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

Volume 2 of 2

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Peer Reviewed Paper:

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Post-training assessment of HACCP knowledge: its use as a predictor of effective HACCP development, implementation and maintenance in food manufacturing

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Abstract

Purpose – HACCP training is acknowledged as a key requirement for the development of effective HACCP systems. However, there are few measures of the standards of training being offered or of the effectiveness of learning that takes place and no agreed methods to measure HACCP knowledge following training. Sets out to investigate this issue.

Design/methodology/approach – A HACCP knowledge questionnaire was developed to measure HACCP team member knowledge following training. Data were collected from 91 individuals in a multinational organisation and predictions were made on likely effectiveness of HACCP systems based on team-member knowledge.

Findings – This paper outlines the preliminary results from a research project investigating the impact of training on effective HACCP implementation in a multinational organisation.

Research limitations/implications – Limitations concerning sample size, timing and possible lack of understanding are discussed.

Originality/value – A new tool to measure HACCP team member knowledge is described and use of HACCP knowledge as a predictor of HACCP system effectiveness is discussed.

Keywords Food safety, Food manufacturing processes, Knowledge management, Training

Paper type Research paper

1. Background

Food safety is an increasingly important public health issue and inadequate food safety control was a key contributor to the 2.1 million deaths from diarrhoeal disease globally in 2000 (WHO, 2002). Annual estimates for industrialised countries indicate that up to 30 per cent of the population are affected by foodborne disease each year (WHO, 2002). Paradoxically, food safety management is an emerging discipline with a limited body of research on effectiveness of foodborne disease prevention strategies. The internationally agreed approach to control of food safety is the joint FAO/Codex[1] hazard analysis and critical control point system (HACCP). Where the HACCP system is understood and applied correctly it is expected to prevent foodborne disease

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(Motarjemi and Kaferstein, 1999). The understanding of the Principles of HACCP is normally achieved through training, which is believed to be a key aspect of successful HACCP (WHO, 1993, 1995; Codex, 1993, 1997; Mortimore and Wallace, 1998, Williams *et al.*, 2003). Training in HACCP is delivered in-house by food companies, by private concerns and by government agencies.

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). Similarly, there are no agreed methods to measure HACCP knowledge following training. This is compounded by a lack of agreed tools internationally to measure the effectiveness of the whole HACCP system. Therefore, not only is the impact of training on HACCP not understood, it is not possible to evaluate the impact of HACCP on standards of food safety. Due to a relative lack of good evidence, the promotion of HACCP by government agencies worldwide as the panacea for foodborne disease control is relatively subjective.

In the UK, the HACCP Training Standards Steering Group (HTSSG) has published introductory and advanced level training standards (UK Steering Group on HACCP Training Standards, 1995, 1999), which have been adopted by a number of training organisations. In the USA, the International HACCP Alliance (1996) has provided a basic course curriculum covering similar areas, as has the Canadian Food Inspection Agency (1995). However, the effectiveness of even these standardised training approaches in terms of food business requirements for the development, implementation and maintenance of working HACCP systems has not been measured.

A typical HACCP training intervention consists of a two to three 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 the requirements of the UK HACCP training standards (UK Steering Group on HACCP Training Standards, 1995, 1999) for HACCP training to be "practically based and contain worked examples". The practical activities allow active learning and practice in knowledge application, consistent with the process of experiential learning (Kolb, 1974).

Experience with a range of food companies has shown that although it is considered that many sites have "done HACCP", frequently the outcome is an inadequate or poorly implemented HACCP System. Many companies also consider that a single training intervention for one or a group of employees is sufficient to achieve development of HACCP. However, experienced HACCP practitioners consider this unlikely (Boccas *et al.*, 2001; Wallace, 2001; de Winter, 1998).

In a multinational organisation there may be a variety of approaches to the application of HACCP at individual sites. This is particularly true where there is a requirement to use HACCP at corporate level but no prescriptive approach to training and the HACCP study process. It is essential to identify the most effective approach(es) in order to make recommendations on global food safety policy and implementation methods.

The present research is based in such a multinational organisation where requirements for HACCP, prerequisite GMP programmes and quality management systems are mandated at corporate level, but responsibility for implementation and

choice of approach are at local level. A corporate HACCP training model is available along with progress review and this option or local support has been taken up by most business units.

The aims of the research pertaining to HACCP training are to:

- establish strategies for assessment of haccp knowledge and haccp effectiveness;
- evaluate the impact of training on successful haccp development, implementation and maintenance; and
- make recommendations for HACCP training and support strategy in multinational organisations.

This preliminary communication describes the development of tools to measure HACCP knowledge following training and explores the potential of HACCP team member knowledge as a predictor of effective HACCP development, implementation and maintenance. Development of methods for standardised HACCP assessment are reported separately (Wallace *et al.*, 2005).

2. Methods

2.1 HACCP knowledge testing

A HACCP questionnaire 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. 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 was validated 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. At validation 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 five HACCP knowledge areas (HKAs) (Figure 1) covering knowledge of HACCP principles and their application (Table I):

The questionnaire (Table II) was administered either by the researcher or a trained quality management professional within the multinational company. A candidate briefing protocol 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.

2.2 Marking scheme

In order to ensure that results were comparable across individuals and sites, a standardised marking scheme was developed. It was also necessary to ensure that the

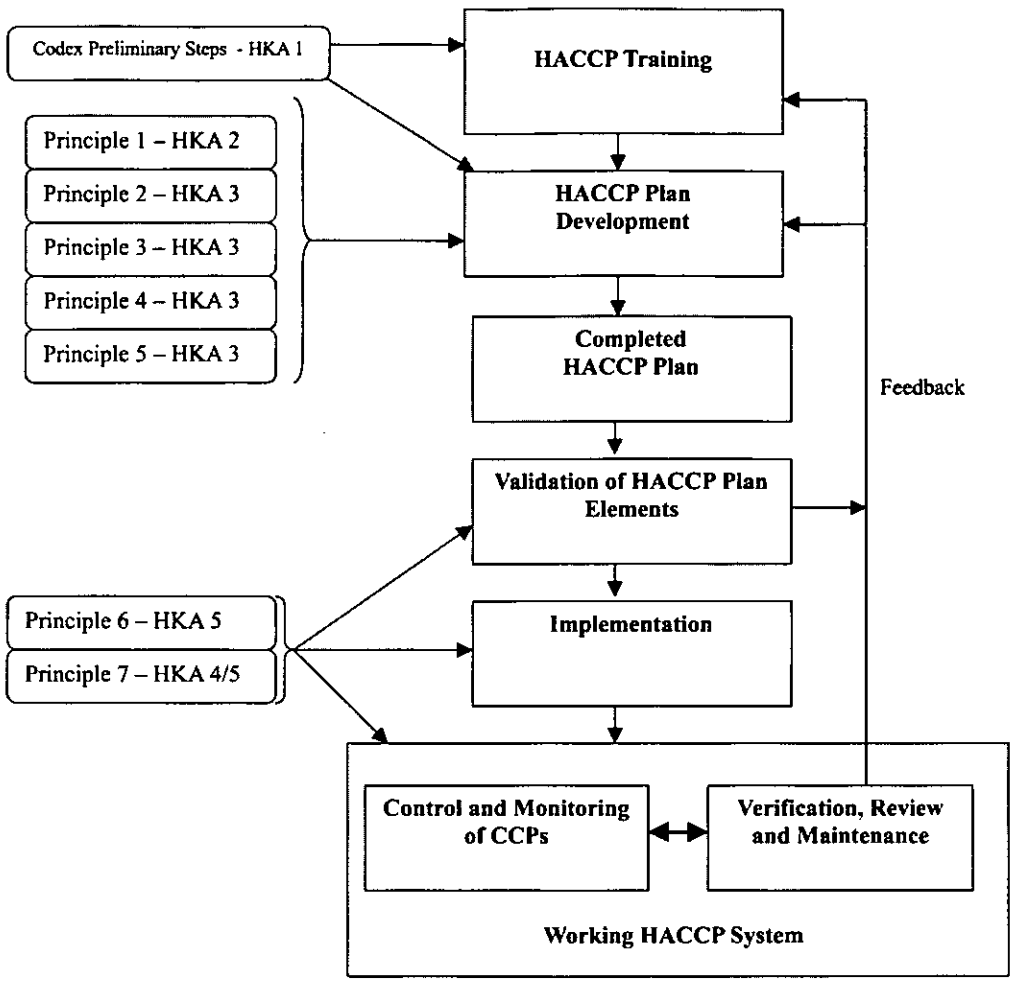

Figure 1.
Relationship of Codex HACCP principles and HACCP knowledge areas (HKAs) to the HACCP development process

Table I.
Knowledge of HACCP principles and their application

HACCP knowledge area	Codex principle(s)
Codex preliminary steps	Codex preliminary steps
Hazard analysis	Principle 1
CCP identification and control	Principles 2-5
HACCP implementation	Principle 7 plus application of work from 1-6
HACCP maintenance	Principles 6-7

marker was independent from the training to prevent any marking bias through knowledge of the trainees. Therefore, after data collection, the submitted questionnaires were assessed by one independent marker using the standardised marking scheme. (Marking rationale is available on application from corresponding author.)

Question no.	HACCP knowledge area	Question	Marks available
1	Hazard analysis	Explain what is meant by a hazard?	2
2	Hazard analysis	Explain what is meant by a control measure?	2
3	Codex preliminary steps	What is the purpose of the process flow diagram in HACCP?	1
4	Codex preliminary steps	Why is it important to validate the process flow diagram?	2
5	CCPs and their control	What is a critical control point?	2
6	CCPs and their control	How can critical control points be identified? List two methods that could be used	2
7	CCPs and their control	What is a critical limit?	1
8	CCPs and their control	Metal detectors are checked every 30 minutes with metal test pieces. What kind of activity is this?	1
9	Implementation	What records might be found in the production area when an HACCP plan has been implemented?	2
10	Implementation	Why is microbiological testing not a good monitoring procedure?	2
11	CCPs and their control	What should happen if there is a deviation from a critical limit?	1.5
12	Implementation	Describe the two main types of corrective action	2
13	Codex preliminary steps	Why is it important that the HACCP study is done by a multidisciplinary team?	1
14	Codex preliminary steps	List the three main disciplines required in a manufacturing HACCP team	3
15	Implementation	What document is completed at the end of a HACCP study?	1
16	Maintenance	List two verification procedures that can be used to determine if the HACCP system is working correctly	2
17	Hazard analysis	Give an example of a hazard from each of the following groups: Microbiological Chemical Physical	3
18	Maintenance	When should an HACCP plan be reviewed?	2
19	Implementation	What type of training is important for line operators when an HACCP plan is implemented in their work area?	2
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
21	Hazard analysis	Suggest a control measure that could be used for hazards associated with raw materials	1.5
22	Hazard analysis	Which two factors should be considered when carrying out the hazard analysis?	2

Table II. HACCP knowledge questions and marking rationale

2.3 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.

2.4 Perception of HACCP ability following training

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

- I had enough knowledge to develop/participate in the development of a HACCP plan straightaway.
- I needed more practice in applying HACCP principles before I was comfortable with developing/participating in the development of a HACCP plan.
- I was unsure of where to start, in order to develop/participate in the development of a HACCP plan.
- Other (please specify).

2.5 Sites and language

The preliminary stage of the research included the administration of the questionnaire to groups of trainees who had received a known level of in-house HACCP training. All respondents 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 III).

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.

2.6 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 considered to be poor where $\leq$ 29 per cent of candidates answered the question correctly; fair where 30-59 per cent of candidates were correct; good at 60-84 per cent; and excellent at $\geq$85 per cent correct. These divisions were chosen to reflect

Country	No. of manufacturing sites	No. of candidates at each site
India[a]	4	10
		10
		10
		8
Zimbabwe[a]	1	2
Egypt[a]	3	15 total across 3 sites (collected as one group)
New Zealand[a]	1	1
South Africa[a]	1	5
Russia[a]	2	14 total across 2 sites (collected as one group)
Indonesia	1	10
China	1	6

Table III.
HACCP knowledge data collection

Note: [a]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

the influence of the team leader and the likely ability of the HACCP teams to work together in these HKAs.

For example, a group of ten candidates completing the questionnaire would normally reflect inclusion of two separate HACCP teams (normal practice is to have HACCP teams of four to six individuals). Less than 29 per cent correct would reflect less than three people in the total group and therefore one to two 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, 2001).

Similarly, in the same group of ten candidates, an overall level of 30-59 per cent would reflect two to three 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 per cent there would be three to four personnel in each team and at ≥ 85 per cent there would be four to five 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 to date but it is the subject of further investigation and will be reported separately.

2.7 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.

3.0 Results and discussion

3.1 General levels of HACCP knowledge

The HACCP Knowledge scores for the test groups are summarised in Table IV. 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 per cent) was seen in the Indonesian group, which also had a low score of 21.1 per cent and a median of 46.7 per cent. Similarly, the scores for India-M ranged from 26.3 per cent to 77.5 per cent with a median of 43.8 per cent. The closest grouped scores were from Russia, ranging from 52.5 per cent to 72.5 per cent and with a median of 57.5 per cent.

Country	No. of manufacturing sites	No. of candidates at each site	HACCP knowledge questionnaire – % scores achieved by candidate group Minimum	Maximum	Median
India[a]	4	10 (site W)	30.0	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)	15.0	65.0	46.3
Zimbabwe[a]	1	2	50.0	50.0	50.0
Egypt[a]	3	15 total across 3 sites (collected as one group)	2.5	20.0	12.5
New Zealand[a]	1	1	57.5	57.5	57.5
South Africa[a]	1	5	25.0	62.5	37.5
Russia[a]	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

Table IV.
HACCP knowledge scores

Note: [a]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

3.2 Time since training and knowledge levels

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

3.3 Perception of HACCP knowledge following training

Results for candidate perception of their ability following training are given in Table VI, 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

No. candidates	Time (months) since training	HACCP knowledge questionnaire – % scores achieved by 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	30.0	57.5	46.3
South Africa (5)	20	25.0	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	15.0	65.0	46.3
Zimbabwe (2)	44	50.0	50.0	50.0
New Zealand (1)	72	57.5	57.5	57.5
Total (91)	NA	2.5	78.9	46.3

Table V.
Time since training and HACCP knowledge

original English version. Perception data are therefore not available for the Chinese and Indonesian groups.

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

3.5 HACCP knowledge and predicted impact on effective HACCP systems
Following analysis of the results in each HKA (Table VII), a judgement on HACCP team knowledge and its likely impact on effective HACCP systems was formed as depicted in Figure 2. 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.

3.6 General levels of HACCP knowledge (Table IV)
The Egyptian group had low levels of knowledge overall, with a range of scores between 2.5 per cent and 20 per cent. Further analysis 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 2 and 1 candidate responses received. Since these sites would both be operating normal sized HACCP teams (four to six 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 has 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 five candidates

Table VI. Perception of HACCP knowledge following training

Perception statement	Number of candidates reporting	HACCP knowledge questionnaire – % scores achieved by candidate group		
		Maximum	Minimum	Median
Enough knowledge to get going	34	77.5	15.0	50.7
Need more practice	42	67.5	2.5	36.9
Unsure where to start	1	65.0	65.0	65.0

Table VII.
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	50.0	50.0	85.0	30.0	60.0	70.0	30.0	0.0	50.0	100.0	100	54.9
	4	32.1	25.0	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	100.0	66.7	60	90	100	100	40	0	62.5	100	0	64.8
	14c	100.0	50.0	80	100	100	90	30	0	62.5	100	100	65.9
Hazard analysis	1	100.0	100.0	75	85	40	50	80	20	62.5	50	100	67.0
	2	92.9	75.0	65	55	40	55	50	30	75	25	100	59.3
	17a	100.0	16.7	100	60	40	50	40	20	37.5	100	100	56.0
	17b	100.0	100.0	100	90	80	90	90	73.3	87.5	100	100	90.1
	17c	71.4	100.0	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	[a]	[a]	20	0	20	20	0	12.5	0	0	20.0
	22b	0.0	[a]	[a]	0	0	10	0	0	12.5	0	0	2.7
CCP identification and control	5	85.7	66.7	60	75	30	20	50	10	56.3	0	100	49.5
	6a	100.0	66.7	80	80	40	70	30	0	37.5	0	0	53.8
	6b	100.0	100.0	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	25.0	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	0.0	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	0.0	20	20	50	20	35	3.3	43.8	50	50	28.0

Note: [a]Question not included in script submitted to this group

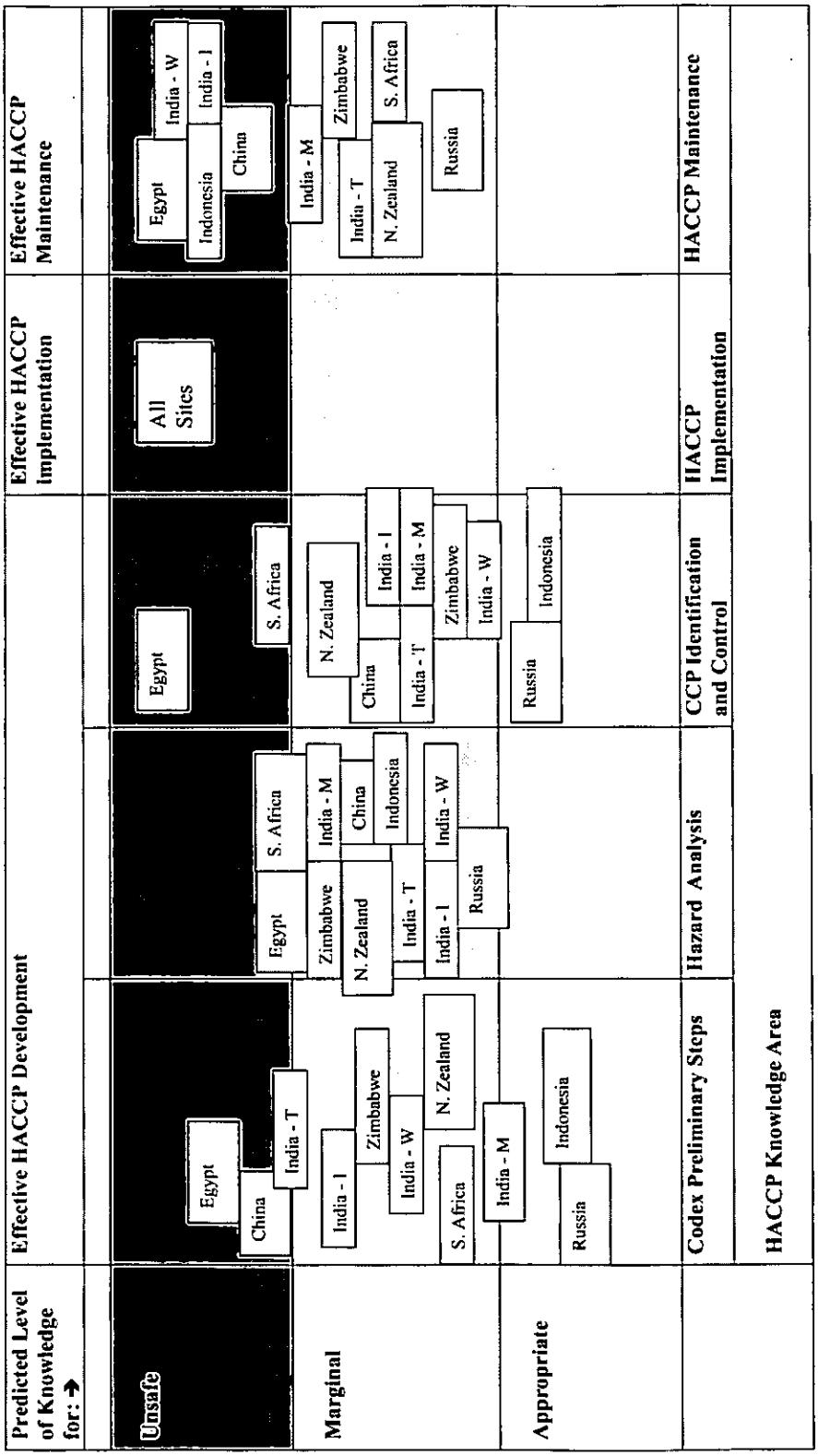

Figure 2.
Judgement of level of HACCP knowledge at sites

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.

3.7 Relationship between time of training and knowledge (Table V)

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 (Whitmore, 1992) list recall after three months as 10 per cent, 32 per cent and 65 per cent depending on whether trainees have been "told", "told and shown" and "told, shown and experienced" respectively. 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.

3.8 Consideration of HACCP ability perception following training

The results for candidate perception of HACCP ability following training are shown in Table VI. A total of 75 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 two perception statements: one who scored 65 per cent 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 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 is 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 per cent.

It is intended that perception of self-efficacy from the viewpoint of the HACCP team will be further studied, through application of the same tool to teams rather than individuals.

3.9 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 VII). 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 was a supplementary question to Q 3 (What is the purpose of the process flow diagram?) and, since 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. The questions used did not allow this to be measured.

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 per cent 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" or "low concern" in terms of food safety. 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. It is not possible to assess this from the knowledge data but this outcome will be reviewed as part of further research.

3.10 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. Figure 2 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 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 per cent 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 VII, Question 15) and similarly New Zealand was 100 per cent correct on process corrective action (Table VII, 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 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 per cent 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.

3.11 Preliminary conclusions and intended further work

The research carried out to date demonstrates 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. Results have highlighted areas of HACCP where knowledge is problematic. 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.

Ongoing research is exploring HACCP knowledge and its application in more depth. This will determine the accuracy of predicted HACCP effectiveness outcomes from HACCP knowledge data reported here, and will include:

- assessment and review of the levels of knowledge in trained haccp team members and HACCP teams at a range of sites;
- determination of the validity of haccp plans developed by trained haccp teams using proposed HACCP assessment tools (Wallace *et al.*, 2005);
- identification and analysis of aspects of in-house business dimensions and how these might impact the HACCP process;
- evaluation of the implementation, verification and maintenance of haccp plans using proposed HACCP assessment tools (Wallace *et al.*, 2005); and
- identification and analysis of aspects of national and cultural dimensions, including how these might impact HACCP training and implementation effectiveness.

It is anticipated that evaluation of findings will allow recommendations to be made for effective HACCP training and implementation strategies in multi-national companies. In this way it is hoped that the research will contribute both to an understanding of the factors involved in successful HACCP training and development, and to the improvement of HACCP systems and their effectiveness.

Note

1. Food and Agriculture Organisation of the United Nations/Codex Committee on Food Hygiene.

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Appendix 1.2

Peer Reviewed Paper:

Wallace, C. A., Powell, S. C., and Holyoak, L., 2005[b], Development of Methods for Standardised HACCP Assessment. *British Food Journal*, 107, 10 pp 723-742

Development of methods for standardised HACCP assessment

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Abstract

Purpose – Assessment of HACCP systems is a key element in assuring the effective management of food safety. However, there is no accepted approach or common methodology available to HACCP practitioners, auditors or regulatory bodies. This paper seeks to examine this situation

Design/methodology/approach – This paper reviews previous approaches to HACCP audit and describes developments in audit and audit methods based on a long-term study of HACCP in a multinational organisation.

Findings – The proposed audit tools provide a useful method for collection of data on the effectiveness of HACCP plans and their implementation.

Research limitations/implications – Limitations of using this approach are identified and discussed.

Originality/value – New audit tools for validation and verification of HACCP effectiveness are proposed.

Keywords Environmental health and safety, Food safety, Quality management

Paper type Conceptual paper

Introduction

Food safety is an increasingly important public health issue. The World Health Organisation (WHO) estimates that in 2000 2.1 million people died from diarrhoeal diseases (WHO, 2002). 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 implementing and improving food safety systems, promoting good manufacturing practices and educating manufacturers, retailers and consumers about appropriate food handling (WHO, 2002).

The hazard analysis and critical control point system (HACCP) is the internationally agreed approach to food safety control. 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 Committee on Food Hygiene, 1993; Codex Committee on Food Hygiene, 1997).

Hazard Analysis Critical Control Point 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. In order for HACCP to be effective, it is essential that it is supported by Good Manufacturing Practice (GMP) or Prerequisite Programmes that control the general hygiene and environmental conditions in a food processing operation (ILSI, 1999; Sperber, 1998;Wallace and Williams, 2001). In a manufacturing operation, food safety management is achieved through the application of system

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"building blocks" – safe product design, prerequisite programmes and HACCP – operating under the framework of the overall operations management system (Figure 1).

The systems of the HACCP "building block" are developed through application of the internationally agreed HACCP Principles (Codex, 1997). For effective food safety management, all three "building blocks" need to be adequately designed and their implementation verified. Assessment approaches are needed to demonstrate effectiveness of the prerequisite programmes, safe product design and HACCP blocks. This paper focuses on the assessment of HACCP.

The HACCP system will prevent food-borne disease outbreaks only if it is understood and applied correctly. There are very few records of food-borne 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, food-borne disease should not occur. 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, reflecting a lack of understanding of, or commitment to the HACCP system (Motarjemi and Kaferstein, 1999).

Measuring the effectiveness of HACCP

Whilst Motarjemi and Kaferstein (1999) argue that positive results may be expected when the HACCP system has been applied correctly, it is also necessary to establish ways of measuring HACCP effectiveness that are not based solely on retrospective analysis of outbreak data. This need is reinforced by experience with a range of food companies, which has shown that, although manufacturing sites often consider that they have implemented HACCP, frequently the outcome is an inadequate or poorly implemented HACCP System. Sperber (1998) believes that the continued auditing and verification of a HACCP system is at least as important and perhaps far more important than the initial development of the HACCP plan.

A WHO consultation in Geneva on the "HACCP System: concept and application" (WHO, 1995) highlighted that ongoing assessments are essential once a HACCP system has been implemented. Both internal assessments carried out by food industry and

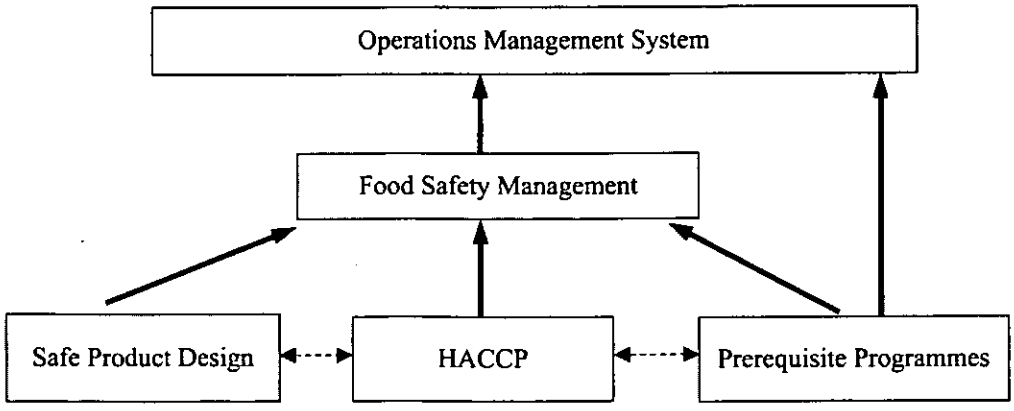

Figure 1.
Manufacturing food safety management model

Source: Adapted from Mortimore (2001)

independent assessments carried out by regulators and third-party bodies should be undertaken. A further WHO Consultation in Geneva in 1998 considered "The Role of Government Agencies in Assessing HACCP" (WHO, 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; and
- 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. Previous publications have also described the roles and approaches taken by government agencies in different parts of the world in assessing HACCP (Kvenberg *et al.*, 2000; Gagnon *et al.*, 2000; Torres, 2000; Merican, 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 (Torres, 2000; Merican, 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.

HACCP assessment criteria

Mortimore and Wallace (1998) divide the application of HACCP in manufacturing into four key stages:

(1) Planning and preparation;
(2) HACCP studies and HACCP plan development;
(3) Implementing the HACCP plan; and
(4) Maintaining the HACCP system.

Whilst the planning and preparation stage is important in laying foundations for HACCP, effectiveness assessment of the HACCP system generally requires evaluation

of the outcomes from stages 2), 3) and 4) (Mortimore and Wallace, 1998). Similarly, the International Life Sciences Institute (ILSI, 1999) describes the assessment of three phases of HACCP:

(1) Technical evaluation of the process of performing the hazard analysis and establishing control measures;

(2) Implementation of the resulting HACCP plan, which includes the process of validation; and

(3) Operation of HACCP, which includes the assessment activities of verification and auditing (Mortimore and Wallace key stages 2), 3) and 4).

Thus, broad criteria for HACCP effectiveness assessment can be established (Table I).

The need for HACCP assessment tools

Both the approach taken by government agencies (Kvenberg *et al.*, 2000) and work with multinational companies 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 (ISLI, 1999; WHO, 1998; Mortimore and Wallace, 1998; 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, including the provision of a 17-question "Food Safety Effectiveness Audit Worksheet" for evaluating HACCP procedures on the production floor and a ten-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. It is also questionable whether the "Food Safety

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 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 hand-over 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 to keep up to date on knowledge of food safety hazards

Table I.
HACCP effectiveness criteria

Effectiveness Audit Worksheet", as written, would elicit information on the effectiveness of corrective action taken at CCPs.

A number of HACCP Audit Checklists and example questions have been published on the internet, e.g. the United States National Conference on Interstate Milk Shipments (NCIMS) Dairy HACCP Audit Report Form (NCIMS, 2004), the Australian Standing Committee on Agriculture and Resource Management HACCP Plan Audit Checklist (Standing Committee on Agriculture and Resource Management, 2003; Cooper and Pronk, 1997). The NCIMS Form (NCIMS, 2004) provides a tick-sheet of items to be covered in assessing both prerequisite programmes and HACCP, while the Australian Standing Committee checklist gives specific questions to be asked about different aspects of HACCP plan development and implementation. Cooper and Pronk (1997) outline methodology that can be used to assess HACCP Plan procedures, e.g. visual observation and records review, and describe eight questions that can be used to assess management support for HACCP and three questions for review of the HACCP plan.

Torres (2000) includes a checklist criteria in his discussion of government agency approaches. He appears to look for presence or absence of HACCP System elements and does not, as written, challenge the effectiveness of these elements.

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.

More recently, (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.

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 (BS EN ISO 19011:2002) 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.

Some approaches (Sperber, 1998) use simple scoring systems based on allocating points to "satisfactory" or "unsatisfactory" ratings whilst others (Gagnon *et al.*, 2000; Mortimore, 2000; NCIMS, 2004) 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 a 95 per cent score but still has a major food safety flaw (Palmer, 2005). It is therefore crucial that any scoring system is carefully designed and that its limitations are clearly understood.

As part of a research programme investigating the impact of training on the effectiveness of HACCP in a multinational organisation, it was necessary to identify standard approaches to assess the effectiveness of HACCP Systems. This was to allow assessment of global data from manufacturing sites that had been collected by trained HACCP auditors using a consistent checklist format. It was also necessary to identify 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 considered to be an essential part of the assessment approach.

The aims of the study pertaining to HACCP assessment were:

- Establish strategies for the assessment of HACCP effectiveness;
- Develop and validate tools to measure HACCP effectiveness;
- Determine the validity of HACCP Plans developed by trained HACCP teams; and
- Evaluate the implementation, verification and maintenance of HACCP plans;

Methods

The methods described here were developed in 2003 for data collection between October 2003 and March 2004. At that time, there was no accepted tool that provided a comprehensive measure of the effectiveness of HACCP system implementation. Hence, it was important to identify a way of assessing the HACCP systems that had been developed by the HACCP teams following training. Previously published guidance on HACCP assessment (WHO, 1998; ILSI, 1999; Mortimore and Wallace, 1998; Mortimore, 2000; Sperber, 1998) was considered and, 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).

The HACCP Audit Tools were designed to assess both the validity of the HACCP Plan (i.e. will the HACCP Plan control all likely hazards?), and the implementation and maintenance of the HACCP system (i.e. is the HACCP Plan working in practice in the factory?). As was recommended practice in previous approaches, 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 a large manufacturing group. On-site assessment was necessary to provide more rigorous assessment of HACCP at a smaller sample of sites.

Tool 1 – A HACCP desk-top audit checklist (Figure 3) was developed by selecting aspects of HACCP audit that focused on the approach to HACCP plan development and its validity. Tool 2 – HACCP verification audit checklist (Figure 4) was developed as a

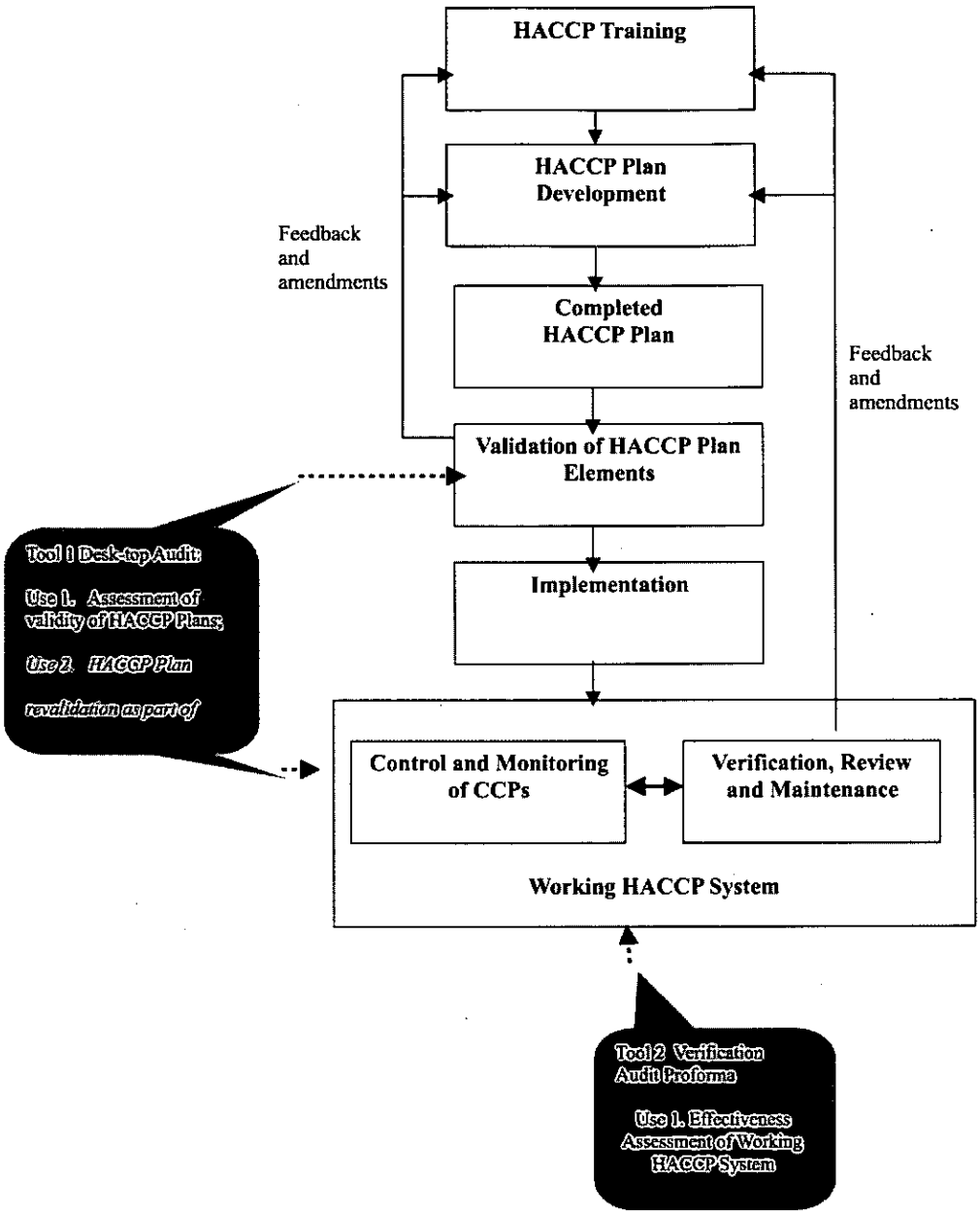

Figure 2.
Use of audit tools in HACCP assessment

complementary checklist that would allow verification of implementation and maintenance at the site.

Tool 1 – HACCP desk-top audit checklist (Figure 3)
In order to assess the validity of HACCP plan documentation, six groups of questions were developed, relating to the steps in a HACCP study, as follows:

(1) Codex preliminary steps and documentation.

(2) Principle 1 – hazard analysis.

HACCP Documentation
Desk Top Assessment Checklist

Assessment Date	
Factory Location	
HACCP Plan Reference	
Product/Process Module	

Section 1 **Overall Assessment of HACCP Plan Documentation**

	Possible Marks	Actual Score
Preliminary Steps and Documentation	20	
Principle 1: Hazard Analysis	20	
Principle 2: Determination of CCPs	20	
Principle 3: Critical Limits	20	
Principle 4: Monitoring Procedures	20	
Principle 5: Corrective Action	20	

Section Score Rating:

Poor	Fair	Good	Excellent
<10	10-13.5	14-16.5	≥17

Auditor's Notes:

Signed: _____

Position: **(HACCP Auditor)**

Date: _____

(continued)

Figure 3.
HACCP documentation desk-top assessment checklist

Section 2: **HACCP System Approach**

Background Notes on HACCP System and general notes on approach (based on information provided)

Section 3: **Assessment of HACCP Plan Documentation**

A) Document management	(Y/N /M)	**Comments/Notes**	**Marks**	
			Poss-ible	**Actu al**
Have all documents been numbered and dated?			2	

B) Codex Preliminary Steps				
1) HACCP Team Members		**Document Version/date:**		
Does the documentation identify HACCP Team members and the skills/functions they represent?			2	
Are all appropriate skills/functions represented?			2	
Are HACCP team members appropriately trained?			2	
2) Product Description		**Document Version/date:**		
Has appropriate background information about the product been included, e.g. formulation details, major process technologies, likely hazard groups, etc?			2	

(continued)

Figure 3.

3) Terms of reference/scope			Document Version/date:	
Is there a statement about types of hazards considered?			0.5	
Are the start and finish points for the study listed?			0.5	
Is the consumer target group stated?			0.5	
Is intended use for product stated?			0.5	

4 & 5) Process Flow Diagram			Document Version/date:	
Has it been signed off and dated as valid by HACCP Team or by Production?			1	
Do all the process activities link up in a logical way?			2	
Do the steps listed describe the process activities? OR Have they been confused with equipment names?			2	
Has rework been included? *Note: consider whether rework or recycling loops are appropriate for this product/process module. If not, omit this question and mark the section out of 19 marks.*			1	
Have all process steps been included with no obvious omissions, including linkages between modular HACCP plans?			2	
Preliminary Steps and Documentation Score			20	

C) Application of HACCP Principles				
1) Hazard Analysis (Principle 1)			**Document Version/date:**	
Does the hazard analysis cover all the steps in the PFD?			2	
Have all hazards that can reasonably be expected to occur at each process step been identified?			6	
Has risk assessment (likelihood of occurrence vs. severity of outcome) been used to identify hazard significance and is this appropriate? *Note: this could be done using a structured risk assessment scheme or through HACCP Team discussion. Consider whether you agree with the assessment and whether there is sufficient justification of the decisions taken. A common mistake is to consider as significant many issues that are really covered by prerequisite programmes, e.g. micro contamination issues due to poor cleaning of equipment.*			6	

(continued)

Figure 3.

Are listed control measures sufficient to prevent, eliminate or reduce each significant hazard to an acceptable level? *Consider whether the control measure will control the hazard on an ongoing basis. A common mistake is to list monitoring procedures or spot checks here – these are not normally effective control measures.*			6	
Principle 1 (Hazard Analysis) Score			20	

2) Determination of CCPs (Principle 2)		**Document Version/date:**		
Have all significant hazards been considered in the CCP identification process?			2	
Has a recognised decision tree been used in this process? OR Have CCPs been identified using experience? *In either case, a record and justification of decisions should be available.*			8	
Have all appropriate CCPs been identified? *Consider whether you agree with the HACCP team's CCP decisions.*			10	
Principle 2 (Determination of CCPs) Score			20	
CCP Management (Principles 3 to 5)		**Document Version/date:**		
3) Critical Limits (Principle 3)				
Are critical limits actually appropriate safety limits for the control of the specific hazard? *Common mistakes are to list operational limits rather than safety limits or to give a range of values. A critical limit should never be a range; it will be an absolute value, e.g. minimum temperature and time combination for milk processing.*			20	
Principle 3 (Critical Limits) Score			20	

(continued)

Figure 3.

4) Monitoring Procedures (Principle 4)				
Will the specified monitoring procedure detect loss of control from the critical limit?	Y		10	
Is monitoring set at an appropriate frequency?	Y		6	
Has monitoring been assigned to an appropriate person/job role? *In general, monitoring should be carried out by line personnel wherever possible.*	Y		4	
Principle 4 (Monitoring Procedures) Score			20	

5) Corrective Action (Principle 5)				
Will specified corrective action address the potentially contaminated product to prevent this reaching the consumer?			8	
Will specified corrective action repair the fault that has caused the CCP to fail?			8	
Has corrective action been assigned to an appropriate person/job role?			4	
Principle 5 (Corrective Action) Score			20	

Figure 3.

(3) Principle 2 – determination of critical control points.
(4) Principle 3 – critical limits.
(5) Principle 4 – monitoring procedures.
(6) 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 six question groups was allocated 20 points. However, weighting of individual questions within each question

HACCP Verification Audit Checklist

Note: This document should be used in conjunction with the HACCP Desk-top Audit Checklist to validate and verify the HACCP Plans and their implementation.

Assessment Date	
Factory Location	
HACCP Plan Reference	
Product/Process Module	

Section 1 Overall Assessment of HACCP Plan(s)

List observations from your assessment of sections 2 to 4 to support your overall assessment, highlighting any non-compliances to the requirements of the defined HACCP Plan or Codex HACCP Principles.

Signed: _____

Position: _____ **(HACCP Auditor)** _____

Date: _____

(continued)

Figure 4.
HACCP verification audit checklist

Section 2 On-site Verification of Process Flow Diagram(s)

Record comments on accuracy of process flow diagram(s) (PFDs) in the PFD Verification Table (photocopy extra copies of this table if necessary.) Where possible, annotate any anomalies on photocopies of the process flow diagrams and attach copies to this checklist.

Process Flow Diagram Verification Table	
Process Step	**Anomaly/evidence**

Figure 4.

(continued)

Section 3 HACCP Implementation

In the factory, assess the implementation of CCPs as defined in the HACCP Plan. Look at the CCP monitoring records and observe monitoring where possible. Also obtain a sample of at least one month's previous records (month randomly chosen by you as assessor) and look though these for evidence of compliance. It will be necessary to reproduce the CCP Assessment Table to record findings for more than 1 CCPs. It is recommended that a sample of ≥ 3 CCPs is examined.

CCP Assessment Table		
CCP Number/Reference:		
	Yes/No	**Comments**
Are record sheets available on the line or close enough for operators to complete effectively?		
Are the records complete and signed off?		
Is monitoring being done at the appropriate frequency?		
Is there evidence of CCP deviation?		
Where there is there evidence of CCP deviation, has defined corrective action been taken and recorded?		
Was corrective action sufficient to prevent release of potentially unsafe product?		
Is there evidence that records have been reviewed and signed off by a more senior member of staff?		

(continued)

Figure 4.

Section 4 HACCP Maintenance Procedures

Consider whether the working HACCP Plans are being adequately verified, reviewed and kept up to date. Use the HACCP Maintenance Procedures Assessment Table to record your findings.

HACCP Maintenance Procedures Assessment Table		
	Yes/No	Comments
Is there evidence of formal verification through audit?		
Is appropriate corrective action being carried out for identified non-conformities?		
Are audit findings used for continuous improvement of the HACCP System?		
Is there evidence of additional verification activities in operation? *E.g. sampling and testing, consumer complaints analysis, record trend analysis, etc.*		
Are the HACCP Plans being reviewed at an appropriate frequency (when there are changes that could affect food safety or at least annually)?		
Have the HACCP Plan documents been updated? Consider the issue dates and any amendments.		
Do the HACCP Plans reflect the current operation? (see also point 2. On-site verification of flow diagram)		
Is the overall verification and maintenance plan appropriate for effective management of food safety?		

Figure 4.

group was developed by considering their relative impact on the development of effective HACCP systems (Figure 3). 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 six points.

Use of tool 1 – HACCP desk-top audit (Figure 3)
The tool design includes the overall assessment score at the front (Section 1) for ease of comparison between assessments. Questions are 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 is 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.

The desk-top audit is conducted as follows:

Initially, HACCP Plan documentation is read through by the auditor to gain an impression of the overall approach. At this stage background notes on the HACCP system and approach are recorded in section 2 (HACCP system approach). The auditor then works through the groups of question in section 3 (Assessment of HACCP plan documentation), using the guidance notes and expert judgement to score each question. At the end of the assessment, the marks for each section are totalled and recorded in section 1 (Overall assessment of HACCP plan documentation) along with supporting notes for the overall assessment. The overall marks are not converted into a percentage value overall, but used as an indication of the strengths and weaknesses in each area of HACCP development. Depending upon the results of this audit, auditors can choose whether to implement Tool 2.

Tool 2 – HACCP verification audit checklist (Figure 4)
The HACCP verification audit checklist 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. It consists of four sections:

(1) Overall assessment of HACCP plans.
(2) Assessment of process flow diagram.
(3) Verification of HACCP implementation.
(4) Verification of maintenance procedures.

For verification of HACCP effectiveness, both tools can be applied together on-site, requiring the trained auditor(s) to visit the site for 2-3 days to perform the assessment.

Use of tool 2 – HACCP verification audit checklist
This tool was designed to be used in conjunction with Tool 1, HACCP Desk-top Audit, to gain an assessment of the effectiveness of HACCP Plans and their implementation/maintenance. Because Tool 2 was intended to highlight anomalies and weaknesses specific to manufacturing sites rather than as part of a larger comparative study, a numerical scoring system was not included in this case. Rather, it was decided to use the accepted quality systems audit approach of conformity/non-conformity identification (British Standards Institute, 2002). However, a weighted scoring system could be envisaged for use in comparative studies.

The HACCP Verification Audit is conducted as follows. First the Process Flow Diagram (PFD) is verified by following the process through the factory. Any anomalies are recorded in section 2 (On-site verification of process flow diagrams) and, where possible, indicated on a photocopy of the PFD. This stage of the audit is also useful in familiarising the auditor with the process and processing environment.

If not done previously off-site, the auditor then assesses the HACCP plan using Tool 1. If this has been completed previously, any points requiring clarification are resolved with input from site personnel. The auditor then chooses a sample of CCPs (normally at least three CCPs) for further investigation in the factory and through historical records. Findings are recorded in section 3 (HACCP implementation).

HACCP maintenance is then assessed and findings recorded in section 4 (HACCP maintenance procedures). The auditor forms an overall judgement on HACCP implementation and maintenance effectiveness, and records this in Section 1, highlighting any non-conformity to the requirements of the defined HACCP plan and Codex HACCP principles.

Audit findings are reported back to site management at a closing meeting and a written report is generated from the checklists.

Pilot study and data collection

Questionnaire design and wording were discussed with three experienced HACCP auditors and tested against five 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.

A group of six HACCP auditors was then trained in the application of Tool 1 and its accompanying scoring system. HACCP Plans were collected from 117 manufacturing sites and these were assessed by the trained HACCP auditors. A further group of four HACCP auditors was trained in the application of both Tool 1 and Tool 2 so that they could be used to assess HACCP implementation and maintenance status in the field. It was necessary to involve two separate groups of auditors due to company logistical reasons. Results will be reported separately.

Discussion

Both assessment tools have now been used to collect data on effectiveness of HACCP plans and their implementation status. This has demonstrated that the tools are a useful way of collecting information about HACCP progress. Throughout this process a number of benefits and limitations have been identified.

Limitations of desk-top assessment include that the assessment can only be based on the paperwork submitted so anything not submitted is not assessed. In this study it was found that further communication with sites may be necessary to clarify details of information provided or to obtain missing information. The approach is further 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. However, 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.

The auditor plays a vital role in the assessment of HACCP systems and both their HACCP 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.

Desk-top audit was found to be a useful way to gain a comparative measure of HACCP development progress and documentation quality at a large number of sites, however it is important to remember that this assessment is based on paperwork alone and so needs to be triangulated with on-site assessment data. From this study it was concluded that the combined use of Tools 1 and 2 by trained HACCP auditors could give a detailed assessment of HACCP Plan validity along with verification of its implementation and maintenance.

As described previously, the use scoring systems in HACCP assessment has been a contentious issue. None of the previously described approaches apply weighted scoring to the differential importance of specific parts of HACCP documentation and system application. This could be one way of establishing a pragmatic scoring system that reflects the consequence of flaws in a HACCP system. It was found that scoring can be used effectively to monitor progress at a particular manufacturing site or to allow comparison of progress within a group of sites, however the scoring system must be carefully designed for its specific use. In this study a scoring system was necessary for Tool 1 in order to assess and compare progress in HACCP at a large number of manufacturing sites. It would also be possible to use the tool qualitatively without the scoring system, to identify lists of weaknesses that need to be addressed for effective HACCP plans.

It is hoped that the tools described here will provide a resource for industry to assess the effectiveness of HACCP systems being developed and in operation at manufacturing sites.

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Ethics Approval Letters

Appendix 1.3

Phase 1 Letter

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Carol Wallace
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Dear Carol,

I am pleased to inform you that your Research Project entitled '**An evaluation of the impact of training on effective use of the HACCP system for food safety management in a multinational organisation**' has been approved by the Psychology Ethics Committee.

Yours sincerely,

Miko Eslea
Chair of Psychology Ethics Committee.

Appendix 1.3

Phase 2 Letter

UNIVERSITY
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Dr Paul Pollard

12th January 2006

To: Carol A Wallace
Copy: Dr Sue Powell, Lynda Holyoak, Professor Peter Aggett

Dear Carol

I am pleased to be able to inform you that your research proposal **"An evaluation of the impact of training on effective use of the HACCP system for food safety management in a multinational organisation."** has been **approved** by the Ethics Committee.

Your reference number for this project is **PSY0405034.** Please use this number in any future correspondence regarding this project.

Good luck with your data collection,

Yours sincerely,

Mike Eslea
Chair, Psychology Department Ethics Committee

Appendix 2.1

HACCP Knowledge and Background Questionnaire

Appendix 2.1

HACCP Training Questionnaire

Part 1 Your HACCP Training

(**Note**: if you have been involved in more than one HACCP training session, please ask for a photocopy of Part 1 and answer separately for each training session)

1	**Did you receive HACCP Training?**
	Yes ☐(go to Q 2) **No ☐ (go to Part 2 HACCP Questions)**

		☑
2	**What type of HACCP Training did you receive?**	
a	Lectures or presentation on HACCP	
b	Mixture of lectures/presentations and practical team exercises	
c	Learned HACCP 'on-the-job' whilst participating in a HACCP study	
d	Other type of training, please specify	
3	**If you attended a HACCP training course/workshop, how long did it take?**	
a	< 1 day	
b	1 – 2 days	
c	2 – 3 days	
d	> 3 days	

4	**When did you receive HACCP training?**	
a	In the last 6 months	
b	6 months – 2 years ago	
c	2 – 4 years ago	
d	> 4 years ago	
e	Can't remember	
5	**Was your HACCP Training:**	
a	An in-house course attended by yourself and colleagues?	
b	An external training course?	
c	Other, please specify	
6	**Did you receive following after the course** (please tick all that apply)	
a	A certificate of attendance?	
b	An examination pass certificate?	
7	**After your HACCP training, did you consider that:**	
a	You had enough knowledge to develop/participate in the development of a HACCP Plan straight away?	
b	You needed more practice in applying HACCP Principles before you were comfortable with developing/participating in the development of a HACCP Plan?	
c	You were unsure of where to start, in order to develop/participate in the development of a HACCP Plan?	
d	Other, please specify	

Please now complete Part 2 HACCP Questions

Appendix 2.1

Part 2 HACCP Questions

No.	Question	For office use only
1	Explain what is meant by a hazard?	
2	Explain what is meant by a control measure?	
3	What is the purpose of the process flow diagram in HACCP?	
4	Why is it important to validate the process flow diagram?	
5	What is a critical control point?	
6	How can critical control points be identified? List two methods that could be used.	
7	What is a critical limit?	
8	Metal detectors are checked every 30 minutes with metal test pieces. What kind of activity is this?	

Appendix 2.1

9	What records might be found in the production area when a HACCP Plan has been implemented?	
10	Why is microbiological testing not a good monitoring procedure?	
11	What should happen if there is a deviation from a critical limit?	
12	When a CCP fails corrective action needs to be taken. Describe the two main areas that corrective action needs to address	
13	Why is it important that the HACCP study is done by a multidisciplinary team?	
14	List the three main disciplines required in a manufacturing HACCP Team.	

Appendix 2.1

15	What document is completed at the end of a HACCP study?		
16	List two verification procedures that can be used to determine if the HACCP system is working correctly.		
17	Give an example of a hazard from each of the following groups:		
	a. Microbiological		
	b. Chemical		
	c. Physical		
18	When should a HACCP Plan be reviewed?		
19	What type of training is important for line operators when a HACCP Plan is implemented in their work area?		
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?		
21	Suggest a control measure that could be used for hazards associated with raw materials.		

22	HACCP requires control of all hazards that are significant for food safety. Which two factors should be considered when analysing hazards to determine their significance?	

Part C Comments

If you would like to add any other comments about your training or HACCP experience please record them below.

Thanks for your help.

Appendix 2.2

HACCP Questionnaire – Marking Guide

Appendix 2.2

Question No.	Question / *Sample Answer*	Mark Breakdown	Marking Rationale
1	Explain what is meant by a hazard?		**2**
	A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect. ***OR***	2 **OR**	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.
	A factor that can cause harm to the consumer. ***OR***	1 **OR**	
	A factor that can make the consumer ill.	1	
2	Explain what is meant by a control measure?		**2**
	Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level. ***OR***	2 **OR**	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.
	A measure that can be used to control the hazard.	1	
3	What is the purpose of the process flow diagram in HACCP?		**1**
	To capture all the process steps in the operation for consideration in the hazard analysis.	1	Simple answer required – to capture all process steps for consideration in study, therefore 1 mark.
4	Why is it important to validate the process flow diagram?		**2**
	Because the flow diagram is used as the basis for the hazard analysis so if any steps are incorrect or missing, hazards may be missed out and the analysis will be incomplete.	1 for basis of hazard analysis; 1 for hazards may be missed if steps missed	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	What is a critical control point?		**2**
	A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. ***OR***	2 **OR**	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.
	A step in the process where the hazard must be controlled to ensure the product is safe.	2	

6	How can critical control points be identified? List two methods that could be used.		**2**
	HACCP Team expertise and judgement	1	2 methods are mentioned in training – CCP decision trees (e.g. Codex) and HACCP team expertise/judgement. 1 mark for each method.
	CCP decision tree (Codex)	1	
7	What is a critical limit?		**1**
	A criterion that separates acceptability from unacceptability.	1	Answer to demonstrate knowledge that this is the boundary between acceptability and unacceptability or safe and unsafe.
	OR	**OR**	
	The boundary/limit between safe and unsafe food production at the CCP.	1	
8	Metal detectors are checked every 30 minutes with metal test pieces. What kind of activity is this?		**1**
	A monitoring procedure.	1	Straightforward answer (monitoring procedure) – 1 mark.
9	What records might be found in the production area when a HACCP Plan has been implemented?		**2**
	Records of CCP monitoring.	1	2 main types of records might be found (monitoring and corrective action records) – 1 mark for each.
	Records of Corrective Action.	1	
10.	Why is microbiological testing not a good monitoring procedure?		**2**
	The time taken to get results (typically 2-3 days) is too long for operational safety, i.e. if a microbiological problem is found after 3 days then there are 3 days worth of potentially contaminated production to deal with.	1	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.
	Also limits of microbiological sampling due to heterogeneous distribution of microorganisms in food matrices.	1	

Appendix 2.2

11	What should happen if there is a deviation from a critical limit?		**1.5**
	The defined corrective action should be taken.	1	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.
	Additional discretionary 0.5 mark if answer includes relevant specific actions, e.g. stop line, quarantine product etc.	0.5	
12	When a CCP fails corrective action needs to be taken. Describe the two main areas that corrective action needs to address		**2**
	Identify and handle (e.g. destroy) the potentially contaminated product.	1	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.
	Repair the process/equipment/etc fault that has caused the CCP failure.	1	
13	Why is it important that the HACCP study is done by a multidisciplinary team?		**1**
	To ensure that the appropriate product and process specific knowledge and expertise is available for the development of an effective HACCP Plan. No one person will normally have all the expertise required.	1	Straightforward answer to ensure appropriate blend of expertise is available.
14	List the three main disciplines required in a manufacturing HACCP Team.		**3**
	Production	1	Disciplines expected are production, quality assurance/technical and engineering/maintenance. 1 mark for each.
	Quality Assurance/Technical	1	
	Engineering/Maintenance	1	
15	What document is completed at the end of a HACCP study?		**1**
	A HACCP Plan (Cadbury India – A HACCP Study Docket)	1	Straightforward answer – HACCP Plan.

16	List two verification procedures that can be used to determine if the HACCP system is working correctly.		**2**
	Audit	1	Expected answers include audit and records review/analysis (possible record examples include CCP monitoring, deviations, product testing, customer complaints). 1 mark for each suitable procedure.
	Records review and data analysis, e.g. from: *a. CCP monitoring* *b. Deviations and product dispositions* *c. Finished product testing – microbiological or chemical* *d. Customer complaints* e. *Etc.*	1	
17	Give an example of a hazard from each of the following groups:		**3**
	Microbiological ***Bacteria** - Salmonella spp., Escherichia coli, Campylobacter jejuni, Vibrio parahaemoliticus, Vibrio cholerae, Yersinia enterocolitica, Clostridium botulinum, Clostridium perfringens, Bacillus cereus, Staphylococcus aureus, Listeria monocytogenes; **Viruses** – hepatitis A, SRSV, Norwalk; **Protozoa** - Giardia intestinalis, Cryptosporidium parvum, Cyclospora cayetanensis; etc.*	1	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.
	Chemical *Mycotoxins, cleaning chemicals, pesticides, allergens, toxic metals, nitrites, PCBs, Dioxins, PAHs, Plasticisers + additives, veterinary residues, etc*	1	
	Physical *Glass, metal, stones, wood, hard plastic, equipment pieces, intrinsic material – e.g. bones + nut shell, etc.*	1	
18	When should a HACCP Plan be reviewed?		**2**
	When there is a (proposed) change to the operation or periodically – at least annually.	1 for changes; 1 for periodically/ at least annually	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	What type of training is important for line operators when a HACCP Plan is implemented in their work area?		**2**
	HACCP Awareness training plus CCP monitoring/corrective action training if they are responsible for monitoring CCPs.	1 for awareness training; 1 for CCP monitor/ corrective action training	HACCP awareness training plus monitoring/corrective action training if they are responsible for these activities. 1 mark for each.
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?		**2**
	Redesign the process, product or equipment to build in control.	1 for redesign process etc; 1 for build in control.	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	Suggest a control measure that could be used for hazards associated with raw materials.		**1.5**
	An effective supplier quality assurance programme		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.
	Additional discretionary 0.5 mark for relevant specific hazard control		

Appendix 2.2

22	HACCP requires control of all hazards that are significant for food safety. Which two factors should be considered when analysing hazards to determine their significance?		**2**
	Likelihood of occurrence of potential hazards	1	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.
	Severity of outcome if the hazard occurs	1	
		Total Possible Mark:	**40**

Appendix 2.3

Phase 1 Candidate Briefing Protocol – HACCP Questionnaire

Candidate Briefing Protocol

Evaluation of training effectiveness through Assessment of HACCP Knowledge following training

Briefing Notes:

- We are doing some research on how well people retain their knowledge of HACCP following training, as part of a larger project on training and HACCP effectiveness. The questionnaire is designed to give us a good feel for the current level of knowledge within the HACCP teams and should help us in identifying and targeting any further training or consultancy support needs.

- We would like to ask all the HACCP team members and any other members of staff who have gone through HACCP training at each site to complete a questionnaire (approximately 30 short answer questions) to help with this study.

- The questionnaire is optional. We do hope that all trainees will participate but they are free to decline. By completing the questionnaire, trainees give consent for their data to be used in the study (this will be anonymous). They are free to withdraw until the data has been submitted to the researcher (C. Wallace).

- The questionnaire needs to be done individually, i.e. without talking to colleagues, and without looking at books or training notes.

- Team members should not be worried if they do not know some of the answers as the questionnaire is testing whether the training was sufficient rather than testing them personally.

- Team members do not need to put their names on the document. All answers and comments will be confidential.

- Questions are usually in English*. If team members are concerned about understanding the questions they can ask the administrator for an explanation but not the answer. They should note that English is not a first language if necessary. * translated versions may be used for some countries, e.g. China, Russia, France.

HACCP Assessment Tool 1 – Desk-top Audit

HACCP Documentation
Desk Top Assessment Checklist

Assessment Date	
Factory Location	
HACCP Plan Reference	
Product/Process Module	

Section 1 **Overall Assessment of HACCP Plan Documentation**

	Possible Marks	Actual Score
Preliminary Steps and Documentation	20	
Principle 1: Hazard Analysis	20	
Principle 2: Determination of CCPs	20	
Principle 3: Critical Limits	20	
Principle 4: Monitoring Procedures	20	
Principle 5: Corrective Action	20	

Section Score Rating:

Poor	Fair	Good	Excellent
<10	10-13.5	14-16.5	≥17

Auditor's Notes:

Signed: _____

Position: _____ **(HACCP Auditor)** _____

Date: _____

Appendix 2.4

Section 2: HACCP System Approach

Background Notes on HACCP System and general notes on approach (based on information provided)

Section 3: Assessment of HACCP Plan Documentation

A) Document management	(Y/N /M)	**Comments/Notes**	**Marks**	
			Poss -ible	**Actu al**
Have all documents been numbered and dated?			2	

B) Codex Preliminary Steps				
1) HACCP Team Members		**Document Version/date:**		
Does the documentation identify HACCP Team members and the skills/functions they represent?			2	
Are all appropriate skills/functions represented?			2	
Are HACCP team members appropriately trained?			2	
2) Product Description		**Document Version/date:**		
Has appropriate background information about the product been included, e.g. formulation details, major process technologies, likely hazard groups, etc?			2	

3) Terms of reference/scope		**Document Version/date:**		
Is there a statement about types of hazards considered?			0.5	
Are the start and finish points for the study listed?			0.5	
Is the consumer target group stated?			0.5	
Is intended use for product stated?			0.5	

4 & 5) Process Flow Diagram		**Document Version/date:**		
Has it been signed off and dated as valid by HACCP Team or by Production?			1	
Do all the process activities link up in a logical way?			2	
Do the steps listed describe the process activities? OR Have they been confused with equipment names?			2	
Has rework been included? ***Note:*** *consider whether rework or recycling loops are appropriate for this product/process module. If not, omit this question and mark the section out of 19 marks.*			1	
Have all process steps been included with no obvious omissions, including linkages between modular HACCP plans?			2	
Preliminary Steps and Documentation Score			20	

C) Application of HACCP Principles				
1) Hazard Analysis (Principle 1)		**Document Version/date:**		
Does the hazard analysis cover all the steps in the PFD?			2	
Have all hazards that can reasonably be expected to occur at each process step been identified?			6	
Has risk assessment (likelihood of occurrence vs. severity of outcome) been used to identify hazard significance and is this appropriate? ***Note:*** *this could be done using a structured risk assessment scheme or through HACCP Team discussion. Consider whether you agree with the assessment and whether there is sufficient justification of the decisions taken. A common mistake is to consider as significant many issues that are really covered by prerequisite programmes, e.g. micro contamination issues due to poor cleaning of equipment.*			6	
Are listed control measures sufficient to prevent, eliminate or reduce each significant hazard to an acceptable level? ***Consider whether the control measure will control the hazard on an ongoing basis. A common mistake is to list monitoring procedures or spot checks here – these are not normally effective control measures.***			6	
Principle 1 (Hazard Analysis) Score			20	

2) Determination of CCPs (Principle 2)		**Document Version/date:**		
Have all significant hazards been considered in the CCP identification process?			2	
Has a recognised decision tree been used in this process? OR Have CCPs been identified using experience? *In either case, a record and justification of decisions should be available.*			8	
Have all appropriate CCPs been identified? *Consider whether you agree with the HACCP team's CCP decisions.*			10	
Principle 2 (Determination of CCPs) Score			20	

CCP Management (Principles 3 to 5)			**Document Version/date:**	
3) Critical Limits (Principle 3)				
Are critical limits actually appropriate safety limits for the control of the specific hazard? *Common mistakes are to list operational limits rather than safety limits or to give a range of values. A critical limit should never be a range; it will be an absolute value, e.g. minimum temperature and time combination for milk processing.*			20	
Principle 3 (Critical Limits) Score			20	

4) Monitoring Procedures (Principle 4)				
Will the specified monitoring procedure detect loss of control from the critical limit?	Y		10	
Is monitoring set at an appropriate frequency?	Y		6	
Has monitoring been assigned to an appropriate person/job role? *In general, monitoring should be carried out by line personnel wherever possible.*	Y		4	
Principle 4 (Monitoring Procedures) Score			20	

5) Corrective Action (Principle 5)				
Will specified corrective action address the potentially contaminated product to prevent this reaching the consumer?			8	
Will specified corrective action repair the fault that has caused the CCP to fail?			8	
Has corrective action been assigned to an appropriate person/job role?			4	
Principle 5 (Corrective Action) Score			20	

HACCP Assessment Tool 2 – Verification Checklist

HACCP Verification Audit Checklist

Note: This document should be used in conjunction with the HACCP Desk-top Audit Checklist to validate and verify the HACCP Plans and their implementation.

Assessment Date	
Factory Location	
HACCP Plan Reference	
Product/Process Module	

Section 1 Overall Assessment of HACCP Plan(s)

List observations from your assessment of sections 2 to 4 to support your overall assessment, highlighting any non-compliances to the requirements of the defined HACCP Plan or Codex HACCP Principles.

Signed: _____

Position: _____ **(HACCP Auditor)**

Date: _____

Section 2 On-site Verification of Process Flow Diagram(s)

Record comments on accuracy of process flow diagram(s) (PFDs) in the PFD Verification Table (photocopy extra copies of this table if necessary.) Where possible, annotate any anomalies on photocopies of the process flow diagrams and attach copies to this checklist.

Process Flow Diagram Verification Table	
Process Step	**Anomaly/evidence**

Section 3 HACCP Implementation

In the factory, assess the implementation of CCPs as defined in the HACCP Plan. Look at the CCP monitoring records and observe monitoring where possible. Also obtain a sample of at least one month's previous records (month randomly chosen by you as assessor) and look though these for evidence of compliance. It will be necessary to reproduce the CCP Assessment Table to record findings for more than 1 CCPs. It is recommended that a sample of ≥ 3 CCPs is examined.

CCP Assessment Table		
CCP Number/Reference:		
	Yes/No	**Comments**
Are record sheets available on the line or close enough for operators to complete effectively?		
Are the records complete and signed off?		
Is monitoring being done at the appropriate frequency?		
Is there evidence of CCP deviation?		
Where there is there evidence of CCP deviation, has defined corrective action been taken and recorded?		
Was corrective action sufficient to prevent release of potentially unsafe product?		
Is there evidence that records have been reviewed and signed off by a more senior member of staff?		

Section 4 HACCP Maintenance Procedures

Consider whether the working HACCP Plans are being adequately verified, reviewed and kept up to date. Use the HACCP Maintenance Procedures Assessment Table to record your findings.

HACCP Maintenance Procedures Assessment Table		
	Yes/No	Comments
Is there evidence of formal verification through audit?		
Is appropriate corrective action being carried out for identified non-conformities?		
Are audit findings used for continuous improvement of the HACCP System?		
Is there evidence of additional verification activities in operation? *E.g. sampling and testing, consumer complaints analysis, record trend analysis, etc*		
Are the HACCP Plans being reviewed at an appropriate frequency (when there are changes that could affect food safety or at least annually)?		
Have the HACCP Plan documents been updated? Consider the issue dates and any amendments.		
Do the HACCP Plans reflect the current operation? (see also point 2. On-site verification of flow diagram)		
Is the overall verification and maintenance plan appropriate for effective management of food safety?		

Notes

Appendix 3.1

Phase 2 Data Collection – Site Visit Work Plan Example

Appendix 3.1

Day	Task	Task Detail	Site personnel involved	Approximate timing
1	HACCP Knowledge – 1	Written Questionnaire	HACCP Team members – working as individuals	45-60 minutes each session. (exam style)
	HACCP Knowledge – 2	Group discussion of HACCP questions and completion of questionnaire	HACCP Team Members – working as a team	60-120 minutes
2	Interviews	Interview about HACCP process on site – • How HACCP was applied onsite • What worked well? • What problems were there? • Has HACCP delivered what was expected? • etc.	Sample from factory hierarchy, to include: • Site Senior Manager • HACCP Team Leader • 2 additional HACCP Team members • 2 supervisors/managers • 2 production operators with HACCP responsibility (e.g. CCP monitors)	Approximately 30-45 minutes per interview.
3	Interviews cont. Cultural Questionnaire	Written questionnaire – 26 questions	30 individuals from site hierarchy	Approximately 20 minutes each
4	HACCP Audit	Operation of site HACCP systems, including detailed review of CCP management for sample HACCP Plans.	Researcher plus site guide (e.g. Quality Manager or HACCP Team Leader) and personnel involved in day-to-day operation and management of HACCP	1-2 days
5	HACCP Audit			

Phase 2 Data Collection –

Briefing Documents and Consent Forms

1. Briefing Notes for Company Management

Briefing Notes - Questionnaires:

- I am doing some research on how well people retain their knowledge of HACCP following training, as part of a larger project on training effectiveness. One questionnaire is designed to give us a good feel for the current level of knowledge within the HACCP teams and should help us in identifying and targeting any further training or consultancy support needs. The second questionnaire asks more general business and individual perception questions, and is being used to determine if the type of HACCP training and support was suitable for the business.

- I would like to ask all the HACCP team members and any other members of staff who have gone through HACCP training at each site to complete a HACCP questionnaire (approximately 30 short answer questions) to help with this study.

- I would like a representative sample of job roles and levels from the factory to complete the general questionnaire.

- The questionnaires are optional. I hope that all trainees will participate but they are free to decline. By completing the questionnaire, trainees give consent for their data to be used in the study (this will be anonymous). They are asked to record their job role/rank only. They are free to withdraw until the data has been submitted to the researcher (C. Wallace). If they have given their name, it will be possible to identify their data for withdrawal at a later date.

- Unless specified, the questionnaires need to be done individually, i.e. without talking to colleagues, and without looking at books or training notes.

- For the knowledge questionnaire, candidates should not be worried if they do not know some of the answers as the questionnaire is testing whether the training was sufficient rather than testing them personally. For the general questionnaire, there is no 'right' or 'wrong' answer and it is their opinion that is sought.

- Team members do not need to put their names on the documents but are asked to record their job role/rank. All answers and comments will be confidential to the researcher and only anonymised group and job role/rank data will be reported in publications/presentations arising from the research. Where a job role could identify an individual, e.g. only one person on site with that job role, steps will be taken by the researcher to generalise the title description and ensure that anonymity is maintained.

- Questions are usually in English*. If team members are concerned about understanding the questions they can ask the administrator for an explanation but not the answer. They should note that English is not a first language if necessary. * translated versions may be used for some countries, e.g. Russia.

Briefing Notes – Interviews and Observation Sessions:

- I am doing some research on HACCP and training effectiveness. Interviews will be used to give us a good feel for how HACCP training was done and received and to identify any problems or issues with the HACCP development process. We will cover HACCP topics and also more general topics that will help to determine whether the methods of training and support were suitable for the site.

- I would like a sample of the HACCP team members and any other members of staff who have gone through HACCP training, as well as staff involved in HACCP implementation on the line to be involved.

- I would also like a representative sample of job roles and levels from the factory to answer some general questions.

- Participation is optional and personnel are free to decline. By participating in the interview/observation sessions, trainees give consent for their data to be used in the study (this will be anonymous). The researcher will record their job role/rank only. They are free to withdraw until the end of the data collection session. If they have given their name, it will be possible to identify their data for withdrawal at a later date.

- Candidates should not be worried if they are unsure of the answers to any questions as this is a data collection exercise only. For general questions, there is no 'right' or 'wrong' answer and it is their opinion that is sought.

- All answers and comments will be confidential to the researcher and only anonymised group and job role/rank data will be reported in publications/presentations arising from the research. Where a job role could identify an individual, e.g. only one person on site with that job role, steps will be taken by the researcher to generalise the title description and ensure that anonymity is maintained.

- Questions are usually in English*. If candidates are concerned about understanding the questions they can ask for the assistance with translation. Where necessary, e.g. Russia, an independent translator may be used.

Appendix 3.2

2. HACCP Research Briefing Notes for Participants

University of Central Lancashire
Preston
PR1 2HE
UK

Researcher: Carol Wallace
Telephone: +44 (0)1772 893657
cawallace@uclan.ac.uk

HACCP Research Briefing Notes for Participants

Background

We are doing some research about how companies implement food safety management systems based on hazard analysis (HACCP). This includes looking at how well people remember HACCP information following training and asking questions about the HACCP process within the business. You have been selected as someone who may be able to help with this research.

You will be asked to contribute to two or more of the following:

- Answering questions from the researcher about HACCP and management within the business.
- Completing a general survey about business approaches and individual goals
- Completing a HACCP knowledge questionnaire (personnel who have received HACCP training only)

The research will help us in identifying and targeting any further training or support needs for the business. We will cover HACCP topics and also more general topics that will help to determine whether the methods of training and support were suitable for the site.

Points to Note:

- Participation in this research is optional. If you would prefer not to be involved please inform the researcher.
- You are free to withdraw at any stage until the data have been entered into the computer.
- Any information that you give will remain completely confidential. You will be asked for your name and job role; however your name will not appear in any reports or discussions.
- Your information may be stored securely in paper and/or electronic form for up to 5 years. Data with individual's names will be accessible only to the researcher.
- Anonymous data, including non-attributable quotations, will be reported and may be published/presented in academic forums. Data will be reported as groups and job roles.

Quotations will be attributed to job roles or participant numbers (e.g. 'participant x stated....'). Where a job role could identify an individual, e.g. where there is only one person on site with that job role, steps will be taken by the researcher to generalise the title description and/or use only participant numbers to ensure that anonymity is maintained.

- Questions will be in English. If you do not understand the question you can ask the researcher to clarify. Where necessary, an independent translator may be used.
- Unless specified, questionnaires need to be done individually, i.e. without talking to colleagues, and without looking at books or training notes.
- For the general survey and interview questions, there is no 'right' or 'wrong' answer and it is your opinion that is sought.
- If you are asked to complete a HACCP knowledge questionnaire, don't worry if you do not know some of the answers. The questionnaire is testing whether the training was sufficient rather than testing you.

Please indicate your willingness to take part by completing the attached form.

Thank you for your assistance.

Appendix 3.2

University of Central Lancashire
Preston
PR1 2HE
UK

Telephone: +44 (0)1772 893657
Researcher: Carol Wallace
cawallace@uclan.ac.uk

HACCP Research Consent Form

Participant Number (UCLAN use only)	
Name	
Job Role	
Rank (e.g. supervisor, line operator)	
Production Site	

I understand the terms of this HACCP research, as detailed in the *'HACCP Research Briefing Notes for Participants'*, and agree to take part. I understand that my data will be kept confidential and stored securely by the researcher and that only anonymous information will be reported.

Signed .....

Date .....

Appendix 3.2

3. HACCP Team Consent Form

University of Central Lancashire
Preston
PR1 2HE
UK

Telephone: +44 (0)1772 893657
Researcher: Carol Wallace
cawallace@uclan.ac.uk

HACCP Team Consent Form

We, the undersigned HACCP Team, understand the terms of this HACCP research, as explained in the HACCP Team Briefing, and agree to take part. We understand that our data will be kept confidential and stored securely by the researcher and that only anonymous information will be reported.

Name (print)	Job Role	Signature	Participant No. (UCLAN use only)

Appendix 4.1 Comparison of Best Individual and Team Scores in each HACCP Knowledge Area

Appendix 4.1 Summary of HACCP Team Answers compared with Individual Team Member Knowledge

			Team Result Worse than best individuals								Team result Same as best individuals								Team result Better than best individuals							
Q. No	HACCP Knowledge Area	Question	India				Australia			S	India				Australia			S	India				Australia			S
			Team 1a	Team 1b	Team 2a	Team 2b	Team 3	Team 4a	Team 4b	Team 5	Team 1a	Team 1b	Team 2a	Team 2b	Team 3	Team 4a	Team 4b	Team 5	Team 1a	Team 1b	Team 2a	Team 2b	Team 3	Team 4a	Team 4b	Team 5
3	Codex preliminary steps	What is the purpose of the process flow diagram in HACCP?					✓		✓		✓	✓	✓	✓		✓		✓								
4	Codex preliminary steps	Why is it important to validate the process flow diagram?	✓	✓	✓	✓	✓									✓	✓	✓								
13	Codex preliminary steps	Why is it important that the HACCP study is done by a multidisciplinary team?									✓	✓	✓	✓	✓	✓	✓	✓								
14a prodn	Codex preliminary steps	List the three main disciplines required in a manufacturing HACCP Team.						✓			✓	✓	✓	✓	✓		✓	✓								
14b tech								✓			✓	✓	✓	✓	✓		✓	✓								
14c eng							✓				✓	✓	✓	✓		✓	✓	✓								
	Codex Preliminary Steps Totals		*1*	*1*	*1*	*1*	*3*	*2*	*1*	*0*	*5*	*5*	*5*	*5*	*3*	*4*	*5*	*6*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*

Appendix 4.1

1	Hazard analysis	Explain what is meant by a hazard?						✓	✓		✓	✓	✓	✓	✓			✓								
2	Hazard analysis	Explain what is meant by a control measure?						✓	✓		✓	✓	✓	✓	✓			✓								
17a	Hazard analysis	Give an example of a hazard from each of the following groups: Micro-biological									✓	✓	✓	✓	✓	✓	✓	✓								
17b		Chemical									✓	✓	✓	✓	✓	✓	✓	✓								
17c		Physical									✓	✓	✓	✓	✓	✓	✓	✓								
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?			✓	✓					✓	✓			✓	✓	✓	✓								
21	Hazard analysis	Suggest a control measure that could be used for hazards associated with raw materials.		✓	✓	✓					✓				✓		✓	✓						✓		
22a Like-lihood	Hazard analysis	Which two factors should be considered when carrying out the hazard analysis?					✓				✓	✓	✓	✓		✓	✓	✓								
22b severity					✓						✓	✓			✓	✓	✓	✓				✓				
	Hazard Analysis Totals		*0*	*1*	*3*	*2*	*1*	*2*	*2*	*0*	*9*	*8*	*6*	*6*	*8*	*6*	*7*	*9*	*0*	*0*	*0*	*1*	*0*	*1*	*0*	*0*

Appendix 4.1

5	CCPs & control	What is a critical control point?					✓	✓	✓		✓	✓	✓	✓				✓								
6a Tree	CCPs & control	How can critical control points be identified? List two methods that could be used.				✓					✓	✓	✓		✓	✓	✓	✓								
6b knowledge				✓					✓	✓	✓		✓	✓	✓	✓										
7	CCPs & control	What is a critical limit?				✓		✓	✓		✓	✓	✓		✓			✓								
8	CCPs & control	Metal detectors are checked every 30 minutes with metal test pieces. What kind of activity is this?			✓			✓	✓		✓	✓		✓	✓			✓								
11	CCPs & control	What should happen if there is a deviation from a critical limit?								✓	✓	✓	✓	✓	✓	✓	✓									
	CCPs & Control Totals		*0*	*1*	*1*	*2*	*1*	*3*	*4*	*2*	*6*	*5*	*5*	*4*	*5*	*3*	*2*	*4*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*

Appendix 4.1

9	Implementation	What records might be found in the production area when a HACCP Plan has been implemented?								✓	✓	✓	✓	✓	✓	✓	✓										
10	Implementation	Why is microbiological testing not a good monitoring procedure?		✓				✓			✓		✓	✓	✓		✓	✓									
12a process	Implementation	Describe the two main types of corrective action.								✓	✓	✓	✓	✓	✓	✓	✓										
12b product											✓	✓	✓	✓	✓	✓	✓	✓									
15	Implementation	What document is completed at the end of a HACCP study?			✓	✓	✓	✓			✓	✓					✓	✓									
19	Implementation	What type of training is important for line operators when a HACCP Plan is implemented in their work area?	✓		✓	✓	✓			✓		✓					✓								✓		
	Implementation Totals		*1*	*1*	*2*	*2*	*2*	*2*	*0*	*3*	*5*	*5*	*4*	*4*	*4*	*3*	*6*	*3*	*0*	*0*	*0*	*0*	*0*	*1*	*0*	*0*

Appendix 4.1

16a audit	Maintenance	List two verification procedures that can be used to determine if the HACCP system is working correctly.									✓	✓	✓	✓	✓	✓	✓	✓									
16b other						✓		✓			✓	✓	✓		✓		✓	✓									
18	Maintenance	When should a HACCP Plan be reviewed?		✓		✓		✓			✓		✓		✓		✓	✓									
	Maintenance Totals		*0*	*1*	*0*	*2*	*0*	*2*	*0*	*0*	*3*	*2*	*3*	*1*	*3*	*1*	*3*	*3*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
	Grand Total		2	5	7	9	7	11	7	5	28	25	23	20	23	17	23	25	0	0	0	1	0	2	0	0

Appendix 4.2 HACCP Knowledge Questions Scores for Individuals and HACCP Teams at each site

1. HACCP Knowledge – Team Member Scores vs. Team Score – India Site 1

				India Site 1			India Site 1		
				Team 1			Team 2		
Q. No	HACCP Knowledge Area	Question	Possible Marks	Team Member Range	Team Member Median	Team Actual	Team Member Range	Team Member Median	Team Actual
1	Hazard analysis	Explain what is meant by a hazard?	2	1-2	2	2	1-2	2	2
2	Hazard analysis	Explain what is meant by a control measure?	2	1-2	2	2	2	2	2
3	Codex preliminary steps	What is the purpose of the process flow diagram in HACCP?	1	0-1	1	1	0.5-1	1	1
4	Codex preliminary steps	Why is it important to validate the process flow diagram?	2	0.5-2	1	1	1	1	0
5	CCPs & control	What is a critical control point?	2	1-2	2	2	0-2	2	2
6	CCPs & control	How can critical control points be identified? List two methods that could be used.	2	1	1	1	1	1	1
				0-1	0	1	0-1	0.75	0
7	CCPs & control	What is a critical limit?	1	0.5-1	1	1	0-1	1	1
8	CCPs & control	Metal detectors are checked every 30 minutes with metal test pieces. What kind of activity is this?	1	1	1	1	0-1	1	1
9	Implementation	What records might be found in the production area when a HACCP Plan has been implemented?	2	1-2	1	2	1-2	1.5	2
10	Implementation	Why is microbiological testing not a good	2	1-2	2	2	2	2	1

Appendix 4.2

		monitoring procedure?							
11	CCPs & control	What should happen if there is a deviation from a critical limit?	1.5	0-1	0	1	0-1	1	1
12	Implementation	Describe the two main types of corrective action.	2	0-1	0	1	0-1	0.5	1
				0-1	1	1	1	1	1
13	Codex preliminary steps	Why is it important that the HACCP study is done by a multidisciplinary team?	1	1	1	1	1	1	1
14	Codex preliminary steps	List the three main disciplines required in a manufacturing HACCP Team.	3	0-1	1	1	0-1	1	1
				0-1	1	1	0-1	1	1
				0-1	1	1	0-1	1	1
15	Implementation	What document is completed at the end of a HACCP study?	1	0-1	0	1	0-1	0.5	1
16	Maintenance	List two verification procedures that can be used to determine if the HACCP system is working correctly.	2	0-1	0	1	0-1	0	1
				0-1	1	1	0-1	1	1
17	Hazard analysis	Give an example of a hazard from each of the following groups: Microbiological Chemical Physical	3	0-1	1	1	1	1	1
				1	1	1	1	1	1
				1	1	1	1	1	1
18	Maintenance	When should a HACCP Plan be reviewed?	2	1-2	1	2	1-2	1	1
19	Implementation	What type of training is important for line operators when a HACCP Plan is implemented in their work area?	2	0-2	1	1	1-2	1	2
20	Hazard analysis	What should the HACCP team do if they have	2	0-1	1	1	1	1	1

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		identified a significant hazard but there is no control measure at that step or any following step?							
21	Hazard analysis	Suggest a control measure that could be used for hazards associated with raw materials.	1.5	0-1.5	1.5	1.5	0.5-1.5	1	1
22	Hazard analysis	Which two factors should be considered when carrying out the hazard analysis?	2	0-1	1	1	0-1	0	1
				0-1	0.5	1	0-1	0	1
		Total	40	21-33 (52.5-82.5%)	Total of above Q medians 29 (72.5%)	36.5 (91.25%)	27-32.5 (67.5-81.25%)	Total of above Q medians 30.25 (75.61%)	33 (82.5%)
					Team member median 26.5 (66.25%)			Team member median 27.75 (69.38%)	

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2. HACCP Knowledge – Team Member Scores vs. Team Score – India Site 2

				India Site 2			India Site 2		
				Team 1			Team 2		
Q. No	HACCP Knowledge Area	Question	Possible Marks	Team Member Range	Team Member Median	Team Actual	Team Member Range	Team Member Median	Team Actual
1	Hazard analysis	Explain what is meant by a hazard?	2	0-2	2	2	1-2	1	2
2	Hazard analysis	Explain what is meant by a control measure?	2	0-2	2	2	0.5-2	1	2
3	Codex preliminary steps	What is the purpose of the process flow diagram in HACCP?	1	0-1	1	1	0-1	1	1
4	Codex preliminary steps	Why is it important to validate the process flow diagram?	2	0-2	1	1.5	0-2	0	1.5
5	CCPs & control	What is a critical control point?	2	0.5-2	2	2	0-2	0.75	2
6	CCPs & control	How can critical control points be identified? List two methods that could be used.	2	0-1	0	1	0-1	0	0
				0-1	0	1	0-1	0	1
7	CCPs & control	What is a critical limit?	1	0-1	1	1	0-1	0.5	0
8	CCPs & control	Metal detectors are checked every 30 minutes with metal test pieces. What kind of activity is this?	1	0-1	1	0	0-1	0	1
9	Implementation	What records might be found in the production area when a HACCP Plan has been implemented?	2	0.5-1	1	1	0-1	1	1
10	Implementation	Why is microbiological testing not a good monitoring procedure?	2	0-2	1	2	0-2	1	1
11	CCPs & control	What should happen if there is a deviation from a	1.5	0-1	0.5	1	0-1	1	1

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		critical limit?							
12	Implementation	Describe the two main types of corrective action.	2	0-1	0	1	0-1	0.5	1
				0-1	0	1	0-1	0.5	1
13	Codex preliminary steps	Why is it important that the HACCP study is done by a multidisciplinary team?	1	0.5-1	1	1	0-1	1	1
14	Codex preliminary steps	List the three main disciplines required in a manufacturing HACCP Team.	3	1	1	1	1	1	1
				1	1	1	1	1	1
				1	1	1	1	1	1
15	Implementation	What document is completed at the end of a HACCP study?	1	0-1	0.5	0.5	0-1	0.25	0.5
16	Maintenance	List two verification procedures that can be used to determine if the HACCP system is working correctly.	2	0-1	1	1	0-1	0.5	1
				0-1	1	1	0-1	0	0
17	Hazard analysis	Give an example of a hazard from each of the following groups: Microbiological Chemical Physical	3	1	1	1	1	1	1
				1	1	1	1	1	1
				1	1	1	1	1	1
18	Maintenance	When should a HACCP Plan be reviewed?	2	0-2	1	1	0-2	1	2
19	Implementation	What type of training is important for line operators when a HACCP Plan is implemented in their work area?	2	0-2	1	1	0.5-2	1	1
20	Hazard analysis	What should the HACCP team do if they have identified a significant hazard but there is no control measure at that	2	0-1	1	0	0-1	0	0

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		step or any following step?							
21	Hazard analysis	Suggest a control measure that could be used for hazards associated with raw materials.	1.5	0-1.5	0.5	1	0-1.5	0.5	0.5
22	Hazard analysis	Which two factors should be considered when carrying out the hazard analysis?	2	0-1	1	1	0-1	0	1
				0-1	0	0	0	0	1
		Total	40	9.5-33 (23.75-82.5%)	Total of above Q medians 26.5 (66.25%)	31 (77.5%)	13-34 (32.5-85%)	Total of above Q medians 18.5 (46.25%)	29.5 (73.75%)
					Team member median 31 (77.5%)			Team member median 17.75 (44.38%)	

3. HACCP Knowledge – Team Member Scores vs. Team Score – Australian Sites

				Australia – Site 1			Australia Site 2			Australia Site 2		
				HACCP Team 1			HACCP Team 1			HACCP Team 2		
Q. No	HACCP Knowledge Area	Question	Possible Marks	Team Member Range	Team Member Median	Team Actual	Team Member Range	Team Member Median	Team Actual	Team Member Range	Team Member Median	Team Actual
1	Hazard analysis	Explain what is meant by a hazard?	2	0-1	1	1	0-1.5	0.25	0	0-1.5	1	0
2	Hazard analysis	Explain what is meant by a control measure?	2	0-1	0	1	0-1.5	0.75	0.5	0-1.5	0	1
3	Codex preliminary steps	What is the purpose of the process flow diagram in HACCP?	1	0-1	0.5	0	0-1	0.25	1	0-1	0	0.5
4	Codex preliminary steps	Why is it important to validate the process flow diagram?	2	0-1	0	0	0-1	1	1	0-1	0.5	1
5	CCPs & control	What is a critical control point?	2	0-2	1	0	0-2	0	1	0-2	0	1
6	CCPs & control	How can critical control points be identified? List two methods that could be used.	2	0	0	0	0-1	0	1	0-1	0	1
				0	0	0	0-0.5	0	0	0	0	0
7	CCPs & control	What is a critical limit?	1	0-1	0	1	0-1	0.5	0	0-1	0	0
8	CCPs & control	Metal detectors are checked every 30 minutes with metal test pieces. What kind of activity is this?	1	0-0.5	0	0.5	0-1	0.5	0	0-1	0	0
9	Implementation	What records might be found in the production area when a HACCP Plan has been implemented?	2	1	1	1	1	1	1	0-1	0	1

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10	Implementation	Why is microbiological testing not a good monitoring procedure?	2	0-1	0.5	1	0-1.5	0.5	1	0-1	0	1
11	CCPs & control	What should happen if there is a deviation from a critical limit?	1.5	0-1	0.5	1	0-1	1	1	0-1	1	1
12	Implementation	Describe the two main types of corrective action.	2	0-1	0	1	0-1	0.25	1	0-1	0	1
				0-1	0	1	0-1	0	1	0-1	0	1
13	Codex preliminary steps	Why is it important that the HACCP study is done by a multidisciplinary team?	1	0-1	1	1	0-1	0.25	1	0-1	0	1
14	Codex preliminary steps	List the three main disciplines required in a manufacturing HACCP Team.	3	0-1	0	1	0-1	0	0	0-1	0	1
				0-1	0	1	0-1	0	0	0-1	0	1
				0-1	0	0	0-1	0	1	0-1	0	1
15	Implementation	What document is completed at the end of a HACCP study?	1	0-1	0	0	0-1	0	0	0-1	0	1
16	Maintenance	List two verification procedures that can be used to determine if the HACCP system is working correctly.	2	0-1	0	1	0-1	0	1	0-1	0	1
				0-1	0	1	0-1	0.25	0	0-1	0	1

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17	Hazard analysis	Give an example of a hazard from each of the following groups: Microbiological Chemical Physical	3	0-1	0	1	0-1	0.5	1	0-1	0	1
				0-1	1	1	0-1	0	1	0-1	1	1
				0-1	0.5	1	0-1	1	1	0-1	1	1
18	Maintenance	When should a HACCP Plan be reviewed?	2	1-2	1	2	1-2	1	0	0-2	1	2
19	Implementation	What type of training is important for line operators when a HACCP Plan is implemented in their work area?	2	0-1	0.5	0	0-1	1	2	0-1	0	1
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	1	1	1	0-1	0.5	1	0-1	0	1
21	Hazard analysis	Suggest a control measure that could be used for hazards associated with raw materials.	1.5	0-0.5	0.5	0.5	0-0.5	0.5	1	0-1	0	1
22	Hazard analysis	Which two factors should be considered when carrying out the hazard analysis?	2	0-0.5	0	0	0-1	0	1	0-1	0	1
				0-0.5	0	0.5	0-1	0	1	0-1	0	1

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	Total		40	6-23 (15-57.5%)	Total of above Q medians 10 (25%)	20.5 (51.25 %)	3-28 (7.5-70%)	Total of above Q medians 11 (27.5%)	21.5 (53.75 %)	2-28 (5-70%)	Total of above Q medians 5.5 (13.75)	26.5 (66.25 %)
					Team member median 10.5 (26.25%)			Team member median 12.75 (31.88%)			Team member median 8.5 (21.25%)	

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4. HACCP Knowledge – Team Member Scores vs. Team Score – Singapore Site

				Singapore		
				HACCP Team 1		
Q. No	HACCP Knowledge Area	Question	Possible Marks	Team Member Range	Team Member Median	Team Actual
1	Hazard analysis	Explain what is meant by a hazard?	2	0-1	0.5	1
2	Hazard analysis	Explain what is meant by a control measure?	2	0-1	0	1
3	Codex preliminary steps	What is the purpose of the process flow diagram in HACCP?	1	0-1	1	1
4	Codex preliminary steps	Why is it important to validate the process flow diagram?	2	0-1	1	1
5	CCPs & control	What is a critical control point?	2	0-1	0	1
6	CCPs & control	How can critical control points be identified? List two methods that could be used.	2	0-1	0	1
				0-1	0	0
7	CCPs & control	What is a critical limit?	1	0-1	1	1
8	CCPs & control	Metal detectors are checked every 30 minutes with metal test pieces. What kind of activity is this?	1	0-1	0.5	1
9	Implementation	What records might be found in the production area when a HACCP Plan has been implemented?0	2	0-1	0.5	0.5
10	Implementation	Why is microbiological testing not a good monitoring procedure?	2	0-1	0	1
11	CCPs & control	What should happen if there is a deviation from a critical limit?	1.5	0-1	0	0.5
12	Implementation	Describe the two main types of corrective action.	2	0-1	0	0
				0-1	0	1
13	Codex	Why is it important that the	1	0-1	1	1

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	preliminary steps	HACCP study is done by a multidisciplinary team?				
14	Codex preliminary steps	List the three main disciplines required in a manufacturing HACCP Team.	3	0-1	0	1
				0-1	0	1
				0-1	0	1
15	Implementation	What document is completed at the end of a HACCP study?	1	0-1	0	1
16	Maintenance	List two verification procedures that can be used to determine if the HACCP system is working correctly.	2	0-1	0	1
				0-1	0	1
17	Hazard analysis	Give an example of a hazard from each of the following groups: Microbiological Chemical Physical	3	0-1	1	1
				0-1	1	1
				0-1	1	1
18	Maintenance	When should a HACCP Plan be reviewed?	2	0-1	0.5	1
19	Implementation	What type of training is important for line operators when a HACCP Plan is implemented in their work area?	2	0-2	0	1.5
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	0-1	0.5	1

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21	Hazard analysis	Suggest a control measure that could be used for hazards associated with raw materials.	1.5	0-1	0.5	1
22	Hazard analysis	Which two factors should be considered when carrying out the hazard analysis?	2	0	0	0
				0-1	0	1
		Total	40	1.5-24.5 (3.75-61.25%)	Total of above Q medians 10 (25%)	26.5 (66.25%)
					Team member median 13.5 (33.75%)	

Appendix 5.1 HACCP Observation Checksheet

Appendix 5.1

Q Question Number	Task Answer Record Person No. * = interruption	Correct/ Incorrect C=correct I=incorrect P=partly	Group Reaction A=accept answer R=reject answer	Questions, statements, rephrasing question Record Person No plus Q, S or R * = interruption	Answer m.o. = majority opinion	Group support comment Record Person No * = interruption	Group Reaction + = positive N = neutral - = negative	Notes

Appendix 5.2

Summary Observational Data for Occasions when Team and Individual HACCP Knowledge Scores Differed

Appendix 5.2

Observed Decision Process in HACCP Teams:

Key: PO = Production Officer (Operator Level)
PS = Production Supervisor
PM = Production Manager
QO = Quality Officer (Operator Level)
QS = Quality Supervisor
QM = Quality Manager
ES = Engineering Supervisor
EHS = Environment, Health & Safety Manager
SM = Stores Manager
MM = Manufacturing Manager (Senior to other Managers)

1. HACCP Team Score lower than Individual Team Member Scores.

1.1 HACCP Knowledge Area – Codex Preliminary Steps

Q	Country/ Site/ Team	Results				Observed Decision Process
		Possible	Team Member Range	Team Member Median	Actual Team Score	
What is the purpose of the process flow diagram in HACCP	Australia Site 1 Team	1	0-1	0.5	0	PO and PS 3 offer suggestions; group agrees; PS 1 offers correct suggestion; PS 3 adds to this, then jokes about last question
	Australia Site 2 Team B	1	0-1	0	0.5	PO suggests it's to record things; QM/PO mention the process; PS suggests it's so everyone knows the process; 2nd PS agrees; QM reiterates that it is a way of mapping and checks that all are happy; the team agrees.
Why is it important to validate the process flow diagram?	India Site 1 Team A	2	0.5-2	1	1	Suggestion from ES; group accept; comment from facilitator (QM) then discussion by PS and PM; comment from 2nd PS; ES checks what to write - PM dictates plus some facilitator input.
	India Site 1 Team B	2	1	1	0	PS makes correct suggestion; QS adds every shift; additional comments from PS and QS; 2nd PS mentions that operator can change; additional comments from QS and ES, who mentions deviations in process.
	India Site 2 Team A	2	0-2	1	1.5	PS makes initial suggestion; discussion and nodding in Hindi involving all team members; QS reads back answers after majority agree; QS clarifies in English and Hindi.

	India Site 2 Team B	2	0-2	0	1.5	Suggestions from PO/QS/2PSs; PS recites answer and QS records; 2nd QS nods agreement; additional comments from POs; 1st QS checks what is written.
	Australia Site 1 Team	2	0-1	0	0	Contributions from PSs 3 and 2 and PO including mentions of validate and review; PS 1 rephrases; group accepts.
List the 3 main disciplines required in a Manufacturing HACCP team	Australia Site 1 Team	1	0-1	0	0	*Team failed to identify engineering expertise.* QM rephrases question; PSs 1 and 2 suggest process knowledge; QM/PS3 add comment about equipment and QA/technical knowledge
	Australia Site 2 Team A	1	0-1	0	0	*Team failed to identify production (1st score set) and technical (2nd score set) expertise.* PS suggests incorrect answer; QM suggests different interpretation of Q; QS and 2 PAs make additional points (one is correct)
		1	0-1	0	0	

1.2 HACCP Knowledge Area – Hazard Analysis

Q	Country/ Site/ Team	Results				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. (Scribe may be using his own language – he has written risk to product rather than harm to consumer and in his own submission he also mentioned contamination to a product.)
	Australia Site 2 Team B	2	0-1.5	1	0	QO makes correct suggestion; further input and discussion from PO, PS, PO; all agree.

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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 (PO), however QM states incorrect; another PO has partly correct and then QM states correct answer following discussion. However it is incorrectly recorded.
	Australia Site 2 Team B	2	0-1.5	0	1	2 POs make specific suggestions - incorrect; QM questions; PS suggests check sheet; 2PSs and PO discuss checking and control measures; PO mentions flow chart and QM reiterates Process Flow Diagram; PO suggests Standard Operating Procedures; QM asks what they should agree on; PO thinks there could be 50 answers; 2nd PO reiterates so many different things; QM reminds team that it is about food safety; QO tells team what she has put in individual submission.
What should the HACCP team do if they have identified a significant hazard and there is no control measure at that step or any following step?	India Site 2 Team A	2	0-1	1	0	Suggestions and discussion involving all team members
	India Site 2 Team B	2	0-1	0	0	PO suggests option; PS agrees, QS comments; 2nd PS says let him speak; further discussion; QS clarifies; further discussion including suggestion of 'modify' by 2nd QS.
Suggest a control measure that could be used for hazards associated with raw materials	India Site 1 Team B	1.5	0-1.5	1	1	EHS suggests SQA; QS mentions audits, specifications and certificates; 2nd QS suggests certificating the supplier's system; QS suggests only buying from approved suppliers; 2nd QS comments; EHS mentions vendor rating; additional comments from QS
	India Site 2 Team A	1.5	0-1.5	0.5	1	Comments from PS/QS/PO; PS mentions SQA; comments from PO and 2nd QS; 2nd PO agrees; comment from PO and 2nd QS; QM (facilitator) and 2nd PO agree

	India Site 2 Team B	1.5	0-1.5	0.5	0.5	Suggestions from all team members; general agreement; QS mentions there are 3 things; PS mentions vendor approval; all agree; 2nd QS checks re. isolation and records; PS thinks it is not a control; further discussion ensues; finally 2nd PS suggests SQA; He and PO mention storage; additional comments from QS and PO.
Which 2 factors should be considered when carrying out the hazard analysis?	India Site 2 Team A (Factor 2 = severity)	1	0-1	0	0	Comments from PS and PO; 2nd PS suggests risk and significance; additional comments from QS and PO; 2nd PO agrees; further comment from QS; PO agrees; further comment from QS; all agree.
	Australia Site 1 Team (Factor 1 = likelihood)	1	0-0.5	0	0	QM rephrases question; PS 2 makes suggestion; PS 3 suggests potential to harm; further comment from PS1/QM; PS3 re-states potential to harm; PS1/QM mention product recall.

1.3 HACCP Knowledge Area – CCPs and their Control

Q	Country/ Site/ Team	Results				Observed Decision Process
		Possible	Team Member Range	Team Member Median	Actual Team Score	
What is a Critical Control Point?	Australia Site 1 Team	2	0-2	1	0	PS 3 suggests control measure; PS 1 states part of process; PS 2 states for consumer; PS 1 gives correct answer; PS 2 elaborates and rephrases as does PS 1; PS 3 states 'ensure no hazards occur; PO reiterates and group agrees; PS 1 restates and records answer; PO and PS 3 rephrase; PS 3 adds; recites wrong answer
	Australia Site 2 Team A	2	0-2	0	1	Suggestions from PO and 2 PSs; QM suggests correct answer; discussion involving all; QM asks if all happy; further discussion and suggestions from all except 1 PS.
	Australia Site 2 Team B	2	0-2	0	1	Specific CCP suggestions from 2 PSs and 2 POs; QM questions why we have CCPs; PO and 2 PSs make additional suggestions; 2nd PO mentions weight control; further debate from 1st PO/QM; QM suggests pin point like metal detector; majority agree; QO gives correct suggestion - point where hazard can be controlled; all agree

How can CCPs be identified? List 2 methods (Answer other than decision tree)	India Site 1 Team 2	1	0-1	0.75	0	QS offers correct suggestion (decision tree); He and EHS mention experience (also correct for part b), particularly experience on the line; 2nd QS suggests looking at hazards on the line *2 people mentioned correct solution in the discussions.*
	India Site 2 Team 2	1	0-1	0	0	Suggestion from PS; PO and QS agree; comment from 2nd QS; PS agrees; QS asks what are the 2 methods; PS explains; POs nod and discuss; QS checks what is written; PS clarifies while PO and QS talk
	Australia Site 2 Team 1	1	0-0.5	0	0	PO states that it's a hard Q - PS agrees; suggestions from other Pos/PSs; QM suggests decision tree (correct); others don't know what it is so QM explains and asks if they were involved - no - it was done by someone else.
	Singapore	1	0-0.5	0	0	QM makes correct suggestion – decision tree – (for part a) and mentions customer complaints; asks what others put; EM - risk assessment; SM - flow diagram; PM - checks; MM returns to room with correcting fluid; QM - customer complaints; reiterates question; EM reads out question; PM suggests process flow diagram; QM repeats; MM suggests step-by-step; QM asks for another method; input from PM but 2nd method is left blank.

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What is a critical limit?	India Site 2 Team B	1	0-1	0.5	0	Suggestion from PO; PS agrees; comment from QS; PS agrees again; further discussion involving all team members; QS records answer.
	Australia Site 2 Team A	1	0-1	0.5	0	PS suggests partly correct answer; QS agrees; QM offers correct answer; all agree; QS states partly correct; additional input from PS.
	Australia Site 2 Team B	1	0-1	0	0	QM asks for ideas; PO suggests metal detection limits; QM mentions parameters; discussion ensues involving 2 POs/QM/PS about detection sensitivity; all agree; QO asks if team want to put an example; QM asks the team if it sounds right; QO asks what the example limit should be; POs agree on example; PO mentions other hazards; QM states difficult to measure for glass/wood; QO says it is easier with temperature.
Metal Detectors are checked every 30 minutes with test pieces. What kind of activity is this?	India Site 2 Tea A	1	0-1	1	0	PS and PO mention CCP monitoring; comment from QS; 2nd QS suggests verification; comments from other team members; 2 QSs discuss verification and monitoring; 2nd QS thinks verification; PO agrees; 1st QS says so it's CCP verification.
	Australia Site 2 Team A	1	0-1	0.5	0	PO operator suggests partially correct answer; PS offers incorrect answer; further discussion with QM, PS and QS
	Australia Site 2 Team B	1	0-1	0	0	PS suggests quality check; QM mentions CCP check and asks what is being checked; PS/PO state that they check if it is working; other PO thinks it is almost validating; QM says check the detector is working.

What should happen if there is a deviation from a critical limit?	Singapore	1.5	0-1	0	0.5	QM suggests partly correct answer - stop line; further input from EM/QM/MM - review; PM checks understanding and records; MM mentions implementation; further input from PM/EM/QM.

1.4 HACCP Knowledge Area – Implementation

Q	Country/ Site/ Team	Results				Observed Decision Process
		Possible	Team Member Range	Team Member Median	Actual Team Score	
What records might be found in the production area when the HACCP plan has been implemented?	Singapore	2	0-1	0.5	0.5	Input from PM; QM suggests process records; further input from PM/MM/QM re. CCP monitoring; further debate; MM mentions that you may not have a CCP; further input from PM/MM/QM; QM states check sheets.
Why is microbiological testing not a good monitoring procedure?	India Site 1 Team A	2	2	2	1	Suggestions from PS, QS and ES; 2nd QS mentions that it is destructive; EHS (scribe) mentions trends; PS agrees on trends; overall agreement. *All individuals got full marks for this individually. Correct themes were coming up in discussion but this question appeared to be somewhat hurried in the discussion – Query scribe role?*
	Australia Site 2 Team A	2	0.1.5	0.5	1	PO suggests answer; PS suggests partially correct answer; QS and PS agree that they had that too; 2nd PS adds correct point; also QM additional correct point; further input from QS; all agree

Describe the 2 main types of corrective action (type 2 process corrective action)	Singapore	1	0-1	0	0	QM - same as previous question; MM - review flow diagram; input from PM/QM; PM again mentions flow diagram; MM states it almost links with previous question; QM checks for 2 answers; QM mentions isolate product & retest; PM states isolate product; discussion ensues about whether to use tippex.
What document is completed at the end of a HACCP study?	India Site 2 Team A	1	0-1	0.5	0.5	PS and PO suggest HACCP Control Chart; QS runs through documents; comments from POs and QM (facilitator); QS asks if he should write HACCP Control Chart; general agreement.
	India Site 2 Team B	1	0-1	0.25	0.5	Comment from POs; PS rechecks question, then suggests HACCP Control Chart; 2nd PS clarifies in Hindi; additional comments from 2 PS; agreement from QS and POs; 2nd QS clarifies and records.
	Australia Site 1 Team	1	0-1	0	0	QM asks what is done once a HACCP is done; PS 2 suggests verification and sign off, which is accepted by the group.
	Australia Site 2 Team A	1	0-1	0	0	PS sup makes partially correct suggestions as does other PS; QM asks what the process would be at end of HACCP study; PS and QS answer; general discussion with input from QM; general agreement inc POs
What type of training is important for line operators when an HACCP plan is implemented in their work area?	India Site 1 Team A	2	0-2	1	1	PS suggests CCP/CP monitoring; ES adds corrective action; facilitators interject; 2nd PS mentions hazard analysis; PM reiterates CCP monitoring and corrective action; additional point from facilitators.
	India Site 2 Team A	2	0-2	1	1	Suggestions from all team members; general agreement; additional points made which PO and QS discuss; 2nd QS records.
	India Site 2 Team B	2	0.5-2	1	1	Suggestions from PS and PO; PS/PO agree; comment from QS; 2nd QS agrees; PS repeats; QS mentions monitoring; discussion involving all members; QS clarifies and records; PS gives wording.

	Australia Site 1 Team	2	0-1	0.5	0	PS 2 suggests GMP; QM suggests CCP training; PS 1 rephrases question; QM suggests on-the-job training and PS 1 records answer.
	Singapore Team	2	0-2	0	1.5	QM mentions how to monitor CCPs; PM says he doesn't remember this question; MM suggests overall HACCP training; QM - awareness; MM - then work area CCP training; QM restates awareness; PM/MM/QM reiterate training on the CCP - how and when to control; PM rephrases question; further input from MM/QM and PM, who records.

1.5 HACCP Knowledge Area – Maintenance

Q	Country/ Site/ Team	Results				Observed Decision Process
		Possible	Team Member Range	Team Member Median	Actual Team Score	
List 2 verification procedures that can be used to determine if the HACCP system is working correctly? (procedure other than audit)	India Site 2 Team B	1	0-1	0	0	Suggestions from PO/QS/PS; 2nd PO nods agreement; further comment from PO/QS/PS; PS suggests review of HACCP plan and training; QS repeats; discussion between PO/QS/PS; 2nd PS says 'no, no, no'; he suggests audit; agreement from PO/QS/PS; QS reviews meaning with PS; general agreement; QS clarifies answer and records
	Australia Site 2 Team A	1	0-1	0.25	0	PS and QM agree that they had problems with question; PS suggests something; further discussion between the two; more examples from QS

When should a HACCP plan be reviewed?	India Site 1 Team A	2	1-2	1	1	QS suggests change; echoed by ES; EHS mentions responsibility; ES asks colleagues to take their time. *Group accepted the first suggestion made. This was partly correct but not the full answer. They quickly moved on to the next section even through one team member asked his colleagues to take their time.*
	India Site 2 Team B	2	0-2	1	1	Suggestions from PS and PO; QS nods agreement; PO adds to answer.
	Australia Site 2 Team A	2	1-2	1	0	PO gives partially correct; QS makes additional point; PS makes additional partial correct point; QM agrees - *interesting that they have the correct answer between them here*

2. HACCP team Score higher than Individual Team Member Scores

2.1 HACCP Knowledge Area – Hazard Analysis

Q	Country/ Site/ Team	Results				Observed Decision Process
		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 QM gives full answer. Group agreement follows further discussion. Scribe records some of the points highlighted.
Which 2 factors should be considered when carrying out the hazard analysis? (factor = severity)	India Site 2 Team B	1	0	0	1	Suggestion from PS; 2nd PS comments in Hindi; discussion ensues; QS asks for clarification; suggested to think about hazard analysis table; PS identifies severity and risk; discussion in Hindi and agreement; QS mentions severity and frequency; PS mentions cause and source of hazard.

2.2 HACCP Knowledge Area – HACCP Implementation

Q	Country/ Site/ Team	Results				Observed Decision Process
		Possible	Team Member Range	Team Member Median	Actual Team Score	
What type of training is important for line operators when an HACCP plan is implemented in their work area?	Australia Site 2 Team A	2	0-1	1	2	Group starts with one partially correct suggestion and 2 other team members agree. Sparks off additional correct ideas added to be other team members in the discussion. Correct recording by scribe.

Hofstede VSM 94 Questionnaire

Source:

Hofstede, G., 1994, *Values Survey Module 1994*, Manual and VSM Questionnaire – English Version, http://stuwww.uvt.nl/~csmeets/~1st-VSM.html, last downloaded 3-2-09.

Appendix 6.1

VSM 94

VALUES SURVEY MODULE 1994

QUESTIONNAIRE

English version

hofstede@bart.nl

INTERNATIONAL QUESTIONNAIRE (VSM 94)

Please think of an ideal job, disregarding your present job, if you have one. In choosing an ideal job, how important would it be to you to ... (please circle one answer in each line across):

1 = of utmost importance
2 = very important
3 = of moderate importance
4 = of little importance
5 = of very little or no importance

1.	have sufficient time for your personal or family life	1	2	3	4	5
2.	have good physical working conditions (good ventilation and lighting, adequate work space, etc.)	1	2	3	4	5
3.	have a good working relationship with your direct superior	1	2	3	4	5
4.	have security of employment	1	2	3	4	5
5.	work with people who cooperate well with one another	1	2	3	4	5
6.	be consulted by your direct superior in his/her decisions	1	2	3	4	5
7.	have an opportunity for advancement to higher level jobs	1	2	3	4	5
8.	have an element of variety and adventure in the job	1	2	3	4	5

In your private life, how important is each of the following to you? (please circle one answer in each line across):

9.	Personal steadiness and stability	1	2	3	4	5
10.	Thrift	1	2	3	4	5
11.	Persistence (perseverance)	1	2	3	4	5
12.	Respect for tradition	1	2	3	4	5

INTERNATIONAL QUESTIONNAIRE (VSM 94)

13. How often do you feel nervous or tense at work?
    1. never
    2. seldom
    3. sometimes
    4. usually
    5. always

14. How frequently, in your experience, are subordinates afraid to express disagreement with their superiors?
    1. very seldom
    2. seldom
    3. sometimes
    4. frequently
    5. very frequently

To what extent do you agree or disagree with each of the following statements? (please circle one answer in each line across):

1 = strongly agree
2 = agree
3 = undecided
4 = disagree
5 = strongly disagree

15. Most people can be trusted	1	2	3	4	5
16. One can be a good manager without having precise answers to most questions that subordinates may raise about their work	1	2	3	4	5
17. An organization structure in which certain subordinates have two bosses should be avoided at all costs	1	2	3	4	5
18. Competition between employees usually does more harm than good	1	2	3	4	5
19. A company's or organization's rules should not be broken - not even when the employee thinks it is in the company's best interest	1	2	3	4	5
20. When people have failed in life it is often their own fault	1	2	3	4	5

INTERNATIONAL QUESTIONNAIRE (VSM 94)

Some information about yourself (for statistical purposes):

21. Are you:
    1. male
    2. female

22. How old are you?
    1. Under 20
    2. 20-24
    3. 25-29
    4. 30-34
    5. 35-39
    6. 40-49
    7. 50-59
    8. 60 or over

23. How many years of formal school education (or their equivalent) did you complete (starting with primary school)?
    1. 10 years or less
    2. 11 years
    3. 12 years
    4. 13 years
    5. 14 years
    6. 15 years
    7. 16 years
    8. 17 years
    9. 18 years or over

24. If you have or have had a paid job, what kind of job is it / was it?
    1. No paid job (includes full-time students)
    2. Unskilled or semi-skilled manual worker
    3. Generally trained office worker or secretary
    4. Vocationally trained craftsperson, technician, informatician, nurse, artist or equivalent
    5. Academically trained professional or equivalent (but not a manager of people)
    6. Manager of one or more subordinates (non-managers)
    7. Manager of one or more managers

25. What is your nationality?

26. What was your nationality at birth (if different)?

Thank you very much for your cooperation!

Appendix 6.2

Worksheet for Hofstede VSM 94 Data Collection

Appendix 6.2

Hofstede VSM 94 Questionnaire

Please think of an ideal job, disregarding your present job, if you have one. In choosing an ideal job, how important would it be to you ...						
(please circle one answer in each line across):		1 of utmost importance	2 very important	3 of moderate importance	4 of little importance	5 of very little or no importance
1	have sufficient time for your personal or family life	1	2	3	4	5
2	have good physical working conditions (good ventilation and lighting, adequate work space, etc.)	1	2	3	4	5
3	have a good working relationship with your direct superior	1	2	3	4	5
4	have security of employment	1	2	3	4	5
5	work with people who cooperate well with one another	1	2	3	4	5
6	be consulted by your direct superior in his/her decisions	1	2	3	4	5
7	have an opportunity for advancement to higher level jobs	1	2	3	4	5
8	have an element of variety and adventure in the job	1	2	3	4	5
In your private life, how important is each of the following to you? (please circle one answer in each line across):						
9	Personal steadiness and stability	1	2	3	4	5
10	Thrift	1	2	3	4	5
11	Persistence (perseverance)	1	2	3	4	5
12	Respect for tradition	1	2	3	4	5
13	How often do you feel nervous or tense at work?	never	seldom	sometimes	usually	alw
14	How frequently, in your experience, are subordinates afraid to express disagreement with their superiors?	very seldom	seldom	sometimes	frequently	very frequently
To what extent do you agree or disagree with each of the following statements? (please circle one answer in each line across):						
		1= strongly agree	2 = agree	3 = undecided	4 = disagree	5 = strongly disagree
15	Most people can be trusted	1	2	3	4	5

Appendix 6.2

		1= strongly agree	2 = agree	3 = undecided	4 = disagree	5 = strongly disagree
16	One can be a good manager without having precise answers to most Questions that subordinates may raise about their work	1	2	3	4	5
17	An organization structure in which certain subordinates have two bosses should be avoided at all costs	1	2	3	4	5
18	Competition between employees usually does more harm than good	1	2	3	4	5
19	A company's or organization's rules should not be broken - not even when the employee thinks it is in the company's best interest	1	2	3	4	5
20	When people have failed in life it is often their own fault	1	2	3	4	5

Some information about yourself (for statistical purposes):

21	Are you:	1. male				2. female				
22	How old are you?	Under 20	20-24	25-29	30-34	35-39	40-49	50-59	60 or over	
23	How many years of formal school education (or their equivalent) did you complete (starting with primary school)?	10 years or less	11 years	12 years	13 years	14 years	15 years	16 years	17 years	18 years or over

			☑
24	If you have or have had a paid job, what kind of job is it / was it?	No paid job (includes full-time students)	
		Unskilled or semi-skilled manual worker	
		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)	
		Manager of one or more subordinates (non-managers)	
		Manager of one or more managers	
25	What is your nationality?		
26	What was your nationality at birth (if different)?		

Hofstede VSM 94 Manual

Contains Guidelines and Formulae for Calculating Dimension Scores

Source:

Hofstede, G., 1994, *Values Survey Module 1994*, Manual and VSM Questionnaire – English Version, http://stuwww.uvt.nl/~csmeets/~1st-VSM.html, last downloaded 3-2-09.

1. How to use and not to use the VSM 94

The Values Survey Module 1994 (VSM 94) is a 26-item questionnaire developed for comparing culturally determined values of people from two or more **countries** or **regions**.

It allows scores to be computed on five dimensions of national or regional culture, on the basis of four questions per dimension: for this, it needs 5 x 4 = 20 questions. The remaining six questions are demographic; they ask for the respondent's gender, age, education level, kind of job, present nationality, and nationality at birth.

Experience has shown that the answers to the 20 content questions vary substantially between nationalities. This is not to say that every respondent of one nationality gives one answer and everyone of another nationality gives another answer, but on average, a sample of respondents of nationality A will (nearly) always score higher, or always score lower, than a comparable sample of people of nationality B (in statistical terms, an analysis of variance shows a significant country effect).

However, answers to the 20 content questions will also be influenced by other characteristics of the respondents, such as gender, age, level of education, occupation, kind of work, and year that the survey was held. Therefore, comparisons of countries or regions should in as far as possible be based on samples of respondents who are matched on all criteria other than nationality or region. They should be matched on any criterion (other than nationality) that can be expected to affect the answers.

The 5 x 4 content questions were selected because, when matched samples from different countries are compared, the mean scores for the countries on the four questions belonging to **the same dimension** usually vary together (if one is high, the other is high, or low if it is a negatively formulated question; if one is low, the other is low, etc.). In statistical terms, the country mean scores are strongly correlated. The mean scores for the countries on questions belonging to **different dimensions** usually do not vary together (are uncorrelated). Therefore, the 20 questions form 5 clusters of 4 questions each. The five clusters stand for the five dimensions of national culture identified in research by Hofstede and Bond.

When samples of respondents of the **same nationality** but with **different occupations** or **different employers** were compared (matched on criteria other than occupation or employer), the same dimensions were not found. Nor were they found when the answers of **individual** respondents were compared. The answers to most of the questions do vary somewhat from one occupation to another and sometimes from one employer to another, and the answers to all of the questions vary from one individual to another. However, the mean scores on the questions for different occupations or for different employers will not form the same five clusters. Nor will scores from individual respondents (instead of mean scores for groups of respondents of the same nationality) form the same clusters.

If the questionnaire is used to compare responses from individuals, from respondents with different occupations or employers, or from respondents belonging to any category other than nations or regions, the answers should be examined question by question and not combined into these five dimensions. There is no reason to assume that the present questionnaire is the most suitable instrument! **The questions and dimensions in this questionnaire have been chosen for comparing countries, and the questionnaire is meant for use at country level.** It should also be suitable for the

comparison of geographical regions other than countries (within one nation or across nations).

The minimum number of respondents per country or region to be used in comparisons is 20. Below that number, the influence of single individuals becomes too strong. The ideal number is 50. Even better is to use more than one respondent sample per country, such as men and women; or people of higher, middle, and lower education. In this case, of course, the numbers 20 and 50 apply to each separate sample.

2. Formulas for index calculation

The 20 content questions allow index scores to be calculated on five dimensions of national value systems as components of national cultures: Power Distance, Individualism, Masculinity, Uncertainty Avoidance, and Long-term Orientation.

All content questions are scored on five-point scales (1-2-3-4-5). Index scores are derived from the mean scores on the questions for national or regional samples of respondents.

Any standard statistical computer program will calculate mean scores on five-point scales, but the calculation can also be done simply by hand.

For example, suppose a group of 57 respondents from Country C produces the following scores on question 04 (security of employment):

10 x answer 1
24 x answer 2
14 x answer 3
5 x answer 4
1 x answer 5
3 x invalid answer*

57 in total

The calculation now goes as follows:

10 x 1 = 10
24 x 2 = 48
14 x 3 = 42
5 x 4 = 20
1 x 5 = 5

Total 54 cases = 125

Mean score: 125 / 54 = 2.31**

* Invalid answers are blanks (no answer) or multiples (more than one answer). Invalid answers are excluded from the calculation (treated as missing).

** Mean scores on five-point scales should preferably be calculated in two decimals. More decimals are unrealistic because survey data are imprecise measures. Using fewer decimals loses valid information.

Power Distance Index (PDI)

-

Power Distance is defined as the extent to which the less powerful members of institutions and organizations within a society expect and accept that power is distributed unequally.

The index formula is

$$PDI = -35m(03) +35m(06) +25m(14) -20m(17) -20$$

in which m(03) is the mean score for question 03, etc.

The index normally has a value between 0 (small Power Distance) and 100 (large Power Distance), but values below 0 and above 100 are technically possible.

Individualism Index (IDV)

Individualism is the opposite of Collectivism. Individualism stands for a society in which the ties between individuals are loose: a person is expected to look after himself or herself and his or her immediate family only. Collectivism stands for a society in which people from birth onwards are integrated into strong, cohesive in-groups, which continue to protect them throughout their lifetime in exchange for unquestioning loyalty.

The index formula is

$$IDV = -50m(01) +30m(02) +20m(04) -25m(08) +130$$

in which m(01) is the mean score for question 01, etc.

The index normally has a value between 0 (strongly collectivist) and 100 (strongly individualist), but values below 0 and above 100 are technically possible.

Masculinity Index (MAS)

Masculinity is the opposite of Femininity. Masculinity stands for a society in which emotional gender roles are clearly distinct: men are supposed to be assertive, tough, and focused on material success; women are supposed to be more modest, tender, and concerned with the quality of life. Femininity stands for a society in which emotional gender roles overlap: both men and women are supposed to be modest, tender, and concerned with the quality of life.

The index formula is

$$MAS = +60m(05) -20m(07) +20m(15) -70m(20) +100$$

in which m(05) is the mean score for question 05, etc.

The index normally has a value between 0 (strongly feminine) and 100 (strongly masculine), but values below 0 and above 100 are technically possible.

Appendix 6.3

Uncertainty Avoidance Index (UAI)

Uncertainty Avoidance is defined as the extent to which the members of institutions and organizations within a society feel threatened by uncertain, unknown, ambiguous, or unstructured situations.

The index formula is

$$UAI = +25m(13) +20m(16) -50m(18) -15m(19) +120$$

in which m(13) is the mean score for question 13, etc.

The index normally has a value between 0 (weak Uncertainty Avoidance) and 100 (strong Uncertainty Avoidance), but values below 0 and above 100 are technically possible.

Long-term Orientation Index (LTO)

Long-term Orientation is the opposite of Short-term Orientation. Long-term Orientation stands for a society that fosters virtues oriented towards future rewards, in particular perseverance and thrift. Short-term orientation stands for a society that fosters virtues related to the past and present, in particular respect for tradition, preservation of "face", and fulfilling social obligations.

The index formula is

$$LTO = -20m(10) +20m(12) +40$$
(revised version 1999)

in which m(10 is the mean score for question 10, etc.

The index normally has a value between 0 (very short-term oriented) and 100 (very long-term oriented), but values below 0 and above 100 are technically possible.

The formula was originally: LTO = +45m(09) – 30m(10) – 35m(11) + 15m(12) + 67. Experience with the first larger-scale application of the LTO questions, across 15 European countries in the context of a large-scale consumer survey, has shown that only questions 10 and 12 produced country scores correlated with other LTO measures.

The questions 9 and 11 should be replaced by new questions which are still being developed. For the time being the questions 9 and 11 were maintained for research purposes.

Appendix 6.3

History of the VSM 94

Appendix 1 of Geert Hofstede's book "Culture's Consequences" (both the 1980 and the 2001 editions) lists the original questions from the 1966-1973 IBM attitude survey questionnaires referred to in his international comparisons of work-related values. Appendix 4 of the 1980 edition presented the first "Values Survey Module" for future cross-cultural studies. It contained 27 content questions and 6 demographic questions. This "VSM 80" was a selection from the IBM questionnaires, with a few questions added from other sources about issues missing in the IBM list and judged by the author to be of potential importance.

A weakness of the VSM 80 was its dependence on the more or less accidental set of questions used in IBM. The IBM survey questionnaire had not really been composed for the purpose of reflecting international differences in value patterns. However, the IBM questions could not meaningfully be replaced by other questions until these had been validated across countries; and to be validated, they had to be used in a large number of countries first. Therefore, in 1981, IRIC (the Institute for Research on Intercultural Cooperation that distributed the questionnaires between 1980 and 2004) issued an experimental extended version of the VSM (VSM 81). On the basis of an analysis of its first results, a new version was issued in 1982, the VSM 82.

The VSM 82 contained 47 content questions plus the 6 demographic questions. Only 13 of the questions were needed to compute scores on the four dimensions identified by Hofstede. The other items were included for experimental use, and IRIC maintained a file on the answers collected by different users in different countries.

An initial analysis of replications using the VSM 81 and VSM 82 was produced by Nico Bosland in a Master's thesis. He analysed (1) what happens if the VSM is used as a test of individual personality (showing that the dimensions do not apply in this case); (2) the results of the replications, including tables to correct for the effect of education level differences on the dimension scores; and (3) the stability of the dimension scores when applied to a new set of country samples (which was less than perfect – a good reason to continue looking for an improved instrument). Bosland's tables to correct for education level have been reproduced in the 2001 edition of Geert Hofstede's "Culture's Consequences", Appendix 4.

An additional reason after 1982 to look for an improved version was that two questions in the VSMs were not applicable to respondents not employed in an organization, like entrepreneurs, students, and housewives (that is, a question about the behavior of the boss, and a question about how long one wanted to stay with this employer).

The number of replications using the VSM 82 in IRIC's file increased, but, unfortunately, it turned out that the samples from different researchers were insufficiently matched for producing a reliable new VSM. This changed when Michael Hoppe published his Ph.D. thesis on a survey study of elites (Salzburg Seminar Alumni) from 19 countries, using among other instruments the VSM 82 (Hoppe, 1990). Eighteen of these countries were part of the IBM set (Austria, Belgium, Denmark, Finland, France, Germany, Great Britain, Greece, Ireland, Italy, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, and the USA). One problem in the validation of the questions was the high level of education of Hoppe's population; his scores had to be corrected using the Bosland tables (see above). A second problem was a restriction of range within Hoppe's set of countries on the dimension of Individualism (very collectivist countries were missing in the set). A third problem was the strong correlation in his set of countries between Power Distance and Uncertainty Avoidance (no countries for the large PD, weak UA quadrant in the PD x UA plot). The latter two problems were resolved by adding data from other surveys for China, Costa

Rica, Malaysia, Nigeria, Taiwan, and Tanzania, although these were, of course, not perfectly matched with the Hoppe data.

In the meantime, the research of Professor Michael Harris Bond from Hong Kong, using the Chinese Value Survey (The Chinese Culture Connection, 1987), had led to the identification of a fifth dimension: Long-term versus Short-term Orientation. In the VSM 94, this dimension appears for the first time together with the other four. The formula for LTO in this manual is based on Bond's CVS survey among students in 23 countries (Hofstede and Bond, 1988; Hofstede, 1991, Chapter 7).

3. Comparison of the VSM 94 with the VSM 82

The table below lists the question numbers in the VSM 82 that correspond to questions in the VSM 94. **Please note that the sequence of the answers for questions 13 and 14 (previously I-21 and I-22) has been reversed, so that answer 5 has become 1, 4 has become 2, 2 has become 4, and 1 has become 5.**

Indexes calculated using the old and new formulas are not necessarily the same! However, the old and new formulas should produce approximately the same score *differences* between countries.

Comparison of old and new Values Survey Module:

VSM 94	VSM 82
01	I-1
02	I-4
03	I-5
04	I-6
05	I-8
06	I-9
07	I-14
08	I-15
09	new
10	new
11	new
12	new
13	I-21*
14	I-22*
15	II-1
16	II-7
17	II-11
18	II-12
19	II-19
20	II-20

* Scores were reversed

Questions I-11, I-13, I-19, I-20, and I-23 of the VSM 82, which were part of the formulas for calculating the first four dimensions, were not included in the VSM 94. Whoever wants to compute the scores using both the old and the new formulas for the sake of longitudinal comparison, should add these five questions to the VSM 94.

The five questions are:

Appendix 6.3

I-11 (format of VSM 94, 01 through 08): have an opportunity for high earnings.
I-13 (same format): live in an area desirable to you and your family.
I-19 and I-20: the descriptions below apply to four different types of managers. Please read through these descriptions first.

Manager 1: Usually makes his/her decisions promptly and communicates them to his/her subordinates clearly and firmly. He/she expects them to carry out the decisions loyally and without raising difficulties.

Manager 2: Usually makes his/her decisions promptly, but, before going ahead, tries to explain them fully to his/her subordinates. He/she gives them the reasons for the decisions and answers whatever questions they may have.

Manager 3: Usually consults with his/her subordinates before he/she reaches his/her decisions. He/she listens to their advice, considers it, and then announces his/her decision. He/she then expects all to work loyally to implement it whether or not it is in accordance with the advice they gave.

Manager 4: Usually calls a meeting of his/her subordinates when there is an important decision to be made. He/she puts the problem before the group and invites discussion. He/she accepts the majority viewpoint as the decision.

I-19. Now, of the above types of managers, please mark the <u>one</u> which you would prefer to work under (circle one answer only):

1. Manager 1
2. Manager 2
3. Manager 3
4. Manager 4

I-20. And, to which <u>one</u> of the above four types of managers would you say your own superior <u>most closely corresponds</u>?

1. Manager 1
2. Manager 2
3. Manager 3
4. Manager 4
5. He/she does not correspond closely to any of them

I-23. How long do you think you will continue working for the organization or company you work for now?

1. Two years at the most
2. From two to five years
3. More than five years (but I will probably leave before I retire)

4. Until I retire.

The formulas used for index calculation of the VSM 82 were (question numbers refer to the VSM 94 except for the five questions listed above):

PDI = (% mgr 1 or 2 in I-20) – (% mgr 3 in I-19) + 25 m(14) – 15

IDV = - 43 m(01) + 76 m(02) + 30 m(05) – 27 m(I-13) – 29

MAS = 30 m(04) + 60 m(05) – 39 m(07) – 66 m(I-11) + 76

UAI = 60 + 40 m(13) – 30 m(19) – (% answers 1 or 2 in I-23)

Note that m(05) occurs both in the IDV and in the MAS formula. For m(13) and m(14), the formulas are based on the reversed numbering of the answers in the VSM 94.

6. Literature

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Appendix 7.1 HACCP Interview Topic Guide

Appendix 7.1

	Interview Topic Guide **HACCP Process and In-house Business Dimensions**
Objectives	• Identify and analyse personnel perception of the HACCP process and in-house business dimensions during the application of HACCP • Provide extension understanding to national/cultural dimensions data

Introduction	• Thanks for participation
	• Background to the research
	  o Purpose
	  o How/why selected as participant
	  o Researcher background
	• Confidentiality and timing
	• No right or wrong answer
	• Not a test of knowledge – only interested in opinions and experiences
	• Free to interrupt, ask for clarification, etc.
	• Permission to record

Background	• How long have they worked for the company? • What job do they do – a typical day?

Management Commitment	• How did they first hear about HACCP?
	• What did management say about it at the beginning?
	• Did someone champion it on-site?
	  o Who?
	• How did management support the HACCP process?
	• Were there any problems?
	• Have senior managers kept involved?
	  o How?

Team Working	• HACCP requires people to work in teams, particularly when developing the system – are projects normally done by teams or individuals? • What other projects involve team-working? – examples.

HACCP Development	• How easy was it to develop a HACCP Plan?
	• Tell about your experience.
	• How did the HACCP teams work?
	  o Were there enough people?
	  o Did they have enough training?
	  o Tell me about the training
	  o Was the training appropriate?
	• Were there any problems?
	• What worked well?

Appendix 7.1

HACCP Implementation	• How easy was it to implement HACCP in the factory?
	  o Other business projects that clashed
	  o Resource
	  o Training for operators
	  o Recording systems
	• How did people on the line react?
	• What about line supervisors/managers?
	• What worked well?
	• Would you do anything differently?
	• What would people on the line say now about the day-to-day operation of HACCP?
	• Are there any resource issues?
	• Are there any training issues?

HACCP Maintenance	• Has anything changed since HACCP was implemented? – processes, products, materials, etc. • How have you managed to keep HACCP up to date? • Who is involved in verifying HACCP? • Who is involved in keeping HACCP up-to-date? • Are the resources sufficient?
Overall	• How well do they think HACCP is working now? • (Following several personnel offering suggestions on a numerical scale (0-10 or %), personnel invited to position their thoughts on a scale of 0-10 if they wished.)
	• Do they think FSM has improved? o Give an example
	• What has been the most difficult part of running the HACCP system?
	• What are the key things to ensure HACCP success?
	• Overall, what do they think the HACCP system has done for the factory?

Appendix 7.2

Global, Organising and Basic Themes with Detailed Interview Comments

Appendix 7.2

Global Theme – Committed Leadership

A Promotional Leadership

A.1 Providing Direction and Support

	'.....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...'	Factory Manager (India Site 2)
	'...support and encouragement....'	Corporate QA (India Site 1)
	'.....because I think we were very much looking into ISO 9000, and they said look, I think it was the senior manager from Australia who said "look as if food manager we should not be looking at ISO 9000 but HACCP as a food manufacturer"....'	Factory Manager (Singapore)
	'...the situation was safe product, food safety first...that was the message from management to the bottom line....'	Manufacturing Supervisor (India Site 1)
	...so the top management who are the owners of this plant....they want the site to do HACCP as a concept...so they were quite open for that one and they were being straight about it....so it was quite good then... ...there was a formal meeting with the officers and then the workmen were talked to what was HACCP, hazard....so top management involvement was quite good.....'	Manufacturing Manager (India Site 1)

A.2 Gaining and Demonstrating Management Commitment

	'(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

A.3 Showing Interest

	'...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.... basically..... and he has ...he has....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"	QA SUPERVISOR (INDIA SITE 2)
	'...it was a top movement and the full support from the top management was there and they understood...we always used to have the meetings and they attended the meetings and initially actually alternate days we used to have a meeting ...just to have...to be on the ball with that....and as a team with	Quality Manager (India Site 1)

	engineering manager, he was leading and A was one of them taking part in things in our team...and we had a lot of quite of discussive meetings.....we were discussing... manager was always involved...the factory manager – he used to come....he used to sit with us with the new flows and the initial plans also...this way we used to have a meeting with the factory manager...'	

A.4 Maintaining Support

	so I think support from regional they told us what we had to do ... get on with it- so in terms of training we had to find our people and look around.	Quality Manager (Singapore)
	'.....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)
	and until the part when we could find out what was the outcome of the HACCP there was good support.....for implementation also like on a par with CCP implementation it was full support actually...'	Manufacturing Manager (India Site 2)
	'...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 don't have very much to do with it.....'	Quality Manager (Australia Site 1)
	'...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...and we've done something and repeat training....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 when I mentioned it the other day....I mentioned about, you know, auditing and going through some things and it was with someone who obviously hadn't been involved before....so I don't know whether it should be more often introduced, you know....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)
	'...more support in our department...more management support...I think it has improved in management. I think things have definitely improved...'	Quality Supervisor (Australia Site 2)

A.5 Driving the HACCP Project

	'...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)

B Targets and Achievement

B.1 Clear Goals and Targets

	'...he said that if all the plants are to be HACCP certified there are some clear cut...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 1)
	'...quite supportive in the sense....interested....they were looking for the system to develop quick – quick results kind of thing...so in the initial phase they were very sup...eh...very aggressive to ensure safe (products)...'	QA Supervisor (India Site 2)

B.2 Monitoring Progress

	'...when it comes to the audit...down to the auditing.... what we have done with the monitoring....the CCP has to be monitored....doing the audit and the audit is a management review...'	Former Quality Manager (India Site 1)
	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)

C Empowerment

C.1 Connecting and Empowering Team Members

	'...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)

C.2 Creating Ownership

	...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)

C.4 Personal Accountability/Responsibility

	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)
	'...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)

D Mobilising Resources

D.1 Time

	'...was top management support so support and encouragement...you know....taking their time to work away from manufacturing...'	Former Quality Manager (India Site 1)
	'...because support was there, people were being freed to spend time...	Manufacturing Manager (India Site 2)
	'...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)

D.2 Financial Support

	'...Well I guess if we want to have money to do certain things we can actually ask for it, you know...at that point in time, well I think the...the thing is that we normally try to run here on a tight ship....some things they require too much money... we have a problem with the absolute, well we've got the RAM system...before they approve... 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)
	'...That was very well budgeted....it was well being talked to the quality manager and financial manager to keep money aside for	Quality manager

	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...'	(India Site 1)
	'...like at the beginning very clearly identify the areas...where money needs to be put in...capex requirements and all so definitely they were the source of ....the capex and all...'	Former 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 Mgr (India Site 2)
	'...if you need money to correct something ...Yeah, yeah, yeah – they empower us on the HACCP team...'	Manufacturing Supervisor (India Site 2)
	'...I've given L the green light to get a person...'	Factory Mgr (Australia Site 1)

Appendix 7.2

Global Theme – Foundations for HACCP

A. Basic Operational Conditions

A.1 Raising Cultural Awareness

	but it really helped with the prerequisites...the gmp programmes and not only that but the quality systems...HACCP plan – it was important...developed by officers but implemented by the operators...not only for the...but overall...when the group of operators...and then we developed the particular job and all...and now operators, I would say not 100% but a few operators they understand the importance of HACCP...they operate the quality system...	Former Quality Manager (India Site 1)
	'...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)

A.2 Prerequisite Programmes

	'...it was not only HACCP but it was all the prerequisites, like...eh... things like glass – sight glasses, equipment....'	Former Quality manager (India Site 1)
	'...the prerequisite was the foundation ....and that was a great training tool....which was clearly distinguishing between the hazard, the general risk and the process risk....you know...that was the first lesson that we had...and then we ...the whole HACCP team went into the prerequisite programmes...there was quite a complex reaction to this...you know, all of a sudden people would say 'Oh my God – never in the past have we looked into this – how can we avoid anything coming into the products and all that'.... we worked on literally what is required...and as, you know, the Standards were very well defined, but there are various ways of doing it differently...and that guideline was what we also did it, you know the 7 QAMs (from all sites) sitting together for almost a year and brainstorming and came out with a draft prerequisite manual..'	Quality Manager (India Site 1)
	'...before project starts, prerequisites must be there...otherwise we can't do HACCP... for implementation stage it took a lot of work....I have washed the operators hands 4 times in a shift, physically I have stopped ....(to do)hand washing ...because they are not ready for it with personal hygiene and hand washing – they are not ready....the GMP was better...it was how can you implement hand washing mostly.....I answer his questions...don't do...first thing don't tell 'wash hands', don't	Manufacturing Supervisor (India Site 1)

	tell....practice – first practice...wash our hands in front of them...we were stopping the line for 5 minutes....I was on count line – there were 21 operators...I say to them....contrary to production, I'll stop the line and... go and stop the line, I want hand washing...at that time we would have to go out...because I was cleaning operators hands....and that has worked...it took let's say 6 months-9 months....there was a way of checking if operators are doing or not doing...it was the same....we think hand washing is very simple but it is not simple...'	
	'...I think getting the prerequisites was quite tough to get started...because HACCP actually would have been OK to do....but getting the first things right took almost a year to more than 2 years, maybe...to get that thing right....because we thought that every question was hanging at the background...it had to be put in...so that was quite tough actually for us...'	Manufacturing Manager (India Site 1)
	'...rather than start with HACCP I would start with...I would say rather the framework or make the basis good...so that includes my GMP and the prerequisites...I would also say thoroughly ...for me it is very important that we think of everything at the unit.... So if I had to implement HACCP I would first do the PRPs and GMP.....if the people are not capable, I would start giving them the training ...because many times they have heard of the GMP hazards and what we call a simple process hazard....they have tried to relate to HACCP...and then we really don't have a CCP for every hazard...they had to be reduced by way of good procedures...'	Former Quality Manager (India Site 1)
	'(the most difficult part is)...I think it is the prerequisites...this is the most difficult part to maintain, implement and consistently ensure that we are maintaining high standards.... because once upgraded the structure you need to continuously upgrade and maintain that....'	Manufacturing Manager (India Site 1)
	'(the most difficult part is)...bringing the level of the site to the level required for food safety....you know that this site was a dairy (farm) and that you know that different production standards were here...and all of this equipment is here....oh no you can't have a (new) table because there is this table...oh no you can't have a (protected) glass.....the structure...I think moving towards this was the most difficult part...and also the guidelines on what was required – this was a bit difficult'	Quality Manager (India Site 1)
	'(the most difficult part is)...Prerequisites we have done for our process...'	QA Supervisor (India Site 1)
	'...Most difficult – eh - the GMP procedures – because it was long and drawn out...'	Manufacturing Manager (Australia Site 2)

	'(the most difficult part is)...whether we manage through the prerequisites or GMPs...but in actual sense, those GMPs are in place – the understanding of that, you know, glass should be covered, etc, but at some point we find that a glass is in there or is broken or is uncontrolled.....like metal we say is all controlled – you can't remove nuts, bolts and all that...so that is one part actually, because if we estimate that it is under control and then we take that into consideration that prerequisite is there (so) we don't need any control, you know, beyond that.....that is a part actually which is...eh...it still, you know remains to be answered...'	Manufacturing Manager (India Site 2)
	"(key factors for success include...)...one is clearly...good prerequisites in place and GMP practices in place...you don't embark on HACCP unless.... your GMP and prerequisites are not in place – first correct that...'	Factory Manager (India Site 2)
	"(key factors for success include...)...prerequisites like...should be literally your prerequisites basically you know.... 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 because ...the kind of assurance we want, I mean part of the non-conformances in the factory, part of the complaints we are getting and things...if we say it is getting covered by prerequisites but it is not....'	Manufacturing Manager (India Site 2)
	"(key factors for success include...)...Prerequisites to start with and support programs...'	Quality & Environment Mgr. (Australia Site 2)
	'...I think the basic fundamental things HACCP has benefited us is in prerequisites ...that has been a huge benefit to the company that is one... the other part of the HACCP the CCP monitoring, because it is in front of you, you religiously, every day you monitor...the prerequisite is beyond your daily job it is outside and you need to focus on that ....that is most important...maintaining high standards and making sure prerequisites are always included, that is very important...'	Manufacturing Manager (India Site 1)
	'...now sometime the operator comes to me and says the prerequisites...can we do very good things...can we do...so it is continuous improvement..... they are helping in the corrective action also...'	Manufacturing Supervisor (India Site 2)

	'...and there is also an increase in prerequisites...'	Operator (India Site 2)
	'...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 & Environment Manager (Australia Site 2)
	'...I think HACCP itself hasn't done very much yet, it's perhaps more GMP...'	Quality Supervisor (Australia Site 2)
	'...it's given people understand that we've got to keep things clean and understand the consequences can be if you don't upkeep that...they didn't in the past...'	Production Team Leader (Australia Site 2)

B. Planning and Process Documentation

B.1 Documentation Standards

	'(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)

B.2 Planning the Approach

	"(key factors for success include...)...find the approach with corporate input...'	Factory manager (Singapore)
	"(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...'	QA Supervisor (India Site 2)
	"(key factors for success include...)....standard of having it defined and implemented...'	Factory Manager (Australia Site 2)
	'(key factors for success include...) '...if it was a new factory they'd have the opportunity to plan the thing....we've had to...'	Manufacturing Area Manager (Australia Site 2)

Global Theme – Training and Development

A. Building Capability

A.1 Confidence (self-efficacy)

	"(key factors for success include...)....People knowing what they are doing....There's probably a lot who have never been trained...'	Production operator (Australia Site 2)
	Not sure where to start/ not fully confident:	
	..... we were kind of not fully confident of how the actual steps and it took us a few cycles to get it right....	Factory Manger (Singapore)
	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 Mgr (Singapore)
	Initially it was difficult to get started actually...from where to start and how to start....	Manufacturing Manager (India Site 1)
	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 Manager (India Site 1)
	I think it's a confidence thing as well...that it's not HACCP...if you're not confident	Quality Mgr (Australia Site 2)

A.2 Building knowledge base

	it was a new concept and it got quite a high level involvement...then we looked for expertise...more expertise... and there was like a little more balance on that side...that is important....getting more driven by the QA person, because you know they had more expertise and knowledge directly...because they have a fundamental understanding, you know, so people are going like that 'it is something to do with quality'...it is quality, quality is quality...so that is the way it goes – mentally people are looking like that...but slowly as we came aware that this is not the way that the system will get driven and implemented...because it has to be the whole knowledge from all key disciplines...because that is what will make the system	Quality manager India Site 1

	strong.....and quickly we then changed our style of working...and the first thing we did was again focussing on the prerequisites, we selected individuals from different functions...here in the (inaudible) area, and we declared them as the champions...	
	Knowledge Base and Gaining Understanding	
	I think the knowledge base at [India site 1] is quite good....people are quite educated and experience is good ...so definitely the depth of knowledge and the depth of communication that has been done has been quite good.....but at (the other site I worked at before) – they were not that knowledgeable or experienced...the whole factory was very new.....we had started like one year/two years kind of thing....so that kind of knowledge was not there....so we hired the quality people who were already there in ISO actually...so we only had that which was known about quality systems and all ...	Manufacturing Mgr (India Site 1)

A.3 Knowledge of Hazards and HACCP processes

	doing the study we had CIPs in this plant so we had a lot of continuous processes and we needed to do a CIP...so we had a lot of fights with engineering also because...and quality...quality was just there...they were supporting us saying yes, you need to do (a CIP)...but we had a bit in that we had production pressures also there....and the support document which quality gave made us very serious because once then we delayed for 8 hours the CIP, suddenly the samples were deficient...there was a rise in TPCs (total plate counts) which was of great concern to us...so that was the many things where suddenly we thought...initially we thought it was just something we had to do for CS but then we realised that it was a hazard, we identified it as a microbiological hazard so that was a very serious thing....so all these things the microbiological, metal and so on...it was a hard time to work through	Quality Mgr (India Site 2)
	So was it quite straight forward then to develop the HACCP plan? Oh yes! *And did you have any problems?* No, not at that time.	Production, Manager (Singapore)
	experiencing of the flow diagram is also a good kind of learning.....when you do all that stuff at the site you may miss some of the steps so when you trace that flow diagram and go onto the shop floor, you will identify some of the activities which are happening in manufacturing you have forgotten to include in flow diagram...so that is another difficulty....so you should, along with that stuff you should do a some kind of online checking of that flow diagram...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)

	no, because after identifying the flow chart it is easier.... first we identify the steps first, then we work on the steps...	Stores Manager (Singapore)
	Well, initially the confusion was there...then we worked through the confusion. So overall was it quite easy and straightforward to do or...? Yes, definitely.	QA Supervisor (India Site 1)
	Eh...it looked quite straightforward and simple...but in actual sense...if we honestly and rigorously do it like, then ..study like with some kind of rigour review...since then people do HACCP study, then one way is that people know about lines you know...	Manufacturing Mgr (India Site 2)
	I don't recall any major problems, I think there was lots of...there were more positive things that came out of it than problems....ehm...there was lots of discussions around well...is this a critical control point or not...is it really the, the....getting back to that route cause, if you like, or that base...ehm...controllability...I think there was lots of good debate around that...there was lots of debates around 'how are we going to fix this'	Factory Manager (Australia Site 1)
	Yeah...it's mostly straightforward...if you get the right people in...after you have drafted the flow diagram, I mean you have to go and walk the line...that's pretty much easy...so it's pretty straightforward, yeah....because if you know someone who knows HACCP then it's straightforward.	Food Safety Mgr (Australia Site 1)
	basically I went through....I didn't find it that difficult at all....basically..	Production Team Leader (Australia Site 1)
	It's relatively easy to, you know, map out, you know, step by step, you know, where the hazards would be and where the gateways and all that...it's sort of fairly logical in that way....ehm...and being involved with 6 people who've got more experience than myself is also good in that regard so, you know, if you're working as a team in that way you get to drop in different ideas...	Production Team Leader (Australia Site 1)
	Difficulties with some of the HACCP concepts or the HACCP process	
	Yeah, it was not to easy, because the people's understanding about the basics was not too clear...initially when we were doing the hazard analysis kind of thing, people take everything as a hazard....this can come, that can...because assumption.... a lot of assumptions was there....so once we go through, then we start asking people...are these	QA Supervisor (India Site 2)

	things just your assumptions or actually we have seen it...so then people tried to say...we have not seen this but we assume this can happen or it was happened say 4 years back...we have done a lot of things in last 4 years and last 4 years we have not repeated this kind of similar problem...so understanding of hazards...that was a really critical area for people...it's not so easy.....and then identifying the hazards within the system and that was another area....that was really, really good experience	
	I think the ...eh....the usage of hazard analysis charts was a little bit complicated in terms of getting it implemented ...because the knowledge base or people maybe not understanding it...but this was just reworded quite simpler and more user friendly...that is what we found ...CCP and CP – where to decide, what to decide.....there actually there were a lot of debates and a lot of arguments some times....which were the CCP and which were the CP and why it should not be.....to arrive at that conclusion using the standard method is much better rather than...I think...this has really helped us in deciding whether it should be CCP or CP...but that was quite difficult to manage.	Manufacturing Manager (India Site 1)
	Not (easy)...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)
	...at the beginning I was very worried.... I would say... you have a tool in your hands ...the Principles ...you understand them...you know how the eh plan has to be... how it has to be gradually put into a logical thing....how/when to validate...put out the records....But 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 that...through analysis....customer complaint...we understand....And then we do it more logically	Former Quality Manager (India Site 1)
	'(the most difficult part is)...Eh...the initial steps, when we're doing the flow chart and when we were identifying and preventing I think is an important step.....'	Stores Manager (Singapore)
	'(the most difficult part is)...the difficult part I seen was just the management of the flow chart the documentation...'	Production Team Leader (Australia Site 2)
	(the most difficult part is) '...Just doing the plans...getting it up and running is a lot of work but it's worth it...'	Process Team Leader (Australia Site 2)

	, 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.	QA Supervisor (India Site 1)
	"(key factors for success include...)...Hazards...identifying the hazards, without a doubt. Get that right first....'	Production Team Leader (Australia Site 2)
	'...Quality was going into the HACCP, yes.....it was becoming too complicated...everything was is control point, everything is control point as it's required ....temperature is important for the quality of the éclair let's say...so that also we were putting as a CCP or CP...so then they are saying does it mean that because of food safety we want to dilute the quality of the product, because you are only focussing on that...that kind of debates used to happen....'	Manufacturing Manager (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, Mgr. (Singapore)
	"(key factors for success include...)...how the operation works....understand the criteria and then look for hazards...they have to do a thorough risk assessment on the line...'	Food Safety Manager (Australia Site 1)
	Early on there weren't a lot of plans completed so there wasn't a lot of experience	Quality Mgr (Australia Site 2C)

A.4 Building Skills

Gen	'...I think (I would do) the one thing differently, I don't know but I always, you know, for any kind of a new thing, you know...eh...I see that practical understanding is better than the theoretical understanding....I would recommend people coming round to my factory...understanding when to do the theoretical lectures and then understanding how effective it is getting implemented...work from that...'	Quality Manager (India Site 1)
	'...about the time the teams were working on HACCP , the training was given to the operators so ...and as the plans developed...was included the record format, because the record format was different from before...totally different...so now they see how they should manage the CCP...how it should be the record keeping...so when the plan was developed we have called the people... crumb people or the moulding people....in crumb we have involved everybody, the oven crumb, the reactor crumb and it was training in HACCP. HACCP training was also done for the operators – the important things...what is control point in your process, what is the CCP in your process....and we have done this particularly for the person working in the job...'	Former Quality Manager (India Site 1)

	'(the most difficult part is)...the skill level of the people...	Manufacturing Supervisor (India Site 2)
	"(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)

A.5 Training

	"(key factors for success include...)...Training would be a thing...you know explaining what it is and why...'	Manufacturing Area manager (Australia Site 2)
	"(key factors for success include...)....training...'	Quality Manager (Australia Site 2)
	"(key factors for success include...)...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)
	'...Yes there has been a lot of training on hazards.....there is a lot things are better.....'	Stores Manager (Singapore)
	"(key factors for success include...)...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' but if you don't know you are using it, then, you know, and appreciate it, then 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, whether it be quarterly or 6-monthly, light refresher, you know...so people are constantly reminded...and still have the skills...'	Production Team Leader (Australia Site 1)
	'(key factors for success include...)....I think it (can) be important for them to be here to see how we run and get trained here...'	Production Mgr. (Singapore)

A.6 Educational Levels

	'(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)
	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 Mgr (Singapore)

Appendix 7.2

B. Communication

B.1 Enhancing understanding of new concept

	'(the most difficult part is)...I think that training is in one way difficult... 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)
	'(the most difficult part is)...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...'	QA Supervisor (India Site 2)
	'(key factors for success include...) '...Make sure everybody understands it....Make sure the training sessions are long enough to explain the whole food safety and HACCP...'	Production Team Leader (Australia Site 2)

B.2 Convincing People

Most difficult part	'...I should say (the most difficult part is) getting people to tell you that there is something wrong.... the communication part..... sometimes engineers just go and change something and you won't know about it until you bring you a process to review.....'	Quality Manager (Singapore)
	'(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	Quality Manager (India Site 2)
	"(key factors for success include...)...sending good quality messages to the people'	Factory Manager (India Site 2)

B.3 Generating collective wisdom

	'...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)

Appendix 7.2

B.4 Raising awareness

	'...the initiative that teams are being decided to work on the HACCP...it has helped well in terms of good coverage of the whole activity....also this training of operators on the food safety...that is a really good experience...and they actually help in terms of bringing the awareness of the food safety....which was quite good in my view....this with the prerequisites are the best things which have happened in this....' and '...I think understanding is one part which I'm sure it has been very well...but I think these...eh...we need to replace that training continuously...so it is not that once you do it and forget it....you need to continuously improve in terms of the food safety environment and the prerequisites...'	Manufacturing Manager (India Site 1)
	'...and it's really about getting that cultural awareness of the importance of it high enough so that people recognise the need to do it properly. .....' and '...probably do the training first up....ehm more thoroughly and to be honest as I look back at the HACCP implementation ... in operations... we didn't make as much progress for quite a while because we were trying to ...ehm...break the back of quite a critical body of work without putting enough resource into it, and it just didn't happen...'	Factory Manager (Australia Site 2)
	'...eventually are the ones who have to make it there..... we get more Hazards there than with machines, yeah, like hair you know..... I mean there are no customer complaints ....but what we feel is that we train people on food...'	Quality Manager (Singapore)
	'...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)
	'...It has drastically...actually the people are aware, the people talk in a similar language...there are no arguments on, you know, some of the quality related issues...there are no opinions, there are no 'ifs and buts'...eh...so clearly I think ...HACCP has brought a lot of synergy between complete supply chain...including vendor, your operations and your customers so there is quite a good synergy, you know...the language is the same...that's the way I can say it...an clearly awareness on some of the things that are food safety related issues...are being talked much ahead, proactively...'	Factory Manager (India Site 2)

	'...Yes, yes definitely....definitely because, I mean when I came here what I saw and what I see today there is an enormous difference...enormous...and it so happened actually, once I came in...just after 2 months, you know, I was exposed to your training actually and after that training we started the work here...and it has given an enormous outcome in terms of food safety controls....'	Manufacturing Manager (India Site 2)
	'...it's improved through the training...there's more awareness than before about what could happen....'	Food Safety Manager (Australia Site 1)
	'...I think it has definitely improved...ehm ...and found out why.... we get more and more sort of, you know, aware, and more and more sort of processes are better controlled...'	Production Team Leader (Australia Site 1)
	'...engage the workforce explain what it's all about ... the food safety management... and it has improved a lot here the awareness ...and every time you go on the shop floor now you see the awareness of foreign matter or any other sort of quality issues....'	Factory Manager (Australia Site 2)
	'(the most difficult part is)...I thought that it was very difficult to communicate....where they did not understand....HACCP implementation is very clear where there is communication...continuous communication....'	Manufacturing Supervisor (India Site 1)
	"(key factors for success include...)...and all the people will become aware of the risk and the hazard...'	Factory Mgr. (India Site 2)
	"(key factors for success include...)...just the awareness...bringing it up more.... it's just reminding them and keeping them in touch with it all...maybe annually or maybe less than that... but it's probably not brought up that much at all...that's what I'd say to improve....'	Production Team Leader (Australia Site 1)

Appendix 7.2

Global Theme – Team Building Processes

A. Team Processes

A.1 Challenging each other

	.....people are always quarrelling and saying why didn't you look at this and look at that? So in fact when E does run the process to see where are the points, actually there is a good eh...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....it was 'look, we did this yesterday but I think this is the right way'...eh and then some of the people get along very well...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...come out with a common understanding...and we'll learn'	Quality Manager (India Site 1)
	...people have got their, you know, ideas with them and they are all strong minded people who get our point across and put them all on the table and work out which is right and which is, you know, not so right	Production Team Leader (Australia Site 1)

A.2 Developing common understandings

	We've all got a good understanding of each other and we work well as a team	Production Team Leader (Australia 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...so that exercise took some time ...eh but the first exercise ...because it was part of believing that it has to be done...it was more of an anxiety what are we required?	Factory Mgr (India Site 2)

A.3 Getting together

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

Appendix 7.2

B. Team Make-up

B.1 Multidisciplinary/Cross-functional

	Increasingly more recently, in the last 2 years or so..we've been making good use of teams ....before that not so broad based the teams...more confectionery on its own (*Note: in this site confectioners is the term used for production operators)*	Factory Manager (Australia Site 2)
	Yes – projects are normally done in teams. .... Generally – ....cross-functional teams, people like V (QA), people form mechanical and electrical trades, people from manufacturing. My personal view is that it works. .....some of the outcomes..... Because we have involvement form the start it works well.	Manufacturing Manager (Australia Site 2)
	there's always been cross-functional input for projects.....	Quality Manager (Australia Site 1)
	Cross functional team or multifunctional team was part of the culture that Cadbury 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 ...that multidisciplinary people are working together on the same objective...was never an issue...and this is true if in factory is almost absent...people always have to have each other's support...so they always work on various projects as a cross functional team or multidisciplinary team. So it was nothing new? Nothing new	Factory Manager (India Site 2)
	Were people here used to working in teams or was that a new thing for them? Basically, that actually was a plus point for the site, because people were working from manufacturing, from asset care, from quality and we had some experts...microbiologists also there...and eh...some, basically some person was there in the team who was kind of HACCP expert you know like Person X or someone like that Did you actually take part in one of the teams yourself or were you involved in a number of HACCPs? NO I was there initially...because I was in quality, you know and I was handling HACCP, you know ...I was part of management team at one point in time actually...but now basically, because all the studies are done actually, I am just involved in the implementation part of CCP etc, you know...more on the manufacturing side now	Manufacturing Manager (India Site 2)

	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 team is working on that...a total quality team, a technical team...technical, quality engineering, asset care and manufacturing....they have devised the team work for that. So it was one of the first things that got teams working? Got the teams working, yes, and ...many things got the operators convinced actually, because when we started involving the operators...they started knowing this...yes these are the things we need to do...why we are doing it....it is not a process....it is not just a SOP it is why...why...it is why we are coming to this.	Quality Manager (India Site 2)
	actually the team formation was the common function....everyone has HACCP training ....was asset care, manufacturing or quality person ...in some groups we have and some we don't have but 3 persons it was core .....it was formation by design...it was like that...for teams....and we have then the hazard brain-storming, for analysing hazards...everything was for team.	Manufacturing Supervisor (India Site 1)
	experiencing of the flow diagram is also a good kind of learning.....when you do all that stuff at the site you may miss some of the steps so when you trace that flow diagram and go onto the shop floor, you will identify some of the activities which are happening in manufacturing you have forgotten to include in flow diagram...so that is another difficulty....so you should, along with that stuff you should do a some kind of online checking of that flow diagram...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)
	'(key factors for success include...) '...combination of the people...'	Food Safety Mgr. (Australia Site 1)

Appendix 7.2

B.2 Team Selection

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

B.3 Didn't use teams

	....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)

B.4 Team Leadership

	Definitely need a strong quality person pushing it...reminding people the week before that they need to come...that's what happened the first few times...which is not a nice thing to do – it should be coming from them...	Quality Supervisor (Australia Site 2)
	all with teams....it was...the first thing we did was identify that someone needs to coordinate it, these activities, because you know, different things were happening and there was no central report available to them to really flesh out the differences and get a common understanding...so that was when we selected one person as a coordinator, and A 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)

C. Supportive Culture

C.1 Commitment/ Accountability

	'...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)
	if there is another commitment,....	Quality Manager (Australia Site 2)
	"(key factors for success include...)...basically everybody has to	Quality,

	be committed to it.....can have all the procedures you like in place but if people aren't following them then it's not going to work.....'	Manager (Australia Site 1)
	'...I think the ...commitment and the drive...the commitment has certainly improved...'	Quality Manager (Australia Site 2)

C.2 Involvement

	....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...that you ...and without the people come together...they have always had the small group activities, but this gave an opportunity to work as a group....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)
	Production people were involved...everyone was involved in it...	Manufacturing Area Manager (Australia Site 2)
	I think probably a few teams...people operators...the whole thing to realise the importance of it...production officers...production is very difficult. It did improve...the first time we reviewed the HACCP plans....not easy and I have one of the easiest departments too.	Quality Supervisor (Australia Site 2)
	there was (only) a few people involved in it in the early days	Production Team Leader (Australia Site 2)
	Well it requires people to work in teams (and) around us quite a close team here in the management anyway...and most people came and had training	Production Manager (Singapore)
	...I mean we sort of form a like ...I suppose anything we do, whether it be launching a new product or launching the new manufacturing system that we are doing now, is we do it as a team....with myself and (mentions 4 others from production) and then the QA plan...and we all sort of meet together anyway every day...so we're continually playing as a team...so it is a team environment.	Production Team Leader (Australia Site 1)

	HACCP team-working definitely from the preparation and planning stage and implementation ....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....because it was not obviously the leader of that group.....managers actually basically want to bring that right down to the operating level....(inaudible)..in that sense it was required.....also a lot of documentation has to be done by the management team....for that also we had a team involved	Manufacturing Manager (India Site 1)
	and of course actually involved were the group for the function of hazard analysis and CCP identification because it was not just manufacturing it was the opportunity for everyone...	Quality Manager (India Site 1)
	'...the initiative that teams are being decided to work on the HACCP...it has helped well in terms of good coverage of the whole activity....'	Manufacturing Manager (India Site 1)
	"(key factors for success include...).....the key thing would be getting the people involved....it's not the system it's the people involvement ....people involvement is the most important thing'	Factory Manager (Singapore)
	"(key factors for success include...)...team building and team-work...and making sure that the operators are there...these people have the main skills for doing things...once they are convince, nothing is a problem...'	Quality Manager (India Site 2)
	"(key factors for success include...)...and we're talking about everyone here aren't we, I mean that's what I think, I mean everyone needs to know more about it... that's what I'd say to improve it...involving everyone on the floor with it....'	Production Team Leader (Australia Site 1)
	"(key factors for success include...)...and probably giving people an appropriate involvement...'	Quality & Environment Mgr. (Australia Site 2)
	'(key factors for success include...) '...Involve the key personnel....'	Production Team Leader (Australia Site 2)
	See in this factory right from the start, we tried to involve operating teams in this process. We are not, never asked as a top-driven kind of process so right from the start we have involved operators, manufacturing executives and their teams....because most of the problems, most of the work is required to be taken on by them only...so when we started forming teams, we have involved all the members from the factory...from operations, from asset care and from quality side....	QA Supervisor (India Site 2)

C.3 Supportive Teams

	so it was quite a supporting kind of thing and I would say, the factory operating, particular operating team, whenever we ask for support they have given freely support and they always give	QA Supervisor (India Site 2)

	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.... (additional inaudible comment)	

C.4 Culture of Working Together

	.... 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 [Company name] Singapore...	Factory Manager (Singapore)

Appendix 7.2

Global Theme – Resource Management

A. Finances

A.1 Managing Cost

	teams were getting support very fast...and it is also financial so they are not getting stuck...so that's the way we put the mentor...and I would say that I was overlooking the entire system also, getting the right system, getting the good guidelines	Quality Manager (India Site 1)
	'(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)

A.2 Capital Expenditure

	'(the most difficult part is)...I think it is related to CAPEX (capital expenditure) some of the things...(need a lot of money)'	Manufacturing Manager (India Site 1))

A.3 Cost of Control

	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...well we're going to have to totally rebuild this and do that and we need a whole lot of mechanical type ...engineering, if you like, fixes...ehm...as we got through the process 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 sugar 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...and I think as the team got used to sort of thinking like that they, as time went on and we got to do the HACCP plans on the line..	Factory Manager (Australia Site 2)
	...initially we identified a number of hazards...and in that case we don't have a certain kind of control measure in our line....like initially we had a problem with chemical contamination with lubricant and at that time we discussed with a lot of technical people and with experts how we can control this but we don't find an easy solution at that moment...then the team at the factory itself worked for 6 months through and they developed the adapter kind of thing which we are placing between the gear boxes and the tank....so we still provided some kind of trace (contamination) protection....so that was the first case....so that takes a lot of time to go into that and it was, this problem also	QA Supervisor (India Site 2)

	occurs at nearly all the factory...because most of the gear boxes are top mounted kind of thing.....so first year we have experienced that kind of thing...later on, because there were money constraints also with us....so we wanted to use food grade kind of oil but it was not so easy to incorporate into the system, requiring a lot more, lot of money to replace the entire thing in one go....but once the HACCP process had gone into it, in the top management's mind, and then we decided – we have controlled the issue – so now we need to eliminate the issue – so now we move to food grade kind of thing.....so one can say that we learn about, learn all these with experience – how to eliminate, how to reduce the problem.	

B. Time

B.1 Getting the Team Together

	It's easy to put a team together it is just trying to find the time to do it...to get them together...but yes...when we explain the requirement and why we are doing it.....what's unacceptable and why we need a HACCP plan...so it's just time really....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)
	'(the most difficult part is)...and the time involvement of everyone...'	Production Team Leader (Australia Site 1)
	It was not that straightforward, it was not that straightforward because eh...operator was involved, and actually we used to spend a day...5-6 hours every time in this meeting.....it was quite a big long discussion....because engineering is there if we need some modifications there...so we have engineering to take the modifications and we can stop and do a process change there.....so initially it was a bit unclear but if you go through that process certainly it helps ...	Quality Mgr (India Site 2)

Appendix 7.2

B.2 Shift Work Issues

	'(the most difficult part is)...The time...the time and the people and also the ...getting it to the people. It's a resources thing...4 days on 4 days off....we lose people for 4 days and we lose them on weekends there's no-one...'	Production Team Leader (Australia Site 2)
	...people at the same time...different shifts...hard to get everybody there	Manufacturing Area Manager (Australia Site 2)
	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)
	...pretty much team-work I would say...and, and ...and saying that, I was on lower shift too....so I suppose it's sometimes it's like usually on back shift you are in amongst it all....I mean like doing different stuff...and other things...but I mean I was on afternoon shift in the chocolate room...so I mean it's like usually afternoon shift and night shift are probably you know the forgotten shifts and such...you are not involved in different types of things that come along like you are on day shift.....in saying that, like I was on afternoon shift and I got involved, which was good. So do people tend to stay on the same shifts then – the shifts don't rotate? Pretty much, yeah, they don't rotate regularly.	Production Team Leader (Australia Site 1)

B.3 Availability and Motivation

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

B.4 Timescales

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

B.5 I don't have time

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

C. Personnel

C.1 New Personnel/Old Staff Leaving – Knowledge and skills gaps

	'...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, at both levels.....if you look at the prerequisites, you can look at the contractors coming in to play...that has got one chance that the engineering has been going on contract...but the other activities upstairs for example. (inaudible)...is going on contract...really there are a lot of prerequisite issues that need to be controlled ...we have a different set of people every day to be trained for that....and if we look at the one in manufacturing because they are sometimes coming inside because proper people aren't there...without knowing the CCPs.....so you also need to take care of that...so it has become a challenge...and I think that we need to look into this as a challenge...and I think that it should not be left like what has happened in the past, but it should have a very structured way of getting these people inside...I mean we should be proactive doing this...you know, it can't be left because ....I mean we know that it is happening, because it is clear that it is a very short time that this condition has taken place...and we are not (inaudible) to it...and we are looking at it....if I know it is a concern then I need to go back...how do I take my temps in place?, how do I take my contractors in place?...right...at what time do I need to take for them to be there immediately...because it can't be absolutely I need to take temps so that I can give them the training...but would that be enough?....because I have spent so many years in understanding this and they have to understand it in a short time...I think that we need to have a good structured programme for that so that you have a basic certificate....nobody has done this but I think there are more structured ways we should be looking at doing...in totality we need to define that all new people will be coming – contractors, those at the product, away from the product...what is the area they need to understand? ....prerequisites, or projects around the process....and accordingly having a structured input to them, an understanding of practically what is happening on the floor and then giving them a certificate – now you are able to work /enter the room...'	Quality Manager (India Site 1)

	'...we've got about 350 odd core (staff), but our total number is about 950, so 2/3 of our total are new employees so if you pick...if you happen to pick one of those they wouldn't have a clue about it...	Factory Manager (Australia Site 1)

C.2 Contractors

	'...maybe a concern is coming when we go for a contractor....because we are having some contractors (during the expansion) and there the prerequisites, the GMPs will come into things...these guys are there and we are trying to fit them in for 6 months but we have given the training....and the foremen workers are there day in day out they are doing the things that are needed and they go on improving and we improve on that...'	Quality Mgr (India Site 2)
	'(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)

C.3 Skilled Resource

	'(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)
	'...you know manpower resourcing...'	Factory Manager (India Site 2)

E Prioritisation

	'.(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)
	"(key factors for success include...)...Making the priorities – so don't get behind on it...'	Quality Supervisor (Australia Site 2)

Appendix 7.2

Global Theme – Embedding the System
A. Implementation Practicalities

A.1 Implementation Difficulties

	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)
	...no way was it easy...	Manufacturing Mgr (India Site 1)
	It wasn't easy...they had the HACCP plan...that's pretty much as far as it went as far as I could see... so I'd say implementation is one of the hardest things...	Quality Supervisor (Australia Site 2)
	'(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 Packing & Logistics Mgr. (Singapore)
	'(the most difficult part is)...the Implementation part...'	Manufacturing Supervisor (India Site 1)

A.2 Establishing and improving control limits

	Yeah, basically what happened was that in the whole factory the major CCP was only the metal detection, and , before we even went for the HACCP study, when doing our prerequisites itself....the prerequisites formally came later on but as a part of GMP only, ehm...we started monitoring our metal detection limits on hourly frequency...before it was even, you know, went through the HACCP, so it was already in the line that they had to do it. So we did not have problems...	Manufacturing Mgr (India Site 2)
	I think this experience was quite a lot...with this initial HACCP plan it (experience) was really needed...what we were doing was looking at the manual and then just writing down...then we have sat for 2 hours and done the process and then cross check and there are no differences....all the ingredients were there and the processes...I was quite happy...the confidence which it gave me...and then the new line has come and now it is just a process and it is a matter of just cross checking and amending as necessary. So with the experience of before, it was quite straightforward	Quality Mgr (India Site 2)
	No I think it was reasonably straightforward because we would have been involved to some extent in making sure that all the CCPs were on the check-sheets because my department created all the check-sheets ...eh...at that stage....and there's not that many complicated CCPs in the factory...it's mostly metal detectors and the odd thermometer...so I don't think that was terribly difficult...they were already used to filling out check-sheets so it was just to continue with that...	Quality Mgr (Australia Site 1)

	...it was pretty standard...I remember the guys all pretty much knew it by heart, I mean they had a check sheet up there with the sieves that they used to check...eh ....twice a shift initially, although it could have been every hour...but I mean it was pretty stringent, pretty good...like all the guys would never...I don't think it ever got missed.	Production Team Leader (Australia Site 1)
	I think the implementation was quite straightforward because the number of HACCP points we have on each line is quite ehm low....	Factory Mgr (Australia Site 2)
	The things like metal detection have been really straightforward	Manufacturing Manager (Australia Site 2)
	there weren't too many surprises...there were things that we were doing already – we just needed to follow the HACCP plan	Manufacturing Area MGR (Australia Site 2)
	I don't think there were any issues. I think we've got the monitoring situation more or less of pat. Any ...we want to do is more or less done	Production Team Leader (Australia Site 2)
	Early on there weren't a lot of plans completed so there wasn't a lot of experience. I have to say that now ...very much more recognised that the production people are part of it...HACCP team identified the gaps....putting in the gaps and the timeline (needs production input)	Quality Manager (Australia Site 2)
	Well it was pretty straightforward in the process area...	Process Team Leader (Australia Site 2)
	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)
	'...for example we have a metal detector is one of the critical control points and yes it is fully implemented and we have a very good control .....but for instance how do we prevent the stuff from getting into the product OK.... and then that process is not very much under control.... is in doing preventive rather than try to stop a problem.... so that's something we're not very effective on.... for instance, metal is one thing that does come in with the raw materials.... we do an audit.... to audit our supplier.... we push forward and say these are the issues we have... but when new product comes in.... yes some has improved but some have not improved but it should be a standard that everyone who supplies raw materials to us has to follow... but we do not have that... yes does indeed need a bit more work	
	'...but clarity was not there from where...how we had got the procedure of say 1.5mm Ferrous, 2mm non-ferrous, 2.4mm SS, you know....that I still feel is not there actually, we don't know...when we did HACCP we thought...from where apart from the hazards...something was also contributed by the limitations of the machine because it cannot test beyond 1.5mm...so that was the factory specific issues...'	Manufacturing Manager (India Site 2)

	'...for like quarantining of the material, that was another extreme area where we had to make a cut off....so some people do not agree – they think rework...'it's not safety it will go for rework'....people had not taken rework also as a potential source of contamination....so they are not identifying this....such kind of problems come in the initial stages....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%....	QA Supervisor (India Site 2)
	'...so the product is released that reaches the temperature...if it's below the required...require 110 around there. ...For every batch we have the records of temperature.... when a batch starts and when the batch finished... is complete. We check and record the temperature accordingly. Yes, the operators will do that. If there is any problem with a batch they tell the team leader who has a look .----and we decide whether the product is going to be over roasted or not..... '	Operator (Singapore)
	"(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...because the HACCP can fail...you can blame the HACCP but if you are eh... 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)

B. Maintenance

B.1 Audit

	we were working separately on that along with the corporate group (CIL)...or even planning the entire audit for prerequisite – cross-factory audits/inter-factory audits...so I was looking more into that sort of a mechanism..	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)
	'...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 by Dr A....and UK coming down...corporate coming down...so we felt that these are the more 'expertised' audit, we could use that as a...eh...you know...expert assessment...but now we are also doing the audits internally...and now this is also the opportunity – you are here – to get one more view and find what more we need to do for the certification...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...'	Factory QAM (India Site 1)

	'...partly because of the requirements of having external audit...so that seems to focus people's minds on things...'	Quality Manager (Australia Site 1)
	'...I think that the most difficult part is, as I said, the fact that it 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, you know...and that's the hardest part of it, 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)
	'...when it comes to the audit...down to the auditing.... what we have done with the monitoring....the CCP has to be monitored....doing the audit and the audit is a management review...'	Former Quality Manager (India Site 1)

B.2 Verification Systems

	'.....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...but I don't know if that is sufficient...because....eh...I think it is unsatisfactory if we get one market complaint of some foreign matter getting into the bar...that is what we are looking at...but when the process activity verification part - 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)
	'...Micro testing...if I can give you an example - the crumb testing – we were working on something like 50,000-60,000 with a SD of 10,000...now it's 25,000 with SD of 2500 - this is a good example for the unit....microbiological and last year we have developed the enterobacteriaceae count for the WIP and finished goods... but now I know my crumb what count it will have, my CDM what count it will have .....if it is more than that it will ring an alarm and you go back and look at your hygiene....it has to be ongoing...and also the market complaints we look at...'	Former 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...'	QA Supervisor (Australia Site 2)

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B.3 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)

B.4 Change Management Systems

	the HACCP plans that I have updated myself...everything's been OK.	HACCP Coordinator (Australia Site 1)
	'...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)
	'.....actually move onto that first of all we have to look at when we put in that modification, if we do it is it going to cause anything to happen to the product....that is the first thing we have to look... and whatever we are going to modify, we would definitely going to trace the data output and have a better product. So normally we will have to study that first before we release and ask the engineers and say we want to do this.....'	Production Mgr (Singapore)
	'...Yes, there is a change review process...the HACCP team would review...I think it has now been gone into our internal system .... if you do anything for Environment, Health & Safety the approval has to be there...so maybe the system could be expanded and it (food safety) can become a part of that system, the HACCP review....but currently it is a separate system....and it will stop for that HACCP approval....'	Manufacturing Manager (India Site 1)
	'.....it was always given a job to the coordinators to keep a track on the group and looking at if changes have happened or not and to take them back through (if changes)...Yes...those people who worked on the technicological team here – product safety, they reported to the group changes, you know, hazard is established....can we report it to the HACCP process flow and look into the hazard analysis...so that is what happened....'	Quality manager (India Site 1)

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	'...I think when we developed the system called change management ...the equipment...the procedure...everyone is required to report to the QA if there is any change in...the raw material , process the equipment....or we change job responsibility in production...we have a very robust system of change management...'	Former Quality Manager (India Site 1)
	Eh...what we have is in terms of any new product on an existing line...clearly we have got a trial protocol...in the trial protocol with the SMT team and the quality team ...we have to go through an understanding of all the ingredients and their ...if there are any issues with that...so any new product on the current line, if there is any different ingredient we have to update our HACCP sheet... If it is a new line then it has to go through what we call ...IOTQ, which is implementation qualification , operation qualification and technical qualification...so in that team all these HACCP plans are all being checked...they are already, you know...so if there are any hazard which are related to the equipment...so in other words they need to be resolved, then you don't start the line...so it is documented...so all the change management documents for that is being documented...there is a protocol that is there and it has to be signed by all the concerned people...and then only the line is cleared for the production...'	Factory Manager (India Site 2)
	'...Eh...I think the understanding is that we ...even now...whenever anything changes in the process or maybe a raw material or maybe some other thing on the line...it will ask for a... ask for basically a HACCP review...basically...so that is being done and we have incorporated some things so we can see if it is a significant hazard or not...'	Quality Manager (India Site 2)
	'...Here it is part of HACCP system embedding in our system....whenever a new change or whenever a new equipment comes, or our operating team is quite interested, they always come to us (QA team) first before the additions and we understand...understand the problem...so how to, how we are going to resolve this...'	QA Supervisor (India Site 2)
	'...We don't have a procedure as such but we do look at things scientifically...and if there is a risk it is updated...so once I get that e-mail we review it...'	HACCP Coordinator (Australia Site 1)
	'.....trying to take a proactive approach...at the start of the process rather...what we're trying to do and it's early days yet...is to have a food safety team and they have a broader scoping.....once a month or once in 2 months...is there any change in the products or process. Also we're trying to work more closely with the process engineering team so that if ...early rather than later in terms of developing the HACCP plan...significant new product or products using different technology...or new ingredients...trying to do it earlier...we're probably not doing it perfectly...'	Quality Mgr (Australia Site 2)
	'(the most difficult part is)...the modification part actually, because ehm...what happens is there is some verification?...'	Manufacturing Manager (India Site 2)

C.. Management Processes

C.1 Making it part of everyday life

	it is a matter of telling them OK you know you are to do this..... maybe once a day in the morning...you do the record...you can explain..... no problem..... Yes, you find that the employees here whenever you tell them to do something they will do it..... they are quite receptive	Quality Mgr (Singapore)
	No, they are quite confident also...they can....they are doing...they know how to do....there is no problem...	Manufacturing Supervisor (India Site 2)
	Initially problems were there but afterwards....after something becomes a common platform..	QA SUPERVISOR (INDIA SITE 1)
	if you start some new work, then initially you always have some kind of teething problem...so that was always there.....however they are working on that teething problem and there afterwards it was smooth as far as he is concerned	Operator (India Site 1)
	'...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)
	'...well probably they won't know that they're actually doing HACCP,..... they will not know each day ..... that its related to food safety..... they know that they need to do it to keep the product safe but they will probably not know that it's called HACCP...'	Qual MGR (Singapore)
	'...I don't know whether they appreciate what is HACCP.... but all the thing is....eh...they might think: 'I think I'm doing my job and what I have done is enough.' .'	Production Mgr (Singapore)
	'...It is part of their job..... I think now they have really got used to it.....'	Stores Mgr (Singapore)
	'...Oh, it is now part of life actually....if it was not about there ...eh ...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)
	'...Eh..Not all people maybe would know HACCP but they know that in my work location or in my area what is important and what is minimum required that I record it or I have not done the job... what I have to do..'	Former Quality Manager (India Site 1)
	'...now that they know, in 1999 they have taken issue but now it is easier, but they see 'it is our responsibility'...it is considered as part of their job...'	Manufacturing Supervisor (India Site 1)
	'...For the last 2 years because of our working on the HACCP...I am saying that has now become part and parcel of the culture...so I don't see any issue, you know, where even the people when they are designing any line...eh they are already	Factory Manager (India Site 2)

	thinking of what kind of CPs they should have, what kind of CCPs should have, what kind of ingredients are there, what kind of hazards are there...' And '...HACCP is now becoming part of the culture...'	
	'...For the people on the line basically the HACCP means like the CCP monitoring now....so then operator on the line might not be aware, what is a HACCP plan and how we roll the CCP and all, but for them, you know, HACCP is easily either a CCP or a CP...because CPs also came out of HACCP plan...that they rigorously do and have an understanding of what has to be done...'	Manufacturing Manager (India Site 2)
	'...Most of them probably wouldn't even think that they were doing it...HACCP...they would probably just think it was, you know, just a check on the system....it's highlighted as a CCP so they know it is an important one...ehm but....just part of the system...'	Factory Manager (Australia Site 1)
	'...In terms of the CCP monitoring we are not concerned...because what we are doing is when we started we had collected the line people together and had this effort with them where we discussed it, and we used to have about a 1 hour discussion with them on SOPs when we went onto the line and discussed it there so people would identify with it....the current operators there would say why are you not doing this?...'	Quality 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...so we have given training on the specifications required and everyone is on the same platform....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...'	QA Supervisor (India Site 2)
	'...I reckon some people would struggle with the terminology of HACCP ...they might say what's that...well OK it's hazard analysis critical control point...and they'd go Oh...they might get it and then if you say the metal detectors...Oh yeah, yeah...because that's what they deal with every day – they look on it as the metal detectors, they don't look at it as a critical control point...they see a date coder – it's a date coder, you know....they sort of get that, you know that sort of terminology and sort of matching them together...ehm...but yeah...actually in terms of the process they ehm...there's no problems there...*So it's become part of their every day job even if they don't know the terms?* Exactly - they are doing it and it has become...they may be doing it and not appreciating what they are doing, but at least they are doing it and they're making sure that that metal detector is working...ehm...and sort of making sure that, you know, that things are OK...'	Production Team Leader (Australia Site 1)

	'..... confident that people on the line are doing it now...'	Factory Manager (Australia Site 2)
	'...Most people would know what HACCP was, certainly if not the term HACCP them. They'd know a CCP...I'd like to think they would know that. I'd say they'd know the process...'	Manufacturing Manager (Australia Site 2)
	'...People on the line seem quite confident now – yes they are...'	Quality Supervisor (Australia Site 2)
	'...it has now become part and parcel of his job the form it is taking...he doesn't do anything different to do....what he is saying also is that it starts from his own, from the home...where he takes care of his personal hygiene first...and then when he comes to the work he should start...eh doing same thing for equipment as well...so it has become a routine to his job...'	Operator (India Site 1)
	'...It is working very well, and they are doing it very religiously after 1 hour, and if there is anything they immediately stop the line and inform the supervisor and the manager, and take corrective action...'	Operator (India Site 2)
	'...it gives you an added advantage of moving the quality up to a high-level and it has improved and it is always improving....it is a system of continuous improvement.... so we are basically moving towards that path even although there has been a lot of improvement....and I believe there is still a space for improvement...'	Factory Manager (Singapore)
	'...Oh yes! And it is still ....maybe every month something improving, improving, improving.....that's the biggest role it (HACCP) has.... I think without HACCP, I don't think we would have been to this standard for what is now world-wide recognised...'	Production Manager (Singapore)
	'...Yeah...certainly it has vastly improved....I would say that it has a thoroughness...e.g. people learn initially about the magnets – we don't know whether it is effective or not....but nowadays we are looking at rare earth magnets...initially we had let's say 5-7000/8000 magnets, now we are looking at 20000 magnets systems....I am talking about the magnet strength...so that kind of system we have incorporated...we are continuously monitoring the sieves.....it used to be that we were monitoring the metal detector once a day – now every hour we are monitoring....so lot of emphasis certainly has gone up...it's not like....eh...it has given real focus...'	QA Supervisor (India Site 2)
	"(key factors for success include...)...and then embedding them into...embedding the sort of critical, ehm maybe not the word critical...the important things into the management systems so that it becomes day-to-day....*later*... have we got all of those bases covered? '	Factory Manager (Australia Site 1)

	"(key factors for success include...)...Don't look on it as a burden...don't look on it as something from quality....look on as something that has to become habitual.....needs to be 2-way...'	Manufacturing Manger (Australia Site 2)
	getting factory involvement	
	...I think it wasn't easy...I think it was a struggle...ehm...to get the factory involved and to get them to understand the importance of it....	Quality Mgr (Australia Site 1)
	like when people are supposed to come in the night shift to do the cleaning part of it....people are supposed to do the maintenance part of it you know....that any activity is contributing to any hazard or not actually...	Manufacturing Mgr (India Site 2M)

C.2 Need for constant reinforcement

	..... At the initial stage they were not very clear so we keep on telling them what are the problems....	Stores Mgr (Singapore)
	'...sometimes it's hard to get people sort of motivated to appreciate what they are about to learn...and they think 'oh yeah...just another training course' drop on along and sit there and just think about what they are going to do on the weekend and you know.....and it will all be in front of them and you've explained it and you're sort of hoping that they understand it and you ask if there are any questions and whether they understand....and they all say yeah, yeah they understand and then you might come out, you know, 2 weeks later and say what's a critical control point?...and get 'I don't know'....so it can be a bit frustrating like that...'	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)
	'...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...that would be the hardest part...trying to ehm...get that point across...the importance of it...and because some of the jobs are a bit mundane and repetitive.....it can be that you go into that state of, you know, next, next, you know...I mean they'll be checking it and writing down a date code and it's wrong....and then they only have to look up to the top there and there's the right date code that should be right on the product for that particular day...and if they've written in the wrong one (on the sheet) and	Production Team Leader (Australia Site 1)

	they're running....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....'	

C.3 Responsibility & Commitment

	Yeah, that was very good with our people...whenever we give a kind of food safety system briefing, people accept it...always it is very well.....in that way always they say 'we will do it' – they never say 'no'	QA Supervisor (India Site 2)
	you get carried away and then you don't use your brain, you know.....but if it is left to you, you may fail 2-3 times....but then you will know what is to be done so that is ever done....I can't tell you whether that is the right approach or the wrong approach but still I can say that one should give the practical exposure to a new team because...eh...it can shorten the time....it can shorten the time....you definitely want to do that....	Quality Manger (India Site 1)
	No it was not there...it was not very clear who will maintain what, who will verify what ...or it was the job of quality person only...the quality person was taking the temperature...the humidity...kind of thing. Now it has gone to the person who is working there.	Former Quality Manager (India Site 1)
	'.....and they know if something is critical, then we've got to control....that's the message that has gone to them...that if the metal detector doesn't work, they know that the line will stop...CCP failure – they have to report and stop the line...that kind of thing they understand....and monitoring of that is important – they have understood that....you know it is very difficult... eh to take them through the whole understanding of HACCP in totality to everyone...you know, it is not easy for even the officer level, but at least they know that this is the quality drive, this is the food safety drive and...eh...it takes care of microbial contamination...it takes care of infestation....it takes care of foreign matter getting into the product....that is what they know...'	Quality Manager (India Site 1)
	"(key factors for success include...)...it's absolutely well owned by the quality manager and the team.....some issues to do with consistency or continuity of people on the shop floor...'	Factory Manager (Australia Site 2)
	"(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 Mgr. (Australia Site 2)
	No it was not easy...the CCP monitoring by operators...we have struggled a lot....they are not agree with doing it...they have said it is not our job...it is someone else's job....our job is do the production our job, cleaning our job...but checking the machines	Manufacturing Supervisor

	is not our job...they think it is quality person's job, not ours.....but what we did, we have started to hold training... and cover these sort of subjects...basically for the operators, we have committed a number of trainings....and with training we make them aware...	(India Site 1)

D. Food Safety System Outcomes

D.1 Product Safety Improvements

	'...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)
	'...Benefit the first instance is....eh.. we all consider the consumer health....first thing...'	Manufacturing Supervisor (India Site 2)
	'...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...'	QA Supervisor (India Site 2)

D.2 Improved Quality

	'...it has improved our quality to a certain level....'	Factory Manger (Singapore)
	'...Oh yes - 110% couldn't even begin to describe the change over the last 7 years...there was nothing...nothing it didn't matter...no quality nothing. And that's not a belittling exercise, it's just...that's just the way it was.....that was the standard... It's come a long way...'	Production Team Leader (Australia Site 2)
	'...I can say eliminating of the real life customer complaints...'	Stores Manager (Singapore)
	'...There is definitely benefit to the company....it is affecting our consumer complaints also...'	QA Supervisor (India Site 1)
	'...(Before) there was a lot of incidents... so many times that has happened.....prior to ... they had to dispose of some raw milk...eh...now with this system implementation...even though volume has gone up....they have not lost a single drop of milk....so in terms of milk yield he says that has improved and secondly also the number of complaints have going down...the 3rd thing is that...eh...there is a lot of focussed attention for quality by the line people...'	Operator (India Site 1)

	'...He says that the product complaints have reduced drastically.....and especially from the depots...eh....where they used to get complaints of ...the lining is coming into the chocolate kind of thing...so it is now particularly good...'	Operator (India Site 1)
	'...you can't say that HACCP alone can ensure the quality...but how do you use HACCP, how do you imbibe HACCP that will give you the quality....'	Factory Manager (India Site 2)
	'...of course...eh...though we get and keep on getting complaints, but ultimately, you know, many complaints (that might have happened) would have been controlled actually by putting in the HACCP system and HACCP plan...I mean the metal and all that for sure like....'	Manufacturing Manager (M)
	'...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...'	QA Supervisor (India Site 2)
	'...the only benefit he says was reduced complaints...he also said that eh because of this the quality has also improved and our product is of international standard for international markets and consumers can eat our products without any problems and without being concerned about food safety...'	Operator (India Site 2)
	'.....when it first went in we had a decrease in foreign matter complaints...over the last couple of years they have gone up again...but we have also had different management in that time as well...so I think if the system is working as it should and you have the support and buy-in of people...then you do see an improvement in especially foreign matter type complaints.....if you don't get that support then the system is not going to run smoothly and you don't see the improvement that you would hope for...'	Quality Manager (Australia Site 1)
	'...I would definitely say it has improved the quality of the product that is sent out...definitely...'	Production Team Leader (Australia Site 1)
	'...It's helped our business and our customers...'	Production Team Leader (Australia Site 2)
	'...For our area it has improved quality...'	Process Team Leader (Australia Site 2)

Appendix 7.2

D.3 Confidence

	'...the HACCP has built... it has given confidence to the customers that our food products are safe, right...'	Factory Manger (Singapore)
	'...I guess we would be much more confident in the product that we produce..... before their HACCP came along we just looked at the quality of the product, the micro levels and so on,..... now the other things are there.....so really it is more confidence....'	Quality Mgr. (Singapore)
	'...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.....and if what I have can go down 100% to the shop floor and they can understand, we can sleep in peace....'	Production Mgr. (Singapore)
	'...It has given the confidence about the quality management system and the food safety management systems....I would say now we don't have to remind the HR person to do medical screening – they do it and we don't have to remind them to...and we don't have to remind them to rework GMP or KPIs and we don't have to remind the stores person to check the supplier certificate...'	Former Quality manager (India Site 1)
	'...definitely benefits...now the confidence of the people has been increased...and they are doing by their will...it is 80% operators – training, recording, monitoring....they have confidence...We can say ...that we are confident ...everything is in place...document is there...'	Manufacturing Supervisor (India Site 1)
	'...there is an increase in confidence level about the food safety and there is also confidence about the product... that it is not having the foreign matter.... so that our consumer has safe...'	Operator (India Site 2)
	'...I think all of us, probably, are reasonably comfortable at the end of each day that is not going to kill somebody or make them sick...'	Factory Manager (Australia Site 1)
System Confidence	'...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 2)
System Confidence	*A major product quality incident from a previous year was narrated*..... 'very confident that it will not happen all over again...'	Operator (India Site 1)

D.4 Pride

	'...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...'	Factory QAM (India Site 1)
	'...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)

D.5 Framework/Tool for Improvement

A. Framework/Tool for Improvement

	'...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...and to give the reason...one example of that...after completing the HACCP study, we have removed about 2 kilometres of pipeline at (the factory)....redundant pipelines that we found through process analysis....	Quality Manager (India Site 2)
	'...one (benefit) basically is that it has given us an opportunity to systematically look into our process...and because we did not have any process flows and all that in documentation – so we could get things into documentation...so once certain things are done actually in terms of documentation, we could literally evaluate what is an issue on the food safety...and ...whether it has been done with full efficacy or not, well actually now are knowing the system – everybody knows the issues...'	Manufacturing Manager (India 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)

	'...I think it has probably made us focus on the process...the critical process sort of...I don't want to use the CCP word, but...but it has, I think it has made us focus on what are the important parts of the line to worry about from a food safety perspective, you know...whatever it is, I think we understand where they are...	Factory Manager (Australia Site 1)
	'...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)
	'...It's improved our awareness of the importance of key steps...'	Manufacturing Area Manager (Australia Site 2)
	'...I think technically the outcomes haven't brought any surprises but I think perhaps the whole process has brought things into focus.....and I guess just the fact that you've got a documented plan means that...you've got a baseline...what has gone wrong, what can we do to improve...it is something to go back to and if you're bringing in a new product you've got something to go back to...'	Quality and Environment Manager (Australia Site 2)
	'...I just think it's brought it into peoples' faces....how bad we were and where we needed to be...identified how badly we were performing ...our CCPs and we weren't monitoring...highlighted how ad hoc our systems were...'	Production Team Leader (Australia Site 2)

Appendix 7.3

Data from Semi-structured Interviews Illustrating Magnitude of Response

1. Individual Background in HACCP

The majority of interviewees (31/37) had first become aware of HACCP within the company, through site-level/corporate training or management input. The remainder of interviewees (6/37) had been exposed to HACCP outside the company, either as part of external education or training, e.g. degree courses or continuing professional development efforts, or when working at other companies that had implemented HACCP.

2. Drivers for HACCP

A number of potential drivers for HACCP were identified by the interviewees – see table below.

	Perception that HACCP initiative was driven by:					
Site	Site Management	Quality/ Technical	Regional/ Corporate	Customer	Legislation	No view given
Singapore	1		2	1		3
India Site 1	6		2			
India Site 2	4		3			1
Australia Site 1	2				3	
Australia Site 2	1	3		2		3
Total	14	3	7	3	3	7

Personnel listed as 'No view given' did not share a perception of the drivers for HACCP. This was either because they had not been involved in the relevant stages of HACCP on site or did not have a feel for what was behind the project.

3. Management Support for HACCP

Out of the 37 interviewees, 26 felt that management support had been available for the HACCP project and 11 did not provide a view on this, either because they had not been involved in the relevant stages or did not have exposure at this level in their job roles. No interviewees felt that there was a lack of support for HACCP, although 3 did feel that management support had decreased or was 'low key' at the time of the interviews.

4. Ease of HACCP Development

People who had been involved in the HACCP development phase on site were asked about the ease of development and whether they thought that they had enough training/experience to embark on the HACCP process. Of 18 interviewees providing answers on ease of development,

8 felt that it had been straightforward or that there were no problems and 10 had found it 'tough' or not straight forward.

When asked whether they felt they had enough training to start HACCP, 14 interviewees considered that they had, while 5 felt that they needed or would have liked further training.

5. Ease of HACCP Plan Implementation

Personnel were asked about the ease of implementing HACCP plans to get the system working in practice in the factory. Of the 26 interviewees stating a view, almost half (n=12) considered that it had been difficult and half (n=13) felt that the process had been straightforward. One further interviewee mentioned that some parts had been straightforward and others more difficult.

6. Perception of how well HACCP was working

Personnel were asked for their impression of how well HACCP was working at the time of the interviews and, following numerical scoring suggestions from some of the early interviewees, were invited to give a score out of 10 to position the factory's progress. There were 33 answers to this question split down logically into 2 main groups:

- HACCP is working well/is in good shape (rated ≥7/10 to 10/10 or good) 24 comments in this range, including 1 person who felt part of the factory only was at this level

- There is room for improvement (rated ≥3/10 to <7/10 or poor/gaps) 9 comments in this range

No interviewees thought that HACCP was in very poor shape nor rated it at less than 3/10.

Appendix 8.1

Recommendations for HACCP Training and Support Strategy in Multinational Food Businesses

Recommendations from Chapter 3

- 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.

Recommendations from Chapter 4

- 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.

Recommendations from Chapter 5

- 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.

Recommendations from Chapter 7

- 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.

Appendix 8.2

Recommendations for Standards and Guideline Developers

- 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.

- 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.