national culture on HACCP effectiveness problematic, some slight indications of a potential relationship between power distance and HACCP knowledge and effectiveness was seen, which would need to be confirmed by further work. The next chapter of this thesis will explore the impact of business factors on HACCP effectiveness.

Chapter 7

Lessons from HACCP Application in Food Manufacture: Individual Perceptions of HACCP and Factors Impacting Success

7.1 Introduction

HACCP literature reveals little about lessons learned during application of HACCP in food manufacture. Of the few studies investigating individual's perception of the HACCP process, most are from a management perspective, often with small business owners (e.g. Taylor and Taylor, 2004[a], Taylor and Taylor, 2004[b]) or investigating potential barriers to HACCP (e.g. Gilling et al, 2001). No previous studies have investigated perception of HACCP and factors impacting its success from the perspective of individuals throughout the management hierarchy of a food company. This is significant as knowledge of 'what makes HACCP tick' within food companies could be used to provide guidance on best practice approaches, thus allowing more successful HACCP application in food manufacture.

Since the multinational food company involved in this research required HACCP at all sites, it could be expected that each of the sites studied would have attempted to apply HACCP Principles. The success of each individual site might be affected by a range of factors and be dependent on how the site overcame the potential barriers to HACCP application (Cf. Chapter 1). As discussed in Chapter 1, the factors involved in the success or failure of HACCP within businesses are likely to fall into 3 main groupings of Operational Management Factors, Personnel Factors and Environmental Factors. These 'Business Factors' are likely to include the following:

Operational Management Factors

- Management and individual commitment
- Resources and support

Personnel Factors

- Training and knowledge
- Personnel interactions and decisions

Environmental Factors

- External pressure – legal/customer/corporate
- National/regional culture

With regard to the environmental factors, there was external pressure working on each site since the corporate decision had been taken to apply HACCP as previously stated. In addition some sites had particular customer requirements for HACCP and one Australian site had to apply HACCP due to its location in the State of Victoria where an audited food safety programme based on HACCP Principles is a legal requirement (State of Victoria, 2009).

The company's 'culture' was defined as 'Performance driven, values led', (Company Documentation, pers. comm.) and the company listed its 'values' as performance, quality, respect, integrity and responsibility. Further, the company required:

- Honesty, openness and courtesy from all colleagues in their business dealings
- All employees to act in an ethical way to protect the company and its reputation, and to respect the dignity and human rights of other colleagues and the people and communities it did business with.
- Quality within all products and actions, from sourcing, manufacturing and food safety to marketing, logistics and customer service; and was
- Committed to providing consumers with quality products which are marketed truthfully, labelled clearly and meet food safety regulations and standards (Company Documentation, pers. comm.).

The impact of National Culture was also studied separately (see Chapter 6). Therefore, the aim of this element of the research was to explore the business factors, in particular operational management and personnel factors, impacting HACCP success at manufacturing sites of a multinational food company from the perspective of the personnel involved in applying HACCP principles and implementing the HACCP System. It was further aimed that this would provide data to triangulate findings from the other elements of the research.

7.2 Methods

It was necessary to identify a method that would be able to collect rich data on individuals' perception of the HACCP process with minimal time and effort burden for participants. A semi-structured interview process was chosen as an appropriate data collection technique to explore interviewee experiences. This technique attempts to understand themes of the 'lived everyday world' of the interviewee through discussion of his or her own perspectives on the events they have lived and worked through (Kvale and Brinkmann, 2009, p27). It is, therefore, an ideal approach to gain understanding of experiences of the HACCP process from the perspectives of individuals within a food factory hierarchy.

Semi-structured interviews involve the development of an outline topic list and suggested questions/question areas (Kvale and Brinkmann, 2009). This allows the interviewer freedom to clarify and probe further as considered necessary from the initial responses.

7.2.1 HACCP Impact Factors Interview Tool

In order to cover a set of key questions whilst allowing flexibility to follow appropriate questioning trails in individual discussions, an interview topic guide (Appendix 7.1) was developed. This tool was designed to explore the interviewees' experience of the HACCP process, including their perception of support for the HACCP initiative and the ease/difficulty of different stages of HACCP application on site. In addition to background data about the interviewees' job history with the company and current role, key questions were constructed in the following topic areas:

- Management commitment and support
- Team working
- HACCP Development
- HACCP Implementation
- HACCP Maintenance

A final set of general HACCP experience questions was included to ascertain interviewees' views on the current status of HACCP and whether food safety management had improved at their place of work, along with what they believed to have been the most difficult parts and key success factors in the HACCP initiative.

In order to sustain interviewer concentration and focus during the interview it was decided that written notes would not be taken, rather all interviews would be recorded and transcribed for analysis. This was achieved by means of a digital voice recorder, which, with the permission of all interviewees, allowed the interviews to be recorded and stored as computer files.

7.2.2 Sampling and Choice of Cases

Stratified purposeful sampling (Patton, 1990, cited by Wengraf, 2001) was used to identify interview cases that would reflect views from throughout the factory structure and hierarchy. Using the Site Visit Work Plan (Appendix 3.1) as a guide, a similar number and level of interview cases was sought at each factory (Table 7.1) to allow comparison of interview findings across sites.

Table 7.1 Interview Sampling at Case Study Sites

	India 1	India 2	Australia 1	Australia 2	Singapore
Job Role	Manufacturing Manager	Factory Manager	Factory Manager	Factory Manager	Factory Manager
	Quality Manager	Manufacturing Manager	Quality Manager	Manufacturing Manager	Quality Manager
	Former Quality Supervisor	Quality Manager	HACCP Coordinator	Manufacturing Area Manager	Production Manger
	Quality Supervisor	Quality Supervisor	Production Team Leader	Quality Manager	Stores Manager
	Manufacturing Supervisor	Manufacturing Supervisor	Production Team Leader	Quality Supervisor	Engineering Manager
	Operator	Operator		Production Team Leader	Production Team Leader
	Operator	Operator		Production Team Leader	Operator
	Operator	Operator		Process Team Leader	
				Production operator	

7.2.3 Interview Process

Interviews were completed by addressing the topics and questions of the HACCP Interview Topic Guide (Appendix 7.1). Questions topic areas were generally covered in the running order of the topic guide, however flexibility was maintained in the use of specific questions to allow further probing and re-questioning as necessary in each individual interview. Where interviewees had not been involved in a particular area of HACCP application at the site and were, therefore, unable to offer their views and perceptions, the topic was put aside and questioning resumed on the next appropriate topic area. Interviews were timetabled to take approximately 30-45 minutes each and the actual range was 5-47 minutes with an average of 22 minutes (median 20 minutes).

To enable production line operators to participate in the interviews, translation was required for a number of personnel in the Indian factories. This was done by an independent translator who, although employed by the same company, was independent from all sites and unknown to the operators. The translator had expertise in HACCP application and was instructed to translate the questions and answers 'word for word' without any attempt to construe meaning.

7.2.4 Transcription of Data Recordings

All interview recordings were transcribed verbatim. Transcriptions were split down into the interview topic areas to enable each topic to be analysed together for all interviewees.

7.2.5 Analysis of Data

Data were analysed using Thematic Networks Analysis, a tool for organising a thematic analysis of qualitative data (Attride-Stirling, 2001) that has its foundations in argumentation theory [24] (Toulmin, 1958). It was chosen as an appropriate tool for analysis of the data in this study due to its proven strengths in examination and visual presentation of the underlying patterns and themes of textual data (Attride-Stirling, 2001; Dykes et al, 2003; Dykes, 2005). Thematic networks analysis allows the different levels of themes in the text to be unearthed and thematic networks to be developed to structure and depict

[24] Argumentation theory (Toulmin, 1958) is a way of analysing the processes of resolving conflicts by exploring the explicit statements being made and their implicit meanings via a formal elaborative structure. This framework allows the initial information or 'data' to be organised via a series of principles or 'warrants' to the conclusion of the argument, known as a 'claim'. In a similar way Thematic Networks Analysis is a 3-level elaborative structure, working from basic themes, through organising themes to global themes.

these themes (Attride-Stirling, 2001). The web-like networks that result portray the themes in a highly visual way.

In common with HACCP application, the process of building up the networks is a structured, stepwise technique. First, at the micro level, the lowest order ideas or 'Basic Themes' are extracted and these are grouped together as the middle order, summarising, 'Organising Themes'. Finally at the macro level Global Themes are established, which make sense of the clusters of themes and encapsulate the principal metaphors of the text (Attride-Stirling, 2001). In practice, this meant analysis was carried out as follows:

1. Detailed, line-by-line read-through of all interview comments
2. Identification of preliminary basic themes
3. Grouping of basic themes under organising theme headings
4. Establishment of global themes to group the organising and basic themes into logical thematic networks

The transcripts were then re-read in a cyclical way, strengthening the understanding of the developing networks through the exploration process (Dykes, 2005).

7.2.6 Trustworthiness of the Analysis

Analysis of qualitative material is an interpretive process and meaning is understood within social contexts based on the researcher's judgment of what is relevant in the data (Attride-Stirling, 2001). The analysis process enables the elicitation of meaning, however inevitably this includes judgement by the researcher. Trustworthiness was achieved in the study design by allowing all interviewees to talk freely about their perspective of the "lived everyday world" (Kvale and Brinkmann, 2009, p27) of HACCP application in food manufacture, without constraining their responses by asking only predetermined questions. Analysis of the data via thematic networks enabled the interpretive elicitation of meaning, however the nature of thematic network analysis is such that the themes and networks that emerge are one evaluation of the data. In this research the fact that the analysis was conducted by a researcher with significant expertise and experience in application and assessment of HACCP systems helps to provide substantiation to the themes and conclusions. To further increase the trustworthiness of the data analysis, a supervisory team member read transcripts and did an independent thematic networks analysis. There were striking similarities between the theme structures identified, thus indicating credibility of the approach.

7.2.7 Quantifying the Magnitude of the Response

Although the main focus of the interviews was to collect qualitative data, the phrasing of several questions within the interview guide also allowed some quantification of the data. These included questioning about the ease or difficulty of applying HACCP principles and on the individual's view of how well HACCP was working at the point in time that the interview was recorded, as well as some background information on where they had heard of HACCP and what they believed had been the main driving force for HACCP. Quantitative coding or scaling of qualitative data in this way is an established method (Jick, 1979, Weiss, 1995) that can be used for simple triangulation purposes. Whilst operating at a much more simplistic level than analysis techniques such as

Content Analysis (Altheide, 1987) this approach was considered a useful tool for estimating the magnitude of some responses.

7.3 Results

Data were compiled as the thematic networks that emerged from the interviews. Thematic data are described in section 7.3.1 and quantitative data emerging from specific questions that illustrate the magnitude of responses are included in the description where relevant, and presented in full in Appendix 7.3. Discussion of findings follows immediately after the results, in section 7.4

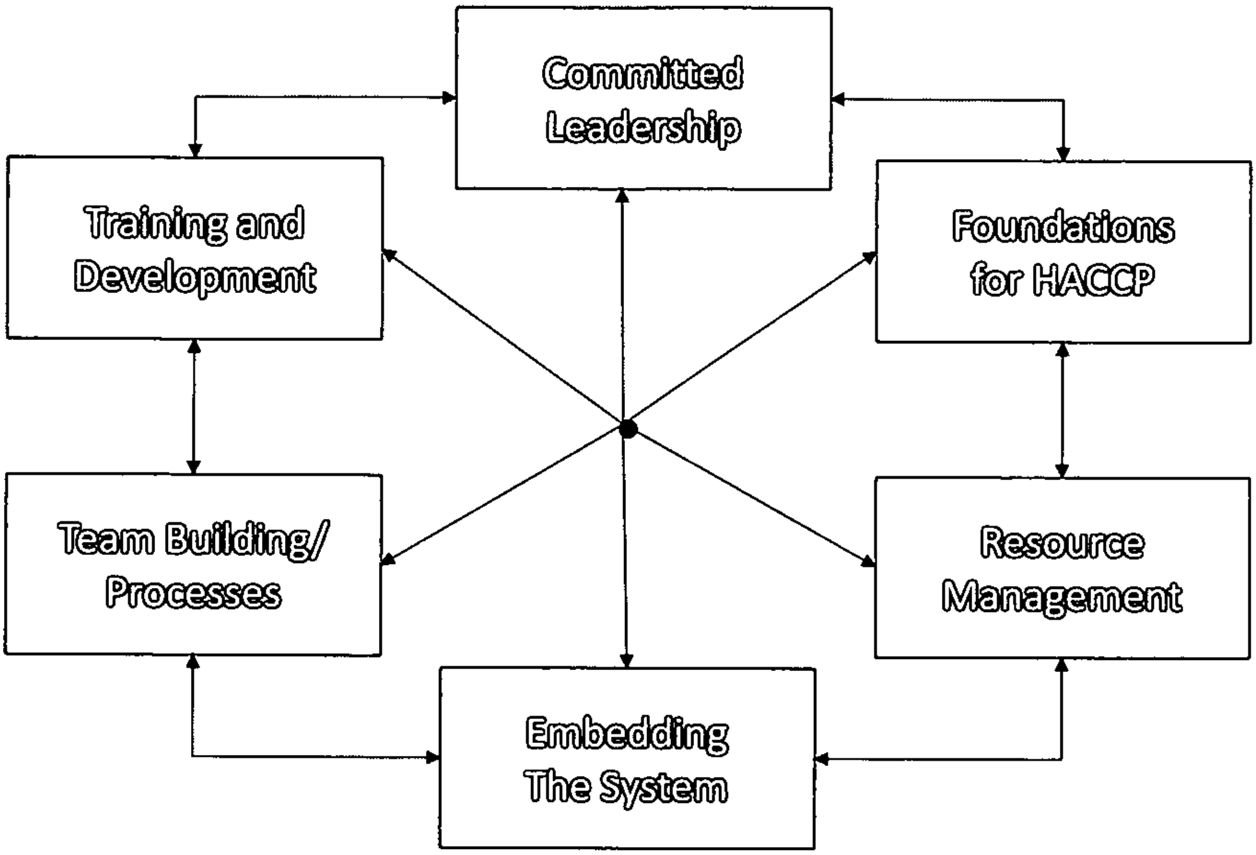
7.3.1 HACCP Thematic Networks

By linking together the basic themes under organising and global themes, HACCP thematic networks emerged from the data. The global themes at the centre of the networks are depicted in Figure 7.1 and the thematic networks identified are portrayed in figures 7.2 – 7.7. Explanation of the thematic networks, using examples of statements illustrating the themes in each network, are presented in the following text and further commentary on the results is given in the Discussion section. Detailed interview findings, organised by global, organising and basic themes are located in Appendix 7.2.

Overall the data emerging from the basic interview themes appeared to fit logically into networks representing 6 global theme areas, and these were given the titles: Committed Leadership; Foundations for HACCP; Training and

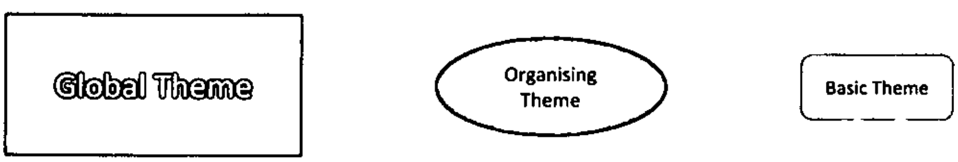
Development; Team Building Processes; Resource management; and Embedding the System; (Figure 7.1).

Figure 7.1 Global Themes from HACCP Thematic Networks



These global themes have no particular sequence or hierarchy and both overlap and interaction between networks is considered part of the overall picture of the HACCP experience. Some networks were more extensive than others, involving a greater number of basic and organising themes. The following text outlines the make-up of each thematic network, with examples to illustrate the basic themes. In each thematic network figure, the diagrammatic key is as follows:

Key:



Illustrative of the basic theme *Providing Direction and Support* were the comments from the Factory Manager at India site 2:

> '...in terms of top management support or we can say supply chain support, eh...clearly...eh...one is that we were...our Managing Director at various forums...eh...he is talking about that all our plants are [to be] HACCP certified...'

and a manufacturing Supervisor at India site 1:

> '...the situation was safe product, food safety first...that was the message from management to the bottom line...'

It appeared from the interviews that top management had generally been committed to and involved in promotion of HACCP from the start. This was further illustrated by the fact that fourteen out of thirty-seven personnel believed that site management had been the driving force behind the HACCP initiative (Appendix 7.3) and this was the largest 'driver' group identified. The theme *Gaining and Demonstrating Management Commitment* was more to do with the need to achieve management commitment throughout the factory hierarchy:

> '[the most difficult part is]...getting the support and buy-in from the factory management ...ehm at sort of area manager and operations manager level...' (Quality Manager, Australia Site 1)

Showing Interest and *Maintaining Support* were 2 closely linked themes illustrating the Promotional Leadership that was seen at the sites. The former is exemplified by

> '...that time the GM Factory was very much interested in the implementation of HACCP at the site...so he has given me the independent opportunity to forward this process into the system....and I would say that was the greatest period to enforce HACCP.... [...] ...let's say definitely he has supported the system basically... anything we asked for HACCP....he would say go ahead and do...'I don't have an issue" (Quality Supervisor, India Site 2)

Whilst the latter indicates the time element involved in HACCP and the need for ongoing support from management to facilitate progress:

'......initial phases it was all about mentioning something new to the people... but it was over a period of time, you know....how the importance got promoted...and how that one time investment takes a long time to return to you a good product....that slowly the management acknowledged it and it was a complete dictate to everyone that we have to go for this...and eh...without we cannot go forward...' (Quality Manager, India Site 1)

However under this theme it also became clear that maintenance of management support was not perceived to be effective at all sites as comments from Australia Site 1 illustrate:

'...Yes...I'd probably say that it has gone off the agenda a bit.....because, I mean, although HACCP is there and people know that there are several things that have changed... [...]...we probably don't bring it up...I don't think we bring it up as much as we probably should...and ....in the mind of people...well like the new people here that... [...]....like I said the new people haven't done it....and I don't know if they [management] have forgotten about it or when we....it must be a couple of years...more than a couple of years since we have done...anyone in the factory has done GMP training....that's my opinion...' (Production Team Leader, Australia Site 1)

'...Its...eh...on the agenda at our management review meetings...which we have...try to have twice a year...we have to have once a year but we try to have twice a year...so it's on the agenda for that...eh...but other than that and letting them know when we pass our audits...they [management] don't have very much to do with it.....' (Quality Manager, Australia Site 1)

Under the theme of *Driving the HACCP Project*, differing views were again expressed at different sites, indicating different perception of management involvement at these locations:

'...and I was the coordinator or champion for it. I used to drive the HACCP process because I was the first person to attend a training course ...' (Manufacturing Manager, India Site 1)

'...No - it wasn't really promoted... I think it was something that was nice to have it was linked in with the ISO system. I think it was more or less not driven from the top management....' (Production Team Leader, Australia Site 2)

The second organising theme emerging under the global theme of Committed Leadership was **Targets and Achievement**. This indicated the roles played by the committed leaders in the closely linked themes:

- Setting Clear Goals and Targets; and
- Monitoring Progress.

Under *Setting Clear Goals and Targets*, the Factory Manager at India Site 2 commented on the use of targets to help achieve the necessary results:

> '...he said that if all the plants are to be HACCP certified there are some clear cut [targets]...as part of their key performance indicators, and key result areas...so all factory managers and all the manufacturing people first had as part of their quarry, in terms of safe and consistent product...eh HACCP certification...' (Factory Manager, India Site 2)

The same manager went on to talk about the processes for *Monitoring Progress* to ensure these key performance targets were achieved:

> '...and it was clearly reviewed...eh... on monthly review...so what is the progress...what kind of support is required...so in terms of resourcing, in terms or tracking and in terms of, you know, performance indicators it was clearly being tracked at senior level...it is still there actually, and in between monthly and bi-monthly to look at the progress with CCPs on the floor...' (Factory Manager, India Site 2)

The role of senior managers in **Empowerment** was mentioned by several interviewees. This included the role played in:

- Connecting and Empowering Team Members
- Creating Ownership; and
- Personal Accountability/Responsibility.

Connecting and Empowering Team Members is illustrated by the following two short quotations:

> '...Yeah, yeah, yeah – they [Senior Managers] empower us on the HACCP team...' (Manufacturing Supervisor, India Site 2);
>
> '...before we just told them to do it...now we try to empower them...' (Production Team Leader, Australia Site 2);

whilst *Creating Ownership* within the sites was also seen as important:

> '...especially since we have the teams set up ...the expectations ...people seem to take more ownership...the expectations for quality ...CCPs and all that...they seem to take that on board now wasn't like that before...' (Production Team Leader, Australia Site 2);

as was the *Personal Accountability/Responsibility* that had developed through the HACCP project:

> '...I think we're far more aware of our corporate responsibility and even our local responsibility to produce safe food...' (Factory manager, Australia Site 1)
>
> '...the responsibility is more...like the microbiology operator...he knows what he has to do today......like now he knows that the monsoon has arrived, so he knows where to focus more. He is quite empowered today...to understand the focus.......tomorrow if there is no monsoon testing to do he will go to the laundry and audit the laundry...or go to the co packer...or we may have certain raw material analyses for the supplier...they are empowered....because they take the responsibility ...particularly in manufacturing....' (Former Quality Manager, India Site 1)

Mobilising Resources was the final organising theme in this thematic network, exemplified by the need for committed senior managers to engage with the requirements for

- Time; and
- Financial Support

to apply HACCP correctly and to address issues identified during hazard analysis. *Time* provision was mentioned by interviewees from India and Australia:

> '...was top management support so support and encouragement...you know....taking their time to work away from manufacturing...' (Former Quality Supervisor, India Site 1)
>
> '...I mean it was important...like I mean I had the time (to do it)...they said...yeah...it was fairly important at the time....helping to get it up and running....' (Production Team Leader, Australia Site 1)

In terms of Financial Support, personnel from both Indian factories indicated that senior managers had been committed to providing the funding required:

> '...That was very well budgeted....it was well being talked to the quality manager and financial manager to keep money aside for the prerequisites...and it was well-studied the gaps that there were....and coming out of that the actions that were required...the costs involved in that – a great exercise was done...' (Quality Manager, India Site 1)
>
> '......it was clearly funded, you know...like there was no question asked if this particular thing has to be done...so that was you can say the top management commitment...' (Factory Manager, India Site 2)

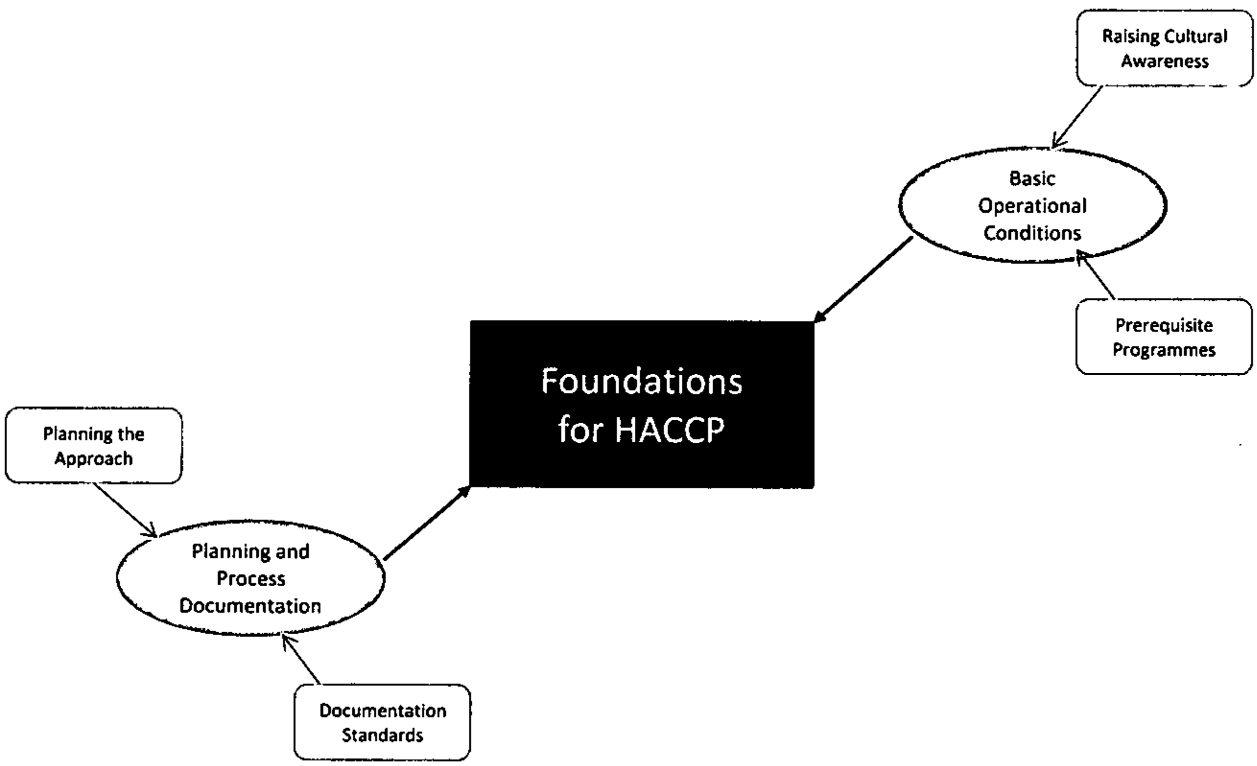
However the Quality Manager from Singapore, whilst stating that the team could ask for money if needed, indicated relief that they had not found anything requiring significant funding following HACCP application:

> '...Well I guess if we want to have money to do certain things we can actually ask for it, you know... [...] ...the thing is that we normally try to run here on a tight ship....some things they require too much money... [...] ... but fortunately I would say that we have gone through the whole HACCP analysis and there wasn't anything that we needed like a lot of money at the time....'
> (Quality Manager, Singapore)

7.3.3 Foundations for HACCP

A HACCP thematic network emerged entitled Foundations for HACCP (Figure 7.3). Most of the points made in this area were involved with the **Basic Operational Conditions** required to support HACCP however the importance of **Planning and Process Documentation** were also highlighted.

Figure 7.3 HACCP Thematic Network – Foundations for HACCP



Basic Operational Conditions included the basic themes of:

- Prerequisite Programmes; and
- Raising Cultural Awareness.

Although this research had not set out to investigate *Prerequisite Programmes*, the importance of getting the basic prerequisite foundations correct and the benefits that the factories had gained from working on prerequisites were highlighted by numerous interviewees in answer to more general questions, such as what HACCP had done for the factory or what the most difficult part of the HACCP system had been. Prerequisite Programmes were mentioned most by interviewees from the Indian factories (Fourteen out of nineteen comments in total about prerequisite programmes, made up of: India site 1 – nine comments; India site 2 – five comments). The remaining five comments about prerequisite programmes came from employees at Australia site 2. The comments imply that these 3 factories had seen a more major impact from engaging in prerequisite programme implementation/improvement as a baseline for HACCP. Comments included:

> '...I think it's very important to include the prerequisites because we have so many things that aren't controlled by CCPs...the GMP the prerequisites is almost more important for us...' (Quality Manager, Australia Site 2)

> '[key factors for success include...]...prerequisites like...[...].... if we say that prerequisites are in place – they have to be you know thoroughly verified, like....so that is the biggest thing I find in HACCP actually, because you can put too much of weight on the prerequisites, and not everything is covered according to that......in an attempt to lower the number of CCPs, people just tend to say ' I don't know, I think it is really controlled by the prerequisites', but in fact it is not actually [...] ...if we say it is getting covered by prerequisites [then it needs to be proven that it is]....' (Manufacturing Manager, India Site 2)

> '...before project starts, prerequisites must be there...otherwise we can't do HACCP... for implementation stage it took a lot of work...' (Manufacturing Supervisor, India Site 1)

This supervisor went on to explain the example of hand-washing and how he had to stop the line four times a shift and make all twenty-one operators wash their hands thoroughly, in order to convey the discipline required. This shows some overlap with the second basic them in this area, *Raising Cultural Awareness*, as exemplified by the following comment from a line operator (via a translator).

'...he has also been helped by the concepts of prerequisites in his personal life as well...ehm... because of this learning, he has implemented many of the personal items at home....so has taught his family why it is important to wash hands....' (Operator, India Site 1)

The other organising theme identified under Foundations for HACCP was **Planning and Process Documentation,** with the associated basic themes of:

- Planning the Approach; and
- Documentation Standards.

Several comments were made about the need for *Planning the Approach* effectively at the start, e.g.

'[key factors for success include...]...right from the project stage, we have to think through and identify what kind of system we are going to develop... so whenever we are going for a new system we have to start with the details... making sure you plan it properly...' (Quality Supervisor, India Site 2)

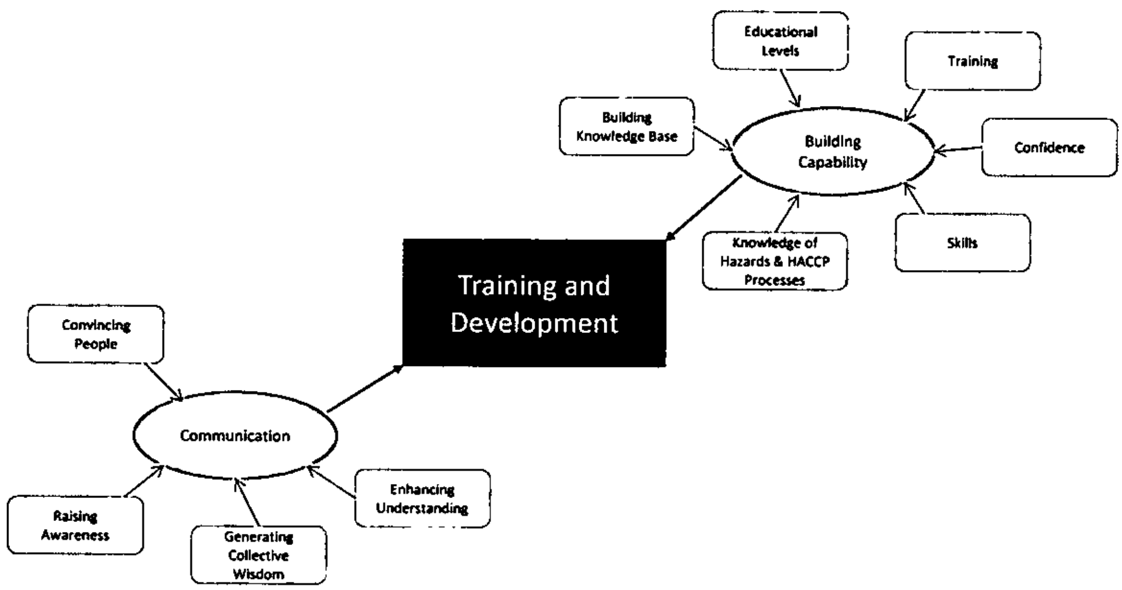
One comment highlighted how poor process *Documentation Standards* had been at the start of the HACCP initiative, highlighting the importance of having good understanding and documentation of processes as a baseline.

'[the most difficult part is]...and I guess it's shown us just how poor our process documentation was at times and how a safety process investigation needed to occur before they start to document actually what happens, you know, because if it was a well-documented process it would have been easier...' (Factory Manager, Australia Site 2)

7.3.4 Training and Development

A number of basic themes were evident in the interviews around experiences of training, knowledge, skills, awareness and communication. These themes grouped logically under the organising themes of **Building Capability** and **Communication** (Figure 7.4).

Figure 7.4 HACCP Thematic Network – Training and Development



Building Capability included 6 basic theme areas as follows:

- Confidence;
- Education Levels;
- Training;
- Building Knowledge Base;
- Building Skills; and

- Knowledge of Hazards and HACCP Processes.

Confidence was mentioned by several interviewees spanning all countries (but not all sites). These comments ranged from lack of confidence in the early stages

> '...well yes I would say there were difficulties because we were not really sure whether what we were doing was correct or not, whether we were doing it the right way you know, and after time, with time we got a bit better...' (Quality Manager, Singapore)

through lack of confidence with specific parts of the HACCP application process, in this example hazard analysis

> '...when you are not really sure whether something is significant or not. In the beginning we tended to put everything as significant ...then over a couple of years we understand...' (Former Quality Supervisor, India Site 1)

to confidence in whether you have really 'done HACCP'

> '...I think it's a confidence thing as well...that it's not HACCP...if you're not confident...' (Quality Manager, Australia Site 2)

Education Levels as a base level for HACCP development were mentioned by personnel from India and Singapore. For these individuals, the generally low level of education in the operator and (in India) supervisor roles had been the most difficult part of developing a HACCP System and the Singapore production manager mentioned this difficulty in two different parts of the interview.

> '...Oh my God I think that [implementation] was the most difficult thing that I think anyone can do because people who are not educated to certain levels..... and they don't know what exactly [you mean]...' (Production Manager, Singapore)

> '[the most difficult part is]...most of our people are not to that level educated..... so it is very difficult to explain to them what it is ....' (Production Manager, Singapore)

> '[the most difficult part is]...like it's education/barriers...because not all officers are qualified...' (Former Quality Manager, India Site 1)

Training was mentioned as a 'key factor for the success of HACCP' by three separate members of the Australia site 2 team, indicating that this had been a valued part of the HACCP initiative at their site, e.g.

> '...Training your operators is probably the biggest one...not just on HACCP but on GMP ...that would probably be my biggest one because if you don't get that right...' (Quality Supervisor, Australia Site 2).

Training was also mentioned by personnel from Singapore and Australia site 1, where the importance of regular and refresher training was also highlighted as a key factor for success, e.g.

> '...obviously regular training and refreshing because you've got to keep it going...well, when you say 'if you don't use it you lose it' ... [...] ... you know you do sort of forget the importance of it and you do forget what you are doing and why you are doing it....so just you know...a continual, ...[...] ... light refresher, you know...so people are constantly reminded...and still have the skills...' (Production Team Leader, Australia Site 1)

With regard to the basic theme of *Building the Knowledge Base* required for HACCP, the Manufacturing Manager at India Site 1 commented on the good knowledge base on site:

> '...I think the knowledge base at [site name] is quite good....people are quite educated and experience is good ... [...] ...but at [the other site I worked at before] – they were not that knowledgeable or experienced...' (Manufacturing Manager, India Site 1)

The *Building Skills* theme included points made directly about skill levels and having the skills on site, as well as points about practical rather than theoretical understanding and the need for operators to have skills in how to control the process, e.g.

> '[key factors for success include...]...working with professionals to get the knowledge from them about how to do that process...it's about having the skills there...' (Factory Manager, Australia Site 2)

Knowledge of Hazards and HACCP processes was mentioned by many interviewees. When asked if the process of developing a HACCP plan had been easy or difficult, a number of interviewees (eight out of eighteen) felt that it had been quite straightforward whilst others (ten out of eighteen) felt it had been more difficult and gave examples of the specific problems they had encountered (see appendix 7.3 for further detail on the magnitude of the responses). The points made underline the need to build capacity and knowledge of food safety hazards and the steps involved in applying HACCP principles at manufacturing sites. Examples of the comments are reproduced below:

> '... it was a new concept....some of the people were doing it...but new concept...and there was a lot of learning about CCPs...for one line 4/5 CCPs something like this....after understanding we....realised some were prerequisites....' (Quality supervisor, India Site 1)

> '[key factors for success include...]...just discussing through the whole thing and you know...understanding what you are looking for....following the HACCP process...' (Quality Manager, Singapore)

> '...it was quite tough...and eh I think that we struggled a lot on the concept of, you know, decision tree....the questions were quite written and eh unless you are fundamentally clear of what you are talking ...of the step ...of protection....and it is very clear...of control measures...significance...probability...severity...if **all** concepts are not clear...eh...you are going against the progress at this time...I think that's the place where we really had a lot of trouble...' (Quality Manager, India Site 1)

The second organising theme in the Training and Development thematic network was **Communication**. This had 4 associated basic themes as follows:

- Convincing People;
- Enhancing Understanding;
- Raising Awareness; and
- Generating Collective Wisdom.

The need for *Convincing People* was identified as one of the most difficult parts of HACCP and engineers were singled out as a group needing to be convinced of their roles and responsibilities in HACCP:

> '[the most difficult part is]...Initially it was only the convincing of the people...initial convincing...but once people get convinced....but part of the difficulty is convincing that you need to put manufacturing in there, quality in there, engineering in there...because the background is different...so we need more training....because manufacturing people when they come on the line they know the consequences....the only concern is on asset care [engineers]....' (Quality Manager, India Site 2)

Enhancing Understanding appeared as a theme in the communication area that was closely linked to training, and particularly emphasised the need to make sure that there was effective communication happening during training such that the trainees came away with true understanding of the HACCP concepts. Delivery of this understanding was identified both as one of the most difficult parts of HACCP and one of the key factors involved in success.

> '... I mean has really what is there in my mind – has it gone into his mind? Has he come to the same level as my understanding....so that is the one difficult part I see and we need to really work on that, you know, that we can get a good input on how to really train...' (Quality Manager, India Site 1)

> '...Certainly understanding of the people is a real, real tough part basically....because sometimes people tend to understand the hazard part differently...that is the most critical part – once the people understand that, really the hazard process isn't a problem...the understanding of the hazards...and the system...' (Quality Supervisor, India Site 2)

Raising Awareness was a theme highlighted by comments from a wide range of interviewees, and this was again considered a key factor for success by some and a difficult area for others, e.g.

> '...I think the positive thing about this is that the people are aware of food safety......they know that they do not touch the product, our product with bare hands....these are the fundamental things people actually understood......that is I think the immediate thing...' (Manufacturing Manager, India Site 1)

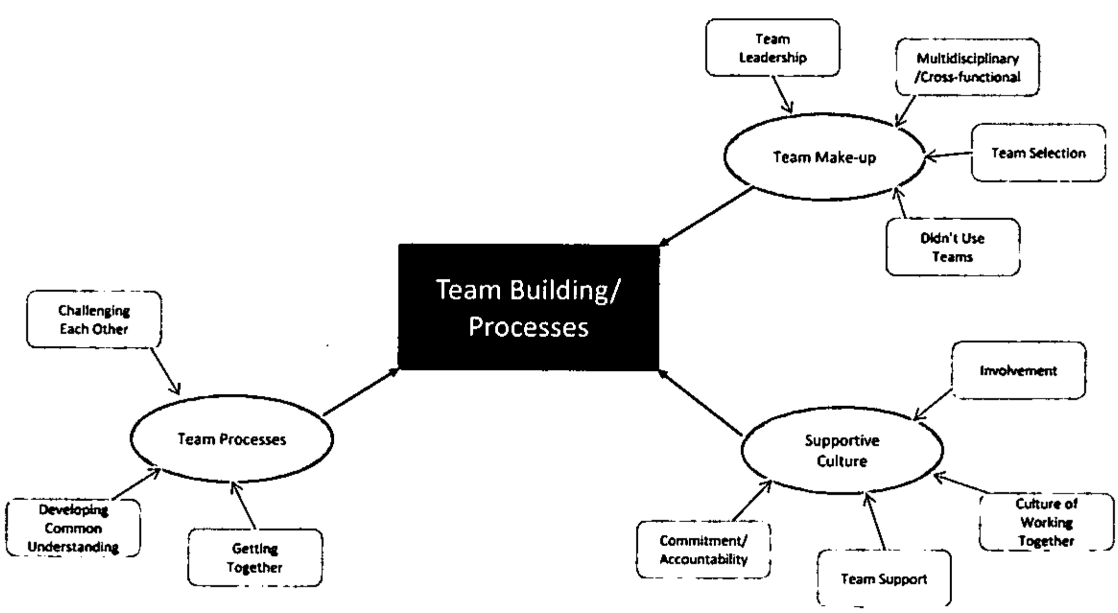
A closely related theme of *Generating Collective Wisdom* was also highlighted here.

> '...the people are having a collective wisdom...they are discussing how we can do... when we are finding any small piece of the metal...we come and the same on the line – working with the line people from where it can come...then they say that they need a machine part – it can come from here....' (Manufacturing Supervisor, India Site 2)

7.3.5 Team Building and Team Processes

Figure 7.5 shows this thematic network, which is made up of the 3 organising themes of **Team Make-up, Supportive Culture** and **Team Processes,** along with 11 associated basic themes.

Figure 7.5 HACCP Thematic Network – Team Building/Team Processes



Under the first organising theme, **Team Make-up**, the basic themes that emerged were:

- Multidisciplinary/Cross-functional Teams;
- Team Selection
- Team Leadership; and
- Didn't use Teams.

The concept of *Multidisciplinary or Cross-functional Teams* was the most widely mentioned point. This was not surprising since a question had been asked about use of multidisciplinary teams and also because these teams have been such a key part of the HACCP system for so long (cf. Chapter 5). It emerged that some factories had been using teams prior to HACCP, whilst others saw it as a new area where they had gained benefits, e.g. in the combined ability of team members to analyse hazards successfully:

> '...then eh other part is that identifying the hazard, you know is it a significant hazard or is it a non-significant hazard...is sometimes an issue so you can make errors ...eh and that way sometimes a cross functional team or multidisciplinary team can really help and identify the eh significance of the hazard, you know...' (Factory Manager, India Site 2).

Interestingly 2 personnel from the same factory (India Site 2) gave different opinions as to whether multidisciplinary teams were a new way of working that had come with HACCP or an established approach. This may have reflected the use of multidisciplinary teams becoming more widespread within the site and correspondingly more people at different levels becoming more involved.

> '...I'd say it was certainly new for them...because if a project was being assigned it was a project team's [engineers from outside the site] baby...they would set up a line and then the manufacturing people would come in and quality would come in and set up

the standards...but since now it is right from the beginning stage...a [multidisciplinary] team is working on that...' (Quality Manager, India Site 2)

'...Cross functional team or multifunctional team was part of the culture that [Company name in India] always had...you know...in...from 1996 – 1997 onwards we always have what we call a cross functional team so it was never an issue ...' (Factory Manager, India Site 2)

Team Selection was identified as a key factor for HACCP success by 2 interviewees:

'...get the right people, you know the ones (who) are going to drive this thing, the food safety...' (Quality Manager, Singapore)

'...getting the right people who can understand....the right team who can really understand the complete process.....right team and right knowledge with them...' (Factory Manager, India Site 2)

Team Leadership, in particular the need for a strong person to coordinate and push the system forward, was also identified as important.

'...Definitely need a strong quality person pushing it...' (Quality Supervisor, Australia Site 2)

'...the first thing we did was identify that someone needs to coordinate it, ... [...] ...so that was when we selected one person as a coordinator, and [Person's name] was given that charge, you know, that she was the coordinator for the different groups...and again, in order to support her, because, as you know, you also need someone also back in...you must show that it is a commercial, top-driven....so each manager from the different functions were being put as a mentor to their group...so that any requirement is there...that she and the teams were getting support very fast...' (Quality Manager, India Site 1)

At one site (Australia Site 1) multidisciplinary teams had not been used (*Multidisciplinary Teams not Used*) in the initial development of HACCP. This was linked with a number of issues to do with ownership and system flexibility (Chapter 3), however the Factory Manager at the time of the interviews shared his perception of why teams had not been used in the time of his predecessor:

'....and the argument was that it was such a big plant and they had so much to do and they had so little time to do it that they just needed to get it done...ehm...and there was probably some truth to that....(inaudible)...but I still think they should have taken a higher approach....' (Factory Manager, Australia Site 1)

The next organising theme under Team Building and Team Processes was that of **Supportive Culture**. This was exemplified by basic themes around

- *Involvement;*
- *Commitment/Accountability;*
- *Team Support;* and
- *Culture of Working Together.*

Involvement was the most frequently mentioned theme in this part of the network and interviewees talked about the fact that people from all levels had been involved and that benefits had been gained from involving all the people.

'...HACCP team-working ... [...] ...it was an immediate involvement of each person....if anything has to be changed...anything has to be done, then each person has to be involved....[...]....managers actually basically want to bring that right down to the operating level...' (Manufacturing Manager, India Site 1)

'....one of the positive things was, you know, it has broken down all the barriers between the departments....eh, you know the delivery.... it has become the fundamental responsibility of everyone ...and in terms of one method it worked very well....it worked because it wasn't just manufacturing looking at the manufacturing...everybody realised that you had to be aware of the one process...[...] ...so that was one thing that was important.....what was strength of team-working...how come individual output is not far superior to the group output...people have realised that – that's the one advantage...' (Quality Manager, India Site 1)

Commitment and Accountability were similarly identified as important issues coming out of HACCP. In this area personnel were referring to the commitment and accountability gained by employees throughout the factory as part of the HACCP process, rather than the management commitment that was essential for HACCP to start and progress.

'...it has made obviously people more accountable for what they are doing and why they are doing it... given people an understanding of what, you know, what they are doing obviously can make a big difference to food safety and can make a huge difference to somebody's life...' (Production Team Leader, Australia Site 1)

'...I think the ...commitment and the drive...the commitment has certainly improved...' (Quality Manager, Australia Site 2)

The related themes of *Supportive Teams* and the *Culture of Working Together* were each mentioned by one interviewee from different sites.

'...so it was quite a supporting kind of thing and I would say, the (site) operating, particular operating team, whenever we ask for support they have given freely support and they always give a new situations, new kind of eh, what we call a newer kind of idea basically....but we have a problem, we can handle like this, we can take this and these are the problems....and they were...the important thing is they have never tried to hide something.... ' (Quality Supervisor, India Site 2)

'.... it went very well and the work has been supported by everyone... the culture is here it is basically working together always as team...that's been all the time at Singapore...' (Factory Manager, Singapore)

The final organising theme in this network was **Team Processes**, which described the experiences of team working during the HACCP development, implementation and maintenance phases, as illustrated by the basic themes of;

- Challenging Each Other;
- Developing Common Understanding; and
- Getting Together.

The need for team members to share knowledge and *Challenge Each Other* through a 'healthy fight' was highlighted:

'.....people are always quarrelling and saying why didn't you look at this and look at that? So in fact when [HACCP team leader's name] does run the process to see where are the points, actually there is a good eh...[debate]... everybody is there with some input...that is how it was...' (Production Manager, Singapore)

'..and it was always you know that someone could get some knowledge to share with the other team members... [...] ... and they say that OK the more you fight, eh the

> more you confront healthily, I think that is the best output for the team...that was accepted by everyone....so everyone challenged each other ...I said to them: 'you challenge each other...' (Quality Manager, India Site 1)

Developing Common Understanding, in particular the need for people at different levels to come to a common understanding of what was important for consumer protection, was also highlighted, e.g.

> '...come out with a common understanding...and we'll learn...' (Quality Manager, India Site 1)

> '...certainly there was a kind of anxiety...there was a kind of reaction that why should we waste so much material ...why should we do that...also at the same time how this control is going to help in terms of quality, that type of thing...so between manager and executive there was more of anxiety or more learning...but between executive and operator it was more of convincing eh ..how it helps...' (Factory Manager, India Site 2).

The process of *Getting Together* to allow communication between HACCP team members was the final theme to emerge in this area:

> '...The nice thing is...get together regularly...I think that's one of the keys...' (Quality Manager, Australia Site 2)

7.3.6 Resource Management

Although Resources had already come up as an organising theme under Committed Leadership (7.3.2 and Figure 7.2 above) who needed to commit to and 'mobilise' resources, it was considered that Resource Management with regard to the ongoing control and day-to-day use of resources was also a thematic network in its own right (Figure 7.6), with associated organising themes of **Finance, Time, Personnel** and **Prioritisation**.

'[the most difficult part is]...again it is linked to the resources...that's a difficult part to manage in the scenario...resource changes and all... the cost of it...' (Quality Manager, India Site 1).

Cost of Control, particularly the tendency for HACCP teams to initially want to progress expensive control options rather than more economic options was also mentioned, e.g.

'...they found problems within the plant...'well how are we going to fix this?' and, you know, initially, as is always the case, they came up with the sort of million dollar options... [...] and as we got better at it we found much more, much better ways of putting in sort of interim measures or more sort of simple measures, you know....I mean, it's nice to be able to design a process to say the full process is never going to go wrong...the reality is that we had plant that was 30 or 40 years old and it's a [product type] plant so you're not going to justify rebuilding it totally...so sometimes you have to come back to ....it's almost a hierarchy of controls, you know, you can't always eliminate the hazard totally...it's a matter of just cutting down or putting in more frequent checks, you know, PM [preventative maintenance] routines that sort of thing to try and cover it...' (Factory Manager, Australia Site 1)

The next organising theme was **Time**, which had again been identified as an issue in the Committed Management thematic network, where people had talked about managers allowing staff time to do HACCP. In this case the more practical issues of time management were highlighted, including:

- Time to Get the Team Together;
- Shift Work Issues;
- Availability and Motivation;
- Timescale; and
- 'I don't have time'.

Time to Get the Team Together was best illustrated by the following comment from Australia site 1:

'...It's easy to put a team together it is just trying to find the time to do it...to get them together... [...] ...and with the number of people that have gone [redundancies over last few years] finding time with the people who remain...' (HACCP Coordinator, Australia Site 1);

Shift Work Issues were highlighted only by the Australian Factories, e.g.

'...I think that's one of our biggest challenges. It's been very difficult for us to launch the teams in the way we should , you know the way we classically should... the programme. It's probably one of the key factors...shifts – they come in for 12 hours and then they're off for 4 days but it's something.....if we're going to do it at all we're going to have to do the best with what we've got... with the problems...moving it forward...' (Quality Manager, Australia Site 2)

Availability and Motivation was also discussed, e.g.

'....[the most difficult part is]...Ehm...probably time and availability and motivation too...I think... ' (Quality Supervisor, Australia Site 2);

Timescale was highlighted as a difficult area to manage, e.g.

'...and the timescale thing has been very hard...and it's not that I didn't like doing it...' (Quality Supervisor, Australia Site 2); and

'I don't have time' was a message coming from one Australian site:

'[the most difficult part is]......because there's only myself......having the time...' (HACCP Coordinator, Australia Site 1)

This comment was in the context of an inherited complex product-led HACCP system that needed to be reviewed into a more manageable modular HACCP system (cf. Chapter 3).

A further organising theme around **Personnel** and issues to do with their management in HACCP was established within the Resource Management thematic network. This included the basic themes of:

- New Personnel/Old Staff Leaving;
- Contractors and Temporary Staff; and
- Skilled Resource.

The issues of knowledge and skills gaps due to new personnel replacing older members of staff (*New Personnel/Old Staff Leaving*) were mentioned by managers in India and Australia:

> '...this is really something of concern...that the older people are going from the factory who were quite well trained...and every time you come across with a new person...each time it is affecting both [HACCP and Prerequisites] ...' (Quality Manager, India Site 1)

This Quality Manager went on to expand on the difficulties of managing prerequisite issues with 'a different set of people every day to be trained for that'. He also discussed the challenges of managing CCPs when new people without the required knowledge come into the factory and identified the need for 'a very structured way of getting these people inside'. His concerns were echoed by the Factory Manager from Australia site 1:

> '...we've got about 350 odd core (staff), but our total number is about 950, so two thirds of our total are new employees so if you pick...if you happen to pick one of those [to talk to about HACCP in the factory] they wouldn't have a clue about it...' (Factory Manager, Australia Site 1).

A related theme of *Contractors and Temporary Staff* also emerged in this area:

> '[the most difficult part is]...with new workmen coming into the system, contractors, casual labour...training there is continuously and you have to make sure they are as good as your permanent workforce...' (Manufacturing Manager, India Site 1).

Skilled Resource availability was a final basic theme under Personnel:

> '[the most difficult part is]...Resource..I think the quality team...like the...just in the skills and knowledge...consultants and contract people to do that...' (Quality Manager, Australia Site 2).

Prioritisation was identified as the final organising theme in the Resource Management thematic network, with the single basic theme of:

- Priorities.

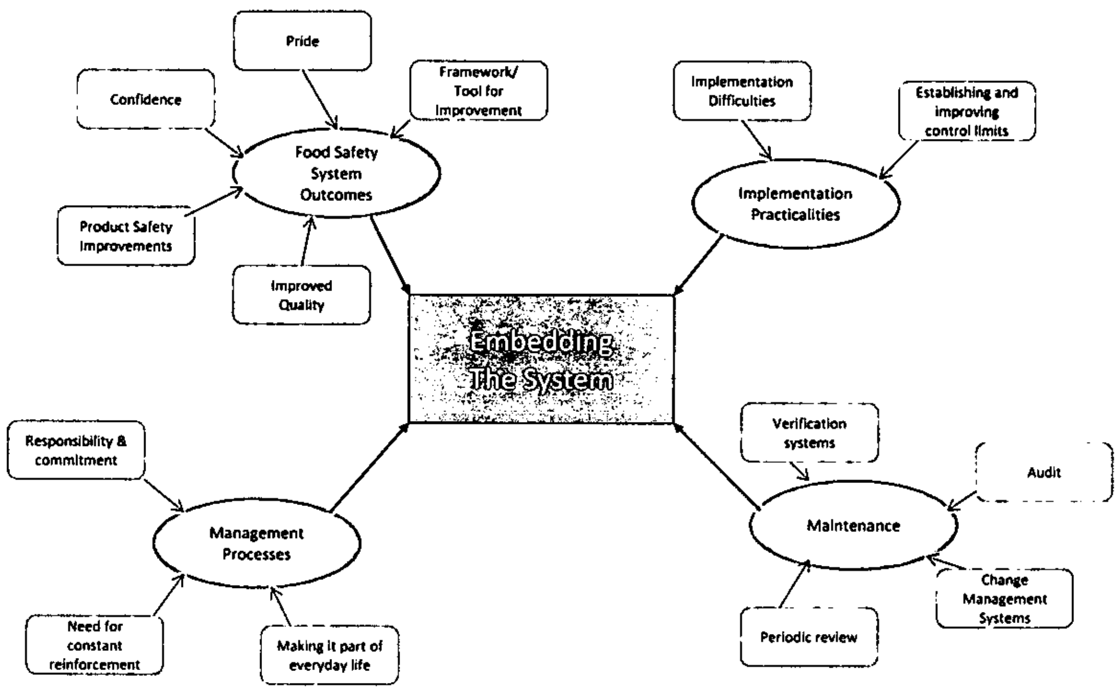
Although this is closely related to time and personnel availability, it was established as a separate theme since it requires managers and personnel to understand and decide what is important to them in how they plan to use the resources available. This is clearly illustrated by the comment from a manufacturing manager, when asked what he believed was the most difficult part of HACCP:

> '[the most difficult part is] ...Mixing it in with all the other priorities...everyone has their own high priorities...' (Manufacturing Area Manager, Australia Site 2)

7.3.7 Embedding the System

Questions had been asked about HACCP implementation and maintenance and comments made in response to these and many other parts of the interviews provided the next HACCP thematic network, entitled Embedding the System (Figure 7.7)

Figure 7.7 HACCP Thematic Network – Embedding the System



Four organising themes were evident from the data in this network, namely **Implementation Practicalities, Maintenance, Management Processes** and **Food Safety Outcomes.**

Implementation Practicalities was made up of the basic themes:

- Implementation Difficulties; and
- Establishing and Improving Control Limits

Interviewees had been asked if implementation of the HACCP Plan, i.e. going from a paper HACCP plan to a practical working system, had been straightforward or whether they had experienced any problems. A number of personnel highlighted *Implementation Difficulties* that they had experienced in this area, as highlighted by comments from the Singapore management team:

> '...basically what I would say implementing and working in the factory, it is not the same as on a piece of paper.... how thoroughly we would follow up on the HACCP controls... we do have certain steps put forward to make sure all things are done.... but is it a 100 per cent followed.... there are some gaps I would say...' (Factory Manager, Singapore)

> '[the most difficult part is]...implementation..... on a high-level we were OK but to bring it down to the shop floor, that's where the main problem was...'
> (Production Manager, Singapore)

Establishing and Improving Control Limits as part of HACCP plan implementation was the other area mentioned by interviewees at all levels of the factory hierarchy. This included comments about difficulties in getting the control and monitoring systems working properly and experiences of how this process had tightened up control. Some people felt that implementation was fairly straightforward because many of the control and monitoring procedures were already in place but making sure that procedures for control and monitoring are actually working was also identified as one of the key factors for HACCP success.

The majority of comments in this basic theme area had come from personnel from Australia Site 2 and India Site 2. At Australia site 2 all had found the process quite straightforward, although the Quality Manager did note that there hadn't been much experience in the early days and the realisation that more production input was needed had come with experience. At India site 2 many of the controls were also already in place but here personnel had identified the need for clarity on exactly what was required to ensure CCPs were under control and had found the systems being tightened up in this area. The three points below are illustrative of the learning taken from HACCP implementation at India Site 2. The last comment in particular highlights the supervisor's concern that product rejected via CCP operation and, therefore, potentially unsafe, could have been put back into the product stream via rework.

> '...that there was lots of teething trouble when maintaining CCPs .... it was a very needy [monitoring] frequency so in the first few years it took a lot to maintain that frequency...' (Operator, India Site 2)

> '[key factors for success include...]...be clear what are your critical control points, CCPs and CPs in place and a good kind of discipline on that is very, very important... [...] ... if regimentation on CP and CCP is not there – you don't ever get the confidence on that...so it [HACCP] can remain on the paper but nothing on the shop floor kind of thing....'
> (Factory Manager, India Site 2)

> '...for like quarantining of the material, that was another extreme area where we had to make a cut off.... [...]....So the CCPs were working but people weren't really understanding the importance of what to do with the reject...not the whole situation – maybe they are complying between 60 and 70% but they are not complying 100%....'
> (Quality Supervisor, India Site 2)

The organising theme of **Maintenance** was typified by comments around:

- Audit;
- Verification Systems;
- Periodic Review; and
- Change Management Systems.

All of these themes reflect elements that would be expected to be in place under the application of Codex HACCP Principle 6: Establish procedures for verification to confirm that the HACCP system is working effectively (Codex, 2003).

Audit was being done at all sites and most sites had experience external 2nd or 3rd party audits in addition to their own internal audits. The benefits of audit were highlighted, however some gaps in audit schedules were also noted, e.g.

> '...once we started we were very strong on the prerequisite audit...but the HACCP audit, by default what has happened over period of the last 2-3 years...it has gone through [external audits by consultants and corporate auditors from the national and international company structure]...so we felt that these are the more [...] ...expert assessment...but now we are also doing the audits internally...[...]...I think that is helping us and we will learn from these audits really, you know, when they are completed...we are learning how we are acceptable...and it is great experience...' (Quality Manager, India Site 1)

> '...if I'm not mistaken, we have done some internal.....but the gap - it could be two years or three years ago....' (Factory Manager, Singapore)

Furthermore, at Australia site 1 a comment highlighted the perception that things were being done to get through external audits rather than necessarily because there was the local acceptance and commitment that they should be done:

> '...I think that the most difficult part is, as I said, the fact that it [HACCP] was done as a campaign...and then trying to just maintain it before it's sort of annual external audit, you know, making sure that things are done, [...]... and it's also the most frustrating part of it because you know, you're doing it because of an audit, you're not doing it because it should be done...' (Factory Manager, Australia Site 1)

This point is interesting as this was the only site where HACCP was a legal requirement, due to its location in the Australian State of Victoria.

Several interviewees also mentioned *Verification Systems* other than audit, including some detailed comments on the additional verification from quality personnel at India Site 1 but also a more negative comment that verification was not done well at Australia site 2.

> '....now, we are checking very nicely all the machines – no doubt about that...we are tracking the data also and, since we know the monitoring of CCPs is going well, we are comfortable...the microbiological analysis is also fantastic because it has been all positive there...and we are tracking – we know things are going right...[...] - that is in place...monitoring of CCP is there....CP/CCP is there...reviews are there...market complaints – we know that everything gets logged...and the system performance is very good over a period of 5 years...' (Quality Manager, India Site 1)

> '...It's a bit of a vague one I think...I don't think it's been done very well to be honest...verifying...I don't think that's something we do very well...' (Quality Supervisor, Australia Site 2)

Only one comment was made about *Periodic Review*:

> '...These are part actually of our monthly review...audit is a part of monthly review ...there is a format for it called MQI, manufacturing quality index, so the HACCP is a major part of that manufacturing quality index.....there are particular parameters that have to be measured...so that is done every month and the food safety measures are there – that is the current mechanism to monitor and ensure that the HACCP is working....manufacturing quality index has all of these things like prerequisites compliance, HACCP compliance, GMP compliance...so once there is one score, which is monitored for all the factories...' (Manufacturing Manager, India Site 1)

The points made here are related to ongoing verification/review that the system is working. However, no personnel mentioned periodic review of HACCP Plan validity, i.e. checking over time that the HACCP plan would still be effective to manage all likely hazards, which suggests that this important task for ongoing HACCP effectiveness could be missed.

Interviewees had been questioned about how they kept the HACCP system up to date when there were changes to processes, products, ingredients, etc. Several interviewees were able to answer about *Change Management Systems*:

some illustrated what they knew about the local system whilst others highlighted weaknesses they perceived in this area.

> '...I guess a challenge for us is going to be to, you know, to recognise how much work is involved in keeping them up to date and putting enough resource in and to put in a change management process to trigger a change in the HACCP plan every time there's a change in the process....We don't have a good systematic change process at all . If there's a change that happens in production because of a new product...ehm... it doesn't trigger an automatic need to modify the HACCP plan and obviously we need a reminder to do that. It's quite a gap...' (Factory Manager, Australia Site 2)

Even in sites where there were change management systems, different responses were given by different members of staff, indicating that the procedures were, perhaps, not well understood by all. At India Site 2, the Factory Manager said that food safety change management was achieved via 'the trial protocol with the SMT [Senior Management Team] and the quality team', which required the change and any new hazards to be reviewed in detail and change management documents 'to be signed by all the concerned people' before 'the line is cleared for the production'. However, the Quality Supervisor indicated that the operating team would come to the quality team for them to 'understand the problem' and establish 'how we are going to resolve this' without any mention of formal documentation requirements.

Management Processes involved in embedding the system were identified as another organising theme in this network, made up of the basic themes:

- Making it part of Everyday Life;
- Need for Constant Reinforcement; and
- Responsibility and Commitment.

In *Making it part of Everyday Life* was a basic theme in this area and many people talked about the processes involved and the fact that HACCP had now become second nature as part of the everyday job, e.g.

> '...I think it is basically a standard for them... its everyday life they don't think anything different...they take it as part of their job, it is what I'm supposed to do...' (Factory Manager, Singapore)

> '...Oh, it is now part of life actually....[...] ... [in] the preliminary stages people used to ask me what it is, why it should be used....now it's like it has become a part of life and nobody asks me why it is required....' (Manufacturing Manager, India Site 2)

> '...As far as CCP is concerned, the people presently are fully committed...even if I am not there or any manager is not there they are taking their own action...[...] ....I don't find any gaps in that area...even if they produce 20 tonnes or if they produce 10 tonnes – it's not a matter of concern...' (Quality Supervisor, India Site 2)

Interviewees also talked about the *Need for Constant Reinforcement*, which had been more important in the early stages of implementation but was necessary on an ongoing basis to keep HACCP as part of everyday life.

> '...I suppose the most difficult part would be ...eh...I suppose it's got to rely a lot with the operators and if they are not doing what they are supposed to be doing and they are just signing it, you know, they just sign their name and they've got the wrong date code and I'll go up to them and they'll say 'Oh, oh' and it's like they're just, you know, within that trance... [...] ...they should be picking up product and looking at it and going 'this is wrong'...they're not cross-referencing with what it should be....' (Production Team Leader, Australia Site 1)

> '[the most difficult part is]...there are some who just go back to old habits...' (Production Team Leader, Singapore)

The final basic theme attributed to the **Management Processes** area of this network was *Responsibility and Commitment*. Interviewees talked about the fact that people had now taken on the responsibility and were committed to running HACCP, but also described their experiences of getting the right people to take on the roles:

'...it was not very clear who will maintain what, who will verify what ...or it was the job of quality person only...[...] ... Now it has gone to the person who is working there...' (Former Quality Manager, India Site 1)

'[key factors for success include...]...people on the floor understand why they are doing what they are doing, why it's important, why it's necessary, and having the backing of the management that, if they are not complying, that there's consequences...' (Quality Manager, Australia Site 1)

The final organising theme that emerged in the Embedding the System network was **Food Safety System Outcomes**. This encircled a range of comments about the different areas where sites had seen benefits through embedding HACCP in their operations, under the basic themes of:

- Product Safety Improvements;
- Improved Quality;
- Confidence;
- Pride; and
- Framework/Tool for Improvement.

Although the HACCP system is intended to manage food safety, only three interviewees, all from India site 2 and including a line operator speaking via a translator, mentioned *Product Safety Improvements* from fully implementing HACCP:

'...the product is now safer, eh ... he has also said that he is checking metal detection..... and he has filmed all the tube lights and the glass to...there is a lot of care is taken to prevent any foreign matter going into food....so now it is much more safer than a few years ago...' (Operator, India Site 2).

This compared with a larger proportion of comments about *Improved Quality* coming from an embedded HACCP system, as exemplified by:

'...it has improved our quality to a certain level....' (Factory Manager, Singapore)

'...I would definitely say it has improved the quality of the product that is sent out...definitely...' (Production Team Leader, Australia Site 1).

One interviewee also indicated the link between the HACCP system for food safety and improvements in quality systems more generally as an indirect benefit:

'...See HACCP has given support to improve...one is to help our quality system, another part is the food safety system...so when we are driving this thing for food safety, the quality of product is also starting...eh...going up...because it's a parallel...sometimes there is the overlapping of each other but once we are improving systems for food safety, automatically quality of our product is also going up.....so that is our indirect benefit we are taking from the system...' (Quality Supervisor, India Site 2).

Further interlinked basic themes of *Confidence* and *Pride* that the workforce had gained from applying HACCP were also mentioned. *Confidence* included both individual confidence that everything was alright and confidence in the system effectiveness.

'...Oh it is better...it has improved ....there is more confidence now – before that we were not having records so confidence was not there....now we are doing from bottom of house – record is there, confidence is there...and basically our input from people is there...' (Manufacturing Supervisor, India Site 1)

'...well from our old days to now, what we are currently...eh...in one simple way, I can say that I can sleep in peace.... so now we can see it has give me peace of mind...I can sleep in peace.....' (Production Manager, Singapore)

Interviewees also talked of *Pride* with regard to working at the standards required of a multinational company and that people had gained a 'prize' because they had the satisfaction of knowing that they were doing their jobs correctly for the consumer:

'...our people are also updated now...they are updated...they think that we are working in a multinational...they are having the proud of working in the multinational...or...now they are very much updated – they feel thrilled...they are doing this one thing...and it is working...they feel thrilled...' (Manufacturing Supervisor, India Site 2)

'...I think that people are finding really...eh that they have a prize....eh and they are getting the satisfaction of thinking that the consumer must be happy...I think down the line people they are sure that we are doing something good for the consumer...that's a strong thing and we take that as a prize...given that part of HACCP....you are at peace when it is time to go home – you are doing your job right...you are not doing something wrong so you need to think what can happen.... so we are proactive...you get a satisfaction when you are going home.....yes...confidence and pride that we are doing it right...' (Quality Manager, India Site 1)

Finally, several people highlighted that HACCP had given their site a *Framework/Tool for Improvement*. Specific comments mentioned the discipline and direction that HACCP had delivered and that the initiative had given focus to the need to improve.

'...I think it's given us a framework to use to improve our food safety and it's given us a fairly simple tool that we can use to analyse where our risks are and assess where we are...' (Factory Manager, Australia Site 2)

'...HACCP has given a discipline actually...yes, as well as the system itself it has given us like a direction of life, actually....when we make a product, we need to do it 1, 2, 3, 4, 5....this discipline it has taught us...because when we used to work we would come from the final point and go back...that's no more...we start from the initial point...and move from there...it has given us this...this is the way we need to work...and then, rest assured it will go right....that's the measure it has given us...' (Quality Manager, India Site 2)

This manager also highlighted the use of HACCP as a process improvement tool as follows:

'...Initially when we had the plan, with the process flow diagram, initially we had that....then we used to put some 3 hours time just to go down through the line and validate that...then when we validated that we used to find a lot of different things from the process flow... that way we discarded a lot of things...[...] ...one example of that...after completing the HACCP study, we have removed about 2 kilometres of pipeline at [factory name]....redundant pipelines that we found through process analysis....' (Quality Manager, India Site 2)

7.4 Discussion

The main aim of this element of the research was to explore the business/organisational factors, in particular the operational management and personnel factors, impacting HACCP success at manufacturing sites of a multinational food company, from the perspective of the personnel involved in applying the HACCP principles and implementing the HACCP system. A further aim was to provide data to triangulate findings from the other elements of the research. The use of a semi-structured interview approach allowed these aims to be achieved, providing a depth of information on the subject via the use of open-ended questions.

7.4.1 The HACCP Thematic Networks

The 6 thematic networks that emerged from the data (Figure 7.1) show good agreement with the postulated 'Business Factors' believed likely to be involved in successful HACCP. Of the 2 sets of factors that the interview process had set out to explore, namely Operational Management Factors and Personnel Factors, there are striking similarities with the Global themes that emerged. At face value, this might be expected due to the questioning areas covered (Appendix 7.1), however the fact that thematic network analysis looks at the texts as a whole rather than individual questions and answers suggest that these were the main pictures emerging from the discussions in their entirety. This is further corroborated by the fact that the data were independently analysed by a member of the supervisory team, whose analysis gave a noticeably similar thematic networks representation.

Operational Management Factors had been thought likely to contain issues to do with management and individual commitment along with resources and support. Taking the thematic networks that emerged, the Committed Leadership and Resource Management networks clearly fit into this area. Furthermore, the thematic networks around Foundations for HACCP and Embedding the system could be thought of as part of Operational Management Factors, the former since this is about establishing appropriate operational conditions as foundations for food safety and the latter to do with operationalisation of HACCP procedures in the wider factory structure.

The remaining 2 thematic networks of Training and Development and Team Building/Processes show good fit with the Personnel Factors postulated to include training and knowledge and personnel interactions and decisions.

The findings also confirm the importance of three of Panisello and Quantick's HACCP Pillars (2001; c.f. Chapter 1) , namely Commitment, Education and Training, and Availability of Resources, in providing the supporting structure for the system, and as discussed in further detail below.

7.4.2 Summation of Findings Emerging from the Thematic Networks

a) Committed Leadership

The organising theme of **Promotional Leadership** was defined as direct involvement in the on-site HACCP promotion by senior managers.

The value of the promotional leadership activities was clearly acknowledged by the interviewees and this backing and support had sustained the activities of the HACCP team members in developing and pushing the system forward, assisting in gaining commitment and buy-in from managers and staff. This had also been fundamental to **Empowerment** of staff throughout the factory hierarchy, allowing people to take ownership and accountability for the HACCP process. The roles of committed leaders in setting **Targets and Achievement** monitoring had underlined the importance of HACCP in the eyes of staff members, both for the company and consumer protection. This was also true for **Mobilising Resources** where willingness to provide necessary finance and secondment time for HACCP were key management roles identified.

Whilst personnel from all factories had demonstrated the importance of committed leadership, differences emerged between the Indian and Australian factories as leadership was perceived to have been less effective by some individuals in Australia. This was either due to lack of promotional leadership or because this support had not been maintained, factors which may have been influence by changes in management or prioritisation of other business projects.

These findings support the claims made in previous HACCP texts (e.g. Mortimore and Wallace,1998; Panisello and Quantick, 2001; Codex, 2003) that management commitment is an essential precondition to successful HACCP. The way that commitment interweaves the themes between this and the other HACCP thematic networks reinforces Panisello and Quantick's argument (2001) that a sustainable model of HACCP can only be achieved with committed leadership as its driving force rather than leadership being driven to commitment via external pressures.

b) Foundations for HACCP

It was interesting that prerequisite programmes and their resulting impact on raising cultural awareness played such a big part in the interview responses, in particular because the research had not set out to investigate this area and, therefore, personnel had not been questioned about their experience with prerequisites. Perhaps it would be expected that established manufacturing sites like these would already have existing Good Manufacturing Practice (GMP) or prerequisite programme procedures in place. However the necessity to ensure that all prerequisites were formalised and verifiable in practice (Wallace and Williams, 2001) had clearly led to a major area of work effort in all factories to assure hygienic **Basic Operational Conditions** in support of HACCP. This gives weight to the view that, although many companies believe that they have been operating to industry standards of GMP for some time, when challenged to prove that these systems are fully effective, the often paper-based systems require substantial improvements to become formalised prerequisites (Wallace and Williams, 2001). It also suggests potential cultural differences in prerequisite programme application within both within multinational organisations and other food companies when manufacturing sites are compared across countries. The importance of cultural up-skilling in hygiene requirements was found to be a key factor in India, where production line operators spoke with pride about the improvements that they had been able to make in their own homes and family life once they understood the importance of hand-washing and other hygiene requirements that the prerequisites had delivered.

The need for planning and for establishing documentation standards that emerged as the second organising theme in this network, **Planning and Process Documentation**, might be expected in HACCP as in other quality management projects (Mortimore and Wallace, 1998), however the identification of weaknesses in existing process documentation that had come from the HACCP process highlight how important it is to review and improve existing documentation as a further baseline for HACCP development, in addition to prerequisite programmes.

c) Training and Development

The importance of training and development to successful HACCP was apparent from points made by the interviewees. This supports existing guidance on training (e.g. WHO, 1993, 1995; Mortimore & Wallace, 1998; Codex 2003) and further confirms the need for suitable training to **Build Capacity** and develop self-efficacy in HACCP teams as well as raising the awareness and education levels throughout the workforce. The role of training in communicating and convincing people of all levels of the importance of HACCP and their essential roles in making the system work should not be underestimated, and it is encouraging to note the 'collective wisdom' that resulted amongst operations staff via the HACCP **Communication** process.

d) Team Building and Team Processes

The use of multidisciplinary teams in HACCP has long been recognised (see Chapter 5). This had instigated questioning on multidisciplinary team-work in the interviews and a number of themes around team building, team support and processes emerged strongly in response to this and other questions, under the organising themes of **Team Make-up**, **Team Processes** and **Supportive Culture**. Key factors were believed to include selecting the appropriate people and strong team leadership, and many personnel had found the culture and support of teamwork to be beneficial in progressing the HACCP system. In the one site where multidisciplinary teams had not been used in the original application of HACCP, this had resulted in a complex system and lack of ownership in the factory, eventually needing to be completely reviewed and rebuilt by the current management and HACCP teams. This gives further support to the concept of teams being essential to HACCP both in the development and implementation stages. Comparing the findings of the interviews with the observational study of HACCP team decision-making (Chapter 5) some parallels arise, such as the importance of team selection and leadership in the process. However, it is interesting to note that the interviewees did not appear to perceive the potential weaknesses of HACCP team decision-making highlighted in Chapter 5, but rather highlighted the positive aspects of HACCP team use from more of an organisational culture perspective. For example, the forming of a supportive culture and benefits of working together and both challenging and learning from each other. This suggests that, although it is clearly important for food companies to understand the potential limitations of HACCP teams and carefully select team members and key team roles accordingly, from the individual perspective the team building and collegiate working involved in HACCP is likely to be one of the rewarding parts of the process, and the relationships built through HACCP may have positive spin-offs in other areas of business.

e) Resource Management

The themes which made up the Resource Management thematic network are illustrative of many of the points highlighted as barriers to HACCP in previous research, i.e. the need for **Time, Finance** and **Personnel** resources, and for **Prioritisation** of HACCP (Gilling *et al*, 2001; Panisello and Quantick, 2001; Taylor & Taylor, 2004[a]; Bas *et al*, 2007). Their appearance in this research underlines the importance placed on effective management of resources by personnel involved in HACCP even when they are not seen as barriers but as important things to get right.

All factories had been able to manage their way through HACCP's requirements for resources, including working around HACCP team members on shift-work, time priorities and providing the necessary financial support. The practicalities of needing to manage the cost of control in a commercial environment were strong messages from some managers, such that the solution for controlling hazards need not be the most expensive option. Whilst this is undoubtedly true, it is important to emphasise that control measures for significant hazards at CCPs must be validated and verified as effective.

The ability to maintain the skilled resources, i.e. factory personnel with required levels of food safety and hygiene awareness was a further key point, with managers describing their difficulties due to redundancies and losing older members of staff. Overlapping with the training and development network, the fact that these managers had identified the need to keep levels of knowledge high in the general workforce and were developing systems to do so is encouraging. Recognition of this need is important for all food businesses that might need to go through commercial restructuring.

f) Embedding the System

The themes of the Embedding the System network demonstrate the journey each site followed to making a 'live' HACCP system from the paper HACCP plan. The practical themes that emerged around **Implementation Practicalities, Maintenance** and **Management Processes** give guidance to food companies on points to watch out for at this stage of HACCP application. Although personnel highlighted areas where they had found difficulties it was clear that they had been able to work through these issues with their site teams, and this should give encouragement to those who think HACCP is too difficult.

Some themes of concern for HACCP effectiveness did arise from the data in this network. The tendency for some sites to let audit schedules slip and the lack of any mention of periodic review of HACCP plan validity are of key concern, as are the apparent weaknesses in change management systems to trigger a food safety review for all proposed changes to ingredients, processes, products and operating procedures. Supported by the weaknesses in working HACCP systems highlighted in Chapter 3, this would appear to be an area requiring further work to ensure ongoing control of food safety and there may be a role for regulators and guidance setters to provide further emphasis on these essential requirements.

The **Food Safety System Outcomes** that emerged in this network highlight the positive benefits that can be gained from implementing HACCP-based systems. Whilst much has been spoken about potential HACCP benefits in previous HACCP texts (e.g. Mortimore and Wallace, 1998) and in HACCP training programmes, few studies have explored this area in practice. The limited literature in this area is mainly derived from studies using survey instruments where managers were asked to choose from lists of potential benefits (Henson *et al*, 1999; Maldonado *et* *al*, 2005; Semos and Kontogeorgos, 2007), whereas in this research interviewees identified the benefits from their own experiences. It is interesting, therefore to see the similarities that arose, underlining these as key benefit areas. The perceived benefits of confidence and pride seen to feature strongly in this study have not been described previously and, while it is possible that these benefits might be found in any food company that has followed the HACCP journey, they are likely to be of key interest for multinationals operating in countries and cultures where initial standards are perceived to be low.

Whilst, by design, this qualitative data only provided a few points of quantification, it is interesting to note some further points in support of the thematic networks discussed above from the data in Appendix 7.3. The majority of interviewees had felt that management support had been available and remained throughout the HACCP initiative, although a few felt that support had decreased over time. The main perception was that site management personnel were driving the HACCP process, with regional and corporate managers also felt to have a key role to play. Both for HACCP plan development and for implementation of HACCP plans, the perception of whether this was straightforward or difficult had an approximately 50:50 split for interviewees giving a view. Further expansion of the reasons for this are given above and suggest that there may be difference between the perception of capability to follow the steps required by HACCP and the complexity of actually achieving this in practice. The majority of interviewees felt that their

HACCP plans were working well, which is useful to compare with the site HACCP assessment findings.

Following the interview process at each site, several managers, including the Regional Director who had received feedback from the sites, expressed a view that the interview process had been a useful tool in reflective contemplation of the HACCP process at each site, and in highlighting how hard people had worked and the benefits they had gained. This was said to have created a 'buzz' about HACCP and food safety, and to have given the site teams a new depth of focus and an eagerness to continue on the HACCP pathway. This suggests that use of such an in-depth review and reflection technique would have benefits for other companies working with HACCP Systems.

7.4.3 Strengths and Limitations

Trustworthiness of the study design and analysis has already been described (section 7.2.6), highlighting some of the strengths of this approach. Further strengths come from the interviewing style used to collect data at each site. Interviewing relies on practical skills and personal judgements of the interviewer (Kvale and Brinkmann, 2009) and is an interactive process relying on effective communication between the interviewer and interviewee. It can be affected by response effects such as environment, socioeconomic status, and race and ethnicity of both interviewer and interviewee (Dijkstra and Van der Zouwen, 1982; Weiss, 1995;). It was found that the combination of effective interview planning along with full explanation of the aims and reasons for interviews helped to overcome potential barriers, assisted by consideration and respectful attention to interviewees at all times.

The fact that the interviewer had previous work involvement with the company and with some individuals from all factories could have influenced the answers along the lines of 'telling the interviewer what she wants to hear'. This is consistent with interviewees desire to be 'good' participants (Orne, 1962), using any cues available in the research (in this case interview) situation, i.e. the demand characteristics, to try and work out the experimental hypothesis so that they can act accordingly to support the hypothesis (Orne, 1962). Because this interview process was an exploration of experiences rather than an attempt to prove or disprove a hypothesis, and interviewees had been told that there were, therefore, no right or wrong answers suggests that the impact of demand characteristics is likely to be low. The structure and openness of the interview process combined with the fact that this was only one part of the research process, which could be triangulated with other findings, provide further support to the interview data being an accurate compilation of individual's perception about the HACCP process at the case study sites.

7.4.4 Further Work

Although it is unlikely that the key themes would change, further examination of this rich data source, perhaps using additional analysis techniques, may allow further useful information to be gained. It would also be interesting to carry out a similar study or studies in other food companies to establish transferability of the findings, particularly to other food sectors and the manufacture of higher inherent risk products, e.g. ready-to-eat chilled foods.

7.4.5 Recommendations for Multinational Food Businesses

- Senior Managers in Food Companies need to be made aware of the benefit of promotional leadership activities, sustained through the entire HACCP process, as a fundamental tool in staff empowerment throughout the factory hierarchy, encouraging staff to take ownership and accountability for the HACCP.
- Food industry managers need to appreciate that, whilst the solution for controlling hazards need not be the most expensive option, it is essential that control measures for significant hazards at CCPs be validated and verified as effective.
- Managers should recognise the need to keep levels of food safety and hygiene knowledge high in the general workforce. Recognition of this need is important for all food businesses that might need to go through commercial restructuring.
- Companies must ensure that HACCP and food safety audit schedules are adhered to and that periodic reviews of HACCP plan validity, i.e. is it still suitable to control all likely hazards, are carried out.
- Companies need to develop robust change management systems that trigger a food safety review for all proposed changes to ingredients, processes, products and operating procedures.

- The use of independent interview as an in-depth review and reflection technique, allowing personnel and businesses to 'take stock' of their progress and learning through HACCP, is recommended as an approach that can assist in renewing focus and motivation in the HACCP System.

7.4.6 Recommendations for Regulators and Guideline Setters

- Further detailed guidance and emphasis on the necessary steps for HACCP maintenance, including verification, review and change management procedure requirements, would be beneficial for food companies.

7.4.7 Conclusions

In support of the other elements of this research, it can be concluded that the interview process was a useful way to gain an in-depth understanding of people's beliefs about the operation of HACCP at their manufacturing sites. The thematic networks analysis provided a highly visual portrayal of the resulting interview data, providing support to the notion that successful HACCP requires the interplay of a number of 'Business Factors', including the operational management and personnel factors discussed in this chapter. Other factors believed to be important for HACCP effectiveness have been identified in the preceding chapters. Further exploration of these HACCP success factors will be delineated in the following chapter (8) such that the impact of personnel, training, culture and organisational factors on effective use of the HACCP system for food safety management in a multinational organisation can be evaluated.

Chapter 8 Discussion

8.1 Introduction

This has been a broad-ranging investigation into HACCP effectiveness in the context of a multinational food company's operations. Using an eclectic mix of methodology it has been possible to gain detailed knowledge of 'what makes HACCP tick' within food manufacturing sites. The aims set out at the beginning of this study were:

Within the setting of a multinational food company, to:

v. Establish strategies for the assessment of HACCP effectiveness;
vi. Evaluate the impact of training on successful HACCP development, implementation and maintenance;
vii. Characterise the relationship between national/cultural issues, business/organisational factors, personnel and training on HACCP effectiveness;
viii. Make recommendations for HACCP training and support strategy in multinational organisations.

The programme of work has allowed aims to be met, as delineated in the preceding chapters. In this final discussion chapter, the interaction of findings from the different research elements will be considered to allow extension of the understanding of HACCP processes in international manufacturing, with reference to the effectiveness of HACCP systems.

8.2 Boundaries, Strengths and Limitations

This study involved investigation of factors impacting HACCP success in one multinational organisation. The phase 1 preliminary study involved fourteen manufacturing sites and phase 2 involved deeper investigation of five case study sites within one region of the multinational food manufacturer. Whilst it is likely that this company's experiences of HACCP are typical of similar multinational organisations, this cannot be determined, and so it is possible that differences in the findings may have been experienced if different companies had been studied. It is also possible that differences might be seen for companies manufacturing products of higher inherent food safety risk than the microbiologically shelf-stable products manufactured here. Nevertheless, a number of striking findings emerged from the study, which are likely to affect multinational manufacturers and, in fact, all food companies to a greater or lesser extent. Thus the recommendations made here for food companies and regulation/guideline setters need to be established and adopted in the wider food safety community.

Strengths and limitations of the specific approaches used have been described in the individual chapters. An overall strength of this research is its use of mixed methodology, providing a rich source of both qualitative and quantitative data, which allowed detailed exploration of HACCP within this multinational organisation.

8.3 HACCP in the Third Millennium – From Space Food to a Global Food Safety Approach

As described in Chapters 1 and 5, the HACCP System had its origins in the US space programme (Ross-Nazzal, 2007; Bauman, 1993). What started as a concept for preventing illness in a high profile, capital-rich project has spread throughout the world and become accepted by industry, regulators, guideline-setters and experts as the approach to management of food safety in the global supply chain (Mortimore and Wallace, 1998; Codex, 2003; GFSI, 2007; WHO, 2007[b]; BRC, 2008).

The progress of the HACCP system to become the approach of choice for managing food safety follows diffusion of innovations theory (Rogers, 2003). Diffusion is defined as 'the process by which an innovation is communicated through certain channels over time among the members of a social system' (Rogers, 2003, p11). The communication channels spread the message about the innovation, convincing more people, companies or organisations to adopt the innovation and the rate of innovation is affected by a number of factors, including social structures and system norms, the presence and reaction of opinion leaders and the perceived consequences of the innovation (Rogers, 2003). With regard to the HACCP system, the perceived consequences of safer food and protection of public health have been key reasons for the adoption. Following the initial communication of the innovation from Pillsbury to the wider US food industry in the early 1970s (Bauman, 1993), the flow of HACCP throughout the world was influenced by opinion leaders; initially Howard

Bauman himself and then followed by groups of scientific experts who recognised the theoretical benefits of HACCP and/or were involved in early adopter companies. This 'invisible college of HACCP experts' (Demortain, 2007, p9) acted as change agents (Rogers, 2003), influencing the innovation adoption decisions of others via the national (e.g. US NACMCF) and international (e.g. Joint FAO/WHO Codex Alimentarius) food safety committees and conference platforms, and leading to the publication and adoption of HACCP Principles and guidelines (NACMCF, 1992, 1997; Codex, 1993, 1997[a], 2003). These positive views of the preventative advantage of HACCP led to its take-up by many large food companies around the world and further diffusion to smaller companies, fed by continued communication and, more recently, legislative frameworks (E.g. EC 852/2004).

In completing this thesis 38 years after the first public discussion of the HACCP concept in 1971 (Bauman, 1993; Mortimore and Wallace, 1998), it is interesting to note the progress of HACCP around the world, however it is disturbing that multinational food manufacturers can still have significant weaknesses in their HACCP systems, as was found in elements of this research. The following sections consider some of the reasons for these findings and make recommendations to improve the effectiveness of the HACCP system in multinational food manufacturing.

8.4 Entering New Territory – Reconfiguration of Knowledge about HACCP

This research has provided a detailed understanding of the processes involved in HACCP application within multinational organisations. It has confirmed some of the previously held, but unproven, beliefs about factors impacting HACCP success and has established new knowledge in a number of areas, in particular the importance of HACCP team make-up and interactions within HACCP teams. Weaknesses in HACCP systems operating in multinational manufacturing have been highlighted and recommendations have been made for the provision of more guidance and assistance to HACCP teams and for the need for assessment as part of the HACCP process. This has been facilitated by the development and publication of new tools that can be used by the food industry to improve the security of its HACCP systems.

8.5 Establishing HACCP Impact Factors

At the start of this thesis (Chapter 1, Figure 1.6) it was postulated that HACCP Impact Factors were likely to fall into three main groupings of Personnel Factors, Operational Management Factors and Environmental Factors. There now follows a discussion of the key findings from the different elements of the research in the context of this prediction.

8.5.1 HACCP and Personnel

Personnel factors likely to be important in HACCP success were predicted to include training and knowledge, and personnel interactions and decisions (Chapter 1, Figure 1.6).

a) HACCP, Training and Knowledge

An understanding of the important roles of training and HACCP knowledge was gained from work in both the preliminary study and the case study research, as described in Chapters 2, 4, 5 and 7. The importance of training in HACCP Principles had been identified (WHO, 1993, 1995; Mortimore and Wallace, 1998; Codex, 2003; Williams *et al*, 2003; Egan *et al*, 2007) yet there were few measures of the standards of training being offered or the effectiveness of learning that training delivers (Mortimore and Smith, 1998).

The preliminary study (Chapter 2) established a potential predictive element for the quality of HACCP development, implementation and maintenance, based on HACCP knowledge levels on site, however comparison of predicted HACCP ability with findings from a large desk-top audit programme within the multinational manufacturer showed poor agreement, indicating that there were likely to be additional factors involved in the development of effective HACCP. Nevertheless, additional knowledge testing of individuals and teams at case study sites in the second phase of the research (Chapter 4) indicated that there was indeed a relationship between HACCP knowledge and competence in developing effective HACCP plans at the team level, particularly for hazard analysis, CCP determination and control systems and for overall HACCP plan development.

It is likely that the poor agreement between predicted ability and effectiveness seen in the preliminary study was because individuals rather than HACCP teams were tested at that stage, and these individuals could have been involved in a range of HACCP teams. Predictions had been based on proportions of individuals at each site with suitable knowledge in each of the five HACCP Knowledge Areas (HKAs) and thus the considered likely decisions by the HACCP teams on site, however the precise team membership associated with the HACCP plans assessed in the preliminary study was not known. The relationships shown in Chapter 4 illustrate the ability to predict the quality of a given HACCP plan by testing the knowledge of the HACCP team tasked with developing it, and demonstrate the benefits of HACCP knowledge testing as a useful tool for food companies, both to identify training/retraining needs for the HACCP team and, when combined with individual knowledge testing, to assist in team selection.

Data from Chapter 5 on HACCP team decision making show that individual knowledge as part of team composition is important however the team decision is affected by both the knowledge and a number of other factors. The likelihood of the team's holistic HACCP Knowledge (Cooke *et al*, 2000) being better than the collective knowledge of individual team members will depend partly on the number of individuals with good knowledge within the team as a 'dumbing down' effect from the best individuals was clearly seen in this study

(Chapter 4), and this is supported by team composition and effectiveness literature (Sundstrom *et al*, 1990; Devine and Philips, 2001; Mathieu *et al*, 2008). As a HACCP practitioner, this was surprising to the researcher since the collective wisdom of generally held beliefs amongst fellow HACCP practitioners and experts (Palmer, pers. comm.) is that the team will be better than individuals at applying HACCP principles to develop a HACCP plan. However if the team consists mainly of people with poor knowledge of HACCP Principle application, with proportionally fewer individuals with good knowledge, there is the very real risk of errors in HACCP plan development leading to food safety problems. Thus it is beneficial for food companies to understand the levels of HACCP knowledge that different individuals possess to allow balanced HACCP team selection, and it was recommended (Chapter 4) that companies consider assigning a specialist 'HACCP Process Facilitator' role to individuals with excellent HACCP knowledge. This would allow these individuals to keep the team on track through HACCP Principle application and allow other team members to concentrate on their discipline specialism.

As stated in Chapter 4, knowledge of HACCP principles does not necessarily imply that all potential hazards will be identified nor that an appropriate understanding of severity or likelihood of occurrence will be available on site to allow correct determination of significant hazards, nor that appropriate knowledge of suitable control measures and their management will be in place. This correlates with findings on HACCP effectiveness (Chapter 3) where limitations with hazard identification and significance assessment were found. It is therefore important to ensure that HACCP team members have the correct blend of training, skills and experience to take decisions about food safety hazard management. HACCP team limitations in this aspect need to be identified and external expertise brought in where necessary. For example it is unusual for expert microbiologists to work at site level within a multinational organisation so this level of expertise could be brought in from corporate departments or outside the company. A recommendation was made (Chapter 3) that companies seek to understand the skills and knowledge limitations of HACCP team members and ensure adequate resource is provided to supplement the team.

Further insight into the importance of training came from the HACCP interview data (Chapter 7), which triangulates some of the findings of HACCP knowledge and team decision elements of the research. The organising theme of 'Building Capability' in the 'Training and Development' thematic network illustrates this well, as 'Training' and 'Knowledge of Hazards and HACCP Processes' were identified by interviewees as key factors for HACCP success, and 'Building Skills' and the 'Knowledge Base' required for HACCP were further basic themes that emerged. The further organising theme of 'Communication' included the basic theme of 'Generating Collective Wisdom'.

Although HACCP training impacts individual and HACCP team knowledge, it can be seen that whether this knowledge impacts the outcome of the HACCP plan also depends on a number of other factors, including:

- Team make-up and skills
- Team decision-making models
- Knowledge of hazards, their significance and suitable control procedures

- Culture
- Organisational support

These factors can be further explored by considering the findings of other research elements.

b) HACCP, personnel interactions and decisions

Since HACCP is a system that relies heavily on teamwork (Mortimore and Wallace, 1998; WHO 1993; Codex 2003) the actions of teams and interactions between individuals and their fellow team members are important in HACCP success. Further to the key finding that HACCP team knowledge was not necessarily as good as the best team members (as discussed above) was the finding that an effect of the team scribe on team decisions was seen from the observational data (Chapter 5). The importance of these personnel interactions and decisions on HACCP effectiveness has been discussed, with reference to the potential for incorrect decisions affecting product safety and recommendations have been made on HACCP team roles and training.

Further exploration of the importance of personnel interactions within HACCP was provided through the interview data (Chapter 7), where different levels of personnel from each factory hierarchy talked about aspects such as their 'Involvement', 'Commitment', 'Motivation' and 'Empowerment'. 'Ownership' and the presence and importance of a 'Supportive Culture' were further themes that emerged and the benefits of team members sharing knowledge and 'Challenging Each Other' were important in 'Developing Common Understandings'.

In fact HACCP training of the complete team is considered by some to be as much about motivation, team building and creating ownership than about achieving the same level of HACCP knowledge in all team members (Heathcock, pers. comm.; Mortimore, pers. comm.). This corroborates the findings from the interview data (Chapter 7) where training and involvement in prerequisite programmes and HACCP were seen as motivational for members of the site hierarchy, and the 'Supportive Culture' of 'Involvement' generated by the HACCP team was identified as a key positive factor in breaking down barriers on site.

The interview process was reported to have given benefits to the sites in addition to its aim of data collection. It was found to be a useful tool for personnel in the reflective contemplation of the HACCP process at each site, and in highlighting how hard people had worked and the benefits they had gained. This was said to have created a 'buzz' about HACCP and food safety, and to have given the site teams a new depth of focus and an eagerness to continue on the HACCP pathway. This suggested that use of such an in-depth review and reflection technique would have benefits for other companies working with HACCP Systems and a recommendation was, therefore, made to consider use of independent interview to allow personnel and businesses to 'take stock' of their progress and learning through HACCP, thus renewing focus and motivation in the HACCP System.

8.5.2 HACCP and Operational Management Factors

Operational Management Factors include the business /organisational factors that might impact HACCP. HACCP impact factor groupings suggested in Chapter 1 (Figure 1.6) included Operational Management factors such as management commitment, resources and management support for the ongoing functioning of HACCP systems. The semi-structured interview process (Chapter 7) allowed these factors to be explored in detail with personnel throughout the management hierarchy at each manufacturing site. Thematic networks emerging from the interview data provided clear support for the importance of 'Committed Leadership' and 'Resource Management' for effective HACCP, and the organising theme of 'Management Processes' in the 'Embedding the System' thematic network provided further clarity on the necessity for ongoing management support to keep HACCP working over time.

a) Management Commitment

Personnel believed that management commitment and support had been available to them and that managers had played important roles in promoting HACCP as the essential food safety management system for their business, in setting and monitoring the achievement of progress targets, empowering their staff and in mobilising the necessary resources for HACCP. This confirms beliefs of the importance of management commitment to HACCP success (Mortimore and Wallace, 1998; Panisello and Quantick, 2001).

b) Resources and Support

Management commitment was also seen as essential to ensure the provision of adequate resources for HACCP in terms of time and financial support, and ongoing resource management was clearly key to HACCP success. The fact that many of the elements of the 'Resource Management' thematic network corresponded to items that had previously been identified as barriers to HACCP success (Bas *et al*, 2007; Gilling *et al*, 2001; Panisello and Quantick, 2001; Taylor and Taylor 2004[a]) underlines their importance in the HACCP process and suggests that these should be seen as important things to get right rather than challenges that stop companies from using HACCP.

8.5.3 HACCP and Environmental Factors

Figure 1.6 also highlighted potential Environmental Factors that were considered likely to impact HACCP success, including external pressures such as legislative, customer or corporate requirements to use HACCP and national/regional cultural dimensions.

a) External Pressures – Legislative, Customer and Corporate Requirements

All sites involved in the research were exposed to at least one external pressure to use HACCP since it was a corporate requirement of the multinational manufacturer. Some sites in phase two of the research were also expected to have HACCP in place by external customers, at least for specified process areas, and one site was required by law to have a food safety management system based on HACCP principles. Whilst these environmental factors are clearly important in starting sites off on the HACCP journey, they did not appear to impact the effectiveness of the HACCP systems produced as weaknesses were highlighted in the systems at all locations in the phase two case studies. This suggests that it is not just the pressure for HACCP stemming from these environmental factors that is important but, crucially, the quality of effectiveness assessment performed once the systems are developed.

b) HACCP and National Culture

National Culture is thought to be one of the Environmental Factors (Chapter 1, Figure 1.6) that may impact HACCP effectiveness and, although HACCP is a system developed in Western settings that has diffused into the globally accepted approach, the potential impact of national culture had not been studied previously. Research on the impact of national cultural dimensions on HACCP application was described in Chapter 6, with individualism-collectivism and power distance (Hofstede, 2001) predicted to have the most likely impact on HACCP. Countries for phase 2 of the research were chosen to give a likely spread of national cultural characteristics based on the previous work by Hofstede (2001). Whilst it was possible to establish positioning on the national cultural dimensions scales for all countries and manufacturing sites in this study and to compare with findings on HACCP effectiveness, the spread on the national cultural dimensions was much tighter than expected. This was suggestive of changes in culture within the countries chosen since Hofstede's (2001) original work in the 1960s and 1970s, however it also made determination of the impact of national culture on HACCP problematic since the country results were close together on the dimensions scales. The data did show a slight suggestion of a relationship between power distance and both HACCP knowledge and effectiveness, however further study with a wider range of countries would be needed to further investigate potential differences.

From the interview data (Chapter 7) a number of points suggested a wider impact of HACCP in India than simply production of safe food. As a developing country the management teams understood the need to raise cultural awareness and up-skill staff considerably, particularly in the basic prerequisite programme elements such as hand-washing. However it was the comments from line operators that truly put this into context, when talking about how they had taken this learning into their personal lives, e.g. by teaching their families about the importance of hand-washing at home. Managers and Supervisors also identified the 'Confidence' and 'Pride' that being part of the HACCP initiative had given to staff on their sites, particularly highlighting the pride of working to multinational standards. These apparent motivational effects of improving standards above what might normally be expected in a developing country (Marthi, 1999) may also be important to other multinational manufacturers and so may benefit from further cross-cultural study.

8.6 Rethinking HACCP Effectiveness and its assessment

An overall theme running throughout this research was that of HACCP effectiveness, with particular reference to establishment of strategies for the assessment of HACCP effectiveness, and consideration of how effectiveness might be impacted by the range of factors discussed above (8.5). It was, therefore, necessary to establish measures of HACCP effectiveness against which impact factors could be considered.

This research proposed new methods for the assessment of HACCP effectiveness (Wallace *et al* 2005[b]; Chapter 2; Appendices 1.2 and 2.4/5) and used these tools both in the phase 1 preliminary study and the phase 2 in depth study of HACCP at case study sites. The methods proved to be practical and workable in assessing HACCP effectiveness, giving a balance of checklist consistency and expert judgement (ISO, 2002). Application of this strategy provided substantial data on system effectiveness and identified a number of weaknesses in HACCP application, which will be discussed below. However, since the start of this research and data collection activities, a number of other initiatives on the assessment of HACCP and food safety management systems have been reported and therefore need to be considered.

Albersmeier *et al* (2009) report on the effectiveness of third-party certification audits in the food chain, and recommend a move from checklists to what they describe as 'risk-orientated auditing'. This is based on findings that there are differences in audit judgements between auditing companies and between individual auditors working for the same auditing companies where a detailed checklist approach was used (Albersmeier et al, 2009). However, although a number of potential reasons for differences in audit judgements are postulated, the authors provide no convincing evidence to suggest that this is due to the checklist approach or that their risk orientated audit approach, which they describe as focussing more strongly on the auditor's personal responsibility whilst allowing the auditor more leeway to act, will be more effective. The approach described in the study reported here, which is both checklist based and requires HACCP expertise in its application, should provide a more effective assessment across a range of sites, since it allows for consistency of application and auditor expert judgement (Ababouch, 2000; Quinn and Marriott, 2002; Wallace et al, 2005[b]).

Jacxens *et al* (2009) describe a microbial assessment scheme to measure microbial performance of food safety management systems. This is of concern as, since one of the reasons cited for moving away from testing to a preventative food safety control system is the limitations of microbial sampling and testing (Codex, 1997[b]; Mortimore and Wallace, 1998; WHO, 1980), it seems like a retrograde step to go back to microbiological testing as such a key component of food safety assurance. In fact Jacxens *et al* (2009, p114) discuss the identification of 'critical sampling locations' thus:

> 'Critical sampling locations (CSL) are defined as locations where microbial sampling provides information about the performance of core control strategies...[...]...loss of control at these locations will lead to unacceptable food safety problems due to contamination, growth and/or survival of microorganisms.'

This would seem to be suggesting microbial sampling at critical control points and, although it is recognised that microbiological results can play a role in verification of HACCP effectiveness, the proposed microbial assessment scheme may lead to confusion with CCP monitoring and a higher profile role for this retrospective and costly analysis. The dangers of giving too much emphasis to microbiological test results were clearly seen in a recent high profile food safety incident, where salmonella-contaminated food was released due to beliefs that the low levels detected in the test would not cause harm to the consumer (Health Protection Agency, 2006, ACMSF, 2006).

Panunzio *et al*, 2007, describe a system of 'Indexes and Indicators for the Quality Evaluation of HACCP Plans' from work on Italian Official Controls Systems. This is based on the four elements of *specificity* (to the individual business), *simplicity* (without superfluous elements), *feasibility* (practical for the operation) and *adherence* (to HACCP Principles and approach). Whilst the aims of this system are laudable in assuring effective HACCP, the HACCP plan evaluation grid that is at its core is overly simplified and misses several important judgements. For example, the approach asks if hazards are described but there appears to be no judgement of whether the hazards are significant for food safety. Similarly the approach asks if control sheets are present for monitoring CCPs but does not appear to look at monitoring effectiveness, nor to challenge any HACCP maintenance procedures. Some improvements to other published audit checklists have been seen, however, an example being the American Institute of Baking (AIB) HACCP Standard audit checklist (2006). The AIB instrument was published after the findings of the preliminary study (Wallace *et al*, 2005[b]), and does include some elements that challenge effectiveness when evaluating HACCP plans, as recommended by Wallace *et al* (2005[b]), e.g. whether the CCPs identified are the correct ones, although this instrument could still be further strengthened.

Luning *et al* (2008) discuss a diagnostic instrument for differentiated assessment of food safety control systems. This is a systems maturity profile approach based on the Quality Management Maturity Grid (Crosby, 1979) and, as such, provides a useful approach to measuring progress and continuous improvement in food safety control systems, including HACCP. However the findings of this research study suggest that there are still weaknesses in the basic application of HACCP Principles such that some food companies or manufacturing sites may not yet be ready for measurement on a maturity scale. Nevertheless, the Luning *et al* tool (2008) is considered to be a useful addition for the field of HACCP assessment, and a combination of the assessment tools proposed here (Wallace *et al*, 2005[b]) and a systems maturity diagnostic instrument (Luning *et al*, 2008) might prove a next step forward in HACCP effectiveness assessment.

Van der Spiegel *et al* (2003, 2005 and 2007) have been active in development of tools to measure the effectiveness of food quality systems. Quality may be defined as fitness for purpose (Juran, 2000) and is often considered in terms of meeting customer requirements as well as being free from deficiencies (ISO, 2005; Juran, 2000). Food safety is an implicit customer requirement of any food product and can therefore be considered a subset of product quality. In the effectiveness measures for quality systems proposed by Van der Speigel *et al* (2007), the individual variables and constructs being evaluated are generalised quality attributes that do not necessarily affect product safety. For example, Van der Speigel *et al* (2007) include percentage of reject products, percentage of complaints about product quality and availability in their list of variables for measuring product quality as an element of quality system effectiveness. Effectiveness measures for Total Quality Management (TQM) systems are often based around the 'cost of quality' concept where costs of failure and costs of getting it right, e.g. inspection and prevention costs, are measured (Zugarramurdi *et al*, 2007). Because HACCP is a preventative, 'right first time' system with the aim of producing safe food for consumption, CCP management systems are generally set-up to be 'fail-safe'. Percentage of reject products might be an indicator of poor quality, but it is the effectiveness of the corrective action loop at CCPs that is significant for food safety and not the percentage of products rejected. Therefore a number of CCP failures is not necessarily a negative aspect of HACCP effectiveness, it is how the CCP failure is resolved using defined corrective action that is important. The true measure of effectiveness is that no unsafe food reaches the consumer. Unlike a quality attribute where the consumer can complain to the manufacturer, a food safety failure can directly affect the consumer's health and even endanger life. Customer complaints are therefore too late and not an appropriate measure of food safety effectiveness, apart from to confirm that the safety control system is working through an absence of food safety complaints. For these reasons this approach to measuring effectiveness of quality management systems is not considered helpful in measuring HACCP effectiveness and, of the recent developments in the field of HACCP and food safety assessment described above, the food safety maturity diagnostic tool proposed by Luning *et al* (2008) is considered to be the most useful, particularly if combined with the assessment framework design from this research (Wallace *et al*, 2005[b]) as previously mentioned.

The findings of effectiveness assessment in this research (Chapters 2 and 3) highlighted a number of weaknesses in HACCP plans that were operating at manufacturing sites. Whilst the preliminary study suggested particular weaknesses in the application of HACCP Principles 1: Conduct a Hazard Analysis and 2: Establish Critical Control Points from desk-top assessment of HACCP plans, the in-depth HACCP assessments at site level (Chapter 3) gave a deeper understanding of the effectiveness of HACCP plans in operation. With regard to the application of HACCP Principle 1, problems were found with hazard significance assessment, including both under and over-identification of significant hazards and failure to identify likely hazards, and confusion was also seen between control measures and monitoring procedures. Review of international HACCP guidelines (Codex, 2003) highlighted that no specific advice or tools are provided to help in the determination of significant hazards and, since this is an area requiring that HACCP teams apply substantial judgement and experience, it was questioned whether HACCP team members working in day-to-day factory roles have the ability to or should be expected to take these decisions without assistance. This led to the recommendations for Standard and Guidelines Setters that further detailed guidance on how to approach hazard analysis needs to be considered in order to assist food companies and that publication of recommendations on the levels of expertise and competence needed to successfully analyse hazards and take critical food safety decisions would also be beneficial.

Within the HACCP plan documentation, weaknesses were again found in the application of HACCP Principle 2: Identify CCPs and it was highlighted that even where teams are competent in CCP identification via the Codex (2003) Decision Tree or other procedures, failures at the previous step of hazard analysis could lead to hazards not being considered in the CCP decision process and hence failure to identify required CCPs and risks to consumer health could ensue. A potential limitation of HACCP audit is also suggested by these findings since HACCP audit often focuses on identified CCPs and their management in practice, as was done in this case. It is therefore vital that HACCP auditors have sufficient expertise and experience in the product sector as well as competence in assessing HACCP, such that errors and omissions by HACCP teams can be picked up and recommendation for rectification immediately highlighted. Recommendations to standards and guideline setters were also made in this area. Further flaws were identified in the application of HACCP Principle 4: Establish Monitoring Procedures, including missing elements of monitoring procedures, so that issues had been identified with the application of three out of the five HACCP Principles applied in the HACCP Development Phase.

Assessment of the implemented HACCP systems working in practice highlighted further problems with monitoring and recording procedures and HACCP maintenance requirements, leading to the judgement that the HACCP systems were not fully effective and had potential implications for product safety. This was corroborated by the interview data (Chapter 7) where individuals highlighted both the challenges of applying HACCP Principles and the implementation difficulties concerned with brining the system down to working on the shop floor.

The Guidance available on HACCP Principle application (Mortimore and Wallace 1998, 2001; Codex 2003) should, if followed, assist food manufacturers to overcome most of the weaknesses identified in the HACCP assessments in this research. Hence, although the areas where difficulties were seen were not new, with the breadth of support material and training available, it was surprising to see that HACCP plans operating at manufacturing sites of a multinational manufacturer should have so many flaws in their application. This raises concern about the status of HACCP plans operating in food manufacturing companies throughout the world. This is of even more concern as there has been a widespread lobby in recent years that 'manufacturing has done HACCP' and that focus needs to shift to the catering arena (Airey, 2005). The findings of this research demonstrate that this is clearly untrue, at least in this organisation, and it is likely that there are many other manufacturing sites around the world with similar problems. The findings of the public enquiry into the recent *E. coli* O157:H7 outbreak in South Wales (Pennington, 2009) further support the position that it is dangerous to assume that 'manufacturing has done HACCP'. In that outbreak the manufacturer, albeit a much smaller company than the multinational organisation described here, had a HACCP plan on file, although it bore little resemblance to the operation, and which, compounded with other serious flaws in prerequisite programmes, management and fraud on the part of the business owner, allowed the outbreak to occur (Pennington, 2009). It also highlighted the weaknesses in HACCP assessment by local authority environmental health practitioners, bringing into question their training and capability in assessment of HACCP systems (Pennington, 2009), and further supporting the recommendation made here that HACCP auditors must have sufficient expertise and experience in the product sector and in assessing HACCP.

8.7 Reconsidering HACCP and Risk

The terms 'risk' and 'risk assessment' are not included in the internationally accepted HACCP Principles (Codex, 2003), however HACCP is, in effect, a tool for managing risk to health caused by potentially hazardous foods and Codex (2003) does recommend that implementation of HACCP should be guided by scientific evidence of risks to human health. Use of the term 'risk assessment' in HACCP has been reported to cause confusion (Sperber, 2001) since the process of formal risk assessment is a quantitative process, normally carried out at government/national level or higher to consider the risk of hazards at the population level (Havelaar *et al*, 2007). This compares with the more qualitative evaluation of hazards, specifically their likelihood of occurrence and severity of outcome, that is completed by the HACCP team for assessment of hazard significance during a HACCP study (Sperber, 2001). Nevertheless, the terms 'risk' and 'risk assessment' are still widely used by food companies (Mortimore, pers. comm.) and structured risk assessment tools may be used by large food companies wishing to standardise the approach taken by HACCP teams at a number of sites (Palmer, pers. comm.). In this research these tools were seen in operation at several sites and flaws were seen at 3/5 sites using them. This is likely to be because of expertise gaps in applying the tools and/or in capability to take decisions about hazard severity and likelihood of occurrence at site level. It seems clear that further guidance is essential in this aspect of HACCP application and that it would be beneficial for Codex to provide further focussed assistance in this area.

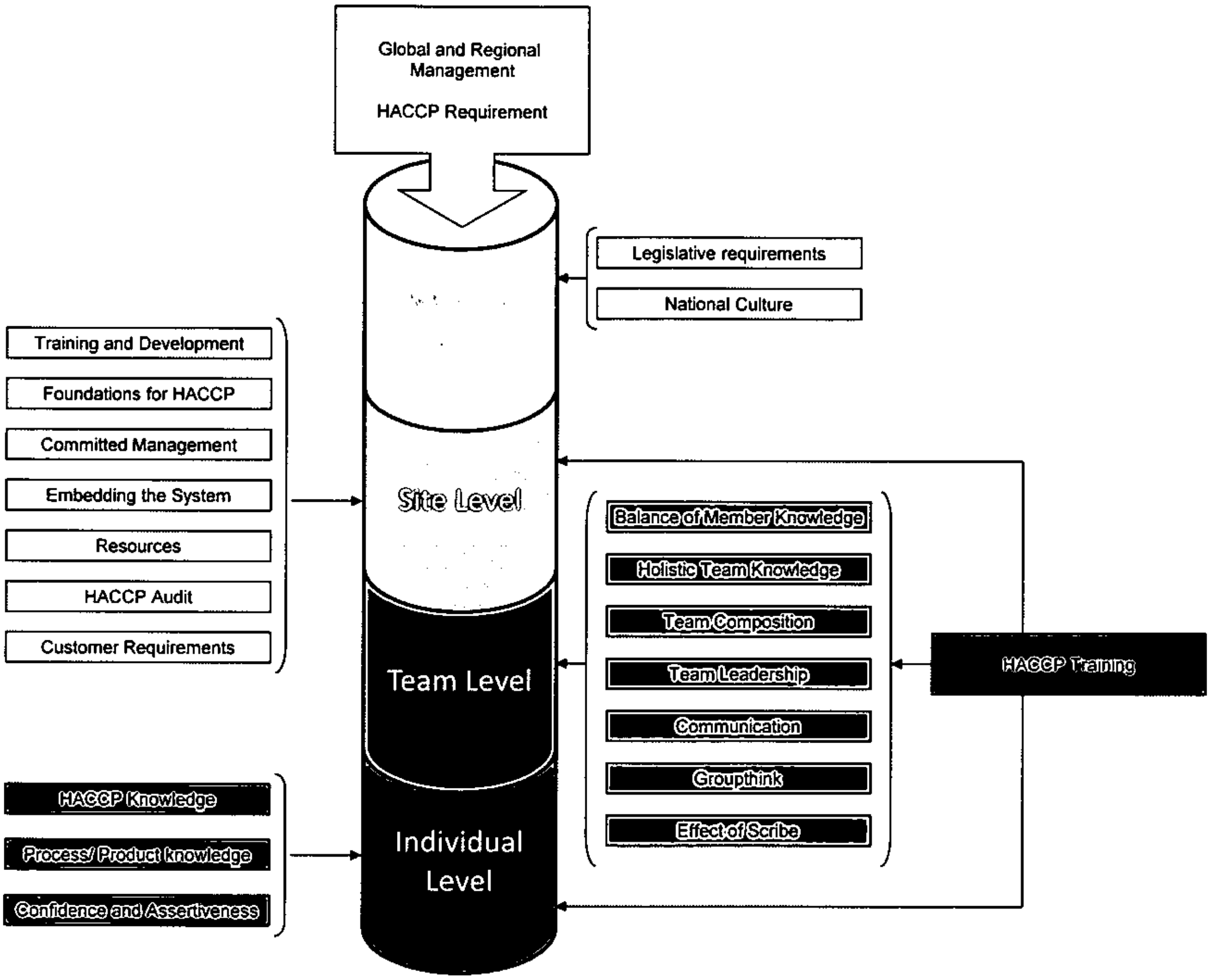
Risk also enters the HACCP debate in terms of the inherent product and/or process risk dependent on the sector of the food industry in which a particular company works, and is usually related to the likelihood of the product being contaminated with, or likely to support the growth of, food pathogens. Although the terms high risk and low risk foods are widely used in industrial settings, there are few definitions available. However the Food Law Code of Practice for England (FSA, 2009) defines high risk foods as 'foods which support the growth of microorganisms or their toxins'. With regard to this definition, the multinational food manufacturer studied in this research would not have been considered to make high risk products, as all products were inherently shelf-stable. This raises the question of whether deficiencies found at such a manufacturer are because the products made are seen by managers to be of low risk and therefore less focus is given to food safety requirements than might be at a manufacturer of high risk products. This is considered to be unlikely because the interview data (Chapter 7) clearly identified the importance of management commitment and senior manager's key role in promoting HACCP use as part of the 'Committed Leadership' HACCP thematic network. It is also not possible to establish if similar levels of deficiencies would be found at a manufacturer of higher risk products, or at a manufacturer supplying primarily private label customers (As a branded product manufacturer, this company would not have been exposed to the requirements of private label manufacturers, e.g. BRC (2008)). However, given that the numbers and levels of personnel at these factories are likely to be typical of manufacturing sites of similar size, that there were at least some people with reasonable HACCP knowledge at each site (Chapter 4), and that most sites had been exposed to external audit of their food safety systems, it is reasonable to conclude that the findings could be typical of multinational food manufacturers in general. This raises concern about the safety of the food chain and suggests that focus on assessment of the effectiveness of HACCP systems in food manufacturing is necessary to establish and improve standards of application.

8.8 A new model of HACCP Effectiveness

From the findings of this research, the following model is proposed for the impact of personnel, training, culture and organisational factors on application of the HACCP system of food safety management in a multinational organisation (Figure 8.1). This model indicates the impact factors operating at different levels of the multinational organisation, namely national, site, team and individual levels. Whilst not intended to depict a linear process, there is diffusion of impact between levels, e.g. the global requirements to implement HACCP, both from global management and legislative standards, may be received at national level but the impact resonates through all levels of the business. Similarly, the effects of national culture would be expected to exist at national level but will affect interactions of individuals and teams within the structure, and the confidence, assertiveness and knowledge, in both HACCP

Principles and site processes, of the individuals at each site will have impact on HACCP team competence and the effectiveness of HACCP at the site level.

Figure 8.1 Factors Impacting HACCP Success



8.9 Implications and recommendations for Multinational Food Manufacturing Organisations

The implications of this research for multinational food manufacturing organisations are wide-ranging, from HACCP team make-up and training, through factors found to be important in successful HACCP, to the importance of HACCP effectiveness assessment. Recommendations for multinational organisations, and, indeed, for other food manufacturing businesses, have been highlighted in the preceding chapters of this thesis and a summary list is provided in Appendix 8.1.

8.10 Implications and recommendations for Standards and Guideline Developers

The implications of this research include that further guidance is needed by food companies and HACCP teams for more effective application of HACCP Principles. Recommendations for developers of Standards and Guidelines have been highlighted in the preceding chapters of this thesis and a summary list is provided in Appendix 8.2.

8.11 Future Research

Several areas have been identified where further research would be beneficial. These included:

- Further study of HACCP team decision-making, including the interactions between individuals, actions of the scribe, and individual vs. team skills;
- A larger study of national culture and HACCP;
- Study of Team Roles (Belbin, 1993) and HACCP team selection;
- Further work on HACCP assessment in multinational companies, perhaps involving refinement to the published audit tools; and
- Supplementary study of the HACCP interview data, with possible extension to other multinational food companies.

Future work in these areas would build on the findings discussed here and allow further extension of the understanding of HACCP effectiveness, thus enabling further guidance to food companies in support of consumer protection.

8.12 Conclusions

Overall the picture that emerged from this research was of factories where management and staff were committed to ensuring that their products were safe for their consumers. People had been on a learning journey as they worked through the stages of HACCP and there was appreciation within management teams of what had been achieved. Whilst there were limitations in the HACCP plans that had been developed and this gave potential for impact on food safety, deficiencies generally came from lack of knowledge, understanding or technical expertise or from previously unstudied effects of interactions within HACCP teams. This indicates the need for further detailed guidance both on HACCP Principle application and in essential levels of skill and knowledge needed by HACCP team members. There were also many good things reported as coming out of the HACCP system, including improvements in hygiene standards and awareness, product safety and quality, and better communication and motivation of personnel, including the delivery of confidence and pride down to the factory floor. Sharing of this good practice, in addition to provision of the necessary additional support to HACCP teams, should enable further diffusion of the HACCP innovation throughout the global food supply chain.

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