A GUIDE FOR THE PREPARATION OF THE

MEAT SAFETY QUALITY ASSURANCE SYSTEM

(MSQA)

FOR

FRESH MEAT
&
PROCESSED MEAT PRODUCTS

SECOND EDITION

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INTRODUCTION

Meat Safety Quality Assurance (MSQA) Second Edition

The second edition of the MSQA Guide replaces the original Guide published in 1994. Continuing developments in the area of food safety generally, and meat safety in particular, have resulted in the need to revise the original MSQA system to make it contemporary.

What is MSQA?

MSQA is a system developed by AQIS. It is based on a modification of the ISO 9002:1994 standard and utilises the Codex Alimentarius Commission Hazard Analysis Critical Control Point (HACCP) methodology to address process control. It. aims to provide export meat establishments with an integrated system which, when applied rigorously, will assist in the production of safe meat and meat products for human consumption.

Why is MSQA Needed?

Domestically and internationally the safety of meat and meat products has and continues to attract attention from consumers and governments alike. Recent serious food poisoning incidents attributable to contaminated meat has further raised the need for systems governing meat production which properly and effectively control the hazards which can compromise meat safety.

As a regulator, AQIS has a responsibility to ensure that meat production systems result in safe to eat products, as free as possible from hazards potentially injurious to humans. Traditional approaches to process control have proven their inability to fully satisfy this goal. AQIS has been employing various quality assurance based systems in the meat industry for the past decade. It is clear that better meat safety outcomes can be achieved through the application of a systems approach to the identification, analysis, prevention and control of hazards.

During 1996 and 1997, the Meat Industry Council sponsored several projects involving the application of HACCP and quality assurance in selected meat establishments. As a result of AQIS's involvement in these projects, together with rapid developments internationally with the application of HACCP in meat processing, it became clear that the original MSQA needed further refinement.

This second edition of the MSQA Guide is the result of this process. It will assist in the design of a quality system which provides a framework for establishments to consistently achieve: good meat safety outcomes; compliance with AQIS requirements; and potentially improve overall business performance through standardised, rigorous management approaches.

STARTING A NEW MSQA OR CONVERTING AN EXISTING AQA

1. Operators wishing to develop a new MSQA or convert their existing AQA to MSQA should contact and discuss the new system or proposed changes with AQIS.

2. It is recommended that a timetable be established for conversion of existing AQAs with deadlines for the various stages, such as:

- planning and training

- an incremental approach to conversion or development may also be considered where one section of a plant is completed before starting on other sections.

3. When all the components of the company's MSQA system (as detailed in this Guide) have been written and implemented, the company may then apply to the Area Technical Manager for approval of the system.

4. Companies are encouraged to involve AQIS staff in the development of the system as they are soundly placed to offer advice on the best practices to be observed.

PART 1

THE COMPANY QUALITY SYSTEM

I. INTRODUCTION AND SCOPE OF THE MSQA SYSTEM

i) Part 1 of this Guide describes a framework in which to develop and design the operational procedures that will drive the MSQA system. Elements 1 to 21 set out the requirements of an MSQA system.

Companies may wish to develop an integrated manual which includes other aspects of a quality management program such as in-house company QA, AUS-MEAT language, as well as the MSQA system.

ii) All categories of export plants can operate under an MSQA system including:

- **abattoirs**
- **independent boning rooms**
- **meat processing establishments; and**
- **cold stores and freight handling facilities.**

The principles in this Guide may also be applied to the game meat, poultry and rabbit processing industries.

iii) The scope of operations that an MSQA can cover are:

- **receival and handling of livestock** - this includes identification, controls on chemical residues, cleanliness of stock and animal welfare
- **slaughter and dressing** - from stunning to the chiller
- **offal rooms** - from receival of green and red offal to carton strapping
- **chilling, freezing and cold storage** - of carcases, carcase parts, packaged meat and offal
- **boning rooms** - from carcase break-down to carton strapping
- **preparation and wrapping of carcases for export**
- **load-out/in** - for inter-establishment transfer and direct export
- **establishment and equipment sanitation** - all aspects
- **meat products**
- **animal food and inedible material** - including security; and
- **export certification.**

II. MSQA MANUAL FORMAT AND LAYOUT

Companies are required to document their quality system describing all procedures employed within the scope of the quality system which will ensure that:

- food safety issues are addressed
- importing country requirements are met; and
- AQIS requirements are met.

The company's quality system may cover operations outside the scope of the MSQA system. These will not be subject to audit by AQIS.

General Approach

The fundamental purpose of quality system documentation is to guide staff. To meet this purpose, documentation ***must*** be:

- useable
- easy to understand; and
- concise.

To achieve this:

- use tables, diagrams and other forms of easily assimilated instructions wherever possible

- group similar sections together, rather than scatter references

- cross-reference thoroughly, particularly recording sheets or logs

- identify recording sheets or logs by a title and form or document number, both of which should be quoted whenever the form is referred to; and

- clearly label flow charts, diagrams, tables and checklists for easy reference.

Manuals and Work Procedures

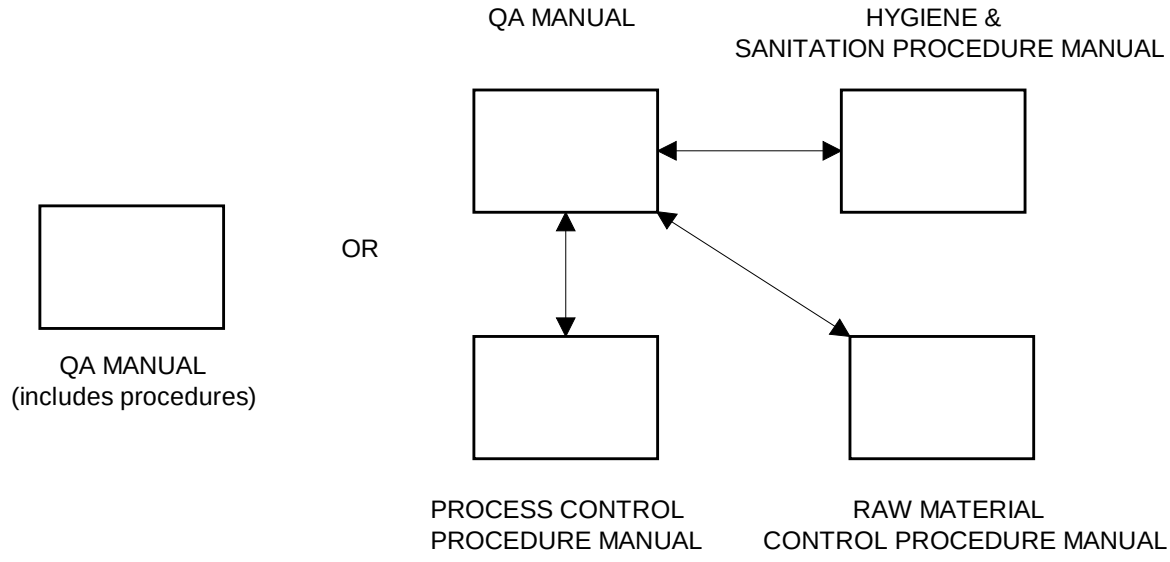
A ***quality manual*** is produced by a company to describe the quality management system at the establishment. It documents policies, procedures and controls which together assure the quality of the finished product.

The quality manual addresses all relevant elements of the quality system (taken from Part 1 of this Guide) by providing an ***outline*** on each element, stating how the quality system meets the requirements of that element. The quality manual acts as a guide or index to the quality system. The outline on each element then cross-references to detailed **standard operating procedures** or **work procedures** explaining exactly how things are done. These may be collated in separate procedures manuals and cross-referenced to the quality manual (see Figure 1).

For example, a slaughtering establishment could have separate manuals for processing, laboratory procedures, hygiene/sanitation, product recall, maintenance, etc. which are cross-referenced to the broad outline in the quality manual. However, for a very small company, the quality manual may be all-embracing, including all work procedures.

AQIS needs access to all quality system documentation at all times.

Figure 1: Examples of Quality System Documentation



Format

To facilitate amendments, all manuals should:

- be prepared in loose leaf form
- have a number and date on each page. The numbering system should preferably identify the total number of pages in each section (eg. Page 1 of 23); and
- include a table of contents.

Major sections or chapters should be tabbed for quick reference. A well structured manual assists all parties, being easier for company staff and auditors to use.

Given that the essence of the quality assurance philosophy is to strive for improvement, no manual is ever finalised.

Alignment of the MSQA System with ISO 9002:1994

An MSQA manual developed from this Guide will generally address most of the elements of ISO 9002:1994. This, however, in no way indicates ISO certification.

Companies seeking ISO 9002 certification may find the following table useful. A certified ISO 9002 system, which fully meets the requirements of this Guide, is acceptable to AQIS.

Table 1: Alignment between an MSQA Manual and the ISO Format

Clause No. in ISO 9001:1994	TITLE	Corresponding Section of the MSQA Guide
4.1	Management responsibility	
4.1.1	Quality policy	1
4.1.2	Organisation	4, 5
4.1.3	Management review	19.2
4.2	Quality system	6
4.3	Contract review	not included
4.4	Design control	not included
4.5	Document control	7
4.5.2	Document approval and issue	7.1
4.5.3	Document changes	7.1
4.6	Purchasing	8
4.7	Control of customer-supplied product	9
4.8	Product identification and traceability	10
4.9	Process control	11, Part 2
4.10	Inspection and testing	12
4.10.2	Receiving inspection and testing	12.2
4.10.3	In-process inspection and testing	12.3
4.10.4	Final inspection and testing	12.4
4.10.5	Inspection and test records	12
4.11	Control of inspection, measuring and test equipment	13
4.12	Inspection and test status	14
4.13	Control of non-conforming product	15
4.14	Corrective action	16
4.15	Handling, storage, packaging and delivery	17
4.16	Control of quality records	18
4.17	Internal quality audits	19
4.18	Training	20
4.19	Servicing	not included
4.20	Statistical techniques	21

1. COMPANY QUALITY POLICY STATEMENT

OBJECTIVE

The objective of this element is to provide authorisation for the implementation and commitment to the policies and procedures documented in the company's quality manual.

1.1 The Quality Policy Statement must be a clear statement describing the quality aims and commitment of the company and how the MSQA system is central to the effective operation of the establishment. It should be signed by a senior executive of the company with the authority to do so.

1.2 The following type of wording is suggested as part of the Quality Policy Statement:

"A procedure is in place to ensure that this quality policy is known and understood by all staff and implemented throughout the company. Company management and employees assess all procedures for efficiency and effectiveness in identifying and controlling defective operations before they affect product wholesomeness or export integrity."

1.3 The Quality Policy Statement may also incorporate Element 2 - Declaration by the Management.

- if this approach is used, all the requirements of Section 2 must be covered within the text of the Quality Policy Statement.

2. DECLARATION BY THE MANAGEMENT

OBJECTIVE

The objective of this element is to record the Chief Executive Officer's personal commitment to the operation of the arrangement with AQIS.

2.1 This statement must include the following:

- a signed commitment by the Chief Executive Officer on behalf of the Company to the quality system outlined in the manual; and
- a statement that the Export Control Act and subordinate legislation will take precedence over any company procedure or action.

3. SCHEDULE OF PROCESSES AND PRODUCTS

OBJECTIVE

The objective of this element is to provide a comprehensive list of all products manufactured by the company and market destinations.

3.1 The schedule identifies all products produced, packaging types and carton sizes, and market destinations.

3.2 Product lines that are produced infrequently must also be included.

4. COMPANY ORGANISATIONAL CHART

OBJECTIVE

The objective of this element is to provide a diagram and summary of those personnel with specific quality-related responsibilities, including the lines of reporting and communication between them.

4.1 It is essential that companies have a management structure which reflects a workable approach to MSQA:

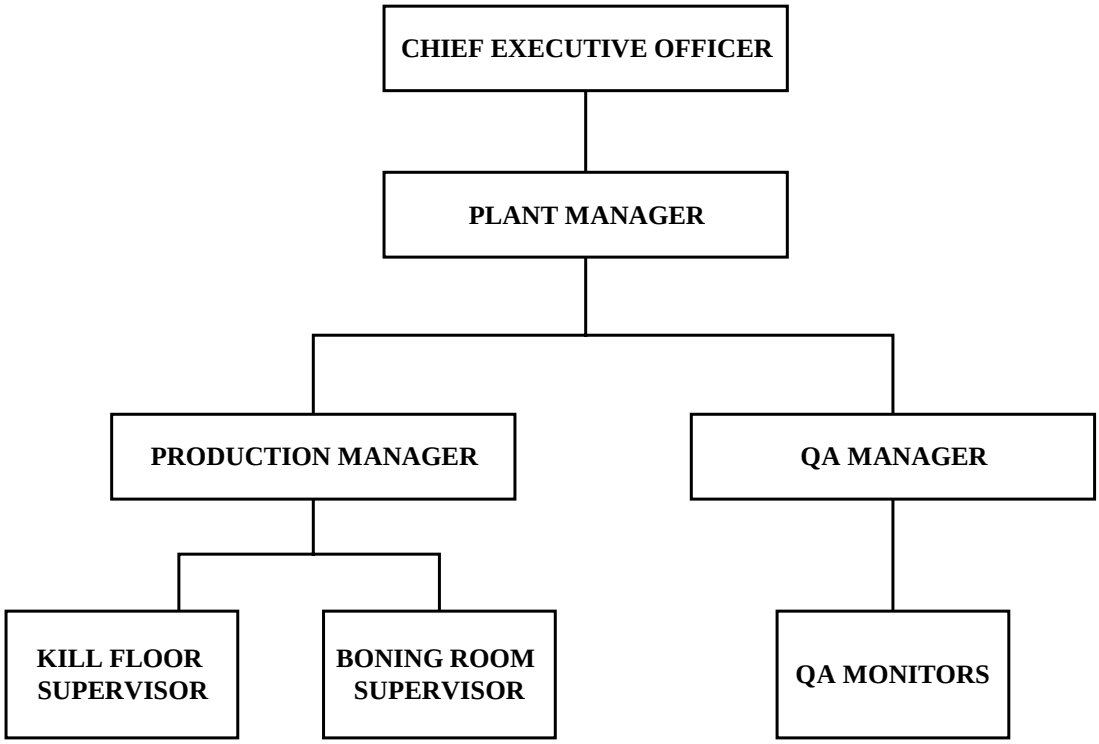
- AQIS recommends a structure where the QA Manager reports directly to the Plant Manager or above.

4.2 The company position responsible for ensuring satisfactory operations in each area of the plant under the MSQA system must be identified:

- deputies should also be considered and the positions from which they are drawn indicated.

4.3 The company management structure must be demonstrated by an organisational chart, such as in the example following.

Figure 2: Company Organisational Chart



5. FUNCTIONS AND DUTY STATEMENTS FOR ALL COMPANY STAFF CONTROLLING THE MSQA SYSTEM

OBJECTIVE

The objective of this element is to define the responsibilities of those staff who undertake quality-related functions. Supervisory responsibilities should also be defined.

5.1 The functions of all persons responsible for supervising the operation of the MSQA system should be fully described. These include:

- their MSQA duty statements, which should be brief and may be cross-referenced to details in other parts of the manual
- what responsibilities they have and what is expected of them; and
- the identification of back-up personnel.

5.2 Include a description of the functions of all other persons performing MSQA monitoring on the establishment, if not in the above.

5.3 This element should also include:

- a description of how QA staff and operational supervisors communicate
- a description of the problem-solving 'tree' of decision-making, if unclear from the organisational chart; and
- a procedure for replacement of the QA Manager.

5.4 It is recommended that a QA Manager be appointed and have at least the following responsibilities for the system:

- ensure that MSQA system documentation is maintained
- ensure that MSQA monitoring is effective
- inform AQIS quickly when serious problems are discovered
- follow up all product involved in problems and have it held until checked and cleared by the appropriate person(s)
- ensure that the regulatory standards are being achieved in all areas of the plant covered by the MSQA system and liaise with AQIS where doubt exists

- analyse the operation of the system regularly and examine feedback information; and

- use analysis and feedback from all sources to suggest changes to the MSQA system.

6. DESCRIPTION OF THE MSQA SYSTEM

OBJECTIVE

The objective of this element is to define the parameters of the quality system operated by the company.

6.1 Describe the company quality system including the following information:

- whether the company manual will be one or more units and how these relate to each other; and
- whether MSQA, Aus-Meat and company specifications are combined or separately presented for each step in production:
  - where combined, the MSQA aspects must be clearly identified.

6.2 Any special company definitions or terminology should be included under this element.

7. DOCUMENT CONTROL

OBJECTIVE

The objective of this element is to outline procedures that provide control over all quality-related documentation such as the quality manual, associated work procedures or instructions, legislation and AQIS documents. This element also sets out the methods for adding, amending or deleting documents as well as the approval for the issuing of documents.

Access, Approval and Amendments to the Company MSQA Manual

7.1 A list of controlled copies of the MSQA manual is necessary. All appropriate staff need to have access to a controlled copy of the MSQA manual or its relevant section(s).

7.2 Proposed variations to the manual must be submitted to the AQIS staff on-plant prior to their implementation. For plants without AQIS staff, notification of the variation is submitted to the Area Technical Manager. Prior AQIS approval of variations to the MSQA system are only required in certain circumstances and these are detailed in Part 32 of the Export Meat Orders.

7.3 The company shall have a documented procedure for the internal approval of changes to the MSQA system. This procedure should identify the company official authorised to approve changes.

7.4 Amended areas of the MSQA manual must be indicated in some way. An asterisk (*) in the margin, for example, is a good method. The bottom of the page should show the amendment number and date of the amendment, eg:

* Amendment No. 1/94, 1/1/97

* Amendment No. 2/94, 17/5/97, etc.

7.5 An example format of an Amendment Register is at Figure 3.

7.6 It is essential that the company has a method for withdrawing superseded forms and documents and uses a method to identify uncontrolled documents such as photocopies.

Access to AQIS Legislative Requirements and Other Notices

7.7 All company staff responsible for the operation of the MSQA system must have access to AQIS legislation and other official documents

- identify where these are kept and how the method for ensuring they are up-to-date.

AQIS Accountable Items

7.8 There must be a procedure for the security and control of accountable AQIS items relevant to the scope of the MSQA system at the establishment. This procedure must include:

- the name of the person(s) responsible for the security of controlled items
- the location of these items; and
- methods for the use, issue or completion (as appropriate) of controlled items.

Figure 3: An Example MSQA Amendment Register

Number	Date	Subject	Sub-Section or Page No.	Approval	Comments

8. PURCHASING

OBJECTIVE

The objective of this element is to define procedures that plan and control the purchase of goods and services used in conjunction with the preparation of products to ensure that they conform to AQIS and other regulatory requirements.

8.1 Companies document procedures for the purchase of materials including:

- approved chemicals (including those used by contractors)
- branding fluids/inks
- product contact packaging materials such as carton liners and poly bags
- outer product wrapping materials such as cartons, stockinet and hessian bags
- carcase tags and their attachment devices.

8.2 Companies also document procedures for the purchase of raw materials, including livestock. These should include:

- specifications for suppliers
- how suppliers are approved
- the list of approved suppliers
- checks done on receipt of raw materials or livestock.

8.3 Companies should also include procedures for the purchase of services. Examples may include:

- laboratory services
- pest control services
- cold storage
- transport.

9. CONTROL OF CUSTOMER-SUPPLIED PRODUCT

OBJECTIVE

The objective of this element is to define procedures that provide control over any product supplied by customers to ensure that those goods are handled according to customer requirements.

Customer-supplied product is any product or material that the company receives from a customer which is ultimately returned to the customer.

9.1 Companies need to describe their procedures for the receipt, handling, storage, use and delivery of customer supplied product. Examples of customer-supplied product are:

- livestock for a contract kill
- packaging materials and containers; and
- labels.

9.2 Procedures should outline what actions will be taken if a non-conformity with customer-supplied product arises, as well as details on how the customer will be informed of non-conforming, faulty, lost or damaged product.

10. PRODUCT IDENTIFICATION AND TRACEABILITY

OBJECTIVE

The objective of this element is to define procedures that identify and trace all product so that in the event of a product 'hold' or recall the product can be readily identified and, if necessary, withdrawn.

Product Identification

10.1 Companies will need to describe their methods for how product is identified at all stages of production. For example, from stock receival through holding pens, ante-mortem, slaughter, boning and load out.

10.2 The company should indicate how they will maintain control over certain product groups which are specifically referred to in AQIS requirements during production, handling and transport. Examples include:

- non-export product
- Halal product
- EU product
- grain fed product.

10.3 The identifying marks and the records relating to each consignment must allow the origin and the treatment history of the product to be traced:

- where these aspects or procedures are documented elsewhere in the manual, reference to that location need only be made under this element.

Product Recall

10.4 A product recall procedure needs to be defined so that any product can be readily traced and recalled. The following requirements should be addressed:

- a nominated person(s) who has responsibility for acting on all requests for traceback and recall, including the recovery, handling and disposal of product, and the follow-up and review of incidents
- a list of contacts if a recall needs to be initiated
- criteria for initiating a product recall; and
- procedure for informing AQIS.

11. PROCESS CONTROL

OBJECTIVE

The objective of this element is to define procedures for production which ensure the safety and wholesomeness of the product and the accuracy of labelling.

11.1 This section needs to describe the methods used to achieve the safe and wholesome production of meat and meat products. It is not necessary to provide all details but to broadly describe the methods used, including reference to HACCP.

11.2 It is recommended that operational details relating to HACCP be incorporated in appropriate procedures of the company MSQA system.

11.3 In addition, separate Standard Operating Procedures (SOPs) need to be developed and referred to under this element. SOPs must be prepared for the following activities:

- Personal Hygiene
- Cleaning and Sanitation
- Chemicals and Food Additives
- Pest Control
- Waste Disposal; and
- Water Supply.

11.4 SOPs may also be used to cover other activities such as:

- Maintenance including Preventive Maintenance
- Livestock Programs (including animal care statement and residues)
- Slaughter and Dressing
- Boning
- Offal
- Refrigeration
- Load-out/in.

11.5 Approved programs and other programs where applicable can be included in this section of the manual (eg. Halal, HGP, non-export meat, hot boning, warm cutting, etc.).

11.6 Detailed guidance on the application of HACCP and its relationship to good manufacturing practice, SOPs and pre-requisite programs can be found in Part 2 of this Guide.

Layout of Establishment

11.7 A simple plan of the establishment should be provided showing the location of major items of processing equipment, receivals and despatch areas, product preparation and processing areas, laboratories, etc.

12. INSPECTION AND TESTING

OBJECTIVE

The objective of this element is to define procedures that confirm the effectiveness of a particular process and the extent to which the product conforms to regulatory requirements.

Receival Inspection and Testing

12.1 Describe procedures which ensure that incoming raw material (eg. livestock, carcases, packaged meat, packaging materials, chemicals, etc.) are not used until confirmed as conforming to specifications. The degree of inspection or test of incoming goods at receival depends on the amount of control applying at Purchasing (refer to Element 8 of this Guide) ie. the existence of arrangements/agreements with suppliers.

12.2 Information on receival procedures and documentation and the person(s) responsible for the receival and inspection of raw materials must be documented. Specifications, agreements and arrangements must be made known by cross-references in the quality manual. The location of these specifications and who has responsibility for them should also be stated.

In-Process Inspection and Testing

12.3 Describe procedures which ensure that product is inspected and tested at appropriate points through the production chain for conformance with regulatory requirements. The criteria for acceptance or rejection of the product must be stated.

Final Inspection and Testing

12.4 Procedures for releasing or detaining stocks of finished product must be described. Criteria for acceptance/rejection should be stated. Procedures for segregation of detained product should be described.

12.5 Where finished product is received from other establishments, procedures for checking of documentation (transfer certificates, etc.) and product assessment (or other arrangements, if applicable) should be described. In both cases, frequency of checks and person(s) responsible for completing and signing recording forms should be indicated.

12.6 Staff member(s) responsible for product control and release should be indicated along with their levels of responsibility including the completion of documentation.

13. INSPECTION, MEASURING AND TEST EQUIPMENT

OBJECTIVE

The objective of this element is to define procedures for calibrating equipment to ensure that test results are valid.

13.1 The company needs to maintain a register setting out:

- all equipment used for inspection, measuring or testing (such as scales, thermographs, automatic chlorine controllers/recorders, all thermometers [portable and fixed], incubators, etc.)
- location of the equipment
- identifying marks, brands, serial numbers, etc.
- if applicable, staff to whom the equipment is issued.

13.2 Records must be kept of the dates of calibration of equipment:

- where calibration is not by an approved laboratory, such as a NATA accredited laboratory, the method of calibration must be described
- also describe the frequency of routine recalibration for key units of equipment and their back-up units; and
- it is recommended that the methodology and frequency of calibrating thermometers be sourced from a recognised authority.

13.3 Identify the company officials responsible for ensuring that each key piece of test equipment is giving accurate results.

13.4 All calibrated equipment must be identifiable and its calibration status apparent to the user. It must be handled and stored in a manner that will not adversely affect its accuracy.

13.5 Procedures for maintenance of key test reagents should also be described, where applicable, including:

- regular standardisation
- proper storage to minimise deterioration; and
- signing and dating of reagent bottles when initially opened or prepared.

14. INSPECTION AND TEST STATUS

OBJECTIVE

The objective of this element is to define procedures which identify the status of product throughout production to ensure that only product properly tested or inspected is used or despatched.

14.1 The company describes what methods are used to identify raw material (eg. livestock, incoming meat, ingredients, etc.) to indicate their inspection or test status.

14.2 The company describes what methods are used to identify each batch of product (eg. by labels, stickers, tags, physical location or other means) to indicate their inspection or test status:

- inspected / not inspected
- accepted / rejected
- on hold / retained, etc.

14.3 The company must always be able to distinguish material and product which has been tested from that which has not.

14.4 A specific person must be responsible for approving material and product for further processing.

15. CONTROL OF NON-CONFORMING PRODUCT

OBJECTIVE

The objective of this element is to define procedures which prevent the inadvertent use or release of nonconforming product (livestock, ingredients, packaging, intermediate product or final product).

15.1 Detail the methods used to retain/hold product known or suspected of not conforming with the critical limits set by the company or AQIS requirements. These will include returned product that is not the subject of a recall As examples:

- for conditions on use of **company retain tags**, include instructions or details on:
  - who can apply the tags
  - what happens to product retained under the tags
  - who can remove the tags; and
  - provide a completed copy of the tag(s).
- any other marking, branding or ticketing system used to control product on moving process lines or chains, etc.

15.2 This procedure should cover identification and segregation, reworking, retesting as appropriate and must specify the company official responsible. Problems and action taken should also be documented.

15.3 Detail company procedures for **disposition of non-conforming product** especially

- product that has lost its foreign country status
- product that has lost its export status; or
- product no longer fit for human consumption.

16. CORRECTIVE ACTION

OBJECTIVE

The objective of this element is to define procedures for addressing nonconforming product and investigating all incidents of nonconforming product and customer complaints, as well as reports and routine test results, to detect and eliminate real or potential causes of problems.

16.1 Companies must maintain procedures for:

- investigating the cause of non-conforming product and corrective action needed to prevent recurrence
- applying controls to ensure that corrective actions are taken and effective
- analysing all processes, work procedures, control measures and previous problems to detect and eliminate potential causes of non-conforming product
- initiating control measures to deal with problems to a level corresponding to the risks encountered
- implementing and recording changes to procedures resulting from corrective action; and
- recording the results of all investigations and actions taken.

17. HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY

OBJECTIVE

The objective of this element is to define methods that will prevent damage or deterioration of the product, particularly after final inspection and test.

Handling

17.1 The company should document methods of handling product that prevent damage or deterioration.

Storage and Preservation

17.2 Procedures must document how product is stored, preserved and controlled so as to minimise risk of contamination by rodents, insects, dust, etc. and to maintain microbiological quality.

17.3 Procedures for the storage and preservation of finished product should be described including:

- stock rotation
- monitoring of product and environmental conditions under controlled storage; and
- control of non-inspected product.

17.4 Labelling and/or other systems used to segregate different categories of finished product should also be included.

Packaging

17.5 The company should describe procedures it has in place for the following processes:

- *packaging* - materials used, where stored, procedures to ensure their fitness for use with food/meat products
- *packing* - who has responsibility, where carried out; and
- *marking and labelling of all packaging* - materials used, who has responsibility.

Delivery

17.6 The company should describe the procedures in place to prevent spoilage, contamination or damage to product in transit to the export destination and the relevant corrective action if this happens. These procedures may include such information as:

- temperature controls; and
- inspection of shipping containers before loading to check that they are clean and sound.

17.7 The company should describe procedures it has in place for handling product which is rejected at the export destination. These procedures should cover:

- tracing affected product
- recovery, re-treatment or disposal of product; and
- follow-up and review of problem.

17.8 Staff responsible for the coordination, handling and disposal of product needs to be documented.

18. MSQA RECORDS

OBJECTIVE

The objective of this element is to define procedures for the collection, collation, storage and ultimate disposal of all records (including computerised records) which form part of the MSQA system.

Records Needed

18.1 List in this section the names (titles or reference numbers) of each document or form that will be used to monitor or control the MSQA system. For example:

- monitoring sheets from each production area
- records of temperatures, water checks, etc.
- hygiene monitoring sheets, pest control reports, etc.

18.2 All forms and monitoring sheets must provide for the printed name and signature of the person(s) responsible for filling in the forms. Space for verification by quality personnel or supervisors should also be included, or some other acknowledgment that activities have been done correctly.

18.3 All records must be legible and easily retrievable.

Examples of Completed Copies

18.4 An example of a completed copy of each document used by the company must be included in this section to demonstrate its correct use.

How Long to Keep Records

18.5 MSQA records must be kept for at least two years, or the full life of the product, or longer if required under legislation.

Data Control

18.6 Wherever MSQA records and data are in computerised form procedures must be in place to safeguard the data, ensure its proper back-up and integrity and controls restricting access to only those company officials with a need to access, update, modify or report on the data.

19. INTERNAL AUDIT AND MANAGEMENT REVIEW

OBJECTIVE

The objective of this element is to define effective internal audit and management review procedures.

19.1 Properly conducted and recorded internal audits are an essential management tool to verify that the MSQA system is in place and effective. Results from these audits, fed into a management review process, help the company assess and improve the effectiveness of their own system. A healthy process of internal audits and management reviews demonstrates to auditors the company's commitment to the system and their abilities to self-correct.

19.2 For establishments with few employees, the internal audit and management review responsibilities may be directly assumed by senior management or merged with other duties.

19.3 The following paragraphs are intended as guidelines on the various types of internal audit and management review options that the company may adopt.

Internal Audit

19.4 Internal quality audits must be properly planned and scheduled, and cover every element of the quality system over a given period of time, normally 12 months.

- Large complex establishments or companies comprising groups of establishments should document and implement comprehensive audit procedures and methodologies similar to those used by AQIS for MSQA programs.

- An example of a method of internal auditing is through the use of 'rolling audits'. Rolling audits are scheduled so that all the different areas of the MSQA system are audited sequentially over a given period. The audit schedule should be planned and documented well in advance to ensure all areas are covered. As a guide, a different area could be audited monthly so that the entire system is audited once or twice within a year.

Management Review

19.5 To ensure the ongoing effective operation of the MSQA system there must be a documented plan in place for the regular review of the system at the managerial level. The management review procedure should state the frequency, method and personnel responsible for the review along with the person(s) responsible for maintaining records of the management review.

- A suggested method for management reviews is through regular meetings attended by senior management and quality personnel. These meetings should be held normally once a month.

- The management review meetings should review the results of internal and external audits, ATM and overseas country reviews, as well as the results of routine monitoring (especially that resulting from the HACCP Plan) and any incidents that have arisen since the previous meeting.

- It is advisable to include a checklist for the review of the MSQA records relating to all monitoring results, internal audits and corrective action.

- The structure of the management review meetings should be documented in the manual clearly stating who is responsible for recording the actions and outcomes of the meeting. The minutes of these meetings should be retained and be available to AQIS staff on request.

19.6 The management reviews should develop confidence that specifications are being met or exceeded under the MSQA system or a realisation by the company that the MSQA system needs amendment.

Feedback of Results to Improve the MSQA System

19.7 Feedback of information from monitoring is essential to the following three areas:

- *Company Management*: this allows resource allocation and planning for changes in problem areas so that improvements resulting in reliable compliance with AQIS requirements are made.

- *MSQA Operations:* feedback to operational areas is essential for the viability of the system as it identifies inadequate or excessive monitoring.

- *AQIS:* to enable repetitious problems to be handled more effectively through a cooperative approach. Good feedback can demonstrate that an MSQA system is working effectively.

19.8 Daily and weekly analysis of the monitoring results provides an early warning system for emerging problems in a particular area.

19.9 Weekly meetings with AQIS staff are recommended for comparison of AQIS verification findings with company monitoring results and to 'post-mortem' the way problems were dealt with during the week.

19.10 Analysis also allows good results to be fed back to the workers so that a balanced view is given where a job is well done.

20. COMPANY TRAINING FOR EMPLOYEES AND STAFF

'A vital part of MSQA'

OBJECTIVE

The objective of this element is to define the company's training program for all staff.

20.1 A well-planned and implemented training program for all employees is the only way to ensure that staff have the necessary skills and knowledge to perform their functions to the standard that is expected of them under an MSQA system.

Introduction

20.2 Training employees to perform their job may sound like a fundamental requirement but it is often overlooked, especially in important aspects of the business such as hygiene.

20.3 It is recommended that all employees be given a copy of their Work Instruction and that they fully understand what is expected of them.

Training Program

20.4 The following information gives companies some guidance for a comprehensive training program. Although companies may not have this level of detail in place, it is acceptable to accurately describe the company's current training program (if any).

20.5 Where companies have a separate training manual, only a reference to that manual is required under this element.

Five Groups of Training

1. Introductory Training for New Employees

- All new employees should receive initial training in general and personal hygiene requirements, the significance of export registration, the purpose of AQIS presence and function, the importance of overseas reviewers, as well as other company related matters.

2. Training for Permanent Employees

- Whether an employee has done the same job for 20 years, or an existing employee is changing jobs, it is still necessary for them to be taught the right way to do the job ('best practice' techniques) based on a written Work Instruction incorporating the control measures.

- Each employee should be given a copy of their Work Instruction which also includes their general and personal hygiene requirements.

- QA staff should be made aware of which employees are doing new jobs, especially if they are working at high risk jobs, to ensure they are proficient.

3. Training for Special Jobs

- Some jobs are high risk jobs and need to be performed at a high standard, particularly where small mistakes may permanently affect product.

- The training for these jobs needs to be thorough and the Work Instruction precisely detailed to achieve the required standard.

- The supervisor / training officer giving the training must ensure that employees selected to do these special jobs can cope with this responsibility.

4. Training for Supervisors

- All supervisors should be trained in and have an understanding of HACCP and the concepts of Quality Assurance:

  – at least one company person should have a good understanding of these areas and be able to teach others.

5. Reinforcement Training

- Regular reinforcement of all employees' Work Instructions is needed, especially where poor knowledge and/or understanding is highlighted during monitoring of the operations.

Training Records

20.6 Records need to be kept for each employee and supervisor indicating the courses they have been on and how many hours training they have received.

Recommended Company Training Needs Summary

Make sure each employee has access to and understands their *Work Instruction*, including General and Personal Hygiene, and test them.

Decide how new starters will be trained and who is responsible for training.

Decide who will give basic training to each permanent employee.

Decide how training in individual Work Instructions will occur and who is responsible.

Give special training to employees in key jobs.

Plan appropriate training for QA staff.

Arrange HACCP and general QA training for supervisors.

Identify at least one person to deliver training sessions for employees.

21. STATISTICAL TECHNIQUES

OBJECTIVE

The objective of this element is to define appropriate statistical methods or sampling plans used in the MSQA system.

21.1 Statistical techniques are utilised where numerical data is gathered and used to assess a product or process. Companies should identify appropriate statistical techniques that will be used to monitor raw material, product quality and process performance.

21.2 Companies should document the trend analysis of results of product and process monitoring.

21.3 Procedures should outline the implementation and control of the use of these statistical methods, as well as the person(s) responsible for the analysis of the results.

21.4 All statistical techniques must be soundly based and capable of being shown to be valid. The sampling program developed for the Meat Hygiene Assessment program is an example of an acceptable statistical method or sampling plan.

PART 2

THE APPLICATION OF

HACCP

and

GOOD MANUFACTURING PRACTICE

22. INTRODUCTION

The HACCP system described in this Part is closely based on the model published by the Joint FAO/WHO Codex Alimentarius Commission.

In this Part, guidance is provided on building effective foundations to support a meat safety system employing HACCP. This is achieved through first implementing a series of pre-requisite programs representing at least good manufacturing practice. Detailed guidance is also provided on the application of the five preliminary steps and the seven principles of HACCP.

At the outset, it needs to be stressed that HACCP should, for the purposes of MSQA, be restricted in its application to only those matters which clearly relate to food safety. Excessive numbers of critical control points lead only to unnecessarily complex monitoring systems which tend to offer less than optimal meat safety outcomes.

Application of the recommended approach in this Part should result in an integrated system capable of delivering sound meat safety outcomes in a manageable framework.

23. DEFINITIONS

1. CCP Decision Tree: A sequence of questions to assist in determining whether a control point is a CCP.

2. Continuous Monitoring: Uninterrupted recording of data such as temperature on a thermograph.

3. Control:

   (a) To manage the conditions of an operation to maintain compliance with established criteria.

   (b) The state where correct procedures are being followed and criteria met.

4. Control Measures: Any physical, chemical or other factor that can be used to control an identified hazard.

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

6. 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.

7. Critical Limit: A value which separates acceptability from unacceptability.

8. HACCP Plan: The written document, based upon the principles of HACCP, describing the procedures for assuring the control of a specific process.

9. HACCP System: The result from the implementation of the HACCP Plan.

10. MSQA Team: The group of people responsible for developing a HACCP Plan.

11. HACCP Plan Review: One aspect of verification in which a documented periodic review of the HACCP Plan is done by the MSQA team with the purpose of modifying the HACCP Plan as necessary.

12. Hazard: A biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

13. Monitor: To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

14. Non-Conformity: A deviation from accepted procedures or critical limits.

15. Pre-Requisite Programs: Procedures, including Good Manufacturing Practice and Best Practice, that address operational conditions providing the foundation for the HACCP system.

16. Random Checks: Observations or measurements which are performed randomly to supplement the monitoring evaluations required by the HACCP Plan.

17. Risk: An estimate of the likely occurrence of a hazard.

18. Sensitive Ingredient: An ingredient known to have been associated with a hazard and for which there is reason for concern.

19. Severity: The seriousness of the effect(s) of a hazard.

20. Step: A point, procedure, operation or stage in the food system from primary production to final consumption.

21. Target Levels: Company specifications which are more stringent than critical limits and which are used by an operator to reduce the risk of a deviation from critical limits.

22. Validation: The process of collecting and evaluating scientific and technical information to determine if the HACCP Plan, when properly implemented, will effectively control the identified hazards.

23. Verification: The use of methods, procedures or tests in addition to those used in monitoring, to determine if the HACCP system is in compliance with the HACCP Plan and/or whether the HACCP Plan needs modification and revalidation.

24. Work Instruction: Job description, in-line specification, work procedure.

24. PRE-REQUISITE PROGRAMS

The production of safe meat requires that the HACCP system be built upon a sound foundation of pre-requisite programs.

These pre-requisite programs, in the form of Standard Operating Procedures (SOPs), provide the basic environment and operating conditions necessary for the production of safe, wholesome meat. They incorporate Good Manufacturing Practice and, wherever possible, Best Practice within their framework.

As a minimum, SOPs must be developed and implemented for the following activities:

- Cleaning & Sanitation
- Personal Hygiene
- Waste Disposal
- Water Supply
- Pest & Vermin Control
- Chemicals including Additives

Additionally, SOPs for the following activities are recommended as they provide greater clarity of operation for what are very important aspects of ensuring safe meat production and ongoing system viability:

- Maintenance including Preventive Maintenance
- Livestock including Animal Care
- Slaughter
- Boning
- Refrigeration
- Product Traceability & Recall
- Management Review
- Internal Audit
- Training
- Calibration

It is recommended that SOP documentation utilise the following format. This format is not compulsory but alternative approaches must be able to demonstrate their adequacy and effectiveness.

Structure for Standard Operating Procedures

- Purpose
- Scope
- Definitions
- Background
- References
- Methodology
- Monitoring
- Responsibility
- Corrective Action
- Records
- Verification

It is necessary to supplement SOPs with specific work instructions for individual or specialised tasks. For example, where cleaning gangs are employed, individual cleaners may require their own work instructions which detail what they do and how this relates to the overall SOPs.

25. WORK INSTRUCTIONS

As part of this process, it is also a requirement that specific instructions for each work station in the production process are prepared and implemented.

These work instructions should:

- describe the tasks to be performed
- identify the order, if necessary, in which operations are to be performed
- detail corrective action to be taken should errors occur
- highlight the critical operations, if any
- define the boundary between acceptable and unacceptable for the task to be performed; and
- be written in simple language familiar to the operator.

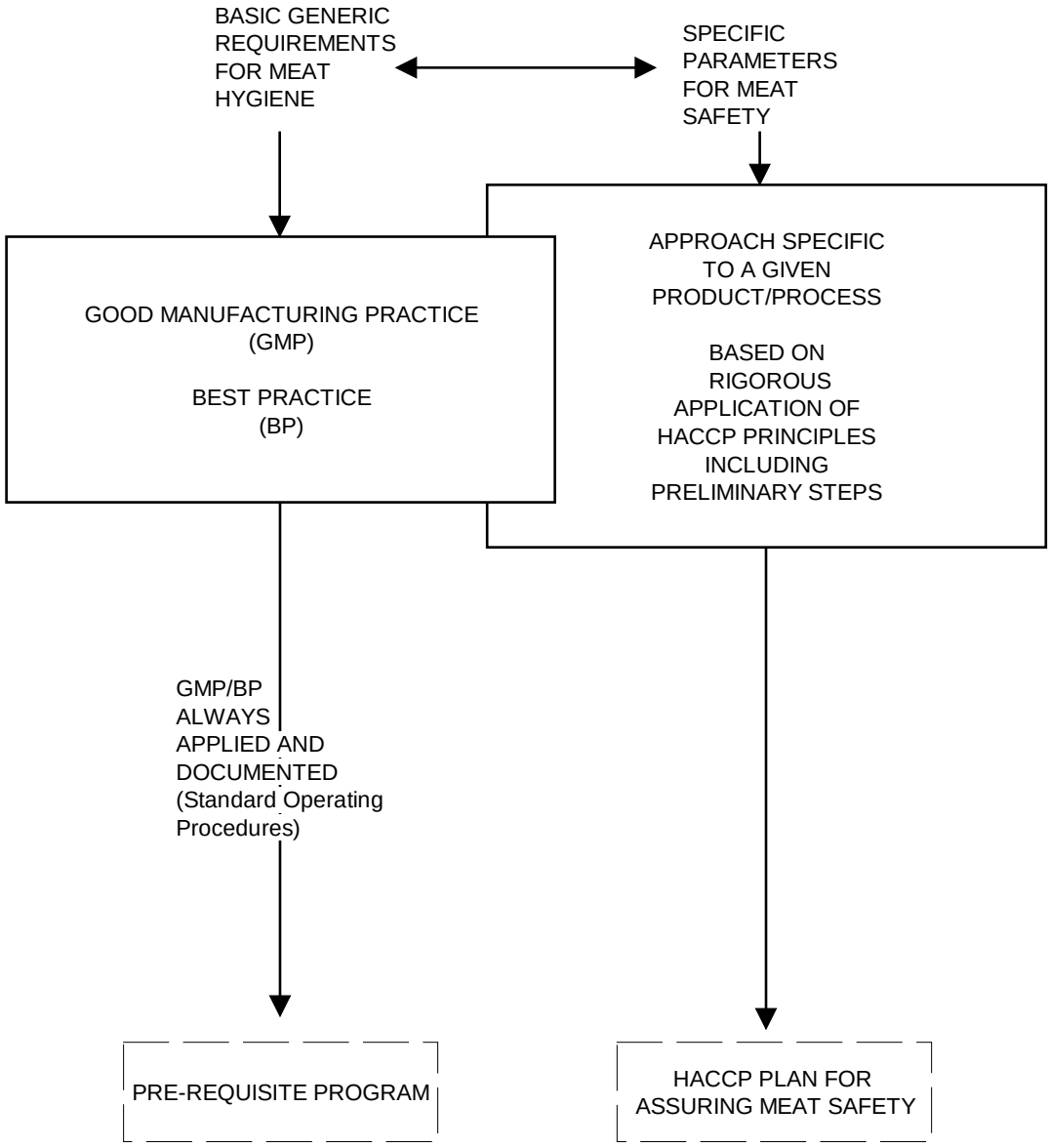
26. MONITORING

SOPs and work instructions need to be monitored to ensure their observance. The Meat Hygiene Assessment (MHA) program provides a basic framework for this monitoring.

This process should be documented and should normally be included in the company's internal audit program (refer to Part 1, element 19). This process also provides the avenue for ongoing analysis and improvement of the organisation's operations.

Figure 4 is a diagrammatic representation of the relationship between good manufacturing practice and HACCP.

Figure 4: Relationship Between Good Manufacturing Practice and HACCP



27. PURPOSE AND PRINCIPLES OF HACCP

HACCP is a systematic approach to the identification, evaluation and control of food safety hazards based on seven principles (see Figure 5). HACCP is applied to each different process at an establishment.

PRINCIPLE No. 1

Conduct a Hazard Analysis

PRINCIPLE No. 2

Identify the Critical Control Points (CCPs) in the Process

PRINCIPLE No. 3

Establish Critical Limits at Each CCP

PRINCIPLE No. 4

Establish Monitoring Procedures

PRINCIPLE No. 5

Establish Corrective Action To Be Taken When Monitoring Indicates That There is a Deviation from a Critical Limit

PRINCIPLE No. 6

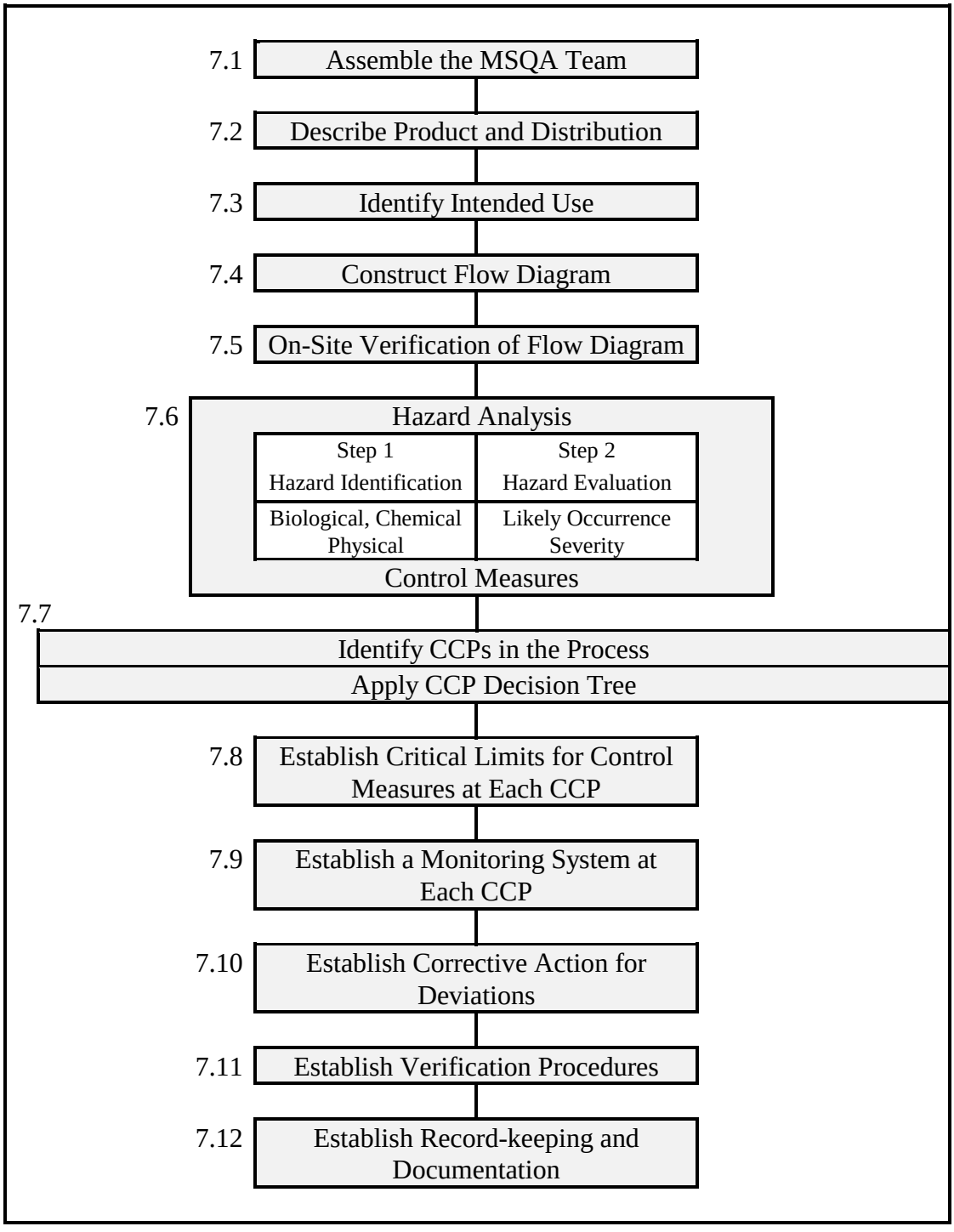
Establish Verification Procedures

PRINCIPLE No. 7

Establish Record-Keeping Procedures

The following pages describe what is required in addressing each of these principles when developing the HACCP component of the MSQA system.

Figure 5: Logic Sequence for Developing a HACCP Plan



28. DEVELOPING THE HACCP PLAN

In order to apply the first principle of HACCP, the following five preliminary steps must be addressed:

28.1 Assemble the MSQA Team
28.2 Describe the Product and the Method of Distribution
28.3 Identify the Intended Use and Consumers of the Product
28.4 Construct a Flow Diagram Which Describes the Process
28.5 Verify the Flow Diagram

In addressing each of these steps, documentation must be created which provides evidence of the completion of these steps. This information needs to be made available to AQIS auditors upon request.

28.1 Assemble the MSQA Team

- The first step in formulating a HACCP Plan is to assemble an MSQA team consisting of individuals with knowledge and experience appropriate to the product and process. It is the team's responsibility to develop each step of the HACCP Plan. Ideally, the team should possess multi-disciplinary skills (eg. engineering, production, sanitation, quality assurance, food technology, marketing, etc.).

- The MSQA team may require external assistance from consultants with expertise in public health risks associated with products and processes.

- Due to the technical nature of some of the information required for a hazard analysis, it may be necessary for an expert to verify the completeness of the hazard analysis and the HACCP Plan. These individuals should have the knowledge and experience to:

  a) identify and analyse hazards

  b) recommend controls, standards, and procedures for monitoring and verification

  c) recommend appropriate corrective actions when a deviation occurs; and

  d) recommend appropriate courses of action if important information is unknown.

28.2 Describe the Product and the Method of its Distribution

- The MSQA team must describe the product fully, including the formulation where appropriate, and the type of packaging.

- The method of distribution should be described, along with information on whether the product is to be distributed frozen, chilled or in shelf-stable form.

- Consideration should also be given to the potential for abuse in the distribution chain and by end-users.

28.3 Identify the Intended Use and Consumers of the Product

- Consumers may be the general public or a particular segment of the population, including infants, the elderly, and the immuno-compromised. It is important that the intended use of the product by consumers be identified. For example, it should be clearly stated whether the product is to be consumed raw or partially cooked. Such issues will affect the likely hazards to be considered later in the process.

28.4 Construct a Flow Diagram Which Describes the Process

- A flow diagram should provide a clear, simple description of all steps in a production process. The diagram:

  – is essential to the success of the MSQA team's work; and

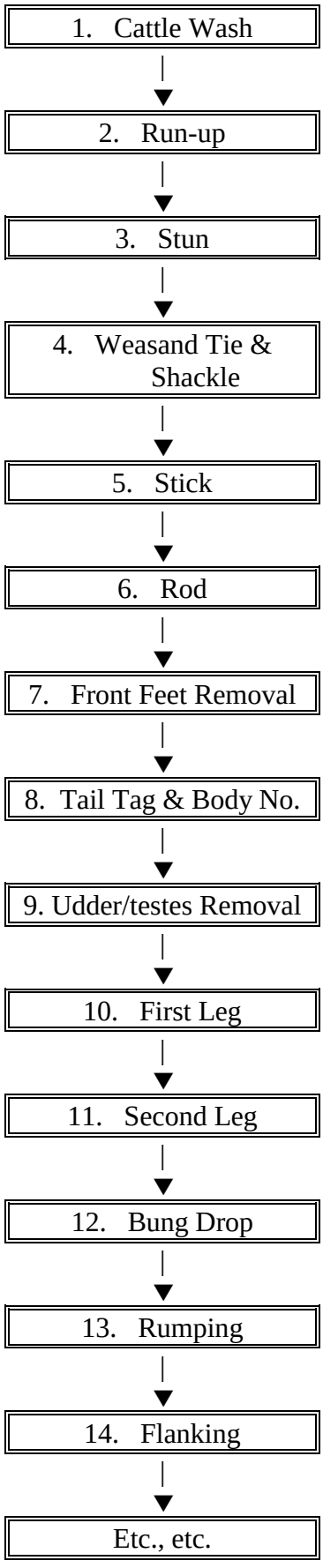
  – serves as a reference for others (eg. auditors and customers) who must also understand the process.

- In addition, the flow diagram can include steps in the product chain which occur at an establishment before and after processing. For simplicity, the flow diagram can consist solely of words (see Figure 6).

28.5 Verify the Flow Diagram

- The MSQA team must test the accuracy and completeness of the flow diagram by confirming the process step-by-step. The diagram should be modified as necessary.

Figure 6: Example of a Simple Flow Diagram for Part of a Beef Kill Floor



28.6 Principle No. 1: Conduct a Hazard Analysis

- A thorough hazard analysis is the key to developing an effective HACCP Plan.

- A hazard is defined as a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

- The hazard analysis has three purposes:

  1) identify significant hazards and associated control measures
  2) modify a process or product to improve safety; and
  3) provide a basis for determining CCPs in Principle 2 (section 7.7).

- Hazard analysis is a two step process involving:

  1) hazard identification; and
  2) hazard evaluation.

- The objective of hazard identification is to prepare a list of potential hazards associated with each process step. The hazard identification is assisted by asking a series of questions appropriate to the specific process and establishment.

  – See Appendix A for lists of example hazard analysis questions applicable to various types of plants and operations.

- The MSQA team decides in the hazard evaluation step which potential hazards must be addressed within the HACCP Plan. Each potential hazard is assessed by considering risk and severity:

  – the method of preparation, transportation, storage, consumers and the product's intended use should be carefully considered during the evaluation of each hazard

  – this process often requires assistance from a member of the MSQA team with relevant scientific training.

- Table 2 provides examples of using a logical sequence in conducting a hazard analysis.

- The MSQA team must then consider what control measures, if any, exist which can be applied for each hazard

  – more than one control measure may be required to control a specific hazard

  – more than one hazard may be controlled by a specified control measure; and

  – control measures may include existing SOPs or work instructions.

- Upon completion of the hazard analysis, the hazards associated with each step in the flow diagram that the HACCP Plan must address should be listed along with the appropriate control measures (see Tables 3 and 4).

Table 2: Examples of How the Stages of Hazard Analysis are used to Identify and Evaluate Hazards*

Hazard Analysis		**Frozen cooked beef patties for food service**	**Frozen pre-cooked, boned chicken for further processing**
Stage 1 Hazard Identification	*Determine potential hazards associated with product*	Enteric pathogens (ie., E.coli 0157:H7 and Salmonella).	Staphylococcus aureus in finished product.
Stage 2 Hazard Evaluation	*Assess severity of health consequences if potential hazard is not properly controlled.*	Epidemiological evidence is that these pathogens cause severe health effects including death among children and elderly. Undercooked beef patties have been linked to disease from these pathogens.	Certain strains of S.aureus produce an enterotoxin which can cause a moderate foodborne illness.
	Determine likelihood of occurrence of potential hazard if not properly controlled.	E.coli 0157:H7 is of very low probability and salmonellae is of low to moderate probability in raw meat.	Product may be contaminated with S.aureus due to human handling during boning of cooked chicken. Enterotoxin capable of causing illness will only occur as S.aureus multiplies to about 1,000,000/g. Operating procedures during boning and subsequent freezing prevent growth of S.aureus, thus the potential for enterotoxin formation is very low.
	Using information above, determine if this potential hazard is to be addressed in the HACCP Plan.	The MSQA team decides that enteric pathogens are hazards for this product. **Hazards must be addressed in the Plan.**	The MSQA team decides that potential for enterotoxin formation is very low. However, it is still desirable to keep the initial number of S.aureus organisms low. Employee practices that minimise contamination, rapid freezing and handling instructions have proven adequate to control this potential hazard. **Potential hazard does not need to be addressed in the Plan.**

* For illustrative purposes only. The potential hazards identified may not be the only hazards associated with the products listed. The responses may be different for different establishments.
Adapted from the National Advisory Committee on Microbiological Criteria for Foods Guidelines (14August 1997)

28.7 Principle No. 2: Identify the CCPs in the Process

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

- The information developed during hazard analysis in the previous section (7.6) should enable the MSQA team to identify which steps in the process are CCPs.

  – Determination of a CCP is facilitated by use of a CCP Decision Tree (examples of decision trees are given in Figures 7 and 8).

  – A Decision Tree is only a tool to assist in determining a CCP and does not substitute for expert knowledge.

- Important points when using a CCP Decision Tree:

  – the Decision Tree is used after the hazard analysis

  – the Decision Tree is used at steps where a significant hazard has been identified

  – a subsequent step in the process may be more effective for controlling a hazard and may be the preferred CCP; and

  – more than one step in a process may be involved in controlling a hazard.

- Examples of CCPs include thermal processing, chilling and testing for metal contaminants.

- CCPs must be fully documented (see Tables 3 and 4 for examples).

- Different establishments preparing the same product can differ in the risk of hazards and the points, steps or procedures which are CCPs

  – this can be due to differences in each plant such as layout, equipment, techniques, selection of ingredients or the process used.

- Generic HACCP Plans can serve as useful guides. However, it is essential that the unique conditions within each plant be considered during development of a HACCP Plan.

Figure 7: Example 1 of a CCP Decision Tree

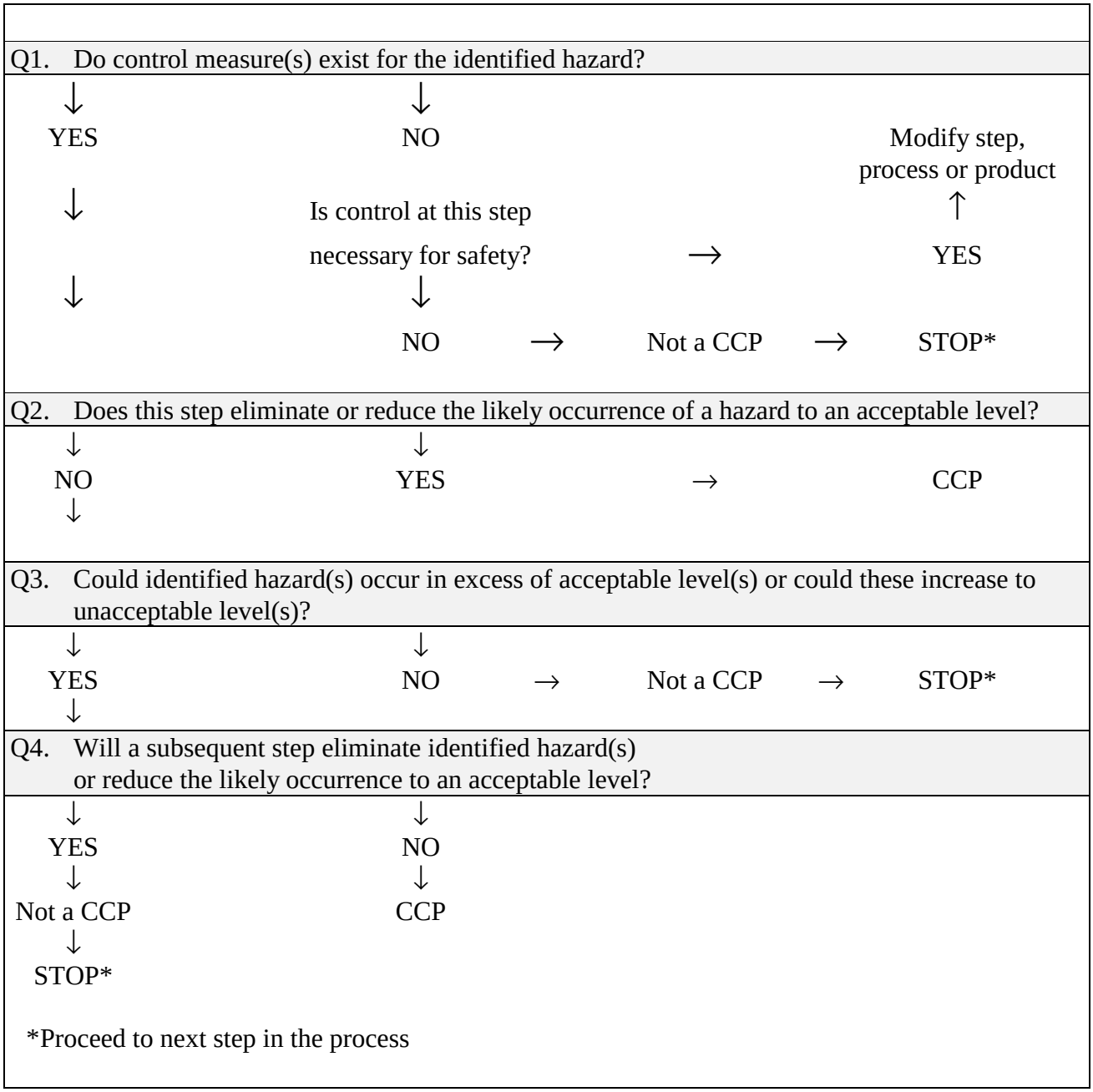


Figure 8: Example 2 of a CCP Decision Tree

Q1. Does this step involve a hazard of sufficient risk and severity to warrant control?

↓ ↓

YES NO → Not a CCP

↓

Q2. Does a control measure for the hazard exist at this step?

↓ ↓

YES NO Modify the step, process or product

↓ ↓ ↑

Is control at this step

Necessary for safety? → YES

↓ ↓

NO → Not a CCP → STOP*

Q3. Is control at this step necessary to prevent, eliminate, or reduce the risk of the hazard to consumers?

↓ ↓

YES NO → Not a CCP → STOP*

↓

CCP

*Proceed to next step in the process.

Table 3: Examples of Decision Making Process in Determining Critical Control Points at Selected Steps in Pig Slaughter

Process Step	Potential hazard introduced, controlled or enhanced at this step	Is the potential food safety hazard significant?	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is this step a critical control point (CCP)?
Dehairing/ Singeing/ Polishing/ Shaving	C: None identified P: None identified B: Salmonella verotoxigenic E.coli	B: Yes	There is a lack of scientific evidence to show that singeing is a control for pathogens. Singeing may reduce but not eliminate contaminants. Significant increases in cross contamination may occur during dehairing and polishing. Polishing will evenly distribute and may even add to the microbial load. Singeing, polishing and shaving have not been sufficiently studied to justify as a CCP. There are other measures further in the process that better control contamination.	Standard Operating Procedure contains detailed instructions for the cleaning and sanitation of equipment including disassembly in accordance with manufacturers' directions. Equipment included in microbiological testing schedule for SOP. Hazards controlled at later steps in the process • previseration wash • trimming visually contaminated carcases • final wash • refrigeration.	No
Bunging	C: None identified P: None identified B: Salmonella verotoxigenic E.coli	B: Yes	Possible faecal contamination from procedure. Even though rupture may occur on some carcases it is impossible to take effective corrective action at this step. It is recommended that improved dressing procedures (bags, plug, etc.) be investigated.	Work Instruction in Standard Operating Procedure details: • correct sanitary procedure for task including use of hook • sanitation practices for hands, equipment and protective clothing between carcases and when contaminated • procedures for identifying carcases if visually contaminated. All workers undertaking this process step are fully trained in all procedures in the Work Instruction and experienced in their performance.	No **[This step may be a CCP in some HACCP Plans]**
Chill	C: Lubricants P: Rail dust Condensation B: Salmonella verotoxigenic E.coli	C: No P: No B: Yes	C & P: Preventive maintenance and Cleaning SOPs to prevent contamination. Control program to eliminate condensation. B: Minimise growth of carcase pathogens through temperature control. There is insufficient scientific data currently available to set specific time/temperature limits as it relates to food safety. Factors such as initial microbial load; chiller temperature; chilling method; air flow; carcase spacing; carcase size; fat cover; chiller management practices; all contribute to highly variable rates of chilling and need addressing on an individual plant basis.	Rapid temperature reduction on carcase surface and in muscle	Yes

For illustrative purposes only.

Table 4: Examples of Decision Making Process in Determining Critical Control Points at Selected Steps in Beef Slaughter

Process Step	Potential hazard introduced, controlled or enhanced at this step	Is the potential food safety hazard significant?	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is this step a critical control point (CCP)?
Hide removal: First Leg Second Leg Udder removal Feet removal Dehorning Head skinning Rumping Flanking	C: None identified P: None identified B: Salmonella verotoxigenic E.coli	B: Yes	Hide contamination is a known source of pathogens. However, there is no scientific evidence to show that sanitary hide removal procedures control pathogens.	Work Instruction in Standard Operating Procedure details: • correct sanitary procedures for all tasks (eg. spear cut to open hide) • sanitation practices for hands, equipment and protective clothing between carcases and when contaminated (eg. using two knife technique) • procedures for identifying carcases visually contaminated. All workers undertaking this process step are fully trained in all procedures in the Work Instruction and experienced in its performance. Contamination on hides minimised by requiring all animals to arrive at the establishment in a clean state and, additionally, by effectively cleaning livestock immediately prior to slaughter in accordance with the Standard Operating Procedure for livestock control.	No **[This step may be a CCP in some HACCP Plans]**
Evisceration: Weasand plug Brisket split Rod and occlude weasand Bunging Bladder removal Gastrointestinal (GI) tract removal Pluck removal Liver removal	C: None identified P: None identified B: Salmonella verotoxigenic E.coli	B: Yes	B: Contents of the gastrointestinal (GI) tract are potential source of enteric pathogens; however, sanitary dressing procedures should address contamination at this point.	Work Instruction in Standard Operating Procedure details: • correct sanitary procedures for all tasks, including the best practice techniques of bagging the bung and plugging the oesophagus immediately after knocking prior to hoisting to minimise the chance of spillage of GIT tract contents • sanitation practices for hands, equipment and protective clothing between carcases and when contaminated • procedures for identifying carcases visually contaminated. All workers undertaking this process step are fully trained in all procedures in the Work Instruction and experienced in its performance.	No **[This step may be a CCP in some HACCP Plans]**

For illustrative purposes only.

Table 4: Continued

Process Step	Potential hazard introduced, controlled or enhanced at this step	Is the potential food safety hazard significant?	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is this step a critical control point (CCP)?
Chill	C: Lubricants P: Rail dust Condensation B: Salmonella verotoxigenic E.coli	C: No P: No B: Yes	C & P: Preventive maintenance and Cleaning SOPs to prevent contamination. Control program to eliminate condensation. B: Minimise growth of carcase pathogens through temperature control. There is insufficient scientific data currently available to set specific time/temperature limits as it relates to food safety. Factors such as initial microbial load; chiller temperature; chilling method; air flow; carcase spacing; carcase size; fat cover; chiller management practices; all contribute to highly variable rates of chilling and need addressing on an individual plant basis.	Proper chilling in an appropriate time period to reduce likelihood of pathogen growth.	Yes

For illustrative purposes only.

28.8 Principle No. 3: Establish Critical Limits at Each CCP

- Critical limits must be established for each CCP.
  - Each CCP will have one or more control measures to prevent, eliminate or reduce hazards to acceptable levels.
  - Each control measure has critical limits associated with it.
- Critical limits must have a scientific basis. Table 5 lists various information sources from which critical limits may be derived. Table 6 gives examples of the types of measures used in critical limits.

Table 5: Sources of Information for Safety Criteria and Critical Limits

GENERAL SOURCE	EXAMPLES
Surveys And Scientific Literature	Literature Searches Computer Databases Internet Predictive Models
Government Agencies and Scientific Committees	AQIS BRS ANZFA NRA
Experimental Studies	Challenge and Inoculation Studies In-House Experiments
Experts	CSIRO Consultants Equipment Manufacturers University and Government

Adapted from L. Moberg, in Pierson and Corlett, HACCP Principles and Application (1992).

Table 6: Examples of Measures Used in Critical Limits

TIME
RATE
TEMPERATURE
HUMIDITY
MOISTURE CONTENT
WATER ACTIVITY
pH
SALT CONTENT
CHLORINE
SPECIFIC SANITATION PROCEDURES
SUPPLIER CERTIFICATION
INGREDIENT SPECIFICATIONS

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- Processing variations need to be taken into account in setting critical limits. Operating parameters may need to be adjusted to more demanding "target levels" to be confident that the critical limit has been satisfied. "Target levels" should, however, not be confused with critical limits. It is possible not to meet a target level, yet the process will still be in control if the critical limit is met.

28.9 Principle No. 4: Establish Monitoring Procedures

- Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control. It should produce an accurate record of operations for future use in verification. Monitoring serves three main purposes:

  1) tracks the system's operation.

     – If it indicates a trend towards loss of control then action can be taken to bring the process back under control before the critical limit is reached or exceeded.

  2) determines when there is a loss of control (the critical limit is exceeded).

     – Corrective action must then be taken.

  3) provides written documentation for use in verification of the HACCP Plan.

- An unsafe product may result if a process is not properly controlled and, therefore, monitoring procedures must be effective.

  – Continuous monitoring is always preferred when feasible, eg. for time/temperature-related control measures using thermographs or for measuring free residual chlorine in water. On slaughter plants, however, continuous monitoring will most likely be the least used monitoring method, since few processes lend themselves to this style of monitoring.

- When it is not possible to monitor a critical limit on a continuous basis, it is necessary to establish a monitoring interval that will be adequate and reliable to indicate that the hazard is under control.

  – Statistically designed data collection or sampling systems lend themselves to this purpose - using this, or any other, method it is important to recognise that critical limits must not be exceeded.

  – Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Microbiological testing, therefore, is seldom effective for monitoring CCPs due to the lag time in obtaining results.

- For some meat products incorporating microbiologically sensitive ingredients there may be no alternative to microbiological testing. In such cases, ‘test and hold’ type approaches may be necessary to ensure that critical limits are satisfied.

- Random checks may be useful for supplementing the monitoring of certain CCPs, eg. assessing equipment and environmental sanitation, airborne contamination, cleaning and sanitising of gloves, etc.

- All records and documents associated with CCP monitoring must be signed or initialled by the person(s) doing the monitoring.

28.10 Principle No. 5: Establish Corrective Action to be taken when monitoring indicates that there is a deviation from a Critical Limit

- HACCP is designed to identify potential hazards and to establish strategies to prevent their occurrence. However, ideal circumstances do not always prevail and deviations from established processes may occur.

- An essential part of an effective HACCP Plan is the action to correct any deviations from critical limits that may occur

  – individual corrective action procedures must be documented in the HACCP Plan for each CCP.

- Corrective action needs to address:

  a) the identification and correction of the cause of the non-conformity

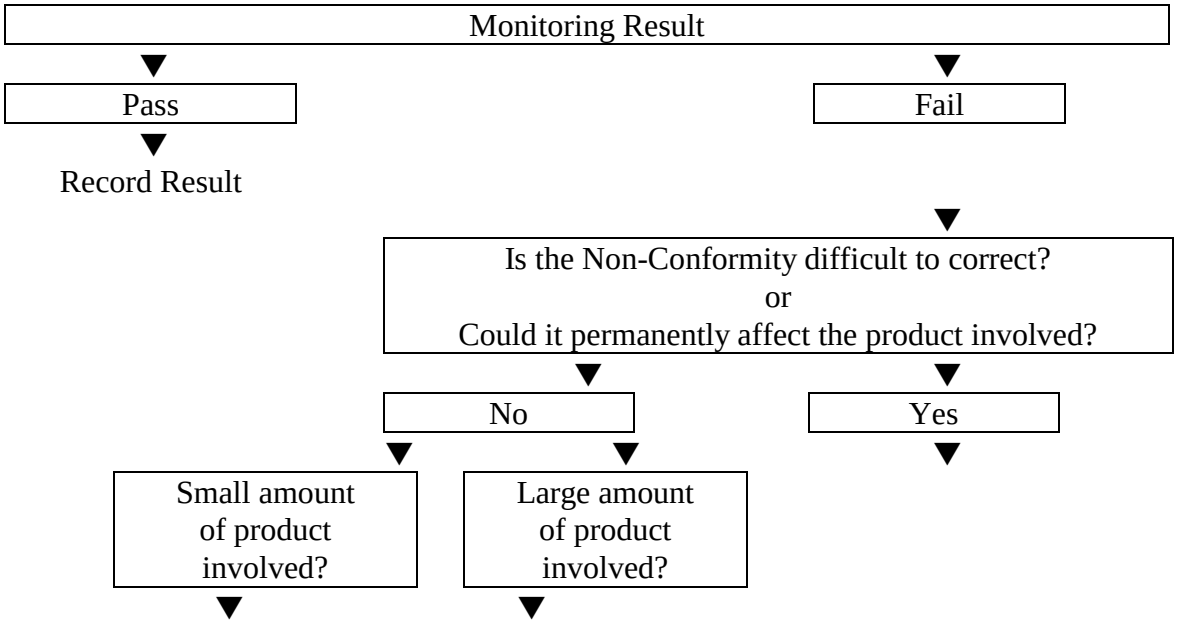
  b) the treatment and disposition of affected product; and

  c) the records documenting the incident and the action taken.

- The people responsible for taking corrective action and for releasing affected product after corrective action has been taken also need to be clearly identified. These people must be thoroughly conversant with the process, product and HACCP Plan.

- When non-conformities are detected, the level, type and extent of response will be dependent on a range of factors. Corrective action procedures need to recognise and accommodate this. Figure 9 examples a Decision Tree which determines initial corrective action.

Figure 9 Example of a Corrective Action Decision Tree for Company Personnel



Is this a Repeat Non-Conformity? No: 1. Take local action to control situation. 2. Retain/rework any affected product. 3. Record result and action taken. Yes: Consider switching to high frequency monitoring	1. Take action to control situation by: • informing person(s) responsible • ensuring further product is not being similarly affected • consider stopping production until situation is controlled. 2. Retain all affected product for inspection and rework. 3. Record results and action taken. 4. Follow-up rework and final outcome. 5. Inform AQIS within 2 hours. 6. Flag incident for further investigation and analysis. 7. Consider switching CCP to high frequency monitoring if a repeat incident.	1. Take action to control situation by: • informing person(s) responsible • having production stopped until situation is controlled • ensuring without delay that further product is not being similarly affected. 2. Retain all affected product for AQIS disposition. 3. Inform AQIS as soon as possible, inform QA manager. 4. Liaise with AQIS regarding proposed changes to allow production to resume and the disposition terms/ conditions for affected product. 5. Record all action, proposed changes and disposition decision. 6. Follow-up the effectiveness of changes and solutions to prevent recurrence. 7. Switch CCP involved to high frequency monitoring until new control measures are proven.

Long-Term Corrective Action

- An evaluation of past monitoring sheets should occur regularly (especially where serious problems have occurred). This assists in identifying follow-up action required to improve the future reliability of operations. Examples include:

  - direct training activities into areas which will help to strengthen weak spots in the company's system

  - improve worker understanding of their Work Instruction through general training in meat hygiene, etc.

  - ensure that workers who rotate through jobs understand the Work Instruction of each job they do

  - better alignment of chain speeds with the job that is 'the weakest link' on the chain

  - physical changes to the work area to make it easier for workers to comply with required standards, such as sterilisation of equipment; and

  - talking to workers and seeking their opinion as to why some problems recur.

- Follow-up action should be recorded and cross-referenced back to the initial problem.

- Temporary solutions may need to be implemented and tested in order to overcome the immediate problem until the true cause has been identified and the problem rectified.

- Inadequate reactions by QA monitors and company supervisors to problems should also be analysed to determine if these problems could be handled better in the future and if company policy needs to be amended.

'No amount of care or skill in workmanship can overcome fundamental faults in the system.' W. Edwards Deming

28.11 Principle No. 6: Establish Verification Procedures

Verification is those activities that determine the validity of a HACCP Plan and that the system is operating according to the Plan.

A vital aspect of verification is the initial validation of the HACCP Plan to determine that the Plan is scientifically and technically sound, that all hazards have been identified and that if the HACCP Plan is properly implemented, these hazards will be effectively controlled. Information needed to validate the HACCP Plan often includes expert advice and scientific studies, and in-plant observations, measurements and evaluations.

The major input from science in a HACCP Plan centres on proper identification of hazards, critical control points, critical limits and instituting proper verification procedures. These processes take place during the development and implementation of the HACCP Plan and maintenance of the HACCP system.

Subsequent validations are performed and documented by a HACCP team or an independent expert as needed. For example, validations are conducted when there is an unexplained system failure; a significant product, process or packaging change occurs; or new hazards are identified.

Verification shows whether the HACCP system is functioning effectively and includes procedures performed on at least a daily basis. Data sources which may contribute to the verification process include HACCP monitoring, internal audit results, analytical tests, as well as external activities such as customer audits, consumer complaints, and AQIS audit and review activities.

Some of the activities which would normally form part of the verification process include:

- collation, analysis and reporting on daily monitoring data. This may also involve trend charting and data comparison from period to period and year to year

- properly scheduled and performed internal audits which fully cover the HACCP system in a 12 month period

- the results of microbiological analysis of samples to confirm the effectiveness of control measures and their critical limits

- the results of audits performed by customers on the production process and its controls compared with the internally generated data and conclusions on the same operations

- structured review of critical limits to ensure that they remain adequate to control the identified hazards; and

- structured review of corrective action records to identify systemic failures or weaknesses.

All verification activities must be documented and available for review by auditors. These documents must be able to display:

- ongoing and effective verification of the HACCP Plan

- how the HACCP Plan is adjusted where verification reveals inadequacies in the control system; and

- sources of the data collated, manipulated and analysed.

In the MSQA system, verification also plays a significant role in the quality system element "Management Review" (refer to Part 1, element 19).

- The results of verification activities needs to be channelled into the work of the management review function to ensure that these vital data sources on the health of the food safety system can be properly considered and addressed as part of the continual improvement of the overall quality system. Figure 10 depicts this relationship.

Examples of verification activities:

A. Company verification **procedures** may include:

1. establishment of appropriate verification inspection schedules

2. random sample collection and analysis of product:

   – statistically based product sampling performed at various strategic stages in the production process is an essential part of a feedback system to indicate trends, for example the condition of carcases leaving the slaughter floor.

3. review of the HACCP Plan

4. review of deviations and dispositions

5. review of CCP records

6. visual inspections of operations to observe if CCPs are under control

7. review of critical limits to verify that they are adequate to achieve control

8. review of written record of verification inspections which certifies compliance with the HACCP Plan or deviations from the Plan and the corrective action taken

9. validation of the HACCP Plan, including on-site review and verification of flow diagrams and CCPs; and

10. review of modifications of the HACCP Plan.

B. Company verification **reports** should include information about:

1. existence of a HACCP Plan and the person(s) responsible for administering and updating the HACCP Plan

2. the status of records associated with CCP monitoring

3. direct monitoring data of the CCP while in operation

4. certification that the monitoring equipment is properly calibrated and in working order

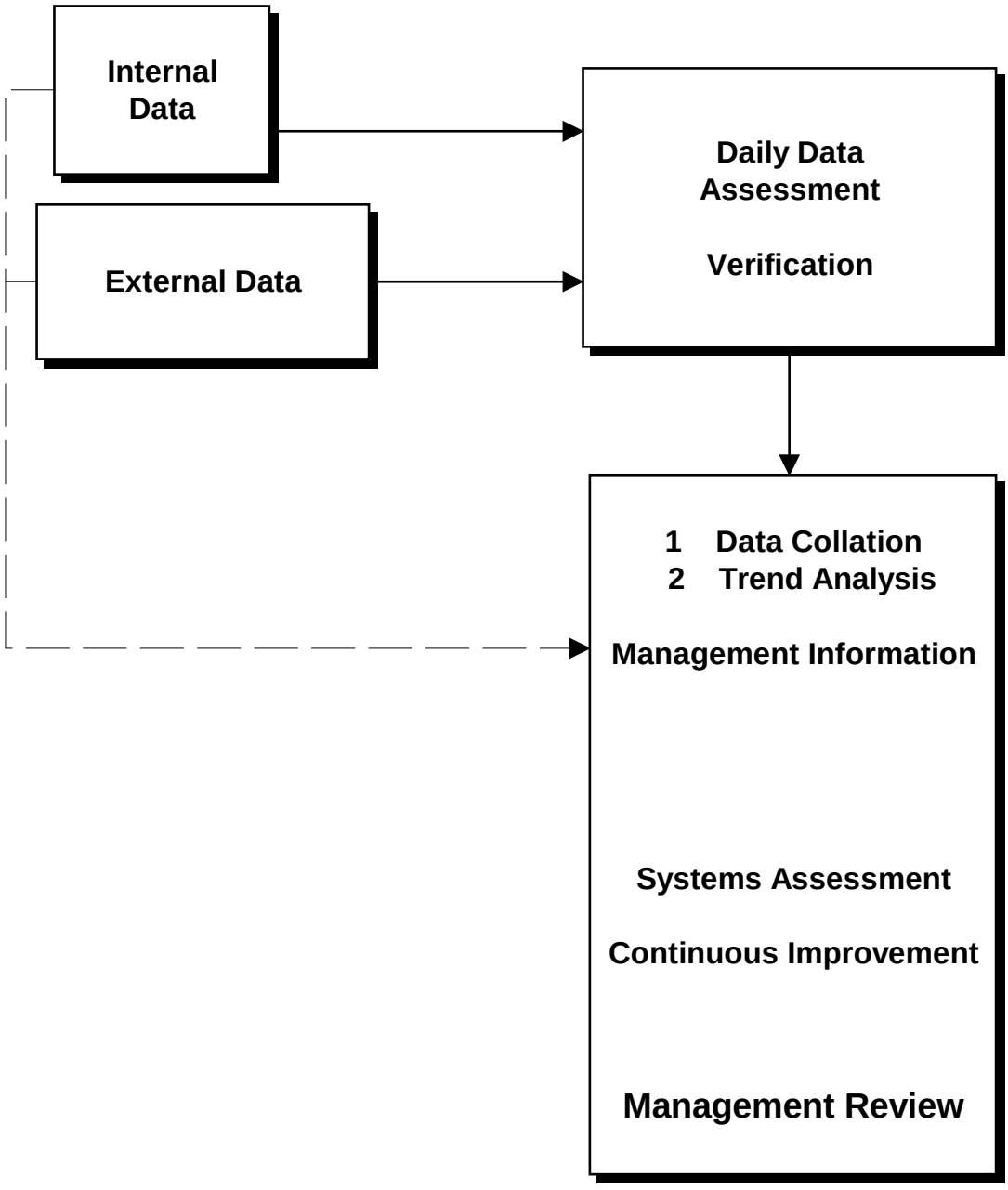
5. deviations and Corrective Actions

6. any samples analysed to verify that CCPs are under control. Analyses may involve physical, chemical, microbiological or organoleptic methods

7. modifications to the HACCP Plan; and

8. training and knowledge of individuals responsible for monitoring CCPs.

Figure 10 **Model of Relationship Between Verification and Management Review**



28.12 Principle No. 7: Establish Record-Keeping Procedures

- The HACCP Plan and associated records must be available at the producing establishment and the records utilised in the HACCP system must include the following:

    1) a summary of the hazard analysis including the rationale for determining hazards and control measures

    2) documentation of the HACCP Plan:

        – the MSQA team and assigned responsibilities
        – description of the product, distribution, consumer and intended use
        – verified flow diagram
        – HACCP table including:
            : significant hazards and control measures
            : steps in process which are CCPs
            : critical limits
            : monitoring
            : corrective action
            : record-keeping procedures
            : verification procedures

Table 7 is an example of a template for a HACCP table

Table 7: HACCP Table

Process Step	Hazards and CCP Reference	Control Measure(s)	Critical Limits	Monitoring Procedures	Corrective Action(s)	HACCP Records	HACCP Verification

Examples of completed HACCP tables are at Tables 8 and 9.

    3) support documentation such as validation records; and

    4) records generated during operation of the plan:

        – CCP monitoring activities
        – deviations and associated corrective action
        – modifications to the HACCP system
        – activities contributing to verification.

Table 8: Example of HACCP Table Using Chilling of Pork Carcases as Model

Process Step	Hazards & CCP Reference	Control Measure(s)	Critical Limits	Monitoring Procedures	Corrective Action	HACCP Records	HACCP Verification
Chilling	Salmonella veroloxigenic E. coli CCP number	Reduction of carcase (surface and internal) temperature within a reasonable time to minimise the multiplication of enteric pathogens.	Establish refrigeration parameters (eg. air flow, suction pressure, coil temperature, etc.) for equipment operation to achieve the following time / temperature limits on carcases: ≤7°C within 12 hours on carcase surface. ≤7°C deep muscle temperature within 24 hours. Effective spacing of carcases.	Continuous monitoring of refrigeration parameters with disk recording thermometer. Monitor surface temperature and internal temperature of product of ten randomly selected carcases / day/ chiller with hand held thermometer. Monitor carcase spacing at time of chiller loading.	Contact maintenance to repair chiller problem; stop product flow until product temperature is reached. Transfer product to a more efficient chiller.	Maintain written records on monitoring and corrective actions for a pre-determined period of time. Recording thermometer records. *All records should be signed, dated and the specific results recorded.* Calibration records.	Random micro testing before and after CCP to match with the baseline microbial data to establish the process is working effectively. Daily review of records for this CCP prior to load out. Daily observation and check of temperatures and procedure being used to obtain temperature.

For illustrative purposes only

Table 9: Example of HACCP Table Using Chilling of Beef Sides as Model

Process Step	Hazard and Reference	Control Measure(s)	Critical Limits	Establishment Monitoring	Corrective Action	HACCP Records	HACCP Verification
Chilling	Salmonella veroloxigemic E. coli CCP Number	Reduction of carcase (surface and internal) temperature within a reasonable time to minimise the multiplication of enteric pathogens.	Establish refrigeration parameters (eg. suction pressure, coil temp, etc.) for equipment operation to reach a carcase surface temperature of 7°C or less within 24 hours. Effective spacing of sides.	Continuous monitoring of refrigeration parameters with disk recording thermometer. Monitor surface temperature and internal temperature of product of ten randomly selected carcases / day/ chiller with hand held thermometer. Monitor carcase spacing at time of chiller loading	Hold product, evaluate significance of deviation, determine product disposition. . Identify cause and prevent recurrence. If needed, notify maintenance to adjust refrigeration parameters to bring temperature into compliance. If needed, adjust carcase spacing and retrain employees.	Maintain written records on monitoring and corrective actions for a pre-determined period of time. Recording thermometer records. *All records should be signed, dated and the specific results recorded.* Calibration records.	Review daily HACCP records prior to load out. Quarterly documentation of refrigeration parameters to achieve established limits. Daily carcase temperature checks should be taken to verify that 7°C is reached.

For illustrative purposes only

Tables 3,4,8 & 9 adapted from the Food Safety & Inspection Services' Generic HACCP Models for Beef and Pork Slaughter (1997).

APPENDIX A

Examples of Questions to be Considered in a Hazard Analysis

The hazard analysis consists of asking a series of questions which are appropriate to each step in a HACCP Plan. It is not possible in these recommendations to provide a list of all the questions which may be pertinent to a specific product or process. The hazard analysis should question the effect of a variety of factors upon the safety of the product and compliance with AQIS requirements.

The following hazard analysis questions have been included to assist the MSQA team in identifying possible meat safety and other hazards at each step - the first set are examples for meatworks, the second set are examples for meat processing plants. They are not meant to be an exhaustive list, nor will all the possibilities described be necessarily relevant at any single plant.

Hazard Analysis Questions

The following are *examples* of questions to be considered in a hazard analysis.

A. Ingredients

1. Does the product contain any sensitive ingredients that may present microbiological hazards (eg. *Salmonella, Staph. aureus*) chemical hazards (eg. antibiotic or pesticide residue, heavy metals), or physical hazards (eg. bone, lead shot, glass)?

2. Is potable water used in handling or formulating the product?

B. Intrinsic Factors

Physical characteristics and composition (eg. pH, water activity, type of acidulants) of the product during and after processing.

1. Which intrinsic factors of the product must be controlled in order to assure food safety?

2. Does the food permit survival or multiplication of pathogens and/or toxin formation in the product during processing?

3. Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps in the food chain?

4. Are there other similar products in the marketplace? What is the safety record of these products?

C. Procedures Used for Processing

1. Does the process include a controllable processing step that destroys pathogens? Consider both vegetative cells and spores.

2. Is the product subject to recontamination between processing (eg. cooking, pasteurising) and packing?

D. Microbial Content of Food

1. Is the food commercially sterile (eg. low acid canned food)?

2. Is it likely that the food will contain viable spore-forming or non-spore-forming pathogens?

3. What is the normal microbial content of the food?

4. Does the microbial population change during the normal time the food is stored prior to consumption?

5. Does the subsequent change in microbial population alter the safety of the food?

E. Facility Design

1. Does the layout of the process line provide an adequate separation of raw materials from finished product if this is important to food safety?

2. Is positive air pressure maintained in product packing areas? Is this essential for product safety?

3. Is the traffic pattern for people and moving equipment a significant source of contamination?

F. Equipment Design

1. Will equipment provide the time/temperature control that is necessary for safe food?

2. Is the equipment properly sized for the volume of food that will be processed?

3. Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce safe food?

4. Is the equipment reliable or is it prone to frequent breakdowns?

5. Is the equipment designed so that it can be cleaned and sanitised?

6. Is there a chance for product contamination with hazardous substances from the equipment (eg. metal slivers, grease)?

7. What product safety devices are used to enhance consumer safety metal detectors, thermal failure detectors, etc.)?

G. Packaging

1. Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?

2. Is the package clearly labelled 'Keep Refrigerated' if this is required for safety?

3. Does the package include instructions for the safe handling and preparation of the food by the end user?

4. Is the packaging material resistant to damage thereby preventing the entrance of contamination?

5. Are tamper evident packaging features used?

6. Is each package and carton legibly and accurately coded?

7. Does each package contain the proper label?

H. Sanitation

1. Can sanitation impact upon the safety of the food that is being processed?

2. Can the facility and equipment be cleaned and sanitised to permit the safe handling of food?

3. Is it possible to provide sanitary conditions consistently and adequately to assure safe foods?

I. Employee Health, Hygiene and Education

1. Can employee health or personal hygiene practices impact upon the safety of the food being processed?

2. Do the employees understand the process and the factors they must control to assure the preparation of safe foods?

3. Will the employees inform management of a problem which could impact on the safety of the product?

J. Conditions of Storage between Packaging and the End User

1. What is the likelihood that the food will be improperly stored at the wrong temperature?

2. Would an error of improper storage lead to a microbiologically unsafe food?

K. Intended Use

1. Will the food be heated or cooked by the consumer?

2. Will the food be consumed in a raw state?

3. Is there likely to be leftovers?

L. Intended Consumer

1. Is the food intended for the general public?

2. Is the food intended for consumption by a population with increased susceptibility to illness (eg. infants, the aged, the infirmed, the immuno compromised)?