

A Guide to

HACCP* Systems

In The Meat Industry

(* Hazard Analysis Critical Control Point)

Volume I

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Preface

Application of HACCP systems in the meat industry is a relatively recent development. This document has been produced by the Ministry of Agriculture Regulatory Authority (Meat and Seafood) [MAF RA (M&S)] Research and Development group in association with the HACCP Steering Group to:

- (i) explain the concepts and principles of HACCP
- (ii) provide guidance on:
 - HACCP development and implementation;
 - auditing HACCP plans;
 - HACCP training;
 - specific application to fresh meat by means of a template for slaughter and dressing and a specific model for slaughter and inverted dressing of lambs and sheep;
 - other HACCP-based applications.

HACCP will continuously evolve and the contents of this document will be updated as new information from both national and international sources becomes available.

Review of HACCP Guide

This industry standard shall be regularly reviewed according to a schedule held by MAF RA (M&S).

The coordinator welcomes suggestions for alterations, deletions or additions to this standard, to improve it or make it more suited to industry needs. Suggestions should be sent to the coordinator on the form on Page P.4, together with reasons for the change and any relevant data.

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Suggestions for Change

Name	
Organisation	
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Email	
Phone	Facsimile
<i>A Guide to HACCP Systems in the Meat Industry</i>	
Section	Suggested Improvements
Signature	
Date	
Please post to:	Assistant Director (Programme Development) NZFSA P.O. Box 2835 Wellington
	Acknowledgment of receipt: Signature: Date:

Amendment Record

Amendments do not become part of this Guide until they have been authorised by the Director (Animal Products) and issued with an amendment form. Amendments to this Guide will be given a consecutive number and dated.

Amendments to the Guide can be identified by the amendment number in the page header and the changes which have been made will be identified by yellow highlighting.

Please ensure that all amendments are inserted, obsolete pages are removed and the record below is completed.

Amendment No:	Date	Entered by:
0	May 1997	MAF RA
1	February 1998	
2	April 1998	
3	August 1998	
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1. Introduction

1.1 Background

1.1.1 HACCP is a widely used science-based control system for assuring food safety.

Food safety is achieved by systematically assessing hazards, developing control systems and focusing on preventative measures. It can be applied throughout the food chain from producer to consumer.

The principles of HACCP can also be utilised in other areas such as product quality.

Whilst in general terms, the whole food production system should be evaluated for possible HACCP application, the suitability of application will vary in different areas.

1.1.2 HACCP was developed by the Pillsbury Company in the United States of America in consultation with the US Army and the US National Aeronautics and Space Administration to ensure food safety for astronauts.

The system was used to manufacture food products with a high degree of assurance that they were safe. This resulted in significantly reduced end product testing.

1.1.3 Over the last ten years, several detailed methods for HACCP application have been documented, primarily for processed and canned foods.

Some of these documents involve extensive analysis and result in a complex application to a particular process. In comparison, development of HACCP plans for raw food may result in a less complex application.

1.1.4 The Codex Alimentarius Commission's Committee on Food Hygiene has developed a guideline document that covers the principles and application of HACCP to all sectors of the food chain from producer to consumer. New Zealand participated in the development of this document and its subsequent revision.

The current document, "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application" which is annexed to the Codex "General Principles of Food Hygiene" is recommended as background reading.

1.1.5 HACCP focuses inspection activities on the critical areas of food safety and improves the scientific basis for the inspection systems operating in the meat industry.

HACCP implementation requires a long term commitment by both industry management and regulators.

Industry also needs to be fully aware of the likely expense of putting a HACCP plan in place, including the ongoing maintenance and reevaluation of such a plan.

- 1.1.6 HACCP will inevitably extend to farm production (preharvest) and will be serviced with feedback information from the fresh meat production and processing industries.

The long term expectation is that HACCP will be applied in an integrated programme throughout the food chain from the farm to the consumer.

- 1.1.7 HACCP is compatible with quality systems such as ISO 9000 series (which address the whole of the management system) and can be used to enlarge upon the process control section of such systems taken up by industry.

HACCP also has considerable overlap with quality system components such as management review, internal audit, product nonconformance, appropriate corrective action and verification.

1.2 International Perspective

- 1.2.1 HACCP is widely accepted as the foremost means of assuring food safety.

While recognition of the system is increasing through active promotion by international bodies such as the Codex Alimentarius Commission, there is still considerable debate on its application, especially to raw food commodities.

Notwithstanding this, there are major moves internationally to adopt HACCP for raw foods.

- 1.2.2 HACCP is well recognised by all of New Zealand's major trading partners.

Some of these countries (such as Canada) are taking a voluntary approach with HACCP implementation.

Others (such as the European Union, the United States of America and Australia) are mandating HACCP into their legislation. This may impact on market access of New Zealand products affected by that legislation.

- 1.2.3 Canada has been proactive in promoting HACCP for all food commodities. Resources available include:

- 38 generic HACCP models;
- volumes I to IV to aid in development and implementation of HACCP;
- financial assistance to help small businesses in the uptake of HACCP;

- training packages.

with the expectation that HACCP will be substantially in place by the end of 1997.

- 1.2.4 The European Union have already mandated HACCP principles into some of their recent legislation. Directives such as the Hygiene of Foodstuffs Directive and Veterinary Directives for meat products, fishery products and milk products refer to these principles.

The impact on countries such as New Zealand exporting to the European Union remains to be seen.

- 1.2.5 Australia expects both export and domestic sectors of the meat industry to have Meat Safety Quality Assurance (MSQA) systems in place by July 1997.

The MSQA programme includes both development of quality systems (following the ISO 9002 standard) and HACCP systems.

For the domestic industry, this is part of the implementation of the national standards of the Agriculture and Resource Management Council of Australia and New Zealand (ARMCANZ).

- 1.2.6 The USDA has recently published its final rule on HACCP for the meat and poultry industry. The key components are:

- the HACCP regulations;
- the Sanitation Standard Operating Procedures regulations;
- the *Escherichia coli* process control testing regulations;
- the *Salmonella* pathogen reduction performance standards regulations.

These regulations already have significant impact on New Zealand food safety control systems for products exported to the United States.

We will be expected to meet the requirements of these regulations or show that we have equivalent systems producing similar outcomes.

- 1.2.7 In the near future, overseas reviewers are most certain to want to review HACCP plans (or an equivalent system) for food safety.

With some overseas legislation already insisting on these HACCP plans, New Zealand companies must be aware of, and keep abreast with, developments in this area to ensure continued market access.

1.3 New Zealand Perspective

1.3.1 Industry

Industry has the primary responsibility of developing and implementing premises-specific HACCP plans to assure food safety. Other potential benefits will also be gained, such as:

- producing a safer product;
- gaining a better understanding and control of operations;
- improving production efficiency and decreasing wastage;
- providing a firm base for application of quality management systems;
- improving product quality;
- influencing raw material suppliers (e.g., farmers) to adopt a similar approach;
- becoming a more competitive supplier;
- participating in changes to current regulatory requirements.

It is recognised that development of tailor-made HACCP plans is time consuming and requires special expertise.

Companies may be restricted in their ability to adopt HACCP because of a lack of these resources, and are recommended to seek external expertise, especially in the developmental stages.

This guideline aims to provide a solid basis from which any company wishing to take up HACCP can begin.

Industry must also ensure that development of the technical skills relating to HACCP is provided for on an on-going basis. They must be aware of future developments with regard to HACCP, both on a domestic and international level and understand how these developments will impact on their business.

1.3.2 MAF RA (M&S)

MAF RA (M&S) currently promotes HACCP uptake by the meat industry on a voluntary basis.

A voluntary approach allows industry to progress HACCP development and implementation at its own speed, without undue influence from the regulator.

MAF RA (M&S) is also involved in other facets of HACCP development and implementation, namely:

- development of technical skills which are updated as more information is gathered about the application and implementation of HACCP;
- providing technical support and review of industry-designed HACCP systems for food safety;
- applied research to determine the most practical and efficient application of HACCP, especially to fresh meat production;
- audit of HACCP plans and systems where required;
- development of validated generic plans;
- monitoring international market access requirements.

MAF RA (M&S) envisage that as validated HACCP plans are increasingly applied by industry, there will be provision to reduce the number and level of prescriptive requirements that currently constitute mandatory Good Manufacturing Practice (GMP).

1.3.3 HACCP Steering Group

The HACCP Steering Group comprising representatives from a number of food producing industries as well as MAF RA (M&S), MAF Quality Management (MQM) and the Ministry of Health, has been formed with the following goals:

- to involve industry and regulators in ensuring a common approach to all aspects of HACCP;
- to provide appropriate and current information on HACCP to all interested parties;
- to promote the philosophy that industry owns and is responsible for the HACCP systems and associated outcomes;
- to update HACCP manuals in association with specific industry groups;
- to assist industry to develop their own HACCP plans;
- to clarify issues relating to HACCP and market access.

1.4 Requirements Prior to HACCP

1.4.1 The expectation is that prior to putting a HACCP plan in place, the premises is:

- operating to GMP requirements;
- operating according to appropriate New Zealand legislation;
- meeting applicable market access requirements.

1.4.2 Market access requirements inevitably results in application of some requirements which, in the opinion of the Meat Industry Hygiene Council (comprising MAF and industry representatives), are not scientifically justified as food safety issues. Many of these issues would be included in the premises prerequisite programmes as described below.

In some cases, market access food safety requirements may directly influence the process and therefore the HACCP plan. These requirements could be highlighted either in the plan or identified separately as market access requirements.

Wherever they are placed, it is essential to ensure that they reflect **current** requirements.

1.4.3 Some food safety hazards are related to activities which may interact within and across various processes and have the potential to influence the food safety outcome of the product.

It is recommended that at the start of HACCP planning, the HACCP team should ensure that all these activities are covered by separate documented systems (Prerequisite programmes).

Effective prerequisite programmes mean that control of those hazards covered within those programmes do not need to be accounted for at each step in a [specific process] HACCP plan.

Many prerequisite programmes will already be effectively controlled through meeting current GMP requirements and standard operating practices (SOPs). This can be verified by results of internal and external reviews or audits (e.g. internal audits, MQM reviews, MAF RA Compliance Group reviews, overseas reviews).

Examples of prerequisite programmes include:

- potable water quality;
- hygiene of facilities and equipment (preoperational and operational);

- operator (and visitors to food areas) hygiene including protective clothing requirements, personal equipment and use of amenities;
- training;
- dropped meat programme;
- food contact materials;
- repairs and maintenance;
- chemicals;
- vermin control;
- waste disposal.

Note that this does not preclude some elements within a prerequisite programme from having a critical influence at a specific step within the HACCP plan. When this occurs, that element would be included in the HACCP plan, e.g. the hygienic requirements for forequarter work up and pelting in a lamb slaughter and dressing HACCP plan or chlorinated water for retort cooling.

Prerequisite programmes may themselves be subjected to HACCP analysis. An example is given in Appendix 10.

- 1.4.4 Consideration should be given as to how the HACCP principles and the final HACCP plan will integrate into any pre-existing management systems, e.g. ISO 9002.

It is important that documented systems are useable and contribute to their intended purpose, e.g. minimising food safety risk, complete process management etc.

If the HACCP plan is integrated into any management system it is important for both internal and external audit purposes that the food safety elements are easily identifiable within the documentation.

- 1.4.5 HACCP is a systematic and science-based control system for assuring food safety.

It ensures that process control moves away from dependence on a traditional approach of endpoint testing of the product.

ISO standards are examples of several QA systems available for industry to use. They are designed with two objectives in mind:

- to provide a customer with the assurance that a quality product or service will be supplied;

- to give the supplier the minimum guidelines to allow the development of an appropriate quality management system which can demonstrate product or service quality assurance to the customer.

HACCP and ISO are complementary to each other and, in practice, companies with ISO systems already present will find HACCP interfacing easily with existing ISO components.

See Appendix VII for a comparison of ISO and HACCP.

2. Definitions

Control (verb): To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

Control (noun): The state wherein correct procedures are being followed and criteria are being met.

Control measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Corrective action: Any action to be taken when the results of monitoring at the Critical Control Point indicate a loss of control.

Critical Control Point (CCP): A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical limit (CL): A criterion which separates acceptability from unacceptability.

Food Safety Objective (FSO): A description of the expectations of hygiene measures that are applied during a particular segment of a food production process. These objectives should include measurable outcomes expected for the final product and may have a qualitative or quantitative association with the level of risk to the consumer.

Good Manufacturing Practice (GMP): Assurance that product is consistently produced and controlled to quality standards appropriate to their intended use and as required by the regulatory authority and industry.

GMP in this context includes Good Hygienic Practice (GHP), Standard Operating Procedures (SOPs), Sanitation Standard Operating Procedures (SSOPs) and umbrella programmes.

HACCP: A system which identifies, evaluates and controls hazards that are significant for food safety.

HACCP audit: A systematic and independent examination of an applied HACCP plan to determine whether activities and related results comply with planned arrangements, and whether these arrangements are implemented effectively and are achieving set objectives on an ongoing basis.

HACCP coordinator: An appropriately trained person responsible for coordinating the application and implementation of HACCP at a premises.

HACCP plan: A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.

HACCP plan summary spreadsheet: A summary of the application of the seven HACCP principles to the selected product and process.

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard analysis: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

Input: Incoming materials such as consumable or non-consumable items added to the product during the process. Consumable items include raw materials/ingredients/food additives. Non-consumable items include wrapping and packaging.

Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Prerequisite programme: A documented programme covering GMP-based food hygiene activities that may interact at a number of process steps within and across various processes in a food premises, and that have the potential to influence the hygiene status of the product.

Revalidation: Reconfirmation that the HACCP plan is complete and will deliver the expected food safety outcomes after changes (modifications) have taken place to the product specifications or the process.

Risk: A function of the likelihood and severity of an adverse health effect on the consumer as a result of exposure to a hazard.

Step: A point, procedure, operation or stage in the food chain, including raw materials, from primary production to final consumption.

Validation of HACCP plan: Initial confirmation that the HACCP plan is complete and will deliver the expected food safety outcomes.

Verification:

- (a) For the processor: The application of methods, procedures (review/audit) and tests in addition to those used in monitoring to determine:
- the effectiveness of the HACCP plan in delivering expected outcomes (food safety objectives), i.e. validation;

- compliance with the HACCP plan;
 - whether the HACCP plan or its method of application need modification.
- (b) For the Verification Agency: Audit of the validated/revalidated HACCP plan in order to:
- recognise the validity of the plan;
 - determine the level of compliance with the valid HACCP plan.

3. Principles of HACCP

For the purposes of this document, the following seven principles that are the basis of the HACCP system have been sourced from the Codex Alimentarius Commission Report of the 29th Session of the Codex Committee on Food Hygiene (1996) (Alinorm 97/13A) "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application".

- | | |
|--------------------|--|
| Principle 1 | Conduct a hazard analysis. |
| Principle 2 | Determine the Critical Control Points (CCPs). |
| Principle 3 | Establish critical limits. |
| 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. |

4. Developing the HACCP Plan

4.1 Introduction

- 4.1.1 The aim of this section is to provide guidance on designing a comprehensive plan that focuses on control of significant hazards at identified Critical Control Points (CCPs) in the process in order to prevent or minimise food safety risk to the consumer.

The HACCP plan requires an in-depth evaluation of the product and the process to determine where specific control is required.

- 4.1.2 This section explains the necessary steps that should be followed in order to design a product-specific HACCP plan.

Templates and generic HACCP plans can assist with this activity and these are provided in Volume II: *Templates and Generic Models*.

Note that the template begins with suggested prerequisite programmes and then moves to Step 3: “Scope of the HACCP plan”. The template presumes that the issues relating to management commitment and the assembly of the HACCP team have been addressed.

Step 1 (*see Section 4.2*): Obtaining company commitment and management involvement

Step 2 (*see Section 4.3*): Assembling the HACCP team

Step 3 (*see Section 4.4*): Establishing the scope of the HACCP plan

Step 4 (*see Section 4.5*): Describing the product and its intended use

Step 5 (*see Section 4.6*): Setting food safety objectives

Step 6 (*see Section 4.7*): Constructing and confirming the process flow diagram

Step 7 (*see Section 4.8*): Writing and confirming job descriptions¹

Step 8 (*see Section 4.9*): Identifying food safety hazards

Step 9 (*see Section 4.10*): Determining Critical Control Points

Step 10 (*see Section 4.11*): Establishing critical limits

¹ There is flexibility as to when the job descriptions are confirmed. This may be left until after the hazard analysis and critical control point determination is complete.

Step 11 (*see Section 4.12*): Establishing a monitoring system

Step 12 (*see Section 4.13*): Establishing corrective action requirements

Step 13 (*see Section 4.14*): Establishing verification procedures

Step 14 (*see Section 4.15*): Establishing documentation and recordkeeping procedures

4.2 Obtaining Company Commitment and Management Involvement (Step 1)

4.2.1 The success of the HACCP system depends totally on the commitment and involvement of the company. Senior management must be proactive in ensuring that this occurs.

The programme will not succeed if company management does not support it and provide the necessary resources, e.g. people, time and money.

4.2.2 The primary responsibility for food safety rests with the company and the people who manage it.

The company must have appropriate operating systems to deliver expected food safety outcomes.

Everybody involved must understand the HACCP process, the rationale behind the programme and the role that they play.

The impact of process failure causing a food safety crisis must always be considered, including the implications to the business. HACCP will minimise the likelihood of this happening.

4.3 Assembling the HACCP Team (Step 2)

4.3.1 The method of introducing and working through the principles of HACCP will vary. The most popular method is through the assembly of a HACCP team whose role is to facilitate the process at the premises. The team should collectively have skills in the areas of:

- the food production process;
- principles and practice of food safety;
- current management systems operating on the premises;

- communications and teamwork;
- change management;
- HACCP principles;
- other skills appropriate for the premises.

4.3.2 The size of the team (or teams) will vary depending on the distribution of skills but may typically range from three to six persons.

The team is responsible for guiding system design in consultation with the rest of the people who work on the premises.

The team may find it necessary to second other personnel to provide skills specific to a particular part of the process.

4.3.3 Initially, the HACCP team should prepare a development programme which identifies activities, priorities, responsibilities and completion dates. This assists in ensuring a systematic approach.

The programme may also be a useful tool in communicating progress to personnel at other premises. This helps to ensure that the programme is jointly owned and operated by the process workers as well as quality assurance and supervisory personnel.

4.4 Establishing the Scope of the HACCP Plan (Step 3)

4.4.1 Ideally, the objective of a HACCP programme is to produce food safety plans that cover all aspects of production within the premises.

It may be feasible for a small premises producing a single product to develop all of this in one step.

For most premises the better method will be to divide the total task into smaller modules that can be progressively developed.

4.4.2 A practical starting point is to identify all the prerequisite programmes.

The HACCP team must also decide if the programmes are adequately covered by existing documented procedures and, if not, ensure deficiencies are addressed.

Once this has been done, the extent of application of an individual HACCP plan can be defined. This should include:

- the product and process;
- specific activities not covered in the prerequisite programmes.

4.4.3 As each HACCP plan is developed, it will be necessary to check that there are no gaps between the controls exercised in the prerequisite programmes and those in the individual HACCP plans.

4.4.4 Where the premises is faced with producing a number of HACCP plans, priority should be given to the area or areas which can have the greatest impact on food safety (e.g. livestock presentation and slaughter and dressing at a meat export slaughterhouse). This should not prevent an initial pilot plan being developed elsewhere, in order to gain experience in the HACCP technique.

4.5 Describing the Product and its Intended Use (Step 4)

4.5.1 Individual products should initially be considered in their own right. Where possible, it is strongly recommended that products be grouped in terms of similar process and intended use. The product description then encompasses a group of products with similar specifications.

4.5.2 A full description of the product is required. This description should include:

- product name;
- important product characteristics (including particular food safety requirements for final product);
- preservation method;
- intended use (e.g. further processing/by consumer);
- correct storage conditions;
- shelf life (including spoilage potential);
- labelling instructions and wrapping/packaging;
- where it is to be sold (local trade/export);
- distribution system.

4.5.3 This information will be used to create a "risk profile" for the product and will help to identify the potential food safety hazards (e.g. if meat is eaten uncooked, then the potential food safety risk to the consumer is much greater than when meat is eaten after thorough cooking).

4.5.4 It is important to consider the expected use of the product, e.g. whether it will undergo further processing and/or how the consumer will use it.

Unusual use, or abuse, may create a greater food safety risk to the consumer than is generally the case.

Consideration may have to be given to the specific food safety needs of particular "high risk" subgroups of the consumer population, e.g. infants and immuno-compromised individuals.

4.5.5 The description of the intended use should identify, where appropriate:

- normal usage conditions, e.g. appropriate storage temperatures, or any consumer limitations with regard to eating the product and how it is likely to be eaten;
- potential for abuse of the product, e.g. the likelihood of incorrect storage or handling of the product, resulting in unacceptable growth of microorganisms.

4.6 Setting Food Safety Objectives (Step 5)

4.6.1 Food safety objectives describe the expectations of hygiene measures that are applied during a particular segment of a food production process. These objectives should include measurable outcomes expected for the final product and may relate specifically to a HACCP plan, to activities outside the scope of a HACCP plan (i.e. prerequisite programmes), or to both.

Where possible and appropriate, food safety objectives should include and describe the level of control of hazards that provides an acceptable level of consumer protection. At present this is rarely achieved, but as risk assessment techniques develop, more information will become available to better determine the associations between the level of hazards in the final product and risks to human health in the consumer population.

For raw products, the food safety objectives will at least reflect the level of control of hazards achievable by Good Manufacturing Practices (GMP) and may only be qualitatively associated with the level of consumer protection. Such objectives may reflect control of specific hazards or control of parameters accepted as **indicators** of hazards (e.g. *E. coli* level as an indicator of enteric pathogen control; "chemical suspect lines" as indicators of specific chemical hazards).

Food safety objectives should be confirmed after hazard identification has been completed, and the responsibilities and likely controls established (see Section 4.9).

4.6.2 It is assumed that food safety objectives will be achieved on an ongoing basis. However, a specific time period may be stipulated for some objectives, e.g. when it is

desired that a process step improvement be achieved within a specific period. For such cases, a review of the objective is required after the stipulated period.

4.6.3 There are considerable benefits associated with setting food safety objectives. These include:

- providing a "target" for control of hazards;
- accurate identification of current food safety information for a particular product;
- achieving food safety "due diligence" expected for meat and meat products;
- providing means for assessing equivalence of different food safety control programmes, e.g. market access.

4.7 Constructing and Confirming the Process Flow Diagram (Step 6)

4.7.1 If a process flow diagram does not already exist, the HACCP team must construct one based on their knowledge of the process.

This diagram provides the foundation for the hazard analysis and must be detailed and complete, listing consecutive steps for the process.

Inputs that must be included are all raw materials, additives, ingredients and food contact materials that will form part of the end product.

Note that prerequisite programmes may already address the control of hazards associated with these inputs and this should be referenced in the HACCP plan.

Edible outputs are also shown on the diagram.

4.7.2 It is important that the process flow diagram fully describes what is actually occurring.

It is, therefore, necessary to physically confirm the process flow diagram by the following means:

- discuss the process flow diagram with each operator in the process to ensure it accurately describes the process steps and all inputs and outputs;
- observe the work that is carried out at each process step and confirm that the process flow diagram is correct.

4.8 Writing and Confirming Job Descriptions (Step 7)

4.8.1 Where a job description does not exist, it should be written for each process step.

The job description should contain a detailed account of the tasks that the operator is required to do at the process step, including the food safety responsibilities.

Confirm the job description by:

- observation;
- discussion (including with the Verification Agency (VA) to ensure that all regulatory requirements have been met);
- taking into account the results of the hazard analysis and CCP determination.

4.9 Identifying Food Safety Hazards (Step 8)

- 4.9.1 Background reading relating to the type of product, its raw materials and other inputs should be carried out before starting hazard identification.

Layout diagrams showing product and personnel flow patterns are also useful.

Remember that environmental hazards should be dealt with effectively, under established prerequisite programmes (see Section 1.4).

- 4.9.2 Food safety hazards **which can reasonably be expected to be found within or transferred to the product** should then be identified for raw material and other inputs at each process step.

The types of hazards that must be considered are:

- **Biological**

These include microorganisms, parasites and biotoxins that have the potential to cause foodborne adverse health effects, e.g. *Salmonella* spp., *E. coli* O157:H7, *Listeria monocytogenes*, *Yersinia enterocolitica*, *Taenia saginata* (*Cysticercus bovis*), *Staphylococcus aureus* toxin.

- **Chemical**

These are chemical residues and contaminants that have the potential to cause foodborne adverse health effects, e.g. residues of pesticides, antibiotics and environmental contaminants such as cadmium and mercury. Food additives may also be hazardous if included at greater than acceptable levels.

- **Physical**

These are materials that could cause adverse health effects when eaten, e.g. bone slivers, glass, metal filings and shotgun pellets.

- 4.9.3 Hazards may need to be specifically defined when a food safety problem is attributed to a particular hazard (e.g. *Taenia saginata*, *Clostridium botulinum*, *Listeria monocytogenes*), or it may be acceptable to group hazards as a class (e.g. microbiological hazards associated with faeces and ingesta).

For fresh meat production lines, transfer of microbiological hazards from one raw material component to another and redistribution of those transferred hazards on the product need ongoing consideration at each step.

- 4.9.4 Responsibilities for controlling food safety hazards must be considered.

Some hazards will remain unaddressed at the end of the process and should be highlighted for consideration elsewhere in the food chain, e.g. at the farm, by further processing or by preparation prior to consumption.

Identification of the processor's responsibilities in relation to control of the identified hazards clearly identifies those hazards which the processor must control within the selected process.

- 4.9.5 The Food Safety Objectives set at Step 5 (refer to Section 4.6) should now be confirmed as appropriate for the product. These objectives should cover all those identified hazards to be controlled by the processor.

- 4.9.6 Documentation and recordkeeping requirements associated with hazard identification are covered in Section 4.15.

4.10 Determining Critical Control Points (Step 9)

- 4.10.1 Critical Control Points (CCPs) are points, steps or procedures at which control can be applied to prevent, eliminate or reduce a food safety hazard to acceptable levels.

Critical Control Points can be determined using a decision tree as a guide (see Figure 1 of Appendix VIII).

Other methods for determining CCPs are also available.

- 4.10.2 Taking into consideration those identified food safety hazards which the processor is responsible for controlling, CCPs are determined by establishing at each process step, the following information:

- whether the hazard could be present in or on the product at unacceptable levels;
- whether a control measure is available.

Consideration also must be given as to whether control of the identified unacceptable level of hazard can occur at a previous process step.

Control at a subsequent step or redesign of the product/process may be necessary, accepting that the processor must control the identified hazard within the process.

4.10.3 Unacceptable levels are determined by considering:

- data (scientific literature, applied research or on-site experience) relating to the achievement of food safety objectives established for the process;
- frequency of occurrence;
- level of occurrence;
- transfer and redistribution;
- the severity of adverse health effects on the consumer (where known).

4.10.4 Some food safety hazards may have more than one CCP, e.g. transfer of enteric pathogens from the gastrointestinal tract (GIT) to the carcass.

Similarly, a CCP may control more than one hazard, e.g. receipt of raw materials.

4.10.5 Documentation and recordkeeping requirements associated with CCPs are covered in Section 4.15.

4.11 Establishing Critical Limits (Step 10)

4.11.1 Critical limits (CLs) are criteria that separate acceptable from unacceptable observations or measurements. They must be specified for all CCPs, as they define the parameters to be met to control the identified hazards and meet established food safety objectives.

Critical limits must be clearly defined and measurable.

Criteria often used include ranking systems for the type and level of grossly-detectable contamination, temperature, time, moisture level, pH, water activity, available chlorine and visual appearance.

4.11.2 Establishing CLs for food safety hazards associated with fresh meat production may be a difficult task in some processes.

For example, while research is now available to validate the microbiological basis for CLs in HACCP systems for ovine slaughter and dressing processes in New Zealand, further work is required for other livestock species.

4.11.3 Documentation and recordkeeping requirements associated with CLs are covered in Section 4.15.

4.12 Establishing a Monitoring System (Step 11)

4.12.1 Monitoring is the planned sequence of observations or measurements to assess whether a CCP is under control relative to its CLs.

Important components of monitoring that must be addressed for each CCP are:

- what type of monitoring is to be done (e.g. continuous, random sampling);
- how the monitoring is to be done (e.g. visual observations, temperature/time measurement);
- the frequency of monitoring (i.e. must ensure the CCP is under control);
- who will have the responsibility for monitoring.

4.12.2 The appropriate frequency of monitoring will depend on the particular process and CCP. In some situations, continuous on-line monitoring is practical and achievable (e.g. continuous temperature data loggers) whereas in other situations (e.g. slaughter line CCPs), the use of statistically valid sampling plans provide a satisfactory alternative monitoring programme.

4.12.3 The person allocated the monitoring task must be fully trained and have appropriate responsibility for the position, preferably including associated activities such as taking corrective actions.

4.12.4 Documentation and recordkeeping requirements associated with monitoring can be found in Section 4.15.

4.13 Establishing Corrective Action Requirements (Step 12)

4.13.1 Specific corrective actions must be developed for each CCP when the CLs are exceeded.

The objectives of taking corrective actions are to:

- rapidly regain control of the hazard(s) at the CCP;
- alter disposition of affected product, where necessary;
- prevent recurrence of the problem where possible. This is heavily influenced by the degree of automation/labour intensity available in the process.

An escalating response should be provided for where ongoing noncompliance with the critical limit(s) occurs.

4.13.2 Corrective actions should also be designed so that they are implemented when the monitoring results indicate a trend towards loss of control at the CCP.

This will bring the process back into control before the deviation leads to a potential threat to public health.

4.13.3 Documentation and recordkeeping requirements associated with corrective actions are covered in Section 4.15.

4.14 Establishing Verification Procedures (Step 13)

4.14.1 **Verification** is the long-term independent evaluation of all components of the HACCP plan, as opposed to **monitoring**, which involves on-line observations and measurements that give quick feedback on the CCPs (thus enabling adjustments to maintain or restore control).

4.14.2 Verification activities confirm whether the HACCP plan is operating effectively and according to documented procedures (i.e. in compliance with the HACCP plan).

For the processor, verification procedures should include the following:

- validation of the HACCP plan (see Section 4.14.3);
- ongoing independent review/audit of all components of the HACCP system, its documentation and records, including corrective actions taken (see Section 4.14.4);
- product tests where appropriate;
- revalidation of the HACCP plan when significant changes/modifications take place to the product/process (including addressing new food safety concerns) or when a significant design fault becomes evident.

For the Verification Agency, verification procedures would include:

- an audit to recognise the validity of a HACCP plan, or
- a compliance audit of a valid HACCP plan.

4.14.3 Validation means confirming that the plan is complete and will deliver the expected food safety outcomes.

Standard techniques should be used that allow in-house comparisons and also comparison with national figures, e.g. the national microbiological database and national “targets” for fresh meat carcasses.

Validation will be used to demonstrate that the HACCP plan is at least equivalent to GMP-based controls. This would be performed over time, allowing for prior implementation of a standardised approach.

In the case of microbiological contamination of fresh meat carcasses, a company should aim for equivalence with national performance, continuous improvement according to MIHC national goals, and lower microbiological counts for specialist end uses such as chilled product.

Generic HACCP plans presented in the Appendices of this Guide provide examples of validation of HACCP plans.

- 4.14.4 Reviews/audits of the HACCP plan must be internal (independent company personnel but may also be extrinsic (third party, customer, regulatory)).

The review may cover the entire HACCP plan or selected parts. However, a full review is recommended periodically to ensure that the HACCP plan continues to meet expected outcomes.

Where possible, reviews should be carried out under a formal audit procedure with appropriate follow up for nonconformances to the HACCP plan.

- 4.14.5 Verification procedures must be documented to ensure that the HACCP plan is complete and functioning to specifications.

All findings must be recorded. For further details, see Section 4.15.

4.15 Establishing Documentation and Recordkeeping Procedures (Step 14)

- 4.15.1 Documentation of all components of the HACCP plan is required.

This includes the details of hazard analysis, CCP determination, CL setting, monitoring, corrective action and verification procedures.

Responsibilities and authorities associated with the HACCP plan are also required to be documented.

- 4.15.2 The HACCP plan summary spreadsheet is the recommended way of presenting an overview of the HACCP plan for a particular product/process (see Appendices VIII and IX for an example).

Summary details should be given on this spreadsheet, referencing the source of additional relevant information where applicable.

This spreadsheet provides an obvious starting point for a HACCP plan audit.

Components should include:

- each process step of the flow diagram;
- hazard identification for identified CCPs;
- the CCP number;
- CL criteria;
- monitoring procedures;
- corrective action procedures;
- verification procedures;
- recordkeeping requirements.

4.15.3 Records must be kept to provide evidence that the HACCP plan is working according to documented procedures.

These records include:

- CCP monitoring results;
- corrective actions taken, and outcomes;
- verification results.

5. Implementing the HACCP plan

5.1 Introduction

5.1.1 The aim of HACCP implementation is to ensure the ongoing effective control of food safety hazards associated with the product and the process.

Company approval and ongoing commitment are required to ensure staff are given adequate empowerment to guarantee the plan's success.

5.2 General Requirements

5.2.1 The first stage of implementation is to ensure the following points are addressed:

- **Training (see Section 6)**

A staff training programme on HACCP should be established in accordance with the ongoing expectations of the company. This must include:

- HACCP awareness training for relevant process operators;
- specific HACCP training for key operators.

- **Resources (e.g. worksheets, equipment)**

Results of Critical Control Point (CCP) monitoring must be recorded. These records may include checklists, automatic temperature records and/or other documents (e.g. suppliers declarations accompanying incoming raw materials) as appropriate.

If instrumentation is used to monitor CCPs (e.g. thermometers, data loggers) then calibration of this equipment needs to be undertaken with sufficient regularity to give confidence in results.

Calibration records must be kept as part of the verification process.

- **Responsibilities for all components of the HACCP plan**

Responsibilities associated with implementation of the HACCP plan need to be delegated to persons covering all shifts and days of the operation.

An up-to-date log should be kept of all CCPs indicating those people responsible for monitoring and taking corrective actions.

All persons responsible for implementing the HACCP plan need to clearly understand the criteria for control, including monitoring procedures, resources needed and corrective actions to be taken.

There are a number of ways that a HACCP plan can now be implemented. Depending on the size and complexity of the operation and resources available, the company must decide the best way to introduce the plan to the workplace.

After a set period of time while the HACCP plan is operational, achievement of the food safety objectives must be confirmed so as to validate the plan. Adjustments may be necessary.

On completion of validation, company management should sign off the HACCP plan as meeting the defined food safety objectives.

- 5.2.2 Records should be kept for at least 2 years, or not less than the expected life of the product(s) covered by the plan, if this is greater. This enables informed decisions to be made when reviewing the HACCP plan and considering changes.
- 5.2.3 A successful HACCP plan will need to be continually supported by effective prerequisite programmes.
- 5.2.4 Access to the company's HACCP plan for food safety, including all supporting documentation and records, may be required by the following:
- government agencies;
 - clients;
 - external auditors.

5.3 Ongoing Management of the HACCP Programme

- 5.3.1 The established HACCP plan(s) for a premises must remain dynamic and be subject to continuous improvement where appropriate. This is part of the overall verification process. The whole plan must be reviewed to reassess its effectiveness when new food safety objectives are established, new food safety knowledge becomes available or there is a change in the raw materials/other inputs/process itself.
- 5.3.2 The company may wish to re-evaluate its expected outcomes from the HACCP plan as monitoring results are collated over a period of time.

If a CCP is continually performing well within the critical limits stipulated in the plan, it may be appropriate to decrease the resource needed for the monitoring of that particular CCP and re-allocate that resource to another more pertinent area.

5.3.3 HACCP may be used in conjunction with quality systems being developed or already in place on a premises. In any integrated quality system, the HACCP food safety components must be independently defined and readily accessible for verification purposes. Additionally, the implementation and effectiveness of the food safety components of the HACCP plan must never be compromised by monitoring or corrective action for non-food safety quality system requirements.

See Appendix VII, The Interaction of HACCP and ISO Systems.

6. Training

6.1 Introduction

6.1.1 Training guidelines have been developed by the HACCP Steering Group in response to an urgent need by both industry and regulators for a meaningful HACCP training package.

The guidelines are designed to show persons providing or receiving HACCP training, the expected outcomes for participants/trainees.

The guidelines are not designed to assess these outcomes.

6.1.2 Using these guidelines as a base, HACCP standards have been developed in conjunction with the Meat Processing Industry Training Organisation and registered with the New Zealand Qualifications Authority.

These standards have associated assessment criteria which assist in determining whether a person has met the standard.

Assessing the outcomes of prior learning against the standard is also possible.

6.2 HACCP Training Guidelines

See Appendix 1 Guideline for HACCP Briefing: Executive Manager

See Appendix 2 Guideline for HACCP Training: HACCP Coordinator

See Appendix 3 Guideline for Introduction to HACCP: Supervisors

See Appendix 4 Guideline for Introduction to HACCP: Operators

6.3 HACCP Unit Standards

See Appendix V Unit Standard 12626

Unit Standard 12626 and the Meat Processing Industry Training Organisation Assessment Checklist can be found in Appendix V. The Checklist is a guide to the forms of evidence to be considered by an assessor when assessing a person as competent against Unit Standard 12626.

7. Auditing HACCP plans

7.1 Introduction

Once the HACCP plan has been implemented, the licensee and other interested parties will want to periodically assess actual performance against the documented system and desired food safety objectives.

This forms part of the verification procedures and is likely to consist of both internal and extrinsic assessment of the HACCP plan.

The HACCP Steering group has produced an audit protocol designed to provide guidance for both internal and extrinsic auditors in assessing whether a HACCP plan is working effectively.

7.2 HACCP Audit Protocol

See Appendix VI Auditing HACCP Plans.

8. Templates and Models

8.1 Introduction

The following template and generic models have been produced by the MAF RA (M&S) Research and Development team to assist the meat industry in the preparation of their HACCP plans.

The template gives the framework for a HACCP plan for slaughter and dressing with appropriate prompts and blank forms for the user to provide information relating to their selected product and process. The forms used are presented as examples only. All explanatory notes in the template can be expanded by consulting the relevant part of Section 4 (Developing the HACCP plan).

The generic model for the slaughter and inverted dressing of sheep and lambs provides an example of application of the template to a particular product and process based on currently acceptable practice in New Zealand. Key components within the HACCP plan, such as the CCP determination and critical limits, are set according to applied research with the New Zealand meat industry.

The template can easily be adapted for application to processes outside slaughter and dressing. The canning generic model is an example of this using existing MAF RA (M&S) requirements in manuals, circulars and/or technical directives.

It must be remembered that the model provides a guide only, and industry must carry out a detailed study of their own products and processes in order to ensure that the resultant HACCP plan is tailored specifically for their premises. Further applied research will be necessary where individual product and process varies significantly from the model in order to validate new CCPs and critical limits.

8.2 Templates

See Appendix VIII.1 Template for Establishing a HACCP Plan for Slaughter and Dressing

8.3 Generic Models

See Appendix IX.1 Generic HACCP Plan for Slaughter and Dressing of Cattle

See Appendix 8 Generic HACCP Plan for Slaughter and Inverted Dressing of Sheep and Lambs

See Appendix 9 Generic Model for Canning (Corned Beef)*

* Users may find the Codex CCP decision tree easier to apply to these models. However, due consideration still needs to be given to FSOs for the final product when determining “acceptable/unacceptable” levels of hazards.

9. Other HACCP-Based Applications

9.1 Introduction

The HACCP principles are versatile in their application and may be applied to many other facets of the meat industry's business as well as ensuring the food safety outcomes for a particular product.

It is also possible to apply these principles directly to some prerequisite programmes mentioned in Section 1.4 in the same way that HACCP is applied to the main process, i.e. covering food safety issues and producing HACCP plans. The decision to do this rests with each individual premises. It is important to note that not all these programmes will lend themselves easily to this approach as in some cases compliance is based solely on GMP and regulatory requirements without differentiation or ranking according to public health significance.

The scope of HACCP application may be broadened, e.g., to include product quality, OSH, animal welfare, export certification and rendering. The essential factor to remember is to ensure each application is readily accessible in its own right to the user.

This section provides an example of application of HACCP principles to a prerequisite programme and to a rendering system to demonstrate their inherent flexibility. Information for these models is sourced from current MAF RA (M&S) requirements.

9.2 Generic Models

See Appendix 10 Generic Model for Potable Water *

See Appendix 11 Model for a Rendering System *

* Users may find the Codex CCP decision tree easier to apply to these models. However, due consideration still needs to be given to FSOs for the final product when determining "acceptable/unacceptable" levels of hazards.

10. Bibliography

The following have been used as source documents in the preparation of this manual:

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11. Frequently Asked Questions (FAQs)

General

- Q1. Can quality, regulatory and market access requirements be included in the HACCP plan?
- A1. Yes they can, but be aware that mandatory requirements for HACCP only relate to food safety. Therefore if you have a HACCP plan with a scope covering more than food safety, and you are about to have a HACCP plan audit by a MAF or overseas regulator, then it may be more difficult to retrieve the documentation and record keeping necessary for the food safety component.
- Q2. Who should be contacted for information regarding HACCP-related training?
- A2. The industry training organisation (ITO) supporting your industry is your contact point for HACCP-related training queries. For example, export meat industry personnel should contact Mike Brooks or Karen Cuzens at the Meat Processing Industry Training Organisation (MPITO) at 04 473 6465. MAF staff can also contact the above ITO.
- Q3. Can a premises include Asure NZ inspection activities in their HACCP plans and have these as CCPs?
- A3. Yes they can. However, Asure NZ must be involved with and agree to the developmental process. Some practical issues that must be considered when Asure NZ activities are included as part of an all-encompassing HACCP plan are:
- All components pertaining to any meat inspection/reinspection activities, including any Asure NZ CCP(s), must be seen to have been agreed to by the Asure NZ management staff for the personnel concerned. This includes the generation of appropriate records.
 - Asure NZ CCPs may come under company activities with appropriate feedback loops that include Asure NZ management staff involvement in controls at a particular level (includes monitoring, corrective action and verification activities).
 - The Asure NZ components of the HACCP plan would need to be validated by company in conjunction with Asure NZ management staff.
 - The Asure NZ components would need to be endorsed in writing (signed off) by an appropriate Asure NZ management official.
 - The implementation and maintenance of the HACCP plan would need to include the ongoing involvement and cooperation of Asure NZ staff as well as the company staff.

Such a HACCP plan must not compromise the integrity of the Asure NZ service (or the MAF Verification Agency who may be providing a verification role for Asure NZ) or provide any conflict of interest.

Q4. A number of consultants are offering their services for the development of HACCP plans. How does the licensee know which consultant is best qualified to assist in the development of a HACCP plan that will meet the requirements of the HACCP Interim Standard (Circular 98/8/1, 98/MIHC/1)?

A4. It is up to the licensee to check out the credentials of individual consultants. MAF Food recommends that they consider the following attributes when selecting a consultant:

- a clear understanding of the HACCP Interim Standard, its requirements and implications for the company;
- knowledge of HACCP principles as defined by Codex;
- familiarity with the contents of *A Guide to HACCP Systems in the Meat Industry*;
- a good technical understanding of the different aspects of food safety, food microbiology and food processing, particularly in relation to the licensee's process;
- knowledge of and experience with the development and maintenance of QA systems;
- auditing skills.

If a licensee employs a consultant to be the HACCP coordinator for the premises' HACCP plans, then that coordinator will need the necessary NZQA qualification 12626 *Coordinate the development and verification of a HACCP plan for a meat processing operation*.

Plans for all products / premises

Q1. Does a HACCP plan have to be completed for product that is not exported to the United States?

A2. The general requirement is that all processes at US-listed premises have HACCP plans regardless of the destination of the product, i.e. a condition of listing. Where a production regime for an entire species does not involve the US in any way, then the premises can be exempted even though the process is taking place within a US-listed premises. These "entire" operations don't usually have to comply with any other US requirement, therefore they couldn't be expected to implement the US HACCP requirement.

This means that some pig slaughtering premises are exempt from producing a HACCP plan, unless they have decided to send a pork product to markets covered by the US requirements in Manual 12 (e.g. American Samoa). Conversely, if some beef products are going to the US market then all beef products from that premises must be covered by a HACCP plan, regardless of whether they are all going to the US (markets).

Product produced under this exemption also cannot be further processed (e.g. at another premises) and exported to US markets.

Q2. Does a HACCP plan have to be completed for product that is produced at a New Zealand abattoir or an export-licensed premises, but is not exported?

- A2. Section 3.1 of Circular 98/8/1 *Interim Standard for a HACCP Plan, HACCP Competency Requirements and HACCP Implementation* requires that each premises which produces meat and meat product to any market other than the domestic market must determine whether any food safety hazard(s) that may be reasonably associated with each product and process exists. TD 98/163 requires that non-US listed meat export premises have their HACCP plans recognised as valid by 1 November 1999.

MISC have not given an implementation date for HACCP in abattoirs as yet. Therefore, where a production regime for an entire species does not involve export in any way, the process for that species is currently exempt from HACCP requirements. This includes where that process is taking place within an export premises.

This means that some premises may be exempt from producing a HACCP plan if they do not export any product from a particular species. Conversely, if some meat products are going to an export market then all meat products of that species produced at that premises must be covered by a HACCP plan, regardless of whether all products are to be exported.

Product produced under this exemption also cannot be further processed (e.g. at another premises) and exported.

Voluntary uptake of HACCP prior to deadlines

- Q1. If a premises is not required to implement HACCP until a certain date, what are the implications of starting HACCP implementation earlier than the mandated date?

- A1. If a premises wishes to implement HACCP prior to the mandated date, then this may be carried out on a voluntary basis, without recognition of validation by the Verification Agency until that mandated date is reached.

However, if a premises seeks recognition of their validated HACCP plan(s) from the Verification Agency, and this is forthcoming, then this will mean that the current interim HACCP standard has to be met in its entirety. This includes both the premises and the Verification Agency, from that point of recognition onwards, even though the mandatory due date has not yet been reached.

Generic plans

- Q1. There are several generic plans on the Internet for the industry to choose from. How do we know which one(s) to use as models, if any?

- A1. The best generic plans for the New Zealand industry are those that have been developed with industry involvement, depicting a generic New Zealand process and duly considering the requirements of the New Zealand industry-agreed standard for HACCP. While international generic models provide interesting comparisons, they do not necessarily reflect New Zealand requirements and processing conditions.

The New Zealand generic plans have been developed by the Animal Products group of MAF Food Assurance Authority in conjunction with meat industry representatives. They

have undergone an extensive consultation process involving MAF and industry representatives, prior to publication.

Q2. How should the generic HACCP plan be used when developing a premises' HACCP plans?

A2. A generic HACCP plan serves as a guide in the development of individual HACCP plans. It shows the logical flow of the HACCP approach applied to a segment of food production (e.g. slaughter and dressing). It is based on a generic process flow and includes those hazards that are of general concern to the New Zealand meat industry. Therefore, the hazards and CCPs identified in the generic plan will not necessarily be appropriate to specific processes/products of individual premises, but all those listed should be considered. Hazards also should not be restricted to those given in the generic plan. Careful thought must be put into the relevance or applicability of information given in the generic plan before they are adopted.

The annex to generic HACCP plans provides background information, which gives the basis for most of the decisions made in hazard identification and CCP determination in the generic plan.

Q3. The generic HACCP plan uses a summary form showing minimal detail in each column, especially for critical limits, monitoring, corrective action, verification and records to be used. Is this enough?

A3. The summary spreadsheet is included in the generic plans as a **summary**. It is not meant to provide a complete example of a HACCP plan in one form. The HACCP team should ensure that detailed documentation (and evidence where relevant) exists for all of the following components of the HACCP plan:

- scope;
- product description and intended use;
- FSOs;
- process flow;
- hazard identification and analysis;
- CCP determination;
- CLs;
- monitoring procedures, including who's responsible, where monitoring will take place, when it will take place, how it will be done;
- corrective action procedures, including who's responsible, how control will be restored, what happens to affected product, how prevention of reoccurrence might be achieved;
- verification procedures, including who's responsible, what verification consists of, how validation will happen, at what frequency ongoing verification activities will follow, when revalidation is necessary;

- documentation and record keeping procedures.

More prompts are being included in the updated templates, and in new and updated generic plans, to remind people to fully document the above information as required. The summary spreadsheet can still provide a summary, referencing all those detailed procedures forming part of the overall HACCP plan.

FSOs

Q1. Individual premises set their own microbiological targets. Why is this so and how will MAF ensure that acceptable microbiological targets are set by premises and that there is some standardisation in the industry?

A1. Individual premises need to set their own microbiological targets because these targets must be related to their own performance and be achievable by their premises. Standardisation will be assisted by the use of national microbiological targets, e.g. for bovines, allowing individual premises to assess where they lie against the current national performance and decide what actions they should take. Note that individual premises targets cannot be set above NMD targets. This evaluation process is further explained in Technical Directive 98/7. MAF's involvement in the evaluation process also is clearly outlined in this TD.

Q2. If an FSO based on microbiological targets is not met, what are the consequences for market access, and what action can the VA take?

A2. If microbiological targets are exceeded, then this should be dealt with according to TD 98/7. Review of the HACCP plan and followup action by the licensee is included in this advice. The set microbiological targets have not been designed as product pass/fail criteria, but specified responsibilities must be carried out in the case of an "alert".

The Verification Agency is expected to assess the documented response of industry to an "alert" and determine whether it is adequate as per the requirements of the above-mentioned TD.

Q3. Should food safety objectives (FSOs) just relate to those hazards in a HACCP plan?

A3. FSOs in the HACCP plan relate to those hazards identified in the initial stages of hazard evaluation. After the decision-making process, involving CCP determination, some food safety objectives may be seen to be dependent on prerequisite programmes rather than the HACCP plan itself, (e.g. as in the generic HACCP plan for cooling and boning of beef). Those FSOs would be validated using prerequisite programme activities rather than the implemented HACCP plan.

FSOs can also be written specifically for prerequisite programmes. IS 8 refers to this when it mentions "food safety outcomes".

Hazard ID and analysis

Q1. What is the suggested hazard analysis format if a premises decides to develop a plan with a scope from slaughter to loadout of boned product?

A1. The format considered to be the most useful in this case would be the revised format found in the *Template for Establishing a HACCP Plan for Further Processing of Meat and Meat Products*. If on-line inspection activities are carried out by MAF, e.g. ante mortem and post mortem inspection, then the processor would want to remove those hazards that MAF deals with, as soon as possible. This could be done by using a hazard responsibilities table and then focusing on those hazards that the processor is responsible for, for the remainder of the HACCP plan.

Q2. What range of hazards should be considered for the hazard identification and subsequent analysis?

A2. The scope of the HACCP application and the prerequisite programmes will influence this choice. Normally the hazards identified are those that are reasonably expected to occur in association with:

- raw material;
- inputs (as defined in *A Guide to HACCP Systems in the Meat Industry*);
- process steps.

Hazards normally dealt with by a prerequisite programme, e.g. personal hygiene, may have to be considered in the development of a HACCP plan for a product and process involving special conditions, e.g. those involving a cook step. Alternatively, these hazards could already be effectively addressed by an appropriate prerequisite programme, e.g. clearly indicating the specific personnel hygiene requirements when working with raw or cooked product. The processor must be able to demonstrate appropriate control of the hazard, either through the HACCP plan or by the prerequisite programme.

Q3. What inputs have to be considered in the HACCP plan?

A3. Inputs, as defined in the *Guide*, are incoming materials such as consumable or non-consumable items added to the product during the process (e.g. ingredients, food additives, packaging). Recyclable or other items that come in contact with the product (e.g. hooks/gambrels) are not considered as inputs. Some premises may want to include food contact processing aides (e.g. legging paper) to ensure that all food contact materials are considered, and that hazards associated with them are adequately addressed. This decision is up to the processor.

Visible faeces/ingesta

Q1. Should visual faecal and ingesta contamination be included in the HACCP plan for slaughter and dressing?

- A1. Yes, it usually gets included as part of “microbiological hazards associated with faeces and ingesta/contamination ex hide”. The New Zealand specification requires that premises have no visible faeces and ingesta on carcasses leaving the slaughter floor. The last point to address this is the retain rail. Critical limits for the retain rail trim include removal of all gross faecal contamination. Individual premises may want to have other CCPs involved, such as a trim step prior to pre-evisceration washing. They also may want to include a separate food safety objective for visible faecal and ingesta contamination.
- Q2. Some premises have added several trimmers in their processing line to deal with visible faecal and ingesta contamination. Is this acceptable considering the potential for trimming to be used to mask the results of unhygienic slaughter and dressing practices?
- A2. It is up to the company to decide how many trimmers are necessary for their operation and where these trimmers will be positioned in the processing line before carcass re-inspection, as per TD 99/41. It should be stressed, however, that trimming of visibly contaminated areas should not be substituted for compliance to good hygienic practices, e.g. the requirements of IS 5. Control measures during slaughter and dressing should be primarily aimed at minimising visible faecal and ingesta contamination on carcasses. Procedures should be in place covering effective monitoring and verification of operator compliance to pre-requisite programmes/SSOPs and/or CCP critical limits.

GMP vs CCPs

- Q1. When does an “established” programme (e.g. chemical residue suspect list procedures) have to be included in a HACCP plan rather than be represented as a prerequisite programme?
- A1. Ideally, all hazards identifiable with the raw material, inputs and process steps should be considered in the development of the HACCP plan. This would include those chemical hazards associated with identified chemical suspect residues. While an “already-established programme” may be seen to be delivering an appropriate level of control under GMP as it does under HACCP, application of HACCP principles is required to ensure that this is in fact the case. Also it may be found that controls are more effective if included in an integrated HACCP plan. If treated separately, it does mean that the approach to hazard identification and control for raw material hazards is going to be fragmented (with some in prerequisite programmes and some in the HACCP plan) and an auditor would be obliged to check the prerequisite programme as well as the HACCP plan for completeness.
- Q2. How are prerequisite programmes and CCPs differentiated? Can a control measure that is covered by a prerequisite programme be made a CCP, e.g. chilling?
- A2. Prerequisite programmes and CCPs can be differentiated by consideration of performance and impact on the process. A process step such as chilling, that already has documented and effective control mechanisms covered under a prerequisite programme, with appropriate records to support this performance, is unlikely to become a CCP in a HACCP plan. However, if this process step is known to be a problem area, and there is an associated history of nonconformance, then the processor is obliged to consider the

impact of this step on the identified food safety hazards when carrying out the hazard analysis of the whole process, and this may result in the step becoming a CCP.

A nonconforming water supply, although covered by a prerequisite programme as above, is unlikely to result in water usage becoming a CCP (or several CCPs) in a HACCP plan for a particular product and process. Appropriate actions to be taken are specified in industry standards as regulatory requirements. Further, water usage is not an individual process step but an activity that is usually involved in many process steps. Therefore it is always easier to control water potability separately, before it impacts on the main process itself, e.g. by readjusting an existing prerequisite programme to improve its effectiveness or by having a separate HACCP plan for water potability.

Q3. When are hazards considered to be addressed by GMP/prerequisite programmes?

A3. Hazards are generally considered to be addressed by GMP/prerequisite programmes when the following apply:

- the potential hazard is addressed by existing regulations and standards, e.g. Meat Regulations, MAF manuals, industry standards, circulars, TDs;
- the potential hazard affects the whole process and cannot be addressed at one specific step (e.g. water potability, personal hygiene, cleanup procedures, hygienic processing);
- the potential hazard directly or indirectly impacts on raw material, other inputs, outputs and/or the process but is addressed outside the HACCP plan (e.g. Supplier Quality Assurance programmes, food contact materials, water potability, waste management, vermin control).

Q4. Can certain components of GMP/prerequisite programmes be considered as CCPs?

A4. Certain components of GMP/prerequisite programmes may be considered as CCPs if the potential hazard can be controlled at specific steps of the process and one or more of the following circumstances apply:

- existing procedures are not effective and/or process failure has occurred;
- improvement in the process is required and/or can still be achieved;
- the step is considered to be critical to the process and making it a CCP would increase the focus on control of the hazard and/or increase personnel awareness, and therefore would assist in the achievement of the FSO.

Thus, it is expected that making a component of a GMP/prerequisite programme into a CCP should directly or indirectly result to an improvement in the process and/or food safety outcomes through increased focus on control at that process step.

For the reasons given above, certain steps (e.g. legging, chilling) have been considered as addressed by GMP in some premises whereas others have considered them as CCPs. The CCP status of these steps can be removed when there is sufficient evidence to

indicate that existing procedures at the particular step (which are components of a GMP/prerequisite programme) are adequate to consistently control the hazard and that no other improvements in the process and/or food safety outcomes can be achieved by making the step into a CCP.

It should be noted that not all prerequisite programmes can be considered as CCPs because the reasons given above do not apply (e.g. water potability, cleanup procedures, waste management, control of chemicals). If any of these programmes is ineffective then the specific system must still be corrected, e.g. as described in IS 8.

Q5. Are there CCPs that cannot be considered as GMP/prerequisite programmes?

A5. Control measures which are components of GMP/prerequisite programmes generally prevent the transfer and/or redistribution of hazards (e.g. hygienic dressing techniques). However, there are other types of control measures applied at certain steps that are not preventive but rather are designed to reduce or eliminate specific hazards. Examples of these are metal detection, thermal processing, and decontamination methods. In most cases, these operations would be considered as CCPs and would not be adequately covered under GMP/prerequisite programmes.

Corrective action

Q1. What corrective actions are required to be taken when monitoring indicates that a critical limit has been exceeded at a CCP?

A1. Corrective actions must take three components into consideration when a critical limit is exceeded. These are as follows:

- rapidly regain/restore control of the hazard(s) at the CCP;
- determine disposition of affected product where necessary;
- prevent recurrence of the problem where possible.

Restoration of control at the CCP should be the easiest component to implement. After all, the CCP has been set up with critical limits and it is just a matter of reinstating these limits.

Disposition of affected product is not always as clear cut, depending on the nature of the CCP. For example, corrective action at a “legging” CCP, where critical limits may be based only on operator technique, does not lend itself readily to product disposition as part of the corrective action process. This is because the CCP is often one of two or three CCPs that relate to an overall microbiological outcome for the carcass and individual site contributions to this microbiological outcome are not observable. However, disposition of affected product at a retain rail CCP involves retaining an affected carcass for further trimming because the critical limits include **visible** abnormalities.

Another example is a carcass that is detected as positive for visible faecal contamination, after inspection. This finding exceeds the critical limit of zero tolerance but when the

moving window is not exceeded, it is reasonable to expect the individual affected carcass to be dealt with, i.e. removal of visible faecal contamination from that carcass and then feedback to the process controllers of the slaughterboard. Further product disposition should only be considered when the moving window has been exceeded and it is deemed necessary to involve a further processing department, e.g. in carcass rechecks or incorporation of an escalating response to an ongoing problem.

Prevention of recurrence of a problem is easier where automation is involved, e.g. a piece of machinery may be easily adjusted or permanently fixed to basically prevent the critical limit being exceeded again. However, where operators are involved at the CCP and it is an operator activity that is being monitored, then a degree of recurrence of the problem is to be expected and must be dealt with by an escalating corrective response, e.g. retraining or removal of individuals from the CCP.

An escalating response should be undertaken where **any ongoing noncompliance** with the critical limit(s) occurs, i.e. preventive measures are obviously not working. Depending on the critical limit at the CCP, the processor also may wish to take corrective action early when monitoring indicates a trend towards loss of control at the CCP.

Corrective actions should be specific for each CCP, but there may be situations where a generic procedure is available (e.g. an escalating response) outlining the principles, and individual actions are then documented according to each expected situation.

Validation

- Q1. Can premises refer to information given in the annex of the generic plan (i.e. background information) as part of their justification for identifying hazards and CCPs for their own plans?
- A1. Yes, information given in the annex may be referred to for justifying decisions made in developing the plan, provided they can be shown to be relevant to the specific process/product.
- Q2. When validating the plan, do all CCPs have to be evaluated even though operating procedures may remain the same before and after HACCP implementation in some instances?
- A2. As part of the validation activity, all identified CCPs should be evaluated to ensure that the control measure applied at that particular step, will achieve or contribute to the achievement of the relevant FSO. The difference lies in the type of data which can be used for validation. When HACCP implementation does not result in any change in operating procedures, historical data may be used for evaluating the CCP. When historical data is not available or is inadequate (e.g. with a new or modified process), then validation may require the collection of new data from the time the HACCP plan is implemented.
- Q3. Are job instructions/descriptions required to be recognised as valid when a HACCP plan is being audited for recognition of validity by MAF VA?

- A3. Where a CCP has a critical limit of compliance to a job description, then the job description(s) relating to that CCP will have to be recognised as valid. Other job descriptions support prerequisite programmes such as hygienic dressing or processing and would be validated as part of implementation of IS 8.
- Q4. If a premises identifies one or more food safety hazards in association with the product and process, and application of the HACCP principles reveals that no critical control points (CCPs) are identifiable, then is a HACCP plan required?
- A4. No. A HACCP plan is dependent on critical control points being identified before it can be completed. However, the first nine steps of Section 4.1.2, *A Guide to HACCP Systems in the Meat Industry* should be completed (see also the mandatory requirements in TD 98/22 and Circular 98/MIHC/1: *Interim Standard for a HACCP Plan, HACCP Competency Requirements and HACCP Implementation* — Section 3.4, elements (a) to (f)). The rationale for the hazard analysis and CCP determination shall be included in the documentation and available for audit.
- Q5. What validation information should be available at the premises for audit?
- A5. At any MAF VA recognition of validation audit, all validation information should be readily available and documented. This includes (but is not limited to):
- skills and resources used in the development of the plan (particularly important for further processing plans);
 - appropriate validation information for each FSO (i.e. proven to be achievable by use of the HACCP plan, statistically valid methods where appropriate);
 - background information on hazards appropriate to the product (e.g. use of generic plans, historical information, scientific literature, etc.);
 - documentation to support CCP determination (i.e. rationale for why hazards were or were not considered significant/unacceptable, effectiveness of control measures);
 - scientifically valid critical limits for each hazard;
 - critical limits relevant to the FSO(s);
 - proof that critical limits are achievable (practical), given the process;
 - proof that monitoring supplies enough information to ensure the CCPs are under control (consider how the monitoring is conducted, what is monitored, frequency of monitoring, including relationship to prevalence of hazard).

This information should also be available for MAF Food Compliance Group audits or MAF VA internal audits, should they require it. Historical monitoring, corrective action and verification records should also be available if required by an auditor, though some older records may be archived and therefore may take longer to access.

- Q6. Should justifications and supporting documents be included in the actual HACCP plan or in separate documents?

- A6. The processor has a choice here. Justifications and supporting documents can be either in the HACCP plan or be elsewhere, with clear reference in the plan to where the information can be found.

Verification

- Q1. What is the status of external reviews as a form of verification/validation?

Point of clarification: Historically “external” reviews/audits have denoted those activities carried out on company systems by an independent outside source such as the client, regulator or other third party. However, audit terminology indicates that this is inaccurate; that these are actually “extrinsic” reviews/audits. Consequently, this definition has been promoted in the interim HACCP standard and any recent amendments to HACCP documents.

- A1. Extrinsic reviews are acceptable as a form of verification, but the company should not rely on these as the primary source of verification information, i.e. companies should be completing their own internal reviews/audits, FSO validation activities, product testing, etc., as the main source of verification information.

- Q2. Can the frequency of HACCP plan compliance audits conducted by MAF VA personnel be part of performance-based verification (PBV) activities?

- A2. The frequency of HACCP plan compliance audits conducted by MAF VA personnel shall be **at least monthly** until a period of 12 months’ implementation has elapsed. This will allow the HACCP system to settle in and initial problems to be sorted out. Thus HACCP compliance audits may become performance-based on a premises by premises basis depending on when the premises HACCP plan was initially recognised as valid.

- Q3. If a premises with a HACCP plan is not processing for an extended period of time (e.g. shutdown), is MAF VA still required to conduct a monthly verification audit?

- A3. Yes, the frequency is stipulated unconditionally in the Interim Standard 98/8/1, Section 5.7, until 12 months have elapsed. At the very least, the premises is likely to be storing product (e.g. cold storage, aging of chilled cuts) and it depends on how this has been managed under their HACCP plan. If this storage has been identified as a CCP, then the plan is still active, and will require appropriate monitoring, corrective action and verification activities undertaken by company personnel. This would require MAF VA verification. If storage activities are being managed by a prerequisite programme, then MAF VA would verify this at the established frequency for this prerequisite programme. It also is possible that during a shutdown, other HACCP plan verification activities will be undertaken by company personnel (e.g. HACCP plan review, calibration, etc.). This again means that the plan is active and producing records, and would need at least monthly MAF VA verification audits.

Recognition of validation

Q1. If after hazard analysis and CCP determination you find that there are no CCPs, and thus no HACCP plan is required (as per TD 98/22), does the work still need to be recognised as valid by MAF VA?

A1. Recognition of validity by means of a MAF VA audit is only required for a HACCP plan; it is not required for work that results in no plan. However, the licensee must ensure that the work has been confirmed as scientifically appropriate by their HACCP coordinator and would be auditable under GMP by MAF VA and the MAF Food Compliance Group.

Q2. Does a US-listed premises killing bobby calves have to have their HACCP plan recognised as valid by 25 January 1999?

A2. If there is sufficient data to complete validation, the plan must be recognised as valid by MAF VA before they start processing bobby calves again next season.

If there is insufficient data for validation, then TD 98/163 comes into effect, where by the licensee carries out a provisional validation, and MAF VA do a provisional recognition of validation (i.e. desktop audit). The premises then has two working weeks to collect data to fully validate the plan, at which point MAF VA conduct a complete recognition of validation audit. The key point is that the premises gets the plan validated and recognised as valid early in the season.

Q3. A non-US listed premises is required to have HACCP in place by 1 November 1999, but has already validated a HACCP plan and had it recognised by December 1998. During a shutdown there have been substantial changes to the process involving new equipment. Some trials have taken place. The premises are presently revising their plan and have asked at what stage do they have to have it recognised as valid.

A3. The premises would need to run the new line under full processing conditions to fully validate the new process and therefore it makes sense that TD 98/163 would apply (i.e. provisionally recognise revised documentation as valid, then a two week working period to collect validation data before having the plan fully recognised as valid). The old plan cannot apply as the process has changed. The premises cannot delay the recognition of the new plan until immediately prior to 1 November 1999 because they have already committed to HACCP.

Q4. When a review results in changes to the HACCP plan, does the plan have to be re-recognised as valid? While awaiting recognition, can a premises immediately implement the changes?

A4. Yes, revalidation and re-recognition is necessary if the changes are significant enough, e.g. involving changes to premises, product, process, intended use of the product, or when process failure that may compromise product safety occurs. The premises will need to implement the changes in order to revalidate the HACCP plan, therefore they will do this under currently available specifications or under the provisions for a new process standard (see Interim Standard 98/8/1, Appendix Three).

Guideline for HACCP Briefing: Executive Manager

1. Purpose

This briefing is designed for senior managers and executives of food businesses planning to introduce HACCP-based food safety systems. It provides a broad overview of HACCP and the context in which HACCP should be utilised.

2. Suggested duration

Two hours

3. Prerequisite requirements for participants

Not applicable

4. Items for trainer to consider

Use examples of:

- success and failure relating to food safety;
- application of HACCP principles;
- each category of hazard;
- market access requirements;
- other benefits.

5. Learning objectives

After attending this briefing, the participant should be able to:

5.1 Recognise the food industry's role in managing food safety issues.

- Understand the importance of HACCP to the food industry.
- Understand the benefits and costs to industry.
- Understand how industry and government can work together to effectively ensure food safety.

5.2 Understand what HACCP is and why the food industry should embrace it.

- Be aware of the history of HACCP and its food safety core.
- Be able to generally compare HACCP to other systems, including sanitation, GMP and quality systems e.g., ISO, TQM.
- Have a basic understanding of the seven principles of HACCP.

5.3 Recognise the threats to food safety and where they can be found.

- Appreciate all potential sources of hazards from “preharvest to table”.
- Understand the categories of hazards (biological, chemical, physical).

5.4 Recognise the relationship between current regulatory and legislative requirements and HACCP.

- Understand the New Zealand regulatory agencies approach to HACCP.
- Understand the position of HACCP in the international market place.
- Appreciate the role of the Codex Alimentarius Commission in ensuring HACCP consistency worldwide.
- Be aware of current variation in interpretation and promotion of HACCP around the world.

5.5 Recognise the role of management in the implementation of the HACCP plan.

- Appreciate the importance of on-going management commitment.
- Appreciate the need to identify and provide resources (including obtaining HACCP help elsewhere e.g., industry codes of practice).
- Realise the associated implementation costs compared to benefits.
- Understand the need for specific employee training.

Guideline for HACCP Training: HACCP Coordinator

1. Purpose

This training guideline is designed for the person who would become the primary coordinator of HACCP development and implementation at a food premises.

2. Suggested duration

24 hours

3. Pre-requisite requirements for participants

3.1 Background — minimum or equivalent:

- unit No 167 — Food Handling — Produce Safe Food;
- unit No 168 — Food Handling — Prevent Food Contamination.

3.2 Participants will need:

- relevant industrial experience;
- understanding of GMP/SOP (essential);
- quality system experience (desirable).

4. Items for trainer to consider

- Present Codex HACCP guideline as the baseline standard (see bibliography).
- Use case studies relevant to the course participants.
- Some on-site training would be desirable.
- Participants should receive a theoretical and practical assessment of their understanding of HACCP as it pertains to this course. This assessment should include a HACCP plan.

5. Learning objectives

After completing this course, and in association with the Codex HACCP guideline and other expertise available within the HACCP team, the participant should be able to:

5.1 Recognise the relationship between HACCP and Food Safety.

- Explain the relationship between HACCP, food safety and quality management systems.
- Discuss the benefits of implementing a HACCP system which include motivating and selling HACCP to Industry and reviewing case studies.
- Discuss HACCP and basic food safety principles.

5.2 Review SOPs and GMP (not a part of the HACCP plan).

- Define SOP.
- Define GMP.
- Discuss the importance of SOP's and GMP.
- Describe how SOP's and GMP's support HACCP plans.

5.3 Identify product and how hazards relate to it.

- Identify types of food items that are produced.
- Discuss the significance of food composition, distribution controls and intended use.
- Define a hazard.
- Understand definitions and principles relative to hazard identification .
- Explain control measures that prevent, reduce, or minimise hazards associated with different types of foods.
- Develop food safety objectives relating to the production of particular foods.

5.4 Present the principles of HACCP and apply them.

- Develop a detailed flow chart of a process and product.
- Discuss the usefulness of task/job descriptions for each process step.
- Conduct and document a hazard analysis of the process and product which includes the following factors:
 - evaluate the rationale for hazard selection;
 - evaluate the occurrence of hazards associated with raw material, ingredients and other significant inputs at each process step;
 - evaluate the significance of hazards in relation to the product, process and end use;
 - identify preventative/control measures available;
 - be aware of the need to evaluate the nature and severity of the risk (risk assessment) in relation to the consumer, wherever possible.
- Identify Critical Control Points (CCP's) in the process.
 - Define a CCP.
 - Identify CCP's by using valid scientific criteria and risk assessment where appropriate.
- Establish Critical Limits for preventative measures associated with each CCP.
 - Define and determine Critical Limits.
 - Set Critical Limits that are relevant to product safety (noting the limitations in relation to raw end product).
 - Document the rationale for Critical Limit selection and its relationship to food safety objectives for the end product (noting the limitations for raw end product).
 - Ensure Critical Limits are documented and measurable.

- Establish CCP monitoring procedures.
 - Define monitoring and explain requirements.
 - Recognise the importance of monitoring.
 - Identify Critical Limits to be monitored.
 - Identify where measurements will be taken.
 - Explain how monitoring is to be conducted.
 - Determine the frequency for taking measurements.
- Identify who is responsible for monitoring.
 - Describe monitoring procedures, sampling plans and methodology used.
- Establish corrective actions to be taken when monitoring indicates that there is a deviation from an established Critical Limit.
 - Define corrective action.
 - Develop corrective actions.
 - Document corrective actions.
 - Identify the personnel responsible for taking correction action.
- Establish procedures for verification that the HACCP system is effective.
 - Define verification and understand how it differs from monitoring.
 - Recognize the importance of verification to support and assure the long term viability of the HACCP plan.
 - Discuss the range of activities that can be conducted as part of verification.
 - Understand what validation of the HACCP plan means.
 - Conduct a HACCP plan review at regular intervals or when significant changes in equipment, ingredients or operating procedures occur.
 - Understand what revalidation of the HACCP plan means.

- Establish effective documentation and record keeping procedures that fully support the HACCP system.
 - Discuss the importance of documentation of all components of the HACCP plan.
 - Discuss the importance of record keeping detailing monitoring outcomes, corrective action taken, verification steps.
- Document HACCP plan details.
 - Identify what information should be included in records.
 - Develop simple, user-friendly records with clear instructions.
 - Recognize the importance of reviewing records as part of the verification process.
- Understand and be able to use generic HACCP plans for different types of food/end-uses.
- Compare and contrast HACCP plans for different types of food/end-uses, e.g., raw frozen; cooked, chilled ready-to-eat; canned product.

5.5 Implement a HACCP plan.

- Describe the commitment from upper management necessary for HACCP to succeed.
- Determine the key factors for successful HACCP implementation, including formulation of the HACCP team.
- Discuss the steps for developing and implementing HACCP in the food premises, including verification of the plan.
- Develop implementation steps supported by GMP's/SOP's.
- Determine and convey realistic expectations of time and commitment to the HACCP system.
- Establish a staff training program in accordance with the expectations of the establishment.

5.6 Understand the factors essential to maintenance and ongoing improvement of the HACCP plan.

- Recognise that the establishment is responsible for producing and maintaining the HACCP plan.
- Maintain a staff training programme in accordance with the expectations of the establishment.
- Establish HACCP plan maintenance and measurement procedures.
 - Recognise that HACCP systems are dynamic and subject to change/updating.
 - Identify factors that significantly impact on a HACCP plan and require review of the system and possible revalidation of the plan.
 - Recognise the need for support systems for key personnel (Supervisors/operators).
 - Recognise the need for ongoing measurement of the effectiveness of the HACCP plans (food safety objectives).
 - Evaluate the appropriateness of different measurement tools that are operation/process specific for HACCP systems.
 - Evaluate data collected from HACCP implementation for future improvement.

5.7 Recognise Regulatory issues impacting on the implementation of HACCP systems.

- Understand the role of the regulatory authority in a non-mandatory environment.
- Understand the role of the regulatory authority in a mandatory environment.

5.8 Recognise Market access issues impacting on the design and implementation of HACCP systems.

Guideline for Introduction to HACCP: Supervisors

1. Purpose

This training guideline is designed to give Supervisors in food premises an appreciation of HACCP and their role in supporting a HACCP system.

2. Suggested duration

Eight hours

3. Prerequisite requirements for participants

Not applicable

4. Items for trainer to consider

In relation to learning objectives outlined below:

- use examples of food-borne illness;
- use group participation where appropriate;
- cover steps in developing a HACCP plan without being too specific. Use CCP decision tree as example only;
- use videos to reinforce what has been discussed.

5. Learning objectives

After attending this introductory course, the participant should be able to:

5.1 Understand the history of HACCP.

- Know what all the fuss is about.
- Appreciate the rise of reported food-borne related illness/problems.
- Know what HACCP is, where it came from and why.

5.2 Recognise the benefits of HACCP.

- Understand the need for assurance that food safety hazards are controlled and food safety is enhanced.
- Understand HACCP in relation to market access requirements.
- Have a general understanding of the cost/benefit issues in relation to HACCP.

5.3 Understand the basic concepts of HACCP.

- Explain what is meant by the scope of HACCP and, where applicable, its relationship to existing quality systems e.g., ISO, TQM.
- Define and give examples of food safety hazards (biological, chemical and physical) CCPs, critical limits.
- Know what monitoring, corrective action, verification and documentation/records means with respect to HACCP.

5.4 Understand the need for management's commitment to HACCP.

- Know the HACCP policy for the premises.

5.5 Recognise what makes HACCP work.

- Understand the general responsibilities and commitment of everybody in making HACCP work.
- Understand the importance of prerequisite programmes.
- Be aware of the steps involved in developing a HACCP plan.
- Understand the supervisors specific role (with prerequisite programmes/good manufacturing practice; specific involvement in monitoring CCPs, taking corrective action and recording).

5.6 Recognise the expected outcomes of HACCP and what it will mean as a Supervisor.

- Understand the meaning of HACCP to different individuals (Companies, Public, Customers, Markets).
- Appreciate the advantages and disadvantages associated with HACCP development and implementation.
- Understand the wider perspective of HACCP; i.e., it is not just going to impact on procedures, monitoring and records.
- Appreciate the need to work closely with the regulator (e.g., regulators in a monitoring or verification role).

Guideline for Introduction to HACCP: Operators

1. Purpose

This training guideline is designed to give operators in food premises, an appreciation of HACCP and their role in supporting a HACCP system.

2. Suggested duration

Two hours

3. Prerequisite requirements for participants

Not applicable

4. Items for trainer to consider

In relation to the learning objectives outlined below:

- use examples of food-borne related illness;
- use group participation where appropriate;
- use video to reinforce what has been discussed.

5. Learning objectives

After attending this introductory course, the participant should be able to:

5.1 Understand the history of HACCP.

- Know what all the fuss is about.
- Appreciate the rise of reported food-borne related illness/problems.
- Know what HACCP is, where it came from and why.

5.2 Recognise the benefits of HACCP.

- Understand the need for assurance that food safety hazards are controlled.
- Understand HACCP in relation to market access requirements.

5.3 Understand the basic concepts of HACCP.

- Know what is meant by the scope of HACCP and, where applicable, its relationship to existing quality systems, e.g., ISO, TQM.
- Know what food safety hazards (biological, chemical and physical), Critical Control Points and critical limits are.
- Know what monitoring, corrective action taking, verification and documentation/records means with respect to HACCP.

5.4 Understand the need for management's commitment to HACCP.

- Know the HACCP policy for the premises.

5.5 Recognise what makes HACCP work.

- Appreciate the general responsibilities and commitment of everybody in making HACCP work.
- Understand the operators specific role (with prerequisite programmes/good manufacturing practice; specific involvement in monitoring CCPs, taking corrective action and recording).

5.6 Understand the expected outcomes of a HACCP programme for the business.

Appendix V: Unit Standard 12626

Meat Processing: Coordinate the development and verification of a HACCP plan for a meat processing operation.

Level: 4

Credit: 30

Final date for comment: November 1999

Expiry date: December 2000

Sub-field: Meat Processing

Purpose: This unit standard is recommended for people coordinating or verifying a Hazard Analysis Critical Control Point (HACCP) system for a meat processing operation.

People credited with this unit standard are able to:

- develop a HACCP plan for a meat processing operation;
- discuss the implementation of a HACCP plan for a meat processing operation; and
- verify the operation of a HACCP system for a meat processing operation.

Entry information: Open

Accreditation option: Evaluation of documentation by NZQA and industry.

Moderation option: A centrally established external moderation system has been set up by the New Zealand Meat Processing Industry Training Organisation.

Special notes: 1. The Ministry of Agriculture Regulatory Authority (Meat & Seafood) publication *A Guide to HACCP Systems in the Meat Industry* is available at licensed meat premises or from:

The Systems Manager (Publications)
MAF Regulatory Authority
P.O. Box 1654, Palmerston North

2. The publication *A Guide to HACCP Systems in the Meat Industry* includes training guidelines for a HACCP coordinator.

3. The credit value of this unit standard is based on the assumption that the candidate has had experience in the meat processing industry at the supervisor level or above, and has knowledge of basic microbiology, biochemistry and chemistry.

4. The Industry Interim Standard is available from:

The Systems Manager (Publications)
MAF Regulatory Authority
P.O. Box 1654, Palmerston North

Elements and Performance Criteria

Element 1

Develop a HACCP plan for a meat processing operation.

Performance criteria

1.1 The development of the HACCP plan is consistent with the Industry Interim Standard and *A Guide to HACCP Systems in the Meat Industry*.

1.2 The HACCP plan is documented and approved according to the Industry Interim Standard.

Element 2

Discuss the implementation of a HACCP plan for a meat processing operation.

Performance criteria

2.1 The discussion identifies the relevance of staff roles and responsibilities in relation to the implementation of a HACCP plan.

2.2 The discussion identifies the staff training required in order to implement a HACCP plan.

2.3 The discussion identifies the methods used to validate a HACCP plan consistent with *A Guide to HACCP Systems in the Meat Industry*.

2.4 The discussion identifies company factors that may influence the implementation of a HACCP plan.

2.5 The discussion identifies factors that a company is required to consider when reviewing its HACCP operation.

Element 3

Verify the operation of a HACCP system for a meat processing operation.

Performance criteria

- 3.1 Verification of the HACCP system is carried out in accordance with the HACCP plan and the Industry Interim Standard.
- 3.2 Records are maintained in accordance with the HACCP plan and the Industry Interim Standard.

Comments to: Meat Processing Industry Training Organisation
Unit Standard Revision
P.O. Box 160
Wellington

by November 1999.

Please note: Providers must be accredited by the Qualifications Authority before they can offer programmes of education and training assessed against unit standards.

Accredited providers assessing against unit standards must engage with the moderation system that applies to those unit standards. (Please refer to relevant Plan ref: 0033.)

NZMPITO Assessment Checklist

Unit Std No: 12626 **Level:** 4 **Credit:** 30

Title: Coordinate the development and verification of a HACCP plan for a meat processing operation

Candidate Name _____ NZQA No: _____ Assessment Date ____/____/____

Assessors Name _____ ITO No: _____ Assessment Result: C NYC FER SRA

Element: 1 – Develop a HACCP plan for a meat processing operation

P.C.	Evidence	Comments	Decision
	Candidate assessed in the role of a Coordinator		C, NYC, FER, SRA
1.1 and	Question: Confirm the candidate’s role in the development of the plan.		
1.2	Question: Ask candidate to demonstrate by reference to the plan their undertaking of the development of a HACCP Plan.		
	Examine: Appropriate prerequisite programmes (range: potable water, personal hygiene, cleaning and sanitation, training) and the documentation of a HACCP plan (capable of implementation). (Ensure it is prepared in accordance with <i>A Guide to HACCP Systems in the Meat Industry</i> and the Industry Interim Standard.)		

	Third Party Evidence: Verify candidate's role in developing HACCP plan.		
P.C.	Evidence Candidate assessed in the role of an Auditor*		
1.1 and	Question: Ask candidate to demonstrate knowledge of appropriate prerequisite programmes and their importance in relation to HACCP plans (range: potable water, personal hygiene, cleaning and sanitation, training, others as relevant to particular HACCP plans).		
1.2	Question: Ask candidate to demonstrate the knowledge and skills to develop a HACCP plan.		
	Review: A verbal or written report on development of a HACCP plan and ensure consistency with the <i>Guide</i> and the Industry Interim Standard.		

Notes

- (1) *This checklist should be used for persons who have not developed a HACCP plan.
- (2) Section 7: Auditing HACCP plans in *A Guide to HACCP Systems in the Meat Industry* is a recommended resource for assessors.

Assessment Results: C = Competent NYC = Not Yet Competent FER = Further Evidence Required SRA = System Requires Attention

NZMPITO Assessment Checklist

Unit Std No: 12626 **Level:** 4 **Credit:** 30

Title: Coordinate the development and verification of a HACCP plan for a meat processing operation

Candidate Name _____ NZQA No: _____ Assessment Date ____/____/____

Assessors Name _____ ITO No: _____ Assessment Result: C NYC FER SRA

Element: 2 – Discuss the implementation of a HACCP plan for a meat processing operation

	Evidence Candidate assessed in the role of a Coordinator/ Auditor	Comments	Decision C, NYC, FER, SRA
2.1	Question: Description identifies relevance of staff roles and responsibilities (management, worker, specialist, job descriptions) (range: sign-off of plan, validation, monitoring corrective actions, verification).		

Notes

Assessment Results: C = Competent NYC = Not Yet Competent FER = Further Evidence Required SRA = System Requires Attention

NZMPITO Assessment Checklist

Unit Std No: 12626 **Level:** 4 **Credit:** 30

Title: Coordinate the development and verification of a HACCP plan for a meat processing operation

Candidate Name _____ NZQA No: _____ Assessment Date ____/____/____

Assessors Name _____ ITO No: _____ Assessment Result: C NYC FER SRA

Element: 2 – Discuss the implementation of a HACCP plan for a meat processing operation

	Evidence Candidate assessed in the role of a Coordinator/Auditor	Comments	Decision C, NYC, FER, SRA
2.2	Question: Describe staff training as outlined in the HACCP Training Guidelines and Interim Standard (range: Manager, Operator, Coordinator, Supervisor). Describe training required for Unit Standard 12626.		

Notes

Assessment Results: C = Competent NYC = Not Yet Competent FER = Further Evidence Required SRA = System Requires Attention

NZMPITO Assessment Checklist

Unit Std No: 12626 **Level:** 4 **Credit:** 30

Title: Coordinate the development and verification of a HACCP plan for a meat processing operation

Candidate Name _____ NZQA No: _____ Assessment Date ____/____/____

Assessors Name _____ ITO No: _____ Assessment Result: C NYC FER SRA

Element: 2 — Discuss the implementation of a HACCP plan for a meat processing operation

	Evidence Candidate assessed in the role of a Coordinator/ Auditor	Comments	Decision C, NYC, FER, SRA
2.3	Question: Description of methods used to validate the plan consistent with <i>A Guide to HACCP Systems in the Meat Industry</i> (discuss all elements of a HACCP plan — refer to Industry Interim Standard); explanation of outcomes against food safety objectives.		

Notes

Assessment Results: C = Competent NYC = Not Yet Competent FER = Further Evidence Required SRA = System Requires Attention

NZMPITO Assessment Checklist

Unit Std No: 12626 **Level:** 4 **Credit:** 30

Title: Coordinate the development and verification of a HACCP plan for a meat processing operation

Candidate Name _____ NZQA No: _____ Assessment Date ____/____/____

Assessors Name _____ ITO No: _____ Assessment Result: C NYC FER SRA

Element: 2 – Discuss the implementation of a HACCP plan for a meat processing operation

	Evidence Candidate assessed in the role of a Coordinator/ Auditor	Comments	Decision C, NYC, FER, SRA
2.4 and 2.5	Question: Describe the company factors that may influence the implementation of a HACCP plan and must be considered when reviewing the HACCP operation (range: HACCP training; competencies; resources; pre-requisite programmes).		

Notes

Assessment Results: C = Competent NYC = Not Yet Competent FER = Further Evidence Required SRA = System Requires Attention

NZMPITO Assessment Checklist

Unit Std No: 12626 **Level:** 4 **Credit:** 30

Title: Coordinate the development and verification of a HACCP plan for a meat processing operation

Candidate Name _____ NZQA No: _____ Assessment Date ____/____/____

Assessors Name _____ ITO No: _____ Assessment Result: C NYC FER SRA

Element: 3 – Verify the operation of a HACCP plan for a meat processing operation

	Evidence Candidate assessed in the role of a Coordinator/ Auditor	Comments	Decision C, NYC, FER, SRA
3.1	Question: Description of verification of HACCP system in accordance with the plan and the Industry Interim Standard and/or examine and/or verify activities checked in accordance with the HACCP plan and Industry Interim Standard.		

Notes

Assessment Results: C = Competent NYC = Not Yet Competent FER = Further Evidence Required SRA = System Requires Attention

NZMPITO Assessment Checklist

Unit Std No: 12626 **Level:** 4 **Credit:** 30

Title: Coordinate the development and verification of a HACCP plan for a meat processing operation

Candidate Name _____ NZQA No: _____ Assessment Date ____/____/____

Assessors Name _____ ITO No: _____ Assessment Result: C NYC FER SRA

Element: 3 – Verify the operation of a HACCP plan for a meat processing operation

	Evidence Candidate assessed in the role of a Coordinator/ Auditor	Comments	Decision C, NYC, FER, SRA
3.2	Question: Describe how records are maintained – Consistent with the HACCP plan and the Industry Interim Standard and/or examine records to ensure they are maintained in accordance with the HACCP plan and the Industry Interim Standard.		

Notes

Assessment Results: C = Competent NYC = Not Yet Competent FER = Further Evidence Required SRA = System Requires Attention

Appendix VI: Auditing HACCP Plans

VI.1 Aims of the HACCP Plan Audit

The HACCP plan audit focuses on effective control of food safety hazards. However, the intent of the audit will vary depending on the type (see Appendix VI.4).

Generally the following outcomes are sought:

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

VI.2 Audit Approach

The recommended audit approach, as outlined in ISO Standards 10011-1:1992 and 10011-3:1992, is to:

- decide the type of audit, including the standard against which the HACCP plan is to be assessed (see Appendix VI.4);
- notify the auditee;
- obtain information prior to the premises audit (see Appendix VI.5);

Preaudit information may be assessed off-site or on-site. The practicalities of this will be determined by the auditor and auditee.

- assess the preaudit information and if necessary target specific concerns to be addressed prior to the audit or for further evaluation on-site;
- select the audit team (see Appendix VI.6)
- brief the audit team;
- visit the premises and carry out the entry meeting;
- carry out the audit (see Appendix VI.7); all observations and nonconformances 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 (see Section 5.4.2 of ISO Standard 10011.1 for the main headings);
- if the auditee disagrees with the conclusions of the audit, they should follow appeal procedures where provided;
- follow up on nonconformances as agreed.

VI.3 Outcome of the Audit

VI.3.1 Assessment of conformance

Using all information available (preaudit and HACCP audit), evaluate the findings. The questions in Appendices VI.5 and VI.7 provide guidance for this. Taking into consideration the aims of the audit process, determine if the HACCP plan is effective.

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

- all necessary prerequisite programmes are in place and are operating without any deficiencies which are likely to compromise the food safety outcome of the HACCP plan;
- it can be demonstrated that acceptable food safety objectives (FSOs) are being met on an ongoing basis (with deficiencies addressed promptly followed by appropriate and documented review);
- in relation to the seven HACCP principles, all components are met to the satisfaction of the auditor;
- actual events substantially match documented HACCP procedures.

A conforming HACCP plan may mean that some or all of the following may occur:

- *the audit frequency may decrease,*
- *regulatory overview/audits may decrease,*
- *a change in audit type may occur,*
- *customised process changes may be sanctioned,*
- *market access is granted.*

VI.3.2 Assessment of nonconformance

VI.3.2.1 All nonconformances should be identified according to specific parts of the related standard.

VI.3.2.2 Prerequisite programme nonconformances

The HACCP plan auditor, if carrying out a separate role to that of a compliance auditor, should only be concerned about the presence of prerequisite nonconformances which have the potential to adversely affect the food safety outcome expected from application of the HACCP plan, and which have not been effectively addressed by the auditee (or the represented licensee). Corrective action may include one or more of the following:

- action by the processor to immediately correct the prerequisite programme(s) deficiencies;
- notification by the HACCP plan auditor to the service provider who has responsibility for verifying the ongoing compliance of the prerequisite programme with statutory requirements/industry agreed standards;
- notification by the HACCP plan auditor to the auditee that the effectiveness of the HACCP plan is seriously compromised, with additional corrective actions being applied as per Appendix VI.3.2.3.

There is the option of aborting the HACCP plan audit at this stage or progressing the audit with the intention of providing additional feedback to the auditee even though the outcome may have been affected.

VI.3.2.3 HACCP plan nonconformances

Nonconformances will be any activities that do not meet the given standard and/or what is documented in the HACCP plan. The auditee will be expected to act on the outcomes of the audit to correct nonconformances within the agreed timeframe. The urgency and scope of the corrective actions will depend on the seriousness of the nonconformances and may include one or more of the following actions:

- action by the processor to correct deficiencies in the HACCP plan;
- an increase in audit frequency;
- an increase in depth of audit;
- recognition of the HACCP plan as having failed to achieve FSOs 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 actions as a regulatory authority may deem necessary, e.g:
 - notification to a regulatory authority,
 - recall of product immediately as per conditions outlined by a regulatory authority,
 - suspension of market access by a regulatory authority.

Regulatory action for nonconformances can only be applied against mandatory requirements.

The auditor will confirm that the proposed corrective actions are satisfactory and how they will be verified.

VI.3.3 Closeout of nonconformances

The auditee will ensure all corrective actions are addressed according to the agreed timeframe.

The auditor will verify that all corrective actions have been taken by the auditee and are effective.

VI.4 Types of Audit

Audit: A systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Audits are carried out against standards. An audit against the HACCP guide would have to be clearly agreed to by both parties prior to the audit.

Recognition of validity

An initial full audit carried out by Verification Agency personnel in order to recognise the validity of the HACCP plan.

Review of validity

A full or partial audit by Verification Agency personnel in order to recognise the validity of changes to a HACCP plan.

Compliance audit

An audit carried out by Verification Agency personnel to determine whether actual practices comply with the documented procedures in the validated HACCP plan.

Internal audit

An audit carried out by the licensee to evaluate the implementation of the HACCP plan. The person or persons carrying out the audit should be independent of the system under consideration.

Extrinsic audit

An audit carried out by customer, regulator or third party of the licensee to assess compliance with the HACCP plan.

Full audit

An audit covering all aspects of the HACCP plan and selected prerequisites (selected by the auditor). A full audit would be necessary on the following occasions:

- initial audit;
- where substantial changes have been made to the product or process;
- according to a minimum frequency as stipulated by a standard or a regulatory authority;
- where the last audit indicated a need for it.

Partial audit

An audit covering selected components of a HACCP plan. At least 20% of the contents of the HACCP plan should be audited and the audit must include a record review.

VI.5 Preaudit Checklist

This checklist provides a detailed guideline to assist the auditor in assessing preaudit information

Preaudit checklist	Comments
<p>1. Quality system</p> <ul style="list-style-type: none">• 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 external audit of the quality system?	
<p>2. Prerequisite programmes</p> <ul style="list-style-type: none">• 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)? <p>For initial audit, check:</p> <ul style="list-style-type: none">• internal review/audit reports,• extrinsic review/audit reports,• nonconformance records,• documentation and records for selected sample of prerequisite programmes. <p>For subsequent audit, check:</p> <ul style="list-style-type: none">• information for the above since the last HACCP plan audit,• information on any changes to prerequisite programmes.	

<p>3. Submitted HACCP plan</p> <p>(See Appendix VI.7 for HACCP plan audit questionnaire.)</p> <ul style="list-style-type: none">• Are previous HACCP plan audit reports available?	
<p>4. Responsibilities</p> <ul style="list-style-type: none">• HACCP competent individual*. <p>*as defined by the industry-agreed standard or regulatory agency</p>	
<p>5. Other information most likely to be accessed on-site</p> <ul style="list-style-type: none">• 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?	
<p>Other comments</p>	

VI.6 Audit Team Qualifications

Auditor qualifications are outlined in ISO 10011-1:1992 and ISO 10011-2:1992 *Guidelines for Auditing Quality Systems*.

The team leader needs to have:

- qualifications and experience as appropriate to the audit, i.e. internal (according to company requirements) or extrinsic (recognised audit qualification by JAS-ANZ or equivalent).

The team also needs to have:

- HACCP experience indicating competence in meeting the expected outcomes of the HACCP Coordinator (see Appendix 2) or as per agreed industry/regulatory standards;
- technical expertise and industry knowledge.

The audit team may consist of only one person if that person meets all the requirements.

The auditor(s) need to be free from bias and influences which could affect objectivity. All persons and organisations involved with an audit should respect and support the independence and integrity of the auditors.

VI.7 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. Nonconformance is serious and is likely to result in actions taken as per Section VI.3.2.3.

HS means HACCP Interim Standard (MIHC Circular 98/MIHC/1).

MHE means Meat HACCP Guide.

HACCP plan audit questionnaire	Comments
<p>1. Is there commitment from Management for HACCP? [Consider both informal or formal]</p> <p>Has the HACCP plan been signed off by Management?</p> <p>Ref: HS 5.1 MHG 5.2</p> <p>Status: Required</p>	
<p>2. Has a HACCP team been established?</p> <p>Ref: MHG 4.3</p> <p>Status: Recommended</p>	
<p>3. Have the team composition and responsibilities been documented?</p> <p>Ref: MHG 4.3</p> <p>Status: Recommended</p>	

<p>4. Is the scope of the HACCP plan defined and documented?</p> <p>Ref: HS 3 MHG 4.4</p> <p>Status: Required</p>	
<p>5. Is there a description or specification for the product?</p> <p>Ref: HS 3 MHG 4.5</p> <p>Status: Required</p>	
<p>6. Does the description cover intended use?</p> <p>Ref: HS 3 MHG 4.5</p> <p>Status: Required</p>	
<p>7. Have food safety objectives been formulated for the HACCP plan?</p> <p>Ref: HS 3 MHG 4.6</p> <p>Status: Required</p>	
<p>8. Is there a process flow description?</p> <p>Ref: HS 3 MHG 4.7</p> <p>Status: Required</p>	
<p>9. Does it reference relevant inputs and outputs at each process step? [If not, have the inputs and outputs been considered elsewhere?]</p> <p>Ref: MHG 4.7</p> <p>Status: Recommended</p>	

<p>10. Has the process flow information been confirmed as accurate?</p> <p>Ref: MHG 4.7</p> <p>Status: Recommended</p>	
<p>Review actual process against process flow information</p>	
<p>11. Has background information been obtained on hazards appropriate to the product?</p> <p>Ref: HS 3 MHG 4.9</p> <p>Status: Required</p>	
<p>12. Has effective hazard identification been carried out and documented for all raw materials, inputs and for each process step?</p> <p>Ref: HS 3 MHG 4.9, 4.15</p> <p>Status: Required</p>	
<p>13. Has the hazard identification considered variability of the process/operators?</p> <p>Ref: MHG 4.9</p> <p>Status: Recommended</p>	
<p>14. CCP determination — has the significance/level of unacceptability of each identified hazard/generic group of hazards at each process step been determined?</p> <p>Ref: HS 3 MHG 4.10</p> <p>Status: Required</p>	

Review hazard significance against selected food safety objectives	
<p>15. CCP determination — has a control measure(s) been identified for each significant/unacceptable hazard/generic group of hazards?</p> <p>Ref: HS 3 MHG 4.10</p> <p>Status: Required</p>	
<p>16. Is there documentation to support the CCP determination?</p> <p>Ref: HS 3 MHG 4.10, 4.15</p> <p>Status: Required</p>	
<p>17. Are unaddressed hazards identified and recorded?</p> <p>Ref: HS 3 MHG 4.9</p> <p>Status: Required</p>	
<p>18. Are unaddressed hazards highlighted for further consideration?</p> <p>Ref: MHG 4.9</p> <p>Status: Recommended</p>	
<p>19. Have measurable critical limits been determined and documented for all hazards covered by a CCP?</p> <p>Ref: HS 3 MHG 4.11, 4.15</p> <p>Status: Required</p>	
<p>20. Are the critical limits scientifically valid for the hazard?</p> <p>Ref: HS 3 MHG 4.11</p> <p>Status: Required</p>	

<p>21. Are the critical limits achievable, (practical) given the process?</p> <p>Ref: HS 3 MHG 4.11</p> <p>Status: Required</p>	
Review critical limits against food safety objectives	
<p>22. Is responsibility for monitoring defined and documented?</p> <p>Ref: HS 5.1 MHG 4.12, 4.15</p> <p>Status: Required</p>	
Check responsibilities with selected staff	
<p>23. Does monitoring supply enough information to ensure that the CCPs are under control? [Consider when, how and what including relationship to prevalence of hazard.]</p> <p>Ref: HS 3 MHG 4.12</p> <p>Status: Required</p>	
<p>24. Are monitoring procedures documented?</p> <p>Ref: HS 3 MHG 4.12, 4.15</p> <p>Status: Required</p>	
<p>26. Are monitoring results recorded?</p> <p>Ref: HS 3 MHG 4.12, 4.15</p> <p>Status: Required</p>	
Review monitoring activities and records against documented procedures	
<p>27. Are responsibilities for taking corrective action defined and documented?</p> <p>Ref: HS 5.1 MHG 4.13, 4.15</p> <p>Status: Required</p>	

Check responsibilities with selected staff	
<p>28. Are the corrective action procedures documented ?</p> <p>Ref: HS 3 MHG 4.13, 4.15</p> <p>Status: Required</p>	
View corrective actions taken against documented procedures	
<p>29. Does corrective action take place when monitoring trends indicate that the process is heading towards a critical limit?</p> <p>Ref: MHG 4.13</p> <p>Status: Recommended</p>	
<p>30. Does corrective action incorporate all the necessary components?</p> <p>Ref: HS 3 MHG 4.13</p> <p>Status: Required</p>	
<p>31. Are corrective actions followed up by appropriate rechecks?</p> <p>Ref: HS 3 MHG 4.13</p> <p>Status: Required</p>	
<p>32. Are corrective actions implemented as per documented procedures and outcomes recorded?</p> <p>Ref: HS 3 MHG 4.13</p> <p>Status: Required</p>	
<p>33. Are corrective actions signed off as completed?</p> <p>Ref: HS 3 MHG 4.13</p> <p>Status: Required</p>	

Review corrective action records against documented procedures	
<p>34. Are there adequate documented verification procedures? [Consider what, when, how, including validation, internal and external checks, calibration of equipment, HACCP plan review, product tests where relevant.]</p> <p>Ref: HS 3 MHG 4.14, 4.15</p> <p>Status: Required</p>	
Review actual verification activities against documented procedures	
<p>35. Are verification responsibilities defined?</p> <p>Ref: HS 5.1 MHG 4.14</p> <p>Status: Required</p>	
Check responsibilities with selected staff	
<p>36. Are the verification findings recorded?</p> <p>Ref: HS 3 MHG 4.14, 4.15</p> <p>Status: Required</p>	
Review verification records against documented procedures	
<p>37. Are document control provisions in place?</p> <p>Ref: HS 3</p> <p>Status: Required</p>	
<p>38. Is a retention period for records defined?</p> <p>Ref: HS 3 MHG 4.15</p> <p>Status: Required</p>	

Other comments:

VI.8 References

Anonymous (1992). Guidelines for Auditing Quality Systems. Part 1: Auditing. NZS 10011.1:1992. Standards New Zealand, Wellington.

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Appendix VII. The Interaction of HACCP and ISO Systems

Introduction

Hazard analysis critical control point (HACCP) is a scientifically based control system for ensuring food safety. It is based on a systematic assessment of hazards, focusing on preventative measures, critical areas of food safety and subsequently developing control systems. This moves process control away from a traditional approach of endpoint testing of product.

ISO 9000 series standards are designed with two objectives in mind:

- to provide a customer with the assurance that a quality product or service will be supplied;
- to give the supplier the minimum guidelines to allow the development of an appropriate quality management system which can demonstrate product or service quality assurance to the customer.

These standards make it quite clear that the users need to tailor the quality system to their individual needs. Practically, this means that a company wishing to achieve ISO certification has a wide choice of scope of application and this is reflected by the wide variation in certified ISO quality systems seen at present.

A HACCP food safety programme can provide the detailed requirements that are necessary to properly implement the food safety component of an ISO-based quality system. This is particularly useful where, after companies have established a formal quality system, they then require a HACCP plan for their product. This may be the result of a contractual requirement, a regulatory requirement or a voluntary need to add specific detail to their existing quality system as it applies to a particular product. Experience already gained by companies that have incorporated ISO will be invaluable in applying HACCP.

Both systems add the following advantages to a company's business:

- a rational approach to control of production parameters including food safety and quality;
- a collective discipline over all levels of the company's organisation;
- motivation of the workforce;
- increased assurance of conformity to set specifications (food safety and others).

Comparison of the components of ISO 9002 and HACCP

When HACCP is used to cover the food safety requirements of a process, it focuses on and provides essential elements which incorporate clearly defined requirements for implementation of process control to achieve food safety. This fits easily into a company's ISO quality system, particularly expanding the section on "Quality in production (process control)".

Consider the seven principles of HACCP.

These are:

- analyse hazards;
- determine critical control points;
- set critical limits for those critical control points;
- establish a monitoring programme for the critical control points to ensure control;
- establish corrective actions for when the critical control points are out of control;
- establish a verification programme that HACCP is effective;
- establish documentation and records to support HACCP.

These principles overlap with several components of the ISO 9000 series standards and this is demonstrated in Table 1.

A detailed comparison of HACCP and the ISO 9002 series standard is shown as follows:

Management responsibility

A. ISO 9002

The quality policy is defined, including objectives and company commitment; documented and applied to all levels of the organisation. The scope for the quality policy can be wide-ranging. Responsibilities, authority and inter-relationships of the organisation are defined and documented. Resource requirements must be identified and provided. A responsible representative for the quality system must be appointed to overview its implementation and maintenance. Management review (with records) of the quality system must occur at defined intervals for assurance of continuing suitability and effectiveness.

B. HACCP

Step 1 in designing the HACCP plan is obtaining senior management commitment and involvement in the HACCP programme. The HACCP team must be agreed upon and assembled (step 2). Resources for the HACCP plan design and implementation need to be agreed upon (steps 1 and 2). Responsibilities for food safety need to be outlined for all appropriate staff. The scope of the HACCP plan (step 3) needs to be clearly defined and will be primarily limited to food safety (although there is the potential to expand into other activities). Food safety objectives need to be set for the product and process (step 5). The interrelationships affecting the process and the responsibilities for the process steps are evaluated and verified (steps 6 and 7). Ongoing verification of all components of the HACCP plan is essential (step 13). Documentation and record keeping are also required (step 14).

Quality System

A. *ISO 9002*

A quality system must be established, documented, implemented and maintained, including a quality manual, procedures and structure of documentation consistent with the ISO standard. Quality planning must be included for all components of the quality system.

B. *HACCP*

Seven principles are defined which are essential to the application of HACCP and its implementation (steps 8-14 inclusive).

Contract review

A. *ISO 9002*

Documented procedures must be established, maintained and coordinated for contract review.

B. *HACCP*

All review requirements where they relate to food safety, including contract review, are considered as a component of the verification procedures of the HACCP plan (step 13).

Note: 4.4 *Design control* does not apply to ISO 9002.

Document and data control

A. *ISO 9002*

Documents and data must be established and maintained relating to the requirements of the standard. Document control procedures must be in place identifying the current revision status. Pertinent issues must be available and obsolete documents removed from use. Changes to documents and data must be reviewed and approved.

B. *HACCP*

Documentation and record keeping procedures are essential to HACCP application (step 14). Document control requirements are not stipulated.

Purchasing

A. *ISO 9002*

The quality system must ensure that purchased product conforms to specified requirements.

B. *HACCP*

Purchased products (where applicable to the scope of the HACCP plan) are considered in several parts of the HACCP design. These include step 4 which evaluates components of a product and associated food contact materials; step 8 which analyses the hazards (some

of which may be associated with purchased product), step 9 which determines whether a purchased product is a critical control point; step 10 which will set the critical limits for the purchased product; step 11 which monitors the purchased product and step 13 which verifies that the purchased product is meeting the requirements of the HACCP plan. Documentation and record keeping will be required (step 14).

Control of customer-supplied product

A. ISO 9002

Documented procedures must be in place to demonstrate control of verification, storage and maintenance of customer-supplied product. Unsuitable product must be notified to the customer.

B. HACCP

Customer-supplied product (where applicable to the scope of the HACCP plan) is evaluated as per the *Purchasing* section (4.6). Feedback to the customer is not stipulated.

Product identification and traceability

A. ISO 9002

Where appropriate, documented procedures must be established and maintained for identification of product at all stages from receipt through to installation. Where traceability is a specified requirement, unique identification of batches or individual product is required and is to be recorded. This is essential for product recall situations as well as in process retain and rework of nonconforming product.

B. HACCP

Initial product description and intended use (step 4) may consider the requirements (if applicable) for identification and traceability. Hazard analysis (step 8) would also consider the impact of lack of positive identification of the product in relation to food safety. Corrective action procedures (step 12) incorporate product identification requirements where applicable (e.g. for retained or reworked product). Verification that both complying and non-complying product is identified and traceable is expected (step 13) and the findings recorded (step 14).

Process Control

A. ISO 9002

Production, installation and servicing shall be identified, planned and controlled. Components must include:

- documented procedures;
- use of suitable equipment and environment;

- compliance with reference standards and codes, quality plans and/or documented procedures;
- monitoring and control;
- approval of processes/equipment;
- criteria for workmanship;
- suitable maintenance of equipment;
- suitable records.

B. HACCP

Designing and implementing a HACCP plan covers all process control requirements (see steps 5, 6, 7, 8, 9, 10, 11, 12, 13, and 14.)

Inspection and testing

A. ISO 9002

Inspection and testing activities must be carried out to verify that specified requirements are met for the product. Documentation and record keeping requirements must be met.

B. HACCP

Verification of the HACCP plan for each process and particular product must occur (step 13). Appropriate documentation and record keeping (step 14) are expected.

Control of inspection, test and measuring equipment

A. ISO 9002

Documented procedures must be available to control, calibrate and maintain inspection, test and measuring equipment used to demonstrate conformance of the product.

B. HACCP

Verification procedures (step 13) would ensure appropriate calibration of equipment used in demonstrating food safety conformance. Documentation and record keeping (step 14) supports this activity.

Inspection and test status

A. ISO 9002

Identification and maintenance of the inspection and test status of product is required by suitable means, indicating conformance or nonconformance.

B. HACCP

Similar requirements as outlined for *Product identification and traceability* are expected.

Control of nonconforming product

A. ISO 9002

Documented procedures are required to ensure that product not conforming to specified requirements is prevented from unintended use.

B. HACCP

Control of nonconforming product is an integral component of the HACCP principle (step 12) covering corrective action. Documentation of corrective actions to be taken and subsequent recordkeeping of actions taken are expected (step 14).

Corrective and preventive action

A. ISO 9002

Documented procedures for implementing appropriate corrective and preventive action are required.

B. HACCP

HACCP requires that corrective actions are documented for each process and the actions taken are recorded (step 12 and 14)

Handling, storage, packaging, preservation and delivery

A. ISO 9002

Documented procedures are required for handling, storage, packaging, preservation and delivery of product to ensure the integrity and quality of the product.

B. HACCP

Depending on the scope of the HACCP plan, these components would be addressed under steps 4, 5, 8, 9,10, 11, 12, 13 and 14 where relevant to food safety. The scope (step 3) would have to include delivery of product.

Control of quality records

A. ISO 9002

Documented procedures are required for identification, collection, indexing, access, filing, storage, maintenance and disposition of quality records. Quality records shall demonstrate ongoing conformance to specified requirements and the effective operation of the quality system.

B. HACCP

While not as specific in the requirements of quality records as ISO 9002, Principle 7 (step 14) stipulates that documentation and record keeping as appropriate to the application of the principles and the HACCP plan, is kept.

Internal quality audits

A. ISO 9002

Documented procedures are required for planning and implementing internal quality audits, verifying the effectiveness of the quality system.

B. HACCP

Internal audits are strongly recommended as a component of application of Principle 6 (step 13) covering verification activities.

Training

A. ISO 9002

Documented procedures are required to identify and provide for training of all personnel performing tasks relating to the quality system. Records are to be kept.

B. HACCP

Training is not covered specifically in the HACCP principles or design steps for HACCP plans. However, it is accepted as an essential prerequisite to HACCP implementation.

Servicing

A. ISO 9002

Servicing activities shall be covered by the quality system where it is a specified requirement.

B. HACCP

Servicing requirements are not covered specifically by HACCP.

Statistical Techniques

A. ISO 9002

Documented procedures shall be provided to cover application of statistical techniques where appropriate to the product and process.

B. HACCP

HACCP principles do not specify particular tools for use in establishing, monitoring and verifying product characteristics and process capability. However, statistical techniques are frequently used in HACCP applications as a monitoring tool (step 11).

Table 1. A comparison of ISO 9002 and HACCP components (note the numbering sequence of ISO headings correlates to the numbering in the standard)

ISO 9002	HACCP
4.1 Management responsibility	Step 1, 2, 3, 5, 6, 7, 13, 14
4.2 Quality system	HACCP principles
4.3 Contract review	Step 13
4.5 Document and data control	Step 14
4.6 Purchasing	Steps 4, 8, 10, 11, 12, 13, 14
4.7 Control of customer-supplied product	Steps 4, 8, 10, 11, 12, 13, 14
4.8 Product identification and traceability	Steps 4, 7, 8, 9, 12, 13, 14
4.9 Process control	Steps 5, 6, 7, 8, 9, 10, 11, 12, 13, 14
4.10 Inspection and testing	Steps 13, 14
4.11 Control of inspection, test and measuring equipment	Steps 13, 14
4.12 Inspection and test status	Steps 13, 14
4.13 Control of nonconforming product	Steps 12, 14
4.14 Corrective and preventive action	Steps 12, 14
4.15 Handling, storage, packaging, etc.	Steps 3, 4, 5, 8, 9, 10, 11, 12, 13, 14
4.16 Control of quality records	Steps 14
4.17 Internal quality audits	Steps 13
4.18 Training	Prerequisite requirement
4.19 Servicing	Not applicable
4.20 Statistical techniques	Step 11

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4.5 Document and data control	Step 14
4.6 Purchasing	Steps 4, 8, 10, 11, 12, 13, 14
4.7 Control of customer-supplied product	Steps 4, 8, 10, 11, 12, 13, 14
4.8 Product identification and traceability	Steps 4, 7, 8, 9, 12, 13, 14
4.9 Process control	Steps 5, 6, 7, 8, 9, 10, 11, 12, 13, 14
4.10 Inspection and testing	Steps 13, 14
4.11 Control of inspection, test and measuring equipment	Steps 13, 14
4.12 Inspection and test status	Steps 13, 14
4.13 Control of nonconforming product	Steps 12, 14
4.14 Corrective and preventive action	Steps 12, 14
4.15 Handling, storage, packaging, etc.	Steps 3, 4, 5, 8, 9, 10, 11, 12, 13, 14
4.16 Control of quality records	Steps 14
4.17 Internal quality audits	Steps 13
4.18 Training	Prerequisite requirement
4.19 Servicing	Not applicable
4.20 Statistical techniques	Step 11