Woodhead Publishing in Food Science and Technology

Making the most of HACCP

Learning from others' experience

Edited by Tony Mayes and Sara Mortimore

CRC

WOODHEAD PUBLISHING LIMITED

Making the most of HACCP

Absolute safety is absolutely unattainable, but effective HACCP implementation is the surest way of delivering safe food

Related titles from Woodhead's food science, technology and nutrition list:

Foodborne pathogens (ISBN: 1 85573 454 0)

A practical guide to identifying, understanding and controlling foodborne pathogens. This book relates current research to practical strategies for risk analysis and control and is designed for both microbiologists and non-specialists, particularly those concerned directly with food processing operations. The first part of the book examines specific microbiological hazards. This is followed by an examination of risk assessment and the concluding section provides a guide to controlling pathogens throughout the supply chain from farmer to consumer.

Food chemical safety: Contaminants Volume 1 (ISBN: 1 85573 462 1)

This volume provides comprehensive information about contaminants in the food industry. The book opens with an explanation of risk analysis and analytical methods used for detecting contaminants. This is followed by full details of EU and USA regulations. The second part of the book provides information about specific contaminants.

Food chemical safety: Additives Volume 2 (ISBN: 1 85573 563 6)

This volume provides comprehensive information about additives in the food industry. The book opens with an explanation of risk analysis and analytical methods in relation to the use of additives in food products. This is followed by full details of relevant EU and USA regulations. The second part of the book provides information about specific subjects including flavourings, sweeteners and colourings.

Details of these books and a complete list of Woodhead's food science, technology and nutrition titles can be obtained by:

- visiting our web site at www.woodhead-publishing.com
- contacting Customer services (email: sales@woodhead-publishing.com; fax: +44 (0) 1223 893694; tel.: +44 (0) 1223 891358 ext. 30; address: Woodhead Publishing Limited, Abington Hall, Abington, Cambridge CB1 6AH, England)

If you would like to receive information on forthcoming titles in this area, please send your address details to: Francis Dodds (address, tel. and fax as above; e-mail: francisd@woodhead-publishing.com). Please confirm which subject areas you are interested in.

Making the most of HACCP

Learning from others' experience

Edited by
Tony Mayes and Sara Mortimore

CRC Press
Boca Raton Boston New York Washington, DC

WOODHEAD PUBLISHING LIMITED
Cambridge England

Published by Woodhead Publishing Limited
Abington Hall, Abington
Cambridge CB1 6AH
England
www.woodhead-publishing.com

Published in North and South America by CRC Press LLC
2000 Corporate Blvd, NW
Boca Raton FL 33431
USA

First published 2001, Woodhead Publishing Limited and CRC Press LLC

British Library Cataloguing in Publication Data
A catalogue record for this book is available from the British Library.

Library of Congress Cataloging-in-Publication Data
A catalog record for this book is available from the Library of Congress.

Woodhead Publishing Limited ISBN 1 85573 504 0
CRC Press ISBN 0-8493-1218-3
CRC Press order number: WP1218

Cover design by The ColourStudio
Project managed by Macfarlane Production Services, Markyate, Hertfordshire (macfarl@aol.com)
Typeset by MHL Typesetting Limited, Coventry, Warwickshire
Printed by TJ International, Padstow, Cornwall, England

Contents

This page intentionally left blank

Preface and acknowledgements

The origins of this book go back to the spring of 1998. When the publishers asked if we would like to consider writing on HACCP, the last thing we wanted to do was another 'how to' book. Both of us had already been involved with publications on the principles of HACCP systems and how organisations could turn those principles into practice. Something different and more useful was needed. A logical progression was a title which explored what had happened to those organisations which had followed the various 'how to' guides. What was it like to translate the theory into practice and to implement a real HACCP system? This idea also fitted in with the wider development of HACCP at that time. By the late 1990s many larger food manufacturers in developed countries in particular had established HACCP systems. There was a fund of experience which might be invaluable for those organisations around the world yet to start HACCP implementation for themselves. At the same time those closest to the subject were starting to reflect on the experience of the pioneers and ask what lessons could be learnt for the future of HACCP. What was needed was a book which brought together HACCP practitioners and asked them to describe and reflect on their experiences. Such a book would need to be an edited collection, drawing in both those from large and small enterprises as well as those responsible for regulation and enforcement. It also needed to be international in its scope. *Making the most of HACCP* was born.

The success of this book depends on the quality of the individual contributors. We deliberately selected those with the most direct experience of HACCP implementation. By definition this meant approaching some of the busiest people in their respective organisations and asking them to describe in detail their experience of HACCP, bad as well as good, essentially for the benefit of others. We are most grateful to the contributors for the considerable

time and thought they have put into the book and for their skill and candour in describing what it was really like translating theory into practice. Everyone concerned with HACCP systems owes them a debt of gratitude. By sharing their experiences so generously, all those wishing to implement HACCP systems for themselves, those thinking about what to do next, and all of us looking for ways to improve the effectiveness of HACCP, have benefited enermously. We are also grateful to the publishers for their patience and support in bringing the collection to fruition and in particular to Francis Dodds for his sterling work in drawing all the chapters together.

Tony Mayes
Sara Mortimore

Contributors

Chapters 1, 14 and 15

Mr Tony Mayes
Microbiology Department
Unilever Research
Colworth Laboratory
Colworth House
Sharnbrook
Bedford MK44 1LQ
England

Tel: +44(0)1234 222380
Fax: +44(0)1234 222277
E-mail: tony.mayes@Unilever.com

Ms Sara Mortimore
Pillsbury Europe
Harman House
1 George Street
Uxbridge
Middlesex UB8 1QQ
England

Tel: +44(0)1895 201133
Fax: +44(0)1895 201101
E-mail: smortimore@pillsbury.co.uk

Chapter 2

Professor Eunice Taylor
School of Leisure, Hospitality and Food Management
The University of Salford
Salford M5 4WT
England

Tel: +44(0)161 295 2027
Fax: +44(0)161 295 2020
E-mail: e.taylor@salford.ac.uk

Chapter 3

Mr Nigel Route
Brio Foods
110 Deeside Industrial Park
Deeside
Flintshire CH5 2UA
Wales

Tel/fax: +44(0)1244 880933
E-mail: nigel.route@briofoods.com

Chapter 4

Mr Malcolm Kane
The Copse
30 Brewery Road
Pampisford
Cambridge CB2 4EN
England

Fax: +44(0)1223 830918
E-mail: malcolmkane@foodcontrol.co.uk

Chapter 5

Mr Todd R. McAloon
Cargill Inc.
204 West 4th Street
Monticello
MN 55362
USA

Fax: (1) 763 271 5711
E-mail: Todd_McAloon@cargill.com

Chapter 6

Dr Balkumar Marthi
Hindustan Lever Research Center
ICI Link Road
Andheri (East)
Bombay 400 099
India

Fax: +91 22 8363680
E-mail: balkumar.marthi@unilever.com

Chapter 7

Mr Doug Rudge
Kerry Ingredients
Portbury Way
Royal Portbury Dock
Bristol BS20 6XN
England

Tel: +44(0)1275 378500
Fax: +44(0)1275 378555
E-mail: Doug_Rudge@kerry-ingredients.co.uk

Chapter 8

Mr Damian Killen
Microbiology Department
H. J. Heinz Company Limited
Kitt Green
Wigan
Lancashire WN5 0JL
England

Tel: +44(0)1942 624306
Fax: +44(0)1942 624119
E-mail: damian_killen@heinz.co.uk

Chapter 9

Ms Judi Lee
National Advisor (HACCP)
Ministry of Agriculture and Forestry
(Meat and Seafood)
95 McGregor Road
RD 2 Papakura
New Zealand

Fax: +64(09) 292 9131
E-mail: leeja@maf.govt.nz

Chapter 10

Mr Alfred Bungay
Canadian Food Inspection Agency
59 Camelot Drive
Nepean
Ontario
K1A 0Y9
Canada

Tel: (1) 613 225 2342
Fax: (1) 613 228 6654
E-mail: Abungay@EM.AGR.CA

Chapter 11

Ms Sirilak Suwanrangsi
Chief – Fish Inspection Center (Bangkok)
Fish Inspection and Quality Control Division
Department of Fisheries
Kasetklang
Chattuchak
Bangkok 10900
Thailand

Tel: +66 2 562 0553
Fax: +66 2 579 6687
E-mail: sirilaks@fisheries.go.th

Chapter 12

Mr John Barnes
Food Standards Agency
Room 501A
Skipton House
80 London Road
London SE1 6LH
England

Tel: +44(0)171 972 5080
Fax: +44(0)171 972 5141/2
E-mail:
john.barnes@foodstandards.gsi.gov.uk

Chapter 13

Ms Carol A. Wallace
Reading Scientific Services Ltd
The Lord Zuckerman Research Centre
Whiteknights
PO Box 234
Reading RG6 6LA
England

Tel: +44(0)161 440 0610
Fax: +44(0)118 986 8932
E-mail: carol.a.Wallace@rssl.co.uk

This page intentionally left blank

Acronyms and abbreviations

AICP	Agar Immersion Plating and Contact
APEDA	Agricultural Produce Export Development Authority
ASME	American Society of Mechanical Engineers
BIS	Bureau of Indian Standards
BRC	British Retail Consortium
CAC	Codex Alimentarius Commission
CCP	critical control point
CCTV	closed circuit television
CDSC	Communicable Disease Surveillance Centre
CFIA	Canadian Food Inspection Agency
CIFE	Central Institute for Fisheries Education
CPM	cans per minute
DAP	defect action points
DGHS	Directorate General of Health Services
DOF	Department of Fisheries
DoH	Department of Health
EFSIS	European Food Safety Inspection Service
EHO	Environmental Health Officer
EIA	Export Inspection Agency
FAO	Food and Agriculture Organisation
FDA	Food and Drug Administration
FIQD	Fish Inspection and Quality Control Division
FMEA	failure mode and effect analysis
Foodnet	Food Disease Surveillance Network
FSCS	Food Safety Control System
FSEP	Food Safety and Enhancement Program

FTRI	Fishery Technological Research Institute
GATT	General Agreement on Tariffs and Trades
GHP	good hygiene practice
GMP	good manufacturing practice
HACCP	hazard analysis critical control point
HLL	Hindustan Lever Limited
HLRC	Hindustan Lever Research Centre
ICMR	Indian Council of Medical Research
IIS	Integrated Inspection System
IQF	individually quick frozen
ISM	International Sterilization Manual
ISO	International Standards Organization
LACOTS	Local Authority Coordinating Body for Food and Trading Standards
MAF	Ministry of Agriculture and Forestry
MAF Food	MAF Food Assurance Authority
MAF VA	MAF Verification Agency
MNC	multinational company
MPEDA	Marine Products Exports Development Agency
MT	metric tonne
NACMCF	National Advisory Committee on Microbiological Criteria for Foods
NMFS	National Marine Fisheries Service
PFA Act	Prevention of Food Adulteration Act
PRP	prerequisite programme
QA	quality assurance
QMP	Quality Management Program
QMPI	Quality Management Program for Importers
R&D	research and development
RSSL	Reading Scientific Services Ltd
SLDBs	Small and less developed food businesses
SMEs	small and medium-sized enterprises
SOP	standard operating procedure
SPC	statistical process control
SPS	sanitary and phytosanitary
SQA	supplier quality assurance
SSOP	sanitation standard operating procedure
USDA	United States Department of Agriculture
WHO	World Health Organisation
WTO	World Trade Organisation

1

Introduction

T. Mayes, Unilever Research, Sharnbrook and S. Mortimore, Pillsbury Europe, Uxbridge

What is this book about? It is not about how to utilise the hazard analysis critical control point (HACCP) system which has been covered many times in numerous publications from international, national and trade organisations and from individual practitioners on a world-wide basis (see section 1.1). Nor is it an account of the role of HACCP in any particular sector of the food industry. This book chronicles the implementation of HACCP in a broad range of situations and asks the following questions:

- What lessons can we learn?
- How could we have done things differently or better?
- How can we make the most of HACCP now and in the future?

1.1 The development of HACCP

The development of HACCP from its initial conception by Pillsbury working together with Natick is well documented (Bauman 1974, 1990; US Department of Health, Education and Welfare 1972). Initially developed as a means of obtaining increased confidence over the microbiological safety of foods used in the space programme, the potential of the technique for ensuring control of food safety hazards in a broad range of foods in manufacturing, distribution, food service and retail situations was soon realised. Although the HACCP concept continued to develop, it did so in a somewhat piecemeal fashion, and it was not until the mid- to late 1980s that HACCP development began to accelerate in a coordinated way. The HACCP concept was endorsed by WHO/FAO as an effective way of controlling foodborne disease in 1983 when the Joint FAO/

WHO Expert Committee on Food Safety advised that HACCP should replace the traditional end product testing approach to food safety assurance (FAO/WHO 1983). Since that time many other respected bodies have published guidelines on the use of HACCP (ICMSF 1988, US National Advisory Committee on Microbiological Criteria for Foods 1992, ILSI 1997, Campden & Chorleywood Food Research Association 1997).

It was only during the late 1980s and beginning of the 1990s that there was a concerted attempt to harmonise, on an international scale, the HACCP approach and the terminology used. Initially, interested groups in the USA, Canada, Europe, Australia and New Zealand pursued the development of HACCP most actively, particularly those representing the larger food manufacturing industries. Although the major thrust for the development of HACCP has always been the management of food safety (primarily by those responsible for food manufacturing), increasingly HACCP has been looked upon as a regulatory tool for the enforcement of food safety. Prior to the early 1990s HACCP developments concentrated upon the principles of HACCP rather than the practical details of HACCP application or implementation. The current Codex Alimentarius HACCP document (CAC 1997) is really the first truly authoritative, internationally agreed document that addresses not only the agreed HACCP principles but also guidelines for its application. This document clearly identifies that the HACCP system consists of the seven principles listed in Table 1.1.

The guidelines for the application of the HACCP system are also clearly outlined in 12 tasks, as shown in Table 1.2. Most people today regard this Codex document as the international benchmark for HACCP.

1.2 HACCP in practice

As stated above, the primary movers in the development of the HACCP system tended initially to be the larger food manufacturers and, latterly, those with a

Table 1.1 Seven principles of the HAACP system

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

Table 1.2 Guidelines for the application of the HACCP system

Task 1	Assemble the HACCP team
Task 2	Describe product
Task 3	Identify intended use
Task 4	Construct flow diagram
Task 5	On-site verification of flow diagram
Task 6	List all potential hazards, conduct a hazard analysis, determine control measures
Task 7	Determine CCPs
Task 8	Establish critical limits for each CCP
Task 9	Establish a monitoring system for each CCP
Task 10	Establish corrective action for deviations that may occur
Task 11	Establish verification procedures
Task 12	Establish record keeping and documentation

regulatory perspective. Although as stated above, HACCP has now been applied to all sectors of the food supply chain, there has been no attempt to identify the lessons to be learned from such a broad-based application. This book seeks to address this issue by inviting contributions from a range of practitioners from all parts of the food industry.

Contributions have been made by authors practising in a wide range of HACCP-related roles across the supply chain including small, medium, and large sized food manufacturers, covering primary conversion and manufacturing, food retailers and those with involvement/responsibility for HACCP training and regulatory enforcement. Contributors were asked to structure their contribution broadly as shown in Table 1.3 and to consider a number of key questions when putting their chapter together.

The issues described in Table 1.3 are most relevant to those organisations implementing HACCP. Those for enforcement agencies/bodies and retailers dealing with manufacturers were considered likely to be different. The brief to these contributors is described in Table 1.4.

The authors have been drawn from a wide geographical basis and from enterprises within a wide range of cultural backgrounds and have been encouraged to outline their thoughts in their own personal style. The reader should therefore accept that the value of the contribution lies in the broad range of experience outlined in the content rather than in a uniform presentation style.

1.3 Key themes

Two contributors to the book address the issues of HACCP application in a primary conversion food sector and look to identify the lessons learned. While

Table 1.3 Key questions for contributors from organisations implementing HACCP

Introduction	• A brief introduction to the industry in which the organisation is involved and any distinctive hazards the industry faces • An outline of the model for HACCP implementation that was followed where appropriate
Planning for HACCP	• How did the HACCP approach fit with corporate strategy? Where was HACCP implementation in the priority list? • How did the business plan its HACCP implementation programme? (e.g. who was in the project team, what timetable/ milestones were established, what kind of budget was available?) • What information was available to the business (e.g. prerequisites, good manufacturing practices, scientific data, references, etc.) and did this prove sufficient? • In what ways did the original plan (the timetable, personnel involved, etc.) change and why?
Implementing HACCP	• What were the major challenges in implementation and how were these overcome? As an example, was hazard analysis the most complex stage? If so, how was it tackled? • What involvement, if any, did the business have with enforcement agencies/bodies in the development of the business's HACCP system? • Did the organisation anticipate all the issues raised by auditors/ enforcement agencies?
Operating the HACCP system	• What benchmarks were used to judge success and how has the system measured up to those benchmarks? • Were there any unexpected difficulties arising from HACCP implementation? How were they managed? • What benefits has the implementation of HACCP brought to the business? • What is the most demanding aspect of running a HACCP system? How is this managed?
Developing the HACCP system	• Has the way HACCP relates to corporate strategy changed since implementation? • What element in your HACCP system has needed development most in the light of experience? • How has the HACCP system changed/evolved since implementation? • How have changes been integrated into the system, e.g. new products or technology? • How has the HACCP system been integrated with other systems, e.g. ISO 9000? • In what ways has HACCP been extended into new product design? • How has the business kept the system up to date (e.g. new hazards, keeping staff motivated)? • Has the implementation of HACCP changed the relationship with the enforcement agencies/bodies? If so, why?
Conclusion	• What was the most unexpected (positive and negative) aspect about implementing and running a HACCP system? • What would you do differently, given the benefit of experience? • Comment on whether the implementation of HACCP has 'added value' in a product safety sense. • What is the future for HACCP?

Table 1.4 Key questions for contributors from enforcement agencies and retailers

Introduction	• Brief description of regulatory framework and nature of enforcement agency, or retail sector and manufacturer relationship. • Brief description of the nature of a HACCP inspection (e.g. stages followed, information expected) or requirement.
Assessment of the HACCP system	• What do you look for (e.g. prerequisites) to see how well the system is working in practice as well as on paper? • Do you use a check-list of key issues/questions to test the effectiveness of a HACCP system? If so, are you happy with this as an approach? • What makes it easier to carry out an effective HACCP inspection? What can organisations do to facilitate your work? • What are the most common areas of weakness in the HACCP systems you have inspected? Why do you believe these problems are widespread? • What are the most common areas of improvement you suggest?
Developing HACCP assessment	• How did your own skills and competencies, and those of your agency/organisation, match up to those required for HACCP system enforcement? • How did you overcome any deficiencies in skills and competencies? • How did you/do you determine your roles and responsibilities with respect to HACCP enforcement? Is there any conflict with industry? If so, how should this be resolved? • Has HACCP enforcement changed the nature of your relationship with industry? If so, in what way? • Do you believe that current inspection/assessment procedures are adequate to determine effective HACCP implementation? If not, how do you believe they should change? • How do you see your role in HACCP enforcement developing in the future (e.g. partnership with industry)?
Conclusion	• Has HACCP implementation affected the role of your agency/organisation with respect to product safety? If so, please elaborate and discuss how you see this developing in the future. • Do you believe that HACCP implementation offers real advances in product safety from the enforcement or retailer standpoint? • What do you believe are the real weaknesses of HACCP as a product safety system, viewed from the enforcement or retailer standpoint? How should these weaknesses be overcome? • What do you see as the future for HACCP viewed from the enforcement or retailer standpoint?

HACCP principles remain the same throughout, the issues to be tackled when considering application to a primary conversion sector of the food chain will be somewhat different from those issues to be tackled when applying HACCP to the manufacturing sector of the supply chain.

The applicability of the HACCP system to small and medium sized enterprises (SMEs) has always been questioned as the formalised, technically based full HACCP system outlined in the 1997 Codex document places severe demands on SMEs in terms of technical data and skilled resource for hazard analysis and time. Although there are a number of publications and studies tackling the HACCP and SMEs issue (WHO 1993a, 1999a; Department of Health 1993), this is an area of HACCP application that has still not been optimised and agreed. This book contains two contributions from practitioners addressing the application of HACCP in SMEs, one from an SME manufacturer and one looking at the topic from a more academic background. The effective application of HACCP principles in SMEs represents a significant opportunity to raise the standard of food hygiene in a very large sector of the supply chain. It is clear, therefore, that we need to take account of all the lessons learned so as to maximise the chance of success. The contributions from the larger organisations demonstrate that they too have not always got it right first time, and have learnt lessons that can be shared with others.

Another issue not tackled during HACCP development is that of the impact of different cultural and language backgrounds; thus successful application of HACCP relies on a cross cultural/linguistic consensus on the meaning and definition of these terms. Translation of key HACCP terms such as 'hazard', 'risk', 'control measure', etc., is fraught with potential for genuine misunderstanding. The success of the Codex approach depends to some extent on an open questioning and debating approach with a number of key individuals contributing in public debate. This can be somewhat adversarial in nature and is essentially a 'Western style' approach. Such an approach is, however, anathema to many countries, particularly those in Asia and India where open debate is frowned upon. The book contains two contributions (one from Thailand and one from India) where open debate is not the accepted norm and these chapters illustrate the mechanisms used to operate HACCP successfully in a 'non-Western' cultural and language background.

The history of the development of HACCP clearly demonstrates that the HACCP system is continually evolving. This is entirely to be expected as HACCP must evolve in response to new information (e.g. allergens as potential hazards), new food processing technologies (e.g. microwave pasteurisation) and the realisation that techniques must be available to assess the effectiveness of HACCP. In the latter case it is only recently that the different roles of verification and validation in determining the effectiveness of HACCP have become clear (ILSI 1999). In the same way the role of prerequisites or good manufacturing/hygiene practices (GMP/GHP) standards has developed over a period of time to the point where today prerequisites and/or GMP/GHP standards are accepted as the essential foundation upon which HACCP must be built, and without which HACCP implementation is unlikely to be successful.

Underpinning all the above is the need for training in both HACCP and supporting prerequisite good hygiene practice. The former is a requirement clearly identified by the WHO (1993b, 1996, 1999b) and FAO (1998). There are a large number of publications in addition to the above dealing with HACCP training (Mortimore and Wallace 1998, Pierson and Corlett 1992, Engel 1998, de Winter 1998, Bryan 1991, Agriculture Canada 1995) and many on government/regulatory internet sites in themselves demonstrating how HACCP has evolved. It is relevant to note, however, that it is only recently that progress has been made in developing a HACCP Training Standard (Royal Institute of Public Health and Hygiene 1998). The book contains one chapter looking specifically at ways of maximising the benefit of HACCP training in a developing, continually evolving system.

At the present time within the USA the Food and Drug Administration (FDA) has mandated HACCP for fish and fishery products and is proposing mandating HACCP for fruit and vegetable juices. The United States Department of Agriculture (USDA) has already mandated HACCP/pathogen reduction requirements for the meat and poultry industry and the US National Marine Fisheries Service (NMFS) seafood inspection programme operates a voluntary HACCP programme for seafood plants. The USA has taken the lead in the use of HACCP as a regulatory tool and other countries look set to follow with a mandatory HACCP approach. There is a growing realisation among regulatory authorities that the use of HACCP by the food manufacturing industry provides them with both an opportunity and a challenge. HACCP implementation provides regulatory authorities with the opportunity for them to make meaningful assessments of product safety management systems by making use of HACCP records. The challenge for regulatory authorities is for them to gain the skills and competencies needed to make the proper assessment of HACCP. The recent FAO/WHO *Expert Consultation on the Role of Government Agencies in Assessing HACCP* (FAO/WHO 1998) addressed the above issues in some detail. The book editors believed at the outset that it was important that this book should contain contributions from individuals with regulatory responsibility for HACCP so that the regulatory point of view, the other side of the 'HACCP coin', could be documented. Accordingly this book contains contributions from experienced individuals well qualified to debate the issues surrounding the enforcement/assessment of HACCP.

One of the major developments of the last 20 years has been the increasing globalisation of trade. This has led to the availability of fresh and processed produce, of ever increasing variety, all year round. Underpinning this globalisation of trade has been the recognition that countries need to be allowed to trade with each other without unnecessary barriers to trade. The World Trade Organisation (WTO) sanitary and phytosanitary (SPS) agreement (WTO 1995a, 1995b), which came into force in 1995 and applies to all sanitary and phytosanitary measures that can or may affect international trade, has gone a long way towards empowering countries to trade freely with each other but increasingly countries are looking to develop and implement the concept of 'equivalence' to further enhance trade. The concept of equivalence recognises that although different countries can have different food safety systems, they can in fact offer equivalent levels of food safety protection. A number of countries have already negotiated equivalency agreements with trading partners, thereby facilitating and simplifying international trade. One of the key considerations of international trade must be the safety of the food being traded. The globalisation of food trade and the recognition that 'emerging hazards' are a significant issue has increased the risk of cross-border contamination of food. The potential for significant transference of contaminated food between countries and/or regions is therefore much increased with potentially catastrophic consequences for public health. The standards, guidelines and recommendations adopted by Codex for food safety are recognised in the WTO SPS agreement as the basis for the harmonisation of sanitary measures and HACCP is a central food safety system of choice promulgated by Codex. It is inevitable therefore that HACCP will play an increasingly important food safety role, not only as the system of choice within individual countries, but also on the world-wide stage as an important contributor to the facilitation of world trade in foodstuffs. Although this book does not contain contributions that specifically address the increasingly important role of HACCP with respect to trade, the international list of HACCP contributors clearly demonstrates the global impact that HACCP is having, and the messages derived from this book, e.g. 'Making the most of HACCP' are therefore particularly relevant.

1.4 References

AGRICULTURE CANADA (1995) *HACCP Curriculum Guidelines*, Agriculture and Agri-Food, Nepean, Canada.

BAUMAN, H.E. (1974) The HACCP concept and microbiological hazard categories, *Food Technology* **28** (9), 30–2, 74.

BAUMAN, H.E. (1990) HACCP: concept, development and application, *Food Technology* **44** (5), 156–8.

BRYAN, F.L. (1991) Teaching HACCP techniques to food processors and regulatory officials, *Dairy, Food and Environmental Sanitation*, **11** (10), 562–8.

CAC (1997) *Hazard Analysis and Critical Control Point System and Guidelines for its Application*, Alinorm 97/13A, Codex Alimentarius Commission, Rome.

CAMPDEN & CHORLEYWOOD FOOD RESEARCH ASSOCIATION (1997) *HACCP: A Practical Guide*, 2nd edn, Technical Manual 38.

DE WINTER, R. (1998) The role of interactive workshops in HACCP training in a multinational environment, *Food Control*, **9**, 2–3, 147–9.

DEPARTMENT OF HEALTH (1993) *Assured Safe Catering: A Management System for Hazard Analysis*, HMSO, London.

ENGEL, D. (1998) Teaching HACCP: theory and practice from the trainer's point of view, *Food Control*, **9**, 2–3, 137–9.

FAO (1998) *Food Quality and Safety Systems: A Training Manual on Food*

Hygiene and the Hazard Analysis and Critical Control Point System, Food and Agriculture Organisation of the United Nations, Rome.

FAO/WHO (1983) *The Role of Food Safety in Health and Development*, Report of a Joint FAO/WHO Expert Committee on Food Safety, Technical Report Series 705 WHO.

FAO/WHO (1998) *Expert Consultation on the Role of Government Agencies in Assessing HACCP*, WHO/FSF/FOS/98.5, WHO, Geneva.

ILSI (1997) *A Simple Guide to Understanding and Applying the Hazard Analysis Critical Control Point Concept*, ILSI Europe Scientific Committee on Food Safety, 2nd edn.

ILSI (1999) *Validation and Verification of HACCP*, ILSI Europe Report prepared under the responsibility of ILSI Europe Risk Analysis in Microbiology Task Force.

INTERNATIONAL COMMISSION ON MICROBIOLOGICAL SPECIFICATIONS FOR FOODS (1988) *Micro-organisms in Foods 4: Application of the Hazard Analysis Critical Control Point (HACCP) to Ensure Microbiological Safety and Quality*, Blackwell Scientific Publications, London.

MORTIMORE, S.E. and WALLACE, C. (1998) *HACCP: A Practical Approach*, A Chapman & Hall Food Science Book, Aspen Publications, London.

PIERSON, M.D. and CORLETT, D.A. (1992) *HACCP Principles and Applications*, Van Nostrand Reinhold, New York.

ROYAL INSTITUTE OF PUBLIC HEALTH AND HYGIENE (1998) *HACCP Principles and their Application in Food Safety (Introductory Course)*, RIPHH, London.

US DEPARTMENT OF HEALTH, EDUCATION AND WELFARE (1972) *Proceedings of the 1971 National Conference on Food Protection*, US Government Printing Office.

US NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS (1992) Hazard Analysis and Critical Control Point System, *International Journal of Food Microbiology,* **16**, 1–23.

WHO (1993a) *Application of the Hazard Analysis Critical Control Point System for the Improvement of Food Safety: WHO Supported Case Studies on Food Prepared in Homes, at Street Vending Operations, and in Cottage Industries*, WHO/FNU/FOS 93.1, WHO, Geneva.

WHO (1993b) *Training Considerations for the Application of the Hazard Analysis Critical Control Point System to Food Processing and Manufacturing*, WHO/FNU/FOS/93.3, WHO, Geneva.

WHO (1996) *Training Aspects of the Hazard Analysis Critical Control Point System (HACCP): Report of a WHO Workshop on Training in HACCP*, WHO/FNU/FOS/996.3, WHO, Geneva.

WHO (1999a) *Strategies for Implementing HACCP in Small and Less Well Developed Businesses (SLWBs)*, WHO, Geneva.

WHO (1999b) *HACCP: Principles and Practice*, a WHO/ICD Manual, WHO/SDE/PHE/FOS/99.3, WHO, Geneva.

WORLD TRADE ORGANISATION (1995a) *Results of the Uruguay Round of*

Multilateral Trade Negotiations 1993: Agreement on Application of Sanitary and Phytosanitary Measures, Centre William Rappard, Geneva.

WORLD TRADE ORGANISATION (1995b) *Results of the Uruguay Round of Multilateral Trade Negotiations 1993: Agreement on Technical Barriers to Trade*, Centre William Rappard, Geneva.

Part I

Small and medium-sized enterprises (SMEs), retailers and HACCP systems

This page intentionally left blank

2

HACCP and SMEs

Problems and opportunities

E. Taylor, The University of Salford

2.1 HACCP and SMEs

2.1.1 Introduction

Practical experience and a review of food safety literature indicate that success in developing, installing, monitoring and verifying a successful HACCP system is dependent on a complex mix of managerial, organisational and technical hurdles. In coping with this set of interrelating factors, even the largest food companies, equipped with significant resources of money, technical expertise and management skills, may face a difficult challenge; the small and medium sized enterprises (SMEs) may feel that the difficulties of HACCP are potentially insurmountable.

This chapter aims to discuss general problems, propose solutions and identify opportunities for SMEs in their attempt to develop systems that are technically sound, appropriate and manageable. It is based on the experience of both practitioners and researchers and uses relevant examples wherever possible.

2.1.2 Definition of an SME

There is no single, clear and widely accepted definition of an SME but they are usually classified by number of employees, turnover and profit levels. This chapter uses EU terminology to classify medium, small and micro businesses and a summary can be seen in Table 2.1. Given that there will be many differences between the smallest and largest SME (varying from the self-employed to 250 employees), discussion will be focused on those companies with *less than 50 employees*, where there is evidence of most difficulty in applying new technology/systems in general and HACCP in particular. Such

Table 2.1 Classification of SMEs

Maximum	Micro	Small	Medium
Number of employees	10	50	250
Turnover (million ECU)		7	40
Balance sheet total (million ECU)		5	27
Max. % owned by larger company		25%	25%

Note: Larger company refers to one or several enterprises not satisfying same SME criteria.
Source: European Commission Recommendation, 3 April 1996, 96/280/EU.

businesses *generally* serve local customers; have a limited share of the available market; are owned by one person, or by a small group of people; are managed by their owners who deal with all management issues usually with little other help; and are independent businesses, not parts of, or owned by, larger companies.

2.1.3 Economic significance of SMEs

SMEs contribute substantially to the production, manufacture and retail of food in both advanced and developing countries. It is argued that they are 'everywhere essential to economic development'[1] as an integral part of all market economies. It is unfortunate that the study of the role of SMEs in economic development has been retarded by lack of reliable statistics at both national and international level. However, figures available from the UK can be used to illustrate the nature of the contribution of SMEs in relation to larger companies (see Table 2.2). It is evident that a substantial proportion of food is produced, processed and sold by SMEs and the safety of their operations affects the integrity of the entire food chain. The recognition of this fact has recently led many governments to focus attention on the control of food safety in these smaller businesses.

2.1.4 HACCP implementation in SMEs

There is increasing evidence that while HACCP is widespread in large food businesses, its use is limited within SMEs. This is reflected in recent studies in

Table 2.2 An analysis of the economic significance of SMEs in the UK (1998)

	Number of businesses	Employment	Turnover
Small	99.2%	44.7%	38.0%
Medium	0.6%	11.6%	13.8%
Large	0.2%	43.7%	48.1%

Source: Department of Trade and Industry. *Small and Medium Enterprise (SME) Statistics for the United Kingdom*, 1998, London, DTI, August 1999.

the UK and Europe which have found that SMEs are less likely to invest in hygiene and food safety than large companies and are less likely to have HACCP in place.[2,3] Indeed, one study identified that for companies with less than 50 staff, HACCP implementation decreased proportionally as number of employees decreased.[4]

This is not surprising given that the move toward HACCP implementation in many companies has been customer driven. This is very evident in UK companies that supply large retailers (e.g. supermarkets) whose contracts often require documented evidence of a HACCP system from their suppliers. This is outside the remit of most SMEs, many of whose customers are the end user (the consumer) as in the case of retailers. The only pressure to apply HACCP for these companies has been from legislation. It is well known that the risk of prosecution for food hygiene offences (within the regulatory system of most countries) is low and therefore changes in legislation provide little motivation for owners to embark on a completely new system of managing food safety. This is especially true if owner-managers do not believe they have a problem anyway – unfortunately a commonly held belief, despite a world-wide escalation of foodborne disease. This lack of motivation has been a significant reason that there has been little uptake of HACCP within small and micro businesses in particular. Other reasons, in particular resource constraints, will be discussed later in the chapter.

It must be remembered, however, that the consumer demands safe food whether it is purchased from a small, medium or large company. The application of HACCP systems (combined with GHPs) within SMEs is a major step forward in protecting public health.

2.1.5 A blueprint for SMEs?

For most SMEs, even if they could be motivated to change, their progress would be severely hindered by a lack of information as to how to apply HACCP principles and what the completed system should look like in the context of their own businesses. While there is widespread agreement that the Codex methodology* is applicable to all food operations, there is little evidence of its successful application within SMEs, particularly the small business. Indeed, attempts to make HACCP fit such businesses often involve a crude scaling down of the principles without evidence to ensure that safety has not been compromised.[5] There is an urgent need to provide high quality, authenticated models that will guide SMEs through the entire HACCP process.

In an attempt to produce such 'blueprints' many generic models have been developed by governments (particularly in North America) and trade organisations. However, most do not extend beyond identification of CCPs and offer no help with implementation and management of the system. There is

* The term 'Codex methodology' will be used to describe the application of HACCP principles following the steps outlined by the Codex Alimentarius Commission.[6]

Fig. 2.1 Retail meat managers enjoying HACCP training.

also no evidence of their validity, suitability or uptake by SMEs. Indeed, Codex have recently published specific guidelines for the application of HACCP in small businesses.[7]

A recent initiative to develop HACCP models for SMEs is the *Accelerated HACCP Project* within the UK meat industry. This is a £9 million government-funded project which aims to implement HACCP in 7,000 independent retail butchers. It was instigated as a direct response to an outbreak of *E. coli* 0157 food poisoning in Scotland, which resulted in 21 deaths. Initial evaluation of the project suggests that the strong commitment of owner-managers to safe food can be harnessed effectively if a blueprint is available and the necessary support given (see Fig. 2.1).

2.2 Setting up the HACCP system

2.2.1 Access to HACCP training

Successful HACCP implementation requires (1) competence in the application of HACCP principles and (2) technical expertise in food microbiology and food chemistry. Although these two areas overlap, they are considered separately so as to focus on the needs of the typical SME.

It is doubtful whether any company can implement HACCP without specific training. This is particularly true for the SME with limited access to information and often without the time or skills to interpret textbook scenarios. Indeed, good HACCP literature is restricted to a handful of user-friendly books amidst a plethora of watered-down manuals of limited use. As discussed earlier, the fundamentals of HACCP methodology are as necessary for the SME as any other company, and the typical short course (two days) is an effective introduction to the concept and the jargon. However, for the SME without in-house technical support, it is important not to 'abandon trainees to their fate after the initial familiarisation is completed'.[8] Further specialist help is required which will consider the development, implementation and management of the system within the constraints of the SME.

Statistics from the UK's major provider of HACCP courses illustrate the limited uptake and availability of even introductory level training, e.g. the Royal Institute of Public Health & Hygiene's Certificate in HACCP Principles, established in 1995 – currently 31 centres in the UK with 4,220 candidates to date. Given that there are 600,000 food premises within the UK, the majority of these being SMEs, this equates to a severe skills shortage. Evidence of this lack of skill has been confirmed not only within food businesses but among the consultants and enforcement officers to whom many SMEs turn for help with implementation.

The expense and efficacy of consultants was investigated in a recent research project within UK SMEs.[9] Companies were paying between £160 and £1,200 for varying degrees of input and several companies said that consultancy had been poor value for money and would not be used in future. More significantly, when the HACCP system in each business was independently audited,* none of the plans that had been developed with consultants were considered adequate.

2.2.2 Technical expertise

The typical SME, as discussed in section 2.1, is often described as having limited resources of staff, time, skills, expertise and finance and therefore has to be dependent on external support. In the context of HACCP this is particularly relevant in terms of technical expertise. Whereas competency in HACCP methodology can be effectively gained through training, this must be complemented with the appropriate knowledge of food microbiology and food chemistry. While the Codex Decision Tree and other such hazard analysis tools are readily available, they rely on the underlying technical expertise of the user.

In SMEs, particularly the micro business, technical competency to undertake hazard analysis is rarely available in-house. A recent government-funded case study of 24 SMEs involved in manufacturing ready-to-eat meat products identified that the employment of experienced technically qualified personnel was the single most important factor influencing the implementation of HACCP.[9] Analysis of company size indicated that this was not the norm for companies with less than 25 staff or a turnover of less than £2 million – in effect, most SMEs. Indeed, research consistently shows that the majority of SME managers have received no more than a one-day basic introduction to food

* The audits were conducted by the European Food Safety Inspection Service (EFSIS) accredited auditors from the Campden & Chorleywood Food Research Association.

hygiene (e.g. the Chartered Institute of Environmental Health's Basic Food Hygiene Qualification). Some of the consequences of such a skills shortage include the following:

- A lack of ability to prioritise the risks from physical, microbiological and chemical hazards. Given the time involved in hazard analysis, it is important for SMEs to focus HACCP studies on the group(s) of hazards that pose the greatest threat to public health. For example, caterers will focus their efforts on microbiological hazards while the soft-fruit grower will be more concerned with foreign body contamination. Many SMEs are unable to make these decisions and attempt to study all groups of hazards at once: a process that invariably ends in confusion, overload and a dilution of control. This scenario impinges on the wider debate as to how risk is perceived by, and communicated to, both the food industry and the consumer.
- The inability to distinguish between the relative risks of different pathogens on particular foods. This leads directly to the common scenario where the HACCP studies involve every pathogen 'in the textbook'. For example, the sandwich manufacturer who spent many weeks developing a HACCP plan to control the growth of *Clostridium botulinum* on lettuce leaves – an anaerobe that would never grow in the presence of air.
- A lack of focus at the stage of hazard identification is compounded by the inability to make technical decisions as to criticality. This results in too many CCPs being identified. This is a problem in many large organisations also, but its root within these companies is usually the misinterpretation of methodology. This can easily be remedied with HACCP training. For the SME the problem is insoluble without recognition of, and access to, technical expertise.
- Given the nature of control needed at a CCP, it is evident that the system can only operate with small numbers of CCPs. Hence the identification of too many CCPs results in a dilution of control and, in effect, a systems failure. An example best illustrates this point. During a recent training session a technical manager from an SME revealed that on a single process line he had identified 143 CCPs. Further investigation revealed that the Company HACCP Manual had been followed explicitly: every process step had to have at least one hazard and every hazard was critical! The reason that he had attended the training was that the system was impossible to implement. A subsequent review established only four CCPs and control was established within weeks.
- Interpretation of microbiological and chemical data on such documents as Certificates of Analysis is another problem area for the SME. Without a thorough understanding of both the science and statistics such documents can easily mislead. For example, a snack manufacturer was buying garlic flavouring on the basis that each batch came accompanied with a Certificate of Analysis to show the absence of *Salmonella* in 25 g of product. Only after a major food poisoning outbreak, identifying this as the source, did the sampling regime come into question: one 25 g sample was tested per tonne of product!

Another factor, perhaps more important than lack of technical knowledge, is that it is often not even recognised. In the UK it is quite normal for someone with production experience to attend a short course on basic food hygiene and subsequently feel competent to undertake a HACCP study involving high risk foods. This over-confidence can be a danger, especially when practices have continued for many years, and is reflected in the saying so often heard from small business owners, 'I've been doing this for 30 years and I've never killed anyone yet.'

2.2.3 Team approach

The SME invariably adapts well to teamwork, bypassing many problems found in larger companies. The relatively small number of employees enables the 'depth' and 'breadth' of the organisation to be represented within one team, enabling greater ownership to develop. It is also likely that managers have worked their way up from the factory floor (and continue to work there when production demands are high) and this first-hand knowledge of operational procedures and empathy for the workforce speeds up the process and accuracy of CCP identification. The subsequent control strategies are likely to be both practical and effective.

For example, a small factory producing garlic butter had a problem of fragments of blue plastic lining from the butter packs getting into the final product. The HACCP team included five people with production experience. While the focus was initially on how to detect the plastic, the storeman quickly identified the cause of the problem as one of staff fatigue when moving large, heavy blocks of butter encased in wood. In the relaxed environment of a 'production' rather than 'management' led team, he was able to admit that the problem arose when blocks were dropped, wood shattered and fragments tore into the plastic with the result that plastic fragments became embedded in the butter. The storeman suggested a very effective control which was subsequently implemented – job rotation so that the amount of heavy lifting was restricted to short time periods. While this scenario may fit any organisation with a good HACCP team, in reality many large companies still write HACCP plans in head office, thus missing the vital role of operatives.

The smaller the SME, the more difficult it is to release staff to attend meetings. It may be necessary to reduce the team size to a bare minimum and coopt members as and when required. For the micro business this still does not solve the problem because even the core team may be equivalent to more than half of the total workforce. In such circumstances innovative methods of teamwork are needed.

For example, a small hospital catering unit employed a total of eight staff. The catering manager was fully committed to HACCP, given the vulnerable group in her care, but could not persuade the hospital managers to pay the staff for half an hour extra per week for team meetings. She therefore resorted to 'clipboard meetings'. While supervising production she would go to each member of staff in turn with her clipboard and identify, by consensus, CCPs and subsequent controls. Although she complained of sore feet and a sore throat, the HACCP system was implemented successfully in six months.

2.2.4 Flow diagrams

The development of detailed flow diagrams is an essential part of the HACCP process, whatever the size of operation. However, there is much resistance to this detail across all sectors of the food industry where a minimalist approach is usually adopted. This is especially evident for SMEs where generic models have been suggested by many national governments as a mechanism for managing the complexities of HACCP. This advice inherently undermines the identification of CCPs as it is usually at the process steps that are not depicted on simplified flow charts that potential problems are most likely to occur. For example, the linear flow depicted in many generic flow diagrams takes no account of re-work!

Another problem is that one generic process step, for example the delivery of raw materials, cannot allow for the assessment of risk of individual foodstuffs. For example, a catering organisation was following a generic flow chart which identified the delivery step as critical. The control measures they adopted involved a temperature check. This led to the time-consuming practice of measuring and documenting the incoming temperature of all perishable foods including oranges, lemons and lettuces! Again, the loss of focus seriously undermined the concept of HACCP, increased paperwork and de-motivated staff who were well aware of the futility of the task they were required to undertake.

For SMEs overwhelmed by the task of producing multiple flow charts it is important to realise that many products have common processes. By working on one HACCP flow diagram at a time these 'overlapping areas' become evident and ways of merging the numerous flow charts – without losing essential detail – become obvious. Thus, one flow chart may eventually represent multiple products but this does not compromise HACCP principles. Most SMEs can find one member of staff with artistic ability, purchase some paper and coloured pens and produce excellent flow diagrams if they are convinced of the necessity.

Even in the catering industry, where one outlet may have dozens of menu items, this procedure can be followed as long as the essence of HACCP is not lost, that is, focus. The identification and control of high risk items must be a priority for HACCP studies, particularly in this sector of the industry. A consultant recently related the problem of a hospital caterer who had been told by the local enforcement officer that a HACCP flow diagram and plan was needed for every menu item including yoghurt and cheese. Both these products were purchased as individual, sealed packs and were only opened on the ward, by the patients, immediately prior to consumption. The caterer was totally de-motivated as his own common sense told him this was unnecessary.

2.2.5 Relationship between good hygiene practice and HACCP

Within a food operation there are many general activities that are in place to control food safety, for example pest control, cleaning and disinfection procedures, equipment maintenance, induction training and personal hygiene practices. This general level of control, applicable across all areas of the food operation, can be considered under the generic term good hygiene practice (GHP). This has been defined as the 'basic hygiene measures which establishments should meet ... for the production of food of acceptable [safety]'.[10] The terms good manufacturing practice (GMP), pre-requisite programmes (PRPs) or GHP are often used interchangeably in this context.

HACCP, in contrast, is directed at individual product/process lines and examines whether there are any additional, specific, significant hazards – above and beyond GHP – which need to be controlled to ensure product safety. The two systems are therefore inextricably linked but distinctly different. This relationship is represented diagrammatically in Fig. 2.2. An example would be the risk of contamination of *Staphylococcus aureus* during sandwich preparation in a busy catering outlet. It would be general good practice to have all food handlers trained in hygienic practice and wearing clean protective clothing. However, the staff preparing the sandwiches may take the additional precaution of wearing disposable gloves. The former measures would form part of GHP while the latter would be a specific control implemented for sandwich preparation in the HACCP plan.

In effect, GMP screens out the general hazards allowing the HACCP plan to focus on the significant hazards that need additional, specific control measure(s) to ensure product safety. Further analysis, using the decision tree or other hazard analysis tools, will determine which of these are CCPs. This screening process results in the identification of a relatively small number of CCPs – one essential criterion for successful HACCP implementation.

A recent survey[11] of 50 SMEs established that none had an effective GHP system in place. This resulted in every process step identified in the HACCP study being cluttered with repetitive, general hazards leading to excessive documentation and, more importantly, the identification of too many CCPs. Post-survey training, which fully explored the role of GHP within HACCP development, resulted in the decision of all of these companies to review and refine GHP, prior to any further work on HACCP.

It is not surprising that GHP and HACCP have become confused given the lack of written guidance on how the two systems interrelate. One exception is in North America where GMP has been a legal requirement in some sectors of the food industry since the 1970s. Interestingly enough, HACCP has yet to become a legal requirement across the breadth of the US food industry. With SMEs in mind, particularly micro businesses, the US Food and Drug Administration* has produced a detailed guide as to how food retailers can develop a system of GHP

* Details of this guide along with extensive information relating to US legislation, enforcement and practice can be accessed using the FDA website.[12]

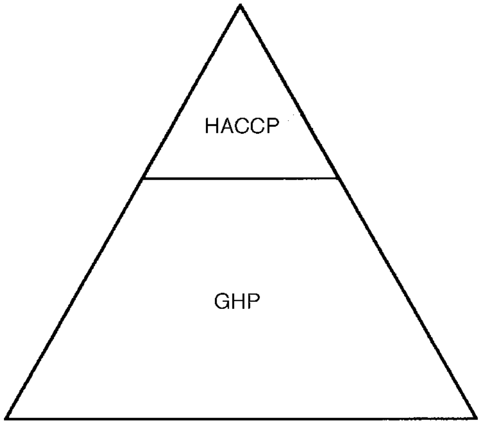

Fig. 2.2 The relationship between HACCP and GHP.

and then build on this to establish additional controls using HACCP principles. This offers a clear route to a comprehensive food safety management system and is recommended reading for all SMEs working in small premises with a large number of overlapping operations.

2.2.6 Resource problems

The typical SME can be described as having a busy day-to-day existence without designated staff to get involved in long-term planning of non-essential activities, i.e. those not directly related to production. In larger companies the training and technical departments often lead the HACCP project: most SMEs do not have these resources. It is evident therefore that even if the SMEs can be convinced of the necessity for HACCP, the allocation of sufficient time for its development becomes a major constraining factor. This is compounded by the requirement for specific HACCP training and the need to access the necessary technical expertise, as discussed in sections 2.2.1 and 2.2.2. To the SME this translates into a heavy financial burden and most owners look to government or other agencies for external help at minimal cost. While the ethics of this are debatable, the reality is that small and micro businesses, in particular, do not feel that *they* should pay for change initiated externally. Some initiatives and opportunities for SMEs are outlined below:

- The UK government, acting through an industry body, has recently attempted to support the large-scale implementation of HACCP in 7,000 retail butchers (see section 2.1.5). The project involved a two-day training course for groups of 20 butchers using material specifically adapted to suit the size and nature of the business. This was followed by eight hours of one-to-one consultancy within the butcher's own premises. While the training and consultancy were delivered free of charge, many butchers complained that 'time was money' and it was 'costing too much'. Indeed, many had to close their business to attend the training and meet with the consultants in the evenings or on Sundays.

- A monthly food safety drop-in resource centre, catering specifically for SMEs, has been set up by a university in the north-west of England. This has been funded by a variety of government and non-government organisations. The initiative is proving highly successful for businesses as they come across specific areas of difficulty such as flow charting, identification of hazards and validation.
- Trade associations also have a part to play in the dissemination of HACCP expertise although the costs of joining have been found to act as a barrier to micro businesses. Various research organisations can also offer significant resources to food businesses but the annual fees are prohibitive to all but the largest SMEs.
- The use of the Internet is developing at an exponential rate and can offer the SME a cost-effective resource in terms of expertise and information. The industry-specific discussion groups allow SMEs to share problems and expertise and there are vast amounts of technical data on-line. This is likely to be of considerable use to SMEs in the future, particularly for those isolated in rural areas.

2.3 Operating the HACCP system

2.3.1 Documentation

One of the criticisms made by SMEs trying to operate the HACCP system is its requirement for documentation. However, researchers and practitioners confirm that the excessive documentation reported is usually associated with the system being developed inappropriately.[13] This highlights the need for effective training in HACCP methodology.

Invariably companies that employ technical staff, with dedicated time for administrative work, have found documentation requirements easier to achieve than those who rely on hands-on managers. For many such SMEs, especially micro businesses, paperwork of any kind is a burden with verbal communication playing a major role in the successful management of their businesses. However, practice has shown that even within the smallest business, HACCP record keeping can be integrated into practice (with minimal disruption) if managers believe it to make good business sense.

The message that must be sold to SMEs is that HACCP aims to ensure food safety with the *minimum* necessary control. It is a system that, if correctly applied, *focuses* control at the CCPs. If the HACCP study has correctly identified a small number of CCPs then this need not be onerous. Fig. 2.3 illustrates the key elements that will demonstrate that the CCP is under control. For most businesses, achieving this level of documentation will produce a significant improvement in food safety and a slow, developmental approach

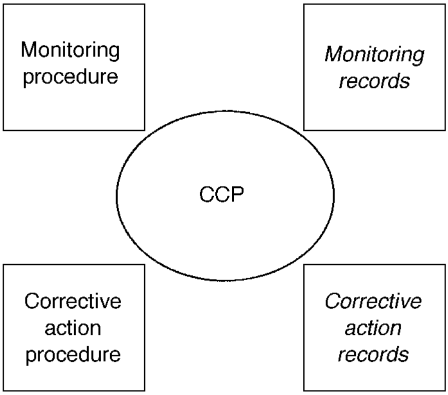

Fig. 2.3 The essential documentation required for each CCP.

should be encouraged to meet further requirements for verification and review (see below).

The use of computer software has been suggested as a good way for SMEs to deal with the development and documentation of a HACCP programme. While surveys have shown that companies with computer hardware enthusiastically purchase various packages, they subsequently find them to be of limited use.[11] Recently, various software packages specifically designed for SMEs have appeared on the market, including some for micro businesses, but it is too early to assess their usefulness. It would seem that in the long term, software may well be an appropriate solution to document control for SMEs. At the present time, however, owner-managers express the need for simple, highly visible documents such as wall charts and white boards (with pencils and pens attached) to encourage routine completion.

2.3.2 Validation

Identification of CCPs must be followed by decisions as to how they can be controlled effectively. In many companies, large and small, such decisions are often based on custom and practice rather than on evidence. HACCP should be seen as an opportunity to justify these practices using whatever means are available. SMEs need not be daunted as many CCPs are based on parameters, such as temperature, time and pH, which can be validated using simple experiments. Indeed, many SMEs enjoy this aspect of HACCP, feeling that they are *taking control* of food safety rather than being pushed into change by external forces.

For example, a self-employed butcher, while undertaking HACCP training, was frustrated by the conflicting advice he received as to safe procedures for cooling cooked hams. His trade organisation, enforcement officer, tutor and textbook all gave differing views. After the training he bought a temperature probe and plotted the temperature of a cooked ham at hourly intervals until it reached a safe temperature. He was shocked to find that, even following the most stringent procedure recommended, this took over 17 hours. He subsequently reviewed and revised all his cooking and cooling procedures until he had confidence that his practices were safe and the subsequent monitoring was valid. This butcher, who had received no formal education for over 30 years, so enjoyed this research exercise that he enrolled at his local university on a part-time MSc in Food Safety Management.

A specific cleaning procedure is another commonly identified measure to control a CCP and the cleaning methods chosen must be shown to work. The use of Agar Immersion Plating and Contact (AIPC or 'Dip') slides have proved useful to validate the effectiveness of cleaning routines. They are cheap, readily available and, in conjunction with the manufacturer's advice, can identify effective cleaning practice.[8]

Some critical limits, for example the shelf-life of new products, will need to be validated by technical experts and the SME must access this expertise as and when necessary. Local educational institutions, trade organisations and enforcement authorities are a useful starting point. It is important for the small and micro business in particular, with limited funds, to focus on specific problem areas when seeking advice.

The monitoring of critical limits should ideally be carried out 100% of the time but this is not possible for many control measures. In practice limits are checked at predetermined intervals. Yet again, *ad hoc* decisions usually determine this frequency and HACCP teams must be encouraged to test out these decisions. For example, a baker cooking pork pies in batches of 100 always tested one pie from the right-hand side of the bottom shelf to ensure that it had reached a safe temperature. His experience told him this was necessary due to the uneven cooking temperature of the oven. After undertaking HACCP training, the baker decided to test his practice by temperature checking the entire batch on one occasion. This confirmed that the pies at the right-hand side of the bottom shelf cooked more slowly than the rest of the batch. If one of these pies had reached the desired temperature then he could safely assume that the rest of the batch had. While he had always known his practice was safe, he now had the evidence to prove it. Again, taking control of food safety in this way proved to be an empowering experience for this owner-manager.

2.3.3 Verification

Once a HACCP plan has been developed and introduced into a food operation it must be maintained on a continuous basis. It is vitally important that those involved in food production follow the requirements of the HACCP plan and record essential detail. An audit trail then exists for verification, at any time, by supervisors, managers, customers or enforcement officers.

As discussed already, one of the criticisms of HACCP made by SMEs is that it requires a great deal of paperwork with records having to be kept at all stages of the production process. Those trying to audit food operations in turn complain of records being incomplete or distributed around the operation, making the audit more of an arduous and painstaking affair than it need be. The advantages of having a clearly thought out and carefully operated verification system are clear: it allows for audits to be quickly and accurately completed; it provides managers with all the data to hand so they can immediately act if problems occur; and it allows operatives to see the whole food system rather than just a small part and so helps them gain ownership of the HACCP system.

One method of managing verification that allows paperwork to be limited while maintaining control is by using a *build-card*, which accompanies the product as it moves through the processing operation. The build-card contains all the necessary details about the product (like a list of ingredients, delivery requirements, customer details). As the product moves along the production line all the details of its processing, such as cooking times and storage temperatures, are recorded on the build-card. The product thus ends up ready for dispatch with a complete history attached and ready for inspection by anyone with a need to know. A copy may also be sent to the customer for their records. This system has been used successfully in a cook-chill operation in England. With over 100 menu items, this was seen to be the most cost-effective solution to document control. The build-card also contained quality details and a diagram of how the meal components should be presented.

More advanced systems use bar-coding technology in order to record necessary information as the product moves along the line, and all the information is kept on a computer so that it can be accessed whenever needed. This type of bar-coding is used in an SME in Canada that produces fats and shortenings for caterers. The system allows for rigorous monitoring of all batches so that product only becomes available for release to the customer when all critical limits are within range and operating procedures have been followed correctly. Any batch, for example, that has not had a microbiological test is not registered on the warehouse system and can therefore not be released for delivery, since any product taken off the shelf by the storeman has to have its bar code scanned and the computer would instantly identify this as problematic.

In addition to routine auditing the HACCP system requires a periodic *review* to demonstrate that it is meeting its objective – producing safe food. Large companies will often employ external experts for this purpose as it is difficult to achieve the independence required using internal staff. This may well be supplemented by microbiological analysis of the food, process and environment. The costs of such activities are prohibitive to most SMEs, particularly small and micro businesses. For these companies the routine visits from enforcement officers and other agencies can be used effectively as an independent review of the safety of the system (see section 2.3.5).

Fierce protectiveness over HACCP plans, which is understandable given the labour that has gone into them, seems to prohibit small businesses from collaborating at this level. However, a network of businesses could work together and audit each other's systems with little or no investment. It is interesting that the butchers taking part in the HACCP initiative, despite being local competitors, were seen to swap ideas and practices and even invite visits from others on the scheme. While these owner-managers are by no means technical experts, they represent a fresh pair of eyes and have much to contribute to food safety reviews. The benefits of HACCP training, by bringing together people with similar problems, cannot be overestimated.

2.3.4 'Ownership' and motivation

Technical barriers have long been quoted as the major hurdle to successful HACCP implementation. However, experience is proving that the major challenge is the development of a system that can actually work in practice, which almost invariably requires a change in the culture of the organisation.

For example, it could be argued that the most important people in the organisation (in terms of food safety) are the operatives who control the CCPs. These employees are often the least paid, least valued and least motivated – a recipe for disaster! HACCP has identified a way forward in terms of *involvement* and subsequent *ownership*. If operatives are (1) told that they are in charge of a critical process, (2) asked to join a team to develop a strategy for dealing with this, and then (3) helped to write realistic procedures in their own 'language', they may become motivated to carry out safe procedures at all times. Such *participation* in technological change and *delegation* of control to those closest to the production process are well-documented driving mechanisms in the management of change and essential to successful HACCP implementation.

It is interesting that the larger the organisation, the more difficult it is to initiate and maintain such culture change. SMEs with their less formal management structures and simpler communication channels are at a positive advantage in this respect. The smaller the organisation, the more likely it is that all those involved in HACCP will have hands-on experience. This further improves the ability of the team to develop a system that operatives and managers alike will own with subsequent commitment and motivation to make it work.

2.3.5 Third-party audits and SMEs

Without in-house technical expertise many SMEs are vulnerable to take advice from everyone and anyone. This can result in HACCP being a patchwork of CCPs developed reactively on the insistence of external auditors or enforcement officers.

For example, in a family-owned meat cutting plant a competent quality manager, after implementing HACCP, recounted a problem with a customer audit. The retailer involved was insistent that the three microbiological CCPs identified in one particular process could not possibly represent a thorough HACCP study. The bottom line was 'the next time I visit, you must have more CCPs or we will terminate your contract'. This is not an uncommon scenario and questions the competence of many third-party auditors.

It is important for companies to have confidence in their systems and challenge the legitimacy of advice from those who have not been involved with the HACCP development. At the very least it is worth asking to see a full curriculum vitae of external auditors to assess their level of competency. While some countries, for example Australia, have stringent requirements for commercial HACCP auditors (including substantial experience of the type of food operation under question), this is by no means commonplace. On the other hand, if the auditor has the relevant knowledge and experience the visit could be used to full advantage and seen as a review of the system in place. Indeed, the audit can become a cost-effective management tool rather than a threat.

2.3.6 Supplier safety assurance

HACCP can only be completely effective if, at every critical control point, real-time preventative control is maintained. While a company can do much to achieve this within its own production process, it is questionable whether there are any real-time controls that can be implemented to assure contamination-free foodstuffs bought in from a third party, particularly if it involves overseas suppliers.

Larger organisations invest considerable time and money in attempts to assure the safety of such food supplies. This often involves detailed specifications which give information as to the presence or absence of microbiological, chemical and physical hazards in the food as well as Certificates of Analysis as evidence to support these specifications and on-site audits by technical staff. They may also restrict purchasing to suppliers who have attained third-party accreditation of their HACCP system.

For the SME there are difficulties in operating any effective system of supplier vetting, given the lack of time and expertise available. The smaller the company, the greater are the problems, with many micro businesses relying on negotiation through telephone contact and often buying from middlemen who are themselves SMEs with little formal control over food safety.

Training in HACCP has been shown to have a positive effect with respect to purchasing practice. If the owner-manager can be encouraged to focus on the need for evidence of a *safe* supplier, this is a good step forward. Many HACCP plans refer to the use of 'only reputable suppliers', with little thought as to what this actually means. An investigation[14] of the purchasing criteria used by 300 professionally qualified catering managers indicated that the term 'reputable' actually related to quality, cost and locality of suppliers. Safety was not even a formal consideration for 96% of these managers. However, after training, many of them asked to see evidence of supplier HACCP plans and some visited their local operations to discuss safety. This must be seen as a significant step forward in the overall context of food safety at the SME–supplier interface.

Looking to the future, formal accreditation for all but the smallest businesses may become commonplace (if costs can be contained). This could considerably improve the process of supplier safety assurance for all SMEs. It is also likely that many more businesses will make use of the Internet and the considerable resource it offers. At the present time model specifications for a wide variety of foodstuffs are available on the Web, giving an invaluable insight into the kind of data required from suppliers to give purchasers confidence of product safety.

2.4 Conclusions

The typical SME manager, who is often the owner, is undoubtedly highly motivated to achieve the best possible standard for the business. This commitment must be channelled into the application of HACCP principles in order to secure safe food. Despite a lack of interest and slow uptake to date, there are many encouraging developments which should help chart the way forward for SMEs.

In general terms, the nature of the risks inherent in the food industry must be communicated more effectively to both producer and consumer. This falls within the remit of local and national government and is high on the agenda in many countries. At the present time a combination of ignorance and optimism combine to block efforts to give safety the high profile necessary to stimulate change.

Current research to develop workable blueprints and benchmark best practice is encouraging, but it is important that the relatively small investments are not wasted with duplication of effort. Governments should work at an international level to coordinate activities and disseminate results. It must also be recognised that HACCP cannot be devised by government committees and needs the active cooperation and piloting among food operators themselves. It is also important to plan and deliver thorough evaluation, against predetermined success criteria. Practitioners should only be encouraged to change when there is evidence that such change is beneficial.

At a more practical level, high quality HACCP training must be widely available, at an appropriate cost, to all SMEs. While the principles remain the same for all food operations, their application needs skilled interpretation for SMEs, particularly for small and micro businesses. A developmental approach is suggested which concentrates on (1) the installation of a fully operational GHP system, (2) HACCP studies to identify specific areas that need additional control, (3) the development of valid CCP control measures and monitoring routines, and (4) appropriate systems of verification and review. This would need to be phased in, over perhaps a period of two years, and therefore relies on an ongoing support network at local level.

Each local area could develop a 'HACCP resource centre' which would provide some of the essential requirements for successful implementation. This may include directories of suitably qualified HACCP consultants, trainers and educational opportunities, funding routes (so often not accessed by SMEs), discussion groups to share experiences, on-hand experts to examine specific problems, and computers with access to the Internet and HACCP software.

Local government offices or educational establishments would be suitable venues. Given the dearth of technical expertise, within small and micro businesses in particular, there is an urgent need to allow access to this type of service. Perhaps SMEs themselves should lobby for such facilities within their locality.

Finally, it should hearten the SME manager to know that all companies, large and small, have problems with HACCP implementation – they are just different ones! The small company adapts well to teamwork and develops ownership with less difficulty, and their flexibility allows practical solutions to be implemented quickly and often at very little cost. If appropriate technical expertise can be accessed and good HACCP training undertaken, they should be very enthusiastic about the task ahead.

2.5 References

1. BANNOCK G, DALY M, *Small Business Statistics*, London, Paul Chapman Publishing, 1990.
2. GORMLEY R T, 'R&D needs and opinions of European food SMEs'. *Farm & Food*, **5**, 27–30.
3. MORTLOCK M P, PETERS A C, GRIFFITH C J, 'Food hygiene and the hazard analysis critical control point in the United Kingdom food industry: practices, perceptions and attitudes', *Journal of Food Protection*, 1999, **62** (7), 786–92.
4. PANISELLO J P, QUANTICK P C, KNOWLES M J, 'Towards the implementation of HACCP: results of a UK regional survey', *Food Control*, 1999, **10,** 87–98.
5. UNTERMAN F, 'Food safety management and misinterpretation of HACCP', *Food Control*, 1999, **10**, 161–7.
6. CODEX ALIMENTARIUS COMMISSION, 'Hazard analysis and critical control point (HACCP) system and guidelines for its application'. In *Food Hygiene Basic Texts*, Rome, FAO/WHO, 1997.
7. WORLD HEALTH ORGANISATION, *Strategies for Implementing HACCP in Small and/or Less Developed Businesses*. Available from http://www.fda.gov (October 2000).
8. MOSSEL D A, JANSEN J T, STRUIJK C B, 'Microbiological safety assurance applied to smaller catering operations worldwide: from angst through ardour to assistance and achievement – the facts', *Food Control,* 1999, **10**, 195–211.
9. HOLT G, Researcher investigating barriers to the implementation of GHP in SMEs, personal communication, October 1999. Details of this UK government-funded research project can be obtained from G. Holt at the Department of Agricultural and Food Economics, University of Reading, tel: 44 (0)118 987 5123, fax: 44 (0)118 975 6467.
10. JOUVE J L, STRINGER M F, BAIRD-PARKER A C, *Food Safety Management*

Tools, Brussels, International Life Sciences Institute (ILSI) Europe, 1998.

11. TAYLOR E A, 'Securing public health through the application of HACCP: a UK perspective', National Conference of the Australian Institute of Environmental Health, *Environmental Health ... Paradise in Focus, Challenges and Risks*. Proceedings. Queensland: AIEH, 1998, 37–41.
12. FOOD AND DRUG ADMINISTRATION, *Managing Food Safety: A HACCP Principles Guide for Operators of Food Establishments at the Retail Level*. Available from http://www.fda.gov (October 1999).
13. MOY G, KAFERSTEIN F, MOTARJEMI Y, 'Application of HACCP to food manufacturing: some considerations on harmonisation', *Food Control*, 1994, **5**, 185–246.
14. TAYLOR E A, 'Food safety in the UK catering industry', PhD thesis, Food Policy Research Unit.

3

HACCP and SMEs

A case study

N. Route, formerly Food and Spice Group, Tunbridge Wells

3.1 Why bother with HACCP?

COSHH, GMP, ISO 9000, EFSIS, HACCP? No wonder so many small to medium enterprises (SMEs) are daunted by the thought of hazard analysis critical control point (HACCP) implementation. Resources are at a premium, everyone is busy getting the new enterprise off the ground or keeping it running. This was certainly the position when I first encountered HACCP systems. The company I worked for was newly formed and struggling to keep up with the deluge of customer orders. I can still hear senior management saying 'We don't have the time or resources to waste on something that is just red tape and of no practical value!' Their arguments were very persuasive as the business had no personnel to implement a HACCP system. In any case, business was doing very nicely without it!

This situation changed with the first customer audit. The customer, a large food manufacturer, asked to see our HACCP plan and quality manual. When we were unable to produce one, the customer explained that they would not be able to demonstrate due diligence unless we had a recognised, audited quality system in place. This meant that no further orders would be placed with our company until the situation was rectified. The potential loss of a major customer removed the initial opposition to HACCP systems. An immediate decision was made to implement a HACCP system and a timetable agreed with the customer for a return visit to audit the system. Having a HACCP system had now become a commercial necessity.

Despite the initial resistance from within the company, SMEs do not need to see HACCP systems as a burden. Instead SMEs can recognise their value as a relatively straightforward method of demonstrating high standards of operation to their customers. With increased pressures on the food industry to comply with new legislation, a system like HACCP makes a business more attractive to customers, and maximises its safety and quality standards and those of its own suppliers. It can also be viewed as an alternative to the more expensive accreditation process for a quality standard such as ISO 9000. This chapter looks at the experience of one SME, Food and Spice Group, in successfully planning and implementing a HACCP system.

3.2 The company

The Food and Spice Group was founded and initially run by two commodity traders, funded by a Spanish-based partner who used it as a vehicle to import his citrus derivative products into the UK market. The company specialised in exotic frozen fruits and vegetables from the Far East. These high value, low volume items were too small for larger concerns to deal in but were nonetheless essential to the boom in demand for more cosmopolitan flavours in food. With a customer base consisting exclusively of well-established food manufacturers, the business soon grew into a profitable trading operation. These companies manufactured a diverse range of products including pizza, garlic bread, soups, sauces, confectionery, blended seasonings and the increasingly popular chilled or frozen ready meals.

As a supplier of raw materials, the company came under increasing pressure from its larger manufacturing customers to move into processing its ingredients (particularly garlic and ginger) into a more user-friendly form. Both of these products were initially imported as peeled, trimmed and IQF (individual quick frozen) from suppliers in China. Our customers were not using the garlic and ginger in the whole peeled form that we supplied, but were turning them into purée. Gradually our customers began to ask us to supply them with garlic and ginger in a purée form.

The company at first sourced ready puréed product from China and India, only to find that levels of quality were, at best, variable, and hygiene standards unacceptably low from some suppliers. The decision was made to set up our own manufacturing operation to meet this particular opportunity in the market. A suitable site was found and within a very short space of time the factory was at full capacity, manufacturing purée products for an ever growing customer base. We outgrew the first facility and found ourselves moving to a much larger factory. At this stage of expansion, HACCP was thought to be irrelevant and only suitable for larger organisations. However, it was also at this point that the company came under pressure from customers to demonstrate an appropriate quality and safety system.

3.3 Scope and resources

In one respect, the timing of the decision to implement a HACCP system was ideal, since the company was about to move to a larger site. I decided that with the new bigger factory, HACCP systems implementation would take place from the start of operations, making it the norm rather than the exception. I also extended the HACCP scope to encompass the supply of ingredients from overseas suppliers. This was an expensive, time-consuming decision, especially for a small organisation like ourselves. It required extensive travel that took me away from the UK facility but, in the long term, it was to prove a worthwhile investment.

Allocating resources for HACCP implementation is a major issue for SMEs. How much can we afford to budget? How long will it take? Will it be worth it? Who will manage it? In a small company there are no easy answers. An SME cannot allocate significant resources to such a project. The use of external resources such as consultants is often too expensive and the results can be variable. SMEs like ours lack the resources to fund training and may not be able to spare key staff. Success depends essentially on the drive and determination of the individual managers and staff within the company. Indeed, such commitment applies to all aspects of running a small business and not just HACCP implementation. HACCP implementation depended both on effective leadership and the dedication of a small team. While strong leadership provided momentum and direction, teamwork meant a shared workload and a wider range of expertise on which to draw. It also meant fuller discussion and more considered solutions, avoiding the pitfalls of hasty or ill-informed decision-making by any one individual. If it is successful, a small but dedicated team can have significant advantages over the greater resources of a large company, providing greater flexibility and speed. We had precious little to show in terms of documented systems, but I did have a first-class factory and staff and the necessary, if somewhat reluctant, support of the senior managers.

My first step was to form a HACCP team. Although the whole production staff was eventually involved in the development of the HACCP system, I felt it necessary to appoint certain individuals as a focus point for HACCP activities. This decision turned out to be the key turning point in making HACCP work. Selecting the right mix for the team is critical. I chose members from each department: production, administration and sales, plus a senior director and myself as sales and technical manager. While only some of the team had direct experience of production and safety issues, sharing the workload across the company proved invaluable. In practice, as with many SMEs, departmental responsibilities also overlapped with, for example, administration handling production as well as other company record keeping. Predictably the senior director soon lost interest and failed to attend team meetings. His workload made attendance difficult and, while he recognised the importance of the project, he was happy to delegate its implementation to the HACCP team. But the rest of the chosen team worked together extremely well. Team members rose to the occasion, often working long hours and in their own time to see the project through. The team created the resource. The team was the resource. Teamwork gave HACCP a life of its own, providing a momentum that no one individual could sustain.

HACCP actually cost us very little in terms of money because, as an SME, we had no option but to utilise existing resources to cope with the initial demands of planning the system. We could not afford training or external consultants. A good example of existing resources is feedback and advice provided by customers. I took the view that a customer audit is akin to having access to a qualified consultant for the day, but without the fee! I therefore read through the reports from all the customer audits to date, gathering information relating specifically to HACCP issues. Then I arranged to visit the technical departments of selected customers and asked them to advise on implementation. With only one exception, all the customers I approached were only too happy to provide help and advice. Some even went as far as to supply examples of documentation and provide assistance with the HACCP plan itself.

The company was not a member of any professional bodies so Internet access became an invaluable tool. By searching the Web for HACCP and related subjects I managed to obtain nearly all the details I needed at very little expense. Quality manual documentation, legislation, Statutory Instruments (SI) documents, sample HACCP plans and useful contacts for queries and information were all found in cyberspace. However, at each stage of the information-gathering process, I made a point of involving the HACCP team, introducing each new piece of information during our meetings so that it would be thoroughly understood, analysed and the relevant parts integrated into our own HACCP system.

It is important to remember that, whatever the source of any information you gather, or however well intentioned any advice you are given when setting up a HACCP system, you must always sift out what is relevant or 'fit for purpose' for your circumstances. In particular, I found auditors from differing companies all had their own interpretation of HACCP principles. Some auditors had a prescriptive approach at variance with the basic philosophy of HACCP systems, insisting on adding CCPs that were not appropriate to the company's manufacturing operations. In one case a trainee auditor, a university graduate with limited manufacturing experience, chose to fail our company because we had not implemented some unnecessary systems listed in his standard audit schedule. The situation was rapidly reversed once the auditor's company was informed of our 'fit for purpose' philosophy. In my experience, some auditors do not understand the basic underlying logic of HACCP systems which is to help both customer and supplier continually monitor and improve their operations in a cost-effective, controlled fashion. It is in everyone's interest, particularly in an auditing situation, to cooperate so that a mutually acceptable conclusion can be reached. I have often questioned the assumptions and recommendations of different auditors, and by explaining the rationale behind the company's HACCP system clearly and simply, have been able to change their view. I do not believe that one should be in awe of customers. A mutually respectful approach is much more productive and benefits both parties. The smart customers know this and choose to work in partnership with their suppliers, recognising that they cannot grow unless their suppliers grow.

3.4 HACCP planning and implementation

Once the decision was made to base the new site on a HACCP system, the first step was to break the manufacturing process down to its basic constituents. If a HACCP system is to work successfully, it has to be understood by all the personnel involved, particularly those on the shop floor who will operate the system in practice. An accurate, comprehensive but clearly set-out process flow chart, accessible to all production personnel, is an essential starting point. A first step was for the HACCP team to create a basic flow chart of all the relevant systems and processes, including the design and layout of the new site.

Introduction of a HACCP system in an established workplace, if not carefully handled, can be a nightmare. Success depends essentially on cooperation. Once the HACCP team had put together the flow chart, I decided to involve all the factory staff, from managers and supervisors to machine operatives and fork truck drivers, in the production of a comprehensive HACCP plan for the site. At each stage of the flow chart, key personnel were consulted about the accuracy of the chart itself, the key hazards and CCPs. When there were disagreements, they were usually resolved by stripping the flow chart back down to basics and taking a fresh look at each element.

One major issue that was constantly raised in hazard analysis was the distinction between safety issues (hazards) and quality defects. Our experience is that it is essential to keep the two separate, and to concentrate on identifying hazards and appropriate CCPs to control them. An example is raw material inspection which can be both a CCP and a quality control point. The HACCP system identified only the relevant CCP. Other quality issues were documented in a separate set of procedures. As a result the HACCP system remained much easier to understand and operate. At all times we tried to follow the motto: ‘keep it simple’.

CCP analysis can be a problem area in HACCP planning, with the temptation to identify too many steps as CCPs. I used a simple flow chart to identify CCPs on each section of the flow chart (see Fig. 3.1). Some items that, on initial analysis, seemed to be CCPs turned out not to be when this formula was applied. The premise is simple: if a step or stage of your HACCP flow chart contains a hazard that is eliminated or reduced to acceptable levels by a subsequent stage, then it is *not* a CCP. This is a basic concept that can still be hard to grasp. It is interesting to note just how many HACCP trained auditors fail to do so.

By involving everyone at grass-roots level, HACCP planning and implementation was achieved well within the schedule agreed with the customer’s auditor (one month). Each person contributed ideas and modifica-

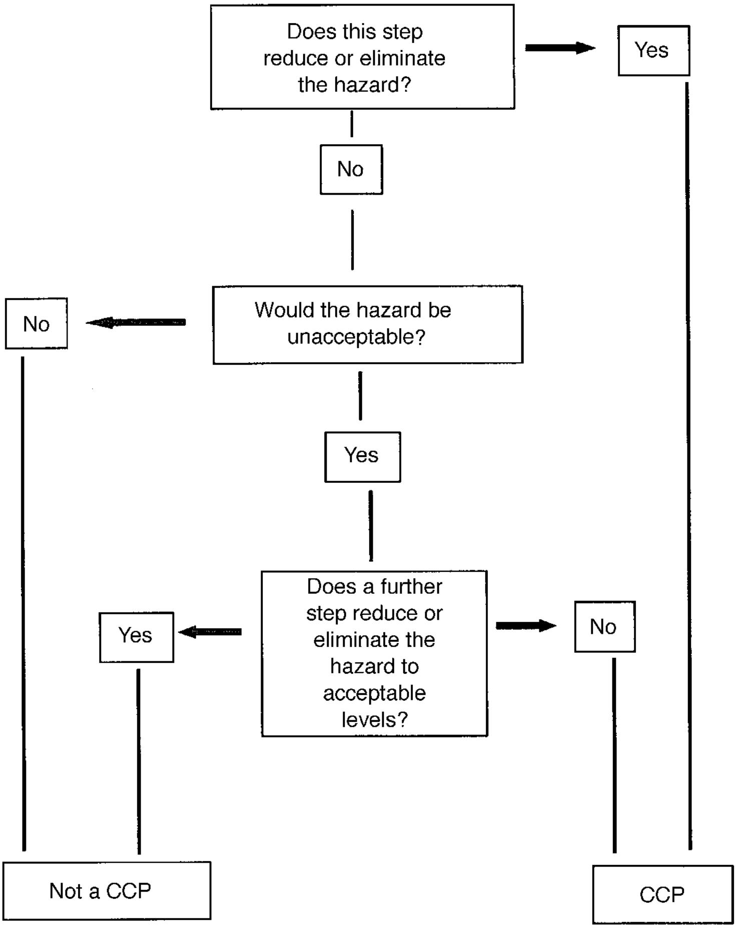

Fig. 3.1 General guidelines for the determination of critical control points.

tions, taking ownership of the scheme simply because they were involved in its design. To test the emerging HACCP plan, I would sometimes deliberately add false or incorrect procedures or statements. To the credit of the team, all points were soon discovered and modified. Even some items that I felt to be accurate turned out to be incorrect. This may not have been discovered if, as with many of the unworkable HACCP plans I have seen in the past, I had formulated the plan in isolation as a manager who thinks he knows better than the person actually doing the job.

On the rare occasions that questions were left unresolved, for instance because of a lack of information or expertise, the HACCP team decided to implement the relevant HACCP procedures on an interim basis and make subsequent improvements after further research. This was also true of many of the HACCP procedures put into place initially. After working with them for a while, team members would inevitably come up with modifications and corrections.

The first customer audits we had after implementing the HACCP system were very intense. I was not prepared for the amount of scrutiny the procedures and documentation would come under. As an example, simply showing an auditor a raw material inspection document in response to their request was not sufficient. I was required to demonstrate the accuracy of the document by taking the auditor through the entire procedure. This included producing the training record for the member of staff responsible for inspecting raw material, taking the auditor through the company's non-conformance procedures and records, and demonstrating a satisfactory audit of the supplier in question. To begin with, the company did not do well, reflecting our inexperience and the speed with which the system had been set up. HACCP implementation involves a steep learning curve and most of the auditors were flexible enough to allow for this. It took several months to rectify fully mistakes outlined in auditors' reports. In some cases audits highlighted anomalies in the customers' audit procedures which gave me the opportunity to question the validity of some recommendations. But once the changes were made we gained the customer approval that had previously eluded us.

3.5 HACCP and supplier operations

A major decision for the company was to extend the HACCP programme to include the company's suppliers. This decision was made for a number of reasons. Many safety problems could be traced back to suppliers, and these needed to be resolved if the company's own HACCP system was to be effective. Effective supplier HACCP systems would put less pressure on our own system. At the strategic level, the company's further expansion depended on improving the quality of our suppliers. If we were to grow as a supplier of quality, value-added ingredients, the quality of the raw materials provided by our suppliers needed to be higher and more consistent.

We had widely varying experiences when incorporating our suppliers into our HACCP programme. Our UK suppliers are mostly in packaging, or warehousing and distribution. Many were more advanced in HACCP than we were, or held some relevant certification. Documentation and systems were readily available to us from these sources, and fitted in very well with our own HACCP requirements.

The situation with our raw material suppliers in the Far East was completely different. They had little or no knowledge of European food standards and requirements, and did not understand why we were asking them to implement their own HACCP systems. Given these problems I was sent to China in an attempt to assist selected suppliers with HACCP implementation. On arrival I discovered that there had already been several attempts by some larger (mainly US) companies to implement a quality system with some of our suppliers. These had all failed because of a mix of supplier inexperience, especially a failure to grasp the basic concepts of quality and safety systems, and cultural differences. As an example of the latter, a Chinese supervisor would not like to admit quality defects openly or have his work criticised, however constructively, by an ‘outsider’ because he would ‘lose face’ in the eyes of his colleagues. If this were to happen in front of his line manager, as occurred with most attempts to explain or implement quality systems, the supervisor would refuse to cooperate and no progress would be made. These difficulties were compounded by visiting companies setting up their own quality systems and documentation tailored to their own regulatory and product requirements. These systems sometimes conflicted with each other and procedures were usually in English and therefore inaccessible to most of the workforce. Having failed to set up an effective quality system with the supplier, some firms simply hired staff to supervise production for specific orders who would then leave the company, taking their procedures and documentation with them. This left the supplier with neither the means nor the motivation to implement their own system. After all, customers could apparently do it all themselves, without any risk or loss of business to the supplier!

Given my experience in the UK, I applied the same formula of forming a HACCP team drawn from the actual people who would implement the HACCP system. After polite negotiations with the presidents of each company, I gathered together the managers, supervisors and key operatives from each department. With cultural differences in mind I coaxed the members of each department into mapping out the process for which they were responsible. This involved getting them to think about each process step and write it down in a form that they could understand. Then I asked them to go away and come back as a department with all the things they thought could improve product safety in their area of responsibility. I had signs made up in Chinese and hung in the meeting rooms which said ‘Don’t bring me problems, bring me solutions!’

This approach was a revelation to them. Traditionally, it had always been the senior managers who would suggest improvements. Staff were simply there to implement their managers’ wishes. To alleviate their nervousness regarding such a radical approach, I explained (through my interpreter) that because the president himself had the utmost respect and confidence in their abilities, he had already agreed to implement their considered recommendations. Behind the scenes I had already complimented the president on his leadership, his excellent staff and their ideas for improvements. He in turn, in the interest of improving his own standing with our company, had given me permission to implement any changes his staff thought necessary!

The various teams returned with numerous criticisms of the current system together with suggestions for improvement. I worked exhaustively with each departmental group producing individual flow charts and HACCP plans, and then merging each part into a single, integrated system. As with staff in the UK, the most lively and animated debates revolved around the distinction between safety and quality issues. By maintaining the focus on safety and using the CCP decision chart I employed in the UK, we developed a simple but comprehensive HACCP plan. One unexpected problem was the response to the need for verification and validation of the HACCP plan. The initial response from some of the teams was that this was unnecessary and could be seen as questioning their competency. In response, I told them their president was eager to see the fruits of their labours in action and I felt sure that they would want to present the HACCP system to him in the best possible light. This resolved their concerns and secured the cooperation of staff in the auditing process. By auditing the HACCP system as though we were a customer, we tried to anticipate customer audit requirements, making modifications as appropriate.

By managing cultural differences with tact and understanding, I was able to secure a genuine commitment and ownership of the HACCP system from the president through to production staff. I told the president that many improvements were made because of his foresight in allowing his personnel to implement the changes. Department staff were also happy: instead of losing face they had been responsible for a successful project in which they could take pride. I made a special point of complimenting the president on the quality and ingenuity of his staff in front of the various departmental teams. He in turn made it clear how proud he felt of his staff and the company.

It is worth noting that these Chinese companies actually had much of the relevant information and record keeping in place before HACCP planning began. The main problem was that this information was not integrated into a single coherent safety system, in part because each department did not share information with other departments in case they lost face in front of their colleagues. Once they were given the appropriate framework and motivation, I was surprised at the level of enthusiasm shown by company staff and the speed with which we were able to implement a HACCP system. Two of the companies I worked with have since gone on to get EFSIS (European Food Safety Inspection Service) approval and are currently working towards ISO 9000 accreditation. In one company I was bestowed the honorary title of 'Mister Teacher' as a mark of gratitude!

3.6 Keeping up to date with HACCP

HACCP should be a self-perpetuating system. Implement it correctly, and all those involved will help improve and maintain the system. I cannot stress enough how important it is to perform a regular self-audit. To begin with, I audited the system on a monthly basis, concentrating on the main areas of weakness located after the previous month's audit. I did encounter some opposition with the first internal audit at our new site. Surprisingly, this came mainly from members of the HACCP team. In particular, I found omissions with record keeping in such areas as raw material inspection and hygiene. The CCPs were being operated effectively, but staff were finding various excuses to avoid the burden of filling in records. It took some time for the situation to be remedied. However, by the third or fourth monthly audit everyone was not only making a conscious effort to address the points made in the previous audit, but they were actively seeking or devising improvements of their own, for example in simplifying documentation and record keeping so that they were both effective and practical. Regular reviews have helped both to pick up the inevitable weaknesses in any new HACCP system and, even more importantly, build a proactive culture among all the staff operating the HACCP system.

Legislation is always changing, not always in favour of SMEs. It is a struggle keeping up to date, but customer audits often provide the best way of doing so if they are viewed as free consultation. We like to have an open approach with both our customers and suppliers, encouraging a relationship of mutual cooperation and respect. Rightly or wrongly, I have continued to challenge auditors where I disagree with their findings. Sometimes this is because they have not fully understood our operations or a procedure, and sometimes it is because I have misunderstood their position. However, a healthy dialogue allows me to keep abreast of new developments in the field of HACCP systems.

In addition, because of the increase in business we have enjoyed as a direct result of HACCP implementation, the company has been able to fund my attendance on relevant courses on the subject. Finally, there is always the mighty resource of the Internet to fall back on.

3.7 Summary

HACCP implementation has proved to be a real asset to a small company like ours. The benefits include the following:

- HACCP implementation has made it easier to gain supplier approval status from our customers, with a subsequent increase in the volume of orders. We have subsequently achieved ‘partner’ status with some of our customers, making us a preferred supplier over our competitors.
- With the benefit of a HACCP plan, we have gained sufficient credibility with our customers that they now feel they need audit less frequently and rarely challenge our systems and products. In effect, having a HACCP system had lessened the amount of effort needed to supply some of our customers!
- A HACCP system can also be viewed as an alternative to the more expensive accreditation process for a quality standard such as ISO 9000.
- Our overall competitive position has improved because we can now demonstrate safety and quality in our service, and in the way we purchase, manufacture and deliver our products.
- Overseas suppliers in particular have improved beyond all measure and I now have the luxury of an approved supplier list to choose from when purchasing. Previously this was a hit-and-miss affair, taking the product from whoever could supply it to us at the right time for the right price, but usually at the expense of consistent quality.

- With increases in food industry legislation bearing down with relentless pressure, a HACCP system provides both high levels of food safety and a framework for anticipating and managing change.
- In an increasingly competitive environment, a HACCP system, if correctly implemented and maintained, encourages a culture of continuous review and improvement in a company. Our work ethic is now firmly grounded in HACCP principles.

HACCP implementation was indeed daunting when we took it on, and resources are still at a premium. I still seek out and ask for help from any source I can lay my hands on: customers, colleagues, reference libraries and the Internet. There is no magic formula to getting it right, but I would suggest the following to other SMEs starting out on HACCP implementation:

- Secure senior management commitment on the basis of the real commercial advantages that a HACCP system can bring.
- Selecting the right team is the biggest single factor in success. Make sure that all departments involved in implementing a HACCP system are represented.
- In preparing for HACCP planning, use the resources you have to hand. In particular, make full use of customers and customer audits. Most customers are likely to be supportive and can offer helpful advice. Make use of the Internet.
- However, make sure that any advice or information you get is relevant to your business. Customers and others are not infallible – do not be afraid to question advice if you think it is wrong.
- Start with the process flow chart. Break down your production operation into simple stages and build up the flow chart from there.
- Remember the motto: ‘keep it simple’. Process flow charts should be clear enough for production staff to follow. Focus on safety issues, treating quality issues separately. Use a simple flow chart like the one in the chapter to identify the control points that are genuinely critical.
- Consult widely. Use the HACCP team at every stage, and, for particular stages, bring in the production staff who will operate the system in practice. If you do, the HACCP plan will be stronger and there will be greater ownership at the implementation stage.
- You won’t get your HACCP system right first time. Expect to make changes. Have regular internal audits to pick up problems and build up a proactive work culture among staff operating the system.
- Involve your suppliers in HACCP implementation: it will pay off in the long term.

If I were to do it again I would insist that the senior management was more fully involved. Even now they remain ignorant of the efforts that were made in this respect. However, as an overview for HACCP, the experience of our small, but perfectly formed, company stands as an encouraging testament for the benefits it provides, not least of all to our bottom line.

4

Supplier HACCP systems

A retailer's perspective

M. Kane, Food Control Limited, Cambridge (formerly Head of Product Safety, Sainsbury's Supermarkets Limited)

4.1 Introduction

This chapter looks at the implementation of HACCP systems in the UK from the point of view of retailers. It looks at how major UK retailers have encouraged the implementation of HACCP systems by food manufacturers supplying them with products for their network of supermarkets. The major multiple retailers' interest in HACCP can be traced back to the 1970s when they began to develop their own-brand range of food products, which became commercially highly successful. Supermarkets were acutely aware of their product liability exposure with own-brand products, which were mostly co-produced for them by third-party food processors and packers. Commercially, they needed to be able to demonstrate 'due diligence' in their safety procedures in the event of a criminal or civil prosecution against them, even before this became a statutory requirement. These pressures led to an early interest in HACCP systems.

4.2 Retailers and the development of supplier HACCP systems

Supermarkets quickly built up in-house food technology departments during the 1980s to monitor their own-brand food supply lines and deal reactively with those food safety issues that inevitably arose. They first started to apply formal HACCP techniques in the mid-1980s with the publication by Sainsbury of a supplier guidance manual on HACCP based on the original Pillsbury text of the early 1960s. The other major food retailers soon followed, developing their own approaches to HACCP planning and implementation. Suppliers with more than one supermarket customer found themselves visited by technologists from each retailer, often with conflicting technical 'advice' on HACCP issues!

Since then the costs of running large in-house technical departments have become a significant competitive disadvantage. In the late 1990s supermarkets began to encourage suppliers to use third-party auditors, approved by the retailers, to audit their safety and quality systems. Concerns were raised about variations in the approach of different third-party auditors. In response to these concerns, the major UK food retailers have, through the British Retail Consortium (BRC), recently agreed a common minimum standard for food safety and quality audits. This standard provides third-party audit companies with a common basis (using HACCP principles) with which to provide a due diligence defence for retailers. UKAS now accredits third-party audit bodies to this BRC standard for retail food supply.

To start with, the major retailers used the HACCP framework as a management troubleshooting tool, because its methodical and logical approach lent itself to the 'reactive' investigation and solution of those food safety incidents that arose on occasions. However, the disruptive costs of product withdrawals and recalls, plus the costs of adverse publicity, soon pushed the supermarkets into developing the use of HACCP systems in a more proactive and preventive way. They began to encourage suppliers to incorporate HACCP principles into their existing quality management systems, i.e. to predict potential food safety issues and build in preventative controls in advance.

Initially, UK retailers found themselves the pioneers in HACCP development, both encouraging their suppliers to adopt HACCP principles and providing the necessary guidance and technical support to allow them to plan and implement HACCP systems. Supermarkets encouraged suppliers in a number of ways, for example by arguing that the successful development of a HACCP system would help a supplier to gain a recognised quality standard such as BS 5750/ISO 9000, at a time when many companies were seeking such accreditation as a source of competitive advantage, though this has now been superseded by the BRC standard. Supermarkets also provided support for suppliers contemplating developing a HACCP system. Sainsbury's first manual for suppliers on HACCP systems, for example, provided a basic template for HACCP planning and implementation, including guidance in such areas as the following:

- selecting a HACCP team and team leader
- constructing detailed process flow charts as a basis for hazard and CCP identification
- procedures for classifying the severity of hazards and isolating CCPs
- procedures for auditing an implemented HACCP plan.

Supermarket staff also provided expertise, for example, on the range of microbiological hazards that suppliers needed to consider, their conditions of growth and methods of control. Initially, the development of HACCP systems was a learning process for both the retailers and the first suppliers implementing

HACCP systems. Some of the problems faced by these suppliers included the following:

- failing to apply the right criteria in hazard and CCP analysis (for instance, by conflating safety and quality issues), resulting in an over-complex and unwieldy initial HACCP design
- unfamiliarity with new systems and responsibilities from line management and staff.

However, supermarkets were able to benefit from their unique position in working with a network of suppliers, able to compare differing approaches to and experiences of HACCP implementation. This experience was used both to strengthen the expertise on which suppliers could draw and develop retailer skills in auditing HACCP systems and making suggestions for improvement. Supermarkets also embarked on a major HACCP training programme for their technologists in the 1990s to consolidate their in-house expertise. Over time, as acceptance and implementation of HACCP principles have become more widespread, supermarkets have increasingly been able to make HACCP implementation a precondition for supplier selection. The technical role of the major retailers has moved towards the administration of a framework of third-party auditing of established supplier HACCP systems.

4.3 Assessing the effectiveness of supplier HACCP systems

The retailers' experience of HACCP implementation by their suppliers has shown that the most successful have been those with a number of common characteristics:

- well-designed and managed prerequisite systems
- existing quality systems, often with certification to a standard such as those within the ISO 9000 series
- a management culture focused on food safety and continuous improvement.

Companies with these characteristics have the right foundation on which to develop a HACCP system. This includes a basic framework of process monitoring and documentation, which can provide a useful starting point for HACCP planning. More importantly, such companies have the enthusiasm and organisational skills to plan and implement a well thought-out HACCP system. It is perhaps not surprising that supermarkets have developed a policy of selecting suppliers from companies with these characteristics, and that, as a result, HACCP implementation has proved a generally rewarding experience for both retailers and suppliers.

There are a number of ways in which supermarkets assess the effectiveness of a supplier's HACCP system. These include:

- regular supplier audits

- monitoring of adverse customer complaints trends, followed by audit visits to isolate and resolve the problems underlying the trend.

The second of these methods is discussed in more detail in the following section which looks at the ways that retailers conduct trend and cluster analysis, based on customer complaint data. Other indicators include:

- variable product quality noticed in routine monitoring
- media reports.

Routine audits assess the effectiveness of HACCP systems in a number of ways. An auditor would first review the documented HACCP plan. An effective assessment of the quality of the plan requires knowledge of the following:

- the product and production processes
- the typical hazards associated with the relevant raw materials and production processes
- the range of controls that should be in place to monitor key processes
- the CCPs and minimum GMP requirements that should be included in the HACCP plan.

Because they have dedicated food safety expertise within their food technology departments, and the privileged experience of working with a range of suppliers on HACCP planning, supermarket staff are able to bring considerable expertise to this initial inspection of a HACCP plan, benchmarking it against other plans and international best practice. One measure of effectiveness is to check whether the plan is under continuous review, for example by looking for revision numbers and dates. This check can show whether the HACCP plan is a 'live' system, responding to changing circumstances, and being effectively implemented and 'owned' by plant management. Another useful indicator of a 'live' HACCP system is the design of CCP monitoring systems and documentation. Clearly set-out procedures for measurement and recording of CCP data, and clear guidance on remedial action in the case of deviation from permitted values, show the care with which the HACCP plan has been put together and is likely to be understood and implemented by line operatives. Review of the HACCP plan would help to determine the audit schedule agreed with the supplier and any special areas of attention in an audit visit to the plant. Modern electronic process control systems can now provide fully integrated HACCP control with corrective actions highlighted at operator interfaces for all CCPs; with the added benefits of reduced paper with improved audit facility.

In the audit visit itself, there are a number of ways of assessing the effectiveness of the implementation of a HACCP plan. These include:

- the use of scoring systems, based on the audit schedule, to provide a more systematic assessment for feedback of overall performance and particular areas for improvement
- questioning department managers', line supervisors' and operatives' understanding about which CCPs they have responsibility for, how frequently they

are monitored and why, and how they deal with any deviations from the permitted values
- sample inspection of monitoring records for selected CCPs to check that measurements are being carried out in the manner set out, and any deviations acted upon.

Speaking to production line staff is particularly important in assessing how effectively a HACCP plan has been implemented and is 'owned' by the relevant staff in the organisation.

Section 4.5 considers a number of common weaknesses in HACCP planning and implementation. These reflect some of the areas of improvement that experienced HACCP exponents have identified in their work with suppliers on the development of effective HACCP systems.

4.4 Gauging the success of HACCP systems: customer complaint data analysis

Supermarkets are in a unique position to analyse how well their suppliers' HACCP systems work. This is because, as the consumer's first port of call, supermarkets are in the front line to capture customer complaint data and analyse it statistically using computer software.

Two systems of customer complaint analysis have been developed by the leading supermarkets:

1. *Trend analysis*, where quality defects are correlated with point of production and used to target quality improvement initiatives or to delete those suppliers who were unresponsive.
2. *Cluster analysis*, where serious customer complaints alleging food poisoning or product contamination are collated as 'clusters' which are analysed for statistically significant correlations. Where the intrinsic risks of the clustered product and the customer complaint symptoms combine in a manner that is capable of professional interpretation as possible food poisoning, an immediate product withdrawal would be actioned and a HACCP-based on-site investigation initiated.

Trend analysis of customer complaint data has long been established in principle, even if in practice the application of statistical techniques had not been uniformly adopted by all supermarkets. Trend analysis allows the identification of the principal sources of product quality problems, and more importantly of the specific causes responsible for the majority of such complaints. In this as in many areas, the 80/20 rule is found to apply, i.e. 80% of problems arise from 20% of the supplier base. Where significant quality problems persist, suppliers may be de-listed by the retailer in question.

Cluster analysis is a more sophisticated concept whereby serious, alleged food poisoning complaints are rapidly screened over a specific time period to establish whether an unexpected number of such complaints in that time period, or cluster, has occurred. This can be established in advance of any trend in such complaints, allowing for pre-emptive action. It relies upon a professional understanding of the normally arising incidence of complaints, an appreciation of the inherent hazards in any product category and information from customer reports of symptoms of the alleged food poisoning.

Today, all the leading supermarkets have adopted a HACCP-based approach to food safety management where trend and cluster data are key inputs for prioritising the investigative and corrective actions of a more focused team of food technologists either in-house or third-party consultants. Supermarkets have become highly adept at managing crises associated with the common causes of breakdowns in HACCP or other food safety control systems.

4.5 Common weaknesses in HACCP systems

Experience of monitoring and auditing HACCP systems suggests that there are three main areas of weakness:

1. The design of the HACCP plan.
2. Failure to maintain the HACCP system.
3. Very occasionally, management neglect of safety as a priority.

Some examples of these sorts of weakness are discussed below.

4.5.1 Design weaknesses: infant food

In the mid-1990s, the CDSC (Communicable Disease Surveillance Centre), a government agency set up by the Department of Health (DoH) to monitor human disease in the UK population, noted an increase (i.e. a cluster) in the number of an isolate of *Salmonella* food poisoning in very young children. A total of 16 cases of this *Salmonella* isolate had been reported for the first six months of a particular year compared with 12 and 7 cases for the whole of the two previous years. An investigation was begun on the basis that the statistical significance of the data was beginning to indicate a serious incident.

By the end of the investigation, the persistence of CDSC and the DoH at the early stage of this incident, when the statistical evidence was weakest, would be totally vindicated. At the start of the incident, however, two cases dated to two or more months previously, and of the 14 remaining, only ten had been subject to case interview. Of these ten, only six were reported as having consumed Brand X infant food, while five were reported as having consumed Brand Y. While these data appeared slim evidence of causal association, the CDSC statisticians also knew that of their 40 planned control interviews (that is interviews of similar families in the affected areas who had not reported with *Salmonella* food poisoning), the first 16 had not consumed Brand X infant food.

Such statistics, which can be typical of this type of food poisoning incident at the early stages, were daunting to all but the CDSC statisticians. Within the week that the investigation had begun, the DoH decided to contact Brand X to present the data and the emerging suspicions of a causal link. Brand X, sensibly, decided to withdraw all the product from sale immediately on the precautionary principle. Following technical debate well into the late evening, the decision to have a public recall was made that same evening and announced on the following day, and an immediate factory investigation was instigated.

A significant proportion of withdrawn product samples were subsequently found to be *Salmonella* positive, though all at a contamination level significantly below the previously accepted infective dose. The CCP was that the product was designed and marketed as an infant food, which implied a target consumer group with a greater susceptibility to *Salmonella* infection, and therefore a 'lower than average' infective dose. The possibility of an elevated susceptibility of infants to lower than average *Salmonella* contamination levels had not been adequately considered in the product formulation or process specification, because it had not been adequately considered in the initial HACCP study of the product, or identified as a CCP.

4.5.2 Design weaknesses: smoked salmon

Traditionally, smoked salmon was effectively preserved for ambient storage with over 15% total salt (on water content) together with heavy smoking involving up to 30% dehydration weight loss. Such a product was shelf stable at ambient temperature, and suitable for postal distribution. Such heavily salted, smoked and dried traditional products have long ceased to be organoleptically acceptable to today's consumer. Smoked salmon today is only very slightly salted and dried (3.5% salt in water), and effectively only flavoured with the smoking process. As a result, smoked salmon today relies upon a controlled distribution through the refrigerated chill chain for its microbiological stability and safety, within a given shelf-life.

When traditional preservation techniques were phased out, it became clear, from a number of customer complaints and queries to many retailers, that some customers were still sending smoked salmon through the post to friends and relatives. It was evident that some consumers were not aware of the significance of changes in processing and their implications for product handling and storage. Most retailers responded by briefing staff at their stores to warn against this practice, and asking manufacturers to include clear advice in food labelling about the unsuitability of mail delivery for this product, and the need for proper chill chain maintenance.

In hindsight, it was clear that revising HACCP plans to incorporate new processing and preservation techniques had failed to take into account food safety implications further down the supply chain and, in particular, the need to educate consumers to abandon traditional practices such as sending the product through the post. Modern smoked salmon bears little resemblance to the traditional product.

4.5.3 Failure to maintain the HACCP system: ropey milk

The term 'ropey' as applied to milk, beer and bread has come down in the history of the food industry. The term 'ropey' is often used without an awareness of the original food derivation. The 'rope', 'strings' or 'slime' refer to bacterial slime produced by bacilli, that is gelatinous and slimy or sticky in appearance. The problem has been known about for many decades, and has long been solved and relegated to the food science history books. Using cluster analysis an incident was discovered in the early 1990s with some pasteurised milk products where customers were complaining about 'slimy' milk, quickly confirmed as 'ropey' milk.

The first reaction of the management in question when confronted with the cluster analysis data was that, as 'the dairy industry hadn't had a ropey milk problem for 20 years', there must have been some error in identifying the nature of the incident. Three weeks later, and following continuing reports of similar customer complaints of slimy milk, they discovered a grossly contaminated rinse water tank that had been added as a secondary increase in cleaning capacity. The added tank had been configured in such a way that while increasing the total volume of final rinse water available, it also inadvertently created a stagnant volume of water. This stagnant volume of water gradually became contaminated with bacilli, and acted as a contamination source for all the final rinse water used in the dairy.

This incident occurred as a result of a management failure to review the original plant HACCP plan in the aftermath of significant plant changes, i.e. the rinse water tank capacity increase. HACCP plans should always be revised after significant plant changes and additions.

4.5.4 Management neglect: *Salmonella* food poisoning with snack salami

Despite the requirement for 'Best before' date marking, salami is actually a 'Best after' product, but no such labelling designation exists. The reason is that salami is not, as often incorrectly described, a raw meat product. It is a product made from raw meat, but the raw meat protein is denatured by the chemical action of curing salts and bacterial acid production. During this curing process bacterial action and bacterial acid production combine with the curing salts, over time, to produce a safe and delicious food.

The curing process involved in the production of salami requires careful attention to temperature, rate of acidity production and maturation time and conditions. Safe salami product, free from pathogens such as *Salmonella*, can be guaranteed by diligent professional attention to the conditions of production. A traditional product like salami can, however, sometimes be produced where the original understanding of the basic craft and science has been lost, and methods of production are continued 'as they have always been' for generations. The product is still safe as long as the process remains unchanged, even if the original craft and scientific understanding has been lost.

However, in the 1980s, when a new management team decided to produce a snack salami of finger thick dimensions, they changed the process with the fateful result of a major *Salmonella* poisoning incident. The process for normal (approx. 3 inch diameter) salami production was faithfully reproduced, but the critical point was missed that the surface area to mass ratio was critically different. The new snack salami dried much quicker. This meant that the water activity fell faster, crucial microbial activity was suppressed sooner and acidity development was incomplete. Under these new conditions, *Salmonella* was protected from the hostile effects of the curing salts and normal acid production from bacterial fermentation. *Salmonella* tended to survive under these conditions. To make matters worse, any snack product is passed through the stomach more quickly than a normal full meal. In the intestines, where less acidic conditions apply, *Salmonella* can survive more easily to infect the host consumer. This incident demonstrated neglect due to lack of understanding of the basic food science. The hazards arising from the change in process conditions should have been identified by a thoroughly revised HACCP plan.

4.5.5 Management neglect: *Salmonella* contamination of dried baby milk

Ultimately all food safety failures can philosophically be attributed to management failure, but there are some food safety failures that can be attributed to management's failure to learn the lessons of food safety history. The importance of highlighting this problem is not to engage in witch-hunting, but to elevate the importance of continuous training and professionalism in the management cadre.

During the early 1980s a UK brand of dried baby milk suddenly suffered a *Salmonella* contamination problem. The CDSC was capable of statistically associating an outbreak of *Salmonella* food poisoning among babies with a particular Brand Z of baby milk powder. Interestingly, at the start there were no actual contaminated product samples as evidence of product contamination. Looking for actual product contamination presented the proverbial 'needle in a haystack' dilemma. All the evidence was statistical association of disease with product consumption patterns. A curious point was that the *Salmonella* outbreak was all caused by a single strain of *Salmonella* rather than a cocktail of *Salmonellae* strains that normal contamination patterns would create.

In the event it was discovered that a hairline crack in the stainless steel lining of the spray drier had allowed a single cell of *Salmonella* to leak into the rockwool insulation lining of the spray drier. There it had enjoyed a degree of protection from the heat of processing and the chemical sanitisers during cleaning, and with the abundant nutrients of the milk product, had multiplied rapidly. During cyclical processing and cleaning, the *Salmonellae* had migrated to and fro across the stainless steel lining of the spray drier, intermittently contaminating the dried milk product. *Salmonella* is more resistant to heat under dry conditions, and some survived to contaminate the dried milk and subsequently infect some children.

The actual incidence of contamination was very low, hence the difficulty of finding actual contaminated product and the practical impossibility of controlling this problem by product sampling alone, but the epidemiological evidence of *Salmonella* poisoning in the baby population was indisputable. All this was relatively easily determined after the event by judicious professional investigation, using HACCP as an investigative tool, but the question remained as to why the circumstances had not been predicted before the event. The simple answer was that the HACCP studies on the process before the incident had been inadequate. If the whole sequence of events in the incident had never occurred before, the HACCP study would have been limited by previous experience and the failure to predict the problem could have been reasonably accepted. This was not the case, however. The precise sequence of events had occurred in Australia some four years previously. The management in question had failed to keep themselves up to date with events in their industry and apply the lessons from similar incidents.

4.6 The future development of HACCP

Retailers have identified a number of ways in which HACCP design and implementation can fail. These include:

- quite commonly, a failure in the design of the HACCP plan, e.g. in identifying risk levels for particular customer groups; or ineffective hazard analysis because of a failure to keep up to date with current research and best practice
- quite commonly, a failure to audit the HACCP plan satisfactorily and particularly the impact of process changes on the hazards originally identified in the plan
- rarely, a failure of managers to understand the basic food science, processes and hazards sufficiently to undertake a proper hazard analysis, which can only be dealt with by a recognition of the need for training with the appropriate commitment and resources to acquire the requisite knowledge and skills
- very rarely, a failure to identify customer safety as the primary management responsibility, which can only be resolved by appropriate training and changes in management culture.

Given the increasing prominence of food safety issues, these last two failures are now rare, although they have by no means been eliminated as competitive pressures in the food industry intensify. Indeed, they may remain significant problems as global sourcing brings new suppliers into the food chain who may be less familiar with food safety issues and HACCP systems. For those more familiar with HACCP systems, the kind of design and verification problems outlined earlier are likely to continue to be applied as the pace of product innovation intensifies and new hazards emerge. Allied to these problems will be the need to keep established HACCP systems ‘fresh’, for example in keeping staff motivated. A programme of ongoing staff training will be important here.

The following discussion looks at a number of possible improvements to HACCP design and implementation, from ways of improving current HACCP systems to how the scope of HACCP itself can be extended.

4.6.1 Improving HACCP analysis: improved process flow diagram construction

Constructing an accurate process flow diagram is the critical starting point in a HACCP analysis. In any process, one of the most likely points that a food safety hazard will occur is where an unplanned process delay or interruption happens. Such a process delay point is often the location where build-up of microbiological contamination can occur.

A process flow diagram system, which aids the identification of any likely delay points, is significantly more efficient as a management tool for identifying hazard points in the process. The original process flow diagram method of the American Society of Mechanical Engineers (ASME) still has much to recommend it in this respect. As can be seen from Fig. 4.2, the ASME method allows a detailed analysis of a particular process against seven key criteria which help identify potential problem areas such as process delay points.

4.6.2 Extending the scope of HACCP: criminal malicious product contamination

HACCP systems have sometimes been seen as having a primarily microbiological focus, confined to particular products and processes. However, HACCP principles can be more broadly applied to other aspects of food safety, for example malicious product contamination. Incidents of deliberate malicious product contamination are now, regrettably, to be regarded as an established criminal practice and food industry hazard. All food manufacturers must acknowledge this and therefore plan appropriate countermeasures. 'Appropriate countermeasures' simply means elevating the protection of product integrity to the same status as all other food safety control measures that comprise normal good manufacturing practice (GMP).

HACCP principles can be employed and specifically focused on this issue. The experience of managing a technical investigation into a criminal malicious product contamination incident that has occurred within the food chain can be employed to develop measures to prevent a contamination problem in the first place.

Every food processing plant is a unique facility that will inevitably have its own unique security problems. But every processing plant can be reviewed logically using HACCP principles, and sensible measures can be implemented to improve security without creating the fortress conditions that would interfere with the proper functioning of the plant. Every criminal who contemplates

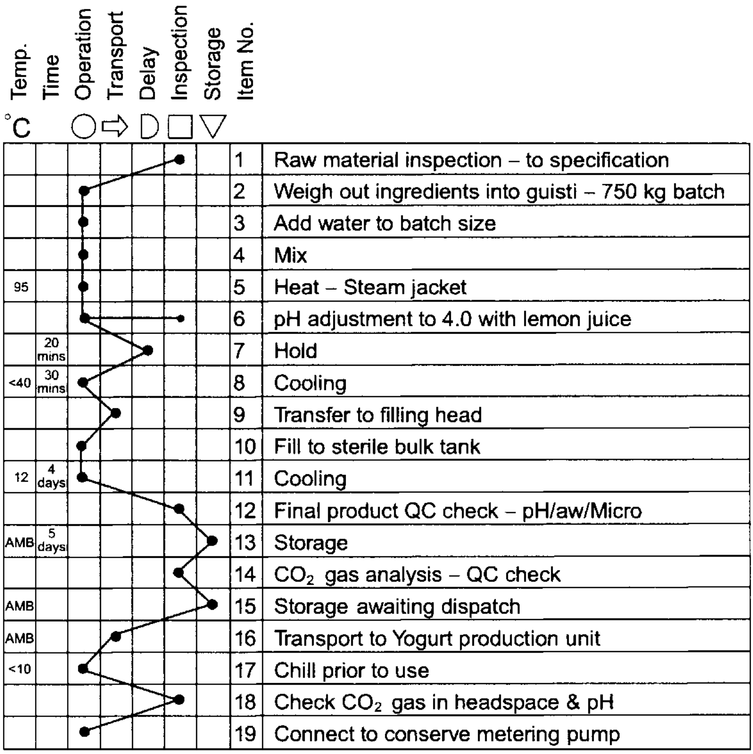

Fig. 4.2 Example of ASME process flow chart (hazelnut yogurt conserve).

deliberate malicious product contamination must have the motive, the means and the opportunity to carry out a crime. HACCP principles can be employed to assist food processors to frustrate potential criminal product contaminators by identifying those with potential motives, restricting the means available and reducing the opportunities to perpetrate their crimes.

Major retailers now issue guidelines to suppliers for dealing with this problem covering such issues as the following:

- staff training in awareness of the problem, identifying potential motives for malicious contamination (e.g. as a result of certain disciplinary actions)
- using a HACCP approach to identify critical points where the product is unavoidably exposed to potential malicious contamination
- security measures (e.g. the use of closed circuit television (CCTV) systems to monitor high risk areas, control of personnel access to high risk areas, colour coding of staff clothing to identify bona fide workers easily in high risk areas, sensors and other instrumentation designed to detect evidence of contamination, tamper-evident packaging)
- crisis management procedures and robust product traceability.

This approach mirrors that used by retailers to deal with malicious contamination in their stores.

4.6.3 Improving the evaluation of HACCP systems: post-launch monitoring of new food products

When new food products are launched, the degree of pre-launch evaluation is limited to panel testing that rarely amounts to more than a few thousand people. More usually only a few hundred people are involved. These numbers bear little statistical significance to the tens of millions of customers that each of the major supermarkets service each week. The customer complaints monitoring that major supermarkets use is also capable of monitoring customer reactions to new products. In the future such existing systems of complaint monitoring could include specific post-launch monitoring of new foods, looking more closely for any emerging food safety problems, for example nutritional issues among more vulnerable sections of the population such as young children or elderly consumers. In fact post-launch monitoring will come to be recognised as an essential element of 'due diligence'. Genetically modified foods could also be monitored by such statistically-based systems. Data from these exercises could be shared with manufacturers of the products concerned, and any general implications for food safety made public so that it can inform future HACCP analysis. In this way HACCP systems can be more effectively evaluated and improved for the future.

4.6.4 Integrated HACCP control systems

The application of HACCP to basic food processing operations calls for the application of specified control procedures at all CCPs, ingredients tracking systems, monitoring and reporting of key factory conditions, cleaning procedures, batch tracking systems and final product traceability. The ease with which these basic requirements can be integrated by modern electronic process control technology has been under appreciated by food manufacturing management, who still currently rely on paper-based control systems.

Of the seven principles of HACCP, four directly address 'process control' aspects. Specifically, these cover:

1. defining the CCPs
2. setting control limits for each CCP
3. monitoring to ensure each CCP is under control
4. taking corrective action when a CCP is out of control.

By definition, a CCP is therefore crying out for the application of automation technology. Where CCPs are controlled automatically, using the full armoury of electronics technologies such as sensing, vision systems, motion control, temperature/process control, operator interfaces, networking, information management and knowledge management, then the production line will benefit from consistent operation, continuous (fatigueless) monitoring, and the guarantee that these points, procedures or operational steps will be maintained in control within specified limits. And this means safer food production systems, records of non-conformances and corrective actions, full traceability, networked management business process information, vastly reduced paperwork, active operator interfaces for input and instructions, with the final bonus of integrated knowledge management systems based on multi factorial statistical process analysis and diagnostics. The future of HACCP implementation will be in integrated active process control systems using the components of electronic automated process control such as PLCs, touch screen operator interfaces, sensors of many descriptions, PID controllers, distributed controller networks, fieldbus networks, vision systems and RF tagging.

4.7 Conclusions

HACCP is essentially a structured way of thinking about the management of food safety. Its effectiveness depends on the ability of food producers to make the most of the analytical framework it provides and, in particular, the knowledge and skills of HACCP teams in such key areas as hazard analysis and CCP identification. Businesses often fear that the main problem with a HACCP system is the administrative burden they think it will impose. In fact the greater challenge it presents is in analysing the way food products are manufactured and the resulting hazards in a systematic way which some businesses have never previously employed.

In reality, because the quality of HACCP teams varies, the quality of HACCP planning is variable and, in some cases, poor. Retailers auditing supplier HACCP systems also continue to discover within some businesses a lack of understanding of HACCP principles among HACCP teams. The effectiveness of implementation also varies with, in some cases, a lack of 'ownership' of the HACCP system by operational staff. Alongside some of the weaknesses identified earlier, common problems include:

- failing to deal with prerequisite systems first as a foundation for HACCP analysis
- over-complex and unmanageable HACCP plans that confuse hazards and quality issues and identify too many control points as 'critical'
- lack of understanding among CCP monitors of their role, purpose and importance, resulting in poor monitoring and record keeping, and failure to take corrective action.

These problems impose a particular responsibility on the quality of auditing in identifying weaknesses, developing understanding and encouraging initial HACCP systems to continue to improve until they reach a satisfactory standard. Government and industry bodies also have a role to play in spreading understanding of HACCP principles and offering support and advice in such areas as the training of HACCP leaders and HACCP teams and information on hazards. It will also be important to strengthen the perceived commercial benefits of implementing HACCP systems. One development here is the emergence of new business insurance products which recognise and reward HACCP implementation. Technology will also play a part: improvements in automated process control, for example, will help to make CCP monitoring easier, and developments in real-time, on-line analysis of key hazards will help to validate and improve the design and operation of HACCP systems. Cumulatively, these forces can make the potential of HACCP systems to manage food safety effectively throughout the food industry into a reality that will benefit consumer and industry alike.

This page intentionally left blank

Part II

Larger manufacturers and HACCP systems

This page intentionally left blank

5

HACCP implementation in the United States

T.R. McAloon, Cargill Inc., Minneapolis

5.1 Introduction

All parts of the food chain share equal responsibility for manufacturing safe food. In this chapter, discussions will be centered on experiences learned from implementing hazard analysis critical control points (HACCP) into the primary conversion segment of the food industry. Although many businesses of varying size and complexity are discussed, the challenges and success of each are quite similar.

Cargill Inc., Minneapolis, Minnesota, is the seventh largest food processor in the world, consisting of 275 food producing plants, operating in over 50 countries, with over 80,000 employees. One might think that HACCP implementation would be relatively easy for such a large company with 'unlimited resources'. On the contrary; because of Cargill's decentralized management structure, it was more like implementing food safety in multiple companies, operating in multiple countries all at the same time. Company size does not dictate ease of HACCP implementation and, in some cases, smaller companies may find this process to be an easier task.

The primary conversion process typically starts with a raw/crude agricultural commodity and transformation begins into an edible food ingredient or food product. In general, suppliers to this segment of industry are farmers who provide starting raw materials such as food animals, poultry, fish, grains, fruits and vegetables. The primary conversion industry can be further split into perishable and non-perishable food categories. Perishable foods are those that support microbial growth and therefore require some form of temperature control to minimize or prevent growth of disease-causing bacteria and spoilage organisms.

Perishable Cargill food businesses include beef, pork, chicken, turkey, and egg processing. It is not surprising that the primary hazards of concern for these businesses are biological in nature. Pathogens such as *Salmonella*, *Campylobacter*, *Listeria monocytogenes* and pathogenic *E. coli* are commonly present in live animals. Although elimination during primary processing is currently impossible, efforts to minimize growth and presence can be taken to reduce risks significantly in order for the next segment (secondary processing) of the food chain to be successful.

The second most important hazards facing perishable food businesses are physical hazards, originating inside the animal itself or generated during processing by equipment and employees. Pieces of bone are probably the most commonly occurring physical hazards since they are a natural component of birds and animals. Metal objects such as buckshot and vaccination needles can potentially be present in cattle, hogs, or turkeys. Wood is sometimes found inside the crops of poultry. Metal and hard plastic items from processing equipment or hand tools are also potential physical hazards that must be considered during hazard analysis.

Chemical hazards such as illegal pesticides or unsafe antibiotic residues could also be of concern in animals, but experience has proven these issues to be of very low risk. In addition, control of pesticide and antibiotic residues in food animals is best accomplished at the producer or farmer level. Other potential chemical hazards facing the perishable foods category of the primary conversion industry include hydraulic oil/lubricants from pumps and equipment, cleaner/sanitizer residues, and heat exchanger fluids such as ammonia and glycol. Most of the time, potential chemical hazards such as these are minimized through the use of plant good manufacturing practices (GMPs), making the need for managing this risk through critical control points (CCPs) unnecessary.

The other category of primary conversion includes those businesses that produce non-perishable foods. Cargill businesses within this category include oilseed processing, corn milling, flour milling, malt, salt, heat-treated juice concentrate, and peanut processing, to name a few. The most significant hazards of concern for these industries are physical hazards such as rocks, metal, wood, and plastic originating in the incoming grain or generated by equipment during processing. These hazards are typically controlled by CCPs such as filters, screens, magnets, and metal detectors during processing.

The second most significant hazards associated for non-perishable products are chemical in nature. Many grains carry the potential of various mycotoxin hazards, depending on weather patterns, storage procedures, and geographical location. Of note is the potential for aflatoxin in corn and peanuts, and vomitoxin in wheat and barley. There is also the potential for pesticide residues in grains as a result of misuse during farming or overspray between fields. In the processing plant, chemical hazards include improper levels of food additives, heat transfer fluids, and chemical residues from processing aids. Allergenic compounds have also become a significant issue over the last 20 years. Biological hazards, in general, are not of concern since pathogens will not grow

Table 5.1 Summary of each business and the principal hazards of concern

Business	Principal hazards
Meats/poultry/eggs	Pathogens, metal, bone
Oilseeds	Pesticides, *Salmonella*
Corn wet milling	Mycotoxins, pesticides
Flour milling	Pesticides, metal, insects
Salt	Metal
Juice	Patulin, pesticides, *E. coli* O157:H7
Peanuts	Pesticides, aflatoxin, metal
Malt	Vomitoxin, metal, *Salmonella* (food malt)

in non-perishable foods, their incidence is generally limited, and control measures are hard to identify unless some form of heat treatment is used in the process. Table 5.1 gives a summary of each business and the principal hazards of concern.

The goal of Cargill's food safety system is to implement HACCP on top of a solid GMP program. The model used for HACCP was the system recommended by the US National Advisory Committee on Microbiological Criteria for Foods (NACMCF). There are seven HACCP principles in the NACMCF model:

Principle 1: Conduct a hazard analysis
Principle 2: Determine the critical control points
Principle 3: Establish critical limits
Principle 4: Establish monitoring procedures
Principle 5: Establish corrective actions
Principle 6: Establish verification procedures
Principle 7: Establish record keeping and documentation procedures.

In addition to these traditional HACCP development steps, the concept of CCP validation was also included into the Cargill system. Validation procedures were established as part of each CCP to prove that the CCP was capable of controlling the intended hazard and continued to control the hazard on an ongoing basis. Validation was, in essence, used to justify scientifically the existence of each CCP.

5.2 Setting up the HACCP system

HACCP design impacts greatly on the future success or failure of the program. However, before designing HACCP systems, companies must ensure that responsibility for HACCP rests on the shoulders of those who are primarily responsible for the business. In other words, food safety must be integrated into the company's culture if any hope of setting up and managing an effective HACCP system is to be realized. The best way to drive changes in company culture is to give overall accountability to a senior company person.

5.2.1 In the beginning

Cargill's success is built on a reputation for providing high quality products at fair market value and company businesses have always had quality control systems in place. In the late 1980s, however, times were changing. Foodborne illness outbreaks were increasing in magnitude and publicity. *E. coli* O157:H7 had just recently arrived on the scene as a significant foodborne pathogen. *Listeria monocytogenes* was on the rise world-wide, having caused recent outbreaks in Europe and the USA. Cargill was also changing its vision for the future to become a more value-added company and realized that a more formalized approach to food safety was needed. In 1990 senior managers at Cargill appointed Dr Austen Cargill to establish a corporate food safety department for the company. Cargill senior managers had the foresight to know that a high level of commitment was needed to make food safety work properly, similar to the personal safety systems that had been established 20 years earlier.

The Corporate Food Safety Department mission was to set policies and provide guidance to each business. This strategy translated into a small core group of technically trained individuals and one lawyer to provide support for interpreting food laws. The responsibility for food safety implementation rested on the business leaders' shoulders. This organizational structure and philosophy set the stage for food safety implementation in Cargill.

The first department task was training for the central Corporate Food Safety staff. In 1990, formal food safety programs were fairly new to most of the food industry. Although there were a few seminars and articles on food safety, most of the help came from consultants familiar with HACCP. One consultant, Dr Howard Bauman, affectionately referred to as the 'father of HACCP', had just retired from Pillsbury and was willing to provide guidance, especially in the area of hazard analysis. Another couple of key consultants were Dr Bill Brown and Dr Dave Theno, both of whom taught HACCP courses and helped review plans for about six months until the Corporate Food Safety staff were sufficiently trained. The main point here is that the best way for a company to get started is to enlist help from a knowledgeable person or organization. During this training period, the mission and goals of the department were more clearly defined into policies for all businesses in the company. Training for senior managers was also conducted in order for all high level managers to understand basic food safety concepts and what it takes to make HACCP successful.

5.2.2 The corporate implementation plan

The overall model used to implement HACCP into the company is shown in Fig. 5.1. Equal emphasis was placed on both prerequisite programs such as GMPs and HACCP. Cargill realized that food safety systems were valuable for all foods, not just perishable ones. However, implementation into all businesses at the same time was impossible. Based on past experiences and potential human health risks, businesses were prioritized for HACCP implementation as shown in Table 5.2.

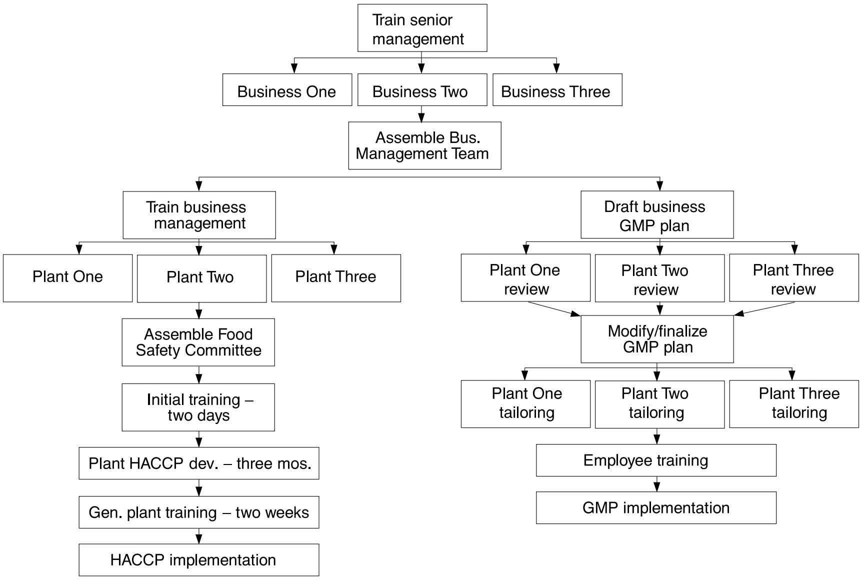

Fig. 5.1 HAACP implementation model.

5.2.3 The business implementation plan

Businesses chosen to implement HACCP were tasked with the responsibility of organizing these efforts with help from Corporate Food Safety. It is important for business leaders to believe in HACCP and drive implementation in their processing plants. The business first established a business team, which included the business operations manager, quality assurance (QA), sales, transportation, engineering managers and a Corporate Food Safety person to provide guidance. A cross-functional team covering all aspects of the business is critical because food safety responsibilities fall on each of these departments. One central person was chosen to lead the business team. This person was required to have good

Table 5.2 Business priority for HACCP implementation

Business	Time frame (year for implementation)
1. Meats/poultry/egg businesses	1
2. Soy protein business	1
3. Malt business	2
4. Flour milling	2
5. Corn milling	2
6. Juice	2
7. Peanuts	2
8. Oilseeds	2
9. Salt	3

technical knowledge and people skills. Most of the time, the key lead was the business QA manager, but sometimes it was the operations manager.

The business needed to accomplish two goals: implementing HACCP and standardizing GMPs. Two options were identified for accomplishing HACCP implementation. The first option was to bring key members from all plants in the business together to train and develop HACCP programs that could then be taken back to all plants at once. The benefit to using this approach is that implementation can be done quickly and efficient cross-communication between managers allows for more standardized programs between plants. The disadvantage, however, is that HACCP plans can become too generic, and without input from other members of the plant team, buy-in becomes difficult.

The second option was to assemble key members at each plant and introduce HACCP to one plant at a time. This approach allows the HACCP plan to be tailored to the needs of each plant and achieves greater buy-in from plant employees. The only disadvantage is that the process is slower and cross-communication between locations is harder to achieve, resulting in diverse plans between plants that are producing the exact same product. In the end, most Cargill businesses chose the second option as the means for HACCP implementation which, in retrospect, was the right choice.

The second business goal was to develop standardized GMPs. Although most plants within a business had similar GMP requirements, they were not the same between plants and quite often not formally managed. It was decided that basic prerequisite GMP programs needed to be standard for all plants in each business in order to lay a solid platform for HACCP. While HACCPs were being written at the plant level, GMP/prerequisite program requirements were being standardized at the business team level. The draft GMP program was sent out to all plants for review and comment and then finalized over roughly a six-month time frame. Standardized GMPs included personal hygiene, sanitation, pest control, water control, air control, recall, labeling, maintenance, rework procedures, purchasing and transportation. To raise the importance of GMPs as a foundation for HACCP, a more formalized process of managing GMPs was also implemented, using a HACCP management framework. The process for development of both HACCP and GMP systems is shown in Fig. 5.1. For simplicity's sake, only the HACCP portion of the model will be discussed in more detail.

5.2.4 The individual primary conversion facility implementation plan

After Corporate Food Safety and the business determined the strategies for implementing HACCP, real efforts began to make HACCP come alive in the plant. Figure 5.2 shows the basic steps that were followed. The first step involved formation of a plant Food Safety Committee, a cross-functional team quite similar to the business team. This team normally consisted of the plant manager and someone from engineering, transportation, QA, a plant microbiologist (if available), the business food safety coordinator and a

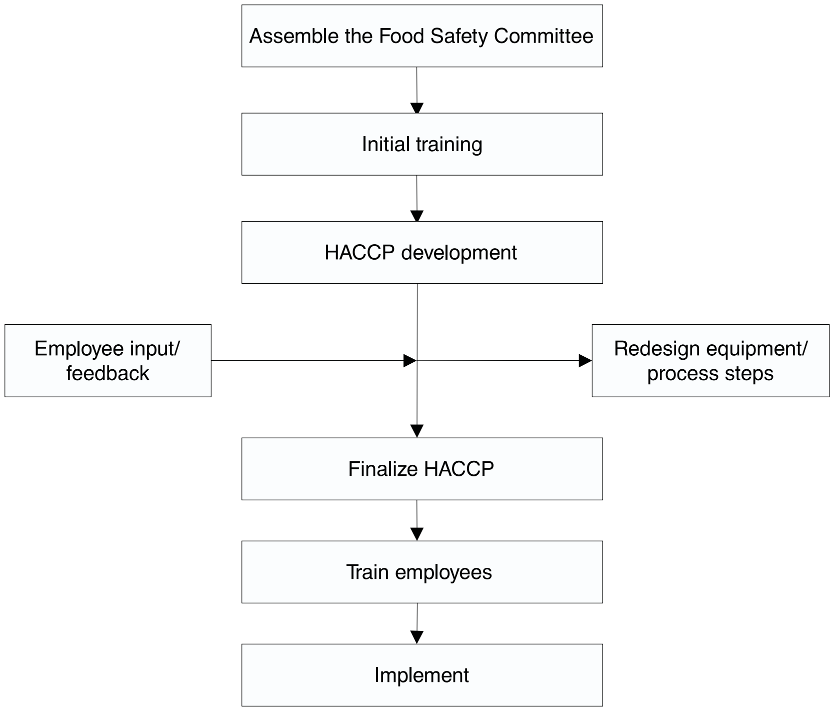

Fig. 5.2 Processing plant HACCP development model.

representative from the Corporate Food Safety Department. A plant food safety coordinator was chosen to lead local HACCP implementation efforts. Usually this person was the plant QA manager. It is important to note that the plant food safety coordinator was not responsible for doing all the work. Instead, this person organized meetings and followed up to ensure that all work was being done. The plant Food Safety Committee then participated in a two-day on-site HACCP training course led by Corporate Food Safety, with help from the business food safety coordinator. Being able to conduct in-house training is a big advantage for a large company because courses can be tailored to a specific need and many employees can be trained at one time. This is much more effective than sending one or two people to an outside course. During this two-day event, all products made using a common process were grouped together, for example, all ground beef products. Most processing locations ended up with one to five processes. The plant Food Safety Committee then chose one process group and started writing the first HACCP plan.

The hazard analysis phase usually took the most time to complete, but it was important that all potential hazards were considered. Open discussion must be encouraged during hazard analysis and, in the end, all potential hazards should fall into one of four areas:

1. Controlled or minimized by CCPs.
2. Controlled or minimized by GMPs.
3. Considered to be of such a low risk that no control is needed.
4. Designed out of the process.

This last option is not always considered but can be the best way to eliminate hazards. As an example, during a hazard analysis for chicken slaughter, one team member pointed out that when bins were dumped into a vat, water from the wheels of the bin could drip down the side of the bin and get into the food, increasing the risk for pathogen presence. The best solution was to modify the bins to prevent water from dripping into the product. The potential hazard was engineered out of the process and therefore no formal control was needed.

Quite often, potential hazards were minimized by the presence of several GMPs and therefore no CCP was needed. This is an important point because although GMPs cannot substitute for a CCP, collectively they can minimize the potential for hazards to occur, thus eliminating the need for a CCP. Sanitation is a good example for *Listeria* control. It is well known that *Listeria monocytogenes* is commonly found in meat and poultry processing plants and that sanitation programs are the best means to control it. Generally, there is not one sanitation step by itself that is critical for *Listeria* control. All sanitation steps on all equipment and environmental sources are equally important. The collective pieces of a sanitation GMP minimize the potential for *Listeria* to occur, so a CCP after a kill step is rarely needed.

Generally, the plant Food Safety Committee completed the first HACCP plan over a three-month time frame. The plant manager and plant food safety coordinator then conducted a general food safety session for all employees to explain the HACCP plan and why it was important to the employees and the company. In addition, specific training was given to employees with CCP responsibilities. Training was generally conducted over two weeks. After training was completed, the HACCP plan for a particular production process was implemented and the group started on the next one in order of priority.

5.2.5 Resource management

Many companies wonder about the cost of implementing HACCP systems. Quite frankly, the cost is based on how well the business has been run prior to HACCP. A previously well-run business will meet 80–90% of all HACCP needs. In this situation, the majority of costs are related to training, document modification, and capital improvements to the facility. Very seldom are additional people required unless the business is large or complex.

In 1990, when the Cargill Corporate Food Safety Department was established, the director of food safety was equivalent to a business president. Two corporate food safety coordinators guided businesses through the process and one administrative support person was added to tie everything together. In 1991, the budget for the fledgling department of this $45 billion company was less than $500,000 per year. At the business and plant level, no full-time people were added. Instead, responsibilities for implementation were added to existing positions. HACCP was seen as a normal part of doing business. Money was allocated on an as-needed basis to correct facility and equipment problems that were identified during hazard analysis, HACCP, or GMP implementation. Over the last ten years Cargill has spent millions of dollars in redesigning/upgrading facilities. No formal process has been established to track spending, because quite often expenditures to improve a process result in production benefits as well as food safety benefits.

5.3 Implementation challenges and solutions

Probably the most important benefits from implementing a HACCP system into a business are the lessons learned from the challenges encountered during implementation. If your business is in the middle of implementing a HACCP system or believes that a HACCP system is already implemented, these challenges may still be out there waiting to be corrected.

5.3.1 Challenge 1 – getting commitment at all levels in the organization

Although senior managers in Cargill were committed to food safety, not all businesses made food safety a priority. Food safety implementation was not automatically added to the overall business plan, so some people only focused on it when they had time. This caused conflicts and slowed down progress. Eventually food safety was added to each business plan and managers were given formal food safety objectives. In other words, food safety objectives became factors for promotion and pay raises, which greatly helped to maintain focus and demonstrated the company's commitment to food safety.

In very large plants, with greater than 1,000 employees and high employee turnover, no full-time person was added to maintain focus on HACCP implementation. The process still worked, but implementation times doubled and day-to-day management was difficult. Eventually, a full-time food safety coordinator position was created to lead food safety in these large plants, which greatly improved overall performance.

5.3.2 Challenge 2 – estimating time required to implement HACCP and GMPs

Each business saw the value of both implementing HACCP and standardizing GMPs. Unfortunately, it was difficult to estimate the amount of time required to implement fully either system. In some cases, processing plant locations thought that GMP programs were standardized and implemented and began to implement HACCP only to realize that they were not ready. In other cases, locations simply tried to implement both GMPs and HACCP at the same time.

Actually, standardizing and implementing HACCP prerequisite systems like GMPs is more difficult than HACCP since GMPs cover the whole facility environment, not just specific points in the process. The time required to implement GMP systems completely can be a year or more. The main lesson here is to focus on the basics first. Do not try to do too much, too fast.

5.3.3 Challenge 3 – employee involvement

Initially, the first HACCPs were written entirely by the plant Food Safety Committee with little or no input from hourly employees. Because hourly employees were not actively involved from the start, they did not always buy into the plan as it was written and quite often they had a better or easier method for monitoring CCPs than that written in the plan. Eventually plant committees learned that writing and implementing HACCP programs worked best when HACCP teams were created at the department level with active input from all employees, especially line operators who became the people responsible for monitoring CCPs. The lesson here is for everyone to remember that 'managers do not make safe food, line workers make safe food'. Line workers must be involved during HACCP development, especially in the area of process flow chart reviews and writing procedures for monitoring CCPs.

5.3.4 Challenge 4 – communication

Active communication within a business or plant takes a great deal of effort, and the same is true for HACCP implementation. In large plants (>1,000 employees), it was a constant struggle to keep everyone informed and to capture good ideas and spread them across the plant. Communication between plants was also, at times, difficult. Sometimes different locations within the business were working on the same problems or recreating the same solutions. Although the business food safety team helped to spread ideas across locations, no formalized process was in place.

Eventually, more formalized communication systems were started. At the plant level, the Food Safety Committee met weekly to keep everyone on the same page. Plant newsletters and other awareness campaigns were also started. At the business level, plant food safety coordinators established weekly conference calls to discuss progress and exchange ideas. At the corporate level, a success story newsletter was established to communicate problems, solutions, and other successes across all businesses world-wide.

5.3.5 Challenge 5 – training

Training is the link between writing a good HACCP and successful implementation. Without active training systems, HACCP will fail. The greatest difficulty was experienced by locations with the highest number of employees with the highest turnover rate. Imagine trying to train 2,000 employees, who speak four different languages, on the basics of food safety while dealing with a 20% turnover rate. Many locations learned that initial training was, in fact, easier than training employees on an ongoing basis.

To deal with the training challenge, all locations incorporated food safety in their newly hired employee orientation training. For ongoing training, many locations created awareness tools such as setting up display cases in hallways containing food safety information or objects found in food. Informational training brochures for safe food handling at home were created. In large plants, food safety topics were added as part of monthly training meetings, conducted by department supervisors with their employees. At the corporate level, Cargill developed and conducted a monthly seminar to train managers within the company. This seminar was eventually complemented by a self-paced CD-ROM directed to production supervisors.

Businesses learned an important lesson while coping with the challenges of training. First, do not just tell employees what to do, tell them why they should do it. Describe why food safety is important to employees and their families. Make it personal! In other words, cover what is in it for them personally; do not just tell them it is part of their job. Most employees do care about the company they work for, but they care most about how food safety affects them personally. Second, describe why their particular job is important and how their efforts will make a difference. Make sure that each person understands that what they do makes a difference. If these training challenges can be conquered, employee buy-in will be strong.

5.3.6 Challenge 6 – corrective action

Conducting a hazard analysis and identifying CCPs can be difficult, but the hardest part of HACCP is writing corrective action procedures that are meaningful, easy to understand, and complete. It is very difficult to write a procedure that applies to all situations. A standard was established that required corrective actions to cover three questions:

1. What will you do with the product?
2. What will you do to bring the process back in control?
3. What will you do to prevent a reccurrence?

Getting line operators involved to ensure that corrective actions were understandable was also a key factor for overcoming this challenge.

5.3.7 Challenge 7 – production ownership

In the beginning, some locations still saw HACCP as another tool for Quality Assurance to use to ensure quality and wanted to make the QA Department responsible for monitoring CCPs. This, of course, is against the premise of a good HACCP system. Cargill's standard is that CCPs are to be monitored by production people producing the food and that QA staff, along with production managers, fill the verification role. The QA Department does not produce safe food, line workers do. Once production understood and believed this concept, the true effectiveness for HACCP to control hazards was realized.

5.3.8 Challenge 8 – documentation

One area of HACCP that usually puts a company to the task is documentation. Even a well-run company usually finds that documentation needs generally exceed what is normally done. The challenge of documentation is a question of how it should be integrated with other documentation being generated during production. Should separate HACCP forms be created or should HACCP information be added to existing forms? Most locations chose to add HACCP documentation to existing forms to reduce the amount of extra paperwork. This option also takes advantage of existing document handling systems, which turned out to be a good choice. However, many existing documents were not structured properly for HACCP needs. Document structure was not uniform and sometimes pieces of HACCP information, such as time of entry or signature lines, were left out. Document use was also not uniform. People often forgot to sign documents, and corrective action reports were incomplete. Auditing helped to correct these issues, along with policies regarding document structure and use.

5.4 Surprises in HACCP implementation

Various surprises were encountered by business units during the implementation phase of HACCP. A pleasant surprise for well-run businesses is that 80% of the pieces needed for HACCP are already in place. HACCP is not a 'new program' to be overlaid on top of everything else. HACCP seeks to identify the few steps in a process that are already in place and elevate them to a higher state of importance. There may be a thousand steps in the process, and although every one is important, only a handful are critical for food safety.

Some business units also realized that GMPs and other prerequisite systems were missing or not well controlled. Prior to HACCP, most GMP requirements were either self-imposed or mandated by government laws. Generally, no formal management system was in place for all GMPs and sometimes requirements were lacking. This forced some Cargill business units into a GMP standardization process.

Cargill businesses knew that HACCP would provide the benefits of ensuring safer food. However, all businesses were pleasantly surprised by other numerous benefits, such as improved process control, lower costs, and reduced rework. In the beginning, businesses just did not realize how valuable HACCP would be.

One of the biggest surprises was that at some locations, line workers became committed to making HACCP work before their supervisors. As was stated earlier, HACCP was not automatically added as part of the business plan or as part of job performance reviews, so initially some supervisors did not view it as a priority over production. Change can be very difficult and it is human nature to resist change, especially when it affects you personally or goes against a personal paradigm. The same was true during HACCP development. Frequently people who were closest to or most knowledgeable about a process were least likely to realize that it needed to be changed or managed differently to reduce risk. An important lesson is that employees should not be afraid to challenge constantly the way things have been done in the past and to keep an open mind for a better way to accomplish any task. Sharing success stories and reinforcement from senior managers is an effective means to foster change.

5.5 Operating the HACCP system

In the overall scheme, HACCP is just one important part of the food safety puzzle. Implementing and managing HACCP is the core of the food safety system. Once this core is in place, businesses need to expand outward to encompass all aspects of food safety. Figure 5.3 shows a management model for food safety. The core of this model, which includes HACCP and GMPs, is

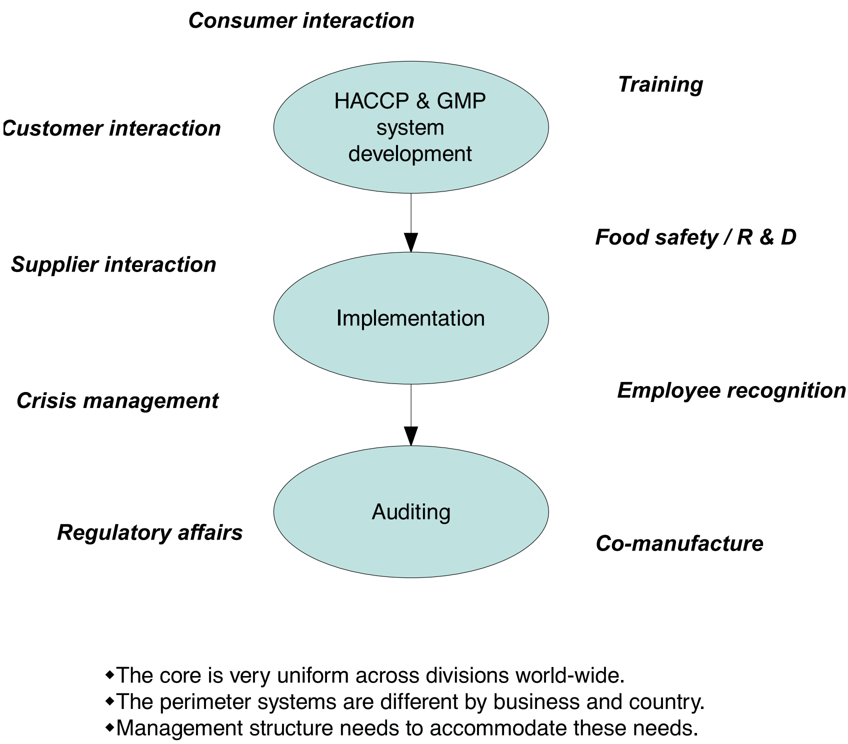

Fig. 5.3 Food safety management model.

standard across all Cargill businesses world-wide. The perimeter systems such as training, co-manufacturers, crisis management, etc., are also required. However, these vary to meet applicable country laws, cultural differences, and other business needs.

5.5.1 Corporate support for HACCP implementation

After HACCP implementation, corporate-level efforts were focused on providing standard tools for all locations in order to make HACCP management easier for the business. It was obvious that all locations needed training materials, so a library of training information was created at the corporate level for use by individual businesses and locations.

The Corporate Food Safety Department kept abreast with new technology, regulation changes, and surveillance for emerging hazards through the routine use of periodical subscriptions, active participation in trade groups, the use of consultants, and attendance at various food safety seminars. This is an effort that continues today.

5.5.2 Auditing the HACCP system

An audit was also needed to gauge success of HACCP implementation. Businesses found that although many outside organizations and customers conducted food safety audits, none of them provided the kind of in-depth soul-searching detail that was needed. Outside organizations lacked the depth of knowledge of the business needed for a complete audit. The old adage applies that the most staunch critic of a business is usually the business itself. A central audit for the company was established rather than requiring each location to create their own. This audit procedure was easy to conduct, detailed but fast, and provided useful feedback for HACCP improvement. The audit focused on HACCP implementation in production areas with questioning directed toward employees with CCP responsibilities and the documents they were using. Although some filed paperwork was reviewed, 90% of the HACCP documents audited were being used in production at the time of the audit. Past experience has shown that it is easy to make paperwork look good. It is much more difficult to ensure that employees are 'living' HACCP during production unless they are thoroughly trained. The Corporate Food Safety Department did not want a filing cabinet audit; they wanted a true effectiveness audit.

On this premise, Cargill created an internal audit, which became the focal point to determine the effectiveness of HACCP implementation. The general goal of the audit was to walk into a production area, ask anyone about food safety and get an educated answer. Simple, but not an easy task. Cargill wanted employees with CCP responsibilities to understand why food safety is important, demonstrate what the CCP/critical limits are, what hazards are being controlled, and what corrective action must be performed when limits are not met. For management employees, the audit focused on systems such as routine HACCP committee meetings, corrective action reporting systems, and training efforts to ensure that HACCP was alive and well.

The Cargill food safety audit format made it very difficult to get a good score unless HACCP was really in place. First-round auditing for most locations yielded scores of 40–70%, which surprised many locations who thought they were doing quite well. After six months of additional fine tuning and increased training, scores climbed to 80–90%. Feedback from auditing not only improved HACCP execution, but also employee training programs.

One important point should be made about auditing. If done correctly, auditing is of great value because it shows where improvements must be made. Audits should never be used as a hammer or as a means to penalize. If this type of adversarial system is established, then more effort to get a good score will be made rather than looking for areas to improve. The result is a high audit score, but a poorly executed HACCP plan. Initially, companies should require audits to be conducted and show improvement, but should not set minimum score standards or penalize locations based on audit scores.

5.6 HACCP management challenges and solutions

Like HACCP implementation, managing a HACCP system does pose some challenges. Companies managing HACCP systems should ensure that these challenges are addressed.

5.6.1 Challenge 1 – employee motivation

Employees are excited during the initial stages of writing and implementing a new system such as HACCP. They understand the importance of food safety and are eager to make improvements. However, after a period of time, like most toys, the novelty begins to wear off. There may be habitual or company stress factors causing employees to drift back into the old way of doing things. In short, things tend to return to normal. To combat this in Cargill, recognition systems were established throughout the company to provide positive reinforcement for individuals, teams, locations, and businesses. Recognition systems do not have to be elaborate, and in fact should be kept simple. Many locations give out free meals, company shirts or simply call a meeting and congratulate the person or team in front of their peers. After locations started recognizing people for their efforts (even if it was considered part of their job), the whole food safety movement in the plant became contagious.

5.6.2 Challenge 2 – ongoing training for veteran employees

Training can be a challenge for any part of a business. Ongoing training for existing employees proved to be more difficult than for new employees. It was fairly easy to integrate HACCP training into new employee orientation, but locations were not as easily able to deal with ongoing training needs for veteran employees. For new employee training, the same message and materials can be used over and over. This does not work for veteran employees who needed additional information or sometimes the same message delivered in varying fashions. To overcome this challenge, businesses developed 15–20-minute monthly training sessions, covering a variety of food safety topics. Some locations developed food safety games to make learning fun.

5.6.3 Challenge 3 – identifying HACCP weaknesses: design flaws versus execution flaws

There are two types of flaws that can occur in a HACCP system. The first flaw is simply one of execution. For example, failing to take corrective action is an execution failure of the HACCP plan. It is a signal that employees do not know what to do and must be addressed with improved training. Conversely, always taking corrective action related to the same cause is a sign of a HACCP design problem. HACCP is a system of prevention and part of corrective action involves taking steps to prevent the hazard from reccurring. This is not to say that all hazards encountered at a CCP will eventually be eliminated. If the same hazard, with the same basic cause, continues to be repeated, then the CCP should be re-evaluated to determine whether the CCP was written properly or is in the right location. To identify these two flaws, locations established a deviation reporting system where compliance with CCP activities was tracked and reasons for corrective action failures were reported.

5.6.4 Challenge 4 – turnover, illness, and vacation

HACCP works well when everyone is trained, but it quickly falls apart if plans to handle turnover, illness, and vacation are not addressed. After a year of HACCP implementation, the majority of poor audit score areas were attributed to turnover of production supervisors with CCP responsibilities. The turnover of hourly employees was actually the easiest to deal with because training requirements were in place for all new employees. The biggest challenge was in covering managers and supervisors who were unexpectedly ill or who went on vacation. HACCP requires a disciplined approach for execution in the plant and tasks are as important as any other production task, including all HACCP paperwork. Some locations created checklists for supervisors that included production, personal safety, and food safety tasks. If a supervisor was gone, then the checklist was passed to the replacement. If the task was record review, then backups were established in case the primary person was absent.

5.6.5 Challenge 5 – new plant start-ups/acquisitions and co-manufacture

Once the food safety ball is rolling and everyone has moved to a new plane of understanding, it is difficult to go back to the beginning of the process and start over. However, this is exactly what must be done with a new plant start-up. Acquisitions are also a challenge because the business and employees will most likely have a slightly different perspective and quite possibly have different CCPs, even though they produce the same product as the acquiring company.

The best advice is not to automatically change things. Spend time understanding their specific process. Learn from their experiences, which will make HACCP better in all locations. Dr William H. Sperber, senior corporate microbiologist at Cargill, with 30 years of HACCP experience, once said that CCPs are traditionally identified using past experience more than anything else. The experience of co-manufacturers and acquired businesses must be utilized so that an optimum approach to hazard control can be achieved.

5.6.6 Challenge 6 – working with government-mandated programs

The success and acceptability of HACCP is truly amazing. HACCP is widely recognized around the world and is now being incorporated into the food laws of many other countries. This challenges global businesses to be open to differing HACCP formats. Incorporating HACCP principles into the legal framework of industrial countries also requires a thorough understanding of HACCP principles and implementation by the relevant governmental agency. Businesses must be prepared to work with and train governmental agencies, which will result in mutual understanding and trust.

5.7 The benefits of a HACCP system

The benefits of HACCP are many, but not always easy to measure. The obvious ones are staying in business, meeting new government regulations, meeting customers' requirements, reduced rework, reduced food safety incidents, and increased shelf-life. Less obvious ones are increased production volumes, increased yields, lower production costs, and competitive advantages. Some of these may be difficult to believe or understand. One may ask how all these benefits can be enjoyed simply by implementing a HACCP system. The simplest explanation is that HACCP is a process control tool that combines science with common sense. This results in an overall better understanding of the process which not only ensures food safety, but also more efficient food production. Here are just a few simple examples of HACCP benefits experienced by Cargill.

In the turkey business, the team focused on understanding the cooling process in detail in order to determine the best means for monitoring a cooling CCP. The unintended result of this new-found process control knowledge not only established the CCP, but also helped to reduce purge by 1% in the finished product, for a yield savings of $150,000 per year.

In the oilseeds business, the team, deep into hazard analysis, determined that a final filter CCP was the wrong size and was placed in the wrong location. The correct final filter was obtained, moved to a better location, and designated as a

CCP. The result was a decrease in rejections for a savings of $60,000 per year. Not only did HACCP save the business money, but it also improved customer relations.

In the flour business, a customer called to complain that a chunk of glass had been found in a load of flour. Upon review of the HACCP records, the business was convinced that the glass could not have originated from their factory. They went to the customer's location and inspected a newly constructed flour bin. After disassembling a valve, they found a Coke bottle, minus the piece found by the customer. Their confidence in their own HACCP not only saved a claim, but also saved the customer from having to recall products made from the flour.

Other businesses have reported success stories related to increased employee awareness as a result of HACCP training. It is amazing how many potential hazards have been caught by employees on the line who, prior to HACCP, may not have noticed the issue or done anything about it. Employees have found everything from metal pieces, improper labeling, improper temperatures, and missing equipment parts. One thing is certain: the sooner a problem is found, the less expensive it is to correct. In this area alone, hundreds of thousands of dollars have been saved by well-trained and alert employees.

5.8 The future evolution of HACCP systems

Keeping HACCP from becoming an isolated program is not difficult to do providing that the business incorporates food safety into the business plan or overall strategy for the company. All functional areas, including operations, engineering, technical services, purchasing, logistics, research, and sales must be involved, have objectives, and be held accountable for accomplishing their assigned tasks. HACCP must be viewed as a total business effort.

If one looks into the crystal ball of the future, HACCP will not only play a role, but will evolve. In the short term, HACCP will continue to be adopted by food companies as well as governmental agencies in food producing countries. It is also expected that the concept of validation will be added and become a more formalized part of HACCP to strengthen the system. HACCP concepts may spread into other aspects of food production. HACCP is a science-based common-sense approach for process control. The methods used for food safety control can be applied to personal safety and general production systems.

In the long term, HACCP provides an opportunity to eliminate the few cases where food safety standards are based on opinion, politics, and emotion and will bring all countries of the world closer to the goal of uniform food safety standards.

5.9 Conclusion

Companies that have implemented HACCP have good hindsight, and those companies that have started down this road can benefit from this experience. However, if the process was to start over, the following should be addressed:

- A formalized process is needed to incorporate food safety into the business's overall strategy. Businesses must plan for food safety with the same intensity that plans are made to control product yields and cost. Food safety must be part of the business's strategic plan to include written goals for all levels of employees in the organization. This will raise HACCP importance immediately and rightfully install it as one of the tools used to measure the success of the company.
- Make sure that a solid foundation of GMPs and prerequisite programs are in place and working prior to implementing HACCP. Otherwise, the business will end up fixing too many things at one time or the process will end up half completed.
- Establish frequent means of communication throughout the organization so that everyone understands progress being made towards the end goal of HACCP implementation. This will not only keep people informed but will also keep efforts in front of people who are busy with other tasks.
- Make production responsible for implementing and managing HACCP systems and get line operators who will be primarily responsible for monitoring CCPs involved early. Managers and QA technicians do not make safe food. Line workers make safe food. Involve line operators in writing CCP task procedures and corrective actions so that they are complete, yet practical and understandable.
- Understand that some people will initially resist change no matter how good the idea. Be patient and help them acclimatize at a pace that is comfortable and allows them to accept change. Encourage change but do not force it.
- Develop initial and ongoing food safety training plans for all levels of employees. The best solution is to create a corporate training department to help establish the curriculum and teach food safety using a common message. If this is not possible, then use information that has been developed by outside organizations. Be sure that training materials are available in all languages commonly spoken in the production facility. Do not underestimate the importance of training.
- Soon after implementation, begin auditing HACCP, prerequisite programs, and general food safety management systems. Auditing will identify weaknesses early so that they can be addressed before bad habits develop.
- Recognize individuals and teams who are making progress or exhibiting desired behavior, even if it is expected. Positive reinforcement encourages good behavioral changes and demonstrates to employees that management is committed. People like to be recognized for doing a good job. Others will change when they realize it is important. However, do not make recognition systems too glamorous or difficult, otherwise expectations will be too high and the process will be too cumbersome. Keep it frequent and simple, yet meaningful.

HACCP is a tool that combines science with a common-sense approach. HACCP requires total commitment throughout the company, starting with the chief executive officer down to all employees. This is probably the most difficult of all HACCP challenges to overcome. It is relatively easy to write a HACCP program and implement it in a food manufacturing plant, but it is not easy to change the culture of a company or to mandate commitment. If this challenge can be eliminated, the success of your HACCP program is guaranteed.

6

HACCP implementation

The Indian experience

B. Marthi, Hindustan Lever Limited, Mumbai

6.1 Introduction

In recent years, the hazard analysis critical control point (HACCP) system has become the accepted safety benchmark for food systems. The HACCP system is a management technique that allows a company to examine systematically all the processing steps involved in manufacture and use of a product, and then identify and manage those processes/operations that are critical to the safety of the product. HACCP systems have become mandatory for a wide range of foods in many countries and are now required for any exports out of India. In this chapter, issues related to HACCP development, implementation and acceptance in India are discussed. Given the disorganised nature of most of India's food industry, establishing effective systems for assuring food safety is an uphill task. There are also serious challenges in developing and sustaining work in areas such as disease surveillance and food safety research that may hamper the effective implementation of HACCP in India.

6.2 The food industry in India

India is the world's second largest producer of foods, and it has been estimated that food production will double from current levels by the year 2005. A quick survey of India's food production reveals the magnitude and the potential of the industry:

- India is the largest producer of fruits and the second largest producer of vegetables in the world.

- Indian dairy production is 70 million metric tonnes (MT), the second largest in the world.
- India produces and exports all the main varieties of spices. Spice production is worth over Rs 35 billion (approx. $800 million) and accounts for 25–30% of world production.
- India grows 22 MT of oilseeds annually, covering most of the varieties.
- Important plantation products from India include tea, coffee, cocoa and cashew.
- India has a large marine products and processing potential with varied fish resources along the 7,500 km long coastline, 28,000 km of rivers and millions of hectares of reservoirs and lakes.
- India's livestock population is the largest in the world with 50% of the world's buffaloes and 20% of cattle, but only a very small percentage (1%) is converted to value-added products.

The scale of overall Indian food production means that the processed food industry will become a very important part of the Indian economy. Consumption of value-added foods is estimated at approximately Rs 225,000 ($52 billion) per annum. The contribution of food processing and production to India's GDP is about 26%. The size of the semi-processed and ready-to-eat packaged food sector is Rs 40 billion (approx. $1 billion) plus per annum and growing at over 20% year on year. Increased urbanisation has also allowed the soft-drink market in India to grow rapidly, and is currently worth Rs 17–18 billion (approx. $500 million).

The overall size of the food industry is, however, not matched by its efficiency. Antiquated practices ensure that India's agricultural production is well below world averages. As an example, wheat and rice yields are 32% and 33% of world levels respectively. These practices are coupled with inefficient storage and distribution, which have led to tremendous wastage. It is estimated that about 40% of the total production of fruits and vegetables is wasted in the distribution chain. This wastage is due to the following:

- variable crop quality
- poor handling and storage on the farm
- an inadequate transport system
- too many intermediaries in the supply chain
- poor storage facilities.

6.3 Food safety in India

India has all the problems associated with a developing country, namely a large population, rapid urbanisation, widespread poverty and lack of access to basic sanitation and hygiene for much of its population. Foodborne illness statistics are not very easily obtainable or do not exist. Diarrhoeal diseases are very common throughout the country. On occasions when there are natural calamities and the existing infrastructure breaks down, there are severe epidemics of infectious diseases, for example cholera and gastroenteritis. However, the contribution of foods to the overall incidence of disease is not known. In studies that have been carried out at the Hindustan Lever Research Centre (HLRC), fresh vegetables were found to contain coliforms at levels ranging from 1×102 to 4×104 Colony Forming Units per gram (CFU/g) (unpublished data). Although comprehensive data are lacking, the situation with meat products is likely to be worse, given the following:

- the lack of good animal husbandry practices in breeding and rearing
- the poor resulting quality of the animals and poultry used for meat
- very poor hygiene in the slaughterhouses where meat is processed
- inadequate systems for storage, distribution and display of meat for sale.

There is also little control over the quality of drinking and process water. The HLRC has carried out studies that show that potable water across the country does not conform to WHO guidelines for safety and quality (unpublished data). When such water is used for food processing, the risk of microbiological contamination is increased significantly.

India, like other developing countries, does not have the necessary infrastructure to maintain the safety of perishable food products. Frequently transport and warehouse conditions are such that food products spend a very long time under undesirable conditions of high temperature, high humidity and poor hygiene. The cold chain in India is very poorly developed, and temperature abuse during storage and distribution can lead to serious safety defects in perishable refrigerated or frozen products such as ice cream.

As well as microbiological contamination, the food industry in India faces significant chemical hazards. Pesticides, for example, are widely and sometimes indiscriminately used with a resulting risk to health. The Indian Council of Medical Research (ICMR) and the Directorate General of Health Services (DGHS), in collaboration with the WHO and the Food and Agriculture Organisation (FAO), have conducted several surveillance studies in India on pesticide residues in fruits and vegetables, which have shown both the use of illegal pesticides and the excessive use of those that are permitted. These pesticides and their residues have also been shown to occur commonly in waters affected by agricultural discharges and make their way into potable water supply.

The food industry in India has to contend, therefore, with major problems in the supply chain. However, its difficulties are not just material. They are also cultural. In a country where overpopulation and lack of food dominate, food safety has not traditionally been a priority. While epidemiology and surveillance mechanisms are poor, the public perception of the risks of foodborne illness is also very low. Consumers do not believe that foodborne illness is a major issue in India, resulting in no strong consumer lobby for food safety. Thus it is difficult for the food industry to sell the concept of food safety and HACCP systems to consumers. This attitude has reduced the commercial rationale for improving food safety in relation to the costs of making such improvements.

In India the food processing industry has been a relatively small sector of the economy, and has only begun to grow in the last decade. In addition, until the liberalisation of the economy in the early 1990s, the Indian economy was largely inward-looking and little influenced by external competition. Until recently, there was little systematic quality management or even agreed standards of good manufacturing practice (GMP). The food processing industry's initial focus was on product and market development, reducing further the impetus to improve food safety systems. Hygiene and safety were part of a cycle where legislation was not very effective and there was very poor surveillance of foodborne disease, which led to an underestimation of risk, which in turn did not provide incentives for the food industry to implement better food safety systems.

Indian food laws are also part of the problem. There are more than 20 different pieces of legislation governing foods which are difficult to follow or regulate. Most of the legislation, for example the Prevention of Food Adulteration (PFA) Act, is very prescriptive and punitive. The PFA Act, for example, was developed in the 1950s when food adulteration was a very serious issue. In recent years, where the emphasis is on safety and quality, such legislation has lost most of its relevance and needs to be rewritten. A committee appointed by the government of India has indeed made the recommendation that a new Food Safety Act be created.

6.4 The development of HACCP systems in India

The slow take-up of HACCP principles in India only began to change with the liberalisation of the Indian economy in the early 1990s. This process had two effects, one of which was to expose Indian food manufacturers to significant foreign competition with far higher standards of product safety and quality. It also stimulated the growth of Indian food exports, and it is in this sector that HACCP implementation has subsequently made most progress, largely in response to the strict requirements on safety and quality enforced by major trading partners such as the USA and EU. As a result of early consignments being blocked as unsafe, the seafood export industry in particular has undergone fundamental changes in the way that it tackles hygiene and safety matters. HACCP systems are now mandatory for this industry. A similar situation prevails in the highly lucrative area of export of fresh fruits.

Given the importance of exports to India's economy, the government has recently proposed several new measures and incentives to ensure safe food processing. The Agricultural Produce Export Development Authority (APEDA), a government agency, provides training and guidance on a regular basis on HACCP implementation and related issues. The APEDA also provides fiscal incentives to manufacturers to implement HACCP in their plants. The majority of exporters are small manufacturers and such incentives are powerful motivators for change. The Bureau of Indian Standards (BIS), the principal institution setting product and process standards for manufacture of all types of products, has recently launched a HACCP certification scheme for food manufacturers. Other bodies introduced by the government to promote and enforce HACCP systems in the export sector include the Export Inspection Agency (EIA) which audits and certifies HACCP systems against international standards; the Central Institute for Fisheries Education (CIFE), specifically in the marine products sector, which provides training support; and the Marine Products Exports Development Agency (MPEDA), which provides advice to exporters on international standards.

There has been a major change internationally in attitudes toward food safety as a result of the deliberations at the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) talks. Due to the implementation of the World Trade Organisation (WTO) rules, food safety procedures are now to be governed by the WTO sanitary and phytosanitary (SPS) agreement. The Codex Alimentarius is now the internationally recognised body for implementing food safety systems. India, as a signatory to GATT, needs to ensure that both the domestic and export sectors of its food industry conform to HACCP principles. It is therefore a good sign that India is an active participant in the deliberations of the Codex Alimentarius Committee on Food Hygiene. India has emerged as the voice of the developing countries in these discussions.

6.5 HACCP implementation: the Unilever approach in India

Globalisation of food trade has allowed a number of important new international players to enter the Indian market. Among these are multinationals such as General Foods, McDonald's, Coca-Cola, Pepsi Cola and Unilever (through its Indian arm, Hindustan Lever Limited (HLL)). In addition, companies like Godrej and other Indian multinationals have significantly strengthened their portfolios in foods. A key point of differentiation between these companies will be the quality and safety of the foods they produce.

Among the various food manufacturers in India, HLL has emerged as the leader in developing and implementing food safety systems over the last eight to ten years. Unilever's food safety systems world-wide are based on the principle of 'safety by design'. This concept is based on prevention. Its key features (illustrated in Fig. 6.1) are as follows:

- product formulations are designed to be inherently safe
- processes are designed in such a way that they deliver safe products.

It is important that these two elements work closely together, since not even the safest product design will deliver a safe product if manufacturing processes are not safe. 'Safety by design' is essentially a farm-to-fork approach that allows Unilever to ensure safety throughout the manufacturing and distribution chain.

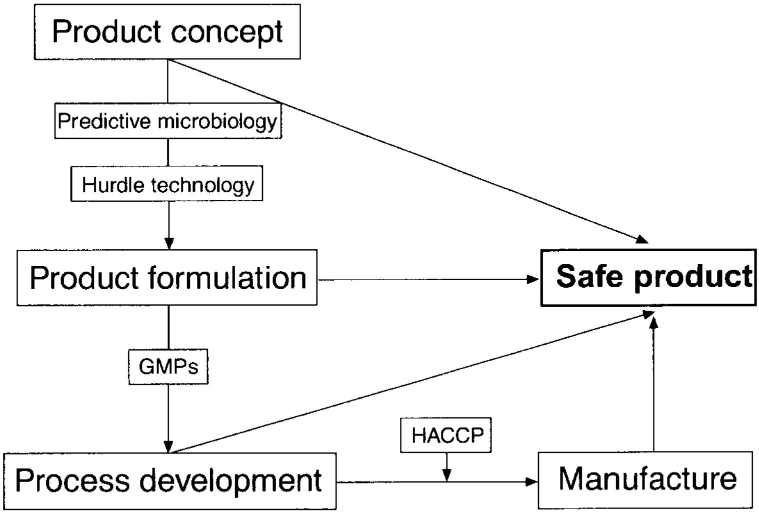

Fig. 6.1 The Unilever philosophy of food safety.

This concept relies on the existence of a variety of robust systems that ensure sustained delivery of safe products. These systems include the following:

- robust, safe product design tools and information (e.g. extensive microbiological research facilities providing skills in predictive microbiology and the understanding of interactions between micro-organisms and product components)
- GMPs and allied systems for cleaning and sanitation to ensure safe manufacture; also included are minimum standards for animal husbandry and agricultural practices, and systems for vendor and supplier approval
- continuous training for all personnel involved in food formulation design and manufacture to ensure that food safety is an ingrained habit
- robust HACCP systems for safe manufacture.

These are supported by the availability of uniform analytical methods across the company, establishment of formal quality assurance (QA) systems, and a structured, comprehensive system of auditing and review. Within HLL, the concept of 'safety by design' has been successfully established in food manufacture and is being extended to non-food products.

6.6 HACCP implementation in practice: the marine products model

HLL exports a variety of marine products to Japan, the USA and the EU. These products include frozen shrimp, cuttlefish, fish fillets, lobster and surimi (frozen fish paste). These products are generally reprocessed by the customer into final products for sale to the consumer. The marine products business has a current annual turnover of approximately Rs 700 million ($16 million) and employs 1,000 people at six manufacturing locations. In 1992, it was decided to implement HACCP systems in marine products manufacture, much ahead of proposed US FDA and EU regulations for seafood imports. As a result of this initiative, the HLL marine products business is now fully HACCP-compliant. HLL has the largest surimi manufacturing facility in India and this was the first such unit to have a fully implemented HACCP system.

6.6.1 Implementing HACCP: the main phases

The Microbiology Section at the HLRC was assigned the task of planning and implementing HACCP systems. HACCP implementation was planned in a series of phases. A preliminary evaluation was carried out to determine the state of readiness of each site. Based on this initial evaluation, the HACCP implementation process was divided into the following phases:

Phase 1: an initial awareness and training programme
Phase 2: a comprehensive HACCP training programme
Phase 3: preliminary audits of all processing units
Phase 4: training of analytical personnel
Phase 5: HACCP implementation itself
Phase 6: certification of HACCP systems.

Overall, the first five phases took 18 months to complete.

6.6.2 Phase 1: the initial awareness and training programme

While the marine products division had an existing QA-based system for manufacture, it relied largely for quality control on sampling and inspection of the final product. Although this fitted in with customer requirements, it was not effective in identifying and resolving safety problems during the production process itself. This reflected wider weaknesses in management. Knowledge of food safety issues and microbiological hazards was very limited in the organisation at that time. Phase 1 therefore involved an initial training and awareness programme for senior managers. The underlying theme of training was that food safety is both a technical and a management issue and, to be most effective, has to be tackled through an appropriate management system such as a HACCP system. It was also emphasised that commitment to food safety has to be top-down and should be demonstrated at all levels within the organisation.

In the first phase of training, business and technical heads participated, along with factory management. About 20 people were trained in this initial phase. Training was carried out by staff from HLRC as well as by experts from the CIFE. Subject areas covered included:

- principles of food safety and the concept of safety by design
- the philosophy of quality assurance
- management commitment to food safety
- GMPs and good hygienic practices (GHPs)
- food microbiology, particularly foodborne pathogens
- principles of sampling and analytical methodology.

The course was successful in winning the commitment of senior management to the HACCP programme and agreeing a schedule for the remaining phases. The main issue arising out of the training course was the need to upgrade prerequisite systems, especially at third-party owned co-packers.

6.6.3 Phase 2: the HACCP training programme

In phase 2 a comprehensive HACCP training programme was conducted for functional personnel. These personnel were selected to form the HACCP implementation teams for the respective factories. These teams included people from the production, supervisory, quality assurance, distribution and hygiene functions. All team members were selected on the basis of their expertise and included, as far as possible, people who were closely involved with day-to-day production operations. Due to the prevailing level of education of operators and workers, it was necessary to have only supervisory personnel in the core HACCP teams.

Staff from the Microbiology Section at HLRC carried out this training. The training module covered the following:

- HACCP principles and the benefits of HACCP systems
- detailed implementation procedures
- case studies illustrating HACCP implementation in practice.

The teams proved extremely enthusiastic about the benefits of HACCP and were charged with the responsibility of cascading down the message of HACCP to shop-floor personnel, and to develop the appropriate training modules for line operators and workers.

6.6.4 Phase 3: preliminary audits of all processing units

In phase 3, preliminary audits of all processing units were conducted to gauge their state of readiness for HACCP implementation. Each factory was audited against internal Unilever standards for safe manufacture and those set by the MPEDA, a government body, and the EIA, the government's export audit and certifying agency. Where appropriate, individual buyer requirements were also used in the auditing process, particularly for larger customers.

The result was to identify a wide variation in the quality of prerequisite systems. A programme of improvements was agreed to rectify these and establish, as far as possible, uniform standards and systems across all factories.

Key improvements in prerequisite systems included:

- improved control of staff access to the production line to prevent, for example, the risk of cross-contamination
- modifying the production line layout to ensure a logical raw material/product flow
- redesign of areas and procedures for receipt and handling of raw materials
- the creation of designated high hygiene areas and procedures
- modifying anterooms to cold stores to ensure reduced levels of environmental contamination
- establishment of microbiology testing facilities with trained analytical staff.

A programme of improvements was agreed together with a schedule for completion. At the same time preliminary HACCP planning began with the preparation of draft process flow diagrams. At this point there was no attempt to carry out hazard analysis and CCP determination, given the need to complete the programme of improvements to prerequisite systems. A major training need identified at this stage was the training of chemists in microbiological analysis, since most factories did not employ microbiologists.

6.6.5 Phase 4: training of analytical personnel

Training of staff in microbiological analytical techniques was scheduled very soon after the preliminary audits of prerequisite systems. The purpose of this programme was as follows:

- to train analytical personnel in microbiological and analytical techniques for the purposes of CCP monitoring as well as local certification needs
- to enable them to subsequently set up a fully fledged analytical facility in the factory.

Factory analysts from the quality assurance laboratories, who would eventually oversee the monitoring of CCPs and other analytical testing requirements, were the target of this training programme. This was a comprehensive, hands-on training programme lasting ten days and covered all areas of microbiological analysis. The training programme contained the following modules:

- principles of microbial nutrition and growth
- sampling plans
- hands-on microbiological analysis
- certification.

The effectiveness of the training programme was gauged through feedback from trainees and a formal examination at the end of the course. The effectiveness of factory microbiological analytical facilities has subsequently been monitored during routine audits carried out in the factories. The MPEDA also routinely audits analytical systems and certifies analysts.

6.6.6 Phase 5: HACCP implementation

HACCP implementation was begun once the improvements to prerequisite systems identified in phase 3 were completed. The first part of the HACCP implementation phase involved the following at each factory:

- finalising and validating process flow charts
- the identification of hazards and CCPs
- preparation of the final documentation for HACCP plans, particularly CCP monitoring and record-keeping documents
- verification of HACCP plans at each of the factory sites.

During this process the HLR microbiology team took on the role of central consultants and facilitators, providing advice and disseminating best practice from one factory to another. At all times, however, it was emphasised that ownership of HACCP systems rested solely with the factories.

Once this stage was completed, one factory was chosen for pilot implementation. The choice of the factory was dependent on factors such as size of operations, level of preparedness and immediacy of need. Process flow charts were finalised and validated, in part to check that modifications agreed in phase 3 had been carried out. The HLR microbiology team spent two to three days at the factory undertaking a comprehensive review of the HACCP plan. Particular attention was given to the quality of hazard analysis, given the previous inexperience of factory staff in this area. Data used to review hazard analysis included:

- microbiological data from the factory
- information from published literature, government and other agency surveys
- the opinions of microbiology and manufacturing experts within the industry.

At the end of this process, the factory HACCP team took over responsibility for implementation. It was agreed that pilot implementation be carried out for a period of six months to work out all the wrinkles in the system and ensure its smooth functioning. After three months and at the end of the six-month trial, the central HLR team reviewed the effectiveness of the HACCP plan. The main problems encountered were with proper documentation of CCP monitoring data. In order to ensure more effective documentation, generic CCP monitoring data sheets were created for use by shop-floor personnel.

Halfway through the pilot study, implementation at the other units was started. Cross-factory visits were very useful for 'live' hands-on experience as well as knowledge sharing. At the end of the six-month period, HACCP was fully and successfully implemented at the pilot site and well advanced at the other sites. Since the manufacturing processes as well as the product portfolio were very similar across all the factories, completion of HACCP implementation at other sites was able to proceed quite smoothly. Within 18 months of the initial training exercise in phase 1, HACCP implementation was completed at all marine products units.

6.6.7 Certification

With the completion of phase 5, HACCP plans were submitted for certification audits by the EIA. The EIA bases its requirements for safe manufacture on a combination of EU as well as US FDA requirements. The EIA is also the approved certifying agency for HACCP in India. All HACCP plans were found to be compliant in audits carried out by EIA auditors. Since during phases 3 to 5 care was taken to ensure that factory operations were in conformance with all statutory requirements, only minor modifications were required after the EIA audits, confirming the success of the HACCP programme.

6.7 Maintaining HACCP systems

Effective functioning of HACCP systems requires continuous review and training to ensure that they remain effective and relevant. Factories have a standard HACCP review programme at least every six months. In addition, several other events will trigger an immediate review:

- changes in raw material, product, process
- any organisational changes affecting staff operating the HACCP system
- infrastructural or equipment changes
- newly published information on hazards that may affect the product
- changes in statutory or Unilever requirements.

All planned reviews, routine or otherwise, are documented. The HLRC central team continues to function as a central scientific resource to advise, for example, on emerging hazards. It also carries out training of new personnel or retraining of existing personnel whenever required, and routine annual audits to ensure the effective working of HACCP.

6.8 The benefits of HACCP implementation

Successful HACCP implementation has had several benefits. HACCP implementation has allowed factories to achieve better product safety and quality, reduce costs, design better products and processes, increase quality awareness among suppliers and improve team spirit. Based on interviews and on data collected as part of HACCP implementation, the following is a list of key benefits:

- HACCP implementation has led to an overall increase in productivity and production efficiency (Figs 6.2 and 6.3). As an example, in a typical ice cream factory in HLL, productivity went up from 3.75 Mh/Liton before HACCP implementation to about 5.5 Mh/Liton after HACCP implementation. This increase in productivity was the result of fewer quality defects interrupting production as well as some of the improvements listed below.

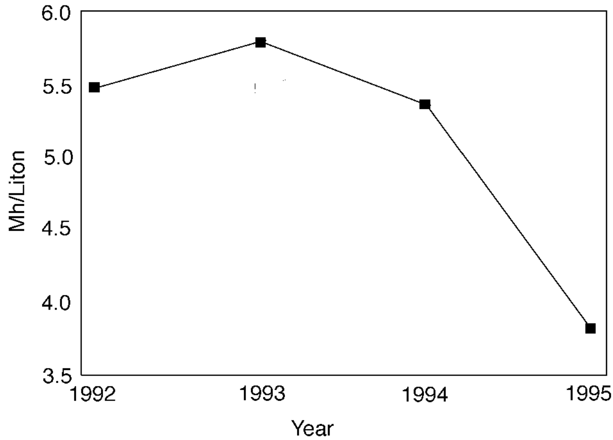

Fig. 6.2 HACCP benefits: increase in productivity in an ice cream plant.

- HACCP implementation has led to increased product safety. This is illustrated in Fig. 6.4, which shows the reduction in *Listeria* counts in ice creams after HACCP was introduced.
- HACCP implementation has reduced the frequencies of shut-down of process lines for cleaning and sanitation. Typically, shut-downs were needed once a day before HACCP, and were of the order of once a week after HACCP.
- HACCP implementation has allowed continuous manufacture for extended periods, without any stoppages due to process breakdown.
- The cost of poor quality product reduced by >10% within six months of HACCP implementation.

Because it involved a detailed and systematic analysis of production operations, and, in particular, a major overhaul of prerequisite systems, HACCP

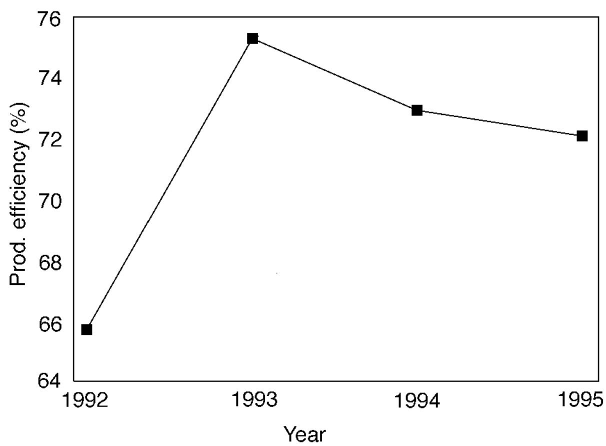

Fig. 6.3 HACCP benefits: increase in production efficiency.

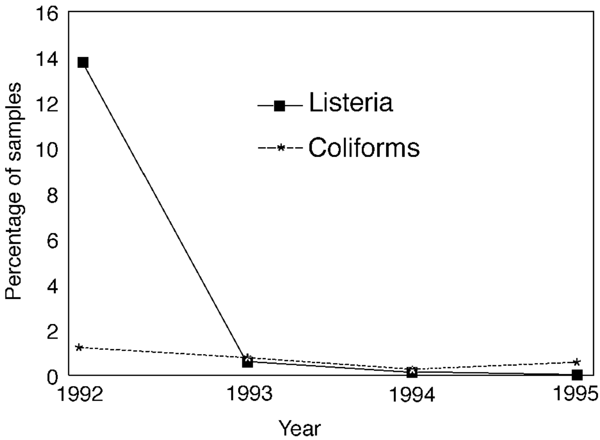

Fig. 6.4 HACCP benefits: product microbiology in an ice cream factory.

implementation has helped refocus manufacturing operations and led to several technical innovations in processing. More broadly, HACCP implementation has introduced a new culture of scientific/analytical thinking and problem solving in manufacture. Because it relies on the initiative of shop-floor staff in monitoring CCPs, HACCP implementation has also led to the empowerment of the workforce. HACCP has proved a self-sustaining system that encourages people to strive for continued improvement and innovation.

6.9 Difficulties in HACCP implementation

Some of the difficulties involved in HACCP implementation in the marine products sector as a whole include the following:

- Lack of information on hazards, especially pesticide and heavy metal residues and many areas of microbiological contamination.
- Poor control of raw material quality from suppliers. Landing and distribution of fish are unregulated activities. Raw material is obtained from vastly differing sources and there are significant qualitative differences. It has therefore proved very difficult to develop supplier HACCP systems.
- Lack of adequate expertise in and mechanisation of processes. The marine products industry has evolved as a largely manual operation due to a lack of technological development. This has led to reduced effectiveness in HACCP implementation, especially CCP monitoring.
- Lack of expertise in HACCP systems. This is especially true of regulatory authorities overseeing HACCP implementation. Thus, smaller companies have had difficulties in obtaining proper advice. HLL has been fortunate in drawing on internal expertise in food safety systems, both in India as well as through Unilever world-wide.

- Non-availability of flexible software support for HACCP documentation. Processing units in remote locations do not always have access to information technology, and software available for preparation of HACCP plans was limited. This has led to the creation of HACCP plans manually.

One of the key factors in ensuring successful HACCP implementation is an effective disease surveillance system. Information is constantly needed, for example, on outbreaks of disease, types and strains of pathogens involved and their behaviour, and types of foods that may be at risk. The USA has installed an 'early warning' system for tracking the occurrence of foodborne disease. This system, called the Foodborne Diseases Active Surveillance Network (Foodnet), tracks the incidence and sources of foodborne illness in the USA through active surveillance and other epidemiological studies, in collaboration with federal and state agencies.

Presently, most HACCP systems are designed using data on hazards available from developed countries such as the USA. However, the type of organisms relevant to them cannot necessarily be indicative of those present in the Indian context. This is particularly true given the low level of hygiene standards in India. Current national data cannot be relied on either as an accurate indicator of the prevalence of foodborne pathogens or their sources. As a result, one of the major weaknesses in the development of HACCP plans in India is hazard analysis. It is imperative that developing countries like India, which will develop an increasingly larger share of the global food market, create their own systems to track foodborne disease.

Such systems would also be greatly facilitated if data on microbial responses (growth, survival and death) from individual countries were collated in a more standardised form. Scientists everywhere are working to develop risk assessment models based on predictive microbiology, using data available through various experiments carried out in-house as well as from around the world. Indian science needs to be plugged into this network and actively collaborate.

6.10 The future of HACCP implementation in India

India requires dramatic changes in its existing food processing systems to improve food safety and reduce the incidence of foodborne illness associated with the consumption of processed and semi-processed products. Its food processing industry needs to adopt HACCP systems universally. Because food safety strategy is broadening to cover the entire farm-to-table continuum, HACCP implementation must also broaden to address all points along the farm-to-table chain. India not only needs to invest in food microbiology research to provide safe foods effectively; it is also important to prevent foodborne disease through minimum standards of hygiene across the supply chain, and through consumer and food handler education.

In the past, HACCP implementation in India has been held back by formidable infrastructural problems. The supply chain makes it difficult to establish even basic hygiene standards, and the food industry remains dominated by small-scale manufacturers with neither the resources nor the motivation to implement HACCP systems. Progress has also been held up by a cycle of poor knowledge of foodborne disease, resulting consumer indifference and inadequate legislation, and a consequent lack of incentive for manufacturers to invest in food safety. This cycle has only been broken in more lucrative export markets such as marine products and fresh fruit. Here a combination of external pressure from trading blocs such as the USA and the EU, and the growing value of the export trade, has encouraged both government and industry to work together and invest in HACCP systems. As a result, despite the formidable obstacles, both large businesses such as HLL and smaller manufacturers involved in the export trade have successfully implemented HACCP systems. However, the overall picture for the marine products industry as a whole remains patchy, and HACCP implementation in the rest of the food processing industry is still rare.

If HACCP implementation is to become more widespread, a key first step in India, as for other developing countries, is for the government to develop a national food safety strategy. As stated by the WHO, food safety has to be a shared responsibility between government, the consumer and industry. India will need to work toward such a national strategy to be able to compete globally. Indeed, a major force promoting HACCP in the long term may well be India's increasing involvement in international trade, exposing its consumers and its food industry to standards prevalent in the EU and the USA, for example.

The WHO provides guidelines for setting up and strengthening national food safety programmes. The four-step process is shown below:

Step 1: Assessment of food safety infrastructure and problems at national level: preparation of a country profile

Step 2: Preparation of a national food safety programme. This step includes actions such as:

- formulating a national food safety policy
- developing and/or updating food legislation
- strengthening food control systems
- promoting voluntary management systems for food safety assurance
- educating food handlers at all levels in food safety
- research and data collection

Step 3: Implementation of the national food safety programme

Step 4: Evaluation of food safety activities.

There are a number of steps that the Indian government can take in building a food safety programme and harnessing the support of consumers and the food industry. One is to work with industry in establishing common standards of GMP and GHP across the supply chain. These minimum standards then need to be reinforced by relevant legislation. Current food laws such as the PFA Act need drastic revision and the creation of a food safety law will be a step in the right direction. Such laws need to foster a food safety culture among both consumers and industry, while at the same time not stifling technical innovation or imposing heavy costs on industry.

Other areas of legislation that need to be reassessed include laws on reservation of certain food categories for small-scale producers. A typical example is ice cream, which was, until recently, a reserved category that only small-scale manufacturers were allowed to manufacture. These types of products require high levels of safety which depend on investment in building an effective cold chain. Such investment is often beyond the small-scale manufacturer. This situation changed in 1999 and ice creams have now been de-reserved, allowing for increased investment by larger manufacturers. The government also needs to reform some aspects of commercial contract legislation. Currently, many aspects of contracts with farmers and other primary producers are not legally enforceable. As a result, while many multinational companies (MNCs) provide valuable support for primary producers, returns in terms of improvements in quality cannot be relied on. This gap in legislation inhibits the spread of improved safety standards back down the supply chain.

At the same time, government also needs to provide support and incentives for industry to implement HACCP systems. The model provided by the APEDA, for example, which provides fiscal incentives to implement HACCP systems, shows that such an approach can be successful in developing HACCP implementation among smaller manufacturers. All this will only be possible through focused training and awareness of food safety issues. Key requirements here are trained and committed personnel at all levels, including government itself; sufficient consumer awareness to make the safety of food an important issue in the marketplace; and the appropriate research infrastructure to identify the key food safety issues. If this can be achieved, the current cycle, which inhibits progress in countries such as India, can slowly but surely be reversed.

6.11 Bibliography

BROWN, M.H.,'Food safety systems', in J.S. CROWTHER and B. MARTHI (eds), *The microbiological safety of processed foods*, New Delhi, 1998.

CII – MCKINSEY & COMPANY, INC., *Modernising the Indian Food Chain: Food & Agriculture Integrated Development Action*, New Delhi, 1995.

CODEX (CODEX ALIMENTARIUS COMMISSION), *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application*, Food Hygiene – Basic Texts, Joint FAO/WHO Foods Standards Programme, Rome, 1999.

FOODNET, CDC/USDA/FDA Foodborne Diseases Active Surveillance Network, *1997 Surveillance Results*, Atlanta, 1998.

KAFERSTEIN, F. and ABDUSSALAM, M., 'Food safety in the 21st century', *Bull. World Health Org.*, **4**, 1999, 47–51.

MEAD, P.S., SLUTSKER, L., DIETZ, V., MCCAIG, L.F., BRESEE, J.S., SHAPIRO, C., GRIFFIN, P.M. and TAUXE, R.V., 'Food-related illness and death in the United States', *Emerging Infect. Dis.*, **5** (5), 1999.

MINISTRY OF FOOD PROCESSING INDUSTRY, 'Report and Policy Statement', Government of India, New Delhi, 1999.

NACMCF (NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS), *Hazard Analysis and Critical Control Point Principles and Application Guidelines*, 1997.

REPETTO, R. and BALIGA, S.S., *Pesticides and the Immune System*, Washington, DC, World Resources Institute, 1996.

SINGH, K., UPADHYAY, K.D., SRIVASTAVA, A.S. and SINGH, S.V., *Pesticides*, **21** (1), 1987, 40–5.

TAUXE, R.V., 'Emerging foodborne infections: an evolving public health challenge', *Emerging Infect. Dis.*, **3** (4), 1997, 425–34.

WHO, *Guidelines for Strengthening a National Food Safety Programme*, WHO/FNU/FOS/96.2, Food Safety Unit, World Health Organisation, Rome, 1996.

WHO (WORLD HEALTH ORGANISATION), *World Health Report*, Rome, 1997.

6.12 Acknowledgements

The author wishes to thank Dr Nimish Shah and Dr Vibhav Sanzgiri, Research Scientists, Microbiology Section, Hindustan Lever Research Centre, Mumbai, India, for their technical inputs to and thoughtful discussions on the subject matter of this chapter.

7

Implementing HACCP systems in Europe

Kerry Ingredients

D. Rudge, Kerry Ingredients, Bristol

7.1 Introduction

Originally founded in 1974 as a dairy farmers cooperative in the south-west of Ireland, the Kerry Group is now a leader in global food ingredients markets, and a leading producer of consumer foods for selected European markets. Established as a public company in 1986 from head offices in Tralee, County Kerry, the Group has achieved sustained profitable growth and pursued a strategic global expansion programme. This has led to the establishment of manufacturing, technical and marketing facilities in Ireland, the UK, France, Italy, Germany, the Netherlands, Poland, Hungary, the USA, Canada, Mexico, Brazil, Australia, New Zealand and Malaysia. The Group currently has over 12,000 employees world-wide, and sales in 1998 were IR£1.73 billion with pre-tax profits of IR£93.9 million.[1]

The Kerry Group is split into three operating divisions: Ingredients, Foods and Agribusiness.

The Ingredients division contributes 63.5% of sales turnover with world-wide activities across a broad product range including savoury ingredients, coating systems, snack seasonings, bakery ingredients, fruit preparations and dairy ingredients. Products are sold either directly to industrial food manufacturers or through wholesale outlets and agents to caterers and smaller users. As a global supplier, Kerry Ingredients is ideally placed to support major multinational customers, while maintaining the flexibility to supply small-scale and more specialist customers locally.

The Foods division contributes 33.6% of sales turnover and is more focused on the European market. The product range includes recipe dishes, cured meats, savoury pastry products, sausages, prepared poultry, flour, baking mixes, spreads, dairy products, juices and mineral water. Products are either sold through major retail outlets, or distributed by a van sales fleet to caterers and smaller retailers. Kerry Foods occupies the number one branded position in the majority of its existing markets and is a major supplier of customers' own-brand products.

The Agribusiness division contributes 2.9% of sales turnover and maintains the link with agricultural producers in Ireland. Feedstuffs are supplied and milk is purchased and collected for use in the production of dairy ingredients. This special relationship with primary suppliers is echoed throughout the business.

Because the HACCP systems that I have been working on are relatively immature, the information in this chapter will reflect experiences gained during the initial stages, up to and including methods of implementation. It will include important lessons learned and things I would have done differently with the benefit of hindsight.

7.2 HACCP and business strategy

It hardly needs to be stated that food safety is the top priority for the Kerry Group, as it is for all responsible food manufacturers. All Kerry manufacturing units have HACCP systems in place which are regularly reviewed to ensure that they continue to be effective.

One common misconception I have found, however, is that many people believe that HACCP is a stand-alone system that will in itself ensure the production of safe food. While it is true that HACCP plays a very important role, it is only one of the elements of an effective food safety management system. Figure 7.1 illustrates this in the form of a 'food safety house' where the foundations represent prerequisite systems, the walls represent HACCP systems and controls and the roof represents general quality systems including traceability and recall procedures.

The HACCP plan is similar to a house layout plan: it identifies which of the 'walls' are 'load-bearing', where they must be built and how strong they need to be. But the house plan itself does not build the walls. Nor does it ensure that they have been built correctly. It is just the starting point. This is also true of the HACCP plan, which details the controls that are required to produce safe food, but these only become effective when HACCP has been properly implemented.

Everybody knows that the walls of a house must be built on solid foundations. HACCP too must be built on solid foundations in the form of effective prerequisite systems such as supplier quality assurance (SQA), good manufacturing practices (GMPs), personnel hygiene and cleaning.

Furthermore, the walls of a house are of little use without a waterproof roof over them. HACCP must be covered by an effective quality system, which is founded on the main structural elements of the 'walls' and protects against exposure to food safety incidents.

Fig. 7.1 The food safety house.

HACCP is of course one of the most important elements of food safety management. Just as a structure is not a house if it has no walls, so a management system cannot control food safety if HACCP is not in place.

This analogy has been useful when explaining HACCP to colleagues. A house is something with which they are all familiar. This makes it easier for them to understand food safety management as a total concept. The relative importance of each of the key elements becomes clear. They quickly realise that HACCP must be totally integrated into the management system if food safety controls are to be effective.

7.3 How big is the job?

This is one of the most common questions asked at the outset of a study, along with: What should be done first? What resource will be needed? How long will it take? How much will it cost? How do we go about it?

When building a new factory the answers to these questions are easy: GMP, hygienic design and pest-proofing measures can be built in at the start. The HACCP study can be performed on the proposed process flow diagram, and all necessary food safety control measures can be designed into the process prior to installation. The quality systems can be developed around the CCPs identified in the HACCP plan. SQA and training can take place during the construction phase. In this way food safety will be totally controlled from start-up.

However, in reality most studies are performed on existing factories. In these circumstances, it becomes much more difficult to answer these questions. The reason for this is that every business is different. The size and age of the factory, the product range, the production processes and the people – these combine to make each operation unique. All of the elements of food safety management are likely to be present in some form; it is unlikely that the business would exist if they were not. But the amount of work required to improve the controls will depend on the maturity of the existing systems.

It is again helpful to consider the food safety house analogy, because a HACCP study on an existing system is very much like renovating an existing house. The amount of work required, the time it will take and the estimated cost are totally dependent on the structural condition at the outset. It is impossible to judge the amount of work that will be required on the house unless a detailed survey is performed by a building expert, and a comprehensive list of faults is prepared.

Ideally, the starting point for a HACCP study should be a detailed audit by an expert in food safety. All elements of food safety management should be assessed for their completeness and effectiveness, and a comprehensive list of defects prepared. It will then be possible to judge the scale of the task ahead.

The next stage in the house renovation process is to analyse the survey. Each of the faults must be considered in turn, and an estimate made of the work required to return the property to sound condition. This will be expressed in terms of materials required and hours of labour involved, so that the estimated cost can be calculated.

Of course, the next stage in the HACCP process is the same. Each of the defects found with the food safety system must be taken through a similar thought process, then materials, labour and cost estimated. It may be necessary to involve an external consultant with relevant experience if this expertise is not available inside the organisation. At this point, it is useful to map out a rough action list, which itemises each of the defects. Blank columns can be left for the work required headed ‘materials’, ‘hours of labour’ and ‘estimated total cost’. Columns should also be left for ‘priority’ and ‘responsibility’. This can then be used as a check-list to ensure that all necessary information is gathered to prepare a project plan.

7.4 Prioritisation in the project plan

It is normally necessary to introduce an element of prioritisation. As with house renovation, there will rarely be a job list that is short enough for all work to be completed immediately and which is easily affordable. There will be constraints such as budget and availability of skilled labour, which must be considered.

There will also be a natural order to the work. It is normal with house renovation to complete structural repair work on the foundations first, then the walls, and finally the roof. There is no point fitting the best roof in the world if the foundations are about to give way! Of course there will always be exceptions to this: in certain circumstances it may be necessary to perform emergency repair work on the roof to make it completely waterproof before starting work on the walls. It may even be necessary to shore up the walls before it is safe to perform the original structural survey!

This is also true for HACCP, where work on the prerequisite systems will normally take priority. Some emergency repair work on the quality systems may be required early in the project to make sure they are watertight. Some emergency food safety controls may need to be introduced even before the HACCP study is performed (e.g. if there is no metal detector in a process this must be installed immediately!).

Once the action list has been completed, it will be possible to produce a detailed project plan. This must take into account the priority rating, the availability of experienced personnel and the time they can allocate to the project, plus the budgetary considerations previously mentioned. The overall length of the project will be heavily dependent on the number and experience of the people involved. It is possible to plan many of the improvements in prerequisite systems to take place concurrently if there are sufficient people to take individual responsibility for each action. The original list can itself be used as the basis for an action plan to drive the non-HACCP improvements. The HACCP study will normally be planned to start before these reparations have been fully completed.

It is obvious that the actions considered as the highest priorities should be tackled first. However, it is important to realise that the *time scales* allocated to these actions must be consistent with their priority rating. If insufficient resources are available to allow the action points to be completed in a realistic time, then the resource must be increased, not the time scale.

It is usual in the project plan to break the HACCP study down into its key phases. This will not be covered in detail here, as it is well documented elsewhere.[2] The phases will of course be studied in detail later in this chapter.

The role of the project manager is also well documented elsewhere. However, because it is rare to find project management skills and HACCP expertise in the same individual, it is often recommended that the quality representative be trained in project management. An alternative approach is to allocate a skilled project manager to the HACCP team, and to train this person in HACCP techniques. In practice, the engineering representative will probably possess the required project management skills. It is probably a better long-term investment for the business to train the engineers to be food safety experts than it is to train the quality staff to be project managers!

During the study itself and during implementation it is usual to encounter complications and additional problems that could not have been foreseen at the outset. These may require additional resource or expenditure to resolve them within the time scale allowed. A builder will always overestimate the time and cost of a house renovation project because the work rarely goes according to plan. When preparing the HACCP project it is also wise to overestimate the time and cost so that there are no surprises at the end.

The final stage in any house renovation project is the interior decoration. In effect, this is a cosmetic exercise which has no effect on the structure, but adds a comfort factor that few of us would be without. When implementing a food safety system into a factory, the primary objective is to make sure that the controls actually work in practice. Making it look pretty is important, but it is best to leave the tidying up until the end.

Just as routine maintenance on the newly renovated house is necessary to stop it deteriorating to its former level, routine maintenance is also necessary on the food safety system to ensure that it stays effective.

More importantly, if further major modifications are to be made to the house, their effect on the structural integrity must be assessed *before* the work takes place. The careless removal of a load-bearing wall could cause the whole house to collapse. This is also true with HACCP. If any major changes in manufacturing methods are proposed, it is essential to reassess the safety implications *before* the change takes place, or it may result in a catastrophic failure of the food safety system!

Finally, external forces such as earthquakes or hurricanes may affect the structural integrity of a house. In the same way exterior influences such as BSE or food scares may challenge the integrity of a food safety system: if the system is well enough designed, it should withstand all foreseeable external forces.

7.5 The Polish experience

7.5.1 Kerry Pegromar, Poland

One of the subdivisions of Kerry Ingredients produces processed fruit products for the dairy, bakery and catering markets, with manufacturing facilities throughout Europe. Much of the soft fruit is sourced from our own factory in Poland. Kerry Pegromar is one of the most modern fruit freezing operations in eastern Europe. Based in Kielce, two and a half hours south of Warsaw, it is in the heart of the soft-fruit growing area of the country.

Individually quick frozen (IQF) strawberries are the mainstay of the business, with several thousand tonnes being frozen in the 20 or so days of the season. Other major IQF products include sour cherries, rhubarb, blackcurrants, redcurrants, gooseberries and blueberries. Total quantity of fruit frozen is over 10,000 tonnes per year. Frozen fruit is also supplied directly to non-Kerry customers throughout Europe.

The processing operation is relatively simple: fruit is graded on receipt, stored for a limited period under refrigeration, washed, pre-sorted, quick frozen in continuous blast freezers, further sorted to customer specification, packed, metal detected and placed in frozen storage prior to dispatch.

Because large volumes of raw material are processed in a very short time, most of the fruit is placed into intermediate frozen storage as ‘semi product’ which undergoes final sorting to customer specification as required through the year.

My involvement with Pegromar began in 1997: my brief was to spend 50% of my time on site helping to implement food safety controls that would be acceptable to UK customers.

At this time food safety systems based on HACCP had already been introduced for key fruit types, although these were relatively immature. SQA systems were well established, with training programmes in place to communicate the required quality standards for the fruit to the suppliers. Traceability was possible back to supplier and day of delivery. Key quality systems were in place and functional, although they were not approved to ISO 9000 standard.

7.5.2 Pegromar project plan

In order to assess the status of the systems on site we decided to employ an external consultant to perform a baseline audit of the factory. This generated a list of actions required to improve food safety controls.

The main areas of concern were GMP, cleaning, pest control, glass auditing and HACCP coverage. A detailed action plan was prepared using a very simple Lotus Approach database: this software allowed the list to be presented in a number of different formats depending on the target audience. A general action list with a brief description of the work required was useful to communicate the scale of the overall task to senior management. More detailed individual action plans were prepared for each responsible person: initially these were limited to the high priority actions so that the length of the list would not overwhelm the recipient. Lower priority actions were then gradually added to the individual action plans as initial tasks were completed.

This method worked well, and was flexible enough to cope with late additions to the list as unforeseen problems were discovered. Improvements highlighted during customer audits could also be included with ease.

7.5.3 HACCP in a foreign language

The HACCP team consisted of the QA manager, the production manager, the engineering manager and me. The team was relatively inexperienced in HACCP techniques, as at the time there was little reference information in Polish and no recognised training courses that they could attend. The original Campden HACCP document had been translated into Polish, and was being used as a guide.[3] I decided it would not be possible for me to train the team formally, and that it would be necessary to lead them through the actual study and to let them learn by experience.

Language was a major barrier, as I did not speak Polish, and the rest of the team did not speak English except for the QA manager, who spoke only a little. It was obviously necessary to include an interpreter in the team so that we could communicate with each other. This caused a number of problems during the hazard analysis stage. First, the meetings took at least twice as long as they would in a single language because everything had to be said twice: once in

English, then once in Polish, and vice versa for the response. Second, because the interpreter was non-technical, it was necessary to look up many of the words in a dictionary, which took up still more time. Third, of course some of the meaning was lost in the translation, which led to much confusion which needed to be resolved through further explanation and discussion. The process flow diagrams proved to be extremely useful communication tools because they were relatively easy to translate into Polish, and provided a common reference point that all team members could understand (see Fig. 7.2).

7.5.4 The HACCP study

The HACCP study itself was undertaken in a number of logical stages. Because of the seasonality of the fruit harvest, when I arrived in Poland in September 1997 there was very little fresh fruit being processed. The new season would not start until May 1998. There was therefore little point starting the study with the arrival of the fresh fruit, as it was already 'semi product' in the freezer. So we decided to divide the study into two main stages, post-freezing and pre-freezing, with the aim of completing both stages by the start of the 1998 season.

The initial HACCP work that had been completed by the local management team had covered each fruit type separately. This made sense because every fruit has slightly different inherent hazards. For example, strawberries are relatively low risk in terms of foreign bodies, whereas cherries have an in-built stone that could choke a child, blackcurrants and redcurrants often arrive heavily contaminated with sticks, and gooseberry bushes carry very dangerous thorns. The various fruit types also require slightly different treatment, so flexibility is built into the process to cope with this (e.g. slicing of rhubarb, pitting of cherries, etc.). Specific hazards associated with each process stage must be identified if they are to be controlled. The same method was therefore adopted for the follow-up study, with each fruit being reviewed separately.

I had to get to know the people and the process quickly. It is not possible to perform a HACCP study effectively if you do not understand the production process. One of the best ways to get to know an unfamiliar factory is to construct a process flow diagram. This may take several weeks, depending on the complexity of the process, but it is essential that the flow diagram is accurate in every detail, because this is also the first stage of the HACCP study. If a step is omitted from the diagram, then it will not be assessed at the hazard analysis stage, and therefore the associated hazards will never be controlled.

Hazard analysis is another key stage in the HACCP process. This must be performed diligently so that *all* hazards are identified for all steps in the process. If a hazard is missed at this stage, it cannot be identified as a critical control point. This may mean that the finished product is still unsafe even after HACCP has been implemented. This would obviously be unacceptable.

We started the hazard analysis with the highest risk fruits in terms of sales volume and food safety (i.e. frozen strawberries, cherries and gooseberries). Since most hazards were foreign bodies, the inexperience of the team was not a

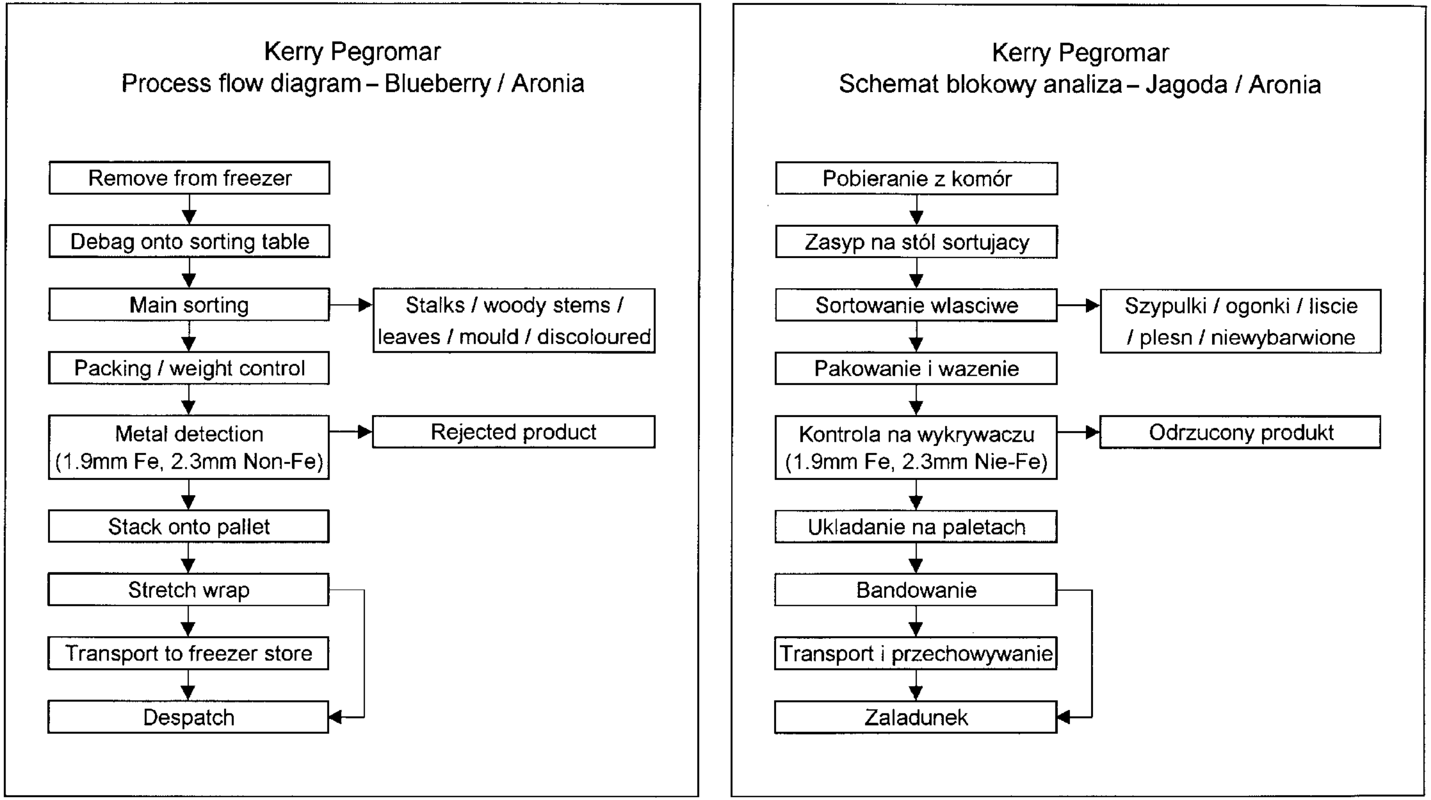

Fig. 7.2 Block flow diagrams in English and Polish were used to aid communication.

major issue; they were easily able to recognise potential food safety issues of this nature. However, on the microbiological front, their inexperience led to a tendency for both spoilage organisms and pathogens to be raised as hazards. This was easily resolved, because points where spoilage alone was concerned were either identified at the time or were removed later during the CCP identification.

Once the team had completed the hazard analysis, it was possible for me to overcome some of the language difficulties by performing the majority of the CCP identification on my own with the help of the CCP decision tree. A decision matrix was used to record the path through the tree for each hazard in case any of the decisions were questioned later. The team was then brought together to review and approve the CCPs. Once this was completed for the three primary fruits, a HACCP control chart was constructed. Although the original intention was to prepare separate control charts for each fruit, in reality the CCPs after the freezing stage were so similar that it made more sense to draft a single control chart for all fruits post-freezing. This was confirmed as the correct approach when the hazard analysis and CCP identification had been completed for the secondary fruits post-freezing, as they too could be covered on the same chart.

The original control chart was prepared in English, and had to be translated into Polish for the team to review and agree the controls for each CCP. Once this was done it was for the rest of the team to complete the implementation and training, as it could only be done in Polish. This was enormously frustrating, because implementation is the final key stage, and I could not influence its progress directly. Worse still, I could not communicate with the trainees to check their level of understanding. All I could do was to audit the results, and to steer the team through to successful implementation.

The same procedure was followed for the raw fruit prior to freezing, except that we could not verify this part of the process flow diagram until the fruit started to arrive. It was therefore necessary to perform the HACCP review on the provisional process flow diagram, because the controls had to be in place *before* the season started. Then as soon as each fruit type began to arrive we verified the flow diagram to make sure it was accurate. When discrepancies were found we revised the flow diagram accordingly, and reviewed the hazards to make sure we had not missed anything. Thankfully, this was a rare occurrence.

The CCPs were included in the quality system so that they would be effectively implemented. This was relatively straightforward, as none of the controls was particularly complicated, and the majority of them were already in place. The quality system for frozen fruit and vegetables was subsequently approved to ISO 9002 by Lloyds Register Quality Assurance in January 1999.

Although we achieved the objectives that we were set, this could not be described as a 'model' project. One of the fundamental requirements of HACCP is good communication. It would have been far simpler if I had spoken Polish, if the team had spoken English, or if they could have been trained in their natural language, then given more freedom to progress on their own. It would not be wise to follow this example unless, as we found, there is no realistic alternative.

7.6 Expansion of the Polish operation

7.6.1 Project outline

In January 1998, the decision was made to install a process line at Pegromar to produce pasteurised fruit preparations for the rapidly expanding yoghurt and ice cream markets in eastern Europe. I was the technical representative on the project team from the beginning, and was able to ensure that food safety considerations were built into the design from the start.

It was decided to build the new process area after the frozen storage stage. This would maintain both logical flow of fruit through the factory and maximum distance from the raw fruit to the pasteurisation process to minimise the risk of yeast and mould contamination.

Logical flow *within* the process area was also a major consideration, along with hygienic design and pest proofing of the processing halls.

For the process, the best design features were taken from sister factories in the UK and France, and combined to make a system that would be at the leading edge of fruit processing technology. But a conscious decision was also made to keep the process as simple as possible. Food safety controls that would virtually eliminate the risk of product contamination by cleaning chemicals were designed into the process, along with features that would ensure that critical processing temperatures were accurate and were automatically recorded.

7.6.2 The HACCP study

A HACCP study was performed on the proposed process flow diagram prior to installation. On this occasion, it made no sense to perform the study from first principles, as none of the team members, myself included, had sufficient expertise in fruit processing for the team approach to be effective. Instead, the existing HACCP plans were taken from sister factories in the UK and France. These were thoroughly evaluated to confirm the similarities with the proposed process and product range. More importantly, the differences had to be highlighted and all associated hazards and CCPs identified and built into the modified HACCP plan. This method worked perfectly well: it stopped us repeating mistakes made elsewhere in the group and allowed us to benefit from their experience. It also saved a lot of time and effort on our part.

Performing HACCP prior to the installation of a new process is probably the most powerful use of this technique. It identifies all critical stages in the process, including those that have been overlooked during conception, and enables them to be designed into the process and installed prior to start-up. It also identifies the process parameters that are critical to food safety so that the most appropriate monitoring equipment can be specified and used from the start. Finally, it highlights the manual process records that are required, so that these can be built into the quality system from day one. It is therefore possible to start production with total confidence in the ability of the process to make safe food.

7.6.3 Operator training

No matter how well a process is designed, it is almost impossible to make it 'operator proof'. Like it or not, the production operators play a significant part in the achievement of finished product quality and food safety standards. It is therefore vital that they know what they are doing and understand the implications of their actions.

Training of operators is often one of the weakest links in the food safety chain. Rarely is sufficient time or resource allocated to the task, and seldom is it adequately completed. To help understand why, think for a moment about learning to drive a car. First, trainees have to learn what all the controls do, then they have to learn the sequence required to make the car move. Next, they practise these control sequences under supervision while driving on the road. At this stage it is necessary for them to think of each action in the sequence before it is completed, making it difficult for them to think about driving safely, so they drive very slowly at first. When they get past this stage they no longer have to think about which gear they need to be in, or which pedal to press. They can then start to concentrate on driving safely, so that they do not cause an accident, which may put someone's life at risk. At this stage they must pass a test to prove that they have mastered the basic requirements needed to go solo.

When we train operators to use a new machine or new process, it is just like teaching them to drive a car. They are not fully trained until running the process equipment is second nature to them. When they have reached this level of awareness, they can concentrate on thinking about controlling food safety, so that lives are not put at risk.

This may be considered by some to be a poor analogy, because it suggests that we want to produce unthinking trainees. Quite the opposite is true – we want to make sure that the trainees are not allowed to 'go solo' or to 'drive' too fast until they are able to control the process so that food safety is never compromised.

The selection and training of operators was to be a crucial factor at Pegromar, because pasteurisation was new to the factory and the operators had no previous experience of this form of processing. The only sensible course of action was to allow the trainees to experience it at first hand.

Three months prior to the target commissioning date, when the Pegromar process was literally still on the drawing board, we selected the three leading operators from existing staff. They were sent to their sister factory in the UK, for three weeks of hands-on fruit processing. This was not ideal because language was a major barrier, which meant that all training and communication had to be done through a non-specialist interpreter. For this reason, the majority of the basic training took the form of physical demonstrations. During the first day the trainees were introduced to a simple recipe. All of the ingredients were present in their correct proportions, and the role of each one was explained. The principles of pasteurisation and subsequent aseptic controls were described in detail. Then the main food safety and quality problems were discussed, with examples being shown wherever possible. A number of laboratory-scale samples were prepared in the presence of the trainees to demonstrate the importance of following the recipe. These included several deliberate failures which served to reinforce this message and to further develop their understanding of the product.

This led to bench-scale and then pilot-scale production trials by the operators themselves. When we were confident that they had mastered the basics, the trainees were placed with leading staff in the factory, and spent an average of two working days in each department. This brief immersion gave the Polish staff an insight into the daily routine of a fruit production unit. Obviously, they were not yet fully trained, but at least they had gained some relevant experience.

Several weeks later the management team went through a shorter but very similar training exercise.

Just prior to start-up the operators were returned to the UK for a further two weeks' refresher training, accompanied by the quality control manager. As well as receiving further training himself, the quality control manager also acted as interpreter for the group, and developed a close working relationship with the rest of the team. This established his credibility as a leader, and earned him the respect of the operators.

7.6.4 Commissioning and start-up

The process was commissioned in October 1998, and as soon as it was operational we began to train the staff in earnest. We devised an economical training recipe, which included all of the functional ingredients in quantities that had to be weighed out (i.e. not full bag quantities). One batch of this was made every day, and filled off aseptically into cleaned, sterilised 800 litre transport tanks. Samples taken during preparation and at the point of filling were tested as if they were finished product to make sure that they met the specification. In this way, we completed the training of the original group of operators and their support staff in all aspects of the Pegromar process. Then using this method and their expertise, we were able to train fully the second shift of operators on site in Poland.

The factory received its first customer orders in December 1998, and made its first real product early the following month. At the time of writing, the plant has been in production for four months, and several hundred tonnes of product has been made. There has not been a single microbiological failure or foreign body issue with fruit preparations made at Pegromar.

7.7 Kerry Ingredients, Portbury, UK

7.7.1 Background

In November 1998, I started work at the Portbury factory near Bristol. This is the newest facility in the seasonings and coatings subdivision of Kerry Ingredients.

Commissioned in 1997, this purpose-built factory was constructed on a greenfield site alongside the M5, one of England's main arterial motorways. The objective was to create a state-of-the-art manufacturing unit that would replace the outdated production facility in central Bristol.

The factory makes a range of dry blended seasonings and savoury flavours. Customers include most savoury food manufacturers in the UK, as well as many others in Europe and the Middle East.

The process is relatively simple: ingredients are weighed out, mixed together, sieved, packed, metal detected, stored, then dispatched to customers. It is made complicated by the sheer numbers involved: around 2,700 finished products are made from approximately 1,500 raw materials.

As would be expected with a new factory, GMP and hygienic design were built in from the start. SQA and raw material controls were good, which is essential with a dry blending operation, because the process does not include a pasteurisation step. The quality and safety of the finished product are therefore almost totally dependent on the raw materials used. Quality systems are effective and are approved to ISO 9002.

7.7.2 Review of existing HACCP plan

My brief was to lead the team through a review of the existing HACCP system to make sure it was still current. The system had been put in place before the factory was built, and was therefore based on the planned process flow diagram. Because the original HACCP plan was very complicated, it was decided to start the review from first principles. Foreign bodies are the main food safety concern with this range of products, so we focused on these first. As a rule, it is best to start the HACCP process with foreign bodies if the team members are inexperienced, because these hazards are easiest to relate to.

The team approach was used to produce the foreign body plan. Then because of the relative simplicity of the process and the time constraints on the other team members it was decided that the technical manager and I should perform the microbiological and chemical hazard analysis. The team then met to review this analysis and to perform the CCP identification. The resulting CCPs were added to the foreign body plan to complete the study in early January 1999.

A detailed process flow diagram had been prepared and used for the review: this included all steps in the process, their interrelationships and all inputs and outputs. A much simpler *schematic* process flow diagram was prepared for inclusion in the HACCP plan. This could be easily understood by operators and could be sent to customers without fear of betraying our technology to our competitors.

When the new plan was compared with the original HACCP, it was reassuring to find that nothing new had been identified. The only difference was that several of the foreign body control points from early in the process had been upgraded to full CCP status. This was because we found that the sieve mesh sizes being used for some products could not be relied on to remove larger nonmetallic foreign matter from the product. While still identified as CCPs, the sieves are also used as part of the verification procedure to ensure that the earlier controls are fully effective.

7.7.3 Implementation and training

Implementation of the plan was relatively straightforward because most of the CCPs were already controlled under the original HACCP plan, and were fully integrated into the quality system. A number of additional work instructions were required to reflect the changes in emphasis, which gave goods-in and warehouse staff more responsibility for food safety.

The most important part of the implementation process was the training of the staff. The objective of this 'operator awareness' training was to get the trainees to understand what the controls were and why they were necessary, so that they would not be tempted to take short cuts that could compromise food safety.

During the training, the first thing the trainees were made to realise was that *they* were the potential consumers. This immediately caught their attention and made food safety a personal issue. From then on, it was relatively easy to raise their awareness of the issues and controls by asking and answering a number of simple questions.

When asked which was more important, quality, food safety or production efficiency, the trainees usually came up with 'food safety' as the right answer. This was made clear to them by emphasising that we could kill somebody if we got it wrong, which could lead to closure of the factory, in which case quality and efficiency would be irrelevant.

The question 'What are the three main types of food safety contaminant?' started to focus the group on issues specific to our process. The food safety contaminants were covered on a need-to-know basis. To have given too much information at this stage would probably have been counterproductive as the operators may not have understood it all, so they would have 'switched off'. At Portbury we only blend together dry ingredients. During the discussion on microbiological hazards neither the characteristics of individual pathogens nor their heat destruction was covered. This information would have been irrelevant, because there is minimal risk of microbiological growth, and no 'kill' stage in the process. The information must be kept relevant to the audience, and if possible specific examples from their workplace should be used to illustrate each point made. During the session, we discussed general microbiological hazards relating to raw materials, cross-contamination from dirty equipment or people, and the risks of water in our process which must be avoided to prevent microbiological growth. In other words, we covered the CCPs from the HACCP plan.

Glass and sharp metal were used as examples of foreign bodies to awaken the imagination of the trainees. The limitations of sieves and metal detectors were then covered in detail. The increasing ineffectiveness of sieves larger than 3–4 mm and the inability of metal detectors to pick up small pieces of metal, including wire and stainless steel swarf, were emphasised. The need for prevention was obvious.

Actual customer complaint statistics relating to foreign bodies were then used to illustrate this. A kind of mini hazard analysis exercise was carried out, where each of the categories was taken in turn, the likely source 'brainstormed' and the preventative measures highlighted. To further emphasise the need for controls, the point was made that the consumer does not normally know that the food is unsafe until after it enters their mouth.

At this stage, the trainees were more than ready to receive some good news. The question 'How can we guarantee food safety?' introduced the subject of HACCP. Again, the information relating to the origins of HACCP was kept as brief and as interesting as possible for the audience. The mental picture of the symptoms of food poisoning in zero gravity was used to good effect to explain why this system was originally developed. The HACCP plan was only mentioned in passing so that the operators knew it had been completed.

They did not need to know every CCP in the process, only those relevant to them, and they had to understand why they were important (if they had not already worked this out for themselves). They needed to know that all CCPs had been identified and were under control, so they could be confident that the product was safe.

They were introduced to the concept of a food safety 'jigsaw puzzle', where all of the pieces must be in place to give a complete 'picture' of food safety. They were told that, as individuals, they were all pieces in that jigsaw puzzle. The schematic process flow diagram was used to show them the overall picture, so that they could see that all of the CCPs were in place. They were then given a pocket-sized laminated card with details of the hazards and controls relevant to their job (see Fig. 7.3). Each of the CCPs was discussed in turn, and the reasons for these controls were reiterated. The operators from each department were trained as a group so that their attention could be focused on controls specific to their area. In most cases, the action to be taken by the operators was designed to either prevent or control the immediate problem. Then if necessary they were to inform their supervisor, so that a management decision could be taken to bring the situation back under control.

The training concluded by considering total quality management and internal supplier/customer relationships, with the emphasis on the importance of supplying safe products and services to internal customers. It was important to leave them with the message that their individual actions could make a real difference to the overall safety of the finished product.

7.7.4 Nonconformity management

One of the most important elements of any food safety system is nonconformity management. This is necessary in case there is a failure at one of the CCPs. However, this part of the system is often poorly developed or badly

Critical Control Points – Packing

CCP	Hazard	Control
10.1	Filler parts falling into product (seals, nuts & bolts, swarf if moving parts work loose).	✓ Inspect filling machine every time it is cleaned. ✓ Make sure all moving parts are present, undamaged & properly fitted.
11.1	Foreign matter inside packaging before filling.	✓ Look out for foreign objects in packaging during filling.
12.1	Failure to detect & reject metal contaminated product.	✓ Check metal detector with test pieces at the start of every batch & end of day.
13.1	Contamination of our, or our customer's factory with foreign matter from pallet (e.g. glass).	✓ Inspect all pallets before transfer to packing area / use.
13.2	Wood / nails from pallet puncture packs.	✓ Use cover sheet on every wooden pallet stacked.

✓ Report all problems to your supervisor

Issued: 1.3.99

Approved By: Douglas Rudge
Quality Systems Coordinator

Fig. 7.3 Plastic laminated 'crib' cards were given to operators.

misunderstood. 'Control of nonconforming product' and 'corrective action' are fundamental requirements of a quality system, and are of course two of the clauses of ISO 9000. It is ironic therefore that ISO 9000 is the main cause of the confusion, because many businesses create two separate systems in order to meet their interpretation of the requirements of the standard. In fact, these two clauses are so intimately linked that they can only be effective if they are managed within a single system.

Portbury were running an 'internal nonconformity sheet', a 'corrective action' sheet and a 'finished product reject' sheet. These three records were replaced by a single 'nonconformity report', which was used in all cases where finished product was affected. This was designed to lead and record the thought processes in the event of a product or manufacturing failure. It was divided into five sections:

1. To control the problem.
2. To investigate the cause.
3. To deal with the product affected.
4. To take corrective action to prevent its recurrence.
5. To review and close the incident.

This was originally introduced as a paper system, which we soon found to be impossible to manage. The nonconformity sheets would get buried under mounds of paperwork on people's desks, and it was difficult to keep track of the stages of completion. We incorporated it into a networked Lotus Notes 'quality' database, which quickly resolved the management issues and brought significant additional benefits. These included the generation of weekly and monthly summary reports, trend analysis, search options and significantly improved communication to all interested parties.

7.7.5 Verification procedures

Auditing is an important part of the maintenance of an effective food safety system. HACCP audits are often performed independently of other audits. Although there is nothing wrong with this method, it suggests to visiting external auditors that the CCPs are operating independently from the rest of the quality system. If the controls have been fully integrated, there should be no need to audit them separately: the CCPs should automatically be covered during routine quality system or hygiene/housekeeping audits. In practice it is relatively straightforward to achieve this, providing that the quality system is well established and the CCPs are clearly identified within it so that they are not overlooked during the audit.

We plan to achieve this at Portbury by including the HACCP plan in the quality database. It will then be possible to list the CCPs automatically on the appropriate audit checklist, along with outstanding actions from the previous audit, saving time and making the auditor much more effective.

7.8 The benefit of hindsight

Most of the points that follow are related to language and communication issues because the majority of this work was done abroad. Some of them have already been raised in earlier sections but they will be explained in more detail here.

The most important thing would be to make sure at the outset that there is a common understanding of food safety among the senior management team. The 'food safety house' analogy was developed quite late on. If this had been available at the start, it would have been used for this purpose. This would have helped significantly at all stages of the project.

Access to computers was also a major problem. The original intention was to use local computers to create the HACCP documentation, because the local management team needed to have the master version of these documents. This was a big mistake. Apart from the obvious problems of availability of hardware and different makes or versions of software from site to site, there was a major problem with language. When working in a foreign language version, the Windows environment is like an alien world, with familiar icons becoming unrecognisable when 'foreign' text is applied to them. Simple tasks like printing were a nightmare at first, as a dictionary had to be used to look up the words before the commands could be made with confidence, making progress very slow. With hindsight, it is obvious that either the English version of the software should have been installed on the local computer, or better still, a laptop should have been available from the start. I now carry a laptop computer, which has proved invaluable, and has paid for itself many times over. If starting out again I would always insist that a dedicated computer be made available; the choice of desktop or laptop should be made to suit the circumstances.

When working with people in a foreign language it is more likely that progress will be made if both parties know a little of the other's language. Obviously the more fluently the language is spoken, the easier it will be to communicate. Probably the best option for implementing any sort of change in another country is to use local experts who can work in their mother tongue. They will then be able to cover the whole project from conception through to implementation and training. If this is not possible and there is no common language between you and the local management team I would strongly suggest recruiting knowledgeable staff locally who can speak both languages fluently. In my experience, it is very difficult to communicate through an interpreter because too much of the meaning is lost in the translation.

To function effectively, the HACCP team members must either be trained or experienced in the principles and techniques of HACCP. When working abroad, the language issues make it much more difficult to train the staff personally. It would have been extremely useful to be able to send staff on a training course in their own language in the knowledge that they would receive the message that was intended. There has long been a need for a standard training package that is internationally recognised, written in simple language so that it can be translated easily. Perhaps the newly available World Health Organisation training package will meet this need in future.[4]

During HACCP implementation, be it in the UK or abroad, operators also need to be trained so that they achieve a level of understanding of the controls required, but more importantly the reasons for these controls. This can only be done effectively in their natural language. Ideally, a member of the local management team should carry out this training, as it is necessary to draw on examples from their working environment. If done well, it will strengthen the working relationship between the manager and the staff. At Pegromar, when a completely new process was installed in their factory it was necessary to send operators abroad to gain relevant experience. If we had to do this again we would always send a member of the management team with them. Their role would be to act as interpreter, to make sure that they were properly treated, to ensure that they really understood the process and to develop the working relationships between the new team members.

While working elsewhere in Europe during the same period as the Polish project, similar problems were experienced. However, a number of additional issues were encountered.

In one case, there seemed either to be differences in the legal requirement regarding HACCP or differences in the interpretation of this requirement. The emphasis at this factory was on the preparation of impressive HACCP documentation that would satisfy the authorities, with seemingly little regard given to the implementation of the controls. Of course, this situation was immediately rectified, but readers should be aware that local management might in some cases expect to work to the 'letter' rather than the 'spirit' of the food safety legislation.

Another issue was one of prejudice, where recent problems of BSE in the UK provoked the 'mad cow' response from some people in Europe. In their eyes, the lack of credibility of UK-based food safety specialists meant that they were highly sceptical of all recommendations made. It was therefore difficult to implement the necessary additional controls. Although I do not know the solution, I feel that this problem needs to be raised so that others may be forewarned.

Most worryingly of all, in Europe there seemed to be a general lack of awareness of the allergenic properties of nuts. Obviously, if nuts are not recognised as a food safety issue, then they cannot be identified during hazard analysis, so will not be controlled as CCPs. It is essential that all such situations are identified and controlled so that lives are not put at risk.

With reference to the HACCP plan, a process flow diagram will always form part of this document. In the early days, we made the mistake of including a fully detailed flow diagram in the plan. Now a schematic version of the diagram is always included, which is easier to understand and is much less commercially sensitive if it is sent to customers.

To end on a positive note, we have recently been able to combine many of the innovations that have been used separately elsewhere. The most significant single development has been the networked 'quality database', which has taken off on the back of the information technology revolution. Although this was primarily introduced as a system to manage internal raw material and finished product nonconformities, it is rapidly expanding and will soon include all aspects of quality systems management in Kerry Ingredients. Specifically, the master copies of all documents and work instructions (including HACCP) will be maintained in the database. Internal audits will also be scheduled and reported here, and all associated corrective actions managed as a live prioritised action plan for each factory. Customer complaint investigations will soon also be incorporated. This system is still being developed at the time of writing, but it is planned to roll this out to all UK factories in the Ingredients division in the near future. The true power of the system will then be realised. It will be possible for anyone, anywhere to view all incidents of raw material nonconformity for all deliveries across the UK. Innovations such as this will eventually make all factories much more efficient. Data that has been held in traditional paper systems will be presented in the form of management information, so that we will finally be able to make informed decisions that will improve the future performance of the business. This will enable us to make the essential transformation from reactive to proactive food safety management.

7.9 References

1. *Kerry Group plc Annual Report 1998*, Kerry Group, Prince's Street, Tralee, Co. Kerry, Ireland.
2. MORTIMORE, S. and WALLACE, C., *HACCP: A Practical Approach*, 2nd edn, Gaithersburg, Maryland, Aspen Publishers, 1998.
3. CAMPDEN AND CHORLEYWOOD FOOD RESEARCH ASSOCIATION, *HACCP: A Practical Guide*, 2nd edn, Technical Manual No. 38, 1997.
4. MOTARJEMI, Y. and VAN SCHOTHORST, M., *HACCP Principles and Practice: Teacher's Handbook*, WHO/SDE/PHE/FOS/99.3, 1999.

8

Implementing HACCP systems in Europe

Heinz

D. Killen, H. J. Heinz, Wigan

8.1 Introduction

Over the last decade consumers of food products have become much more aware of food safety issues. This concern has led both to the introduction of new enforcement agencies (such as the Food Standards Agency in the UK) and the strengthening of the powers given to existing enforcers such as Environmental Health Officers (EHOs) in Britain. At the same time there is increasing competition in the food industry, with accelerated technological and product innovation. This pace of change increases food manufacturers' exposure to potential food safety problems. Whether large or small, food processors are acutely aware of the consequences of a food poisoning incident linked to one of their products. Setting aside the criminal or civil proceedings that might ensue, companies such as Heinz must consider the impact of such an incident on public loyalty to, and trust in, their brands. In addition, as Europe's largest food manufacturer, and with many production lines running at 1,000 cans per minute and with a total of up to 25 million cans per week, the financial implications of a major product recall for a large food processor like Heinz are enormous. It is essential therefore that food processors have the right preventative measures in place. The HACCP system provides the tools for such an approach, allowing the food industry to ensure that it has food safety under control before potential problems arise and reach the public domain.

Heinz's traditional approach to food safety management was a prescriptive one, driven by detailed mandatory requirements and guidelines for particular products and processes. An example of this approach was Heinz's own International Sterilisation Manual (ISM), first compiled in 1977. This manual set out common standards and procedures for the sterilisation of low acid canned foods (cans and jars) for all Heinz affiliate companies and co-packing manufacturing operations. Although it provides an essential foundation of good practice, and is regularly updated, under certain circumstances it may not always be able to keep up to date with the pace of product and process innovation, and is not always able to reflect the requirements of individual plants. The latest edition was revised and reissued, and now cross-references the need to utilise HACCP and its principles, with HACCP being a critical part of the ISM. The HACCP systems approach that Heinz has adopted, in conjunction with the guidelines set out in the ISM, is more flexible and more suited to its range of manufacturing operations and the rate of product and process innovation.

8.2 The manufacturing background

The Heinz site at Kitt Green in Wigan (in the north-west of England) was opened in 1959 at a cost of £7 million. There are 12 production lines, some of which are able to fill and sterilise at a rate of 1,000 cans per minute (CPM). The lines fill low acid (pH > 4.50) or acidified products in cans and glass jars, mainly baked beans, soups and pasta products. The site covers 54.25 acres, incorporating a distribution centre that handles approximately 10,000 pallets of finished goods every week. The distribution centre supplies over 1,000 million cans every year, of which approximately 50% are manufactured on site. The site uses 1,400 tonnes of beans, 300 tonnes of vegetables, 134 tonnes of tomato paste and 5 million gallons of water every week of the year.

The basic production process is as follows. Ingredients are first received and checked against specification. They may either be pre-prepared by the supplier or size reduced on site. Ingredients are then batched according to recipe and cooked. After further quality checks, batches are dispatched or pumped for filling in cans. *En route* to filling, ingredients are screened for physical contaminants, for example, by passing through a metal detector. They are then filled into a pre-rinsed can. Once filled, the end is double seamed onto the can, creating a hermetic seal. The can is then transported to the appropriate steriliser and subjected to a sterilisation or pasteurisation process, depending on the product type and characteristics. After sterilisation, cans are dried and transported for labelling and packing before being palletised and transported to the distribution centre.

8.3 The main hazards

The main hazards for thermally processed products can be categorised as follows:

- pre-process or incipient spoilage of raw materials
- contamination from chemicals (e.g. pesticides), allergens and toxins

- contamination from foreign bodies
- inadequate sterilisation in removing microbiological hazards
- post-sterilisation contamination of cans and jars (e.g. because of damage in the final stages of production, storage or distribution).

The resulting product contamination can affect the safety of the product immediately. In other cases, it may only affect product quality initially, although such contamination may have the potential to become hazardous if not identified and dealt with. As a result pre-process spoilage and post-process contamination were considered in the HACCP studies of particular production lines.

The control of microbiological hazards is particularly dependent on effective sterilisation and the subsequent prevention of post-process contamination. This process renders a product commercially sterile either by the application of heat alone or in combination with pH and water activity. Commercial sterility differs from total sterility in that, after commercial sterility, organisms or their spores can survive but, because of the conditions prevailing in the container, are not able to grow to produce toxins or spoil the product. The primary public health concern with low acid canned food is the formation of a potent neurotoxin called botulinum toxin (the most potent toxin known to humankind) produced by *Clostridium botulinum*, which also produces heat-resistant spores. The boundaries of growth for this organism are well understood: it will not grow at a pH < 4.50 and a water activity (Aw) of <0.92. These criteria form part of the critical product characteristics that determine the type of thermal process to be applied. With products that have a pH > 4.50 and/or an Aw > 0.92, a process often referred to as a minimum 'botulinum cook' is applied to ensure commercial sterility.

There are a number of differing process types in which heat treatment is involved:

- fill, hermetically seal and apply heat treatment
- heat treat, aseptically fill and hermetically seal
- hot fill and hermetically seal.

In each case the sterilisation process depends on a series of technical operations that must be carefully and accurately performed to ensure the safety of the food in each of these cases. Key common factors include:

- process time
- process temperature
- temperature distribution in the steriliser
- agitation type (e.g. end over end or axial).

There are many factors affecting the effectiveness of heat penetration of the product, such as the following:

- Product characteristics such as:
    - changes in ingredient viscosity

  - starch types and potential to sheer thicken or sheer thin.
  - solids to liquid ratio
  - recipe control for pH or Aw levels
  - particle size.

- Filling characteristics such as:

  - variations in product garnish weights
  - multi-component filling
  - filling temperature
  - product headspace especially for agitating sterilisation processes.

- Holding time on line prior to heat treatment, including:

  - initial product temperature after holding time on line
  - ingredient clumping as a result of extended holds.

While the basic requirements for effective sterilisation are clear, there is a complex mix of factors that influence its effectiveness from product to product and process to process. The challenge of HACCP analysis is to identify and control each of these factors.

8.4 Introducing the HACCP programme at Kitt Green

The HACCP programme at Kitt Green went through a number of stages:

- initial approval
- defining the scope and approach
- team selection, training and preparation
- analysis of prerequisite systems
- hazard and CCP analysis
- implementation
- verification and validation
- ongoing monitoring and auditing.

The main stages are discussed in the following sections. Clearly, initial approval by senior management to undertake a HACCP programme was critical, given the significant investment in time and resources required. Given the central importance of food safety to Heinz, and sponsorship of HACCP principles by Heinz Headquarters in the USA, the senior management team at Kitt Green was enthusiastic about developing a HACCP system for the site from the start. However, it was important to explain HACCP principles in detail to the senior team, and outline what HACCP implementation involved, since HACCP principles were new to some senior managers. A detailed description of the HACCP implementation programme allowed a full discussion of the importance of the programme for Kitt Green and for the senior team to appreciate the resource implications.

8.5 Scope, approach and timing

Overall responsibility for the management of the HACCP programme was given to the microbiology team at Kitt Green. They were most familiar with and committed to HACCP as a concept, had the requisite expertise in hazard and process analysis, and had project management skills developed from involvement in the development of the quality management systems already in place.

One of the first decisions the team had to make was the scope of HACCP analysis. The team decided to prioritise food safety hazards, including chemical and physical as well as microbiological hazards, and to leave spoilage issues to one side initially. However, it was recognised that spoilage problems highlighted potential hazard issues and the team decided that such spoilage problems should be logged as they were identified during the HACCP study for each production line, and revisited once the HACCP systems for all the production lines were operating successfully. In retrospect, although it produced some lively debate among the HACCP teams about the potential safety implications of spoilage problems, this decision proved very sensible. It allowed the teams to focus more effectively on the key hazards and CCPs, and to produce a practical HACCP system for each production line.

Another key planning issue was the approach to adopt. It was decided to conduct HACCP analysis by production line rather than by product. This made sense since a number of products shared an identical sequence of processes. To avoid unnecessary duplication, it was considered sensible to concentrate on the key steps in a particular production line and to deal with product-specific issues as part of the HACCP analysis of each particular step. The only exception to this rule were those lines where the same or very similar equipment was used, in which case a number of very similar lines were reviewed at the same time. Production lines were prioritised according to the severity of hazards and analysed sequentially with a dedicated HACCP team assembled to develop a HACCP system in each case. Although analysing production lines in turn made the overall HACCP programme slow, it was felt to be more manageable to do this rather than have a number of HACCP teams working simultaneously on different lines. In retrospect this was a wise decision. Resources were not stretched too much at any one time, and succeeding HACCP teams benefited greatly from the experience and analyses of the earlier teams.

It was thought initially that it would take an average of two months to develop and implement a HACCP system for each of the 12 production lines. In practice, there were significant delays, particularly in trying to maintain the same core team members throughout the study, and each study took an average of three months. Although deadlines did slip, it was agreed that the priority should be a thorough and complete HACCP analysis in each case rather than rushing the process to meet the original deadline. From initial planning to final implementation, the overall HACCP programme took three years altogether to cover all 12 production lines from ingredient receipt through to packaging. In practice, the individual HACCP studies were completed and implementation achieved well within this period. However, full implementation was not considered to have taken place until, in some cases, new equipment had been purchased and installed. In these cases implementation was not formally completed until a final review of the HACCP system with the new equipment in operation. In retrospect, the HACCP process could have been speeded up by grouping lines with a similar configuration, adding time to the individual HACCP studies but saving time across the complete HACCP programme.

8.6 Setting up and managing HACCP teams

8.6.1 Selection

Separate teams were set up for each of the production lines. Team leaders were drawn from the microbiology team. The core team consisted of the following:

- microbiologist (team leader)
- one of the engineering team familiar with the design and operation of the production line
- a member of the Quality Assurance (QA) department or an individual with relevant QA experience
- the production line manager in charge of day-to-day operations
- a member of the research and development (R&D) team.

The inclusion of someone from the R&D team was felt to be important partly because R&D had experience of the product range for a particular production line, and partly because, being one step removed from day-to-day production operations, such team members could bring a fresh perspective to team discussions. The inclusion of engineering and R&D staff also proved useful in dealing with those hazards requiring alternative solutions not encountered in the day-to-day running or repairing of existing equipment.

To this core team were added temporary team members brought in to analyse a particular process stage. These temporary members were usually the relevant line operators with the greatest experience of running the relevant process equipment. Other temporary team members included staff from the manufacturers of line production equipment, especially when the equipment was new to the company. Involving equipment suppliers helped to ensure that all problems were highlighted and that the team was able to utilise the supplier's experience of operating issues in other companies.

At any one time HACCP teams numbered a maximum of five or six, although some teams were occasionally larger. In practice, keeping teams to this number worked well, allowing a full discussion and contributions from all team members, but without the meetings becoming too long or unmanageable. To begin with, HACCP teams also had a facilitator, also drawn from the microbiology department. These facilitators were responsible for recording the key points of the discussion and keeping the action plan up to date. Such support allowed the team leader and members more freedom to discuss the key issues.

As experience of team management and membership increased, the need for facilitators decreased, and they were not used for some of the later HACCP teams.

The selection of team members can be difficult, particularly as those required are the most knowledgeable about a process and therefore in greatest demand for the day-to-day running of the production line or a particular piece of equipment. However, without the right core team members from the start of the study, or the inclusion of temporary team members in the analysis of a particular production stage (as required by experience and expertise), HACCP analysis will be compromised from the start. One problem in selection was the tendency of some managers to push themselves forward with comments like ‘I can answer all the questions relating to issues for that piece of equipment’ or ‘the operator’s too busy, I’ll cover these areas’. It is important that this is resisted as the operator knows the equipment best and as such is essential to team discussion.

8.6.2 Preparation and training

Team leaders attended courses at the Campden & Chorleywood and Leatherhead Food Research Associations, reinforced by subsequent in-house training by the microbiology team. The in-house training included practical exercises to help team leaders prepare for the experience of HACCP planning. Once selected, team members were given a two-hour introduction to HACCP principles by members of the microbiology team. This introduction proved important in explaining their roles to the various team members and motivating them to contribute. The introduction was then used to move straight into a preliminary discussion of the hazards associated with the production line in question. This discussion was used as a brainstorming exercise with all team members encouraged to participate. The purpose of the discussion was partly to start the process of hazard analysis, partly to motivate the team by highlighting the significance of their work in protecting consumer safety, and partly to get all the team members contributing and starting to work together. This initial hazard analysis was then revisited and refined as each stage in the production line was analysed in detail. In practice, this approach proved very successful in introducing the first HACCP teams to their task and starting the process of HACCP analysis and design. Guideline documents such as the Campden Technical Manual no. 38,[1] WHO[2] and Codex[3] guidelines were used as training materials and models for the HACCP planning process.

A key element in preparation was the quality of information on the production line under investigation. Team leaders asked engineers to provide line layouts and detailed drawings in advance. Drawings proved particularly useful in helping the team to understand a particular process stage or piece of equipment. In this respect, it was important for team leaders to ensure that all the team members understood the detail in the drawing and were able to picture the actual piece of equipment being described on the production line. Team members were encouraged to make presentations about a particular process stage as a way of getting to know unfamiliar equipment. Frequent visits to the line or equipment were sometimes required to reinforce understanding. In some cases, an actual piece of equipment was brought to the meeting itself. On one occasion, the use of a scale model proved very useful in assessing a process, for example in determining where and how operators' intervention was required during the process. This material proved essential in supporting the presentations made by relevant line staff about a particular process stage to the HACCP team.

A final essential ingredient in effective preparation was that by the team leaders. To be able to initiate and guide discussion effectively, team leaders needed to have made their own preliminary analysis of hazards, and to be familiar with the production lines being analysed. This preliminary work included analysing relevant customer complaint data, e.g. to isolate potential problems, and assessing current production problems, e.g. points at which products or parts on the line needed to be 'quarantined' while a quality or production problem was being resolved. This initial research helped team leaders to anticipate key issues and keep the study flowing smoothly. The quality of this preparation was critical to the ability of team leaders to run teams successfully. New team leaders were also fully briefed by those leading the first teams and, where appropriate, mentored by their more experienced colleagues.

8.6.3 Team management

An early problem in managing HACCP teams was ensuring that all team members were motivated to contribute and allowed to do so fully. There were a number of problems to overcome, particularly in involving line operators in meetings. It became clear that, on some occasions, line managers inhibited line operators by their presence. Some operators were wary of admitting that they were not aware of a hazard or of mentioning problems with operating machinery they may not have brought to the attention of a manager. This fear could only be overcome by setting appropriate ground rules from the start, particularly in encouraging a full contribution from all team members and a willingness to be critical and honest about working practices in the interests of improving food safety.

A particular problem in involving line operators was an initial suspicion and cynicism about membership of a HACCP team. Some attended reluctantly only because they had been told to do so. In particular, they came to meetings with the assumption that, having not been consulted in the past, they would not be listened to or their suggestions acted on. Team leaders overcame these reservations by explaining the purpose of HACCP analysis and pointing out the importance of contributions from all team members, particularly line operators who were most familiar with production operations. Some of the most cynical line staff then became some of the most enthusiastic participants, suggesting improvements that were subsequently implemented and are still used on production lines today.

There were, however, also occasional problems to overcome in managers' attitudes. Some managers were sometimes unwilling to accept problems highlighted by line operators. On one occasion, indeed, a manager had to be asked to leave a team meeting temporarily because he would not accept an operator's analysis of a potential problem. Further analysis revealed that a potential hazard existed and that remedial action was required. More generally, managers with more traditional attitudes found taking part in a HACCP study difficult, having been used to a more prescriptive management culture of being told what to do. It took time for them to get used to analysing problems and suggesting solutions for themselves, responding proactively rather than passively.

It was essential for all team leaders to ensure that even the most basic questions were asked. Even when the answer was known, asking an open-ended question sometimes led to new and important areas of discussion. An important rule for team leaders was that nothing should be taken for granted and everything must be challenged. It was sometimes tempting, for example, to rush through a step in the process because of lack of time or an impending break (for example, for refreshments). Ensuring that each step was fully analysed depended on the ability of the team leader to go through all the potential issues systematically and to check the views of all the team members before moving on.

Meetings were generally kept to no more than two to three hours' duration to ensure that team members did not become too tired to contribute fully. Punctuating meetings with supplier presentations and line reviews was also helpful in keeping up enthusiasm and creativity within the team. As with any team problem-solving meeting, it was not uncommon for discussion to go off at a tangent, for example in identifying hazards for other production lines or picking up quality issues. A key skill for team leaders was in ensuring that such issues raised were logged for separate discussion and the meeting brought quickly back on track. As a result of team member availability it was not always possible to follow each manufacturing line sequentially, e.g. by starting with ingredient receipt or batching. In this case, setting a clear agenda and timetable to cover all process steps at some point was essential, with particular attention given to the links between steps in the production line.

8.7 Prerequisites

Before the HACCP teams could begin to design a HACCP plan for a production line, it was necessary to analyse the prerequisite systems in place at Kitt Green. These included such areas as supplier quality assurance (for raw materials), sanitation and pest control, traceability and product recall systems, and plant maintenance (for example, of sterilising equipment). Given the nature of the production process and hazards involved, the first and last of these proved the most important.

The Kitt Green site already had a strong system for supplier quality assurance. Suppliers were audited annually by a separate vendor improvement team. Depending on the type of raw material and supplier history, raw ingredients were approved on the basis of a certificate of conformance to specification, or sampled for physical, microbiological and chemical hazards. As part of the HACCP study, all the suppliers were re-audited and an improved sampling regime put in place for high-risk raw materials.

The other major area for analysis was the relevant production line equipment itself and accompanying operating procedures. It was here that the main areas for improvement were found. The main hazards in sterilisation lie in an often complex mix of product and process variables that influence the effectiveness of sterilisation. Analysing this mix at each step in a production line, in relation to each product type, constituted the main work of the various HACCP teams. In many cases this meant looking in detail at weighing, filling and mixing processes and equipment, for example to check their accuracy and efficiency. While small deviations in the performance of any one of these might not constitute a hazard, a combination of such deviations did have the potential to reduce the effectiveness of the sterilisation process.

Preliminary analysis of some production lines by the relevant HACCP team uncovered some inadequate equipment and procedures. These needed to be dealt with as a prerequisite to effective HACCP implementation. Various kinds of problem were uncovered. In some cases, equipment was found to be poorly designed, making it difficult for staff to monitor, adjust or maintain it. A programme of equipment redesign and upgrading was begun to resolve these problems, prioritising those that were selected as CCPs. Equipment suppliers were brought in both to analyse equipment and to suggest improvements. This programme allowed a reassessment of maintenance procedures which were also improved so that potential problems could be more easily anticipated and dealt with before they might impact on safety and quality.

HACCP teams also uncovered some poorly designed operating procedures which line operators struggled to understand and which were ambiguous or difficult to implement in practice. These needed to be rewritten to make them clearer and more user-friendly for the relevant staff. This process involved talking through the procedures with the staff themselves and, where possible, using their own wording for the procedures. Procedures were broken down into a series of simple steps which could be followed more easily. New procedures were then reinforced by suitable operator training which emphasised the purpose of such procedures and their importance for food safety.

On other occasions, it became clear, when operators were asked by the HACCP team to explain a standard procedure themselves, that they had their own sometimes inaccurate interpretation of the procedure. These problems could sometimes be traced back to the practice of training operators ‘on the job’, that is by working alongside a more experienced colleague. Operators were not always aware of the significance of what they were doing, and had not always had a procedure explained in sufficient depth to them. A programme of retraining was initiated, emphasising not just the procedures but their purpose and role in product safety and quality. This was combined with a review and improvement of some of the operating procedures themselves to minimise the scope for misinterpretation.

8.8 Hazards and CCPs

Hazard analysis for canned products is, in some respects, simpler than for some other food products. The hazards in canning are generally well understood, as well as the basic processes required to eliminate them. However, this is also where the danger lies in that complacency can creep in. As continued, sporadic food poisoning incidents involving canned foods show, mistakes still occur, making HACCP systems as important for the canning industry as for any other food processing operation.

The first HACCP teams tried to rank hazards on a scale of 1 to 3, based on severity and probability of occurrence. In practice, this proved cumbersome and unhelpful and was soon abandoned. All hazards posing a significant health risk were given equal weighting. In practice, this made the work of HACCP analysis easier and did not lead to any later problems in the design of each HACCP system.

HACCP teams first established which of the process steps constituted a CCP using the common-sense maxim of whether that step was essential to eliminate a potential hazard, or whether a later step in the production process served that function. Later, some of the HACCP teams made use of the CCP decision tree outlined in the HACCP manual produced by the Campden & Chorleywood Food Research Association (Technical Manual no. 38). In practice, this method proved cumbersome to use, and teams reverted to the earlier practice with no loss in the quality of the HACCP systems they designed.

Given that the requirements for controlling hazards in canning are well understood, establishing critical limits for CCPs was relatively straightforward. The work of the HACCP teams in this area was also helped greatly by existing systems at Kitt Green. Under existing procedures, all products, both existing and new, had been scrutinised by the microbiology team and detailed specifications governing product formulation and precise process requirements established in each case. These were reviewed and refined by the HACCP teams in identifying both CCPs and appropriate critical limits.

8.9 Implementation and verification

HACCP systems were implemented gradually, with each production line treated separately. In each case, CCPs were set up in a rolling programme over a number of weeks. The implementation process at Kitt Green was greatly facilitated by two factors. One was the existence of a well-established ISO 9000 quality management system, with tried and tested process monitoring and supporting documentation. This system provided a strong foundation on which to build the relevant CCP monitoring and recording procedures for each production line. Staff were already familiar with monitoring production and inspecting performance records to look for problems.

However, the most important single factor in a smooth implementation process was the involvement of line operating staff in the original HACCP teams. This proved to have a number of sometimes unexpected benefits at the implementation stage. In some cases, the line operators brought into the HACCP teams to help analyse a particular process step were, if that process step was designated a CCP, the best candidates for CCP monitoring. In these cases, CCP monitoring staff already had the knowledge and motivation to carry out their task effectively. Even when this was not the case, such staff were able to use their practical experience to help design procedures and documentation which their line colleagues could use easily and effectively. In some cases, they were also able to assist in the training process and act as mentors for CCP monitoring staff. Equally importantly, they acted as HACCP champions on the shop floor. Having the respect and trust of their colleagues, they were in the best position to explain the concept of a HACCP system and motivate their colleagues to support the implementation process.

However, the HACCP management team recognised from the outset that the process from HACCP design to implementation could only be a starting point. The key to the long-term success of HACCP systems at Kitt Green was seen to lie in effective verification. It was assumed that there might inevitably be both weaknesses in the original design of each HACCP system and weaknesses in implementation. Addressing these potential failings was seen as critical.

At Kitt Green two separate verification systems were established. The first involved line managers verifying CCP monitoring records after they had been signed off by the appropriate CCP monitor. The second was the creation of a sterilising audit team, popularly referred to as sterilising inspectors, reporting directly to the microbiology department and independent of production. The inspectors were selected from the most experienced and able operators on a production line, usually responsible for sterilising operations. Inspectors were given the task of auditing all CCPs by sampling, checking and countersigning CCP monitoring data. They were also given the responsibility of checking whether CCP monitors had the right knowledge and understanding of their duties, and questioning them about any problems or non-compliance incidents. Along with maintaining an effective surveillance regime the sterilising inspectors were acknowledged experts in their own right, able to provide round-the-clock on-the-spot advice to all production operators. They also had responsibility for providing periodic independent checks that equipment was functioning properly. As an example, they provided an independent check of water chlorine levels which were then compared against on-line monitors. They were also responsible for annual checks on the temperature distribution within sterilising chambers and vessels. Tests involve inserting temperature loggers into the chambers and comparing the profile within the chamber to that temperature monitored on the operator’s work station. Inspectors have the authority, based on their practical experience of production operations and problems, to suggest extra checks or improvements to monitoring of production operations. They were also given the power to quarantine product and assume authority for managing a food safety incident if a serious problem arose.

In addition to these verification systems, the HACCP management team also set up a statistical process control (SPC) analysis regime which, together with regular sampling of both unfinished and finished product, was used to spot any emerging problems and so check that the design and implementation of each HACCP system was effective. If a non-compliance incident is recorded during CCP monitoring, or a problem identified by a sterilising inspector or through SPC, for example, a review is immediately undertaken and any lessons learnt in improving the design or implementation of the HACCP system for a particular production line.

Over the past eight years Heinz has developed a process of grading all non-compliance incidents as critical, major and minor (as with ISO 9000). A critical non-compliance incident is one that could put the business at risk (i.e. a food safety risk). An example would be the failure to quarantine and destroy 'rogue' or 'non-controlled' containers, that is containers that have either fallen or been removed from conveying equipment. A major non-compliance incident is one that results from a significant deviation from ISM requirements that could cause a consumer complaint. A minor non-compliance incident would be an event that fails to meet the ISM, its support procedures, company or departmental procedures but poses no harm to the consumer. A key target for the management team of each production line is to ensure that they do not receive reports of any critical or major non-compliance incidents. If a critical non-compliance incident is identified, the production management team has to present the reasons that the non-compliance incident occurred to senior managers and what measures the team has put in place to prevent its recurrence. This requirement has driven real improvements in such areas as operator training and support, and equipment modifications, as ways of ensuring a very robust system and the control of all critical points.

8.10 Keeping up to date

A number of systems have been put in place to ensure that HACCP systems are kept up to date. All staff involved in the running of HACCP systems for particular production lines have been issued with training 'passports'. These are records of all the training undertaken by a member of staff. The sterilising inspectors conduct annual training programmes for all operators, managers and sterilising controllers, after which their training passport is approved and they are certified, for example, to continue operating a particular piece of equipment. Approval only takes place after a verbal examination by the sterilising inspector about the equipment and relevant procedures, including the appropriate action to take if, for example, a critical limit is exceeded. If operators are unable to answer key questions satisfactorily, they undergo further training. Until they are approved, they are not allowed to operate CCPs and can only operate other equipment under supervision. New operators are given training and then have to work alongside a trained operator for a minimum of four weeks. They then receive final training and a verbal test from the sterilising inspector before being approved to operate equipment independently. Such training helps to keep staff up to date with any changes and sustains their commitment to their HACCP duties.

Any process or equipment change is now automatically the subject of an independent HACCP review. Engineering staff responsible for such changes are all given training in HACCP principles and, together with a member of the microbiology team and the production line manager, they review any change against the existing HACCP plan for the affected production line. Any new hazards and CCP issues are agreed and the HACCP plan changed accordingly. Where required, operating procedures are changed and retraining organised. If a piece of machinery is new or requires substantial modification, the equipment supplier and operating staff may be called in to assist in analysis. Techniques such as failure mode and effect analysis (FMEA) are used to work through a piece of equipment's potential weaknesses and how they can be overcome. Only once the analysis is complete and the HACCP plan suitably revised can the equipment change be authorised by both microbiology and engineering personnel.

Changes in product formulation are also subject to HACCP review. This review begins with a kitchen recipe where potential hazards are defined. Critical process parameters are then agreed and CCPs reviewed and incorporated into provisional process sheets as part of the detailed planning process. A decision would be made at this stage as to whether a complete HACCP review is required or, depending on the degree of similarity with existing products and processes, an existing HACCP study can be modified. The recipe and each step in the production process is then signed off by a member of the microbiology management team. This approval allows the product development department to take the recipe into the factory. A number of trials would then follow, and then an extended run to ensure that all CCPs were under control. At each trial a series of tests would be conducted on CCPs to verify that they were working, and that there are no issues in scaling up the process to full production. Providing that there were still no outstanding issues, the microbiology and product development teams would sign off the final approval, allowing full production to go ahead.

All suppliers of raw materials to the Kitt Green site are now expected to have a fully implemented HACCP system. HACCP systems within new companies are audited by a member of the vendor audit team. Subsequent annual audits are undertaken by the vendor audit team as part of their supplier quality assurance programme. Members of the team receive appropriate HACCP training and use the original audit as a basis for further audits. The effectiveness of supplier HACCP systems is tested by recording any non-compliances from the regular sampling and checks on raw material coming into the factory, particularly for high-risk materials.

The entire HACCP system for each production line is reviewed every three years on a rolling programme with a number assessed each year as they come up for triennial review. This review provides an opportunity to assess all the innovations and changes (e.g. alterations agreed because of line improvements, or in response to a critical or major non-compliance) made in the interim. Each review is undertaken by members of the original HACCP team for the production line together with some new team members, sometimes from other HACCP teams. Including new team members brings in a fresh perspective and new ideas.

8.11 Benefits and drawbacks of HACCP implementation

The most obvious benefit of HACCP implementation to Kitt Green over the years has been a steady reduction in the number of safety and quality problems, leading to a drop in customer complaints and improved productivity. The HACCP system for each production line has also allowed operating staff to identify and tackle potential problems much earlier than before, when there was greater reliance on material and product sampling to spot errors. This more rapid response has led to less product having to be quarantined, whilst a problem is investigated, and increased line utilisation as problems are dealt with more promptly.

HACCP implementation, therefore, has brought significant long-term financial benefits to Kitt Green. These have more than offset the short-term drawbacks which relate to the time and resources that a HACCP programme involves. To be successful, it requires the involvement of key personnel who need to be taken away from production operations for a significant period. The Kitt Green experience suggested that a HACCP study could take anything from 40 days (average 6.5 days per person for a HACCP team of six) for a small study (for example, a small-scale filling and sterilising operation) to 160 or more days (23 or more days per person for the same size team) for a review of a complex line with numerous batching, filling and sterilising options. This time does not include other commitments such as the preparatory work of the HACCP management team or the preparation required by the individual HACCP team leaders.

In the longer term, however, the experience of HACCP planning and implementation has brought even broader benefits. The process of consultation in HACCP design and increased responsibility in CCP monitoring, for example, has encouraged production staff, from line operators upwards, to adopt a more proactive attitude to their work. Instead of expecting more senior staff to provide solutions to problems, staff are more ready to analyse the way they work for themselves, identify problems or improvements and suggest their own solutions.

The HACCP analysis of each production line also provided a unique opportunity to analyse each piece of equipment in real detail. Identifying CCPs allowed HACCP teams to focus attention particularly on the most important equipment and its key features. The spin-off benefits of such analysis was a much better understanding which has led to a better maintenance regime, quicker fault identification and repair, improved operating procedures and, in some cases, to equipment redesign. The results have been significant decreases in production line down-time while repairs are made and corresponding increases in line productivity.

In these ways HACCP implementation has provided both an analytical tool and a more proactive work culture which have prompted continued improvements to safety, quality and competitiveness. The foundation laid by HACCP systems has been particularly important for Heinz's continued competitiveness at the beginning of the new millennium. As customer expectations of product quality have risen, product specifications have become more demanding and competition has intensified, the Kitt Green site found its ratio of non-conforming to conforming product increasing rather than decreasing over time. Improvements to the production lines as prerequisites to HACCP implementation have helped to reverse this trend.

HACCP implementation has also laid the foundation for a new development which has continued these early improvements: process analysis. Process analysis is simply a detailed review of every aspect of a production line. Its aim is to identify the critical points governing the line's productivity and final product quality, to establish key performance indicators for these critical points, isolate any weaknesses they may have and make improvements to both equipment and operating procedures. Building on the experience of HACCP analysis, process analysis teams have been assembled for each production line, with a team leader taken from the senior production staff, together with team members taken from the quality department, engineering and production line operatives. A particular emphasis, based on the experience of HACCP analysis, has been on consulting production line operators for their views and suggestions on the process steps for which they are responsible, as well as bringing in equipment suppliers to help analyse the strengths and limitations of particular pieces of equipment. As with HACCP analysis, all key equipment has been analysed in detail for its quality of performance. With the benefit of the HACCP experience, a more realistic time scale has been set, with nine months allowed for the complete analysis of the more complex production lines. This process has carried on the legacy of HACCP analysis in improving understanding and control of processes, and has already resulted in significant improvements in quality and productivity, reversing the trend in the ratio of non-conforming to conforming product.

The development of such initiatives as process analysis has shown the more unexpected side of HACCP as a system. It is not just a safety management tool but a new, more proactive way of working which allows businesses to understand and control their operations much more effectively.

8.12 References

1. *HACCP: A Practical Guide*, 2nd edn, Campden Technical Manual no. 38, April 1997.
2. F.L. BRYAN *Hazard Analysis Critical Control Point Evaluation: A Guide to Identifying Hazards and Associated Risks with Food Preparation and Storage*, World Health Organisation, Geneva, 1992.
3. *Codex Guidelines for the Application of Hazard Analysis Critical Control Point (HACCP) Systems*, adopted by the 20th Session of the Joint FAO/ WHO Codex Alimentarius Commission, 1993.

This page intentionally left blank

Part III

Regulation and training

This page intentionally left blank

9

HACCP enforcement in New Zealand

J. A. Lee, Food Assurance Authority, Ministry of Agriculture and Forestry, Wellington

9.1 Introduction

Use of hazard analysis critical control point (HACCP), based on the internationally accepted seven principles as promoted by the Codex Alimentarius Commission, is rapidly increasing in New Zealand. There are several reasons for this, including the activities of the two government agencies responsible for food administration in this country and the impact of market access requirements on the food export sector.

The Ministry of Agriculture and Forestry (MAF) is responsible for food administration in association with exportation of animal and plant products while the Ministry of Health administers the requirements covering the domestic market. However, boundaries between the two ministries have not always been clear, particularly for those foods moving from an export production environment to the domestic sector. This has necessitated closer cooperation over recent years with the intent of delivering the safest food possible in the most cost-effective way, and this intention has progressed to a jointly agreed approach to food administration[1] depicted by the optimal regulatory model (see Fig. 9.1).

The optimal regulatory model primarily focuses on government setting the appropriate food standards, administering legislative requirements and approving necessary components of the system; food industries taking responsibility for food safety issues as part of their HACCP-based risk management programmes; and independent auditors verifying that industry has complied with requirements.

In line with the regulatory model, some food safety legislation in New Zealand has already been revised.[2] The Food Act 1981 has been amended to

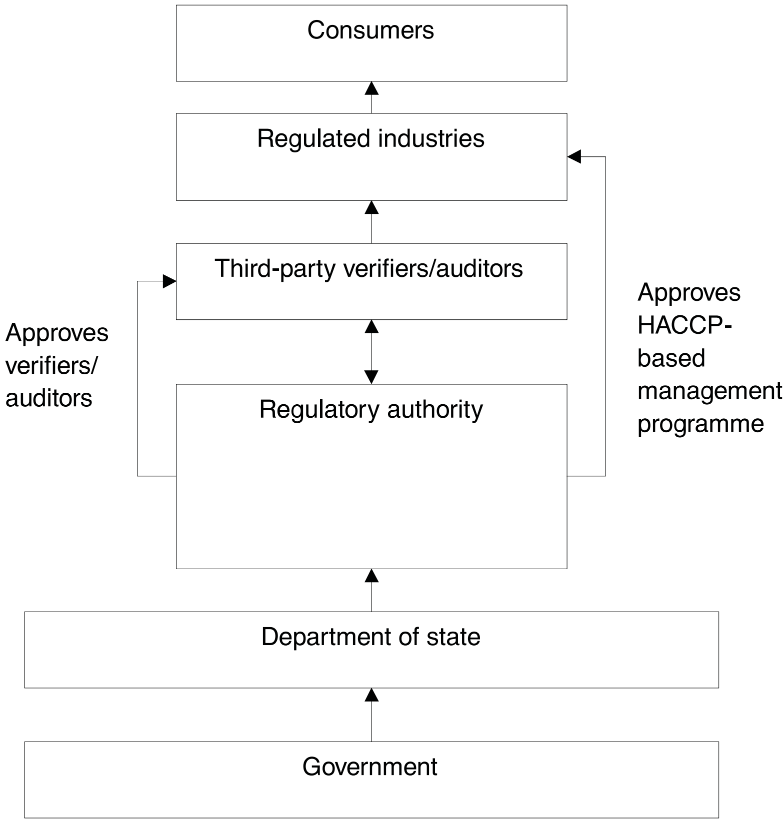

Fig. 9.1 Optimal regulatory model.

include HACCP principles as a requirement for food safety programmes. While this is still a voluntary option for the domestic food sector, administered by the Ministry of Health, it does give the food industry the opportunity to take on more individual responsibility for food safety and, in doing so, gain exemption from existing prescriptive food hygiene regulations.

Other legislation introduced on 1 November 1999 will see further advancement in application of the regulatory model, under the administration of MAF, which will focus on risk management programmes as a key component of the Animal Products Act 1999.[3] Risk management programmes will be HACCP based and will include the identification, control and management of food safety hazards and other risk factors such as hazards relating to animal health, risk factors affecting wholesomeness of the product and truth of labelling.

This chapter on HACCP enforcement will primarily focus on the activities and experience gained by MAF in enforcing HACCP principles in the export meat and seafood sectors in New Zealand.

9.1.1 Regulatory framework

Recent restructuring within MAF has resulted in the formation of a Food Assurance Authority (MAF Food). This authority has key objectives relating to food safety which include:

- promotion of food safety
- effectiveness and credibility in providing food safety assurance
- consistent application of food safety requirements
- provision of meaningful performance parameters for industry
- meeting international obligations
- influencing international standards.

MAF Food has the responsibility for setting and administering New Zealand standards for the export food sector, in particular those standards covering animal products and edible plant products. It provides food safety assurance to overseas markets with an increasing focus on HACCP. MAF Food also has a dedicated compliance and investigation group which maintains a schedule of compliance audits covering both government verification agency audit performance and industry performance to New Zealand and overseas market access requirements.

The MAF Verification Agency (MAF VA) is the part of MAF responsible for verifying that a particular industry sector is meeting food safety, market access and any other regulatory requirements on an ongoing basis.

9.1.2 Relationship with food industry

MAF has actively promoted and participated in a close working relationship with the food industry sectors that fall under its jurisdiction, for several years. This has proven to be extremely beneficial to both parties, providing a means of effective consultation over food safety issues, including agreement on particular food safety strategies. With these strategies in mind, MAF Food has committed increasing resources to facilitating HACCP implementation. This includes:

- national coordination activities
- development of regulatory/industry HACCP policy
- specialist technical advice
- development of generic HACCP plans, including a detailed literature review annexed to each generic plan – this provides relevant scientific information on the different hazards, their prevalence and the effects of key process steps
- provision of regional technical support
- international liaison.

Development of regulatory and industry HACCP policy has been driven primarily by a HACCP steering group facilitated by MAF Food and consisting of a mix of regulatory and food industry participants. With the aim of harmonising both the food industry and regulatory approach to HACCP in New Zealand, and using the Codex Alimentarius Commission's (CAC) HACCP guideline[4] as the recognised international base upon which to build, this group has provided an excellent forum for discussing HACCP issues. Issues that have benefited from such discussions have included:

- prerequisite programmes
- HACCP development and implementation
- HACCP training
- auditing HACCP plans
- use of templates/generic models
- market access issues concerning HACCP.

9.1.3 Voluntary versus mandatory HACCP

Voluntary uptake of HACCP has been actively promoted by MAF since the early 1990s. This was believed to be the most appropriate approach for the food industry sectors to use for the following reasons:

- production of a safer product
- gaining a better understanding and control of operations
- actively encouraging raw material suppliers to adopt a similar approach
- providing a firm base for the application of quality management systems
- improving product quality
- improving production efficiency and decreasing wastage
- becoming a more desirable supplier
- active participation in a changing regulatory approach to food safety assurance.

It meant that industry was able to control the degree of HACCP uptake itself and it was generally perceived that a voluntary approach would lead to better 'buy-in' than would a mandatory scheme.

Voluntary uptake, however, proved to be slow and it was not until 1994 that a noticeable increase in HACCP application was seen, being primarily driven by increasing consumer awareness in food safety, the influence of industry's own clients and impending overseas market access requirements such as those of the USA, with their implementation of HACCP for meat, poultry and seafood sectors.

Market access requirements have heavily influenced New Zealand's HACCP strategies from the mid-1990s. While the sanitary and phytosanitary agreement provided us with the opportunity to negotiate equivalent food safety programmes based on a continued voluntary application of HACCP, this was seen as an increasingly isolated position to be in. In fact, New Zealand was one of the few exporting countries that was not proposing mandatory implementation.

There were several other good reasons ultimately to move away from a voluntary HACCP environment. With no regulatory HACCP standard to work to, food industry sectors were exposed to diverse client demands that could not be counteracted by reference to a generic national standard based on New Zealand conditions. There was widespread potential for inconsistent implementation within and across food industry sectors. The role of MAF VA was ill defined and, as a result, there was a reluctance from both industry and MAF VA to provide adequate resources to verify HACCP plans. The opportunity to reassess good hygienic practice in light of what HACCP could offer was compromised.

Ultimately, the export meat and seafood sectors found that they had already made considerable investment in HACCP under a voluntary scheme and had achieved considerable milestones, such as the implementation of the national microbiological database (export meat) and the HACCP competency standards (export meat and seafood). These initiatives would not be lost under a mandatory HACCP environment, and the concerns outlined above could begin to be addressed. Thus the voluntary approach to HACCP was not pursued as the most appropriate option and the decision to operate in a mandatory HACCP environment was endorsed by industry standards councils.[5]

A mandatory HACCP environment meant that new policies had to be developed, particularly to address issues such as equity across the industry sectors, definition of the regulatory interface and adequate resource capability. Achieving consistency in implementation of mandatory HACCP requirements was the desired outcome.

9.2 Developing HACCP assessment

Under a mandatory HACCP programme, the requirement for HACCP assessment by the regulator is an integral part of any regulatory specification. However, its development is dependent on the presence of two key factors, the first being a clear, relevant and meaningful HACCP standard and the second being enough adequately trained staff.

9.2.1 Roles and responsibilities

MAF Food, as the standard-setting body of MAF, is responsible for developing and maintaining relevant HACCP standards in close consultation with the food industry sectors concerned, in order to ensure that they are meaningful, practical to apply and deliver the desired food safety outcomes. The standard-setting process has therefore involved extensive consultation with various food industry personnel, involving them directly in HACCP standard development and updates through participation in regulatory/industry working groups. These working groups are responsible for developing the initial draft standard which is then widely circulated within MAF, the food industry sector and other stakeholders for comment. Finally the standard is jointly signed by MAF Food and the relevant food industry council, resulting in an industry agreed standard.

Once this standard is implemented, MAF VA is responsible for ensuring that the food industry is applying and implementing the HACCP requirements as per the standard, i.e. MAF VA carries out the HACCP assessment. There is another level of assessment that also exists within the MAF structure. MAF Food's Compliance and Investigation Group assesses the performance of MAF VA on an ongoing basis and this group will include an assessment of how the HACCP standard is being delivered and also MAF VA's ability to audit it effectively. Direct feedback can then be given to MAF Food on the ongoing suitability of the HACCP standard and whether any changes are necessary.

9.2.2 Developing the skill base: HACCP competencies

In line with HACCP uptake by the food industry sectors, there has been the inevitable and increasing need for HACCP training and competencies to be developed, not only for food industry personnel but also for relevant regulators within MAF. Ideally HACCP training of both parties should be developed in unison, in order to obtain the most consistent results in terms of application of the HACCP standard.

The export meat and seafood sectors have been proactive in addressing the HACCP competency issue by linking into existing strategies developed within New Zealand to upskill the general population. This approach has meant that these industry groups, in consultation with MAF Food, have developed their own industry-specific HACCP competency qualifications which have also been available for regulatory staff to use.

The HACCP qualifications currently available[6] have focused on different levels of competency in HACCP application and implementation, e.g. one competency standard for coordination of the development and verification of a HACCP plan for a meat or seafood processing operation, and another competency standard for supervision of HACCP at the workplace.

HACCP-competent people in the coordinating role are required to underpin the application of HACCP specifications in two primary ways. Where no HACCP plan is required, i.e. there are no critical control points (CCPs), the HACCP-competent person has to confirm this with appropriate documentation supporting the decision-making process. This documentation must be available for regulatory audit. Where a HACCP plan is required, the HACCP-competent person has responsibilities for development, implementation and the ongoing verification of the HACCP plan.

From a regulatory perspective, MAF requires that all MAF VA personnel auditing HACCP plans, and compliance assessors auditing MAF VA, have the appropriate HACCP competency standard covering development and verification of HACCP plans.

The competency standard for supervision of HACCP, though based on a lower skill level, has been valuable in providing competency for supervisors who are routinely expected to review HACCP records, especially CCP monitoring records. This supervisory standard has become part of the HACCP requirements for the seafood export industry to assist in HACCP review requirements and is particularly useful for small premises that often do not have a person with the higher HACCP competency qualification readily available.

Applicants for HACCP competency standards are assessed against stated outcomes using a standardised check-list, and are deemed ‘competent’ when they have successfully met all requirements of the standard. The assessment may be a combination of written, oral or practical evidence which, together, gives the assessor the confidence that individuals have met the outcomes stated in the competency standard. Industry staff may be assessed against a HACCP plan that they have developed or that someone else has developed, as long as they can clearly explain how the HACCP plan was developed and how it can deliver the stated outcomes. In the case of the regulatory staff being assessed, their HACCP skills are tested against an ability to audit such a plan effectively, knowing what components must be present and what the plan can deliver.

Comparing HACCP competency standards with HACCP training courses available, the main difference between the two is that the competency standard enables the individual’s ability to deliver certain skills in relation to HACCP to be thoroughly assessed. A training course often leaves an individual’s abilities untested. Thus the trained but unassessed person may go back to the workplace without the ability to develop and implement a HACCP plan that will realistically meet the requirements and achieve the food safety outcomes.

9.2.3 Developing a HACCP standard

A HACCP standard is required once the decision is made to mandate HACCP. The standard[6] is developed in consultation with industry, using the CAC HACCP guideline[4] as the starting point. The expectation is that the food industry has already established good hygienic practice prior to the development of the HACCP plan(s) for their operations and can effectively demonstrate this with documented systems. These systems are known as ‘prerequisite programmes’ (PRPs).

PRPs, based on good hygienic practice and meeting individual countries’ food legislative and market access requirements, are the internationally recognised norm to an otherwise overwhelming task of hazard identification and analysis of everything associated with the food. However, there is considerable benefit in returning to those PRPs at a later stage to ascertain what they deliver in terms of contribution to achieving food safety outcomes directly associated with the product. In fact, in some cases, PRPs or their equivalent have not been established adequately as effective documented systems by a food business prior to HACCP implementation, but this may have been ignored to some degree, in favour of promoting HACCP. In these cases, HACCP progress is inevitably hindered by the inadequate performance of those PRPs.

Common PRPs present at food premises in New Zealand include, but are not limited to, the following:

- sanitary design
- potable water quality
- sanitation and clean-up procedures for edible areas and food contact surfaces (pre-operational and operational)
- personal hygiene (protective clothing requirements, personal equipment and use of amenities)
- training
- hygienic dressing or processing (dressing/processing techniques and procedures, cleaning and sterilisation of equipment)
- food contact materials (specifications, handling and storage)
- repairs and maintenance of equipment
- control of chemicals
- vermin control
- waste management
- condition and welfare of stock
- handling and disposition of detained and non-conforming products.

The HACCP standard[7] applies to those premises where any food safety hazard(s) that may be reasonably associated with each product and process exists. Where no food safety hazards are identified, the premises is expected to reassess the product(s) and process(s) whenever significant changes occur. Examples of 'significant change' include change to product, intended use of product, process, premises and food safety objectives. Where one or more food safety hazards and, consequent to hazard analysis and CCP determination, one or more CCPs are identified, a HACCP plan is required.

New Zealand experience has shown that from a practical point of view, the internationally recognised seven principles of HACCP are insufficient to produce a meaningful HACCP plan by themselves. Another four elements have therefore been added to these principles to give eleven essential elements for each HACCP plan. These four elements are:

1. Scope of the HACCP plan.
2. Description of the product, its intended use and the intended consumer.
3. Food safety objectives.
4. Description of the process.

These are followed by the seven essential principles of HACCP:

1. Hazard identification and analysis.
2. Identification of the CCPs, if any, needed to control or eliminate those hazards found to be unacceptable in relation to food safety objectives set.
3. Critical limits that have been established for each CCP.
4. Monitoring procedures for each CCP.
5. Corrective action procedures (including measures to restore control, deal with affected product and prevent recurrence), developed for any non-compliance with critical limits.

6. Verification procedures including validation, ongoing review/audit and revalidation when significant changes occur.
7. Documentation and record keeping appropriate to the above elements.

Scope

Defining the scope of a HACCP plan is an essential element of a HACCP plan because it provides a clear message as to what the plan incorporates. It will inform the reader (both user and auditor) of the following:

- what the HACCP plan covers and what it does not, i.e. what can be expected to be covered elsewhere by PRPs
- whether the application of the HACCP plan is only for food safety or is wider than food safety
- the boundaries of application of the HACCP plan, i.e. the start and end point of the process, thus also defining the scope of hazard identification.

Description of the product, its intended use and the intended consumer

Describing the product, its intended use and the intended consumer is an essential element of a HACCP plan because it provides information needed to make decisions on expected food safety outcomes for the product in relation to the intended consumer. This will increase in importance as applied risk analysis gives us more information in the future about the relationship between individual hazards and their effect on the consumer population.

Food safety objectives

Food safety objectives are considered one of the most important elements within the HACCP plan. They provide a measurable 'food safety' outcome for the product, often in qualitative terms as not enough information is available to associate the level of control of hazards within a HACCP plan to the level of risk to the consumer population, especially with raw foods. The *Guide to HACCP Systems in the Meat Industry*[6] defines a food safety objective as 'A statement based on a risk analysis process, which expresses the level of a hazard in a food that is tolerable in relation to an appropriate level of consumer protection. When justified by either a qualitative or quantitative risk assessment, the food safety objective should express the level of the hazard as its maximum tolerable concentration and/or frequency.' Thus food safety objectives give new meaning to internationally accepted phrases seen in many a HACCP guideline, text or HACCP standard such as 'unacceptable levels of hazards' (or conversely 'acceptable levels'), referred to in hazard analysis and CCP determination, and 'critical limits'.

Critical limits deliver directly or contribute cumulatively to a certain food safety outcome, i.e. the food safety objective. An example of a direct relationship between a critical limit and a food safety objective can be shown with a food safety objective relating to metal detection, e.g. to remove metal from the product to a specified target level. The targets are the critical limits and these are the specifications of the metal detector.

Critical limits that contribute cumulatively to achieving a food safety objective are often associated with a microbiological food safety outcome. Consider the following two examples of food safety objectives for a slaughter and dressing process and a canning process respectively:

1. To minimise transfer of microbiological hazards from the gastrointestinal tract and the hide to the carcass, and their redistribution, to levels not exceeding specified microbiological targets.
2. To ensure commercial sterility of product by destruction of all viable micro-organisms of public health significance as well as those capable of reproducing under non-refrigerated conditions of storage and distribution.

In both cases, critical limits are measurable visual criteria at one or more process steps, e.g. visual observations of operators at key hide removal steps (slaughter and dressing), and seaming under vacuum and heat processing steps (canning). Achievement of these critical limits collectively within each process leads to the food safety objective being achieved for the product.

Food safety objectives have been readily accepted by the New Zealand meat and seafood export industry as an integral part of their HACCP plans but other food industries have yet to be exposed to this concept and the value that it can offer to application of HACCP. Internationally, the concept also is under consideration particularly in association with the determination of parameters surrounding equivalency agreements between trading countries.

One of the most successful applications of food safety objectives in New Zealand has been in association with the implementation of a standardised microbiological monitoring programme[8,9,10] for all US-listed bovine and ovine meat slaughter premises and packing houses. This programme enables the participating premises to use summary data so that they can individually assess their microbiological performance on a premises-by-premises basis and in relation to the national performance. These data are often used as a basis for establishing individual microbiological targets for HACCP plans for slaughter and dressing.

In summary, the main benefits for industry from application of food safety objectives[11] include the provision of:

- a description of the expected/desired extent of control of foodborne hazards resulting from application of a sanitary measure
- a target that ensures that HACCP plans are outcome focused, achieve expected food safety goals and have inherent flexibility
- an expression of due diligence by reflecting expectations with respect to specific processes
- clear identification of any limitations that a HACCP plan may have in terms of what can be achieved in controlling hazards.

This is a considerable advance on stating that a HACCP plan will deliver ‘safe’ food without qualifying what ‘safe’ actually means.

Description of the process
A description of the process is an essential component of the HACCP plan. It may be done in conjunction with hazard identification and analysis or separately. The main thing is that it is done thoroughly and accurately. It provides a reality check for those involved directly or indirectly with the process, reinforcing what is actually occurring. The accurate process description will remind the HACCP team of all factors to be considered.

Validation as part of the verification process
In New Zealand, validation of the HACCP plan is seen as the essential first part of the industry's verification programme and is specifically mentioned as part of the verification element in the HACCP standard. Validation is the responsibility of the food industry and must be under the guidance of the premises' HACCP-competent person.

Validation consists of two components: first, the initial confirmation that the HACCP plan is complete in that it has satisfactorily covered and documented all the required elements, and second, that the implemented plan will achieve food safety objectives. Validation has been a difficult process for regulators to define clearly, given the wide range of processes, and for industry to understand. With this in mind, MAF has published guidance on validation,[6] including it as an integral part of comprehensive generic HACCP plans available on the Internet (http://www.maf.govt.nz) to assist in development of premises-specific validation procedures.[12]

9.3 Assessment of the HACCP system

9.3.1 Framework for carrying out an effective HACCP audit

In the current mandatory HACCP environment for the meat and seafood export industries, MAF has established audit requirements within the HACCP standard[7] for MAF VA audit personnel. At present, there are three types of regulatory audit that can occur in accordance with the HACCP standard:

1. An audit to recognise the validity of hazard identification and analysis where no HACCP plan is required.
2. An audit to recognise the validity of the HACCP plan.
3. An audit to ensure ongoing compliance with a recognised (and validated) HACCP plan.

At present, MAF VA personnel carrying out the 'recognition' audits are required to have the appropriate HACCP competency standard, a recognised audit qualification and technical and industry experience appropriate to the audit.[13]

MAF VA personnel undertaking compliance audits of 'recognised' HACCP plans currently do not need to have the HACCP competency standard but must have the audit qualification as mentioned above. This lack of a requirement to have any formal HACCP training or meet any HACCP competency standard when carrying out a compliance audit has led to some problems in the interpretation of HACCP plan deficiencies. The level of HACCP awareness among compliance audit staff is, however, currently under review and strong recommendations have been made to upskill these HACCP plan compliance auditors.

The HACCP plan audit focuses on effective control of food safety hazards. The depth of the audit will be determined by performance. However, the following outcomes are generally sought regardless of the frequency of the audit:

- determination as to whether all required elements are present in the HACCP plan and that they are addressed adequately
- determination as to whether the procedures are effective with respect to achieving acceptable food safety outcomes for the product/process on an ongoing basis
- determination as to whether actual events comply with validated documented procedures.

A recommended audit approach has been issued by MAF and is included in HACCP guides available to the industry. Essentially, the audit approach follows that suggested and outlined in ISO Standards 10011-1:1992[14] and 10011-3:1992[15] and includes the following main headings:

- decide the type of audit, e.g. full or partial, including the specifications against which the HACCP plan is to be assessed
- notify the auditee
- obtain information prior to the premises audit
- assess the pre-audit information (either on-site or off-site) and if necessary target specific concerns to be addressed prior to the audit or for further evaluation on-site
- select the audit team
- brief the audit team
- visit the premises and carry out the entry meeting
- carry out the audit; all observations and non-conformances should be acknowledged by the auditee
- carry out the exit meeting and deliver the conclusions of the audit, deciding how to accept corrective actions (if required) and how to verify those corrective actions
- write formal report.

9.3.2 Relationship of prerequisite programmes

It is essential that the auditor appreciates the intimate relationship that PRPs have to the HACCP plan and are prompted to investigate the performance of the PRPs *prior* to beginning the HACCP plan audit.

There are several ways that the auditor can obtain information about the performance of the PRPs. They should check which PRPs are present at each individual premises and determine whether these programmes fall outside the scope of the HACCP plan. PRPs are expected to be authorised by a responsible company person. There should be evidence of an ongoing acceptable level of compliance with the documented programmes from several sources, for example:

- ongoing monitoring records
- internal audit/review
- extrinsic audits
- non-conformance records.

The auditor also should examine records from a selected sample of PRPs deemed relevant to the HACCP plan under audit. The outcome from evaluating the PRPs may well determine whether the audit for recognition of a HACCP plan (initial audit) or compliance audit of a HACCP plan will continue.

9.3.3 Recognition of a validated HACCP plan

Under the current HACCP standard,[7] recognition of a HACCP plan that the premises has validated is the first requirement prior to implementation and, where relevant, prior to gaining access to overseas markets. The recognition audit is carried out by a MAF VA auditor with the appropriate qualification as mentioned in section 9.2. Recognition of the HACCP plan must start with an appreciation as to how effective the PRPs are, as discussed above. This is followed by evaluation of documentation comprising the validated HACCP plan, including evidence to substantiate:

- hazard identification and analysis
- CCP determination
- critical limit determination
- validation.

Essentially the auditor must be satisfied that all eleven elements required in the HACCP plan are present, that they have been applied in a relevant manner applicable to the product and process and that they have been validated appropriately in line with acceptable food safety objectives for the product. There must be enough evidence to demonstrate that the food safety objectives can be achieved on a consistent basis.

Once the evaluation of documentation has been completed, the auditor must then check that what is actually occurring during processing fits with the documented procedures. A record review is an essential part of this reality check. This latter activity also forms the primary part of any compliance audit carried out by MAF VA on a recognised HACCP plan.

In some cases, e.g. where a new premise starts up or a company decides to begin a new product, information is not available for the food premises HACCP-competent person to complete validation. Thus the premises must seek provisional recognition of the documented HACCP plan by MAF VA prior to commencing production. Completion of the validation process is then allowed to occur once the process is implemented and information can be collected. This occurs over a set time period, usually the equivalent of two working weeks. The MAF VA auditor is then able to complete the recognition of validation of the HACCP plan.

9.3.4 Using a check-list

Check-lists have been found to be very useful in carrying out HACCP plan audits. They assist greatly in ensuring a consistent approach by auditors, helping to focus the auditor on the key outcomes to be obtained from a HACCP plan. Examples of recommended check-lists[6] can be seen in Tables 9.1 and 9.2 covering pre-audit activities and HACCP plan audit activities respectively. However, check-lists can never be all inclusive as each HACCP plan is developed and implemented on a premises-specific basis. Therefore the auditor must be mindful that the check-list is just a useful tool and that the final judgement call(s) will always rest with the individual auditor or audit team.

9.3.5 Dealing with outcomes of HACCP plan audits

The MAF VA auditor, on completion of the audit as described above, collates all findings, both pre-audit and HACCP audit, to determine the audit outcome. The check-lists will provide a useful starting point for this exercise. The auditor will decide if the HACCP plan is working effectively, taking into consideration the aims of the audit process which focus on the following outcomes (depending on whether the audit is an initial recognition of validation audit or an ongoing compliance audit):

- determination as to whether all required elements are present in the HACCP plan and that they are addressed adequately
- determination as to whether the procedures are effective with respect to achieving acceptable food safety outcomes for the product/process on an ongoing basis
- determination as to whether actual events comply with validated documented procedures.

Conformance

The HACCP plan is deemed to be conforming (effective) when all the following have been met:

- all necessary PRPs are in place and are operating substantially in compliance with regulatory requirements
- all eleven elements of the HACCP plan are present, have been applied correctly and have been documented

Continued on page 161.

Table 9.1 Pre-audit check-list
Note: This check-list provides a detailed guideline to assist the auditor in assessing pre-audit information.

Pre-audit check-list	Comments
1. Quality system • Is there a quality system? • What is the scope of the quality system? • How does the HACCP plan link with the quality system? • Is there an extrinsic audit of the quality system?	
2. Prerequisite programmes • What are the prerequisite programmes? • Are they addressed separately to the HACCP plan? • Is there evidence of authorisation by a responsible company person? • Is there evidence of an ongoing acceptable level of compliance (as per industry/ regulatory standard)? For initial audit, check: • internal review/audit reports • extrinsic review/audit reports • non-conformance records • documentation and records for selected sample of relevant prerequisite programmes. For subsequent audit, check: • information for the above since the last HACCP plan audit • information on any changes to prerequisite programmes.	
3. Previous HACCP plan audits • Are previous HACCP plan audit reports available? • Is there documented evidence of issues raised at the previous audit having been addressed satisfactorily?	
4. Responsibilities • Have HACCP-competent individuals* been involved with the HACCP plan?	

Table 9.1 (continued)

• Is there evidence of this involvement? *as defined by the industry-agreed standard or regulatory agency	
5. Other information most likely to be accessed on-site • Are HACCP training records available? • Have layout plans for product and personnel flowpaths been considered? • Are suppliers' guarantees/validations available? • Are job descriptions/work instructions available? • Are hazard ID resources available?	

Other comments

Table 9.2 HACCP plan audit questionnaire

Note: This questionnaire is a guide only. A status has been given to each question to **assist** the auditor in evaluating the outcome of the audit. The final judgement call rests with the auditor.

Key

Recommended means considered of value in developing, implementing and maintaining a HACCP plan but not essential for a successful outcome to the HACCP plan audit. May be mentioned in the audit report to assist the auditee.

Required means part of the HACCP standard. Non-conformance is serious and is likely to result in sanctions.

HACCP plan audit questionnaire	Comments
1. Is there commitment from Management for HACCP? [Consider both informal or formal] Has the HACCP plan been signed off by Management? Status: Required	

Table 9.2 (continued)

2. Has a HACCP team been established? Status: Recommended	
3. Have the team composition and responsibilities been documented? Status: Recommended	
4. Is the scope of the HACCP plan defined and documented? Status: Required	
5. Is there a description or specification for the product? Status: Required	
6. Does the description cover intended use? Status: Required	
7. Have food safety objectives been formulated for the HACCP plan? Status: Required	
8. Is there a process flow description? Status: Required	
9. Does it reference relevant inputs and outputs at each process step? [If not, have the inputs and outputs been considered elsewhere?] Status: Recommended	
10. Has the process flow information been confirmed as accurate? Status: Recommended	
Review actual process against process flow information	
11. Has background information been obtained on hazards appropriate to the product? Status: Required	

Table 9.2 (continued)

12. Has effective hazard identification been carried out and documented for all raw materials, inputs and for each process step? Status: Required	
13. Has the hazard identification considered variability of the process/operators? Status: Recommended	
14. CCP determination Has the significance/level of unacceptability of each identified hazard/generic group of hazards at each process step been determined in accordance with food safety objectives? Status: Required	
Review hazard significance against selected food safety objectives	
15. CCP determination Has a control measure(s) been identified for each significant/unacceptable hazard/generic group of hazards? Status: Required	
16. Is there documentation to support the CCP determination? Status: Required	
17. Are unaddressed hazards identified and recorded? Status: Required	
18. Are unaddressed hazards highlighted for further consideration? Status: Recommended	
19. Have measurable critical limits been determined and documented for all hazards covered by a CCP? Status: Required	
20. Are the critical limits scientifically valid for the hazard? Status: Required	

Table 9.2 (continued)

21. Are the critical limits achievable (practical) given the process? Status: Required	
Review critical limits against achievement of food safety objectives	
22. Is responsibility for monitoring defined and documented? Status: Required	
Check responsibilities with selected staff	
23. Are monitoring procedures documented? Status: Required	
24. Does monitoring supply enough information to ensure that the CCPs are under control? [Consider when, how and what including relationship to prevalence of hazard.] Status: Required	
25. Are monitoring results recorded? Status: Required	
Review monitoring activities and records against documented procedures	
26. Are responsibilities for taking corrective action defined and documented? Status: Required	
Check responsibilities with selected staff	
27. Are the corrective action procedures documented? Status: Required	
View corrective actions taken against documented procedures	
28. Does corrective action take place when monitoring trends indicate that the process is heading towards a critical limit? Status: Recommended	

Table 9.2 (continued)

29. Does corrective action incorporate all the necessary components? Status: Required	
30. Are corrective actions followed up by appropriate rechecks? Status: Required	
31. Are corrective actions implemented as per documented procedures and outcomes recorded? Status: Required	
32 Are corrective actions signed off as completed? Status: Required	
Review corrective action records against documented procedures	
33. Are there adequate documented verification procedures (consider who, what, when, how)? Are responsibilities defined? a) Validation: • Has the HACCP plan been checked for adequate and complete documentation? • Has the HACCP plan been validated in terms of consistently achieving each food safety objective? • Has the validation process been fully documented? b) Ongoing review/audit: • Has any/all of the following activities taken place: internal/external checks, calibration of equipment, HACCP plan review, product tests where relevant, extrinsic review? • Have the findings been fully documented? c) Revalidation: • Has this occurred? • For what reasons? • Has the revalidation process been fully documented? Status: Required	

Table 9.2 (continued)

Review actual verification activities against documented procedures **Check responsibilities with selected staff** **Review verification records against documented procedures**	
34. Are document control provisions in place? Status: Required	
35. Is a retention period for records defined? Status: Required	

- food safety objectives are acceptable and relevant to the product and are being consistently met
- actual events substantially match documented HACCP procedures with appropriate records as documented evidence.

An effective HACCP plan can influence the follow-up activities to the audit, e.g. the MAF VA auditor may select actions as follows available under the HACCP specifications and performance-based verification requirements as applicable:

- the audit frequency may decrease
- the scope of the audit may change
- customised process changes may be sanctioned
- market access may be granted (where HACCP is a mandatory requirement).

Non-conformance

The HACCP plan is deemed to be non-conforming when any part of the HACCP specifications and what is documented procedure in the HACCP plan, is not complied with. This does not mean that the HACCP plan has necessarily failed the audit. All non-conformances should be identified according to specific parts of the related standard.

The MAF VA auditor must consider PRP non-conformances which have the potential to affect adversely the food safety outcomes expected from implementation of the HACCP plan, and which have not already been effectively addressed by the premises. In this case, corrective action may include one or more of the following:

- action by the processor to correct the PRP(s) deficiencies immediately
- notification to the service provider who has responsibility for verifying the ongoing compliance of the PRP(s) if that person is different to the MAF VA auditor undertaking the HACCP plan audit
- notification to the auditee that the effectiveness of the HACCP plan is seriously compromised.

The auditor must make a decision to either abort the HACCP plan audit at this stage or progress the audit with the intention of maximising feedback to the auditee, even though the outcome of the HACCP plan audit has been seriously affected.

Non-conformances relating directly to the HACCP plan will be expected to be addressed by the premises in a timely manner. The urgency and scope of the corrective actions will always be influenced by the seriousness of the non-conformances and may include *one or more* of the following actions in conjunction with the requirements of performance-based verification and market access expectations:

- action by the processor to correct deficiencies in the HACCP plan
- increase in audit frequency applied by MAF VA
- increase in depth of audit applied by MAF VA
- recognition of the HACCP plan as having failed to achieve food safety objectives on a consistent basis with review required of the entire plan
- immediate remedial action by the processor
- recall of product immediately by the processor as per recall procedures
- suspension of production by the processor
- other sanctions as deemed necessary by MAF VA including time listing the premises for market access or a recommendation for delistment from a particular market.

The MAF VA auditor will confirm that the proposed corrective actions are satisfactory and how they will be verified. The premises is then expected to ensure that all corrective actions are addressed according to the agreed time frame and this is verified at some later date by the MAF VA auditor.

9.4 Conclusion

9.4.1 Progress with HACCP

HACCP implementation has done much to increase food safety awareness in New Zealand. HACCP training and the introduction of competency standards have dramatically improved industry knowledge from managers to operators on-line. Industry personnel at many levels now have a much greater understanding of how their operation actually works. This same attention to attaining HACCP competency has seen a dramatic improvement in the HACCP knowledge levels among MAF personnel as well.

MAF's relationship with the food industry sectors continues to grow. This last decade has seen a dramatic increase in the need to consult with food industry sectors as they have moved into HACCP mode, both voluntarily and in a mandatory environment. Some 18 months of mandatory HACCP implementation for the export meat and seafood industry has given clear insight as to how HACCP is working, both from a regulatory and industry perspective. Audit findings have highlighted weaknesses in HACCP implementation, particularly in relation to setting food safety objectives, validating HACCP plans and providing adequate documentation and record keeping. These issues have been discussed and reviewed in consultation with all stakeholders and, where necessary, changes to mandatory HACCP requirements have been made to clarify requirements further.

Increased consultation also has occurred with the Ministry of Health (as the administrator of food legislation for the domestic market), reflecting government's desire to harmonise the approach to food safety across all food industry sectors in New Zealand. As HACCP principles become more integrated into food safety and risk-based programmes under New Zealand legislation, they will assist industries to achieve food safety outcomes for their products consistent with fitness for purpose.

Consumers are slowly increasing their awareness of food safety, realising the importance of good hygienic practice when handling and preparing food or eating out. They are beginning to apply that knowledge to what they buy and eat. Consumer representatives also are playing a more active role in food industry councils, which will also assist general consumer understanding of food safety issues, including those associated with the application of HACCP.

9.4.2 Outstanding issues

Some outstanding issues are inevitable given the desire to improve continually the practical application of HACCP. These issues include the following:

- HACCP application across the food chain
- hazard identification and analysis including for PRPs
- setting food safety objectives in line with developments in risk analysis
- validating HACCP plans in line with achieving food safety objectives
- skill maintenance for HACCP-competent persons
- application of HACCP to small business.

HACCP application across the food chain

Ideally, HACCP application is expected across the food chain to all types of foods in an equivalent manner, giving appropriate food safety assurance to all consumers. Reality, however, is far from this ideal.

Some segments of the food chain lend themselves to easier application of HACCP than others. Often application of HACCP principles to primary production is limited and food safety hazards can be better addressed by supplier quality assurance systems.

Processors of raw foods often find themselves in difficulties when endeavouring to apply HACCP to their products, especially if they already have good hygienic practice well established. Application of HACCP over and above this often provides little improvement in food safety outcomes as measured by achievement of food safety objectives. Thus HACCP should not be the only answer to achieving desired levels of food safety assurance if other means can demonstrate equivalent results.

Hazard identification and analysis
Hazard identification and analysis must continue to improve with the emphasis on sound science and risk analysis. PRPs (or their equivalent), underpinning HACCP, are likely to come under increasing scrutiny and will ultimately have HACCP principles applied to them in a transparent manner, where this application fits and is relevant. This detail could be expected to be captured in food industry codes of practice, providing a sound basis upon which individual food operators can develop their own documented PRPs, giving added value to the HACCP plans. New Zealand's requirements under the Animal Products Act 1999 will go a considerable way towards addressing these concerns.

Food safety objectives
Food safety objectives will continue to become more meaningful to HACCP exponents as risk analysis improves food safety linkages to human health. Increasing interest is already occurring internationally as food safety objectives are promoted as an essential component of equivalency agreements between trading countries to express the 'expected/desired extent of control of foodborne hazards resulting from application of a sanitary measure'.[9]

Validation
Validation continues to provide a challenge both to regulatory and industry personnel, as further clarification of requirements is sought. Statistical sampling regimes must play a significant part in this determination of what is enough supporting evidence to demonstrate consistent achievement of food safety objectives.

Skill maintenance for HACCP-competent persons
As HACCP knowledge expands and improves with time, so must the skill level of HACCP-competent people. Food industry training organisations and regulators are grappling with this issue at present, developing strategies to deliver a continuing education programme.

Application of HACCP to small business
Application of HACCP principles to all activities surrounding food production has also had its limitations. HACCP does not work well in small food businesses with limited resources. Not only is the regulator often faced with a limited skill base at this level of operation, but the limitations are particularly evident when trying to apply the principles of verification and record keeping. Unless the small operator can coopt other similar operators to partake in a verification programme designed to encompass a food group rather than individuals, the regulator may have to confine application of verification requirements to extrinsic involvement only. Record keeping must be minimal but enough to support HACCP application at this level.

9.4.3 The international perspective

HACCP is not applied in a similar manner world-wide. Given the Codex Alimentarius Commission's HACCP guidance document, individual countries have interpreted these seven HACCP principles in a variety of ways that best fit their country's needs, both practically and politically. Consequently, exporting countries must replicate these HACCP requirements or endeavour to demonstrate an equivalent programme according to the provisions of the World Trade Organisation sanitary and phytosanitary agreement. The problem is that global experience with HACCP across all food sectors, particularly involving raw foods and small businesses, is still very limited and many gaps remain in the scientific knowledge needed to underpin food safety assurances.

International understanding of HACCP and its application will continue to grow, not without intense debate, especially over issues described above. With time this should lead to a more consistent and realistic application of HACCP globally as advances in science and practical experience influence the trends.

Advances in risk analysis are destined to play the most significant part in the evolution of HACCP across the food chain as more information becomes available to strengthen linkages between individual food safety hazards, types of food and intended consumers.

Finally, expect HACCP plans to become the new PRPs of the future. As science advances and technology changes, food production will change and improve, and what is HACCP today will become the basis of, or prerequisite to, new advanced HACCP plans tomorrow.

9.5 References

1. *Assuring Food Safety: An Integrated Approach to Regulating the Food Sector in New Zealand*, Wellington, Ministry of Agriculture and Forestry; Ministry of Health, 1998.
2. Food Act 1981 – Amendment 2, New Zealand Government, 1996.
3. Animal Products Act 1999, New Zealand Government, 1999.
4. *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application*, Annex to CAC/RCP 1-1969, Rev. 3, FAO/WHO, Rome, 1997.
5. J.A. LEE and S.C. HATHAWAY, 'Experiences with HACCP as a tool to assure the export of food', *Food Control*, 10: 321–3, 1999.
6. *A Guide to HACCP Systems in the Meat Industry*, Ministry of Agriculture and Forestry, Wellington, 1999.
7. *Industry Standard for a HACCP Plan, HACCP Competency Requirements and HACCP Implementation*, New Zealand Meat Industry Standards Council, Wellington, 1999.
8. *National Microbiological Database (Bovine and Ovine Species): Specification for Technical Procedures*, Manual 15, Ministry of Agriculture, Wellington, 1997.

9. S.C. HATHAWAY and R.L. COOK, 'A regulatory perspective on the potential uses of microbial risk assessment in international trade', *International Journal of Food Microbiology*, 36: 127–33, 1997.
10. S.C. HATHAWAY, R.L. COOK and P. VAN DER LOGT, 'National microbiological monitoring of red meat production', 6th World Congress on Meat and Poultry Inspection, Terrigal, Australian Quarantine and Inspection Service, 1999.
11. J.A. LEE and S.C. HATHAWAY, 'The challenge of designing valid HACCP plans for raw food commodities', *Food Control*, 9: 111–17, 1998.
12. J.A. LEE, C.M. ESGUERRA and S.C. HATHAWAY, 'Practical advances in HACCP application in the New Zealand meat export industry', 6th World Congress on Meat and Poultry Inspection, Terrigal, Australian Quarantine and Inspection Service, 1999.
13. *Guidelines for Auditing Quality Systems. Part 2: Qualification Criteria for Auditors*, NZS 10011.2:1992, Standards New Zealand, Wellington, 1992.
14. *Guidelines for Auditing Quality Systems. Part 1: Auditing*, NZS 10011.1:1992, Standards New Zealand, Wellington, 1992.
15. *Guidelines for Auditing Quality Systems. Part 3: Management of Audit Programmes*, NZS 10011.3:1992, Standards New Zealand, Wellington, 1992.

10

Enforcing safety and quality

Canada

V. McEachern, A. Bungay, S. Bray Ippolito and S. Lee-Spiegelberg, Canadian Food Inspection Agency, Nepean

10.1 Introduction

Within the past 50 years there has been a great deal of change in the food industry. The number and variety of food products that are available to today's consumers has increased dramatically and at the same time the consumer's attitude and expectation of food has undergone a significant change. Only a few decades ago, the majority of consumers purchased their fruits, vegetables and meats at the local grocery store and prepared their meals at home. In most cases these food products were produced in local processing plants which received their raw materials from the regional farm and fish industries. These products had limited distribution and were produced in volumes to satisfy local and regional needs.

Now more than ever the consumer is apt to pop something into the microwave, order a pizza or head off to a restaurant for their meals. Technological advances in food processing and the modernization of transportation and food distribution mechanisms has not only increased the variety of the foods we eat but it has also presented new hazards and concerns that must be addressed. Outbreaks of foodborne illnesses now have the potential of being national, continental and even global. At the same time consumers have become more demanding about the content and quality of what they eat, and more aware of food safety issues. All these developments have imposed new demands on government inspection of food manufacturers and retailers.

10.2 The background to food safety inspection in Canada

In Canada, at the federal level, responsibility for food safety and inspection has been shared by four federal departments, Agriculture and Agri-food Canada, Health Canada, Industry Canada and Fisheries and Oceans Canada (Canadian Food Inspection Agency Corporate Business Plan 1998). To enhance the effectiveness and efficiency of the Canadian food inspection system the government of Canada, on April 1, 1997, amalgamated the food inspection activities of these four departments under the Canadian Food Inspection Agency (CFIA), reporting to the Minister of Agriculture and Agri-food Canada.

The CFIA is responsible for all federal food inspection activities extending from the production of animal feeds along the food production chain to the distribution and retail stages. The Agency's mission is safe food, animal health and plant protection. For the first time in the long history of food inspection in Canada, a single federal agency is responsible for food inspection. The Agency's formation brought together 26 different food, animal and plant health inspection programs. These programs share many similar fundamental food inspection principles, goals and objectives but have evolved independently under different environments and different forces. Consequently, different approaches and methods are used in achieving their goals. The level of government intervention and industry responsibility varies from program to program. Products of equal risk, but of different commodity groups, are subject to different inspection regimes. Furthermore, these programs are not static but continue to evolve to meet the changing needs of the marketplace. To prevent continued program divergence and to ensure that program evolution follows a common set of principles and a common discipline, all programs are moving to a common systems-based approach.

10.3 Enforcement: from product to systems inspection

As the food industry has evolved, so has the government's approach to food inspection. The first Canadian Fish Inspection Act was enacted in 1919 to address the fraudulent activities of unscrupulous fish traders which threatened the European and New England markets by damaging the reputation of Canadian fish products. Over time food inspection programs transformed into comprehensive multi-faceted programs that addressed not only fraudulent practices, but also food safety and quality. Government resources were concentrated in the food processing plants which provided an ideal opportunity to inspect the processing conditions and the final products prior to distribution.

These inspections were based on a traditional approach which focused on snapshot inspections of the processing plant environment and comprehensive sampling and inspection of the final product. The plant processing environment was evaluated against prescriptive construction, sanitation and hygiene requirements. The product inspections included label evaluations, organoleptic analysis and microbiological and chemical analysis. Laboratory analyses are carried out to detect a limited number of chemical, physical and biological indicators of unacceptable products or processes. Under the traditional inspection approach a paternal relationship between the inspector and the processing plant developed where the inspector identified the problems and the plant then took corrective action. In many cases the inspector fulfilled the role of safety and quality control and, because the system relied heavily on final product inspection, mistakes were not identified until they were already processed into the product.

In the 1980s the international marketplace began making greater demands on the food processing industry and government food inspection agencies to provide assurances that food products were nutritious and safe. This was prompted by informed and knowledgeable consumers who now expected zero risk in their food products. As a result, importing countries started to request government certification of more and more food products. Under the traditional inspection program this meant more inspections. However, there were no new resources to perform these additional inspections.

New or re-emerging pathogens have also forced a re-evaluation of previous views and accepted approaches to controlling foodborne illnesses. The emergence of new pathogenic agents such as *E. coli* 0157:H7 has changed the production and process controls for a wide variety of products. Recognized pathogenic micro-organisms are now being identified in new vehicles and products to which they were never linked previously. The pace of change in the types of pathogen risk faced by the food industry meant that traditional inspection regimes, and the operating standards and procedures on which they were based, have struggled to keep up with new hazards. Similarly, the increasing rate of technological and product innovation has also made it more and more difficult to keep official construction, hygiene and operating standards up to date and relevant.

All of these factors have forced industry and governments to look for new innovative ways to achieve safe and wholesome food products. At the same time, government regulatory agencies are also facing new challenges associated with a complex, globalized and technology-driven food industry. Industry has realized the benefits from developing effective food safety and quality control systems and the regulatory agencies have had to develop more efficient techniques to verify the effectiveness of these new industry programs.

Traditional inspection methods, such as sampling and analysing products, or inspecting food processing establishments to assess levels of sanitation and hygiene, are snapshots in time and are reactive to problems already present in the factory or the finished food. This approach does not provide consumers with the desired level of confidence in the food products they consume. The adoption of a systems approach demands that the food industry understands its responsibilities and is knowledgeable of the regulatory and food safety requirements associated with its business. Under a systems approach, industry is required to develop and implement effective control measures to prevent food safety hazards, fraudulent products, diseased animals or potential plant pests from reaching the marketplace. These control measures are based on science and must be validated as effective. The systems verification approach is preventive and proactive. It moves away from the strategies of 'see a problem – fix it' to a 'see a cause – prevent it' approach. By using such a systems approach, industry can demonstrate that due diligence was practised and product integrity maintained while under its control.

As governments and the food industry move toward a systems approach to food inspection, government's role changes from inspecting for compliance of specific production lots and processing conditions on a specific day, to assessing the effectiveness of industry control measures in achieving food safety and regulatory compliance. Under this approach, government inspectors have many tools to assess the effectiveness of industry's controls. Records of production, control measures and corrective actions, etc. gathered by industry over a period of time can now be reviewed by the inspector. In addition, traditional inspection techniques can be used to focus on areas where non-compliance is identified or simply to verify that the control measures are effective. In effect, the systems approach does not discard relevant traditional inspection methods but continues to use them where it is appropriate. Overseeing by government of industry practices becomes more comprehensive, flexible and responsive to change.

Government food inspection agencies are also responsible for taking the appropriate enforcement action when non-compliance is identified. This can range from detaining a product until further analysis establishes it as either compliant or non-compliant, to the removal of a processor's right to operate. Whatever the enforcement action, it must be fair, predictable and equitable. The systems approach will enhance government food inspection agencies' ability to direct resources based on the level of risk of a product and historical levels of compliance by a food processor.

10.4 HACCP as an industry control system

The development of any management system involves three basic components:

1. Know what standard has to be met.
2. Identify the control measures to be used to meet the standard.
3. Identify the corrective procedures to be followed when the standard is not met.

Once a system is developed, its implementation and maintenance requires a series of support elements to ensure that the system is effective and is being implemented as planned. These elements can be summarised as follows:

- *validation*: before a control system is implemented, the processor must validate the control measures to ensure that they are effective in meeting the required standards

- *control verification*: processors should build into their systems an extra level of controls to verify that the control measures are being implemented as written; verification should include a complete review of the system (for example, annually) as a basis for incorporating changes to products and processes, and making improvements to the system
- *record keeping*: effective record keeping is essential in any control system to provide evidence that the system is being properly implemented; such records will be essential evidence for regulatory authorities in assessing the effectiveness of the control system.

In most respects these HACCP principles correlate closely with the various system elements identified above. One area of difference lies in the contrast between the emphasis in the Codex principles on hazard identification as the first step in a HACCP study and identifying the appropriate standard as the first step in a general systems approach.

Government in Canada has a key role to play in setting standards as a framework within which HACCP planning can take place. These standards also provide the foundation of the food inspection program. This role for government can be accomplished by drafting reference standards for each industry sector which describe the goals and outputs that safety management systems such as HACCP systems must fulfil. These standards, for example, consolidate international requirements in such areas as prerequisite systems (e.g. hygiene procedures), guidance on particular hazards and the setting of critical limits.

10.5 Government food safety programs

The CFIA has several successful programs that are based on the systems approach and provide reference standards for industry to follow.

10.5.1 QMP: fish processors

The CFIA's mandatory Quality Management Program (QMP) applies to all fish, seafood and their products processed for export from Canada or traded interprovincially. Its objective is to verify that these products are processed under conditions that meet all regulatory, trade and food safety requirements. The QMP facilitates the export of Canadian fish and seafood products by meeting international requirements for hazard analysis critical control point (HACCP) systems. The effectiveness of QMPs is verified by CFIA inspectors.

10.5.2 QMPI: fish importers

The Quality Management Program for Importers (QMPI) is carried out by importers who have voluntarily chosen to assume additional responsibility under a shared or enhanced QMPI. In these cases, a written QMPI submission must be prepared to address licensing and notification, labelling, ingredients, packaging materials, process controls for canned and RTE products, storage, final product and recall procedures. The CFIA reviews and approves the QMPI submissions and conducts verifications of the importer's systems.

10.5.3 Food Safety Enhancement Program (FSEP)

The CFIA's Food Safety Enhancement Program (FSEP) is a voluntary program designed to encourage the development and maintenance of HACCP-based systems in federally registered agri-food processing establishments involved in processing dairy, meat and poultry, processed fruits and vegetables, shell egg and processed egg commodities. Under FSEP, the company is responsible for the development, implementation and maintenance of prerequisite programs (PRPs) and HACCP plans. Written document review and on-site verifications are conducted by the CFIA.

10.6 Regulatory verification versus audit

As government food inspection agencies and the food industry implement food inspection programs based on HACCP systems, the government's role will shift from purely inspection to encompass more of an auditor role. This transition will pose some significant challenges to an organization that has evolved under the traditional approach to inspection. An audit is defined as 'a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives' (ref: ISO 8408). To paraphrase, it is an assessment of a management system, whether it is concerned with quality or safety, to determine whether it is doing what it says it is doing.

The audit takes a systematic approach in that, before the audit commences, the scope is agreed by all parties, the specific elements of the system that will be audited are identified, check-lists are prepared and reviewed by the audit team, specific audit activities are designated to each member of the audit team and the date and duration of the audit is set and agreed by both the auditor and auditee. In order for an audit to be credible it must be performed by an independent and impartial party and the audit results and conclusions must be based on objective evidence that is verifiable. The audit must measure a system against a 'defined' and agreed upon reference standard and be performed by a competent auditor and audit team that is trained and experienced in the sector being audited.

There are two principal activities carried out under the audit. The first is an audit of the company's documented system. This is sometimes referred to as a desk audit as it involves mostly a review of the documented system against the agreed reference standard. The second component of the audit is referred to as the compliance audit. The compliance audit is carried out once it has been established, through the system audit, that the company's system meets the reference standard. The compliance audit focuses on the application of the system and verifies that the company follows the control procedures as described in their system.

At the conclusion of either the systems audit or the compliance audit, the auditor and the audit team prepares an audit report which identifies the non-conformities or non-compliances that were observed during the audit. The auditee is then required to prepare a corrective action report describing the actions (what, when and who) that will be taken to rectify the non-conformities. The corrective action report is reviewed by the auditor and either accepted or returned to the auditee for amendments. Once corrective actions have been taken, the auditor will determine whether a follow-up visit is necessary to verify whether the relevant corrective actions have been taken and are effective. Once all of the non-conformities have been satisfactorily dealt with by the company, the auditor closes the audit.

The audit approach is a very effective method of testing and challenging a company system such as a HACCP system. An audit may be performed at the request of the company and seen as an opportunity to have an independent and knowledgeable third party assess a HACCP system in a non-adversarial environment. The results of the audit are seen as opportunities to strengthen the system and a necessary step in the cycle of continuous improvement. The relationship between the company and the auditor does not extend outside the mutually agreed scope of the audit.

When comparing the relationship between a government food inspector and a food processing company with the relationship of an auditor and that same company, there are some significant differences. The client of the regulatory inspector is the consumer, whereas the auditor's client is the company. The majority of assessments performed by the government inspector are not at the invitation of the company and at the best of times may be considered by the company to be a distraction and an annoyance. The relationship may be seen by the company as more adversarial since government inspectors are obliged, by the nature of their mandate, to act when a non-compliance with regulations is identified. The auditor passes responsibility for any non-conformity identified in the audit over to the company to deal with. On the other hand, if a government inspector identifies a non-conformity that violates regulatory requirements or may have the potential to generate a health and safety risk to the consumer, the inspector is obligated to take immediate steps to protect the consumer. The government inspector will take the appropriate action depending on the seriousness of the non-conformance but it may require that product be detained or recalled or may possibly involve the suspension of the company's food operation. The government inspector plays an important part in the food control system designed to protect the consumer. The auditor's role, although it has a positive impact, does not carry an equivalent level of responsibility as that of the inspector.

Although the systems approach to assessing industry compliance has required that government inspectors adopt auditing methods and techniques, the

Canadian food inspection system maintains inspectors as the primary assessor of industry compliance. The CFIA has also developed a new approach to assessing industry operating HACCP systems, referred to as 'regulatory verification'.

Regulatory verification applies a combination of audit and inspection techniques in assessing industry compliance and reacting to regulatory non-compliance. This approach provides government inspectors with both audit and inspection tools to assess the effectiveness of industry controls. Auditing techniques such as analysing and verifying documented controls, reviewing records and corrective actions, interviewing company employees carrying out CCP monitoring activities, and observing the application of control activities in-plant, are types of audit techniques used by inspectors when performing a regulatory verification. In addition, traditional inspection techniques can be used to focus on areas where non-compliance is identified or simply to verify that the control measures are effective. The regulatory verification approach is a comprehensive in-depth assessment of industry's controls and outputs which applies both audit and inspection methods. It allows the inspector to evaluate information and data gathered over time by the company, to perform inspections of the product and the plant environment and to focus verification efforts on the key areas for risk and compliance. This allows the decisions of the inspector to be based on a greater amount of information than in the past and gives more flexibility in assessing industry controls.

10.7 Regulatory verification of company food safety systems

The term 'regulatory verification' describes a set of activities that are carried out by, or on behalf of, a government regulatory body, such as the CFIA, to assess compliance of a company's food safety control system (FSCS) to a specified reference standard. The reference standard defines the requirements that the industry FSCS must meet, based on the relevant legislation and regulations. Regulatory verification includes both inspection and audit activities conducted in order to challenge and confirm, or deny, that industry controls are well developed, correctly implemented and effectively maintained.

For businesses that have a documented FSCS, the regulatory verification consists of three distinct phases:

1. The industry self-verification.
2. The assessment of the written system.
3, The assessment of the implemented system.

Regulatory verification is conducted using a team of inspectors under an overall team leader. This does not necessarily mean that a large group of individuals is required to assess an FSCS such as a HACCP system. However, it does reflect the need for a range of talents and a diversity of skills and knowledge. This team can be available in person, or via a network of available experts who can be consulted on particular points or brought in to assist in a particular stage in an inspection as required. Throughout the regulatory verification process, good communication with industry is emphasized.

10.7.1 Industry self-verification

Prior to implementation of an FSCS, the business should conduct an in-house assessment to determine whether all required components of the system have been addressed. This exercise is called the industry self-verification. In order to assist industry in this step, regulators have developed check-lists based on the appropriate regulatory requirements. Self-verification check-lists should be concise and easy to use. Check-lists have also been used by companies to plan the development of the FSCS as well as a final check before implementation.

The process for industry use is fairly simple. Upon completion of the FSCS, one of the management team, preferably independent of the system development team, should use the check-list to verify that the components are all present prior to submission of the documented plan to the regulatory agency for acceptance. The check-list would then accompany, or precede, the FSCS submission to the regulatory agency.

Industry self-verification can be mistakenly regarded as a 'paper exercise'. This is a false perception. From the food industry's point of view, self-verification check-list is a useful tool for development and completion as well as verification of the FSCS. For regulators, the industry self-verification process helps to bring an FSCS up to the required standard and promotes industry ownership of the FSCS. Check-lists help to determine whether the industry FSCS is sufficiently developed to proceed to the next stage, the systems verification.

10.7.2 Systems verification

The objective of the systems verification is to assess the written FSCS against the reference standard to determine whether the written document is complete and technically and scientifically sound. The process of systems verification has several distinct stages:

- planning the systems verification
- conducting the systems verification
- communicating the systems verification results.

Planning the systems verification

In order to assess and acknowledge any written FSCS, it is essential that a set of criteria be prepared which will serve as the basis for assessment. The criteria must be developed from the reference standard and should interpret the requirements of the reference standard for the written FSCS. The criteria can be developed in the form of a check-list and assessment guidelines to be used by the regulator. Every effort should be made to balance ease of use of the guidelines with the need for sufficient criteria to conduct a comprehensive assessment of the written FSCS. The systems verification is a well-organized process. Regulators will not begin a systems verification until the industry self-verification indicates that the written FSCS is complete and ready for assessment. It is important to remember that each FSCS is unique, and the regulator must remain open to different approaches in meeting the systems verification criteria.

Conducting the systems verification

The process begins with establishing a systems verification team. This may include both technical or scientific personnel as required. It will be necessary to have all relevant documents available, i.e. the FSCS itself, including any supporting documentation (e.g. the research underpinning hazard analysis), the self-verification report, and any relevant industry guidance documents.

The systems verification is a paper review of all major components of the FSCS. This would include the PRPs and flow diagrams, hazard analysis, control measures, corrective action plans, etc., but would not include very detailed procedures such as specific work instructions. This check-list is used to assess the completeness and soundness of the written FSCS. In making this determination, it is essential that the regulator consider the interaction between various parts of the FSCS, for example the prerequisite systems and the HACCP plan. These elements cannot be assessed independently of one another.

A common difficulty in conducting the systems verification is determining the level of detail required to find the written document complete and sound. It is important to differentiate between 'complete and sound' and the ideal written FSCS that individual regulatory personnel may envisage. The systems verification does not attest to the effective implementation of the FSCS, only that the written system is found to meet the requirement of the reference standard.

Regulators expect that it will take time for a business to create an effective documented FSCS. Time is needed to analyse and develop the first draft of the written system, to test the procedures through implementation, and then to revise the written procedures, at least once but more likely over several system generations. The regulatory system should facilitate, and even encourage, this test-and-revise approach.

Communicating the results

The company should be provided with a written report indicating any deficiencies found in the written FSCS. Regulators are cautioned to avoid the opportunity to suggest ways to revise the written system for two reasons: industry authorship of the document will improve its workability and if regulators are involved in developing the system it may create conflict when the system is being assessed during implementation.

10.7.3 Compliance verification

The compliance verification is the on-site assessment of the implemented FSCS. Compliance verification has a twofold objective: to verify that the FSCS is implemented as written and that the system is effective in meeting the requirements set out in the reference standard.

The compliance verification is based on audit principles. The process is designed to conduct a meaningful assessment in an efficient manner. In order to accomplish this objective, regulators will evaluate a 'thin slice' of the FSCS, i.e. a comprehensive but narrow review of selected aspects of the FSCS. As an example, in a large food production facility a regulator would limit the compliance verification to an in-depth investigation of the controls in place for only one of many products produced.

The compliance verification has four phases:

1. Planning.
2. Opening.
3. Investigating.
4. Closing.

Planning the compliance verification

The scope of the compliance verification is determined by such factors as plant compliance history and the level of risk presented by the product and processes involved. The first step in the compliance verification is the development of the compliance verification check-list. The compliance verification check-list is prepared using the company's FSCS and in advance of the on-site verification. Check-lists are devised to address the scope and objectives of the verification. The check-list should contain specific activities to be conducted to test the application and effectiveness of the FSCS. Appropriate activities include interview questions for key personnel, observation of specific operational procedures, reviewing records, monitoring testing procedures, and the sampling of materials for analysis. The check-list may be expanded during the course of the compliance verification if required in order to determine compliance to the reference standard. The compliance verification check-list is an important record of an individual assessment. With each new assessment of a plant, the previous check-list should be reviewed and used as the starting point for the creation of the new check-list.

Opening the compliance verification

The compliance verification begins with an opening meeting with the plant management. At this meeting, the inspection team should explain the objectives of the compliance verification and its scope. At this time, company representatives should pose any questions of their own regarding the compliance verification. The plant management should be encouraged to provide someone to accompany the regulatory personnel during the compliance verification. When an industry representative accompanies the regulator, a number of benefits are realized:

- the representative witnesses the regulator's observations in real time, and is more likely to understand the reasons behind the inspectors' eventual findings
- the company representative can provide answers to questions immediately
- the company representative can introduce the inspection team to key personnel whom the inspectors may wish to question.

Involving the company in this way improves the transparency of the regulatory process and communication between the two parties. Wrap-up meetings should be held with the processor each day that the compliance verification continues, and so that plant management is kept informed of progress. Of course, when any issue of critical significance is found (i.e. relating to the safety of a food product) the plant management must be informed immediately.

The investigation
To conduct the compliance verification, the regulator follows the plan established by the compliance verification check-list and proceeds with the investigation. The investigation is a series of planned activities to collect objective evidence in support of the inquiry. The results of all findings are recorded. Objective evidence is qualitative or quantitative information. Examples of objective evidence include:

- information contained on company records
- facts related during an interview with a plant employee
- inspector observations
- laboratory results
- product inspection results
- measurements made by an inspector.

An instance of system failure is called a non-compliance or non-conformity. A non-compliance may be either procedural or performance-related and minor or critical with respect to food safety. When a regulator has reason to believe that there is a non-compliance, this belief should be supported by the kind of verifiable evidence noted above.

Closing the compliance verification
The regulator's findings, including any non-compliances (supported by evidence), are documented in the compliance verification report and presented to the company at a closing meeting. Since the regulator has a daily wrap-up meeting with the company, the contents of the final report should not be a surprise to the company. The purpose of the closing meeting is to discuss all of the findings of the compliance verification with all relevant levels of the company management to ensure that there is an understanding of the results.

During the closing meeting, the company will be asked to initiate corrective action plans for each non-compliance identified. When the company has provided corrective action plans, at the meeting or at a later date, these will be reviewed and, if satisfactory, will be accepted by the regulator. The regulator will also verify at a later time that the corrective action is implemented by the company.

10.8 Common barriers to regulatory verification

There are two kinds of barrier to effective regulatory verification:

1. Barriers within regulatory agencies themselves.
2. Barriers within industry.

10.8.1 Barriers within regulatory agencies

Government agencies may encounter difficulties in moving from a traditional inspection approach to a regulatory verification approach. It is important for regulatory agencies to recognize barriers and develop the appropriate strategies to overcome them. Common challenges to instituting regulatory verification include:

- the cost of change
- people.

The cost of change

Over the long term, a regulator verification approach to assessing industry control systems will cost less and provide greater assurance of safety in the food system than a traditional approach. However, the transition period between programs will be a burden on both monetary and human resource. Governments should expect to go through several years of implementation before realizing cost savings. In assessing the cost of introducing a systems approach to food inspection, government should take account of the cost of not moving in this direction.

People

Regulatory personnel may be resistant to change, attributable to moving from the known to the unknown territory. The movement to regulatory verification is accompanied by the need for new skills, such as audit techniques. The attitude of resistance to change may be overcome by communicating the benefits of using a systems approach to food safety, both to the public, the industry and the regulatory personnel.

Regulatory personnel may feel uncomfortable with the new knowledge, skill and expertise requirements associated with an industry system verification approach. Regulators will need a good understanding of the hazards associated with food products, processes and their controls. Regulatory verification relies on the personal judgement of trained, experienced personnel. The approach recognizes human experience, memory, perception and creative thinking as perhaps the most powerful assessment tools available. In contrast to the rigid standards and pass–fail criteria associated with traditional inspection methods, regulatory verification requires a more proactive and flexible approach.

10.8.2 Barriers within industry

There are a number of barriers within industry to the adoption of HACCP systems:

- motivation
- attitudinal change
- experience.

Motivation

In some sectors, such as fish processing, food safety systems based on HACCP principles (such as QMP) are mandatory for businesses trading overseas or between provinces within Canada. This program has covered the great majority of larger and medium-sized businesses in this sector. In common with experience in other countries, wider adoption of HACCP systems such as the voluntary FSEP has been most widespread among larger processors with significant export activity, where adoption of HACCP systems is a necessary step to exporting to the USA or the EU. In these cases the commercial rationale is strong and resources and skills are more readily available to develop HACCP systems.

Small and medium-sized enterprises (SMEs) have been slower to adopt HACCP systems. There has been greater unfamiliarity with the concept, less of a commercial rationale to adopt HACCP systems and concerns about the costs and resource requirements involved. This picture is gradually changing as small businesses become more aware of HACCP systems and their potential benefits, particularly through contact with government inspection staff who are able to explain the real commercial advantages in such areas as enhanced productivity and product quality and increased attractiveness as suppliers.

Attitudinal change

The traditional relationship between inspectors and food processors was a paternalistic one, with inspectors effectively performing a quality control role for some businesses. Processors concentrated on production, fixing safety and quality defects retrospectively as they were identified through inspection of finished products. Implicit in this relationship was the belief that safety was, at least in part, the responsibility of government. This culture of dependence also assumed that companies fixed problems as they arose rather than trying to anticipate and prevent them.

HACCP systems require an active approach to the management of food safety with the emphasis on prevention rather than cure. They require businesses to use official reference standards to identify hazards, control measures and corrective procedures for themselves, and to set up, implement and validate their own tailor-made food safety systems. Some businesses have found it difficult to make this transition. The result has been to rely too heavily on external advice, resulting in poorly designed and understood HACCP systems that fail to reflect the particular conditions of the business.

The move from an attitude of dependence to one of responsibility also needs to feed through all sections of the business, from the managers of the business to those responsible for monitoring CCPs. All those responsible for CCPs, for example, need to be able to understand a critical limit, identify when it has been exceeded, take the appropriate corrective action, record what has occurred and, ideally, suggest remedial action to prevent a recurrence. Part of the compliance verification process is concerned with identifying how far plant employees understand the new responsibilities they have within a HACCP system.

Experience

The development of a food safety system is a significant challenge for any business, and it may take some time before it is working smoothly and effectively. Indeed, in the regulatory verification process the CFIA explicitly recognizes this initial development phase. The three phases of industry self-verification, systems and compliance verification are designed to identify where a business is in the development cycle. Industry self-verification is the first opportunity for a business to test the completeness of its food safety system against an official check-list. Many businesses use the self-verification process to refine and improve their food safety system before they decide to proceed further with the regulatory verification process. Systems verification provides a further opportunity to test and improve the robustness of a company's food safety system, before the final stage of compliance verification and the on-site inspection and final compliance verification report. This approach has the great advantage to industry of allowing businesses to test and improve food safety systems at a number of points, making the development process much more effective. It allows the CFIA both to assist in the process of development and to make the best use of its resources.

10.9 Future trends: the Integrated Inspection System

Presently, the Agency's inspection programs work well in maintaining Canada's food inspection system as among the best in the world. Naturally, these programs will continue to evolve and improve in order to meet the challenges of new hazards, pests and diseases, and to respond to the advancing globalization of trade. The main challenge for the CFIA is one of integrating these programs effectively. The formation of the CFIA has brought together some 14 separate inspection programs. While sharing many of the same principles and goals, each had evolved separately and consequently had differing approaches and methods. The level of government intervention and industry responsibility varied, and products of equal risk, but of different commodity groups, were subject to differing inspection regimes. Finally, individual programs are at differing stages in the move from an inspection to a systems approach.

In order to prevent continued program divergence and to ensure that program evolution follows a common set of principles and a common discipline, the

Integrated Inspection System (IIS) concept was proposed. In the Corporate Business Plan (1997–2000), the CFIA identified the development of the IIS as the mechanism that will guide the evolution of all Agency inspections programs under a consistent approach.

The proposed IIS can be described as one inspection system for all food commodities where industry is responsible for controlling their product and processes in compliance with recognized standards, and government is responsible for setting standards, verifying the effectiveness of industry's control systems and taking appropriate interventions as necessary. The objectives of the proposed IIS are as follows:

- to provide uniform food health inspection strategies that provide an appropriate level of food safety and consumer protection
- to address international regulations in order to facilitate market access for Canadian food, animal, plant and forestry products
- to provide an effective and efficient food inspection system that is open and transparent to all stakeholders
- to integrate the goals, objectives and activities of all players along the food continuum.

Integration under the IIS contains two parts: internal and external.

10.9.1 The internal integration of government inspection programs

The proposed IIS model describes the conceptual framework for development of the IIS. The IIS model contains the IIS Reference Standard and the IIS Verification Reference Standard. The two Reference Standards serve as blueprints to guide the development of industry control systems and the government verification system to assess the effectiveness of industry controls. The reference standard has been based on concepts from the ISO 9000 series and the fundamental principles of audit. It specifies the safety and quality system requirements designed for application by all stakeholders, including industry, government and third parties, along the food continuum.

The Reference Standard contains eight basic elements (see Table 10.1). The application of the Reference Standard will be flexible and not all elements will be applicable to all inspection programs. In some cases the controls may be very basic and focus on maintaining a sanitary environment for handling food products. In others, there may be comprehensive regulatory and trade requirements and specific food safety hazards that must be controlled. Inspection programs will be required to take account of all elements of the Reference Standard.

The proposed IIS Verification Reference Standard will identify the government's strategy to verify industry control systems. The strategies will be scaled appropriately to reflect industry's control measures. For example, traditional inspection technique is a strategy used for industries that do not have any control systems in place. Auditing techniques will be used where safety and

Table 10.1 IIS Reference Standard elements

1. Scope and application
2. Background information
3. Control elements
   - environmental controls
   - hazards controls
     – food safety controls
     – animal health controls
     – plant protection controls
   - regulatory/trade controls
4. Recalls and traceability
5. Training
6. Record control
7. Document control
8. Verification

quality management systems have been implemented. In the instances where a third party is involved in verifications of industry's controls, the CFIA will take on a role similar to an ISO registrar to assess the third party's verification system.

10.9.2 External integration along the food continuum

The second component critical to the development of the IIS is the proposed external integration of food safety and quality strategies along the food continuum. The objective is to examine current food safety control strategies and to determine whether they are the most effective and appropriate. It will provide the opportunity to interlink and build on the different control measures and address any risks that may have been overlooked currently.

It is proposed that this initiative will be conducted with representation from all segments of the food industry from production to retail, consumer groups, federal and provincial food inspection agencies, and academia. The task will be to map out the food continuum for their specific products and then, with scientific support, identify the hazards along the food continuum related to safe food, consumer protection and export market access. The current control measures will then be evaluated to determine their effectiveness and efficiency in preventing, eliminating or reducing the hazards to acceptable levels. In cases where the inspection system can be enhanced, the IIS Reference Standard may be used to develop new control strategies. This approach will identify the most effective points for control along the food continuum, the control measures that are to be implemented, who is best suited to deliver the controls, how the controls will be verified and who is best suited to verify them.

The strength of the integrated food control system will depend on the involvement of all stakeholders in working cooperatively to achieve the desired outcome. The result will be a food control system developed, verified, communicated and implemented by all stakeholders. The benefits are far-reaching. The industry will be able to build valuable partnerships and to implement more efficient systems to ensure that their products meet all applicable food safety, regulatory and trade requirements. Consumers and our international trade partners will have greater confidence that the products will meet their expectations of safety and consumer protection. Regulatory agencies will be able to make more effective use of their resources to direct their activities corresponding to the level of risk.

10.10 Summary

There are a number of features which, collectively, make the proposed integrated food control approach to HACCP implementation distinctive:

- the focus on setting specific industry sector standards, based on HACCP principles, as a framework within which industry can design tailor-made HACCP systems for each business
- the regulatory verification process itself which makes the best use of audit and inspection skills in ensuring industry compliance with relevant food safety standards
- the stepped approach to regulatory verification which maximizes cooperation between the regulatory authority and industry in developing and improving food safety systems while making the most effective use of resources
- the emphasis on transparency and good communication in the regulatory verification process, which encourages both sides to learn and improve.

In these ways the proposed approach can help to take the regulation of the food industry into the 21st century.

11

HACCP implementation in the Thai fisheries industry

S. Suwanrangsi, Department of Fisheries, Bangkok

11.1 Introduction

This chapter is based on the experience of the Thai Department of Fisheries in working with the fishery industry in Thailand on HACCP implementation. It shows some of the main problems encountered in implementing HACCP successfully, and how the industry and government have sought to overcome them.

11.2 The international fish trade

The importance of HACCP systems to the fishery industry in countries such as Thailand reflects the increasing importance of the international trade in fresh fish and fish products. Fish, shellfish and fishery products are widely traded, with no less than 195 countries having exported part of their production and some 180 countries having reported fishery imports of varying amounts in 1996. The international trade in fish now represents 37% of total world fish production. The value of world exports of fish and fishery products reached US$52.5 billion in 1996. In 1997 international exports of fish and fishery products (excluding seaweed) were almost 46 million tonnes, growing by 2.4% compared to 1996. Japan currently imports US$15.5 billion worth of fish and fishery products, accounting for 30% of the total world imports of fish. The USA imports US$8.1 billion, accounting for 14% of the total. Norway is the leading exporter (with a fish trade worth US$3.4 billion), contributing 7% of total fish exports. Currently developing countries provide about 15% of all fish and fishery products entering the global market.

Table 11.1 World fisheries production and utilization (million tonnes)

	1990	1992	1994	1995	1996	1997[1]
Production						
Inland						
Aquaculture	8.17	9.39	12.11	13.86	15.61	17.13
Capture	6.59	6.25	6.91	7.38	7.55	7.70
Total inland	14.76	15.64	19.02	21.24	23.16	24.83
Marine						
Aquaculture	4.96	6.13	8.67	10.42	10.78	11.14
Capture	79.29	79.95	85.77	85.62	87.07	86.03
Total marine	84.25	86.08	94.44	96.04	97.85	97.17
Total aquaculture	13.13	15.52	20.77	24.28	26.38	28.27
Total capture	85.88	86.21	92.68	93.00	94.63	93.73
Total world fisheries	99.01	101.73	113.46	117.28	121.01	122.00
Utilization						
Human consumption	70.82	72.43	79.99	86.49	90.62	92.50
Reduction	28.19	29.3	33.47	30.79	30.39	29.50

Note: [1] Preliminary estimate.
Source: FAO (1998).

The main types of fish production are shown in Table 11.1. This shows that marine capture remains the biggest sector, representing 70% of total fish production, but that there is now a significant aquaculture sector, breeding fish in controlled environments, which accounted for 23% of total production (over 28 million tonnes) in 1997.

11.3 The fisheries industry in Thailand

Overall fish production in Thailand accounted for approximately 3.5 million metric tonnes annually in 1997. Capture fisheries accounted for 85% of this total with aquaculture production accounting for the remaining 15%. The Thai fisheries industry has enjoyed substantial export growth for more than a decade. Exports increased from US$2.3 billion in 1990 to US$5 billion in 1997, before falling to US$4.1 billion in 1999 as a result of the economic crisis in Asia and increasing price competitiveness in the fisheries market.

The different types of fish product exported in 1999 were (by volume) canned tuna and other canned seafood 45%, frozen shrimp 12%, frozen cephalopods 8%, frozen mollusc 4%, other frozen fish products 18%, and fresh fish 17%. Japan was the main importer of Thai fishery products until the end of 1997. In 1998, the USA became the largest importer, accounting for 31% of total production. Other major importers are the European Union (EU), Australia, Canada and other Asian countries. China has emerged as a significant importing country in the past few years, with significant potential for the future.

Most of those involved in both the marine capture and aquaculture sectors are small-scale operators. These operators sell their catches to wholesalers who supply fish to both the domestic and export markets. About 25% of fish production goes for further processing. There are approximately 2,450–2,600 fish processors, comprising the following:

- processors using traditional methods (such as drying), dominated by a large number of small-scale operators
- 144 frozen products processors
- 118 fishmeal factories producing animal feed
- 50 canneries
- three major firms dominating tuna processing (accounting for 70% of production).

Larger-scale factories (those employing 300 to the largest employing 15,000 employees) represent only 10% total processed fish production by volume.

11.4 The Fish Inspection and Quality Control Division

The Department of Fisheries (DOF) is one of the 11 main agencies reporting to the Ministry of Agriculture and Cooperatives. The DOF is the principal government agency dealing with the fisheries industry and is responsible for the development of this sector, including the introduction of new technologies, research, regulation and inspection. The DOF has been involved in fish inspection and quality control since 1964.

Within the DOF the Fish Inspection and Quality Control Division (FIQD) is responsible for implementing fish inspection and quality control programs. Its mission is to ensure that products produced by approved processors are safe, of good quality and meet a range of minimum standards, including those required by major importing countries. The main activities of the FIQD include:

- monitoring the environmental quality of coastal waters and aquaculture areas
- enforcing minimum hygiene standards in marine capture and aquaculture
- monitoring the use of drugs and chemicals in aquaculture
- inspecting fish handling and processing establishments
- approval of fish processing establishments for export
- certification services
- product compliance, quality and safety surveillance
- research and training.

In 1991, the DOF introduced a voluntary HACCP fish inspection program. The program involved reviewing inspection procedures and training for inspectors, training for industry, and pilot HACCP implementation by selected firms. Close monitoring of the effectiveness of HACCP implementation within the fish processing sector has been carried out by inspection of facilities and the provision of audit and accreditation services. In 1996 HACCP implementation became mandatory for FIQD approved fish processors under the jurisdiction of the DOF. The DOF requires that approved processors have their HACCP program audited by the FIQD.

The FIQD also provides a range of support services to the fish processing industry, including:

- basic training on the principles and application of HACCP to the fishery industry
- more advanced training on specific HACCP elements such as hazard analysis, handling documentation, validation and verification procedures for the industry
- guidelines on hazard identification
- guidance on the legislation and requirements of particular importers.

The DOF research and development division, the Fishery Technological Research Institute (FTRI), also provides both guidance on the improvement of prerequisite systems and advice on the development of HACCP systems.

11.5 The need for HACCP in the fisheries industry

There are a number of forces driving concerns over safety in the fisheries industry. These include:

- the increased importance of the international trade in fish, leading to increased risks of contamination as perishable fish products are moved greater distances along more complex supply chains
- the growing trade in fresh fish, made possible by improved transportation, with a much higher risk of contamination
- the increasing numbers of new or re-emerging pathogens that have the potential to contaminate fish
- more vulnerable populations with potentially lower immunity to new imported pathogens; in developed countries this vulnerability may be increased by an ageing population, while in developing countries immuno-compromising diseases like AIDS may increase the risk of infection from contaminated imports.

In recent years the global community has been seeking a common approach to maximizing quality and safety of all food products. This approach includes the use of hazard analysis critical control point (HACCP) systems as a means of assuring proper food handling, processing and retail sale to consumers. The use of HACCP systems in the fishery industry is now on a global scale. Since it first emerged, the concept has increased in importance, partly through its endorsement by Codex Alimentarius, and particularly with the endorsement of HACCP systems to control imported fish and fishery products by the EU and USA, two of the most important fish importers. Currently over 40 countries have announced HACCP initiatives for the control of fish production, processing and distribution. The Codex Committee on Fish and Fishery Products is currently revising the Code of Practices for Fish and Fishery Products to incorporate HACCP concepts. The revised Code of Practices will cover:

- prerequisite programs covering fishing vessels, aquaculture farm and processing plants
- HACCP-based food management systems for ten types of fish and fishery products, including transport and storage.

However, the Codex consultation process means that finalization of this code is not likely to take place until 2003 or later.

11.6 Hazards associated with fishery products

Fishery products differ from other types of food in a number of ways. Each species of fish, molluscan shellfish or crustacean may have quite different hazards which also vary from one country or region to the next. Most fish is still harvested from a wild population where control is not possible before fish are caught. The fish processor is limited in choice for the fish species and the condition of the catch landed by fishermen. Aquaculture has resolved those problems to some extent by creating a more controlled environment for fish breeding before harvesting. However, aquaculture species have distinct hazards of their own. Table 11.2 summarizes the main hazards associated with aquaculture fish and wild caught species. It should be noted that the nature and seriousness of such hazards varies from species to species, as well as with such factors as dose levels and environmental conditions.

11.7 Key issues in HACCP implementation

It has been estimated that over 70% of fish products traded internationally had quality defects ranging from decomposition, contamination with pathogens or foreign bodies to discrepancies in stated weight and incorrect labeling (Emberly 1999). This failure illustrates the scale of the problems faced in effective implementation of HACCP systems. Given the involvement of small-scale producers in developing countries in the supply chain, there are major weaknesses in basic good manufacturing and hygiene practice. These weaknesses illustrate the importance of HACCP studies paying particular attention to prerequisite systems such as hygiene, traceability and product recall procedures (Emberly 1999). HACCP can only be effective if it is based on a solid foundation of good manufacturing practice (GMP), sanitation standard operating procedures (SSOPs) and clear standard operating procedures (SOPs).

This requirement is all the more important because HACCP will be most effective if applied across the whole supply chain ‘from water to table’. This approach implies that HACCP must start at the aquaculture and harvesting stage

Table 11.2 The main hazards associated with aquaculture fish and wild caught species

Species	Hazards	
	1. Biological hazards	
Aquaculture species, wild caught species	• Parasites	Trematodes – clonorchis, opistochiasis, paragonimiasis, intestinal trematodiases Nematodes – anisakiasis, gnathostomiasis Cestodiases – diphillobothriasis
Aquaculture species, wild caught species	• Bacteria	Indigenous bacteria – *Clostridium botulinum* type E, *Listeria monocytogenes, Vibrio* spp., *Aeromonas* sp. and *Plesiomonas* sp. Non-indigenous bacteria – *Salmonella* spp., *Shigella* spp., *E. coli*, *Campelobacter* spp., *Staphylococcus aureus*
Aquaculture species, wild caught species	• Viruses	Viral diseases (associated mostly with molluscan bivalves) – hepatitis type A, Norwalk virus, calicivirus
Aquaculture species, wild caught molluscan bivalves	• Marine toxin	PSP, DSP, ASP
Specific wild caught species	• Other toxin	Ciguatera toxin, scrombotoxin (histamine)
	2. Chemical hazards	
Aquaculture species	• Agrochemical	Chemical fertilizers, water treatment compounds, algicides, herbicides, pesticides, disinfectants
	• Chemotherapeutants	Antimicrobial agents, parasiticides, hormones
	• Feed ingredients, additives and contaminants	
Aquaculture species, wild caught species	• Metals	Copper, other heavy metals – Hg, Cd, Pb, As
Aquaculture species, wild caught species	• Organic pollutants	Polychlorinated buphenyls (PCB), dioxins, insecticides (chlorinated hydrocarbons)

and continue through processing, distribution and retail handling to consumer education. However, to date HACCP systems in the Thai fishing industry have generally only been applied to processing in the factory. There have been some initiatives to address HACCP implementation within aquaculture. These include:

- catfish production and processing in the USA (Boyette 1996)
- shrimp production in Thailand (Tukvinas and Suwanrangsi 1996)
- fish farming in Ireland (Garforth and Reilly 1999).

As a result of these projects, codes of practice are now being developed by the Codex Committee on Fish and Fishery Products to cover both aquaculture and marine capture. However, there are currently significant gaps in developing HACCP models for both these sectors.

Even within fish processing, there are a considerable number of HACCP systems from which to choose. Some general models such as those set out by Codex, the EU and the US Food and Drug Administration (FDA) seafood HACCP program concentrate on food safety. Other models such as those developed by the US National Marine Fisheries Services and the Canadian Quality Management Program, for example, also include quality issues. The Australian government, for example, has developed SQF 2000, a system combining HACCP and selected elements of ISO 9000. The Codex Committee on Fish and Fishery Products is currently revising the Code of Practices for Fish and Fishery Products to incorporate HACCP principles and also essential quality issues such as composition and labeling. Its model proposes the use of defect action points (DAPs) based in part on critical control points (CCPs) in HACCP systems. The current range of models can be very confusing, even for experts, let alone the small-scale processor, and puts a greater responsibility on the regulatory authorities to provide clear guidance and training.

Where, as in Thailand, the fisheries industry is still dominated by small primary processors, resources are also a major issue, in terms of both the finance and expertise available for HACCP implementation. Guidance on HACCP systems needs to take account of these limitations, and there is a greater need for government support. In practice, for many of those involved in the industry, the first priority needs to be sound prerequisite systems. Once these are functioning effectively, experience with fish processors in Thailand suggests that HACCP systems become much simpler to design and manage, both for large and small businesses.

11.8 Preparing for HACCP implementation

Experience with a large number of businesses attempting to implement HACCP systems suggests there are a number of common issues in effective preparation for HACCP implementation:

- commitment and understanding
- resources
- building the HACCP team
- meeting differing HACCP standards
- language.

11.8.1 Commitment and understanding

Securing a genuine commitment to HACCP implementation is a critical issue. Many Thai businesses expressed an initial indifference to the concept. A common response was complacency: businesses had operated for many years without serious problems or complaints, so why the need for change? A major force for changing attitudes was commercial pressure, particularly once HACCP implementation became a prerequisite for exporting to the USA and the EU, and an important way of boosting trade with other countries such as Canada and Australia. Where firms have not come under pressure from customers or needed to respond to the needs of particular export markets, HACCP implementation has remained extremely patchy.

An important difference between those companies successfully implementing HACCP systems and those who have encountered problems has been in the depth of their commitment to and understanding of HACCP principles. Those who found HACCP implementation difficult were often those responding reluctantly to external regulatory or consumer pressures. Given the demands of implementation, the HACCP concept requires a more positive commitment, based on a realization of the need to improve product safety, a desire to take greater responsibility for consumer safety, and a belief that a HACCP system can enhance the overall quality of a company's performance. It also requires a proactive approach with a business taking more active control of its production operations. Companies that did not actively embrace HACCP principles were more likely to rely too much on sometimes conflicting customer requirements, to make uncritical use of generic HACCP models, and to find it difficult to maintain momentum in the face of the demands of setting up an effective HACCP system. Only when management viewed HACCP implementation as an essential tool for the improvement of product quality and safety, and for building a stronger competitive position, was it likely to make HACCP a success.

Experience suggests that securing this level of commitment and understanding among senior management can be facilitated by a briefing session, perhaps involving staff from the DOF or a marketing expert who can demonstrate the commercial benefits of a HACCP system as well as its key principles. This initial briefing needs then to be followed up by a full discussion of the advantages and disadvantages of undertaking HACCP implementation, including the likely costs (see below). Only once senior managers have had an opportunity to debate the issues fully and reach a consensus to proceed, should HACCP planning begin. Experience of trying to 'sell' the HACCP concept to businesses often unfamiliar with it suggests that building understanding and enthusiasm among senior managers can be a gradual process with sometimes several briefing sessions required to work through what is involved. Embracing a HACCP philosophy requires moving from a reactive culture, responding to external pressures, to a proactive one, seeking to exert a much greater control over a business's operations. This shift in culture can be a slow process, but it needs to take place if HACCP implementation is to succeed.

11.8.2 Resource requirements

One issue that needs to be addressed at an early stage is the likely costs of undertaking a HACCP program. In practice, the main costs for Thai businesses have been in the following areas:

- upgrading prerequisite systems (the major source of cost)
- training
- consultancy and external audit costs.

Cato (1999) reported that estimates of the cost of implementing HACCP systems in seafood processing factories ranged from as little as 0.3% of the total value of sales for US shrimp processors to over 9% of annual export sales for the Bangladesh shrimp processing sector. He further reported that the cost of upgrading Bangladeshi shrimp processors and government regulatory facilities in 1997 was US$18 million.

Training is another major commitment for which businesses need to plan and cost at the outset. Companies often underestimated the amount of training required. These commitments include:

- sanitation and hygiene training for line personnel in building effective prerequisite systems
- in-depth training for the HACCP team leader: companies implementing HACCP systems successfully were those willing to send team leaders on accredited courses, so that they could be sure of having someone familiar with all the stages of HACCP implementation
- training for HACCP teams, often through a one-day course on HACCP principles and the role of HACCP teams
- audit training to equip personnel to carry out internal audits
- training in monitoring and verification skills for CCP staff.

Many companies had limited experience of training. The most successful spent time auditing likely training requirements, researching available resources and drafting a training plan, including developing training records for staff where these were lacking.

Given the demands of HACCP implementation, support from government agencies proved particularly important for many companies. An important step for many businesses, once they had assessed the main challenges in developing their own HACCP system, was to research the range of government support available. This support includes:

- initial briefing on the benefits and principles of HACCP
- information on and funding for accredited training courses
- funding available for external consultancy services
- training materials
- briefing on international and national standards
- generic HACCP models as a starting point for HACCP design
- advice on hazard analysis
- availability of fisheries inspection staff to answer specific queries
- regulatory audit recommendations.

11.8.3 Building the HACCP team

Working with companies on HACCP systems suggests that core teams of two to three people work best, with others brought in occasionally to advise on specific issues. This size is often the most feasible for smaller companies in particular. HACCP team leaders are usually selected from the senior quality assurance (QA) staff. Other team members would be drawn from senior production and product development staff. Teams are more effective if they include someone with specific responsibility for recording key decisions and maintaining an action plan.

Given the importance of prerequisite systems as a foundation for HACCP systems, and the major improvements sometimes required, many companies have found it necessary to form a separate team or teams responsible for these areas. In some cases one team has been specifically responsible for improving hygiene control, with another responsible for other prerequisite systems. Both reported to the overall HACCP team leader. This division of labour has allowed businesses to focus resources much more effectively, rather than try to deal with prerequisite systems and HACCP design within the same team. In most cases, it is necessary to conduct a HACCP study and improve prerequisite systems at the same time. Improvement of prerequisite systems is, for many processors, a lengthy process, given existing weaknesses and the costs of change. Delaying a HACCP study until all required improvements to a prerequisite system have been made is often not an option, particularly in meeting mandatory export requirements. Where necessary, HACCP studies have included extra CCPs to compensate for outstanding improvements in prerequisite systems.

11.8.4 Meeting differing HACCP standards

A particular problem facing businesses exporting to a range of markets is that they face differing requirements and competing HACCP models from differing national administrations. An additional problem is a constant stream of changes and additions as differing national regulations evolve.

This problem of multiple and moving standards places a particular responsibility on government. The DOF works closely with the industry in defining the common minimum requirements for a HACCP system which will meet the main requirements of a company's export markets. Some companies have then developed a basic HACCP plan, which, once implemented, they have then gradually developed to meet particular national statutory requirements where necessary. Regular review, often in consultation with the DOF, is required to keep up with developments in differing national jurisdictions.

11.8.5 Language

Language is a major challenge to the successful implementation of HACCP in non-English speaking countries. Even in English, explaining HACCP concepts and procedures in terms that technicians and workers at the plant level can cope with is formidable enough. Translation into a foreign language can result in confusing the meaning of even the basic HACCP terms such as 'hazard'. In some cases, newly emerged pathogens, for example, do not have any local language name and cannot be precisely translated, making it difficult to distinguish them from other pathogens and to explain their nature and dangers.

The demands of translation are compounded by the fact that, to meet export customer and market requirements, HACCP plans need to be in English, whereas to be comprehensible to company staff they need also to be written in Thai. These problems have been resolved in part by government translation of key HACCP documentation which has then been made available to companies, often as part of initial training sessions on HACCP principles. These have provided the raw materials for developing HACCP plans in Thai. A basic error made by a number of companies was to try to undertake some of the translation work themselves, using in-house expertise, often located within the marketing department. These attempts were usually unsuccessful, resulting in inaccurate and misleading material.

11.9 Designing the HACCP system

Successful design of a HACCP system was seen to depend on a number of factors:

- scope, prerequisites and models
- hazard analysis
- CCPs and critical limits
- documentation.

11.9.1 Scope, prerequisites and models

Many companies trying to develop HACCP systems made a fundamental initial error in failing to restrict the scope of the HACCP system to what was realistic and practical. While, as has been seen, many current models available to companies incorporate quality as well as safety issues, successful HACCP design depends on separating the two and concentrating on safety first. It also depends on dealing with prerequisite systems separately from HACCP design, using improvements in the former as the foundation for the latter. Failure to set these priorities led to overcomplex and unwieldy HACCP designs, crowded with CCPs covering quality as well as hazard control, and sometimes trying to cover basic hygiene issues too.

DOF staff have developed generic HACCP models for fish processing. These have proved a helpful starting point for companies embarking on HACCP design. However, the depth of a company's understanding of HACCP principles and preparation for HACCP design has shown itself in the degree to which such models have been reworked to fit the particular requirements of the business. Effective HACCP design depends on a company taking responsibility for its own HACCP design appropriate to its own products and processes. A few companies attempted to work with generic models as they were. This mentality demonstrated the kind of failures in commitment, understanding and shift in culture discussed earlier.

11.9.2 Hazard analysis

Hazard analysis proved one of the major challenges for many businesses. While many of the hazards affecting fish products are well documented, a significant number of businesses were ignorant of the full range of hazards and their potential impact on their products. They were used to reactive hazard analysis, dealing with individual hazards as they arose, particularly in response to customer concerns over final product quality. In many cases businesses lacked in-house microbiological expertise.

Fisheries department staff had a key role to play in assisting businesses start the process of hazard analysis. They developed a simple hazard table, dividing hazards into biological, chemical or physical hazards, further subdivided by species. This framework provided a starting point for a HACCP team. DOF staff also provided guidance on key information sources to consult, together with training materials on some of the main hazards, and initial advice based on experience with similar businesses. HACCP teams were also encouraged to analyse the business's own records on quality control problems. DOF staff also suggested ways in which each hazard might be recorded and its severity and likelihood of occurrence assessed, with the evidence used for this analysis recorded. All this material was used in training programs and workshops with companies.

To avoid any conflict of interest between the DOF providing advice/data for hazard analysis while also inspecting and regulating businesses, the FIQD limited its role to providing general guidance related to potential hazards and reference criteria for establishing critical limits. Given their role in inspection, staff did not make specific recommendations concerning individual business HACCP studies. The DOF research division, the FTRI, does provide technical assistance on HACCP design, implementation and validation, since FTRI staff are not involved in inspection and audit.

11.9.3 CCPs and critical limits

Because they confused quality and safety issues and failed to define the scope of the HACCP study, a number of businesses produced HACCP plans that incorporated a maze of CCPs which could not be monitored adequately and which resulted in a mountain of records. Experience of HACCP plans across the fish processing sector suggested that, once prerequisite systems were operating effectively, and once quality issues were separated out, most HACCP systems were relatively simple with far fewer CCPs than many original HACCP plans.

Some businesses, retaining the more reactive business culture discussed earlier and lacking confidence in their own resources, were too ready to add in CCPs recommended by customers, without having undertaken their own analysis as to whether the CCP was required. The importance of a business taking responsibility for and ownership of HACCP design is emphasised by Dimento (1999). He described a dialogue with the FDA over whether the batter application step in the breading process in his business needed to be a CCP. The company was able to make a strong case, based on a thorough understanding of the relevant hazards and its own processes, backed up by the appropriate scientific literature, that the FDA was mistaken in insisting that this process step need be a CCP, given modern continuous batter application technology. The result of the company's case was to modify the FDA's position, resulting in it establishing more realistic temperature control limits for batter application processes. This change provided a significant financial saving to processors without compromising food safety.

Businesses setting up CCPs sometimes found difficulty in establishing critical limits, given different recommendations in the scientific literature or conflicting requirements from differing regulatory authorities. On these occasions DOF staff provided reference criteria on the appropriate limit to set.

The validation of critical limits was another area of difficulty, especially for small-scale processors who could not run their own challenge tests. The DOF has been able to provide some support in the use of government or university research laboratories to run challenge tests. However, there remain gaps in appropriate guidance on validation procedures for critical limits, and this is an area where the DOF itself is still developing the appropriate technical knowledge and skills.

11.9.4 Documentation

Creating and managing HACCP documentation is an obvious area where businesses face difficulties, usually from creating too much documentation of poor quality. DOF staff responsible for regulatory audits will review the HACCP plan for the appropriateness to individual process, product and technical integrity of the draft documentation. Many of the problems are the result of confusion and poor individual document design. Experience suggests that it is important to keep documentation simple. CCP monitoring procedures should, for example, deal with a few essential issues such as the following:

- the purpose of the CCP
- the critical limit to be monitored
- how it is to be monitored
- the person responsible for monitoring
- where results are to be recorded
- how frequently
- what to do if the critical limit is exceeded.

If the wording is kept simple and the procedure can be quickly grasped by line staff, the procedure will be effective. An appropriate reference number and date can be added to show when the procedure was last reviewed. Experience suggests that only once individual documents are finalized is it appropriate to put together the main HACCP procedures manual. This should contain any supporting material that auditors might need.

A key issue is to keep documentation for prerequisite systems and that for HACCP systems separate. As has already been noted, although it can delay HACCP implementation, it is critical to deal with weaknesses in prerequisite systems as a priority, including problems in documentation. Many companies took several attempts to get the design of their documentation systems right, testing out what worked best with line staff and what proved most effective in capturing monitoring data.

11.10 Implementation issues

There have been a number of common problem areas in implementation:

- lack of motivation and appropriate training among line staff
- poor audit procedures
- difficulties in maintaining the system.

11.10.1 Line staff motivation and training

Getting the support of line staff for successful HACCP implementation proved a major challenge for many companies. Many line operatives were relatively unfamiliar with the range of hazards affecting the products they produced and even, in a few cases, with basic hygiene practice. Some had little experience of systematic record keeping. Just as importantly, most were unused to taking the initiative in decision making, expecting to refer any problems immediately to managers. This sometimes made the new role of CCP monitoring and, in particular, responsibility for taking corrective action difficult to grasp.

These problems made good quality training particularly important. The DOF has provided a range of training aids, including audio-visual materials, to help build awareness of hazards and the principles of HACCP systems. Concentrating on hazards and getting staff to suggest how they might be dealt with proved an effective way of introducing the HACCP concept. Clear and simple step-by-step procedures and documentation for CCP monitoring were also essential in helping staff take on new responsibilities. Labeling machinery as a CCP and putting up posters around the factory about hazards also proved useful for some companies in raising awareness. It was most important, however, for managers to ask staff regularly about their new responsibilities, particularly as some staff were reluctant to admit that they had not understood everything for fear of losing face. Asking a CCP monitor to describe the key hazards, explain their duties and to take a manager through the monitoring data proved the best way both of getting staff to think through what they were doing and to test how well they understood their new role.

11.10.2 Audit procedures

Since many companies only started to implement HACCP systems at the end of the 1990s, many have not yet had the opportunity to conduct their first and full internal audit. In some cases, firms have been slow to do so because they are unfamiliar with the concept. Many tend to delay auditing because they are concentrating on day-to-day production issues and ensuring that their HACCP systems are operating smoothly. The DOF has encouraged all businesses implementing HACCP systems to undertake an annual internal audit and, providing that support and encouragement are offered, most firms try to do so. A few firms are more resistant to internal auditing altogether. These firms are typically those used to dealing with safety or quality problems reactively in response to customer complaints, and who are unused to analysing their processes for themselves to anticipate problems and identify improvements. Such firms typically wait for an official inspection to pick up any problems. It is these firms, struggling to make the shift to taking greater responsibility for understanding and controlling their own production operations, that have had greatest difficulty generally in implementing HACCP systems successfully.

Many businesses lack the resources to fund an external audit, and must rely on appointing an internal audit team. Because auditing is still not widespread, support from the DOF has proved essential for many companies. The DOF is able to recommend accredited courses for internal auditing. Given the pressures in dealing with day-to-day issues, it is easy for audits to slip and therefore particularly important to set a deadline for training auditors, planning and conducting the audit and providing a written report.

It is particularly important for companies to be confident in their HACCP systems, and to have audited them for themselves, because customer and regulatory audits can sometimes be misleading. It is easy to forget that HACCP is a new concept for regulatory agencies and their staff too. Spiller (1999) has pointed out, from experience of working with inspection staff in the USA, that inspectors can make the wrong judgements which can be successfully challenged by a business. Many official inspection regimes and their staff are still making the transition from the traditional emphasis on sampling and laboratory testing of raw materials and products and hygiene/GMP inspection to auditing the effectiveness of HACCP management. In addition, regulatory staff will inevitably have a more theoretical approach to HACCP, based on generic models for a particular sector, which may make some of their recommendations inappropriate and impractical for a particular business. If companies are not aware of these limitations, they may passively accept changes which complicate rather than improve a HACCP system.

The DOF has tried to develop an audit procedure that takes into account the particular circumstances of a business. This entails making the reference standards and guidelines for a regulatory audit available, and agreeing the scope and schedule of the audit in advance. Some companies, unfamiliar with the role of an audit, have taken up a defensive attitude, avoiding providing information where they felt they might be weak. The DOF has tried to educate companies about the purpose and value of an audit in identifying improvements for the mutual benefit of business and regulator.

Common issues raised by audits include:

- the poor quality of prerequisite systems, particularly in hygiene and sanitation
- the inadequacy of hazard analysis
- inappropriate selection of CCPs
- inadequate validation of critical limits
- poor monitoring methods and frequency of monitoring
- the ineffectiveness of monitoring procedures, and the failure to take corrective action when required
- deficiencies in the company's own audit procedures.

11.10.3 Maintaining the system

Setting up and operating a HACCP system in the first year has proved a major challenge for many companies. A newer challenge is keeping HACCP systems up to date in subsequent years. A number of ways of achieving this have proved successful:

- internal and regulatory audits have provided businesses with many suggestions for improvement
- regular review of customer complaints and the business's own records of safety and quality problems
- a regular programme of staff training
- building up essential reference materials, on key hazards for example, and providing access to the Web for the HACCP management team.

Since HACCP implementation is still relatively new in Thailand, this is an area where both businesses and regulatory agencies are still building up experience and expertise.

11.11 Measuring success: the benefits of HACCP implementation

There are a number of ways of measuring the success of a HACCP system, including:

- successful third-party or regulatory audit and accreditation
- improved access to export markets
- the contribution of an accredited HACCP system to achieving preferred supplier status with key customers
- fewer customer complaints
- improved productivity through reduction in safety and quality problems.

Experience from auditing companies in the Thai fishing industry has also meant that government inspectors feel it less necessary to inspect firms with accredited HACCP systems as frequently as others. Companies have reported other benefits, notably that HACCP systems have given line staff much greater confidence, independence and understanding, reducing their reliance on managers to solve day-to-day production problems. Once embedded, firms have also found they could extend HACCP principles into areas of quality, identifying critical areas for quality control and building up systems for controlling them more effectively. Above all, HACCP systems have given Thai companies greater confidence. Many companies in Thailand have, on the foundation of their HACCP systems, expanded their value-added product lines to include more ready prepared foods, confident of their ability to manage the food safety and quality of such products. The market for these products has also grown as a result of buyers' and importers' confidence that HACCP controls are in place. This development has been noted more generally in the seafood industry (Morrison 1999).

The value of HACCP systems in fish processing can be seen in the way that companies have retained them in preference to other management systems such as ISO 9002. Sumner (1999) reported the experience of 22 companies in Australia in implementing both HACCP and quality systems. About half of the companies were predominantly exporters with all involved in both primary and secondary processing. Each company was given assistance in the design and implementation of its QA system, with support both in the first year of operation and in paying for certification. Three years after implementing both the HACCP and QA system, only 10 of the 22 companies had retained their ISO certification, while all had carried on with HACCP systems. Reasons for not continuing the ISO certification included the second- and third-party audit fee, no obvious financial advantage in having the certification logo and the burden of maintaining the system for small businesses.

11.12 Conclusions: the future of HACCP

If there is a single factor determining whether a firm will implement HACCP successfully, it is its management culture and its capacity to embrace the philosophy underlying the HACCP concept. This is perhaps the biggest single challenge facing a business considering HACCP implementation. HACCP systems demand a business and staff at all levels willing to take more responsibility for and control of the business's operations, rather than relying on others to identify problems and improvements, whether they be customers, regulators or more senior managers.

The success of HACCP implementation in the Thai fisheries industry has also been dependent on close cooperation between industry and government, and the willingness of the latter to play a proactive role in HACCP implementation. The Thai government has provided advice, training and financial support. Through the DOF it provides, for example, guidance on international standards, translations of key documentation, generic HACCP models, information for hazard analysis, training programs and materials. This proactive role is critical in a country where, until comparatively recently, the HACCP concept was new, prerequisite and other safety systems were often weak, and resources were lacking. The momentum for HACCP implementation has been driven, for both government and industry, by a long-term export strategy in which HACCP implementation was essential both to access to and success in key export markets.

There are a number of improvements that need to be made. These include the following:

- HACCP systems are still concentrated in processing. So far they have not been extended further along the supply chain, particularly in marine capture and aquaculture. Cato (1999) has argued for the extension of HACCP principles into such areas as retail sale and consumer handling of fish products.
- HACCP take-up among smaller businesses remains poor.
- Government needs to keep abreast of changes in HACCP regulations and standards internationally, and to exert pressure for greater standardization.
- There need to be improved practical guidelines for hazard analysis.
- Inspectors need to gain more expertise and experience in effective inspection techniques, translating HACCP theory into effective practice. As an example, inspectors need to be able to use generic HACCP models flexibly, accepting variations that are appropriate to a particular business.
- There needs to be more research in such areas as the validation of critical limits.

11.13 References

BOYETTE, K.D.C., 'Quality control of HACCP in catfish industry', in *Fish Inspection and Quality Control, and HACCP: a Global Focus*, Proceedings of the Conference, Arlington, Virginia, Technomic Publishing Co., Inc., Lancaster, 1996.

CATO, J., 'The economics of seafood safety and quality and HACCP implementation in world seafood market', The 3rd International Fish Inspection and Quality Control Conference, Halifax, Nova Scotia, 1999.

DIMENTO, B., 'HACCP in the USA market: how it works down South', The 3rd International Fish Inspection and Quality Control Conference, Halifax, Nova Scotia, 1999.

EMBERLEY, B.J., 'Possible developments on the regulatory side of fish inspection in the coming decade', FAO/DANIDA Advance Seminar on the Implementation and Economics of HACCP Based Systems in the Fishery Industry, Hirtshals, Denmark, 1999.

FAO, *The State of World Fisheries and Aquaculture*, Rome, 1998.

GARFORTH, D. and REILLY, A., 'Design and implementation of HACCP-based quality assurance programmes for aquaculture', The 3rd International Fish Inspection and Quality Control Conference, Halifax, Nova Scotia, 1999.

MORRISON, C., 'HACCP industry experience in the UK', The 3rd International Fish Inspection and Quality Control Conference, Halifax, Nova Scotia, 1999.

SPILLER, P., 'United States HACCP experience', The 3rd International Fish Inspection and Quality Control Conference, Halifax, Nova Scotia, 1999.

SUMNER, J., 'HACCP and quality assurance systems in Australian seafood industry', The 3rd International Fish Inspection and Quality Control Conference, Halifax, Nova Scotia, 1999.

TUKVINAS, S. and SUWANRANGSI, S., 'Hazard control in aquaculture', in *Fish Inspection and Quality Control, and HACCP: a Global Focus*, Proceedings of the Conference, Arlington, Virginia, Technomic Publishing Co., Inc., Lancaster, 1996.

12

Implementation and enforcement in the United Kingdom

J. Barnes, Food Standards Agency, London

12.1 Background

UK government initiatives to encourage the implementation of HACCP-based food safety control systems began in the early 1990s. This reflected the growing international recognition that HACCP was the management system of choice to ensure food safety and consumer protection. The initiatives also responded to key recommendations made by a UK Expert Committee which examined the rise in UK food poisoning during the 1980s. With regard to HACCP, the Committee Report[1] recommended that:

- food processes should be designed on HACCP principles
- enforcement staff should seek to encourage HACCP through their inspection activities
- enforcement staff should receive appropriate training in HACCP systems and their application.

Early initiatives focused on increasing the general awareness of HACCP and ensuring that appropriate training courses and materials were available to both the food industry and enforcement officers. For example, the professional Core Curriculum for local government environmental health officers (who constitute the major part of the UK Food Safety Inspectorate) was examined to ensure that it contained enough practical training to enable inspectors to carry out assessments of HACCP-based systems. A nation-wide programme of training and awareness seminars for both industry and enforcement officials was also carried out and a range of HACCP materials, training aids and packages were developed or encouraged to help facilitate HACCP implementation in food businesses.

Some parts of the UK food industry, particularly the larger manufacturers, were quick to implement HACCP management systems and such systems were required within commercial supplier specifications and contracts. Also, companies with HACCP in place, particularly within ISO 9000 (quality control systems) were more able to sustain 'due diligence' defences available in UK law from 1990 in the event of a food safety problem.[2] As such, enforcement authorities, even in the early 1990s, were increasingly being required to assess the adequacy of HACCP systems on a legal basis where these systems were being put forward by businesses as part of a due diligence defence. However, enforcement officers also had a key advisory role with smaller businesses during this period, increasing their awareness of HACCP and encouraging them to put HACCP-based controls in place.

12.2 UK legal requirements for HACCP

Since 1993, as part of the European legislative framework to support the single market, HACCP-based requirements have been progressively introduced into UK law through the implementation of a range of EU food hygiene directives.

The Hygiene of Foodstuffs Directive 93/43EEC (covering food retailers, caterers and manufacturers of non-animal origin products), for example, requires certain principles of HACCP to be applied in these food businesses. Although the current legislation does not include an explicit requirement to document the system, in line with government advice, enforcement officials do encourage appropriate documentation and record keeping.

Separate European product specific legislation governs establishments manufacturing products of animal origin, i.e meat products, fish products, egg products and milk products. With the exception of fresh meat and milk, the legislation requires HACCP-based 'Own Checks' controls to be in place. These 'Own Checks' controls do require establishments to document procedures, such as the identification of critical points, monitoring arrangements and sampling regimes. Individual establishments also need to be approved by the authorities in order to trade.

12.3 The regulatory authorities

Historically, UK government responsibilities for food safety and hygiene have been shared between the Ministry of Agriculture, Fisheries and Food (MAFF) and the Department of Health. Between them, these two government departments developed and implemented the UK food policy and legislation including policy related to HACCP. On 1 April 2000 a UK Food Standards Agency was established which radically altered these arrangements and the Agency now has the UK policy and legislative responsibilities for food safety and food standards from farm to fork. The Food Standards Agency is a non-ministerial government department, governed by an independent 14-member board, accountable to Parliament through health ministers.

However, the day-to-day enforcement of food safety in the UK, including the enforcement of legal requirements relating to HACCP, is in the main discharged by local environmental health officials working in approximately 500 local authorities. Key exceptions to these arrangements relate to enforcement work within the fresh meat sector such as slaughterhouses and cutting plants, and on-farm dairy control. These sectors fall to the Food Standards Agency's Meat Hygiene Service and Dairy Hygiene Inspectorate respectively. However, currently there are no requirements for HACCP in the EU legislation applicable to these two sectors.

Environmental health officials have legal powers to:

- enter food businesses at all reasonable hours, if need be by force
- serve official notices to secure improvement and regulatory compliance
- close down food businesses immediately where there is imminent risk to public health
- prosecute proprietors or individuals for breaches of food safety and hygiene legislation
- detain and/or seize food failing to meet food safety requirements.

The activities of local enforcement officials are guided by statutory codes of practice made under the Food Safety Act and issued by central government. These codes contain advice on enforcement approach; recommended inspection frequencies; the nature of inspections to be carried out; and guidance on assessing HACCP-based requirements. These official codes are also supplemented by guidance issued by the Local Authority Co-ordinating Body for Food and Trading Standards (LACOTS).

In the UK food establishments are invariably subject to commercial auditing associated with supplier requirements. This reflects the very high percentage of UK food retailed through large supermarkets, which routinely assess supplier standards. Although the scope of these audits can cover other issues, e.g. quality, they usually incorporate assessments of the HACCP food safety arrangements, particularly when the audit is carried out within a recognised accreditation framework. Whilst such audits are not directly related to enforcement activities, they make an increasingly valuable contribution to food safety. Government enforcement codes of practice also allow commercial audits, particularly by accredited third parties, to be taken into account by local enforcement officials when considering the nature and frequency of their inspections.

12.4 Take-up of HACCP by the UK food industry

Implementation of HACCP by the UK food industry does vary across food sectors. The legal 'Own Checks' requirements and the associated approval arrangements which apply to establishments manufacturing products of animal origin have resulted in a high proportion of these businesses implementing effective HACCP-based controls. This process has been influenced by the direct marketing benefits such systems offer businesses, particularly in the context of supplier requirements.

The implementation of HACCP or HACCP-based control systems in small and medium-sized enterprises (SMEs) – which represent the bulk of the over 600,000 food businesses operating in the UK – is more patchy. For these businesses, in the main retail and catering operations, there are significant practical barriers which have held back implementation rates.

Government funded studies have sought to identify these practical barriers to HACCP implementation.[3] Whilst barriers are likely to occur in any business regardless of size, they seem to be more acute in SMEs where the marketing benefits of introducing HACCP control systems are less clear. One UK survey[4] identified the following issues:

- *Cost*: HACCP was perceived as expensive, especially by smaller retailers and caterers. Such businesses were less able to identify any tangible benefits to balance out the costs of HACCP. Manufacturers on the other hand were more able to see the trading advantage HACCP gave them.
- *Time*: The more limited staffing and resources available in small businesses and the relative expense of external support meant that, in practice, HACCP implementation relied on managers putting in such systems themselves. This competed against many other jobs to be carried out.
- *Complexity*: HACCP was generally perceived as complex by managers of smaller businesses, particularly where many different products might be routinely handled, as in catering.
- *Perception of risk*: Interviews with managers, particularly in the retail and catering sector, indicated a generally low perception of the risks posed by their handling or preparation practices. This low perception of risk, even where establishments routinely handled both raw and ready-to-eat foods, influenced their motivation to introduce HACCP controls.

A recent WHO Expert Consultation examining HACCP implementation strategies for small and less developed food businesses (SLDBs) highlights the fact that these barriers are by no means restricted to the UK, and lists these and others which need to be overcome in any implementation strategy.[5] The consultation report put forward a number of measures to help address the barriers. These included:

- central production of sector specific generic HACCP guidance which could be readily tailored by the business
- reducing the complexity of HACCP plans and records by grouping together products with similar characteristics and which undergo similar processing steps
- the provision of accessible and relevant training on food hygiene and HACCP.

The regulatory nature of UK HACCP-based controls requirements means that in practice enforcers have an important role to play in overcoming these barriers and ensuring effective systems are in place. This is particularly important in SMEs, as local authority enforcement officials are frequently found to be the main sources of information and route for advice on food safety for these types of business. The UK HACCP implementation strategy, therefore, involves enforcement officials offering advice and support on HACCP as part of their routine enforcement approach. The nature of the advice necessary will vary across businesses, from those which have significant in-house technical resources and skills to draw on, to those businesses where their technical capability is very much smaller or absent altogether.

12.5 HACCP and enforcement

HACCP represented and still represents a culture change for many UK food businesses. Whilst most proprietors tend to accept the need for visually clean, well maintained premises, the concept of assessing risks and managing food safety in a more formalised way is not so readily assimilated alongside the many other competing commercial priorities.

HACCP not only imposes certain management disciplines, it also requires an underlying knowledge of food hygiene and safety that in some cases may necessitate additional training. Government codes of practice therefore advise enforcement authorities to adopt a graduated approach to the enforcement of HACCP.[6] As a first step towards securing compliance, authorised officers are asked to adopt an educative approach and discuss the legal requirements relating to HACCP, as well as training, with the proprietor. As such, attendance on a recognised food hygiene and safety course might be the first step toward a business putting HACCP-based management controls in place.

For businesses subject to product specific legislation, such as manufacturers of products of animal origin, effective HACCP-based controls would need to be in place for the business to be approved. However, in these businesses it is also more likely that in-house capabilities would reduce the reliance on external support.

The main purpose of the enforcement inspection is to establish whether food is being handled and processed hygienically and whether the food is safe to eat. Assessing the risks arising from the food business activities in the UK does, therefore, include an assessment of the effectiveness of any HACCP-based system and controls in place.

The inspection will also aim to identify any contraventions of food safety and hygiene legislation and seek to have them corrected through appropriate enforcement action or advice. In practice, these specific legal hygiene requirements which apply to premises structure, personnel and equipment form an important platform (prerequisite) for any HACCP control system.

Inspections will be part of a planned programme, e.g. as part of a six-month, yearly or longer inspection cycle, and include a thorough assessment of any relevant HACCP documentation, together with a visual examination of the premises, including checks on CCP controls. More targeted inspections or visits to establishments may result from a complaint or specific project or investigation. Such visits might also result in an assessment or partial assessment of the HACCP system.

Where food businesses have a documented food safety management system, officials are advised to vary their inspection approach and make use of the relevant material. Where there are satisfactory management controls as part of a well thought out HACCP system, and the authorised officer has confidence in the management of the business on the basis of previous inspections, the assessment of the in-house HACCP-based controls could be a significant part of the inspection and take up a major part of the time involved. The main purpose of any subsequent visual or physical examination would be to confirm that CCPs have been correctly identified and the necessary controls are in place. In some cases, on the basis of professional judgement, this could involve testing critical equipment or taking samples for independent analysis.

The need to assess HACCP has increased the focus of inspections on initial discussions with the proprietor or representative on the hygiene systems and procedures in place. This will include scrutiny of relevant documentation such as records relating to the monitoring of CCPs. As a result, inspections incorporating assessment of HACCP initially take significantly longer than previously was the case and may increase the need for follow-up visits. This has had an impact on overall numbers of inspections carried out in the UK, and this potential impact needs to be considered in any HACCP implementation strategy.

12.5.1 What will the enforcer be looking for?

A number of issues are listed below which enforcers may consider when assessing HACCP-based systems, and which might affect their subsequent questioning and lines of enquiry.

- *Confidence in the food business management controls*:
  - The track record of the company. Its willingness to act on previous advice and its enforcement and/or complaint history.
  - The attitude and activities of present management to hygiene issues, the level of in-house food hygiene knowledge and training.
  - Technical knowledge within, or accessible to the business.
  - The level of documentation and in-house food safety management controls, including verification procedures or any external third party quality assurance.
- *Adequacy of the HACCP arrangements*:

  - The scope of the HACCP system. Does it reflect the extent of business activities and take proper account of the nature of the product and its intended use?
  - Expertise – is sufficient in-house expertise present? Who developed the plan and control arrangements? Has appropriate use been made of external or generic guidance to ensure soundly based controls?
  - Flow chart – does it reflect practice? Is it routinely reviewed?
- *The hazard analysis*:
  - Have all reasonable hazards been identified?
  - Who completed the analysis?
  - Has due regard been given to any relevant industry guidance, expert report or published information relating to the sector?
- *Assessment of risk*:
  - What is the history of problems or complaints related to the premises? Officers may wish to see any records relating to complaints.
  - Severity and imminence of any hazards – are vulnerable customer groups supplied?
- *Assessment of controls*:
  - What are the specific controls in place?
  - Have all relevant critical controls been identified and are they operating to any recognised/legal standards, e.g. required temperatures?
  - Have critical limits been identified? Are they realistic, measurable and relevant to the process? How were they determined, are they sufficient and what monitoring takes place?
  - Are food handlers adequately instructed/trained, particularly where they are involved in any monitoring procedures? Are corrective actions sufficiently identified, understood and operated?
  - Are records maintained correctly? Enforcers might target an individual product or batch.
- *Verification procedures*:
  - Are there in-house checks that the HACCP system is working correctly?
  - What are the verification procedures?
  - Are they adequate?
  - Are documented HACCP procedures being followed and reviewed?
  - Are the necessary tools/equipment in place to ensure procedures can be followed or checks made?

12.5.2 How can you help prepare for an inspection?

Regulatory assessments of HACCP are likely to follow a similar pattern to any effective internal verification process. As such routine in-house monitoring will help provide much of the groundwork for any inspection. The following pointers should help facilitate inspections, providing benefit for both parties:

- *Records and documentation*: It is good practice to document the controls and keep records, even where this is not a legal requirement. Enforcement authorities may sometimes inform food businesses of inspections, particularly where HACCP systems are being assessed for the first time; however, many proceed on an unannounced basis. As such, keep documentation readily retrievable. Whether paper or electronic, the ability to access key documentation readily not only enables better management control, it will also oil the wheels of any inspection. Key documents will include:
  - the HACCP plan
  - significant procedures stemming from the plan
  - plans relating to layout and services
  - flow diagrams of the operation/operations
  - any monitoring records relating to identified CCPs
  - any verification activities.

  Documents need not be extensive where operations are not complex. In essence they should be sufficient for there to be confidence that controls are in place and maintained. In larger establishments, enforcers are unlikely in practice to be able to examine all documentation in the course of an inspection. They may, for example, select specific records relating to the day or a product and form a judgement on the system on that basis.
- *Training*: Records or procedures relating to training/instruction of staff on food safety should be readily to hand. Training in food hygiene and HACCP, particularly training associated with any nationally recognised course, will be viewed as an important component for an effective HACCP system.
- *Monitoring*: A significant focus of the inspection will be on the in-house monitoring arrangements, particularly those relating to the monitoring of CCPs. Demonstrating that routine in-house monitoring takes place and that staff have both the training and equipment to enable them to monitor effectively, will go some way in establishing that the legal requirements are being met.
- *In-house technical ability*: In-house staff who have particular food safety knowledge or responsibilities should be on hand where practical to answer questions and/or inform about the arrangements in place. These staff may be able to provide valuable information about the arrangements and the necessary controls which can help the enforcement process.

12.6 Common problems with HACCP systems

Listed below are some examples of common problems found with HACCP systems in businesses:

- *The HACCP system is too complicated*: This can be the case in smaller businesses where the driving force for the system has been largely reactive and in response to legislative requirements, rather than an evolving management process. Even in large manufacturers, supplier requirements can be quite onerous and result in very complex systems not ideally suited to the business. Sometimes arrangements reflect off the shelf packages rather than the evolving needs and capabilities of the business itself. Simple systems and controls well understood and readily incorporated in the day-to-day operations and capabilities seem to be more successful and sustainable.

- *The HACCP system is not used*: Well prepared, documented manuals and procedures are present on site but not incorporated into day-to-day activities. This is relatively straightforward to see during any routine inspection and is often the consequence of overcomplicated, externally derived systems.
- *Too many critical control points identified*: There is a tendency to specify any hygiene control measure as critical. Whilst many operations need to be controlled and supervised on a routine basis, the number of CCPs, e.g. incorporating determination of critical limits, routine monitoring and corrective actions, should ideally be as few in number as possible. This cuts down on the relative complexity and degree of documentation necessary, and ensures resources are effectively focused.
- *Lack of monitoring*: Monitoring is crucial to effective control. As such, monitoring arrangements should be suited to the business processes and capabilities. Official inspections very often identify that routine monitoring of CCPs is not taking place, particularly where this is a manual process. Simple management checks and records will reduce the likelihood of this occurring.
- *Lack of corrective action*: Routine monitoring can become a non-thinking exercise. It is not unusual to examine business records, and see logs which indicate that critical limits have been breached, but no corrective action taken. Records are only a means to an end, not an end in themselves, and simple checks should be made to guard against this.
- *Poor hygiene*: Basic hygiene deficiencies within premises will undermine the HACCP system, which is why they are regarded as a prerequisite. For example, the increasing concern about microbiological hazards such as *E-coli* 0157 and *Listeria monocytogenes* make effective cleaning and disinfection procedures of paramount importance. Such prerequisite programmes, which are also basic legal requirements, can sometimes be found lacking alongside the HACCP ‘system’ which has assumed an almost mystical pre-eminence.

12.7 Future HACCP arrangements

The UK Food Standards Agency includes a remit to encourage the implementation of HACCP controls in the UK food industry. Sector specific initiatives will continue to be developed to accelerate HACCP take-up. For example, one recent centrally funded initiative in the retail butchery sector included the development of a generic HACCP manual, wall-chart and signage, free on-site advice and two days’ food hygiene/HACCP training. This was provided to over 7000 butchers. Existing training programmes for enforcers and industry are also being reviewed to identify further guidance material and tools to help more businesses put effective and practical food safety management systems in place.

On the European front, the EC recently issued a consolidated text on its proposals to fundamentally review the existing European food hygiene legislation. This contains a requirement for HACCP applicable to all European food businesses, with the exception of primary production. Future discussions to agree the text will no doubt draw from the experience of member states implementing the current HACCP-based regulatory requirements.

12.8 A personal perspective

There is currently a great deal of focus on the applicability of HACCP to smaller food businesses. Indeed within this chapter I have highlighted some of the difficulties faced by food businesses and enforcers. I believe that the take-up of HACCP in smaller operations has not been helped by HACCP's early association with larger manufacturers and its codification by Codex.[7] For example, its application in larger processors and the Codex Code of Practice guidance promotes the concept of teams of experts, and detailed specific product analysis. Whilst relevant for manufacturing establishments, it is clear that this approach is not well suited to smaller establishments handling large numbers of products, such as caterers.

Codex codification of HACCP has been very helpful in an international context. Indeed I have contributed to this process. However, this has probably served to restrict HACCP's evolution and further adaption to make it more suited to particular sector or business needs. This has helped to fuel concern and the perception that HACCP is too complex and ill suited to smaller food businesses.

Fortunately, international discussions are now taking place in the Codex Food Hygiene Committee which seem likely to result in the elaboration of further guidelines on HACCP application, particularly relevant to smaller non-manufacturing operations. These discussions reflect the conclusions and recommendations made in the WHO Expert Consultation Report and take account of the practical barriers to HACCP implementation in smaller operations.[5]

There is growing appreciation that HACCP, like any management system, needs to be flexible enough to take account of the practical needs of the business seeking to apply it. Whilst the seven principles provide an important framework to assist its common understanding and assessment, those principles should and can be applied in practice in different ways depending on the business type and complexity. There is a view, which I share, that this needs to be more formally recognised and described by Codex.

I believe HACCP is relevant to all types of food businesses. The responsibility for managing food safety and ensuring consumer protection rests with the business, whatever its size. HACCP serves to make this responsibility clear. No amount of external inspection can compensate for inadequate day-to-day food safety awareness or management, and nor should it try. HACCP provides a logical way through which food safety management can be approached. It also provides a common framework to help proprietors, managers and enforcers in their assessment and subsequent confidence that operations are under routine control. The challenge (which in my view we have not yet met) is to ensure the HACCP-based controls, in small businesses in particular, are effective and proportionate and owned by the business.

It is my personal view that we are moving to second generation HACCP, which more effectively balances the practical needs of the business for a flexible and proportionate management system, with the needs for an internationally understood framework and approach. HACCP will be taken from the technocrats (like me), de-jargonised and given to the managers to adapt and truly incorporate into their business decision making. As someone recently said to me, 'HACCP is too important to be left to the experts!'

12.9 References

1. *The Microbiological Safety of Food (Part 1)*, Report of the Committee on the Microbiological Safety of Food, HMSO, ISBN 0 11 3212273 9.
2. Food Safety Act 1990, HMSO, ISBN 0 10 541690 8.
3. FOOD STANDARDS AGENCY, Research Programme B13, *Microbiological Risk Management*.
4. FOOD STANDARDS AGENCY, Research Project B06002, *Evaluation of Barriers to Use of Food Hygiene Management Systems through the UK Food Industry*, University of Wales Institute, Cardiff.
5. *Strategies for Implementing HACCP in Small and/or Less Developed Businesses*, Report of a WHO Consultation in collaboration with the Ministry of Health, Welfare and Sports, The Netherlands, 16–19 June 1999.
6. Code of Practice No. 9, Food Hygiene Inspections (Revised) 2000, Food Standards Agency.
7. CODEX ALIMENTARIUS COMMISSION, *Recommended International Code of Practice – General Principles of Food Hygiene*, CAC/RCP 1 1969, Rev 3.

13

Effective HACCP training

C. Wallace, Reading Scientific Services Limited, Reading

Reading Scientific Services Ltd (RSSL) is a leading supplier of outsourced scientific services, including consultancy, training, research and analysis. A wide range of HACCP training courses are provided through RSSL's training company, Food Industry Training – Reading (FITR), a joint venture with the Department of Food Biosciences at the University of Reading.

13.1 Introduction

> HACCP is carried out by people. If the people are not properly experienced and trained then the resulting HACCP system is likely to be ineffective and unsound. (Mortimore and Wallace 1998)

Effective training is critical to the successful implementation of HACCP. Training in HACCP has two main roles:

1. It helps to develop awareness and motivation in the workforce for food safety management.
2. It provides technical and practical knowledge enabling trainees to participate in HACCP development and implementation.

Failure in either role will leave staff unwilling or unable to meet their HACCP responsibilities. There are a number of reasons that training can be less effective than planned in meeting these objectives. These include:

- motivation: initial resistance to training among trainees
- understanding: the failure to appreciate the kind of training required

- targeting: training the wrong people and/or providing the wrong level of training at the wrong time
- follow-up: the lack of follow-up from training
- quality: inconsistent and/or poor quality in training provision
- resources: the lack of resources for effective training, particularly for small and medium sized enterprises (SMEs)
- coverage: not training enough people.

This chapter looks at how to design and implement effective HACCP training, overcoming these potential problems to ensure achievement of the desired learning outcomes.

13.2 Training needs analysis

It is important to consider the differing levels of HACCP training needed within an organisation. Trainee groups will include:

- senior management
- the HACCP team and team leader
- CCP monitors and their supervisors
- other production staff.

The roles that these people will play in HACCP development and implementation will define their learning needs and will help in the development of training and learning objectives for each group.

Once the senior management team has committed itself wholeheartedly to implementing a HACCP system, an evaluation of the training requirements of all these groups will be an essential part of the initial planning for HACCP application. An effective evaluation will need to take account of the learning needs of the groups outlined above, from HACCP team leader to the workforce as a whole, and the appropriate timing for such training. It may be appropriate for a member of the HACCP team to take responsibility for the training needs evaluation, working in conjunction with the organisation's own human resources function to produce a detailed training plan as part of the HACCP implementation plan. It is important at this stage to review the comprehensiveness and effectiveness of existing training in food hygiene since this will be an essential prerequisite to specific training in HACCP implementation.

In addition to training in HACCP techniques, training in associated skills needed to develop and implement a HACCP system may be required, e.g. project management skills and leadership skills. Possible training objectives for different groups of staff are outlined in Table 13.1. The resulting HACCP training programme and its outcomes will need to be documented as part of the overall HACCP implementation plan.

Table 13.1 Possible training objectives for different groups of staff

Group	Training objective
Senior management	1. Understand the general principles of HACCP and how they relate to the food business. 2. Demonstrate an understanding of the training and knowledge requirements for HACCP team members and the workforce as a whole. 3. Demonstrate an understanding of the links between HACCP and other quality management techniques and programmes and how a combined product management system can be developed. 4. Understand the need to plan the HACCP system and develop a practical timetable for HACCP application in the whole operation.
HACCP team leaders	*HACCP system and its management*[a] 1. Demonstrate an up-to-date general knowledge of HACCP. 2. Explain how a HACCP system supports national and international standards, trade and legislative requirements. 3. Describe the nature of prerequisite programmes and their relationship with HACCP. 4. Demonstrate the ability to plan an effective HACCP system. 5. Demonstrate a knowledge of how to lead a HACCP team. 6. Demonstrate an understanding of the practical application of HACCP principles. 7. Demonstrate the ability to design, implement and manage appropriate programmes for verification and maintenance of HACCP systems. 8. Explain the methods to be used for the effective implementation of HACCP. *Additional topics* 1. Demonstrate an understanding of the nature of hazards and how they are manifested in food products/operations and give relevant examples. 2. Demonstrate an understanding of the intrinsic factors governing the safety of product formulations and methods that can be used to assess safety of new products. 3. Carry out the steps to identify significant hazards relevant to the operation and determine effective control measures, i.e. assessment of risk (likelihood of occurrence and severity). 4. Demonstrate an understanding of the training and knowledge requirements for HACCP team members and the workforce as a whole. 5. Develop appropriate training programmes for CCP monitoring personnel. 6. Demonstrate an understanding of the links between HACCP and other quality management techniques and how a combined product management system can be developed.

Table 13.1 (continued)

Group	Training objective
HACCP team members	*HACCP system*[b] 1. Justify the need for a HACCP system. 2. Show how the legal obligations on food business proprietors to analyse food hazards and identify critical steps in the business activities should be met in their appropriate industries. 3. List and explain the importance of the principles of HACCP. 4. Describe the method by which hazard analysis may be carried out and appropriate control measures ascertained to assess the practical problems. 5. Identify critical control points including critical limits to ensure their control. 6. Develop suitable monitoring procedures for critical points and explain the importance of corrective action procedures. 7. Verify the HACCP system by the use of appropriate measures. 8. Carry out the steps to introduce and manage a fully operational HACCP system. *Additional topics* 1. Demonstrate an understanding of the nature of hazards and how they are manifested in food products/operations and give relevant examples. 2. Demonstrate an understanding of the intrinsic factors governing the safety of product formulations and methods that can be used to assess safety of new products. 3. Carry out the steps to identify significant hazards relevant to the operation and determine effective control measures, i.e. assessment of risk (likelihood of occurrence and severity). 4. Develop appropriate training programmes for CCP monitoring personnel.
CCP monitors	1. Understand the general principles of HACCP and how they relate to the food handler's role. 2. Perform CCP monitoring tasks, record results and initiate appropriate actions.
Auditors of HACCP systems	*HACCP and regulatory auditing*[c] 1. Provide up-to-date general knowledge of HACCP and its relationship with national and international standards, trade requirements and legislative requirements. 2. Examine the role of good hygiene practices as a foundation for HACCP-based food safety management systems. 3. Provide a comprehensive revision of the application of HACCP principles for the development of HACCP-based systems for food businesses.

	4. Consider the design and management requirements associated with the application and implementation of HACCP-based food safety management systems in food businesses. 5. Enhance the skills required for the assessment of HACCP-based food safety management systems. 6. Consider the tools available to educate food business operators in the principles of HACCP and to provide advice and support during development and implementation of food safety management systems.
	Additional topics 1. Understand the need for audit preparation including the development of suitable check-lists. 2. Perform HACCP audits using sampling, questioning, observation and assessment skills. 3. Construct audit reports giving clear indication of findings and corrective action needed.
General workforce	1. Understand the general principles of HACCP and how they relate to the food handler's role.

Sources: [a] = UK Steering Group on HACCP Training Standards (1999)
[b] = Royal Institute of Public Health and Hygiene (1995a)
[c] = UK Food Standards Agency (2000)

13.3 Training and effective learning styles

Training is often seen as an activity that goes on in the 'classroom'. Indeed, much initial training does take place away from the trainee's ordinary activities in group training sessions. There are three immediate limitations to training of this kind:

1. 'Classroom' sessions are inevitably limited in time: staff may only be able to attend occasional training programmes, with the risk that the impact of such training gradually becomes diluted over time.
2. Training away from the production operations themselves may make it more difficult to relate what is learnt back to the specific operations.
3. There may also be issues of motivation in employees attending HACCP training sessions for the first time. They may be viewed initially with suspicion and cynicism, at best as an irrelevance, at worst as an unwelcome fad foisted on an unwilling workforce by management.

These issues need to be considered in designing the HACCP training programme.

The training needs of particular groups, and the kinds of training programme they require, are explored elsewhere in this chapter. Whatever group is being trained, it is important to be aware of the range of learning styles among any group. While some trainees may be capable of absorbing large amounts of data in a classroom setting, others will be less accustomed to this kind of environment and will require a range of techniques if they are to learn effectively. Some

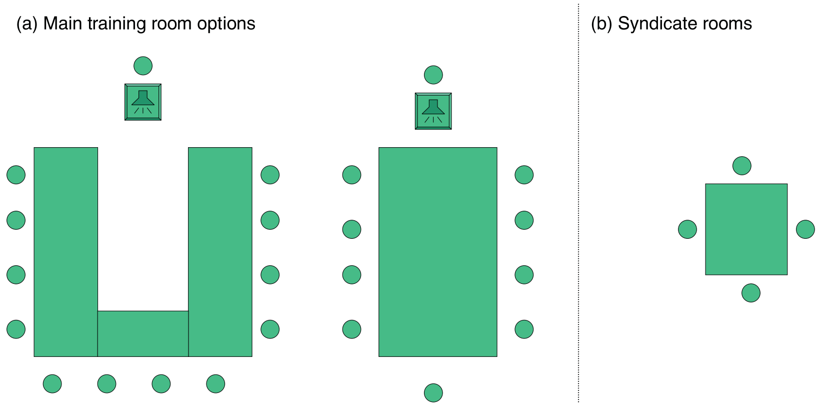

Fig. 13.1 Effective seating configurations for training.

will have negative preconceptions of training as a dull, passive and unproductive process, which will have to be overcome in the early stages of the training session. The right kind of seating arrangement designed to break down a sense of formality and encourage participation will help counteract such preconceptions and create the right kind of learning environment (Fig. 13.1). Getting trainees to introduce themselves or each other is a useful way of breaking the ice. Communicating a genuine sense of enthusiasm to the trainees is also essential, given the importance of non-verbal signals in communication.

Given that many trainees may be unused to taking in large amounts of factual data in a short space, trainers need to avoid long periods where they are talking to an essentially passive audience. Where this is necessary, the use of visual aids such as computer presentations, overheads and flip charts will help reinforce and enliven whatever a trainer says. Many trainees will also be unused to both absorbing what is being said and taking notes, so handouts summarising the key points will both allow trainees to concentrate on understanding and reinforce learning after the training session is over. This can be done by providing minimised versions of overheads used in any training session or by developing a simple training support booklet, e.g. *HACCP: Your Questions Answered* (Mortimore and Wallace 1997). Another possibility is to provide handouts in the form of laminated pocket-sized cards listing issues such as key hazards and control measures for regular consultation.

Learning is always more effective if it is made interactive. Asking questions and encouraging participation and debate encourages trainees to think actively about what they are learning. 'Doing' is often the best way of learning effectively, and training sessions should mix theory with practical application. Trainers can use group workshops to work through practical examples. Presenting findings to other groups can be an excellent way of focusing minds and generating a sense of involvement from members of a group. In such an environment, trainees themselves take on a training role, explaining issues and supporting other members of their group to ensure that the group as a whole succeeds.

Any initial classroom briefings must be part of a wider training programme that is seen to build on these beginnings. It is critical to follow through with either more detailed training for those involved in HACCP implementation, CCP monitors for example, or clear signs that a HACCP system is being developed and implemented in the organisation. In general, to be most effective, training should have follow-up such as action points with feedback on action taken. It may be appropriate to have some more formal assessment of training outcomes as part of such follow-up, perhaps via an exam (as a conclusion to an intensive training session for HACCP team leaders, for example) or assessment of performance in HACCP implementation by the relevant supervisor or line manager. This follow-up needs to be seen both as an integral part of the training process and as a way of assessing its effectiveness. More fundamentally, training outcomes may need to be linked to revisions to job descriptions, revised individual and departmental objectives, and changes to performance appraisal and bonus schemes.

13.4 Appointing HACCP trainers

Organisations must also decide who will do the training, i.e. whether the use of external trainers will provide the most effective training, or whether to use their own resources for some or all training. With the exception of large companies, where there may be a central pool of expertise, most organisations will be dependent on external training providers for at least the initial training of the HACCP team and team leader, given their central role in HACCP planning and implementation. There are a number of advantages to the use of *reputable* outside trainers:

- they should have expertise in HACCP principles and methodologies
- they should have the experience, personnel and materials to deliver effective training programmes quickly and efficiently
- in some cases, such training can lead to a formal qualification generally recognised in the industry, which will support verification.

These advantages may also be seen in internal training where the company has appropriate in-house resources.

There may also be a number of disadvantages in using outside trainers:

- the quality of some training provision may be variable
- the cost of using external providers may be substantial to some businesses
- there is potential for reliance on generic training which does not relate to the particular circumstances of the organisation.

Although some HACCP training is of very high quality, there is considerable variability in the standard of training available, given the lack of regulation and standardisation in this area. In some cases, while HACCP trainers have the necessary expertise, they may lack general training skills and experience. In others, providers may be experienced trainers but lack expertise in HACCP. Some early HACCP training has been bolted onto existing hygiene courses, without the necessary conceptual leap from hygiene management to hazard analysis, risk assessment and control (Mortimore and Smith 1998).

There have been a number of initiatives to resolve this problem. In New Zealand, for example, the meat and seafood industries, in consultation with the Ministry of Agriculture, have developed their own industry-specific HACCP competency qualifications covering such areas as coordination of the development of a HACCP plan, and supervision of a HACCP system in the workplace (see Chapter 9). The former is appropriate to HACCP team leaders and auditors, and the latter to supervisory staff responsible for the performance of CCP monitoring staff. In the UK, a group of HACCP practitioners, trainers, regulators and enforcers, the UK Steering Group on HACCP Training Standards, has sought to achieve more consistency in HACCP training by developing introductory and advanced HACCP training standards (RIPHH 1995a, UK Steering Group 1999). These standards have been designed as a benchmark against which to assess training courses for HACCP team leaders (the advanced standard) and HACCP team members (the introductory standard). The standards have been used by awarding bodies such as the Royal Institute of Public Health and Hygiene as a basis to certify the content of HACCP training courses, offer examinations as verification of trainee achievement, and to approve and register trainers. In the USA, the International HACCP Alliance provides a similar accreditation programme for HACCP training courses against detailed training objectives (International HACCP Alliance 1996).

Familiarity with these standards will help those responsible for training within organisations implementing HACCP systems to assess their training requirements as well as the content of courses available from external providers.

The problem of external training being generic and not specific to the operation can be dealt with in a number of ways:

- By early liaison between provider and client organisation on training course design to include, for example, material on the organisation's own processes.
- By approaching an organisation simultaneously for training and consultancy. In the UK, for example, MAFF has funded a combined package for retail butchers consisting of a two-day training course followed by free consultancy designed to assist the actual process of HACCP implementation. Another example might involve initial training of the HACCP team and then on-site facilitation of the HACCP process by an experienced consultant.

It is important to note, however, that sending one person on an external open course of one to two days' duration is unlikely to give them enough knowledge or experience for them to be expected to come back and manage the development and implementation of HACCP without further training/support.

The question of whether to use an external training agency for the training of CCP monitors and production personnel is complicated in part by the greater scale and cost involved in training this larger group. One solution is to involve an external agency in training in-house staff who then carry out general training of production personnel. In this example trainers may be selected from supervisory staff who have the relevant production experience and authority both to absorb and communicate HACCP principles and skills effectively. Delegating training in this way has the potential advantage that the trainer may well know the trainees and the relevant production operations, understands trainees' needs and concerns, and has their trust. However, if in-house staff are used to train CCP monitors and other staff, they need to have the right training competencies: enthusiasm and motivational abilities, training and communication skills, the ability to manage groups of trainees, as well as an in-depth knowledge of the HACCP issues for which the training has been devised. Given the importance of this training, it may be appropriate to send potential trainers on a course that provides an examination certificate in HACCP principles to ensure the appropriate level of HACCP knowledge and allow the potential trainer to build confidence. It may also be useful for these supervisory staff to have some knowledge of learning styles so that they can tailor the kind of training and support they are providing to meet individual needs. They may well require support in their first training sessions, with coaching from professional trainers and feedback on the effectiveness of their first attempts at training.

13.5 Training and senior management

The senior management team clearly needs to be fully supportive of a HACCP programme if it is to be successful. Senior managers need to grasp both the importance of HACCP to the organisation and the immediate and long-term resource issues involved in implementing a HACCP programme. This is not always a straightforward task. Motivation can be a problem, particularly with SMEs where HACCP can initially be viewed as a bureaucratic burden imposed from outside, rather than as an essential tool in the management of product safety. Research by such organisations as the World Health Organisation has shown that some SMEs regard HACCP as unnecessary, expensive, complicated and time consuming to implement. There can also be problems in understanding the concept and role of HACCP, for example in relation to prerequisite systems such as good manufacturing practice (GMP) or to existing quality systems.

A key element in successful training at this level is an open discussion with full participation from all disciplines, particularly those who will need to commit the most resources to the development and implementation of the HACCP programme. Indeed this step may need to occur before the organisation becomes committed to using HACCP. The senior team must feel a sense of involvement in and ownership of HACCP, and this can only be achieved if, individually and collectively, they have had an opportunity to talk through all the issues. While it may be helpful, if an organisation is new to HACCP, to use an outside agency to open a discussion by outlining what a HACCP system is and how it works, the discussion will need a

HACCP ‘champion’ from within the organisation’s own ranks able to relate the implementation of HACCP to the organisation’s goals and needs, and to illustrate the particular benefits of a HACCP system to the organisation.

In dealing with the question of motivation, it is important to stress the practical benefits of effective HACCP implementation, not least for SMEs. These benefits include:

- focusing resources more efficiently on the key areas of safety concern
- increasing the confidence of existing customers and regulatory authorities, resulting in the need for fewer product checks or audit requirements
- compliance with a major element of some supplier quality assurance schemes, for example those of some major retailers
- improved attractiveness to other potential customers within the food industry
- demonstrating ‘due diligence’ in the event of any criminal or civil legal action
- improvements in the level and consistency of product quality, and in process efficiency: this is often a consequent effect of the general tightening of standards that HACCP brings.

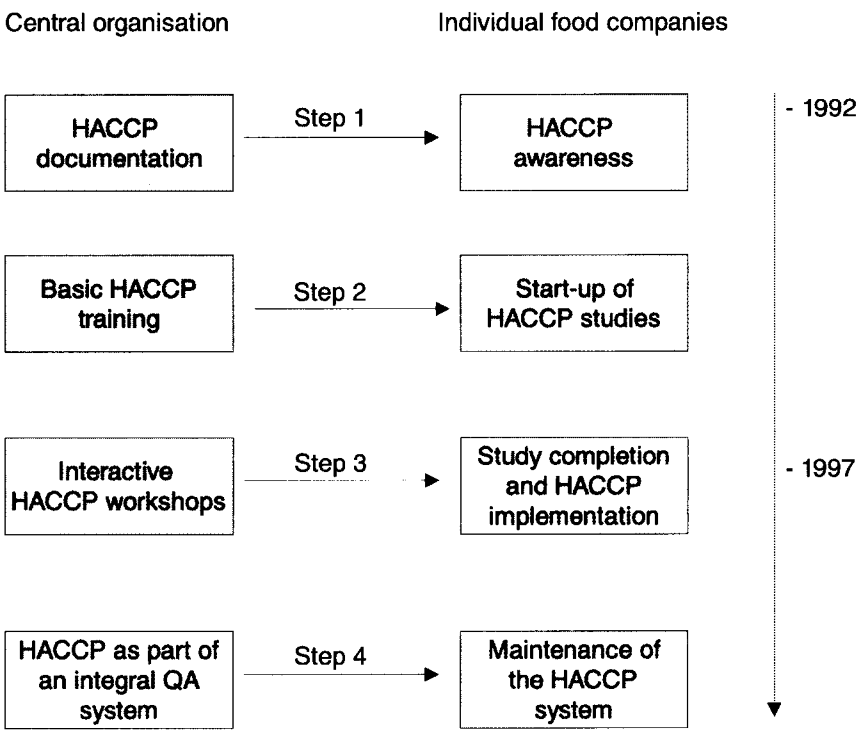

Fig. 13.2 HACCP roll-out in a multinational foods environment (source: de Winter 1998).

In explaining the nature of HACCP, a useful diagrammatic representation is shown in Fig. 13.2 where HACCP at the centre deals with significant hazards specific to the process, prerequisite programmes support HACCP by managing general issues and the quality management system effectively manages both elements in practice. Formal certification of the quality system to a standard such as ISO 9001 may be a bonus but is not a requirement. The use of models such as this helps trainees to understand how food safety and quality systems complement each other and overcomes the frequently asked question: 'Why do I need HACCP if I've already got an internationally recognised quality system?'

13.6 Training the HACCP team and team leader

Most HACCP initiatives start with the appointment of a HACCP team and HACCP team leader. Their skills will be the essential driver of the HACCP programme, so an effective training programme is essential. Responsibility for the formation and training of the team often relies on the team leader's initiative so the right training for such a role is critical. There are a number of problems in making training for both leader and team effective, including:

- ignorance of the range of skills and training required
- the resulting reliance on a one-off course for the team leader, neglecting the importance of also training other team members
- getting the timing right – training can be too early and wasted.

Of these, the first is the most serious since it will lead to an underestimation of the training needs of a HACCP team and leader. This failure will be compounded if training is undertaken too early. Before training is contemplated, it is important that the decision to implement a HACCP system within the organisation has already been taken by senior management. It is also essential that an outline schedule for HACCP implementation is agreed, in which the training of the HACCP team leader and team is the first step. If this is done, there will be a clear focus for the training and it can immediately be followed up by starting to put the training into practice.

The HACCP leader requires a range of skills. The advanced HACCP training standard mentioned in section 13.4 identifies the key requirements of any team leader training programme, and is designed to benchmark such programmes against an agreed standard of good practice. These skills are summarised in Table 13.1. In addition to specific subject knowledge, the standard also emphasises broader skills such as those of project management, team leadership and information management (in overseeing implementation of an effective and practical system of HACCP documentation).

Given the range of such skills, it is essential to select a team leader with at least some existing leadership and project management experience, and not just the right subject knowledge. It has also been suggested that it may, in some circumstances, be better to train good project managers in HACCP skills, rather than HACCP experts in project management (see Chapter 7). Other practitioners suggest that a production/operations manager will be an effective leader due to their day-to-day requirement to get things done on schedule and within budget. This profile suggests that the team leader needs to be a relatively senior member of the organisation. By definition such people are usually the busiest in the organisation, and there may be a temptation to delegate the role to a less experienced or more junior member of staff. Given the pivotal role played by the team leader, and how demanding it is, giving in to such a temptation may compromise the entire process of HACCP implementation.

De Winter has described the training of HACCP team leaders within a multinational setting (de Winter 1998). In this model (Fig. 13.2), a central task force developed initial briefing documents and implementation software, and organised the training programme. The latter consisted of the following:

- Initial briefings on HACCP principles for QA managers and site directors to promote awareness and enthusiasm among key personnel.
- Week-long HACCP training courses for HACCP team leaders from individual companies and all the major product groupings (ice cream products, for example), with the objective of equipping them to begin the process of HACCP implementation independently.
- Once implementation was under way, workshops based on real implementation issues within a specific factory for each of the product groupings. These workshops allowed delegates to discuss common experiences and problems, share best practice and benefit from detailed advice from the central QA and microbiology group. Delegates then cascaded best practice within their own companies.
- Subsequent briefing sessions for individual product groupings to review performance and discuss changes.

He outlined an initial week-long course with a mix of lectures on HACCP issues consolidated by group exercises on HACCP analysis and planning to reinforce learning and provide a bridge to the process of implementation itself. This initial training was followed up within a year by a series of workshops for team leaders working in the same product areas. Each workshop took place in a factory, which provided a real-life case study on which the delegates worked collectively.

A similar approach has been used by the author within Cadbury Schweppes (Fig. 13.3) where an initial introductory course for team leaders and senior team members was followed up on-site by HACCP facilitation workshops involving the whole HACCP team(s). This approach allowed the site HACCP teams to learn HACCP study skills while working on their own processes. The outcome of this facilitation approach was not only effective training for HACCP team members, but also the completion of draft HACCP plans for real process modules, which could then be reviewed, validated and implemented.

A key outcome of the facilitation workshops, in addition to the draft HACCP plans and timetable for other HACCP modules, was the development of detailed

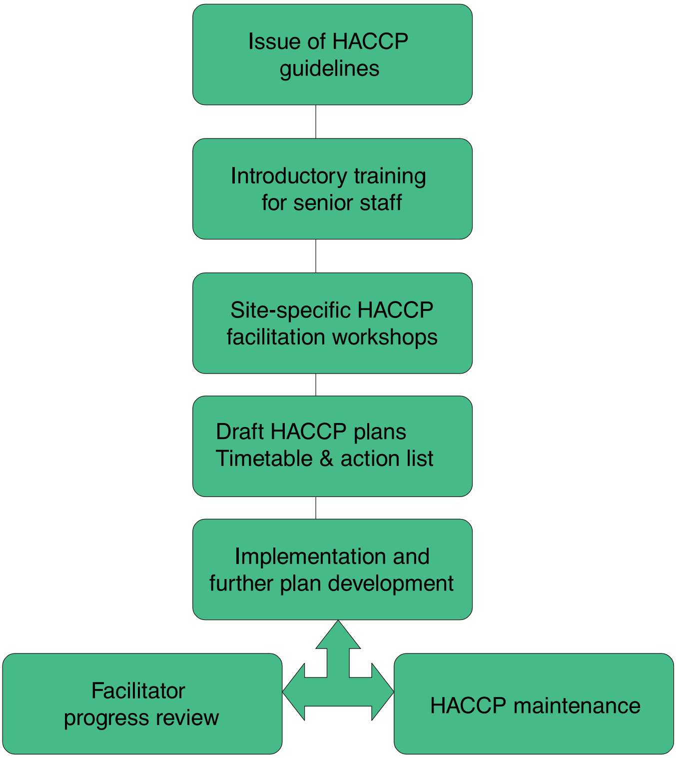

Fig. 13.3 Cadbury Schweppes International HACCP training approach.

activity lists outlining all the items to be addressed in order to implement the HACCP plans. These lists included items such as specific areas of prerequisites that required strengthening, engineering work on equipment to design out hazard access points and development of new procedures or work instructions in addition to the standard HACCP implementation activities of training and setting up monitoring/recording systems. By giving individual responsibility for each of these activities, site management was able to review and manage the progress of HACCP implementation more effectively. This contrasts with typical approaches to HACCP training either as open courses or company in-house courses, where the trainees are left with some understanding of how to do a HACCP study but are much less clear on how to move from the paperwork HACCP plan to a working HACCP system.

Following the Cadbury Schweppes facilitation workshops, the trainer was involved in ongoing progress review and encouragement of the HACCP teams through to the successful implementation of HACCP plans. This type of ongoing support and facilitation from experienced HACCP practitioners is extremely valuable but rarely seen where external trainers are used, usually due to its inherent cost.

13.7 Training CCP monitors and others

Effective monitoring of CCPs is critical to the success of any HACCP plan. CCP monitors must therefore be instructed in basic HACCP philosophy and, in particular, the range of skills involved in monitoring. They need to understand the nature of the hazards for which their CCP has been identified, how the CCP itself functions, and the nature and significance of the measurements they are taking. They need to understand the difference, for example, between a target level and a critical limit and what levels have been set for each. Finally, they must understand how to take corrective action if a deviation occurs, and to keep the appropriate records.

The training of CCP monitors is best left until the implementation phase. If carried out before then, the delay between planning and implementation will mean that much of the impact of the training may be lost, and staff may become demotivated. Such training can be difficult because the role of CCP monitors may well require new working practices and an unfamiliar level of responsibility and initiative. It might involve getting to know a particular production process in more depth, learning about unfamiliar hazards, and getting to grips with new skills in data analysis and record keeping. Employees may well be unused to taking decisions on corrective action on their own initiative. A simple briefing would be insufficient to resolve all these issues satisfactorily. One solution would be for trainers to involve CCP monitors in describing the relevant hazards and the nature of the CCP for themselves, and in developing their own working practices and instructions. A simplified process chart, based on the HACCP plan, could be used as a starting point for this process. Such an approach is valuable because it is interactive, encourages the monitor to 'own' the approach and allows the trainer to check and correct the trainee's understanding. This more interactive approach would have the additional benefit of using the employee's own experience of a process and daily working practices to make HACCP implementation more effective and user friendly. Indeed, there may be a genuine need to unpick bad working practices, poor equipment design and overcomplex working procedures highlighted as a result of the analysis of existing prerequisite programmes or during process analysis. Working with staff to identify and solve these problems should be seen as part of training.

Once again, follow-up needs to be an integral part of the training. Supervisors will need to be trained to provide appropriate support in the early stages of monitoring. They should ask CCP monitors periodically to take them through their new role, questioning them on key points and asking about suggestions for improvements, as well as sample checking CCP data for themselves to see if target levels are being effectively monitored and acted upon. There may well be a need for further training to reinforce points, as well as periodic refresher training to resharpen monitoring skills. Training needs also to be reflected in changes to job descriptions, new objectives and appraisal or bonus schemes.

Some level of HACCP training in the rest of company is also essential, especially in production areas. All production staff will need a basic understanding of the importance of food safety, the role of a HACCP system in maximising food safety, how it relates to what they do, and the particular importance of CCP monitoring. One problem in such training is that of getting the right depth and balance of information for this broader group. One approach to such training has already been outlined (see section 13.3). Where a group may not have common production experience, an alternative approach to explaining the concept of HACCP analysis would be to start with a very basic and common process (e.g. making a cup of coffee), get the trainees to help construct a process flow diagram, brainstorm possible hazards and identify CCPs. Equipped with this basic conceptual understanding, they could then be introduced to the HACCP plan for the process or processes with which they were most familiar, and their role in effective HACCP implementation. In some cases trainees may have an inadequate grounding in good hygiene practice. If such training has already taken place, do staff need a refresher course? If so, could this be linked into HACCP training? As an example of such a course, the Royal Institute of Public Health and Hygiene (RIPHH) has developed a first certificate in food safety (1995b), which takes a risk-based approach to food hygiene including the HACCP concept.

The wrong level of training for this group can cause confusion and damage motivation. Chilton (2000) describes the lessons learnt from the provision of an initial training intervention that was 'heavy on the theory side of HACCP, but lacking on the practical implications for the employee'. The training provided was a scaled-down version of the material provided for supervisors and emphasised commitment, responsibility and change without dealing specifically with how each employee's job would be affected. The training was re-written to cover the basic questions:

- What is HACCP?
- Why is HACCP important?
- What commitment is required?
- What does the company have to do?
- What do I, as an employee, have to do?
- What happens next?

and the resulting sessions proved to be highly successful.

Answering such simple questions will help any organisation get the message across to the general workforce and this can be done by management or supervisors to give a personalised company approach. Training aids are also commercially available to help with this function such as the RSSL video, *HACCP – How the System Works* (Reading Scientific Services Ltd 1996).

13.8 Special issues in training

There are a range of problems in training within differing countries. Most obviously, language can be a potential barrier in training where the trainer and the trainees do not speak the same first language. Translators are frequently not conversant with HACCP principles, and it is essential to check appropriate translation and definition of terms, e.g. hazard, risk, control and CCP. If possible, it is best to bring in a bilingual expert in HACCP from outside, or recruit a bilingual member of staff with relevant knowledge. Cultural differences can also be a problem. There may be differences in attitudes to the importance of food safety and differing perceptions of food safety risks. In some countries there may be differences in management style which might, for example, make junior managers and operational staff reluctant initially to act on their own initiative and become fully involved in HACCP implementation and ownership.

SMEs may have particular problems with HACCP training. They may both lack the internal resources to organise training themselves and the financial resources to use an external training provider. Government agencies can provide some training support. The World Health Organisation has held a consultation meeting and published guidelines specifically for HACCP implementation within small businesses (WHO 1999), which provides a planning framework for HACCP implementation, including training. In the UK, for example, MAFF has developed a range of general HACCP materials, training aids and packages, and has funded specific training among retail butchers. SMEs can access such materials either directly by approaching MAFF or by consulting their local Environmental Health Officer.

In the UK, MAFF has also funded food technology transfer centres with the aim of transferring knowledge and technology to SMEs at low cost. These centres, such as 'Food Knowledge and Know-how' based at Reading University, allow SMEs to gain access to expert knowledge and training in many areas including HACCP. Local universities and colleges are also often able to offer low-cost training solutions.

SMEs can also approach customers with HACCP systems for advice and support, including advice and materials on training. The Internet can also be a useful source of information on a range of HACCP issues, both as a place to find specific information and as a forum for discussion groups to share problems and experiences. The expertise of external training providers can also be exploited most economically by using them to train company staff, perhaps members of the HACCP team, as trainers for other company staff. In addition, training sessions can be combined, for instance by a joint course covering both food hygiene and HACCP.

Multinationals also present a range of problems in effective HACCP training. These are often associated with obtaining the same standards of HACCP training at different locations around the world. This can be overcome by using a centralised or centrally run training programme at least in the initial stages, but may involve the language difficulties mentioned above. Central training of local trainers and the provision of training resources in the appropriate language can be an effective solution. Another approach would be to define learning objectives for particular trainee groups and invite local training organisations to submit proposals for review.

Additional problems can be seen in businesses that have high turnover of staff. In these cases it is best to choose longer-term staff members where possible for the key HACCP team roles; however, there may still be change of personnel within the team. This will require additional training to bring new members up to speed and the remaining team members must work together to help new members understand the concepts. High staff turnover in the general workforce will almost certainly affect CCP monitoring and the underlying foundations of effective prerequisite programmes. Here it is important to provide a regular framework of HACCP/hygiene awareness and refresher training as well as detailed specific training for newly appointed CCP monitors.

Problems are also seen due to lack of experience and training for assessors of HACCP systems. This group includes regulators and enforcers, customers and third-party auditors. Some large food businesses have found themselves in the position of having to defend their HACCP plans because the auditors or assessors have less of an understanding of how to do HACCP than does the HACCP team that developed it. This can be very difficult and it is not unknown for companies to have to put in extra CCPs that are in reality only CCPs because their customers or auditors told them to do so.

Steps are being taken to address this issue in certain areas. Inspectors who are auditing on behalf of retail customers to the British Retail Consortium Technical Standard for Suppliers of Retailer Branded Food Products (British Retail Consortium 2000) are required to have a minimum standard of HACCP training of the RIPHH introductory-level Certificate in HACCP Principles or proven equivalent experience. Though not inspecting HACCP systems in the same depth as a full HACCP audit, these inspectors are important in highlighting the need to review and strengthen existing HACCP systems. There have also been moves to provide effective HACCP training for enforcement officers. In the UK, enforcers from a number of areas have recognised the need for training and in the past have attended open courses or contracted reputable training providers to train their staff. A number of large companies have also invited enforcement officials to join their in-house HACCP training. A new initiative in 2000, backed by the Food Standards Agency, has seen the development of a syllabus for a HACCP assessment course for enforcement officers (UK Food Standards Agency 2000). It is anticipated that as the enforcement officers gradually build up their experience, then the effectiveness of their assessment of HACCP systems will be improved.

13.9 Summary

Training is the single most important element when setting up a HACCP system, which provides not only the technical skills required to implement HACCP but also helps to change the attitudes of people. Training should not just be a ‘classroom’ activity, but an ongoing programme in the workplace; not just an isolated event, but a catalyst for lasting change. This will help HACCP become a part of the organisational culture.

Training needs to address not just key HACCP principles and methodologies, but common problems such as the following:

- not understanding the foundations required for HACCP, the prerequisite programmes
- where to go to remedy deficiencies in technical expertise
- ensuring the correct level of training for all staff
- failing to identify significant hazards and/or identifying too many CCPs, i.e. confusion between control points and CCPs
- not knowing what to do at the end of the HACCP study so that the HACCP plan remains a paper document on the shelf rather than becoming a living system
- developing unwieldy documentation.

There are currently no recognised international or national standards for HACCP training, although a number of groups around the world have proposed approaches and developed training objectives and standards. Clearly such recognition would help to ensure consistency of approach by training providers and help to provide mutual confidence in HACCP application for effective food safety around the world. At the time of writing, an international workshop on 'An international future for standards of HACCP training' is planned for the 2001 Noordwijk Food Safety and HACCP Forum. It is to be hoped that initiatives such as this lead the way to true harmonisation of HACCP training standards.

13.10 References

BRITISH RETAIL CONSORTIUM, 2000, *Technical Standard and Protocol for Companies Supplying Retailer Branded Food Products* (Issue 2), London.

CHILTON, J., 2000, *HACCP From the Front Line – Part 2*, Chilton Consulting Services, www.chiltonconsulting.com

DE WINTER, R.J.F., 1998, 'The role of interactive workshops in HACCP training in a multinational environment', *Food Control*, **9** (2–3): 147–9, Elsevier.

INTERNATIONAL HACCP ALLIANCE, 1996, *Basic Course Curriculum*, www.haccpalliance.org/

MORTIMORE, S.E. and SMITH, R.A., 1998, 'Standardised HACCP training assurance for food authorities', *Food Control*, **9** (2–3): 141–5, Elsevier.

MORTIMORE, S.E. and WALLACE, C.A. 1997, *A Practical Approach to HACCP: Training Programme*, Blackie Academic and Professional, London (2nd edn in press 2001 as *HACCP Trainers Resource Pack*, Aspen Publishers Inc., Gaithersburg).

MORTIMORE, S.E. and WALLACE, C.A. 1998, *HACCP: A Practical Approach*, 2nd edn, Aspen Publishers Inc., Gaithersburg.

READING SCIENTIFIC SERVICES LTD, 1996, *HACCP – How the System Works* (introductory video), Reading.

ROYAL INSTITUTE OF PUBLIC HEALTH AND HYGIENE, 1995a, *HACCP Principles and Their Application in Food Safety (Introductory Level) Training Standard*, London.

ROYAL INSTITUTE OF PUBLIC HEALTH AND HYGIENE, 1995b, *The First Certificate in Food Safety*, London.

UK FOOD STANDARDS AGENCY, 2000, *Syllabus for HACCP Assessment Course for Enforcement Officers*, London.

UK STEERING GROUP ON HACCP TRAINING STANDARDS, 1999, *HACCP Principles and Their Application in Food Safety (Advanced Level) Training Standard*, RIPHH London.

WHO, 1999, *Strategies for Implementing HACCP in Small and/or Less Developed Businesses*, Report of a WHO Consultation, WHO Food Safety Programme, Geneva (www.who.int/fsf)

This page intentionally left blank

Part IV

Conclusion

This page intentionally left blank

14

Conclusions

S. Mortimore, Pillsbury Europe, Uxbridge and T. Mayes, Unilever Research, Sharnbrook

14.1 Introduction

If you have read each of the contributions in this book prior to starting on the conclusions you will already recognise the fact that there are some clear themes running through the chapters. In Fig. 14.1 we have attempted to group them under five separate headings, although they are inextricably linked, as we will see in the discussion that follows. Whilst the number of companies and regulatory authorities who have contributed to this book is not large enough to form the basis for a statistically-based piece of research, contributors have been deliberately drawn from large and small businesses in both the developed and developing markets, and from four continents across the globe. What they have in common is hands-on experience of real HACCP systems. They are not theorists but practitioners. This emphasis on practical experience is the most exciting thing about this book and the lessons that we can extract from that experience.

It is interesting to note that 40 years after the HACCP concept was first conceived and 30 years after it was first published, there are so many controversial issues still associated with its effective implementation. Is this because the concept is flawed in some way? Barnes mentions the codification of HACCP in 1993 through Codex Alimentarius Commission (CAC). Through the publication of an international HACCP standard and accompanying guidelines, there is a standard international reference to the principles and implementation of HACCP systems. However, it is clear that there remain not only many problems but also many misconceptions associated with the use of HACCP methodology. Many countries are represented on the CAC, and a few of its members are contributors to this book. It would be interesting to evaluate how

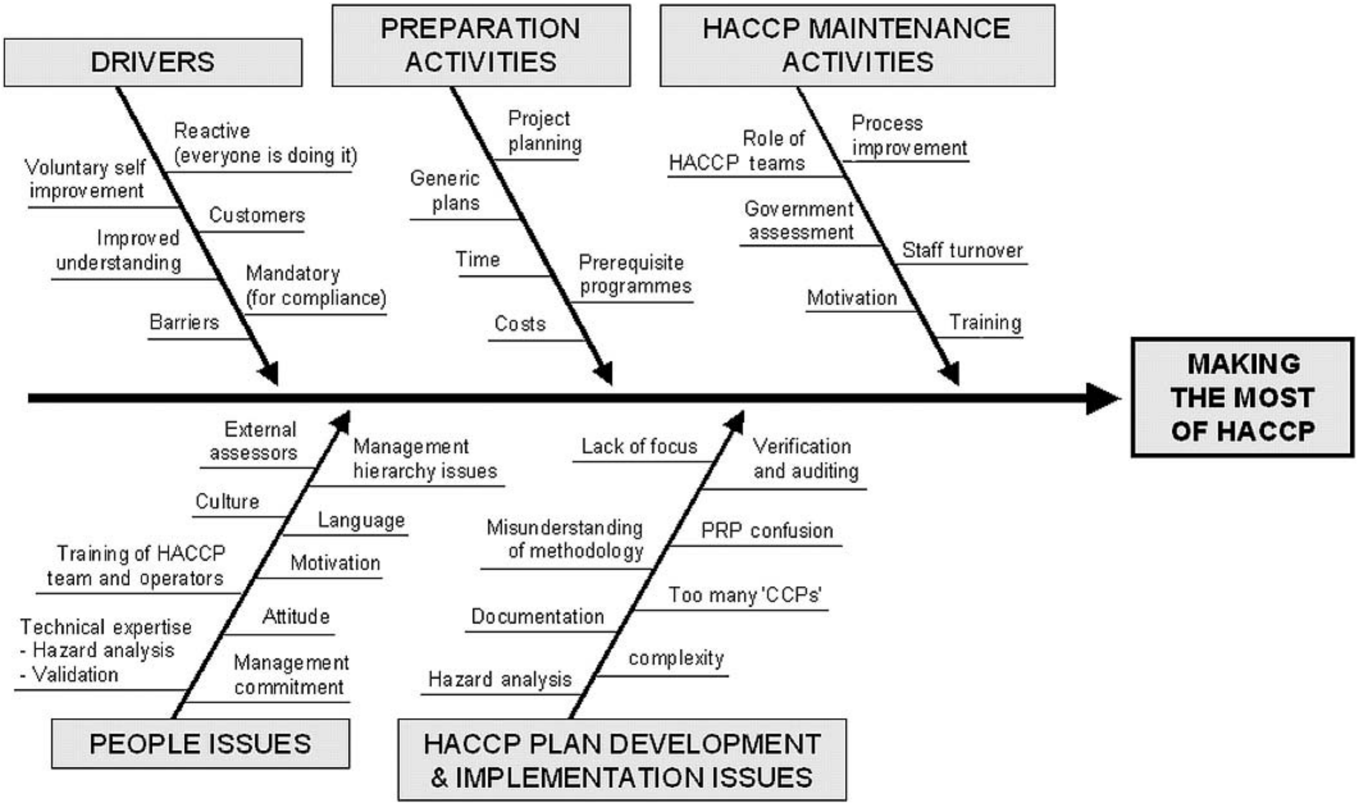

Fig. 14.1 Common themes and issues observed in implementation.

many of the other members have actually participated in a HACCP team. How many years might it be since they worked in a foodservice kitchen or in a food plant, if they ever did? How representative, therefore, of the users of HACCP is the body responsible for drawing up the rules? A controversial point to make perhaps but it highlights the importance of reflecting on the experience of those who have hands-on experience of putting principles into practice and the problems they encounter. How can these problems be addressed? We will attempt to offer some suggestions as we examine each of the themes identified. In many cases we can offer pointers on avoiding common pitfalls, though some issues require action at government level. Hopefully readers will be drawn from both camps: those who are yet to begin their HACCP programmes or who want to improve on what they have, and those who are responsible for regulation and setting the standards. The rest of this chapter looks at each of the five themes identified in Fig. 14.1 and what can be learnt in each case about problems and solutions in successful HACCP implementation.

14.2 Learning 1: drivers for HACCP

Typically the motivation for putting in a HACCP system tends to come from:

- customer pressure (Kane, Suwanrangsi, Route)
- regulatory requirement (Marthi, Taylor, Suwanrangsi)
- desire for self improvement (Killen, Lee, McAloon).

Taylor notes that many SMEs are ignorant of food safety issues and the management systems required to deal with them, and that the only pressure to adopt HACCP comes from legislation. This view is echoed by Suwanrangsi, and both authors point to a lack of real motivation even with legal compliance as a driver. Taylor suggests that this is because the risk of prosecution for food hygiene offences is low in many countries. However, the consumer expects safe food, whoever produces it, in whatever size business and in whichever country. In India, Marthi points out that there is no perception of risk by the consumer and therefore no desire to improve food safety from their end of the supply chain. With no perception of risk, it is difficult for industry to sell a food safety management concept to consumers which in turn reduces the commercial rationale for improvements in relation to cost. India, like a number of other countries in Asia and South America, has a history of over-population and lack of food. It took trade problems with seafood exports to the USA and Europe to prompt the Indian government to mandate for HACCP in that sector. As a result India now acts as a spokesperson for developing countries in Codex policy-making on HACCP.

In Thailand there is also a large seafood export industry but Suwanrangsi makes clear that the industry still did not embrace HACCP at first. They relied too much initially on external pressure, customer advice and generic models which resulted in ineffective systems. The real change in momentum came when HACCP was seen as essential for competitive success in improving both safety and quality. In Thailand businesses needed external pressure to influence attitude change, but they needed to see and understand the benefits in order to take the initiative in HACCP implementation. The importance of companies taking the initiative for themselves is emphasised by other contributors. In New Zealand, Lee describes an unregulated voluntary approach, noting that it results in a better 'buy-in' than mandatory approaches. However, it can be slow to happen (unless driven by customers) and it can be inconsistent in that no single standard is adopted.

Barnes, Taylor, McEachern and Route all noted the slow uptake of HACCP by SMEs. In Route's case it was customer pressure that got the momentum going. The typical senior management view was that they had neither time nor money for implementation of an activity that they perceived as irrelevant. Once HACCP became a commercial necessity attitudes changed. Route concludes that this driver is essential since, in small businesses, very little can be achieved without key management commitment, although he notes that HACCP implementation can take place without the active involvement of senior management.

Why then do SMEs not see HACCP as a real benefit? Why do they shy away from it? Barnes rightly points to the WHO consultation (WHO, 1999) on small but also less developed businesses (SLDBs). Several authors (McEachern, Taylor, Barnes) point to concerns about costs, time, complexity, perception of risk, and lack of understanding of commercial rationale. They even suggest that this reluctance may, in part, be due to the initial uptake of HACCP by larger manufacturers (Barnes). As pioneers in HACCP implementation, some large manufacturers developed large, unwieldy and complex HACCP systems. This over-bureaucratic approach was not initially acknowledged but instead seen as a sign of their superior knowledge. With hindsight it is possible to see that lack of understanding, the need for political balance, the divergence of approaches between industry-owned, voluntary HACCP systems, and government-sponsored, mandatory HACCP systems, all contributed in some way towards the development of a 'large industry' HACCP model that did not take account of SME capabilities.

In summary, it seems that the best HACCP systems are developed by businesses that are self driven. The prompt may come from the regulators or customers or an enlightened individual within the company. Key levers to support the adoption of HACCP will include:

- Acknowledgement of the continuing rising trends in foodborne illness – HACCP needs to be diligently adopted throughout the industry if this is to be permanently reversed.
- The need for businesses to see HACCP for what it is – as a 'minimal' system allowing businesses to understand and focus on the critical safety areas, and be better able to use resources effectively.
- The business benefits of HACCP in terms of customer reassurance, competitive advantage, process improvement, need to be better communicated and real examples publicised where possible.

- The need for HACCP to be seen as a tool for 'empowerment' allowing businesses to devolve control of CCPs in an organised and safe way – involving employees, who are the ones who make safe food in any case.
- In the future it is likely that HACCP will become outcome oriented and will be more clearly linked to a reduction in the risk of consumer foodborne disease.

Government involvement in particular can be helpful with SLDBs. McEachern relates how contact with government inspection staff helped to sell the benefits to SMEs in Canada. Suwanrangsi also suggests that a proactive and close collaboration between industry and government can really help in successful implementation of HACCP through promotion of HACCP and its benefits, advice, training and other resources, and financial support. A similarly close collaboration between industry and government also offers the best opportunity for an effective assessment of HACCP implementation and improvements to HACCP systems (see Chapter 15).

In reading the regulatory chapters one is struck by the changing roles of regulators. McEachern describes the difficulties in moving from a traditional inspection to a verification role although he is convinced that the latter provides a greater assurance of food safety. The difficulties arise partly in getting regulatory assessors with the skills to conduct a verification audit (acknowledged by Lee, Barnes, Taylor and Suwanrangsi). They also come from persuading food businesses that they need to change their expectation that government inspectors will come in with a tick list and simply tell them what to do. Under a HACCP system, the food business is responsible for making safe food and the regulator is responsible for verifying that the operator is capable of doing so. Lee describes a similar shift in New Zealand to a model where the government sets food safety standards, the food industry accepts responsibility for food safety management through HACCP systems, and independent auditors verify that industry has met its responsibilities.

One of the major challenges facing governments is the level of support they provide to industry. Governments have responded in differing ways to the needs of their food industries in HACCP implementation, but have tended to increase the level of support provided as they have become more aware of industry needs. Lee describes the New Zealand government providing generic HACCP plans backed up by information on key hazards and process steps, help in setting up a national microbiological database for the export meat sector, and other technical support for the food industry. Suwanrangsi points to the similar development of generic HACCP plans and advice on hazards in Thailand, and Marthi emphasises the need for government involvement in providing relevant information on hazards for Indian food processors. The New Zealand government has also worked with the industry to develop HACCP competency qualifications for both industry and regulatory personnel. Barnes and Taylor note the UK government developing resource centres and training materials as well as funding HACCP training and consultancy, developments also described by Suwanrangsi in support by the Thai government for key export sectors such as fish. This growth in support emphasises in particular the importance of people as a key resource in HACCP implementation, their education and training, and their development of a true understanding of the HACCP method – what it is and what it is not. These 'people' issues are discussed in the next section.

14.3 Learning 2: people

In drawing out the issues raised by the contributors, overwhelmingly the biggest number is related to people – their lack of training, poor-quality training, attitudinal problems, technical knowledge and much more. This was not just a question of needing more training, but a much deeper issue which we will attempt to analyse. It underpins all other activities, including the preparation process for HACCP implementation.

14.3.1 Motivation, attitude and cultural issues

The purpose of training can be described as twofold (Wallace):

- to develop awareness and to motivate
- to develop technical knowledge (in this case in HACCP planning and implementation) enabling full participation in development and implementation of the system.

Failure to achieve either of these aims properly could lead to failure of the HACCP system from the very beginning. As mentioned earlier, it is harder to develop a HACCP system in the absence of management commitment. In fact, it is harder to have a reliable food safety and quality programme of any sort. Prerequisite hygiene programmes are an essential partner to the HACCP system and management commitment is needed for these to be embedded in the heart of the business.

It was interesting to read McAloon's reports of setting bonus incentives for managers based on continuing good performance in food safety management, suggesting that continuing commitment to food safety may need incentives. It may be there when people have spare time or are involved in a specific project (e.g. HACCP plan development), but it cannot be assumed to be present on a routine basis. Another recommendation by McAloon was that, to get food safety into the culture of the company, it is a good idea to assign responsibility for HACCP implementation to a senior company person. This can be seen as a 'positive act' as opposed to stating, as many companies do, that 'all senior managers are responsible'. There must be real leadership at top level whatever size the business. Such an approach also provides the HACCP team with a senior level 'champion' who can ensure that their interests are listened to in the right quarters.

Management commitment is cited as being an essential starting point in most textbooks and journals on this subject, and we have highlighted a couple of ways of achieving such commitment. What about the lower levels in the organisation, the supervisors and operatives? Often they can be cynical, with a 'seen it all before' attitude and a reluctance to adopt new work practices. Sometimes this attitude has developed as a result of a prescriptive management culture – management being unwilling to accept the views of more junior employees. Both Killen (UK) and Route (China) mentioned this and offered some ideas for securing employee commitment and participation. Killen suggests that, on occasions, the managers and operatives can be separated for any hazard analysis and problem-solving work. This enables a freedom of thought and speech during team sessions and gets the best out of both groups. It requires cultural awareness by the HACCP team leader but, gradually, as both groups see the value of the other, they can come back together. In Route's example there were real cultural differences between East and West to be acknowledged and utilised to achieve the end result. When working in a foreign culture it is essential to understand those differences when beginning a business relationship. 'Challenging' as a way of problem solving is not normal in the Chinese work ethic and therefore tact and understanding was needed in order to work within this culture. Validation and verification activities, for example, were viewed initially with suspicion as questioning employee competence, and care was needed in communicating what was needed. However, it seems, in this example, that employees demonstrated a genuine commitment and enthusiasm once this initial concern was overcome, amply repaying the effort involved.

In some cases the company culture is identified as a problem for managers and operatives alike. Suwanrangsi describes a reactive culture where they wait for the official inspection before doing anything. McEachern describes a paternalistic culture where food safety is seen as a government responsibility. In these cases government departments were active in trying to act as a catalyst for culture change, e.g. through briefing sessions for senior management. The point was made that it was better to start the change in attitude prior to starting any work on the HACCP programme.

At operator level, several chapters (Rudge, McAloon, Route, Killen) mentioned the need for their active involvement at an early stage. McAloon points out that the line workers, not the managers or the Quality Department, make safe food – so involve them. Managers in the Quality Department are, of course, critical, both in the development stage and in a verification role once the plan is implemented. However, ownership has to transfer at some stage – hence the importance of involving line staff sooner rather than later. There is broad agreement that employees should be involved in writing the HACCP plan but differences appear when considering at what stage. Rudge describes how a number of employees were brought together as a team to draw the Process Flow Diagram and carry out a Hazard Analysis but that he and a colleague were responsible for determining CCPs. This approach might alarm the purists (i.e. a HACCP team needs to consist of four to six people, ideally, and should be multi-functional) but there may be good reasons for taking an alternative approach. In this case there were language issues at the Polish plant in question, but anyone who has observed and participated in a number of HACCP teams will know that discussion can be lively, technical and, on occasions, acrimonious. For the less technical members of a HACCP team this might actually prove to be demotivating and confusing. Having them review the output might be a better approach. Killen notes a similar approach in describing how the HACCP team leader, in undertaking a preliminary Hazard Analysis, can help in preparation for team meetings. It may be best to involve line staff most where they have the most to contribute, particularly in such areas as process analysis, where they may well have the most hands-on experience, and in designing CCP procedures and documentation, where they can reflect the practical issues involved in CCP monitoring.

14.3.2 HACCP Teams

A discussion of HACCP Teams leads nicely on from the above. There is some broad agreement amongst the contributors in this area:

- HACCP is best done as a team (five or six people at the maximum is said by Killen better to enable full discussion and contribution from all members).
- The HACCP Team needs to be multi-functional and have a knowledge that has depth and breadth across the enterprise (McAloon, Taylor, Killen and Route).
- SMEs have limited resources but this can be turned to advantage in that the team members tend to be really close to the process and have in-depth knowledge (Taylor, Route). A small team can turn out to be flexible and dedicated to the job they have been asked to do, and the individuals selected can act as a catalyst for change. Ownership of the HACCP plan by those who will then have to implement it results in a stronger system.
- Challenge within the HACCP team is important as the most senior person, or the person with the most technical-sounding job title, does not always have all the ideas or all the answers. This environment of challenge culture is worth developing if the HACCP system is to be as good as possible.
- Using operator level people in the team, even for just one part of the process, can be a great benefit. They go on to make excellent CCP monitors, act as HACCP champions on the shop floor, can help to design documentation and generally help to improve the process.

14.3.3 Use of consultants, external support, information sources

It is well debated and documented that SMEs rarely have the skills, knowledge or resources needed to develop and implement a HACCP programme. It was gratifying to read that skills shortage at the start of HACCP implementation is not just related to the size of a business but is also a problem for larger organisations (McAloon, Rudge). This is where the use of internal or external expert consultants can be a good way of getting started. Several examples are given, some fairly innovative, of how to fill the knowledge gap.

Use of expert external consultants

McAloon related how this was done within Cargill (Fig. 14.2). Whilst this is what was done for HACCP, the same approach could be used for any new programme.

Large companies do not necessarily have company experts already within their employ and the employee who knows more than the others is wise to admit that they do not know everything. An external expert was utilised at Cargill for a period of six months with the aim of developing in-house expertise that could then be cascaded throughout the business.

The experience of SME's use of external consultants was more mixed (Taylor). Problems included the variable quality of consultant advice, the unfamiliarity of SMEs with the key issues on which advice was needed, and the consultant's unfamiliarity with the business's particular processes and requirements. Taylor and Barnes suggest that these problems can be overcome by better initial training for SMEs, allowing them to do more of the groundwork before approaching a consultant, selecting an approved consultant, and using consultants to develop and help validate a HACCP system rather than employing them right at the start.

Use of internal experts

In Rudge's case, a similar approach was taken at the next level down from where McAloon started. In this example Rudge himself became the vehicle for ensuring that what was known at a business headquarters level was transferred to the operating plants. He facilitated visits between sister plants as a way of sharing this knowledge. Marthi describes a similar scenario using both external support and staff from the company's research centre to disseminate knowledge and understanding of HACCP principles at senior management level, and then

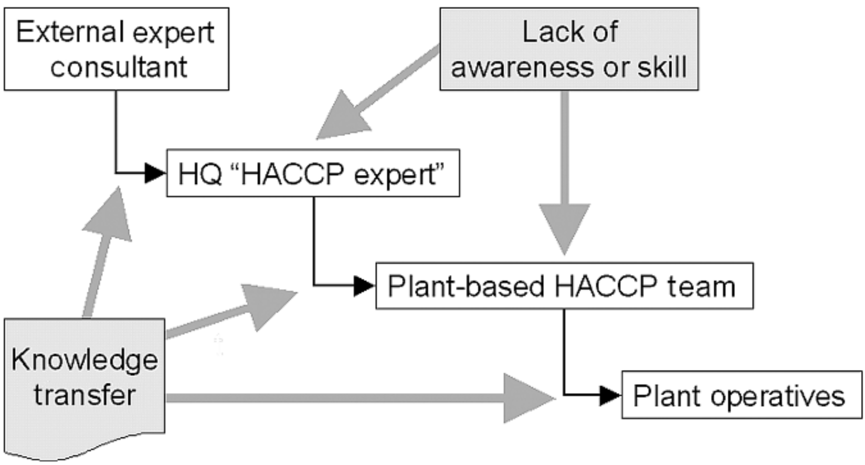

Fig. 14.2 Skills and knowledge transfer in Cargill.

within the management teams at individual factories. The disadvantage of this process of cascading knowledge from the centre was that experts were not always familiar with the individual businesses and had to learn. Rudge emphasises how useful the development of the Process Flow Diagram is, at this point, to aid understanding of a particular operation and its particular characteristics.

Customers, regulators, published work, competitors
With some innovative thinking information can be found fairly cheaply. Some examples and solutions are provided in the chapters. As an example customer audits can be seen as free consultancy, particularly in relation to prerequisite systems governing hygiene and GMP. If auditors are experienced, through seeing many different HACCP systems, such audits can be very helpful (Kane). However, care needs to be taken as sometimes the auditor has limited practical experience and understanding, and the business has to challenge recommendations made (Route). Figure 14.3 illustrates some of the sources of knowledge and skills transfer.

Regulatory inspectors and assistance
We have heard already how the role of the regulators is changing and that, for many start-up businesses and SMEs, rightly or wrongly this is the main source of information. As with auditors, however, the quality of such information and advice depends on the training, experience and understanding of regulatory staff. Suwanrangsi notes a dialogue between a company and regulator which resulted in the latter reassessing the need for a particular CCP.

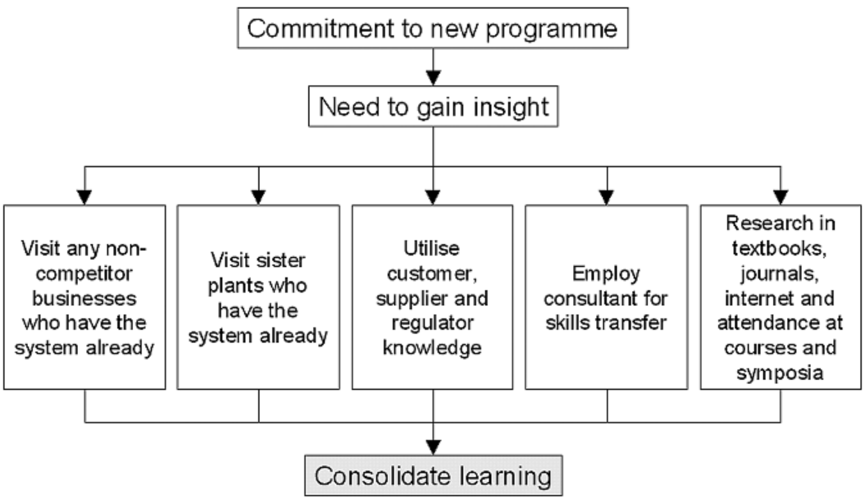

Fig. 14.3 Sources of knowledge and skills transfer.

Published work
Route mentions the internet but, in addition, there is an increasing array of publications in which to discover information. A significant amount of information is available if a company is proactive and looks for it. One afternoon spent identifying relevant published information prior to begining the HACCP plan would, in the majority of cases, be time very well spent. Taylor describes the development of resource centres to vet and pool relevant information so that companies can access reliable information more easily.

Competitors
Taylor describes how, in the UK, the HACCP initiative for butchers enabled them to put aside their competitiveness and to share ideas, conduct visits to each other's premises and to exchange good practices. In this instance the whole meat retail sector was compromised by a serious outbreak of E.coli food poisoning, making cooperation between businesses a necessity in restoring consumer confidence.

14.3.4 Language issues

A couple of contributors shared important lessons related to language and communication. Many of the published materials and experienced HACCP expert consultants are Western in origin and, whilst materials can be translated (although even this can be difficult if non-technical translators are used), the expert consultants and trainers are rarely sufficiently fluent in other languages to enable effective knowledge transfer. Some solutions to overcoming language issues are:

- Translate the Process Flow Diagrams and use them for communication (Rudge).
- Use a bilingual expert in HACCP rather than a translator wherever possible (Rudge).
- Allow extra time for training and project work as everything takes twice as long (Rudge, Route).
- Check the competence of the translator carefully as sense and meaning can easily be lost (Rudge). If possible use in-house people, though be careful if they are non-technical, e.g. marketing or sales personnel (Suwanrangsi).
- If training through an interpreter, find other means to check understanding as it will be difficult (and frustrating!) trying to do this through the interpreter (Rudge). Other means might include some form of validating multiple-choice tests.
- If there is someone locally who is fluent in English then train them as a trainer rather than have a third party expert try to train the whole group through an interpreter.

Appropriate language is important for communication through the business. Suwanrangsi makes the point, which I am sure many practitioners share, that company procedures must be in terms that workers understand at their own level. Whilst export businesses may need to present HACCP information to overseas customers in the customer's own language (in many cases this may well be English), at plant level the information needs to be in the local language. It must also be presented in simple terms that will be easily understood. Rudge actually recommends not sharing all information with operators but providing specific information that is relevant to them if it is to be inculcated throughout the organisation. In Rudge's case laminated cards were provided with the information that was really needed by operators to do their job as opposed to giving them a confusing amount of 'background' information.

14.3.5 Lack of expertise and technical knowledge – educational issues

Whilst most people can understand the concept of HACCP, not everyone has the technical knowledge and expertise to use HACCP principles for effective food safety management. HACCP is a logical and common sense approach to control potential foodborne hazards. The concept can be, and in some countries including the UK is, explained to schoolchildren. With a talented trainer even the most hardened cynic can be made to see that it is based on a sound principle. There remain, however, a number of really important educational rather than training issues to resolve if it is to be made possible for all food businesses to adopt it.

Misinterpretation of methodology

Whilst the concept is straightforward, to be able to perform a Hazard Analysis and determine criticality takes a lot more knowledge than can be absorbed on a two-day training course. Typically, as quoted from Taylor (although this is not solely a problem confined to SMEs), there is:

- difficulty in prioritising risks, for example, physical vs. microbiological risks
- lack of appreciation of which pathogens are relevant (all the bugs that can be found in the book end up appearing in the HACCP plan)
- inability to understand the epidemiology and therefore which pathogens are of concern.

Lack of availability of expert advice and training

There are over 600,000 food businesses in the UK alone, placing great pressure on resources in terms of training, education and expert support either from government or from third-party experts. Taylor says that the single most important factor in getting a HACCP system implemented was the access to an experienced specialist. In Thailand this expertise is provided by the government, at least for the seafood industry, though due to the conflict of interest (government is also the assessment body) regulators have to be fairly general in the advice they give. The inability to make informed and knowledgeable decisions results in confusion, overload and dilution of control. This is one of the biggest causes of system failure.

Calibration and standardisation of training providers
Both Rudge and Wallace mention the difficulties in locating a reputable source of HACCP training. There is at present no recognised international body that can certify training centres, trainees and their materials. There are various national organisations but comparison of training providers on an international basis is not possible. We offer no immediate solution and can recommend only that qualifications are thoroughly assessed for both proven experience of HACCP and Hazard Analysis and training skills, as opposed to lecture and presentation skills. It remains a rarity to find both in the same individual.

14.3.6 Problems related to HACCP training and education

This is not highlighted as a major barrier or difficulty by any of the contributors, yet many of them make helpful recommendations for ensuring that this is done properly. In Wallace's chapter there is guidance on learning styles and classroom layout with a list of reasons why training may be ineffective and what can be done to make it successful (Table 14.1). However, much of the knowledge and skills required for HACCP implementation cannot be acquired through a single short training intervention. Knowledge of hazards and their control, along with good hygiene and manufacturing practice, takes years to acquire. Many businesses would need to buy this expertise in either through new recruits or the use of consultants. Barnes suggests the need to move to 'second-generation' HACCP systems which are less prescriptive and more suitable to particular kinds and scales of food business. This shift may involve greater emphasis on strengthening the prerequisite good hygiene practice, and the use of generic HACCP plans which can easily be adapted to certain types of food business. Although he writes from the perspective of a larger manufacturer, McAloon points out that strengthening prerequisite systems can make HACCP planning and implementation much simpler, a point endorsed by Taylor in her experience of working with SMEs. Increased support reinforced by external inspection by government, says Barnes, will not compensate for inadequate food safety management – nor should it try to. The role of government in providing a knowledge base to fill the educational void in both large and small business needs, however, to be re-examined. This may come with the adoption of Risk Analysis Principles particularly as HACCP becomes outcome oriented (see Chapter 15).

14.4 Learning 3: preparation for HACCP

The time spent preparing to develop a HACCP system is time well spent. Almost all of the contributors have some lessons to offer in this area. As a general observation, businesses often tend to launch themselves straight into the drawing up of process flow diagrams and having a go at a hazard analysis. Lack of preparation leads to confusion, over-complex and ineffective HACCP systems.

Table 14.1 Reasons for ineffective training

Reason	Possible solution
Lack of motivation	Ensure that the trainees are briefed prior to undertaking the training. They need to know what their role is in relation to the topic and why they are being sent on the course. When they are on the course it should be made relevant to them. Both Rudge (house analogy) and McAloon stress that they should not just be told what to do but why they should do it.
Lack of understanding of the type of training needed	It is necessary to understand the task to be achieved following the training. For example, if a trainee is charged with leading a HACCP programme then a half-day 'Introduction to HACCP' course will not produce an expert who is up to the job. The other aspect here is the learning approach to take. Considering the behavioural approach, Rudge uses the car analogy which is the correct approach when training employees to do such things as washing their hands. But it is probably not appropriate when training CCP monitors when you need to create a non-thinking 'auto-pilot' style of operative. In fact this is cited by Barnes as being one of the causes of failure at the CCP monitoring/corrective action stage. A cognitive approach combined with experiential learning is likely to be more appropriate. As an example, Kerry took operatives to a sister plant to watch, participate and learn. Suranwangsi mentions that training should be kept simple but that operatives should be involved in order to aid understanding. Operatives are often not used to taking decisions or using their initiative, a behavioural approach to training would not encourage this. Killen described an experiential approach as being potentially problematic, so we learn that there may be pitfalls to encounter. He points out that giving training 'on-the-job' can sometimes reinforce bad habits if not carefully managed and that a suitable solution is to back this up with classroom training in addition to assessing competence on the job.
Training the wrong people or training at the wrong time	A number of considerations can be highlighted from the experience of the editor such as expecting someone like a maintenance technician who is new to the food industry to be able readily to grasp the principles of HACCP (Wallace also recommends ensuring that trainees have been trained in hygiene beforehand). Another mistake would be to train a HACCP team who then do not begin the project until 12 months later.
Lack of follow-up	Reinforcement after training is a well-documented requirement if the learning is to be cemented in the minds of the trainees. Wallace described the Cadbury Schweppes approach of following the introductory course with a facilitated workshop.

Table 14.1 Continued

Reason	Possible solution
Poor-quality training	This can encompass a lack of understanding on the part of the trainer, a lack of ability to transfer knowledge effectively, a poor scope and quality of training materials and inappropriate learning styles. These will all contribute to a poor outcome. There are advantages in using in-house trainers. McAloon supports this by pointing out that courses can be tailored to suit the group of trainees and more people can be trained. As a result of developing in-house trainers you also create HACCP champions and, as a greater level of expertise is required to run a training course, the overall skill base within the company reaches a higher level. As mentioned in the text, there is no recognised standard for HACCP training certification and, therefore, when using external trainers it can be difficult to assess the quality of trainer beforehand. Businesses have to choose between the good and the bad – and cost is not necessarily a good indicator.
Coverage – not training enough people	This can be a problem, particularly for SMEs who cannot afford to send many (if any) people on external training courses. The benefit to having in-house trainers is that more people can be trained.

14.4.1 Prerequisites for HACCP

Which comes first in terms of development – prerequisite (hygiene) programmes (PRPs) or HACCP? Lee argues that the prerequisites should always come first as, otherwise, HACCP development could be hindered. Suwanrangsi, Kane, Taylor, Rudge, Barnes and McAloon all agree. The most successful implementation of HACCP is done within an environment of well managed prerequisite hygiene programmes. This is also the recommendation of Codex (Codex, 1997a, 1997b). Can you be working on HACCP and PRP development at the same time? In practice this is generally what many businesses do, but Suwanrangsi suggests that it is advisable to set up separate project teams, both of which might report to the HACCP Team leader. This approach allows the business to focus resources and skills more effectively. Rudge advocates the use of baseline audits as a good way of assessing the quality of PRPs. This can be done in-house if skills and knowledge are available, or by a reputable third party. In the vast majority of cases PRPs will already be in place, but, as McAloon points out, they just may not be termed as such, formally managed or standardised.

14.4.2 Cost vs. fiscal benefits

Business managers are usually interested in how much HACCP will cost to develop and implement. Technical and quality managers will quote, from

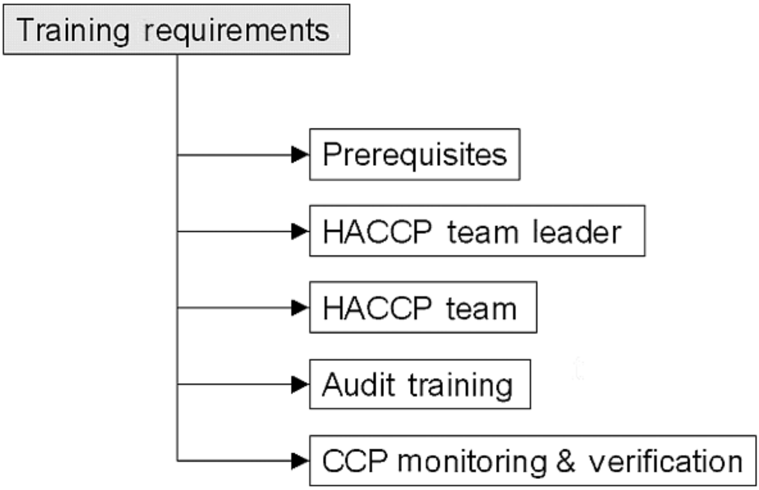

Fig. 14.4 HACCP training requirements.

various publications, the benefits that the company will achieve once HACCP is implemented, but examples are rarely given. Companies are not very good at, or do not have the accounting systems for, tracking cost benefits and attributing them directly to HACCP or to any other quality initiative. In this book we have two very good examples. McAloon puts a figure alongside some real benefits and Marthi mentions an increase in productivity, efficiency and product safety (decrease in Listeria counts). He reports less downtime in production and a reduction of over 10% in the cost of poor-quality product to the business after only six months. What a great set of examples to take to senior management!

It is better to acknowledge that there will need to be an investment in order to reap such rewards – how much is hard to estimate. As McAloon points out, it depends totally on how well the business was being run prior to HACCP. Rudge and Marthi say the same thing. It also depends on what resources are available within the organisation already and what training is needed. Suwanrangsi says that many companies underestimate the amount of training that is needed and the areas that it must cover (Fig. 14.4).

A baseline audit of training requirements, researching the available resources and then drafting a costed training plan will help to avoid surprises later on. As Rudge mentions, it is better to overestimate in terms of budget requirements.

14.4.3 Time issues

After wanting to know how much it will cost, the second question is usually 'how long will it take?'. The time required depends on a number of factors:

- knowing the starting point and how much there is to do
- what resources are available – knowledge, people, time and money

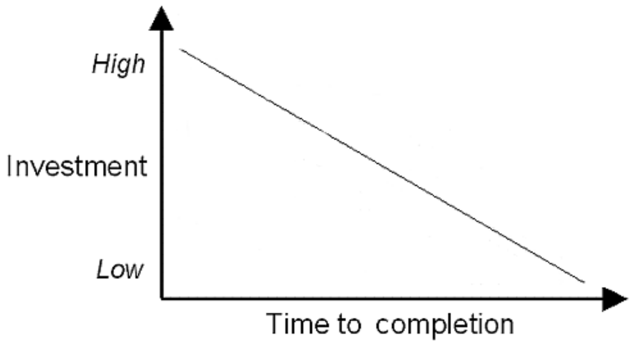

Fig. 14.5 Cost/time ratio diagram.

- the size of the business in terms of sites and production lines
- the complexity of the business (for instance, it will take longer to develop a plan for a chilled Pizza company than for a frozen sweetcorn line)
- the scope to be undertaken in the HACCP study – microbiological, chemical and physical.

To some degree there is a relationship/trade off between the level of investment and the speed with which a HACCP system can be implemented (Fig. 14.5).

The contributors demonstrate the variation. Route quotes two weeks following customer pressure – and for a simple dry blending process this seemed to be possible. Marthi mentions eighteen months as one example. A valuable lesson shared by McAloon is that the timescale for development of GMPs or PRPs can be a lot longer. GMPs cover an entire facility and often involve the implementation of a behavioural change by operatives and management that cannot be rushed. The main lesson is not to try to do too much too fast – be realistic in your expectations.

14.4.4 Generic HACCP plans

Generic HACCP plans are examples of HACCP plans developed for a particular food commodity or process that may be used for guidance (WHO, 1999). The use of these plans is still hotly debated in some circles but several of our contributors reported the use of generic models and their potential benefits. Generic HACCP plans are developed and used in a number of ways:

- *As an industry template*. Here a model HACCP plan is developed, often with input from members of a trade association, together with brought-in experts.
- *In-company generic plans*. This could be, for example, for fast-food restaurant chains. A company may develop one model HACCP plan because its plants or restaurants are making the same range of products using the same prescribed processes across a number of locations.

- *Government/academic prepared models*. A number of institutions have prepared HACCP plans that can be used by businesses as a start point. A number of generic HACCP plans are now available on the internet.

The important thing to remember (Suwanrangsi, Rudge, also WHO, 1999) is that the generic plans must be localised to reflect what is really happening in relation to a specific food or process. In Thailand, government inspectors assessed the amount of reworking of generic HACCP models and used this as a measure of business commitment to and understanding of effective HACCP implementation. In Rudge's case the plan from a sister company was used as the start point and subsequently adapted, saving a lot of time and effort. Barnes also mentions the SLDB report (WHO, 1999) that suggests that generic plans may form a useful starting point. Alternatively, they can be used once the business HACCP team has completed its HACCP plan as a check that their output is not inconsistent with expectations. A potential drawback is that, whilst the use of generic plans may save time and effort, true understanding and ownership must still be developed through developing a specific plan for the business from the start. If a generic plan is implemented without adaptation to the product/process in question, then the local HACCP team will not have been through the detail of the hazard analysis, etc. sufficiently to have ensured that the generic plan was appropriate, and would certainly not have taken real 'ownership' of the plan. Commitment to such a plan is therefore likely to be questionable. In reality, the availability of appropriate generic plans is worth researching and well worth considering when starting a programme, but the local HACCP team must develop its own understanding of HACCP principles, adapt the generic model to the needs of the business and take ownership of its own HACCP plan.

14.4.5 Project planning

Once the baseline audits, availability of generic plans, scope of the HACCP system, etc., has been determined, the business will benefit from the preparation of a full project plan. This may not be highly detailed but it will help to track the progress being made and will prompt the HACCP team to structure the HACCP system and to prioritise tasks. There are a few examples of this kind of planning, all from the larger enterprises. Two conclusions can be drawn:

- A large company is at a disadvantage over an SME given that the size of the task is often much larger. Cargill, Heinz, Unilever and Kerry have many plants worldwide that have, as do other multinationals, multiple production lines within each plant.
- Management teams in larger organisations are used to a more structured approach to project management. This is, perhaps, something that SMEs can learn from.

Even a large business does not have infinite resources in terms of skilled, knowledgeable people or capital to spend on GMP improvements or HACCP implementation. They are commercial enterprises just like SMEs and they have to prioritise. In the case of Cargill this was done by a risk assessment of the business. This was logical and made the task more manageable. A key lesson here is not to do more than can be managed. Cargill focused on training and supporting their priority plants in HACCP implementation before moving on to other plants. Killen notes that Heinz had to decide whether to perform Hazard Analysis on multiple production lines simultaneously, and thus quickly, or sequentially. They chose the latter option because, like Cargill, it did not overstretch their resources and they benefited from accrued knowledge as they moved from line to line. In contrast Barnes mentions the option of grouping HACCP plans by product and process in order to reduce complexity. Grouping HACCP plans by product and process does provide significant resource savings where, for example, a large number of products, differing only by raw materials content, are manufactured on the same process line.

14.4.6 Communication within the business

Not many contributors mention this but it presents a problem for many companies. Again we see SMEs at an advantage in terms of communication within their business simply on a matter of scale. McAloon reports on the difficulty and challenge in communicating food safety within a plant that has over a thousand workers. Some solutions are offered that may be helpful in small and large businesses alike:

- proactively set up a formal system for communication, e.g. a food safety committee
- publish newsletters with information on anything from HACCP development and progress to environmental microbiological results or interesting research summaries and snippets on foodborne disease outbreaks
- run competitions and awareness campaigns and make it fun.

Whatever approach is taken it is important to keep food safety uppermost in the minds of the workers. A short training session on hygiene when they join the company and then nothing more is a sure way to ensure that they are both unaware and unconcerned.

14.5 Learning 4: HACCP plan development and implementation

After training, if there is one other issue that comes up again and again in the book, it is the complexity of HACCP plans and having too many CCPs! This is, of course, linked to a lack of understanding and hence poor quality, or insufficient, education and training. It is unfortunate that many leading HACCP proponents and publications do not clearly understand or agree on the relationship between prerequisite programmes and HACCP, making matters worse. It must be understood that HACCP is an evolving tool and there is no definitive set of rules. Very few microbiologists, engineers, production or quality managers could claim to be expert in all aspects of food safety management. It may be better to admit this and combine to agree a comprehensive set of guidelines that pulls together HACCP and prerequisite good hygiene practice. We can only highlight this as an issue and, meanwhile, use the lessons gained during the development of HACCP plans. It might be helpful if we used the Seven Principles as subheadings.

14.5.1 Principle 1 – conduct a hazard analysis

Hazard analysis is probably the most difficult principle to carry out correctly for many in both large and small businesses, because of lack of expertise in hazard analysis. Training in HACCP principles and techniques will not equip individuals to be able to undertake hazard analysis unless they have the appropriate understanding of microbiological and chemical hazards. Physical hazards are easier to manage. Experience suggests that people with an awareness of the plant and common sense can often manage such hazards effectively. Two examples that highlight the difficulties are provided by Marthi and by Rudge. Marthi describes how difficult it can be to obtain hazard data from raw material suppliers. He also notes the difficulty of relying on hazard information based on epidemiological data from the USA that is not necessarily relevant or applicable in India. However, as there is no effective disease surveillance programme in India, he and other manufacturers currently have very little choice.

Rudge raises the issue of allergens that are regarded as significant in many developed countries, particularly in the USA and in the UK, but are not seen as a problem in many other countries. How is the plant HACCP team able to decide whether to include them in the hazard analysis if they are not aware that they are a problem? Government level microbiological risk assessment (see later) may help, at least with regard to micro-organisms.

Lee and Suwanrangsi mention government involvement in identifying and providing data on microbiological and other hazards for a specific food sector. An internationally agreed database on hazard prevalence by raw material/product/country or region together with a similarly agreed epidemiological database linking hazards with foodborne disease would be an immense contribution towards improving the quality of hazard analysis in all sectors of the industry, particularly for SMEs. All such data are available. It only needs someone to assemble it in a HACCP user-friendly format!

A point worth mentioning is that made by McAloon in terms of identifying controls for hazards. Instead of putting a control in place, the best method is to remove the hazard by designing it out through process or product redesign. Marthi makes a similar point in discussing the Unilever concept of 'safety by design'. This approach is often the least used option in contrast to dealing with it in a prerequisite programme or via CCPs.

14.5.2 Principle 2 – determine the critical control points

The biggest problems here seem to be the confusion surrounding the relationship between PRPs and HACCP, and the tendency to include quality as well as safety issues. Killen describes the need to focus on food safety and to reduce CCPs. At Heinz they keep a separate log of spoilage issues that can be dealt with separately and managed by non-critical Control Points (CPs). Suwanrangsi mentions the difficulty that arises through reference to available HACCP models that incorporate both safety and quality control points. It is then necessary for inexperienced companies to try to separate the two in order to deal with the non-safety points through PRPs and the safety-critical points through CCPs. The same author mentions how inexperienced customer auditors sometimes require a manufacturer to include additional, unnecessary non-critical CCPs. This problem was also mentioned by Route, Wallace and Taylor.

McEachern and Lee also highlighted the problem of regulator understanding of HACCP plans. The New Zealand government for example, has, like others, actively sought to develop standards of competency, appropriate qualifications and training programmes for their auditors, but the process takes time. Customer auditors may be even more variable in their competence. It is interesting to compare Kane's positive view of how customer review of supplier HACCP plans can be helpful, where there is an experienced auditor, with the frustration voiced by those asked to add extra and unnecessary 'CCPs' by auditors with less experience.

Perhaps the fact that there is dialogue and disagreement between suppliers, customer and regulator is actually helpful towards increased mutual understanding of effective HACCP implementation. Suwanrangsi mentions that businesses that are most proactive in their culture have the simplest and most effective HACCP plans – they are the ones with well-organised PRPs, a willingness to take full ownership of HACCP and good management skills. The reactive and less confident businesses are those that end up with the over-complex and burdensome systems with far too many CCPs.

Taylor states that good hygiene practice and HACCP have become confused and that there is no clear guidance in the 'standards' on PRPs. The Codex hygiene principles provide the best framework in terms of an international standard but they are lacking in detail and are therefore open to misinterpretation. Taylor provides one diagrammatic representation of the relationship between PRPs and HACCP systems (see Fig. 2.2 on p. 22). Another is provided in Fig. 14.6 (Mortimore and Wallace, 2001).

Management by CCP, CP or PRP depends on understanding the significance of hazards. GMPs can minimise the potential for hazards to occur but they cannot substitute for a CCP as can be seen in an example given by McAloon. Suwanrangsi mentions that additional CCPs might be appropriate as a temporary measure whilst PRPs are being developed. It is unlikely that PRPs would be used to control significant hazards in any case, but adopting this practice, with appropriate labelling, may be useful as a transitional step. It is important to remember that HACCP should be built upon an established framework of

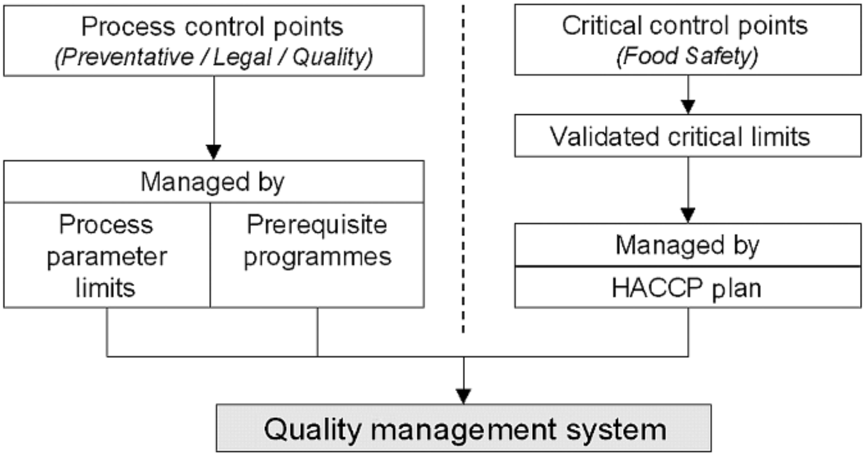

Fig. 14.6 Control point differentiation.

prerequisites/GMPs so the Suwanrangsi approach should be treated with caution, and used only as an interim measure.

14.5.3 Principle 3 – establish critical limits

There are few mentions of this stage in HACCP development in the contributions but it is likely that this can be a problem area, especially for SMEs and less well developed businesses, where relevant expertise is lacking. These businesses may need to use external consultants or other advice to validate limits they establish.

14.5.4 Principle 4 – establish a system to monitor control of the CCP

Barnes and Kane highlighted the issue of CCP monitors who do not understand what they have to do. Route also mentions CCP monitors failing to complete all the paperwork. These problems are substantiated in the UK, for example, by routine inspections. The solution must be found both in training (see earlier), involving line staff in the development of CCPs and supporting documentation, and also through the reinforcement of expectations and systems that can be achieved through regular verification activities.

14.5.5 Principle 5 – establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control

The point that Barnes makes about CCP monitors being on ‘auto-pilot’ and failing to take corrective action when needed has already been discussed, and is potentially a major weakness in a HACCP system. Kane gives a number of examples where even if a HACCP system was in place, if no corrective action had been taken then a food safety failure would have occurred. It is essential that the procedures are clearly documented and that the CCP monitors are trained to take action. McAloon offers a useful lesson: in writing meaningful corrective action procedures, Cargill set a standard that covered the basic requirements in terms of content. This is an excellent idea, offering rigour and with the ability to involve the operatives in writing CCP procedures within a set framework.

14.5.6 Principle 6 – establish procedures for verification to confirm that the HACCP system is working effectively

Almost all contributors recognised the benefit of audit as part of verification. HACCP principle 6 also encompasses the requirement for validation and verification. The recent ILSI Monograph on Validation and Verification (ILSI, 1999), clarifies the role of the above two activities which, unfortunately are not well explained in the benchmark Codex HACCP text (Codex, 1997b), and consequently are misinterpreted by many people. Part of the role of validation is confirmation that the identified CCP will control the identified hazard. Rudge mentions making sure that the controls will work in practice as opposed to just looking good on paper. Verification is confirmation that the validated CCPs are under control by ensuring that the activities outlined in the HACCP plan are actually carried out! The failure of CCP monitors to monitor CCPs or take corrective action can be addressed through regular verification activity. A key lesson is that having this programme makes the management of CCPs a lot easier and also highlights why it is important to have only the few essential CCPs in the plan. Having to adopt verification on a large number of unnecessary ‘CCPs’ is what makes HACCP seem to be a burdensome and irrelevant exercise.

Verification activities include a review of critical records, consumer complaint monitoring, calibration of critical measuring devices and audit. McAloon sees self-audit as the key to long-term success. This is a view also expressed by others. Some ideas that might be of help include:

- Internal auditors require a high degree of knowledge and experience. Ideally this should have been gained from working directly on the process being audited.
- Auditors must be independent of the process being audited, but it still works well if they are drawn from production personnel involved in the process.
- The staunchest critic of the business is the business itself – try to ensure that the audit function is viewed positively and acknowledge that the intention is to improve the system.
- A regular (e.g. monthly) audit, if done well, will not only identify deficiencies but can also encourage staff to suggest improvements and ways of simplifying procedures.

14.5.7 Principle 7 – establish documentation concerning all procedures and records appropriate to these principles and their application

Given that in some countries (e.g. the UK) there has been a legal requirement for a HACCP approach but with no requirement for documentation, it was surprising that there were only a few comments in this area. Again, the main problem is correctly identifying the true CCPs that enable documentation to be made manageable. Some ideas were offered by the contributors in dealing with the problems they had observed or encountered:

- How to integrate documentation without adding complexity (McAloon); the answer lies in using existing paperwork and forms. Auditing helped to highlight where these needed modification and an operator can be asked to help in the redesign.
- Management of critical records, especially those related to non-conformity (Rudge); use of simple databases is recommended as a solution where paper systems become unwieldy. The lesson here is to emphasise that the HACCP system is there to work for the benefit of the business and to add control. Using a database means that not only can records be organised but trends can more easily be analysed, which is better for longer-term preventative actions.
- Documentation is most easily managed where there is an existing quality management system. Taylor points out that many of the SMEs do not have the benefit of such a framework to build on.

In summary, the main problems that have been highlighted related to over-complex HACCP plans with too many CCPs. This is, largely, a result of misunderstanding and confusion between PRPs (for CPs) and CCPs. However, there were some more surprising discoveries made by McAloon during the development of the HACCP programmes at Cargill.

- Eighty per cent of the pieces needed for HACCP were there already – they just needed organising. This is probably the case for many large and small businesses.
- Line workers showed commitment earlier than their supervisors.
- Challenging the status quo is good practice.

14.6 Learning 5: HACCP maintenance activities

Kane observes that, from a retailer perspective, it is clear that failure to maintain HACCP systems can be a major weakness. As an industry there are numerous examples where food safety incidents occurred as a result of a process change (e.g. a food poisoning outbreak caused by hazelnut yoghurt in the UK – where a reduced sugar formula was not assessed for revised thermal process requirements).

14.6.1 How to keep momentum going

After all the effort of getting a HACCP plan developed it can be difficult to keep the motivation and momentum going, particularly once the next major project comes along. This is a key issue to bear in mind when starting a HACCP programme. To use the HACCP programme to create a sustained and proactive commitment to food safety takes a lot of thought and planning. McAloon describes how recognition tools can be used to good effect. Simple and inexpensive rewards can make a big difference to the ongoing commitment within the workforce. Marthi describes the workforce as becoming 'empowered' which, once achieved, should not be undermined.

14.6.2 People issues – staff turnover, ongoing training, absenteeism

It is often easier to train new people into the business than to train your existing employees. In an established HACCP system there will usually be two guaranteed training needs as a result of staff turnover and the legacy of veteran employees. It is important to recognise the differences between the two groups and to plan a different approach to ensure that both groups are trained properly.

Training new employees as a result of staff turnover

This is a problem not just for large companies but also for SMEs who often employ casual workers, particularly in the foodservice sector. McAloon really drives home this point with the example of one plant employing 2,000 people speaking four different languages, where there was 20% annual turnover. He also shared the fact that after twelve months of the HACCP programme being operational the turnover, particularly at supervisor level, was having an impact and could be seen in their internal audit scores. There are a number of solutions to consider:

- An orientation programme for HACCP activities can be set up. As Wallace points out this can also be done for hygiene training.
- Ensure that key workers are identified (CCP monitors, supervisors) and that where job descriptions exist, their special food safety responsibilities and training needs upon recruitment are clearly identified.

Refresher training for existing employees

McAloon suggests short bursts of training (15–20 minutes each month) which can be more easily incorporated into the regular work pattern than half-day or full-day courses. Absenteeism is another problem for many businesses and it is necessary to build cover for key workers into the system rather than to assume that they will never take a vacation or get sick.

14.6.3 Larger company issues

There are a couple of lessons that are mainly related to larger multinational businesses.

What happens to the corporate HACCP support team once the HACCP project is completed?
McAloon relates how important it is to agree roles and responsibilities (for instance between the plant and headquarters) and communicate what these are. While the plant team usually maintains the HACCP system, the HQ team may be used to develop a library of resource and training materials. Alternatively they may assume responsibility for tracking and communicating information on such things as emerging hazards, or they may be used in a verification role – reviewing HACCP plans and auditing. These are important and useful activities and it may be possible for smaller businesses that do not have this resource to get some of these services via other means, e.g. industry trade associations, regional food safety clubs, food research associations and reputable consultants.

How should acquisitions and co-packers be incorporated into the HACCP system?
Again, this is a point raised by McAloon, but one that will be recognised by anyone working in a larger company. The key lesson is not changing anything in a rush or automatically. Instead one should acknowledge the experience of the people working for the newly acquired company or co-packer. It is important to understand their point of view before starting the HACCP development project in much the same way as described earlier, i.e. baseline audit, training plan, project plan, etc.

14.6.4 Process improvements

Killen and McAloon shared their experiences in this area as it is obvious that, for progressive companies, HACCP is seen as an opportunity for improvement. HACCP helps a business to understand its processes better, introduces a range of improvements, and acts as a platform from which to go on to use more complex process improvement tools.

14.6.5 Regulatory assessment

There are a number of approaches described in the texts which can be compared to the very good recent WHO/FAO Consultation on the role of regulatory bodies in the assessment of HACCP (WHO/FAO, 1998): Guidance on Regulatory Assessment of HACCP). While HACCP verification (Principle 6) is clearly a key responsibility of the food business, regulatory assessment provides both an important service to the company, in providing an objective assessment of a HACCP system, and serves the consumer by virtue of the fact that the regulator is acting on their behalf to ensure compliance with food safety standards. A number of lessons emerged from the regulatory contributions:

- Checklists can be a useful tool (Lee) but they can never be all inclusive and the assessor needs to apply experience and judgement.

- The relationship between an inspector and a food company can be seen as adversarial (McEachern). In the Canadian programme, as in most if not all countries, regulatory inspections are not done at the invitation of the company.
- Regulatory assessment can be used to promote industry ownership of and competence in HACCP, i.e. as a confirmation that all of the required components are in place.

What comes across with all the regulatory contributions, and to some extent Kane's retailer perspective, is how important it is for industry and regulator to work together for the benefit of the consumer whom they both serve. The changing roles and different approaches taken by regulators are interesting and their views are helpful to all businesses who have to operate further back in the supply chain to ensure the safety of raw materials. If the food safety regulation programme is well developed, is there any need for businesses to audit their own suppliers or is this a duplication of effort?

14.7 Where next for businesses with HACCP systems?

Once they have set up a HACCP system, where do businesses go next? How should they develop established HACCP systems? Are there opportunities highlighted in the individual contributions, or are there changes already happening within the industry and/or regulatory environment that will facilitate change? Certainly we have learned that a number of businesses have used HACCP as a springboard for continuous improvement. McAloon, Rudge and Killen take the view that it can lead very logically into process analysis and subsequent improvements. Kane suggests that the concept can be extended into other aspects of food safety such as malicious contamination. The approach can also be applied to non-food areas – McAloon mentions human safety. Alternatively, the energy and cultural change that may have developed through the use of the HACCP approach can be harnessed to drive other quality initiatives. Can HACCP be used further in other ways, as a competitive tool to drive broader business benefits? Perhaps the opportunities may include:

- setting up measuring systems to monitor overall HACCP plan performance and to identify improvements to the system, for example in CCP compliance
- referring to published benefits (for example cost saving, waste reduction, process improvement, sanitation downtime reduction) and setting objectives for achievement of measurable costed improvements
- extending the skills developed to other non-food safety or non-hazardous areas of the business, for example the critical sensory attributes of the product, or identifying the critical process steps in a commercial transaction process
- ensuring access to emerging hazard data and to being proactive in making sure that the HACCP system is reviewed against this data

- setting up a system to ensure that equipment, process or recipe changes are captured and incorporated into the system
- reviewing regulatory and consumer assessment frequency based on good performance
- reducing the QA costs associated with the current practice of end product testing by relying instead on validated HACCP plans to provide real 'on line' process and product control. Apart from providing the manufacturer with an increased confidence in the safety of the product (the *raison d'être* for HACCP), this has a number of additional benefits, including the quicker release of products to market with a reduced requirement for storage of product 'on hold'.

14.8 Summary

It is time to pick up some of the issues first raised in the introduction. Is the concept of HACCP flawed in some way? A number of issues have been raised in this chapter which suggest the need to reassess HACCP principles as they have subsequently developed and been codified. These issues are:

- continuing confusion over the relationship of HACCP to prerequisite programmes (PRPs)
- the early development of what can be seen as a more elaborate 'large industry' HACCP model, partly by Codex and other experts, and partly by the early pioneers of HACCP systems, who were mostly large companies.

There is now a move to 'second-generation' HACCP models allowing greater flexibility and putting more emphasis on prior development of effective PRPs with simpler HACCP systems focusing much more effectively on the key hazards. This approach is seen as more effective for SMEs and businesses in other parts of the food chain than manufacturing, for example food service operations. It suggests the continued need to reassess what HACCP principles really mean in practice. What does the practical experience described in this book tell us about those principles?

- It confirms that, when a business understands those principles well and has the commitment and resources to carry them out, HACCP works. A number of contributors describe the major contribution of HACCP not only to food safety but to the overall competitiveness of the business.
- Often, 80 per cent of the requirements for a HACCP system are already present; they simply need to be identified and integrated into a HACCP framework.
- HACCP is a 'minimal' system allowing businesses to make the most of their existing systems and focus resources more effectively on the critical safety areas.
- Because HACCP is a minimal system, it is clear that HACCP is not just the province of the multinational but is equally applicable to SMEs too. Indeed,

SMEs have a number of advantages over larger companies in HACCP implementation, including simpler processes to analyse, simpler lines of communication, greater flexibility and speed.
- If implemented effectively, HACCP can bring significant commercial benefits, not just in avoiding the legal and financial implications of a serious food safety incident, but in reducing costs and improving productivity. It is also empowering, allowing a business to understand and improve its processes, and producing more proactive employees able to contribute more to the business.

If HACCP can work so well, why do so many businesses have problems with it? The contributions in this book suggest the main problems are:

- Wrong perceptions of the value and complexity of HACCP implementation, often linked to low motivation in embracing HACCP and its benefits; poor motivation can sometimes be linked to difficulties in measuring and quantifying the benefits of a HACCP system.
- The need for culture change within an organisation; HACCP requires a proactive culture throughout the organisation, from senior management to line operators, involving greater responsibility for identifying and controlling hazards. Some organisations have a more traditional and hierarchical culture in which managers respond reactively to food safety issues and line staff are given little opportunity to show initiative.
- Misunderstanding of the HACCP concept, for example in incorrectly identifying CCPs.
- Lack of appropriate expertise in such areas as hazard analysis.

These problems clearly affect not only large and small companies in the food industry but also regulators and customers (such as retailers) who set and enforce standards, and provide advice and support. Such fundamental problems then lead to a familiar series of HACCP system failures:

- a misunderstanding of the role of PRPs, the hazards to look for and the nature CCPs, resulting in over-complex and unmanageable HACCP systems
- ineffective monitoring and corrective action, due to failures in organisational culture, poor training and verification procedures
- poor documentation, as a result of over-complex HACCP systems
- poor validation, especially for SMEs lacking the relevant expertise on hazards.

Against this background of common systems failures, there are distinctive problems across countries, including language, cultural differences and quality of infrastructure. The core problems which produce HACCP systems failure have, in varying degrees, affected the contributors to this book, and they provide a range of proven, practical solutions to them which have been summarised in this chapter. The contributors demonstrate that, although there are challenges to HACCP implementation, they can be met and the rewards are well worth the investment. One common theme, especially for SMEs, is the importance of appropriate support from others, whether regulators, trade bodies or customers such as retailers. As well as setting and enforcing standards, governments, for example, are developing innovative ways of promoting understanding of HACCP, developing training and other resources, and providing expertise to fill such skills gaps as hazard analysis. Partnership, whether within particular sectors of the food industry, between customers and suppliers, or between government and industry will be an increasingly important factor in making HACCP implementation more effective and widespread in the food industry.

14.9 References

CODEX COMMITTEE ON FOOD HYGIENE (1993) 'Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) System', in *Training Considerations for the Application of the HACCP System to Food Processing and Manufacturing*, WHO/FNU/FOS/93.3 II, World Health Organisation, Geneva.

CODEX COMMITTEE ON FOOD HYGIENE (1997a) 'Recommended International Code of Practice, General Principles of Food Hygiene', CAC/RCP 1-1969, Rev 3 (1997) in *Codex Alimentarius Commission Food Hygiene Basic Texts*, Food and Agriculture Organisation of the United Nations, World Health Organisation, Rome.

CODEX COMMITTEE ON FOOD HYGIENE (1997b) 'HACCP System and Guidelines for its Application', Annex to CAC/RCP 1-1969, Rev 3 in *Codex Alimentarius Commission Food Hygiene Basic Texts*, Food and Agriculture Organisation of the United Nations, World Health Organisation, Rome.

ILSI (1999) *Validation and Verification of HACCP.* International Life Sciences Institute, Europe, Monograph Series, Brussels: ILSI Europe.

MORTIMORE, S. E. and WALLACE, C. A. (2001) *HACCP: Food Industry Briefing Series*, Blackwell Science, UK.

WHO (1998) *Guidance on Regulatory Assessment of HACCP.* Report of a joint FAO/WHO consultation on the role of government agencies in assessing HACCP. WHO/FSF/FOS/98.5, Geneva.

WHO (1999) *Strategies for Implementing HACCP in Small and/or Less Developed Businesses,* World Health Organisation, WHO/SDE/FOS/99.7, Geneva.

15

The future of HACCP

T. Mayes, Unilever Research, Sharnbrook and S. Mortimore, Pillsbury Europe, Uxbridge

Although the system that we know as HACCP has been around for 30 years now, there was little development of the original Pillsbury/NASA/US Natick army concept until the late 1980s/early 1990s. In just over a decade since then the HACCP system has undergone a transformation from its original concept to one that is now codified, accepted internationally as the most appropriate means of ensuring food safety, and implemented to various degrees, on a global basis. Just over a decade ago it would have been difficult to predict the changes that lay ahead. Similarly, it may be difficult to predict with much degree of accuracy those changes to HACCP that will occur in the foreseeable future. However, some forces for change are clearly on the horizon now, and it is worth looking at these to try to judge what the future of HACCP is likely to be.

There are a number of forces for change that will impact upon HACCP in the years to come. These include:

- the increasing globalisation and harmonisation of trade between countries
- the changing role of governments and regulatory authorities in the assessment of HACCP
- the role of HACCP in new science/food safety initiatives such as Quantitative Risk Analysis
- the need for application of HACCP throughout the supply chain.

In addition to the specific forces for change there will always be the ongoing requirement for the continuing improvement of the HACCP system based on practical experience. The problems highlighted in the preceding chapters of this book certainly point to this need.

15.1 Globalisation and harmonisation of trade

The introduction to this book touched on some of the implications for HACCP resulting from the globalisation of trade, the World Trade Organisation (WTO), and the Sanitary and Phytosanitary (SPS) agreement. The increasing globalisation of trade has focused government/regulatory attention on the issue of equivalency in food safety and quality management. As international food trade continues to grow (currently in excess of $500 billion per year), it has become obvious that no one single country is completely self-sufficient in terms of its food needs. The projected growth in world population from 6 billion in 1999 to an estimated 8–10 billion in 2050, with the majority of such growth being in developing countries, means that there will be a significantly increased demand for more food.

More efficient, and therefore more industrialised, food production will be required with the potential for more movement in foodborne pathogens and more widespread food safety problems. More people will be immunocompromised and will be more sensitive to foodborne pathogens. There will be an increasingly urgent need to improve control over food safety to prevent widespread, globalisation of foodborne disease arising from globalisation of the food supply. There will be an ever-increasing need to control the safety of both imported and exported foods from all countries, to protect the consumer from unsafe food and to prevent the dumping of unsatisfactory quality food. HACCP has become the universal system of choice for the control of foodborne hazards for the majority of food manufacturing countries, as shown by the increasing adoption of both voluntary and mandatory HACCP systems for both internationally and domestically consumed products in many countries.

The SPS agreement, which focuses on safety issues, requires that measures taken by individual countries are:

- applied only to the extent necessary to protect human health
- based on scientific principles
- not maintained without scientific evidence
- based on an assessment of the risk to health that is appropriate to the circumstance.

Whilst the SPS agreement recognises standards, guidelines and recommendations promulgated by Codex Alimentarius, WTO member countries that adopt Codex standards as sanitary measures do not need to justify these measures. However, the fact that Codex promulgates HACCP as the food safety system of choice means that HACCP will be used as the benchmark process by which food safety is ensured in practical terms. The implications of this are significant. Not only does this require a universally agreed *modus operandi* for HACCP to enable harmonised application, but it also requires an agreed mechanism to judge the acceptability, or not, of HACCP implementation and effectiveness in controlling foodborne hazards. The former requirement is met by the Codex Alimentarius 1997 benchmark HACCP publication (Codex, 1997), but the latter point brings us to the issue of equivalence.

Article 4 of the SPS agreement states:

> Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Members' appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.
>
> Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary and phytosanitary measures.

The concept of equivalence basically means that an exporting country need not apply the same control measures for processing as those used in the importing country, provided the degree of food safety assurance delivered is deemed equivalent to that of the importing country. This also applies to the inspection system used by both countries (Orriss, 1999). The concept of equivalence is one of the most contentious issues in food safety at the present time. Whilst some countries have already begun negotiation of equivalency agreements, there is still much debate concerning the principles underlying equivalency and precisely how it is possible, in practical terms, to determine the equivalency of imported products. Codex Alimentarius is currently seeking agreement on a better definition of equivalency. At the present time it is likely that the determination of equivalence will involve consideration of three tiers of information:

- the infrastructure within a country
- the laws and regulations with respect to food safety
- Food Safety Objectives/HACCP/SPS agreement.

The concept of Food Safety Objectives will be discussed in a later section, but it seems most likely that determination of equivalency will have to include, amongst others, a consideration of the HACCP system currently applicable to the food/country involved. HACCP seems certain therefore to play a key role not only as the food safety system of choice but also as a key element in the determination of equivalency of the food safety systems between countries.

Hathaway (1999) provides a good description of the issues surrounding the judgement of equivalence and the use of Food Safety Objectives. A key step for the future will be to agree practical guidelines for the determination of equivalency internationally. Such an agreement would still leave open the question of monitoring compliance (done by the importing country?), and question the role of initiatives such as HACCP certification. Will an internationally recognised standard for HACCP certification have a role to play as a measure of HACCP system effectiveness, or will a more complex system be required to assess the effectiveness of a multifaceted Level of Protection/FSO/

HACCP system? It is also possible to identify where conflicts of interest could arise in the future. The challenge of maintaining appropriate standards of food safety (equivalence) in the face of political pressures to allow/increase freedom of trade will be one of the biggest challenges facing Codex and national regulatory agencies in the future.

15.2 Changing role of governments and regulatory bodies

National governments have a responsibility to ensure consumer health and safety by introducing and implementing legislation relating to food safety. In terms of specific measures such as HACCP, government agencies have a strategic role to play in the implementation of HACCP and a regulatory/enforcement role to play in the assessment of industry-owned HACCP systems. The recent WHO/FAO Consultation on Guidance on Regulatory Assessment of HACCP (WHO/FAO, 1998) addressed the issues of how regulatory agencies should assess HACCP systems. The Consultation recognised that government agencies need to show leadership by promoting and facilitating the implementation of HACCP. The type of activities that government agencies need to consider include:

- facilitating training programmes for industry
- providing guidance, expertise and, where necessary, legislation
- encouraging the development of training material for industry, government and other interested parties
- formulating a programme to assess HACCP.

As the implementation of HACCP systems continues to increase on a worldwide basis, the traditional role of the food safety agencies, including that of food inspectors, is having to change to adapt to the new ways of industry working. In addition to the inspection of industries for compliance with GMP and other relevant guidelines, officials are also now faced with new responsibilities for the assessment of HACCP systems. There is no doubt that government/regulatory agencies need to rethink the way in which they assess food safety control and the above Consultation was intended to provide government agencies with guidelines on regulatory assessment, focusing specifically on:

- the role of government agencies and their responsibilities with regard to HACCP assessment
- the essential activities which need to be carried out when assessing HACCP
- how to perform essential activities adequately.

The implementation of HACCP with its emphasis on product safety and use of CCPs, provides both industry and regulatory bodies with a more logical method of ensuring the safety of foods than was previously available. Whilst industry, as developers and owners of HACCP systems, has developed its own approaches to assess the effectiveness of in-house HACCP systems over a period of time, government and regulatory agencies now find that they need to consider how they can assess HACCP systems from a regulatory point of view. In this regard government and regulatory agencies should learn from the experience gained within industry on the appropriate methodology to assess HACCP systems (including GMP/prerequisite requirements). Annex 3 of the Codex Consultation report contains a description of an approach that has proved successful in the industry assessment of HACCP.

One of the major problems that government and regulatory agencies have to address is that, because HACCP is a more science-based system of food safety control than those previously used, the majority of government/regulatory assessors do not, themselves, currently have the requisite skills and competencies to assess HACCP systems satisfactorily. There is therefore a need for assessors to receive education in such areas as hazard analysis as well as training in HACCP principles, much of which must be of a practical nature, in order for them to be capable of assessing HACCP systems with confidence. Even this may not be enough. Assessors may need to get involved actively in HACCP studies (experiential learning) in order for them truly to appreciate the approach.

Another major hurdle for government/regulatory agencies to overcome lies in the amount of time and the nature of the resource required to assess HACCP systems satisfactorily. Whilst some HACCP systems in SMEs can be assessed in a short time period if the assessor has the right skills and competencies (see above), many HACCP systems in large manufacturing plants require significant amounts of time from the assessor for a thorough evaluation. This requirement is currently in conflict with the amount of skilled resource available to government/regulatory agencies. This is potentially a serious problem.

Assuming the assessors have the appropriate skills and competencies, a further key task is to facilitate an assessment process that is searching and meaningful yet can be completed within a relatively short time frame. An answer lies in the role of validation. The recent ILSI Monograph on the Role of Validation and Verification (ILSI, 1999), clarifies the different roles of validation and verification well. Validation is, basically, concerned with ensuring that the scientific and technical content of the HACCP plan is correct, and should be carried out before HACCP plan implementation. Verification is about ensuring that the HACCP plan owners do what they say they will do in the HACCP plan and this should be carried out on an ongoing basis. In addition, at regular but infrequent intervals (e.g. one year), a full reappraisal of the HACCP plan should occur.

A summary of evidence gathered during validation would therefore provide a government/regulatory assessor with data upon which the scientific and technical competency of the HACCP plan could then be judged. A summary of the evidence gathered during verification would similarly provide the assessor with data upon which could be judged the rigour with which the HACCP plan was implemented. Summaries of validation and verification would therefore seem to offer assessors data upon which, with the requisite skills and competencies, they would be able to make a judgement on the plan's scientific and technical content, and the rigour of its implementation. Such an assessment could be made within one day even for a complex HACCP plan. For this initiative to become a reality, both industry and government/regulatory assessors have a responsibility to work together and agree a process that satisfies the requirements of both groups.

Validation and verification should be applied in SMEs as well as large manufacturing plants. In SMEs the evidence for validation and verification can and should be as simple as possible, otherwise it will not be collected. Whilst the principles of validation and verification should be applied sympathetically to SMEs, there are genuine problems for SMEs in terms of the availability of time and skilled resource to carry out hazard analysis. Government and regulatory bodies have an important role to play in the mentoring of SMEs to help fill the gaps in technical knowledge and other resources. In this regard the use of industry sector specific 'generic' HACCP plans can, with guidance, prove very valuable in getting SMEs started and later as a check that what they have achieved is in line with industry expectations.

Similarly, the subsidised training of SMEs in HACCP plan development and implementation can contribute significantly to overcoming the barrier to start HACCP that SMEs find so hard to overcome themselves. This help, together with ongoing support, is one of the real opportunities that government/regulatory agencies have in making a significant improvement in food safety standards on a worldwide basis. However, the fact that government/regulatory agencies can have a dual role of both mentoring HACCP implementation and assessing HACCP system effectiveness means that there is a potential conflict of interest. It is therefore essential that assessors do not assess HACCP systems that they also helped to design and/or implement.

15.3 The role of HACCP in new science/food safety initiatives

It is now clear that HACCP is only part of the series of events and processes required for food safety, regulatory compliance and customer satisfaction. One of the problems that HACCP suffers from is that it is really a system of food safety hazard identification and control and the application of HACCP rarely, if ever, considers the reduction in risk to the consumer. A typical criticism of HACCP is that it is not outcome oriented and it is therefore difficult to assess its benefit. As Orris and Whitehead (2000) point out, a hazard is defined as a biological, chemical of physical agent in, or condition of food with the potential to cause an adverse health effect. However, the term 'potential' is subjective and is interpreted broadly from remotely possible to highly probable. Orris and Whitehead also point out that there is often confusion about what constitutes a hazard, leading to further inconsistency in HACCP application.

The challenge is to assess the application of HACCP in the context of its contribution towards eliminating or reducing the risk of foodborne illness to the consumer. The practicalities underpinning control of food safety leading to measurable reduction in consumer risk is currently a major goal for both industry and governments alike and is invoking considerable scientific debate. Space does not permit a detailed review of all current thinking, but the following discussion will illustrate the role that HACCP may play in the future in this important development.

The SPS agreement requires members to ensure that their SPS measures are based on a risk assessment, taking into account techniques developed by relevant international organisations. The Codex Alimentarius Commission (CAC) has prepared a draft document on Risk Analysis guidelines relevant to the above. Risk Analysis as defined by Codex consists of the following three processes:

1. risk assessment
2. risk communication
3. risk management.

Risk assessment is the science-based process that provides data for use in risk management decision making. The application of risk analysis to food microbiological hazards is a significant challenge due to the lack of good quality quantitative data on topics such as exposure assessment, but increasingly quantitative risk analyses (QRA) are being published for major pathogens/food types. As knowledge increases we should expect more QRA studies to be published. It is proposed that the outcome of a risk assessment should be a Level of Protection (LOP) (e.g. estimated number of cases per year in a certain food per 100,000 of the consumer population). Risk management should then be used to decide if this LOP is acceptable or appropriate (ALOP). The outcome of QRA should therefore be an acceptable (appropriate) level of protection (ALOP). The ALOP is a level of consumer food safety risk that would then be adopted as food safety policy by the national government.

For international trade there is an implicit obligation of WTO members to determine their ALOP. The current thinking is that Food Safety Objectives (FSOs) will then need to be developed to represent the ALOP. Food Safety Objectives are intended to translate a level of risk (ALOP) to a level of hazard. A working definition of the term FSO would be: 'a statement based on a risk analysis process which expresses the level of a hazard in food that is tolerable in relation to an ALOP.'

An example of an FSO would be: '$<$ 100 L. monocytogenes per gramme of food at the moment of consumption.' This example of an FSO is both measurable and verifiable and could be used to judge equivalence. The role of HACCP would be as the practical food safety control system, implemented on the factory or kitchen floor, required to deliver food product complying with the above FSO. HACCP would still stay as an industry owned, practical system of hazard control, but it would now be outcome oriented and would have to meet the FSO. As such, HACCP systems would then be linked to consumer risk via the FSOs and the relevant ALOP. The concept of FSOs would also allow for the assessment of the stringency of different HACCP systems. There is no doubt that currently HACCP systems covering the same hazard/product combinations in different plants/companies/countries differ in their stringency because they have been developed without the benefit of having to meet a measurable outcome. The use of FSOs would allow the comparison of different HACCP systems addressing the same hazard/product combination.

It is important to reiterate that the above discussion is currently the subject of much scientific debate and there are conflicting views from those summarised here. It is also true to say that many of the practical issues have yet to be resolved. However, whilst the specific details may change with the passage of time and scientific debate, the authors of this chapter are convinced that the future role of HACCP will be as part of a total food safety system incorporating many, if not all, of the concepts outlined above. Such a move would strengthen the role of HACCP significantly by making it outcome oriented, but would still leave ownership of HACCP as the responsibility of industry as it is now. Most importantly, it maintains the practical 'hands on' nature of HACCP as it is now, and does not impose an unnecessary additional burden of scientific assessment on the development of HACCP plans.

Many SMEs already find it difficult to carry out the current requirements for hazard analysis on their own and require additional technical support. It is crucially important for both present and future users of HACCP that we do not impose additional burdens (e.g. risk assessment) on HACCP planning, otherwise a substantial part of the very good work done over the last 30 years will be wasted. The above scenario maintains the correct balance between HACCP practicality and science and has much to commend it.

15.4 Application of HACCP further along the supply chain

The history of HACCP shows clearly that the major thrust for HACCP development came initially from the large manufacturers and subsequently from regulatory interests. The current CAC benchmark document clearly reflects the skills, competencies, technical knowledge, etc. of the larger manufacturing organisations. As Barnes has pointed out in Chapter 12, the concept of teams of experts and detailed product-by-product examination may be relevant for manufacturing plants, but it is not well suited to smaller establishments (SMEs) such as caterers handling large numbers of products. Taylor and Route have also pointed out in their chapters many of the problems faced by SMEs in trying to implement HACCP. A recent WHO (1999) consultation examined HACCP implementation studies for small and less developed food businesses, and there is hope that this and other related initiatives will lead to a more appropriate HACCP approach for SMEs.

What the early history of HACCP illustrates, however, is that HACCP development has been quite narrowly focused. There is a need to extend the application of HACCP, or HACCP principles, beyond the food manufacturing industry to cover the whole food chain from 'farm to fork' more effectively.

There is an increasing awareness that the whole of the food chain needs to have safety as a priority. In this regard the codification of HACCP, and its perceived ownership by large manufacturers and regulators, probably does not help. However, the authors of this chapter believe that HACCP is applicable to all sectors of the food chain.

The principles that underlie HACCP (i.e. the identification of significant hazards and associated critical limits and control measures to ensure control of relevant hazards) can be applied to any sector of the food chain, provided that the principles are applied in different ways depending upon the business type. The practical application of HACCP principles should be tailored to the particular food sector/business size under consideration, enabling the philosophy underlying HACCP to be applied without all the 'baggage' that comes with the full codified version that is most applicable to large manufacturing organisations.

Barnes makes the point in his chapter that this flexibility of approach needs to be more formally recognised by Codex. Provided that a flexible approach is used there is no reason why HACCP cannot be applied successfully on the farm, in slaughterhouses, in primary crop production, in retail and food service sectors as well as manufacturing. Some businesses are doing this but it needs to become commonplace. There remain important issues to be resolved (e.g. the lack of a killing step CCP in slaughter operations), but the future of HACCP should embrace the widespread application of its principles across the entire food supply chain.

In a similar vein, it could be argued that as HACCP implementation spreads across the globe it is most likely that differences in local culture, native industries, and locally accepted standards could lead to very fragmented application of the currently accepted HACCP system. One could ask if this is likely to be a problem if it happens. The answer is given above, that provided the philosophy underpinning HACCP is the same, the practical application of the principles should allow flexibility. Codex Alimentarius has a key role to play in this regard, and should be seeking specifically to endorse a flexibility of approach that will enable a genuinely inclusive application of HACCP basic principles. This would ensure that global users of HACCP will be confident that HACCP can be made appropriate to their needs, and in so doing, prevent the development of 'HACCP alternatives' or 'different versions of HACCP'.

15.5 The continued development of HACCP

The above discussion has allowed us to speculate how four specific forces for change could affect the future of HACCP. In addition to these specific issues there will always be other, more general issues which will require HACCP to evolve in order to maintain its effectiveness. There is an increasing realisation that HACCP is not a static system that can be 'put on the shelf' once the HACCP plan has been finalised, but a system continually evolving in the face of new challenges and in the light of practical experience.

15.5.1 New/emerging hazards

One of the disturbing features of food safety has been the identification of a number of new and/or emerging hazards that have occurred over the last decade. Microorganisms such as *Eschericia coli* 0157:H7, *Listeria monocytogenes*, and *Salmonella enteritidis* have all led to foodborne death or illness. Similarly there is heightened awareness and concern in the USA and Europe about the increase in allergic reactions to food. HACCP has had to evolve to accommodate such hazards. This ability of HACCP to evolve as a result of new challenges and improve as a result of practical experience is an essential feature behind the success of HACCP to date, and it will continue to be essential for the future success of HACCP. One interesting consideration for the future is that currently food safety control is focused on acute microbiological hazards. Recent research has indicated that some foodborne microorganisms may be associated with chronic disease. If this subsequently is proven to be the case then HACCP, as the food safety system of choice, will be required to adapt to include consideration of hazards with chronic effects. This will involve specific consideration of chronic effects during the hazard analysis process.

HACCP may also be extended to encompass hazards not previously associated with HACCP systems. As an example, Kane makes a very interesting point in Chapter 4 that, from the retailers' point of view, food manufacturers should consider malicious product contamination as a food safety hazard. Kane makes the point that HACCP principles can be specifically focused on this issue and control measures implemented to reduce the opportunity for deliberate product contamination, just as retailers have had to deal with the prevention of malicious contamination in their stores. In reality it is believed that very few manufacturers include malicious contamination as a realistic hazard in their HACCP plans, rightly or wrongly because they believe the risk to be low. It is of course possible when considering own label brands that the perception of such risk is viewed to be much lower by the manufacturer than by the retailer who, should such a contamination incident occur, would have to face the immediate consequences.

Kane also makes a very interesting point concerning post-launch monitoring (PLM). Kane's point is that data from customer complaint monitoring that retailers carry out could include specific post-launch monitoring of new products, looking more closely for any emerging food safety problems. Such data could be shared with product manufacturers and fed back into future product launches and HACCP systems. Use of PLM data in this way would presumably fall under the current HACCP terminology of verification. As such, PLM, whether carried out by the retailer or the manufacturer, has the potential to improve the quality of both current and future HACCP plans significantly.

It is not uncommon to hear people at international conferences say 'this is an aspect of HACCP that I was not aware of'. Such statements do not demonstrate a lack of consistency or a weakness in the HACCP system. On the contrary they demonstrate the essential ability of HACCP to continue to evolve in response to new food safety challenges. HACCP practitioners should never believe that once the HACCP plan is prepared then the job is finished. HACCP is a long-term commitment and practitioners must review and verify their HACCP plans on a regular basis to ensure they remain appropriate.

15.5.2 Food safety management systems

The future of HACCP must also take into account the roles played by several other food safety management systems. Management systems such as Total Quality Management (TQM), the ISO 9000 series, Good Manufacturing Practice (GMP), Good Hygiene Practice (GHP), Prerequisites, Quality plans, etc. will all have some impact on the future of HACCP. In effect, HACCP must form a key element of an integrated approach to food management. HACCP, underpinned by GMP/Prerequisites, should form those elements of the programme targeted at food safety (ILSI, 1998). The food safety management programme itself is a component of the company's larger Quality Management System (e.g. ISO 9000 series), and long-term managerial strategy (TQM). In this way it is possible to see clearly the role that HACCP will play as part of a total integrated management plan. It is clear that HACCP must not be viewed as a stand-alone system for, without the proper underpinning support of GMP/Prerequisites, HACCP itself cannot hope to function effectively, and without integration with other food management tools, the specific role of HACCP mediated product safety cannot be defined clearly within a company's overall management strategy.

15.6 Summary

When we talk about the future of HACCP it is important to remember that even in larger companies, which were the first to implement HACCP, the systems are still relatively new, and in some medium-sized and smaller-sized companies HACCP principles are still being implemented for the first time. It is also important to remember that the speed of HACCP implementation is not uniform across the globe. Industries in many countries are currently tackling HACCP for the first time. There is plenty of scope for HACCP implementation in some countries/regions/sectors of the food business to continue to develop up to the point already reached in the USA/Europe/Canada/Australia/New Zealand, etc. For some, the future of HACCP can be seen clearly in the progress already made by others, and this in itself would be a tremendously valuable step forward for many. In those countries where HACCP is well accepted there is still much to do, particularly in extending the system further down the supply chain to truly cover 'farm to fork' and in further collaboration between industry and regulatory agencies to ensure valid, cost-effective assessment of industry-owned HACCP systems.

It seems certain that HACCP will play an increasingly important role as the food safety system of choice for food manufacturers and regulatory agencies and also as the system of choice when considering the safety of foods traded internationally. HACCP will continue to evolve in response to new food safety challenges and as a result of experience in use. A particularly exciting development will involve the use of HACCP in conjunction with new concepts of acceptable level of protection and food safety objectives. Such a development offers the promise that HACCP will become outcome oriented and will be clearly linked to a reduction in consumer foodborne disease. Such developments must be the subject of open, transparent debate, preferably under the guidance of Codex Alimentarius, and must include representatives from all sectors and sizes of industry as well as regulatory agencies. All developments in the HACCP system must maintain the essential 'hands on' practical nature of HACCP, remembering that HACCP principles must be applicable in the factory, slaughterhouse, butchers shop, etc. and must be applicable to large, medium-sized and small industries. The imposition of unnecessary science on the HACCP system must be avoided at all costs.

Not all future developments in HACCP will be adopted at a uniform pace globally, nor need they be. Codex has an important role to play in ensuring that, whilst the principles of HACCP remain the same for all, there is flexibility in the practical application of such principles. Countries/companies/industries that are now experienced in the implementation and assessment of HACCP have a responsibility to pass on to others the lessons learnt, both good and bad. Safe food is the aim of all; there should be no competitive advantage in having a 'better HACCP plan'. It is essential that we all learn from the past. We hope the contents of this book will go some way towards ensuring that the essential lessons from HACCP implementation and assessment are available to a wider audience.

15.7 References

CODEX ALIMENTARIUS COMMISSION (1997) *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application.* Report of the 29th Session of the Codex Committee on Food Hygiene, Alinorm 97/13A, Appendix 11, CAC, Rome.

HATHAWAY, S. (1999) 'The principle of equivalence'. *Food Control*, **10**, 261–65.

ILSI (1998) *Food Safety Management Tools.* Report prepared under the responsibility of ILSI Europe Risk Analysis in Microbiology Task Force.

ILSI (1999) *Validation and Verification of HACCP.* International Life Sciences Institute, Europe, Monograph Series, Brussels: ILSI Europe.

ORRISS, G. D. (1999) 'Equivalence of food quality assurance system'. *Food Control*, **10**, 255–60.

ORRISS, G. D. and WHITEHEAD, A. J. (2000) 'Hazard analysis and critical control point (HACCP) as part of an overall quality assurance system in international food trade'. *Food Control*, **11**, 345–51.

WHO (1999) *Strategies for Implementing HACCP in Small and/or Less Developed Businesses.* World Health Organisation, WHO/SDE/FOS/ 99.7, Geneva.

WHO/FAO (1998) *Guidance on Regulatory Assessment of HACCP.* Report of a joint FAO/WHO consultation on the role of government agencies in assessing HACCP. WHO/FSF/FOS/98.5, Geneva.

Index