To:	**Holders of VISC Industry Agreed Standard 8**
Subject:	**VISC Industry Agreed Standard 8, Amendment 1**
Date:	7 August 2000
Enclosures:	Amendment Coversheet Industry Standard Amendment

Amendment Details: This amendment includes a revision of Section 5.6, relating to Customised Processes, and the relevant changes to evaluation and verification as required by TD 99/66. *To view a summary of the changes click here.*

Remove old pages	**Insert new pages**
Remove all old pages	Insert all new pages

Please **sign off and date** the Amendment Record, and file this update letter in the back of your manual for quick reference.

Amendment authorised by:

(signed)

Tony Zohrab
Director (Animal Products)
MAF Food, Animal Products Group

Industry Standard 8

Quality Assurance

Notice of Copyright

Preface

Venison Industry Standard 8 has been developed jointly by Industry, MAF Verification Agency and MAF Food Assurance Authority and is endorsed by the Meat Industry Standards Council and the Venison Industry Standards Council.

It is the New Zealand standard for quality assurance for premises licensed, in terms of the Meat Act 1981, and premises approved by MAF Food Assurance Authority.

It is an official circular issued by the Food Assurance Authority of the Ministry of Agriculture and Forestry, pursuant to the Meat Act 1981, under the delegated authority from the Director-General of Agriculture and Forestry.

Review of Venison Industry Standard 8

This industry standard shall be regularly reviewed according to a schedule held by MAF Food Assurance Authority (Animal Products).

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

The co-ordinator of this standard is:

Programme Manager (Risk Management Programme)
Food Assurance Authority (Animal Products)
PO Box 2526
Wellington

Telephone: (04) 474 4100
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Suggestions for Changes

Name: _____

Organisation: _____
_____
_____

Email: _____

Phone: _____Facsimile_____

Venison Industry Standard 8

Section	Suggested Improvements

Signature:	Date:
Please post to: Programme Manager (Risk Management Programme) MAF FAA (Animal Products) PO Box 2526 Wellington	**Acknowledgement of receipt:** Signature: Date:

Amendment Record

Amendments to this manual will be given a consecutive number and will be dated.

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

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Contents of Volume II

1. Introduction

Scope

Venison Industry Standard 8 (IS 8) describes the quality systems that are necessary to provide assurance that the food safety and regulatory outcomes which support branding and certification and for which the Director-General is accountable have been developed and implemented. Outcomes which are detailed in various ISs and directives provide the Licensee with flexibility to decide how these outcomes may be achieved.

IS 8 outlines the responsibilities of the Licensee in determining an appropriate system of operation and control, and provides the authority and mechanism for the Verifier to recognise a documented system that is capable of delivering the appropriate food safety and regulatory outcomes. Further, provided the documented system continues to deliver those outcomes, the document may become the recognised operating standard for the premises.

Any recognition of an intended process or performance is conditional on validation and verification that the product or byproduct for which a brand or an export certificate is required conforms to the New Zealand legislation, including criteria agreed by the Director-General and any requirements of an importing country.

1.1 Outcome

The recognised standard for branding, export certification and continued production in licensed premises and premises approved by MAF FOOD includes a documented system for the production of products and byproducts.
This system must be:

- properly evaluated with regard to the validity of the systems of control; and
- appropriately verified to ensure compliance with New Zealand legislation, including criteria agreed by the Director General and to any requirements of an importing country.

1.2 Definitions

The authority placed upon standards within this IS is indicated by using the following definitions:

Unless otherwise noted, terms will have the same meaning as described in the Meat Act 1981 and its pursuant regulations or the Shorter Oxford Dictionary.

Branding includes the use of the official inspection legend in any form.

Certificate means any document attesting to any condition or fact, including any wording, approved by the Director-General for the purpose of:

- accompanying or pertaining to the internal transfer of products or byproducts between licensed or approved premises; and
- accompanying or pertaining to the export of products or byproducts to overseas markets; this includes authorising the preparation of export certificates.

Competent person is a person with any specific competency as defined in any standard, specification or requirement, who may provide expert technical advice within the scope of the particular standard, specification or requirement.

Evaluator is a person who is approved by the Director-General to evaluate and recognise the validity of documented system.

Industry standard is a standard or collection of standards that have been issued jointly by the Regulatory Authority on behalf of the Director-General and the industry consultative body recognised as representing the interests of the appropriate industry sector.

Verification Agency means a body charged with the responsibility of ensuring that the requirements of New Zealand acts, regulations, MAF FOOD specifications, and importing country requirements are implemented and adhered to by Licensees and other persons/activities to which the legislation applies.

Input means all consumables, e.g. raw materials and ingredients, and non-consumables, e.g. packaging materials.

Licensee has the same meaning as defined in the Game Regulations 1975 and, in summary, means a person or trustee corporation who is managing that property which is defined as the premises.

Premises in respect of the use of the term premises, this applies only to the premises as defined in any document relating to its' Licensing, or approval by MAF Food.

Process outcome means the definable aspects of a finished product or byproduct and includes:

- technical attributes;
- biological, chemical or physical characteristics that relate to the safety of food; and
- conformance to the legislative or similar requirements of New Zealand and importing countries.

Production criteria includes any procedure, set of procedures or processing method, and their respective process parameters and control parameters, for the

processing of a product or byproduct. The process parameters and control parameters will include measurements and tolerances.

Production system is an organised sequence of procedures or functions that are applied in the production of food or byproducts. This will include production criteria and process outcomes, in respect of products and byproducts, and performances or obligations in respect of regulatory outcomes either directly or indirectly related to products or byproduct.

Shall expresses a mandatory requirement of this Industry Standard.

Should/may expresses a recommended provision which when followed may assist in achieving the required outcome.

Verifier means a person employed within a Verification Agency with the primary responsibility for verification activities at the premises level.

Validation, in relation to recognising the validity of a production system, is to confirm the documented system describes the relevant production criteria and that the system is capable of delivering the required food safety and regulatory outcomes.

Verification, in relation to recognising the continuing validity of a production system, is to determine compliance with requirements of the documented system, including the effectiveness of the production system, the system of control, and the accuracy of the sampling and measurement procedures.

1.3 General Principles

1.3.1 Cross references

The requirements for quality assurance described in this Industry Standard shall be applied together with any processing standard or production system required by any Acts, Regulations, MAF Food Specifications or importing country requirements.

1.4 Layout of Industry Standard

1.4.1 Scope

Each section commences with a scope which broadly describes the activity to which the requirement applies.

1.4.2 Outcome

The outcome is the principal requirement. It is a statement of what is intended to be achieved and is a fundamental component of the New Zealand system for

ensuring the safety of food derived from animals, excluding fish, minimising hazards associated with byproducts and ensuring compliance with importing country requirements. It provides a basis for determining equivalence of alternative general or specific principles with the New Zealand standard.

1.4.3 General principles

The general principles described in the Venison Industry Standard are based on principles of quality assurance that are relevant to the specific section. Application of the general principles should deliver the required outcome.

1.4.4 Specific principles

1.4.4.1 The specific principles described in the Venison Industry Standard are recognised as methods of delivering the required outcome.

1.4.4.2 International recognition of any method may differ from country to country and specific importing country requirements shall be consulted.

1.4.4.3 There are no headings which identify specific principles. A specific principle will be identified as any major heading (with two-digit numbering and in a bold, 14pt typeface) which occurs in sequence after general principles.

1.4.5 Explanatory notes

Any description in this Venison Industry Standard which is enclosed in a single bordered box does not form a part of the requirement. It is an explanatory note which is intended to expand the general intent of the particular requirement and may serve to clarify compliance with the requirement in some instances.

1.4.6 Director-General

Where-ever it is a requirement in this Industry Standard to report to, or seek the approval of, the Director-General then the requirement shall be addressed to the Director of Animal Products.

2. Authorities and Responsibilities

Scope

This section contains the respective responsibilities and authorities for the Licensee, Evaluator, Verifier and Verification Agency:

- validating; or
- recognising the validity of; or
- verifying

production criteria used at the premises.

2.1 Outcome

There shall be clearly defined responsibilities for:

- the Licensee, in the production of products and byproducts to achieve the required process outcomes, and
- the evaluator, in the evaluation and recognition of validity of production criteria which conform with the required regulatory and food safety outcomes
- the Verifier in the verification of validated documented systems.

2.2 General Principles

2.2.1 Licensee to document systems, validate and verify compliance

2.2.1.1 The legislative requirements for premises and the required process outcomes shall be described by the Licensee in documentation that is appropriate to the premises, the nature of the licence and the production systems.

2.2.1.2 The Licensee is responsible for validating that the production system when implemented in the premises will comply with the regulatory and food safety outcomes described in the documented system.

2.2.1.3 The Licensee is responsible for verifying that ongoing production complies with the documentation and the expected regulatory and food safety outcomes specific to products or byproducts.

2.2.2 The Evaluator to validate

The Evaluator is responsible for evaluating and recognising the validity of the system described by the Licensee in the documentation.

2.2.3 The Verifier to verify

The Verifier is responsible for verifying on-going compliance with the requirements of the documented system during production.

2.3 The Licensee

2.3.1 Standard of documentation

The Licensee shall document, according to the principles outlined in Section 4, all production systems and processing standards, including their respective process outcomes, that are necessary to meet the requirements of New Zealand legislation and, where appropriate, the certification requirements of any importing country.

2.3.2 Responsibility for advice given by a competent person

The Licensee is responsible for the validity of any production system that has been designed by a competent person (employed or engaged by the licensee) and for the respective process outcomes based on that design or advice.

2.3.3 Maintaining systems recognised as valid

The Licensee is responsible for maintaining operations, and a system of verification, of any processing standard or production system according to performance parameters defined in those documented systems which have been recognised as valid by the Evaluator.

2.4 The Evaluator

2.4.1 Validation responsibilities

2.4.1.1 The Evaluator is responsible for evaluating a documented proposal against relevant criteria and for determining the validity of the intended standard of performance.

2.4.2 Competency of the Evaluator

2.4.2.1 Evaluators, and their competencies, shall be approved by the D-G.

2.4.2.2 Evaluators shall only evaluate documented systems that are applicable to their approved competency.

2.5 The Verifier

2.5.1 Verification responsibilities

The Verifier is responsible for planning the on-going and systematic audit of production to verify that the Licensee complies with the production system that has been recognised as valid and that the system of control continues to be effective.

2.6 Verification Agency

2.6.1 Providing a competent Verifier

The Verification Agency is responsible for ensuring that a Verifier who has been appointed to a premises is capable of competently carrying out the technical supervision of all production systems that are appropriate to the type of licence issued in respect of the premises.

2.6.2 Providing technical assistance

The Verification Agency is responsible for providing technical assistance to the Verifier in order that the process outcomes of any production system are fully understood by the Verifier and an effective verification plan is developed and implemented.

2.7 Authorities

2.7.1 The Director-General

The Director-General is accountable for approving production criteria and will approve production systems only where specifically provided for. Refer also IS 8: Section 5.4.

2.7.2 The Evaluator

The Evaluator shall evaluate all production systems in order to:

- recognise the appropriateness of the production criteria;
- the validity of the production system; and
- compliance with the conditions of the licence,

2.7.3 Continuity of recognised validity

Any approval granted according to Section 2.6.1, or recognition of validity according to Section 2.6.2, will continue, provided:

- the production system intended by the Licensee complies with the production criteria, including any amendment, that has been approved by the Director-General;
- the production system has been recognised by an evaluator as valid, and
- the Verifier verifies the maintenance of the production system.

3. Validation

Scope

Validation comprises all those activities used to confirm that a documented production system is complete and is capable of delivering the required food safety and regulatory outcomes.

3.1 Outcome

A documented production system shall be competently evaluated by the Licensee and an approved Evaluator to confirm that it is complete and is capable of delivering the required food safety and regulatory outcomes.

3.2 General Principles

An evaluation of a documented system shall be conducted by the Licensee and an approved Evaluator.

3.2.1 The Licensee

3.2.1.1 The Licensee shall evaluate the prepared document to ensure that it conforms to all requirements for documented systems prior to evaluation an evaluator.

3.2.1.2 Production aspects that are relevant to food safety and regulatory outcomes and are not adequately documented shall be corrected before submitting the document to an Evaluator.

3.2.1.3 A documented production system shall be evaluated by an Evaluator prior to the company commencing any commercial production for which routine use of brands and/or export certification is required.

3.2.2 The Evaluator

3.2.2.1 An approved Evaluator shall evaluate the documented system to determine that it conforms to all requirements.

3.2.2.2 The evaluation shall place an emphasis on aspects of the production system that are relevant to food safety and regulatory outcomes.

In carrying out an evaluation, the Evaluator may take into account aspects of a commercial nature where loss of control may have a significant effect in relation to food safety, e.g. holding product under unsatisfactory conditions during processing delays, excessive re-working of out-of-specification products.

3.2.2.3 The evaluation shall be carried out systematic manner according to a documented protocol. A record of the evaluation shall be maintained by Evaluator.

> The documented evaluation protocol should align with the format of the licensees documented systems. A documented protocol and records of any evaluation should be available for audit by the Licensee and MAF Food.

3.2.2.4 When an evaluation has determined that all relevant aspects of the production systems have been documented, the production system shall be recognised as valid.

3.2.3 Evaluation

3.2.3.1 All evaluations shall take into account the following aspects:

- the proposed documented system, see IS 8; Section 4;
- the intended process outcomes and the methods used to validate them, see IS 8; Section 5.3.2;
- the production criteria, see IS 8; Sections 5.4, 5.6, 5.7 and 5.8;
- the prerequisite activities, see IS 8; Section 5.5;
- the process control and process conformity, see IS 8; Sections 5.9 and 5.10;
- procedures for verifying the effectiveness of the system of production and control, see IS 8; Section 6;
- process records. The proposed records shall be specific to the intended system of production, in the particular premises, and they shall include the measurements that are to be made at the appropriate control points.

3.3 Audit of the Validation

3.3.1 Validation subject to audit

Validation of production systems performed by an Evaluator shall be subject to audit, as part of an external audit carried out by the Director General (MAF Food Compliance Group).

> The validation protocol and records of the evaluation may be reviewed by the Licensee.

3.3.2 Inadequate documentation

3.3.2.1 Where any audit considers that the documentation of aspects relating to food safety and/or regulatory outcomes are inadequate, the auditor shall carry out an audit of the verification activities, see IS 8; Section 6.

3.3.2.2 If the audit of the verification activities confirms that inadequate documentation has a direct bearing on the effectiveness of the production system or its control to deliver the required food safety and/or regulatory outcomes, the Licensee shall

correct and re-validate the documentation and the respective system of production and/or control.

(i) Production shall cease and the corrections shall be made before production starts if product had been produced that presented a food safety hazard.

(ii) Export certification shall be withdrawn from respective markets until the corrections are made if products or byproduct failed to meet regulatory requirements.

(iii) The corrections shall be made within a reasonable time if no hazardous products or market restricted products or byproduct had been produced.

3.4 Recognising a System as Valid

3.4.1 Notation

The documented system that has been evaluated and assessed as complying with all relevant requirements shall be noted by the Evaluator using a unique identification system and signature. The recognition will only relate to the pages and the version of the assessed document.

3.4.2 Register

The Evaluator and the Verifier of the relevant premises shall maintain a register of all current documented systems that have been recognised as valid. The register shall record a title of the recognised system, a brief description of the scope of activity, the location of all relevant company documents, the pages and version that has been recognised as valid and any amendments.

3.5 Revalidation of Documented Systems

3.5.1 Major changes

Revalidation of a documented system previously recognised as valid shall occur under the following circumstances:

- when the licensee changes the production system or changes the production criteria; or
- when there are changes to regulations or importing country requirements; or
- when routine, cyclical reviews of existing documentation are conducted.

3.5.2 Minor changes

Where minor changes occur to a production system, previously recognised as valid, the evaluation may consider only the effect of the change and may not necessarily require a complete re-validation of the document, see IS 8; Section 4.6.

3.6 Appeals

A documented system that is recognised as valid is expected to become the operating standard by which the premises will be seen to be meeting its legal obligations.

3.6.1 The Licensee may dispute the outcome of any validation and exercise his/her rights to appeal to the Director General.

3.6.2 Before lodging any appeal with the Director General the Licensee shall initially address any concerns with the Evaluator.

3.6.2.1 The Evaluator may re-evaluate all or part of the documented system to satisfy themselves as to the adequacy of the initial validation.

3.6.2.2 Where the dispute relates to production criteria that have been developed to meet a special technological requirement of the Licensee, the Evaluator shall seek a re-evaluation of relevant parts of the documentation by a competent person who is independent of the Licensee and the Evaluator. The selection of an appropriate competent person shall be acceptable to both parties.

4. Documented Systems

Scope

This section sets out the requirements for documentation describing any production system, or part of a production system, at a premises.

4.1 Outcome

The production systems required to produce a product or byproduct, including production criteria, process outcomes and verification activities, shall be described in a suitably formatted and auditable document.

4.2 General Principles

4.2.1 Application

The licensee shall document procedures and systems required to produce a product or byproduct where it is a requirement of any premises, product or byproduct that the production system is to be validated or that the Verifier is required to declare, by certification, any condition relating to a product or byproduct.

The extent to which documentation is required is primarily governed by the requirements for certification and branding. The Industry Standards outline production criteria for products or byproducts which are an agreed interpretation of requirements for branding and certification.

4.2.2 Programme contents

Documentation relating to the production of a specific product or byproduct shall include a description of the following elements:

- the process outcomes;
- the title(s) of the people who are responsible for achieving the outcomes, in particular those people who are authorised to implement all necessary control measures;
- the prerequisite programmes;
- the system inputs, e.g. raw materials, production aids, packaging materials;
- the range of facilities and equipment;
- the sequence of operations, and the outcomes expected at each operation where appropriate;
- the control points, including any supporting data and analysis, including food safety hazard analysis where applicable;
- the control limits, monitoring procedures and the corrective actions that will be applied at the appropriate control points;

- the procedures that will be used to verify the effectiveness of the system of control, including calibration of the recording systems, checks, audits and relevant product tests; and
- the records that will be kept, including those records necessary to verify regulatory outcomes that are necessary for certification of a product or byproduct.

Where multiple resources can be used in the production of a specific product/byproduct, all should be documented as acceptable alternatives to avoid a re-validation procedure when an alternative resource achieving the same result is used, e.g. different; process rooms, or dicing equipment, or ingredient suppliers.

4.3 Format

All information shall be presented in a format which facilitates validation, internal process control, on-going monitoring, checking and verification by the Licensee, evaluation by an approved Evaluator and audit and verification by the Verifier.

4.4 Utility

The documentation shall be presented in a form which is readily accessible to all personnel who are responsible for the production system, its control, its supervision, monitoring, verification and evaluation.

4.4.1 Evaluation

Documentation of a production system shall be clear and facilitate evaluation of the proposed system of production by the Licensee and an approved Evaluator.

4.4.2 Process control

The relevant documents shall be available to those people identified in the production system who are assigned the authority and responsibility for the production and its control.

4.4.3 Audit

All documentation shall be in a format suitable to enable any reviewer or auditor to form a clear and unambiguous opinion about the appropriateness and compliance with the validated production system.

4.5 Traceability

4.5.1 Records to form part of the documentation

All relevant production records shall form part of the documented system, this will include: records of measurements made at the appropriate control points and inventories of raw materials and finished products and byproducts.

4.5.2 Electronic records

4.5.2.1 All relevant electronic records of production shall be regarded as records and form part of the documented system.

4.5.2.2 Electronic records shall be:

- backed up;
- handled;
- stored; and
- protected from corruption,

according to requirements of the ISO 9000 series standards, 1994 editions, for the protection and preservation of electronic data.

4.5.3 Record-keeping

4.5.3.1 The records described in the documentation of a production system recognised as valid shall be maintained throughout all production.

> The usefulness of records may be enhanced by including information that relates to standards or criteria specific to the specific operation, the action limits and/or the control measures.

4.5.3.2 The records shall include the date and the signature of personnel who have the responsibility and authority for monitoring and control at the appropriate control points. In the case of electronic records compiled by personnel, the person entering the data shall be identified according to systems developed for the protection of electronic records, see 4.5.2

4.5.4 Inventories

4.5.4.1 An inventory shall be maintained for all raw materials and finished products and byproducts. The inventory shall form part of the documentation.

Raw materials means consumables, such as ingredients, and does not include the non-consumables such as wrapping materials. Non-consumables such as inspection legend materials will need to be inventory controlled as part of the prerequisite activities.

4.5.4.2 The quantities of raw materials used and finished products or byproducts produced shall be reconciled with the details contained in any certificate relating to the internal transfer of materials or the export of products or byproducts.

4.5.4.3 Products or byproducts produced as a consequence of a process failure shall be separately inventoried. The reasons for the process failure or market restriction shall be clearly identified in the inventory. Refer also to IS 8: Section 5.10.

4.5.5 Retention of records

The documents relating to a production system recognised as valid shall be retained by the licensee for as long as the certificates relating to the internal transfer of materials and the export of the production are required to be retained.

4.5.6 Access of the Verifier to records

All relevant production records and inventories shall be accessible to the Verifier, the Verification Agency and MAF Food Compliance Group at all reasonable times.

4.6 Document Control

4.6.1 Issue and control of the document

The Licensee shall implement a system for the issue and control of changes or amendments to a validated and recognised document that is equivalent to the principles for document control outlined in generally accepted industry standards for quality systems, e.g. the ISO 9000 series of standards.

4.6.2 Re-validation of changes or amendments

Any change or amendment to a production system previously recognised as valid shall be evaluated by an approved Evaluator according to the procedures outlined in IS 8, Section 3. If the proposed change has a significant effect in relation to the food safety or regulatory outcome, the documented system shall be re-validated.

Changes or amendments to a production system that do not have any significant bearing on food safety or regulatory outcomes do not necessarily require re-validation of the production system provided the change relates to the use of an alternative resource that achieves the same result, e.g. different; process rooms, or dicing equipment, or ingredient suppliers. Refer also to IS 8: Section 3.2.3.

5. Production Criteria

Scope

This section sets out the criteria that production systems must meet to be recognised as valid by an approved Evaluator. Criteria will include those requirements of Industry Standards; relating to hygiene and sanitation, pre-slaughter, slaughter and dressing, edible processing, byproduct processing, storage and transportation, and to criteria approved to meet specific requirements for production.

5.1 Outcome

The production of any product or byproduct shall conform to generally accepted criteria for their production, or to criteria that have been approved to meet specific technological requirements of a particular product or byproduct.

5.2 General Principles

5.2.1 Process outcomes and production criteria to be defined

The process outcomes and criteria for the production of any product or byproduct shall be defined by the Licensee.

5.2.2 Production criteria to be approved

The production criteria shall conform to generally accepted criteria, or to criteria that have been approved by the Director General as meeting the food safety and regulatory outcomes of a product or byproduct according to the provisions for customised processes, technical publications or those derived using experimentation and/or HACCP systems.

5.2.3 Market access

The production criteria shall provide for compliance with any importing country requirement.

5.2.4 Source of production criteria is to be identified

The source of production criteria that are intended to be used in any production system shall be clearly identified, e.g. IS 6: Section xxx. Where production criteria have been devised to meet the particular technological requirements of a product or byproduct, the method of scientific justification for that processing shall have been approved by the Director-General.

5.2.5 Validation to include approval of production criteria

The recognition of a production system as being valid shall include an evaluation of the documented system to:

- verify that the description of the intended production criteria, including the manner in which the production system will be operated and controlled in the premises, conforms to criteria that have been specified in processing standards approved by the Director-General, and
- verify that procedures are in place to correct any unsatisfactory outcome resulting from process design or control faults.

5.3 Process Outcomes

The outcomes of a process shall be measured by the technological effect, the food safety component and regulatory component.

5.3.1 Technological effects

The licensee shall define the process outcomes by the intended technological effect and select appropriate production criteria to achieve the outcome.

The intended technological effect is commercial in nature and forms the main purpose for the process.

5.3.2 Food safety component

5.3.2.1 The licensee shall use approved production criteria where the food safety outcomes have been determined and approved. The food safety outcome shall be re-validated in the event that a deviation from control parameters specified in the approved production criteria is necessary due to modifying the technological outcome.

The food safety component may also be referred to as the food safety outcome.

5.3.2.2 Where specific food safety process parameters and control parameters have not been defined in any production criteria, e.g. an acidified product with low water activity, then process parameters and control parameters shall be fully validated in the context of HACCP, refer to Section 5.8.

5.3.2.3 All significant aspects of food safety concern shall be described in terms of their biological, chemical or physical hazard for the production system. Appropriate validation methods shall be used to describe and quantify, where applicable, food safety concerns with respect to the production criteria and the proposed installation of the process in a premises.

5.3.2.4 Methods of measuring and/or describing characteristics of products or byproducts may include, but are not limited to:

- microbiology;
- chemistry;
- physical measurements;

- sensory tests;
- statistical techniques; and
- process modelling.

Details on the use of these methods is outlined in IS 8: Appendices A-F.

5.3.3 Regulatory component

All relevant aspects of compliance with New Zealand legislation and the regulatory requirements of the importing country shall be addressed by the documented production system. The specific document may reference system controls which will ensure regulatory compliance. In these cases the system controls will be regarded as prerequisite activities. See IS 8: Section 5.4.

Regulatory components relate to conformance to legislative or similar requirements of New Zealand and foreign countries for both products and byproducts. The regulatory component may also be referred to as regulatory compliance or the regulatory outcome.

5.4 Generally Accepted Criteria

5.4.1 Manuals and Industry Standards

5.4.1.1 Where criteria for the production of any product or byproduct are outlined in any manual or industry standard, the criteria may be regarded as generally accepted criteria for the production of that type of product or byproduct. The control parameters which relate to food safety outcomes shall be applied as a minimum requirement for processing.

5.4.1.2 Criteria for the production of products and byproducts that have been published by the Meat Research Institute of New Zealand (MIRINZ) as:

- Technical Reports; or
- Record Memoranda,

shall be regarded as generally accepted criteria, provided the control parameters that relate to food safety outcomes are included in the criteria and are applied as a minimum requirement for processing.

5.4.2 Technical publications

5.4.2.1 Criteria developed for the production of products and byproducts that have been published in any other series of MIRINZ publications or peer reviewed journals or by other research institutes, such as the Commonwealth Scientific and Industrial Research Organisation (CSIRO), Australian Meat Technology (AMT), Campden

and Chorleywood Food Research Association (UK), shall be reviewed and may be approved by the Director-General.

5.4.2.2 Where production criteria are derived from approved technical publications:

(a) the criteria shall be documented according to the requirements of IS 8: Section 4.

(b) production shall be carried out using the process parameters and control parameters that are consistent with the methods described in the publication.

(c) the initial production system shall be operated on a batch basis until the production criteria are validated.

(d) products or byproducts produced during the initial production shall not be released until the production criteria have been validated. Products or byproducts, and the production criteria, shall comply with any requirement of an importing country, see Manual 12.

(e) the results of the initial production shall be reported in a clear manner and include all raw data and sufficient information to demonstrate validation of the production criteria.

5.5 Prerequisite Activities

5.5.1 Application and documentation

Prerequisite activities shall be documented. Those that have been described in other documented systems, and have been determined by an Evaluator to be in conformity with appropriate criteria, do not need to be restated in the proposed document but shall be cross referenced.

Prerequisite activities relates to those activities which are in addition to generally accepted criteria and must be substantially in compliance with legislative requirements in order that the Licensee may operate effectively on a routine basis, irrespective of using alternative general or specific principles, e.g. customised processes, HACCP, new technology or experimentation.

5.5.2 Prerequisite activities include but are not necessarily restricted to:

5.5.2.1 *Licence conditions*

The permitted activities listed on the premises' licence and the conditions of use attached to the licence.

5.5.2.2 *Market access*

The listing of a premises by any importing country.

5.5.2.3 *Potable water*

A management plan for the delivery and maintenance of potable water.

5.5.2.4 *Cleaning and sanitation programme*

A programme for the cleaning and sanitation of the premises, vermin control and the management of chemicals.

5.5.2.5 *Hygiene assurance*

Pre-operational and operational hygiene assurance programmes.

5.5.2.6 *Hygiene of personnel*

Health and hygiene requirements for personnel.

5.5.2.7 *Food contact wrapping materials*

The management of food contact wrapping materials and the hygienic handling of packaging.

5.5.2.8 *Refrigeration management*

A programme for the management of refrigeration.

5.5.2.9 *Inward and outward goods*

A programme for the receiving, storage and shipping of products, byproducts and other goods.

5.5.2.10 *Recall of products and byproducts*

Procedures for the recall of products and byproducts.

5.5.2.11 *Personnel training*

Personnel training programmes.

5.6 Customised Processes

5.6.1 Application

Process parameters for products may be customised where this has been specifically allowed for in any industry standard.

Customising of a process is intended to allow for an alternative means of achieving the outcome of a standard. In general, this will allow process parameters to deviate from those specified as being the minimum required.

5.6.2 Licensee responsible for customisation

5.6.2.1 The Licensee is responsible for the development of a customised process and the quality of evidence that justifies customisation. In developing the process, the Licensee may take into account:

- observations of the premises or facilities;
- historical data from processing the type of product at the premises;
- historical process parameters;
- data from equivalent types of processes
- new data

5.6.2.2 The Licensee shall take into account the principles outlined in IS 8:Appendicies A to F when constructing the evidence which justifies customisation.

The Licensees can either undertake customisation using their own competent people or can use consultants or a combination of both. The Licensee will ultimately be held accountable for the production criteria.

5.6.3 Documentation of process criteria

The proposed customised process shall be documented and shall include, but not restricted to:

- the process outcomes
- the deviation from specified minimum parameters to be customised
- the new process parameters and control parameters
- the process limitations
- data, the data analysis and conclusions which support customisation

5.6.4 Evaluation by an independent Evaluator

5.6.4.1 The proposed documented process shall be evaluated, by an independent evaluator approved by the D-G, for the quality of evidence (adequacy and appropriateness of the data, the data analysis and conclusions) presented by the Licensee to justify customisation.

5.6.4.2 If the quality of evidence supports customisation, the independent evaluator will provide a report to the D-G specifying the customised process criteria and recommending they be approved.

5.6.5 Processing according to customised parameters

5.6.5.1 If satisfied with the recommendation of the independent evaluator, the D-G will approve processing according to one of the following scenarios.

5.6.5.2 In the case of customising existing or historical processes, products may be branded subject to complying with the approved process parameters, control parameters and process limitations.

5.6.5.3 In the case of customising new processes, processing may commence provided actual process data is collect within 2 weeks of commencement of processing and analysis of the data validates the process outcomes. Products shall not to be released until the process outcomes have been validated.

5.7 Experimentation

5.7.1 Application

Experimental processing shall apply where new technology or new procedures are intended to be introduced in licensed premises for which process outcomes have not been validated and the production criteria have not been determined by any previous scientific study.

> Experimental processing does not apply where previous scientific studies have been conducted and the results of such studies have been published, see IS 8, Section 5.4.2.2.
>
> The experiment may be contrary to existing New Zealand law and an exemption from requirements, according to the provisions of Section 50 of the Meat Act 1981, may be necessary .

5.7.2 Pilot studies

Small scale studies may be carried out to establish the feasibility of research projects subject to complying with the following principles:

- there shall be a brief, documented, description of the study;
- studies directly involving product shall be restricted to small definable batches;
- the study shall not interfere with normal production;
- the study shall be carried out under the supervision of the representative of the Verification Agency;
- a pilot study should not be repeated;

- all product produced in such studies shall be retained and treated as a process failure. Refer also to IS 6: Section 2.

5.7.3 Planned and documented research studies

Any research that is intended or required to develop new concepts or apply new technologies shall be properly planned and documented.

5.7.4 Study objectives

The objectives of any intended studies shall be clearly stated. All subsequent activities including literature research, experimental design, study methods and methods of analysis, shall fully support the objectives.

5.7.5 Use of good science principles

The study shall be conducted according to good science principles. Any study intended to be conducted in licensed premises shall be under the supervision of a scientist who is familiar with the principles of research.

5.7.6 Appropriate scientific reporting

The results of any study shall be presented in a form consistent with scientific reporting and in a format that would meet peer review requirements.

5.7.7 Science-based outcomes

The validity of any conclusion drawn from any study is dependent on the data that is obtained and the analysis of that data.

5.7.7.1 *Literature search*

The intended study shall include a literature search to support the overall experimental design and selection of study methods.

5.7.7.2 *Quality of data*

The experimental design shall include principles relating to data collection and data checking, outlined in IS 8: Appendix V.4 and shall be conducted with appropriate parallel controls. The design should also address replicate studies.

5.7.7.3 *Study methods*

The study methods shall be appropriate for the nature of the study. The methods of obtaining data measurements shall be calibrated according to the principles outlined in IS 8: Section 7.

5.7.7.4 *Methods of analysis*

The methods of analysis of the data shall be appropriate to the nature of the test and shall be consistent with generally accepted standards for statistical analysis.

5.7.8 Proposal to conduct an experiment

A proposal to conduct an experiment shall be approved by the Director-General prior to the start of any studies. An approval will be granted if it is determined that the experimental protocol would provide representative data and result in valid conclusions.

5.7.9 Experimental protocol

The proposal shall be in the form of an experimental protocol and include the following information:

5.7.9.1 *Statement of purpose*

A clear statement of the purpose of the experiment and the desired process outcomes.

5.7.9.2 *Review of regulatory requirements*

A review of current regulatory requirements to determine:

(a) if an exemption from any requirement of legislation is needed, and

(b) if any market access limitation exists for the experimental products.

5.7.9.3 *Literature review*

A balanced and representative résumé of the literature of previous studies conducted in similar or related fields.

5.7.9.4 *Preliminary studies*

A full report on any preliminary study that may have been undertaken. Preliminary studies will not have produced any product, i.e. articles intended for sale for human consumption.

5.7.9.5 *Experimental method*

A description of the experimental method including:

(a) the nature of the treatments;

(b) the control and experimental groups and the number of replicate studies intended to be conducted;
(c) the nature of the measurements and the laboratory analytical procedures to be used;
(d) the sample sizes, the selection method and sample handling procedures;
(e) the method for data processing and analysis; and
(f) any other information relevant to carrying out the experiment.

5.7.9.6 *Time frame*

The time frame required to conduct all studies, collect data, analyse the results and prepare a report.

5.7.9.7 *Principal researcher*

The name and brief curriculum vitae of the principal researcher.

5.7.10 Director General

The Director-General will review the protocol and shall either:
- approve the experiment, subject to imposing any conditions considered necessary which shall be of an administrative nature only and will not relate to the design of the experiment; or
- return the proposal to the principal researcher for revision of the experimental design.

5.7.11 Disposition of product

The disposition of any product produced during the conduct of an approved experiment shall be determined by the Director-General.

5.7.12 Ceasing the experiment

Any approval to conduct an experiment, and the conducting of the experiment, shall cease after all of the experimental data has been collected.

5.7.13 Cancelling experimentation

The Director-General may cancel any approved experiment if there is any unauthorised change in the experimental protocol or if, during the conduct of the experiment, the resulting product is likely to endanger public health or cause any byproduct to be unfit for purpose.

5.7.14 Reporting

A full report on the experiment shall be produced by the principal researcher. The report should be of a standard that would be acceptable to a peer reviewed

technical journal. All raw data generated in the experiment is to accompany the report.

5.7.15 Validating the production criteria

If the experiment validates the acceptability of the process outcomes, the Director-General may approve processes incorporating criteria based on the new technology or new procedure.

5.7.16 Intellectual property

The details of any experiment are the property of the Licensee and any consultant or other body that has contributed to the intellectual property. These details are protected from disclosure by New Zealand laws.

5.7.16.1 *Experimental details may be disclosed*

The details of any experiment may be disclosed by the Director-General under circumstances outlined in 5.7.15.2 and 5.7.15.3. Where these circumstances are not acceptable to the Licensee, the Director-General may review the approval of the experiment or the provision of export certification.

5.7.16.2 *Evidence used for New Zealand justification of approval*

The evidence relating to any research that resulted in the approving of a process, processing criteria, standard or system of operation may be required to demonstrate to foreign regulatory authorities New Zealand's justification for that approval. Depending on the nature of the study, the evidence may also be required for peer review and for publishing in the scientific press.

5.7.16.3 *Principles may be used for national standards*

Any principle or criteria derived from a research study, and approved, may be used by the Director-General to develop any general industry standard 24 months after the date upon which the results of the original study were approved.

5.8 HACCP (Hazard Analysis and Critical Control Point Systems)

Production systems incorporating criteria and operational controls based on hazard analysis and critical control point systems are recognised as valid provided the criteria have been fully developed, validated and verified according to the requirements for HACCP systems. Refer to *Guide to Implementation of HACCP in the Meat Industry*.

5.9 Process Control

Process control relates to determining and describing a system of control based on a systematic analysis of the production criteria relative to the process outcomes.

5.9.1 Process analysis

5.9.1.1 *Statement of outcomes*

The process outcomes and production criteria shall be clearly stated. In this regard the proposal may need to be compared with the appropriate production criteria to determine conformity with the approved criteria (see IS 8: Section 5.3)

5.9.1.2 *Process flow*

(a) The proposed sequence of operations shall be described in terms of the premises' facilities.

> For the purposes of analysis, a process flow diagram should be constructed to ensure that all processing steps and inputs are considered and to identify where the requirements of the proposal may conflict with existing activities.

(b) Where conflicting activities are identified they shall be addressed.

(i) Conflicting situations that are prohibited by New Zealand or foreign market requirements shall be resolved.

(ii) Conflicting requirements of different markets may occur, these shall be addressed when processing for respective markets.

(iii) Where conflicts are not prohibited but could result in an adverse food safety outcome, process controls shall ensure that actual conflicting situations do not occur.

> Conflicting activities may include, but are not restricted to:
> - co-mingling of products and byproducts and/or their respective workers.
> - co-mingling of cooked or ready to eat and raw or partially processed products and/or their respective workers.
> - co-mingling of dirty and clean products, e.g. green offals, hide-on hide-off situations, and/or their respective workers.

5.9.1.3 *Compounded products*

(a) Where any product contains more than one ingredient:

- the composition;
- the level of permitted additives;
- finished product standards; and
- the labelling,

will need to conform to the legal requirements of the intended market, including the New Zealand food regulations for those products intended for the domestic market.

Market requirements differ and products formulated or prepared for one country may not comply with the requirements of a different country.

(b) The Licensee is responsible for producing products that comply with the legal requirements for food of the intended market and shall determine the requirements as to composition, levels of permitted additives, finished product standards and labelling of compounded products intended for export.

Manual 12 may contain some information about foreign legal requirements for food but, currently, it is not to be regarded as a comprehensive or up-to-date list of the legal requirements of any country with regard to food additives, composition or labelling of compounded products. The procedures and responsibilities for providing information about foreign legal requirements for food has yet to be clarified.

(c) Evidence of intended compliance with the relevant legal requirements for food shall be included with the proposal.

5.9.1.4 *Personnel*

Personnel identified in the documentation by the Licensee shall have the proper authority and responsibility to carry out the actions required at all control points in the production system

5.9.2 Control points

5.9.2.1 The documented system, with the aid of the process flow diagram, shall identify the appropriate control points, with regard to food safety outcomes, and other control points with regard to regulatory outcomes.

5.9.2.2 Any hazard that directly affects a food safety outcome shall be controlled to within tolerances permitted by the approved processing standard.

5.9.2.3 The mechanism of control shall be designed to control the hazard, i.e. to minimise or eliminate the entry of the hazard into the product/byproduct.

A generic food safety hazard analysis will have been conducted for all approved production criteria and the process parameters, the control parameters and the appropriate control points for food safety outcomes will have been determined, refer to IS 8: Section 5.3.2. Refer also to relevant texts on HACCP and risk analysis for discussions on hazard analysis.

5.9.2.4 The methods of measurement and the system of control shall be sensitive to the appropriate characteristics of the product or byproduct and responsive to the relevant standard.

5.9.3 Control parameters and tolerance limits

5.9.3.1 Control parameters shall be defined for each hazard at the respective control point in any production criteria and/or production system.

5.9.3.2 Control parameters for any appropriate control point shall be defined and documented by the Licensee. The control parameters will consist of:

(a) a sample or number of samples to be measured;
(b) the method and unit of measurement; and
(c) a level of acceptability which shall be the tolerance limit.

5.9.3.3 The level of acceptability may relate to the value of a single sample or, where several samples are taken, a percentage of the samples that must comply with a given value (IS 8: Appendix E).

> A tolerance limit may consist of a numerical interval about a target number, e.g. +/-, or where several samples are taken, a percentage of the samples that may exceed a given value (IS 8: Appendix E). The amount of tolerance at any given control limit will depend on the normal variance or process drift that occurs at the particular operation and the impact that the particular operation will have on determining the overall outcome. Tolerance limits should be statistically valid. If they are initially assigned arbitrarily they should be validated when installing the process.

5.9.4 Sampling

5.9.4.1 Sampling of a process shall be designed to monitor the operations that are directly responsible for achieving the process outcomes.

> A degree of end product testing of finished product or byproduct may also be appropriate but, while it may determine a process outcome for the tested item, it will not necessarily control the process. Some automatic control systems may operate by continuously sampling a characteristic of the product and/or process. For example, temperature may be constantly monitored and the information may be used to control the thermal device. Surveillance activities, and the application of controls on the automated system will, however, be necessary.

5.9.4.2 When evaluating process control, the attribute or characteristic that is to be sampled shall be representative of the function or operation that is to be controlled.

5.9.4.3 The documented system shall describe a sampling plan which includes the attribute or characteristic that is to be measured and the measurement that will be made, the number of samples that will be taken at the same time and a frequency of taking samples.

5.9.4.4 The sampling plan shall be designed using appropriate statistical techniques (IS 8: Appendix E).

5.10 Processing Conformance

Process conformance relates to the production of products/byproducts according to criteria appropriate to food safety or regulatory outcomes and the respective controls which are applied at appropriate control points in the process.
For the purposes of evaluation, a non-conformance is when the control limits, or tolerance limits, are exceeded at any appropriate control point. Products or byproducts that have been produced during periods when a non-conformance occurred are defined as non-conforming products/byproducts.

5.10.1 Restoring process control

5.10.1.1 The documented system shall describe the corrective actions that will be taken to restore the functional operating parameters at all appropriate control points.

5.10.1.2 The description of actions shall authorise the person who is responsible for a particular operation to carry out all actions necessary to restore control.

(a) Where loss of control at any point can be expected, on a frequent or infrequent basis, then the actions necessary to restore control shall be detailed.
(b) The decision to stop or slow the rate of processing will depend on the nature of the non-conformance, the actions necessary and the anticipated time needed to restore control.
(c) If further non-conforming products would be produced in the time that will be needed to restore control, then processing shall cease.

5.10.1.3 Processing shall cease if the corrective action involves people who are not present during operations, e.g. technical specialists or managers.

5.10.2 Disposition of non-conforming production

5.10.2.1 The documented system shall describe procedures for identifying and dealing with non-conforming production.

Non-conforming production relates to those situations that can be reasonably expected to occur based on the production criteria, control limits and tolerances that are appropriate to the process. Documentation that is specific to a type of product is not expected to describe procedures to deal with rare events or events that are not directly related to controlling the process, e.g. plant or equipment failures. These events should be dealt with under other control systems, e.g. hygiene and sanitation programmes, refer to IS 3.

5.10.2.2 The procedures for identifying and separating non-conforming production shall be described.

The degree of separation will depend on the non-conformance. Production that fails to meet the requirements of a specific market may be held in a common area. Production that fails to meet a food safety outcome should not be mixed with other production.

5.10.2.3 Recall procedures shall be described where non-conforming production may have been released, e.g. shipping of production pending final test reports.

5.10.2.4 Reprocessing of a type of non-conforming product/byproduct may be immediately put into effect where the document describes appropriate reprocessing procedures, e.g. boning room re-inspection plans, reprocessing canned products, etc.

5.10.2.5 If procedures are not described for the immediate reworking or reprocessing of affected lots, appropriate systems shall be identified that will ensure non-conforming product/byproduct are immediately dealt with. These systems may be in the form of pre-requisite programmes.

(a) Where the non-conformance relates to an adverse food safety outcome, then the procedures shall describe how to:

(i) protect the lot of product from further deterioration, e.g. freezing;

(ii) obtain a full history of the events relating to the non-conformance.

(b) Where the non-conformance relates to an adverse regulatory outcome, then the procedures shall describe how to restrict or deal with the non-conforming lot according to the requirements of the regulations, including access to foreign markets.

5.10.2.6 Where non-conformance relates to a commercial or technological process outcome, and the Licensee intends to re-work the lot, the documented system shall include procedures for the re-working if normal production or food safety outcomes or regulatory outcomes are likely to be affected in any way.

5.10.3 Prevention of recurrence

Preventing non-conformance is central to the philosophy of quality assurance.

All relevant cases of non-conformance shall be investigated to determine if the failure relates to the process design or to process control. Refer also to IS 8: Section 5.

5.10.4 Records

Records shall be kept of all non-conformances. The records shall include the corrective actions taken and the disposition of non-conforming production.

5.11 Process Failure

5.11.1 Evaluation of process failure

Process failures shall be evaluated to determine if the cause is a fault in the design of the production criteria or a fault in implementation of the criteria or the controls.

5.11.2 Design faults

Design faults relate to the adequacy of the production criteria or the relevant control parameters which result in the routine production of product that does not conform to appropriate food safety and/or regulatory outcomes.

In these cases, processing shall cease and the production criteria, or the relevant control parameters, will need to be reviewed by the Licensee and the Director-General and validated, by the Director-General before processing can re-start.

5.11.3 Implementation and control faults

Implementation and control faults relate to the documentation, implementation and or control of a production system in particular premises which results in the routine production of non-conforming product/byproduct. If the routine non-conformance relates to a food safety hazard in product, then the recognised validity of the process shall be suspended until the in-house process control parameters have been re-established and re-validate.

6. Verification

Scope

Verification includes all activities that determine compliance with requirements of the documented system, including the continued effectiveness of the production system, the system of control, and the continued accuracy of the sampling and measurement procedures.

6.1 Outcome

The production system shall conform to the requirements of the documented system recognised as valid and shall continue to be an effective method of achieving the designed process outcomes.

6.2 General Principles

6.2.1 Quality control

6.2.1.1 On-going quality control activities shall include reviewing data obtained from the measurements and observations required in the production records to determine their compliance with control limits and tolerances, and reviewing the corrective actions that have been taken.

6.2.1.2 The data shall be used to observe trends.

6.2.1.3 The methods of measuring and verifying process outcomes shall include those outlined in the appendices to IS 8.

6.2.2 Licensee audit

6.2.2.1 All relevant production records shall be systematically audited by the Licensee on a regular basis to verify that the recognised documented production system, and the expected process outcomes, have been achieved.

6.2.2.2 All Licensee audits shall be carried out in a transparent and traceable manner according to a documented protocol.

6.2.2.3 The audit should be carried out by a person who is authorised by the Licensee and is independent of production, familiar with the requirements of the documented system, and familiar with the system of production and control.

6.2.2.4 The audit shall report on the performance of the production system and the control system with regard to:

(a) compliance with documented procedures; and

(b) the delivery of the required outcomes.

6.2.2.5 Audit findings shall be used to effect overall corrections and improvements to both the production system and the control system.

It is essential that the audit is carried out by a person who is objective and impartial so that an accurate view of the production system and the outcomes can be obtained. The principles of performance based auditing should be applied to determining the frequency of audits by the Licensee.

6.2.3 External audit

6.2.3.1 The Verifier shall carry out verification activities on a regular basis to assess the production system for conformity with the documented system recognised as valid. The Verification Agency shall conduct an internal audit of the Verifiers' verification activities.

6.2.3.2 The Director-General shall, from time to time, carry out an external audit of the verification activities of the Verifier and the Verification Agency to determine the conformity of the validation and recognition procedures with the requirements of Refer also IS 8.

External audits of documented production systems recognised as valid will include those conducted by the Verifier and the Director-General, i.e. MAF FOOD Compliance Group. The documented audit protocol should take into account the Licensees' systems of documentation and operation. The principles of performance based auditing should be applied to determining the frequency of verification activities and external audits.

6.2.3.3 All external audits shall be carried out in a transparent and traceable manner according to a documented protocol.

6.2.3.4 External audits carried out by nominees of the Licensee for purposes of maintaining registration or accreditation with acknowledged systems of quality management, e.g. ISO 9000 series, shall not substitute for the external audits required to be carried out by the Verifier or the Director-General.

6.3 Conformance with the Documented System

The validated and recognised documented system is the legal specification for the production or carrying out of any process, act, system or thing carried out in a licensed premises. Failure to conform to the production system recognised as valid may result in an adverse food safety or regulatory outcome and withdrawal of branding and/or certification of products or byproducts.

6.3.1 Obligation of the Licensee

The Licensee shall carry out all requirements of the documented system recognised as valid and carry out activities to verify the continued effectiveness and conformance of the system.

6.3.2 Responsibility of the Verifier

The Verifier shall verify the effectiveness and continued conformance of the documented system recognised as valid as a condition of providing branding and/or certification for products and byproducts.

6.4 Effectiveness of the Documented System

6.4.1 Review of audits

The results of the internal and external audits shall be reviewed to determine the effectiveness of the production system and control system in achieving the desired outcomes. Any review of audits shall be reported in a clear manner and shall be available to the Verifier, in the case of Licensee reviews, and to the Licensee in the case of reviews by the Verifier.

6.4.2 Establishing process capability

6.4.2.1 The Licensee shall determine the capability of the documented system to achieve the desired process outcomes as soon as the recognised production system has been installed.

6.4.2.2 Data obtained from the initial records and observations shall be analysed using appropriate methods to quantify the general or specific outcomes, determine the process variability and to verify the control limits and/or tolerances. The frequency of recording measurements and monitoring should be increased during initial processing to rapidly establish the baseline performance characteristics.

6.4.3 Verification by the Verifier

6.4.3.1 The Verifier shall make an independent evaluation of the data and the production system to verify the effectiveness of the documented system and to maintain the recognition of validation.

6.4.3.2 The Verification Agency shall provide technical assistance to any Verifier, when necessary.

6.5 Non-conformances

6.5.1 Corrective action

6.5.1.1 Corrective action shall be specified if a non-conformance occurs at a control point in a production system that relates to the control of a food hazard, as determined by the approved production criteria, or a regulatory outcome.

6.5.1.2 Verification activities shall include evaluation of the production records and observations for the effectiveness of corrective actions and the effectiveness of actions designed to prevent or reduce variability and, thus, the probability of non-conformance occurring.

6.5.2 Effectiveness of corrective actions

The actions taken in the event of any non-conformance shall correspond with those corrective actions specified in the documented control system. The actions shall prevent non-conforming production being branded, released into commerce or certified for export until the food safety and/or regulatory outcomes have been determined.

6.5.3 Effectiveness of preventive actions

Processing modifications and changes designed to reduce variability and prevent non-conformance shall be appropriately validated before implementation. The continued verification of the effectiveness of these preventative actions shall be undertaken by the Licensee in conjunction with the Verifier.

7. Calibration

Scope

This section comprises the requirements for calibration of measuring devices in the premises

7.1 Outcome

Any measurement that is required to demonstrate the conformity of any relevant characteristic or attribute with a production criterion in a documented system recognised as valid shall be accurate.

7.2 General Principles

7.2.1 Calibration certificates

Every measuring device, or reference standard e.g. reference thermometer or reference weights, shall have a current calibration certificate before it can be used. The certificate shall be issued by a competent person and may specify tolerances where appropriate.

7.2.2 Re-calibration

Re-calibration of the device or reference standard shall be carried out according to the recommendations of the competent person. A new calibration certificate shall be issued attesting to the re-calibration.

Minimum frequencies for calibration and re-calibration should be determined for each device on the basis of the stability of the device and the critical nature of the measurement.

7.2.3 Quality control checks

7.2.3.1 In-house quality control procedures that are capable of detecting changes in the accuracy of the device shall be implemented by the Licensee.

7.2.3.2 In-house quality control checks shall be carried out against reference standards on a frequent basis.

7.2.4 Restriction on use of devices

Measuring devices that do not have a current calibration certificate or have been subsequently affected by a change in their accuracy shall not be used.

7.3 Measuring Devices

7.3.1 Scales and instruments

7.3.1.1 Weighing scales, thermometers, pH meters, flow meters and similar devices, or their respective reference standards, shall be calibrated by a laboratory that has been appropriately accredited to ISO Guide 25.

7.3.1.2 In-house quality control procedures shall include:

(a) check weights in the case of weighing scales;

(b) ice point checks in the case of thermometers expected to work in the range -40 °C to 100 °C.

(c) checks against buffered solutions in the case of pH meters; and

(d) any other checks recommended by the calibration laboratory.

7.3.2 Laboratories

Laboratories shall be approved by the Director-General.

Laboratories that comply with the requirements of the Meat Industry Laboratory Approval scheme, MILAB Approval Ltd, are approved by the Director-General. The name of the laboratory, the address, the signatories and the approved tests are available from The Administrator, MILAB Approval Ltd, P.O. Box 345, Wellington. The list of laboratories will appear in [Manual 15]. In-house quality control checks are a requirement under the MILAB scheme.

7.3.3 Chillers and freezers

7.3.3.1 Automatic temperature recording equipment that is required for temperature controlled rooms shall be calibrated. Refer also to IS 2.

7.3.3.2 On-site calibration shall be performed by a competent person.

7.3.3.3 In-house checks shall be carried out using independent but calibrated thermometers.

7.3.4 Processing equipment

7.3.4.1 The manufacturer should include recommendations for calibrating measuring devices incorporated into processing equipment. Where a manufacturers' recommendations are not provided, calibration and in-house quality control checks shall be performed according to the advice of a competent person.

7.3.4.2 The measuring devices and control apparatus associated with automated control systems shall be calibrated according to the recommendations of the manufacturer or installer. In the absence of such recommendations, the system shall be calibrated according to the recommendations of a competent person

7.3.5 Computer controlled devices

Systems that are under computer programmed control shall be verified using calibrated measuring devices.

7.3.5.1 Access to the programmed control parameters shall be protected.

7.3.5.2 The Licensee shall maintain security over access to the programme.

7.3.5.3 A register shall be kept of all programmes and the occasions on which entry to the operating parameters was authorised in order to minimise unauthorised access to, and corruption of, the programme parameters.

7.3.5.4 Any alteration to the programme shall be recorded.

7.4 Subjective Inspections

7.4.1 Personnel

7.4.1.1 People who make subjective inspections or tests directly on products or byproducts shall be fully trained before commencing any inspection and recording function.

7.4.1.2 *Defect or grade checks*

The licensee shall ensure that only adequately trained and competent people undertake defect or grade checks.

(a) Training may be in-house, in which case the training programme should be peer reviewed, and the Licensee shall maintain a training record showing the training provided and that a minimum level of achievement has been attained by each person.

(b) Training may be external, in which case training providers shall be recognised in the particular field and shall issue certificates of competence to a trained person.

7.4.1.3 *Sensory testing*

This is a specialised test and shall be conducted by, or under the directions, of a competent person (IS 8: Appendix D). The panellists shall be capable of detecting the particular sensory characteristic under test.

7.4.2 Calibration and in-house checks

Appropriate comparative tests shall be used to calibrate or "check the checkers".

Note: Non-parametric tests are appropriate for comparing inspections where count data is involved and measurement data is unavailable. Student's *t* tests or two sample tolerance tests are appropriate for comparing inspections where measurement data or characteristics are involved.

8. Branding and Certification

Scope

This section lays down the conditions under which products and where appropriate byproducts are able to be branded and products and byproducts are able to be certified.

8.1 Outcome

Where production complies with all relevant requirements, the Verifier, on behalf of the Director-General, may permit the branding of products as being fit for human consumption and may certify that products and byproducts conform to the requirements of an export market.

8.2 General Principles

Brands and certificates are the property of the Director-General and their general form and application are protected under the Flags, Emblems, and Names Protection Act 1981 and the Meat Act 1981.

8.2.1 Products

The food safety and regulatory requirements for the production of products intended for human consumption shall be fully described in documented systems recognised as valid. Where it can be verified that the production conforms to the documented systems, the products may be branded and/or certified for export or otherwise released for use.

8.2.2 Byproducts

The regulatory requirements for the production of byproducts shall be fully described in recognised documented systems. Where it can be verified that the production conforms to the documented system, then byproducts may be released for use and/or certified for export.

8.2.3 Restriction on non-conforming product or byproducts

Products or byproducts that do not conform to the intended food safety or regulatory outcomes shall not be branded, released for use or certified for export.

8.3 Branding

8.3.1 Director-General

The Director-General is accountable for defining the specific nature of, and application of, all forms of the official inspection legend (brand).

8.3.2 The Verifier

The Verifier is authorised to allow products that conform to requirements of a production system recognised as valid to be branded with the official inspection legend.

8.3.3 Application of the brand

The application of the brand in any specific instance shall be in accordance with requirements for branding that are outlined in IS 5, ISs 6, 12 or [15].

8.3.4 Supply of brands

The supply of any brand, or official inspection legend, shall be in accordance with the requirements outlined in [Manual 15].

8.4 Certification

8.4.1 Director-General

The Director-General is accountable for defining the specific format of any certificate for the export of products or byproducts. Refer also to Manual 12.

8.4.2 The Verifier

The Verifier is authorised to issue certificates for products or byproducts which comply with the requirements for export certification specified in Manual 12.

8.4.3 Verifier accountability

The Verifier is responsible for the authenticity of any certificate and the conformity of the certificate with the form and nature specified by the Director-General.

Appendix A. Microbiology

A.1 Outcome

The microbiological characteristics of products and byproducts shall be used as an indicator of the adequacy of process interventions and, in the case of products, process hygiene and the potential to adversely affect the safety of food. Databases shall be kept from which the microbiological characteristics of products and byproducts shall be periodically assessed.

A.2 Definitions

Contamination, when used in the context of microbiology, means any number of bacteria, including pathogenic bacteria, that are present at levels greater than that which is usually expected for the type of product or byproduct. If a "usually expected" level has not been established for the particular type of product or byproduct, then it means any level of bacteria greater than that which may have been established by any general criteria.

Microbiological monitoring programme is a documented system whereby the effectiveness of measures to control the hygiene of production can be validated and verified through microbiological evaluation.

A.3 General Principles

A.3.1 Application of a microbiological monitoring programme

The specific requirements for microbiological evaluation of products, byproducts, production systems or the environment are outlined in ISs 3, 5, 6, 7, 12 and 15. A microbiological monitoring programme shall be implemented wherever a microbiological evaluation is required.

A.3.2 Approved laboratories

A.3.2.1 All microbiological analyses shall be performed in a laboratory that is participating in a quality assurance scheme that has been approved by the Director-General, as set out in [Manual 15], e.g. MILAB.

A.3.2.2 The laboratory procedures and analytical methods shall conform to the requirements of the quality assurance scheme.

A.3.2.3 If the laboratory quality assurance scheme does not have a requirement for an analytical method, then analyses shall be performed by methods that are currently accepted by the intended market and appropriate for the nature of the product or byproduct.

A.3.3 Handling samples

The procedures for taking samples, handling and transporting the samples to a laboratory for analysis shall be detailed by the laboratory. As a minimum, these procedures shall conform to the requirements of the quality assurance scheme.

A.3.4 Sampling for validation

The sampling protocol used for validation purposes shall be determined using the principles outlined in IS 8: Appendix E.

A.3.5 Sampling for verification

The sampling plan used for verification purposes, i.e. the type and number of samples, the specific analyses to be performed and a recommended acceptance number, should be outlined in the particular requirement for microbiological evaluation. If the sampling plan has not been specified, then principles outlined in IS 8: Appendix E and elsewhere in IS 8: Appendix A, shall be used to determine an appropriate sampling plan.

A.3.6 Dispositions

The disposition of any product, byproduct or production system shall be based in part on data obtained from a valid sampling plan, or protocol, and a determination of the degree of conformity with, or divergence from, reference standards or appropriate databases for similar product, byproduct or production systems.

A.3.7 Databases

Databases relating to the microbiological characteristics of similar products, byproducts or processes may be used to establish national reference guidelines.

A.4 Microbiological Databases

A.4.1 Application

Data obtained from any microbiological evaluation of a product, byproduct or process may be compiled into a database, see also Manual 15. Unless otherwise specified, the database shall provide the reference standard for the microbiological characteristics of the process or product, or where appropriate byproduct.

A.4.2 Specificity of databases

The database shall clearly identify:

(a) the different products, processes or byproducts to which the data relate;

(b) the circumstances under which the data was obtained, e.g. process validation studies, routine monitoring, special investigations, etc.; and

(c) the type of sampling, i.e. random and quasi-random sampling in which data can be assumed representative of the product is to be distinguished from "worst case" oriented sampling procedures.

Note: Data obtained from an assessment of non-conforming production or follow-up studies after indications of process failure, and data-related experiments, shall be clearly identified and shall not be included in routine database summaries.

A.4.3 Units of measurement

The units of measurement shall be actual counts, with the area, volume or weight of material over which the count was taken, as well as the inferred counts for standard areas, volumes or weights.

A.4.4 Minimum number of data points

Before being used to describe a process or product, a database shall contain at least 30 data points of the specified microbial indicator, e.g. aerobic plate counts or pathogen counts, relating to that process or product, referred to a common unit of measurement.

The value of any database as a reference standard for a process or part of a process is limited by the variability of the data. While there is natural variation between samples (characteristic of the process), variation may be a reflection of the accuracy of repeated sampling at the same site, the use of composite samples, mixing different types of samples (swabs v. excisions) and using different analytical methods.

A.4.5 Parameters of a database

The database shall be periodically summarised by parameters relating to the distribution of the data. Following parameters should be considered:

(a) The counts should be transformed into a standard or common unit of measurement. Normally a further transformation by taking logs to the base 10 will also be required, but this second transformation may vary according to the situation.

(b) Where logs to the base 10 are used, the percentage of counts, per unit of measurement, in the ranges 0.1 to 0.99, 1 to 9.99 ($1x10^{-1}$ to $9.99x10^{-1}$, $1x10^{0}$ to $9.99x10^{0}$) etc., should be given.

(c) The means and standard deviations of the transformed counts, or alternatively the median (50th percentile) and the interquartile range should be given.

(d) The area of transitional concern (the area of transitional concern relates to 3 class sampling plans), the 80^{th} percentile (mean plus 0.84 x s.d.) and the maximum accepted count should be given.

A.4.6 Outliers

Outliers are values outside the range to be expected from the mean and standard deviation of the distribution of transformed counts.

(a) Outliers shall be investigated to determine if the particular result relates to a characteristic of the process or to sampling, handling or analytical procedures. If the particular result naturally falls within the frequency distribution curve for the database, then the value should be accepted;

otherwise it should not be included with any new data added to the database.

(b) There are various statistical tests that can be used for the detection of outliers, but the following table may be used as a rough guide:

Number of data points	Outlier
30	more than 2.1 s.d. from the mean
50	more than 2.3 s.d. from the mean
80	more than 2.5 s.d. from the mean
200	more than 2.8 s.d. from the mean
500	more than 3.0 s.d. from the mean

A.4.7 Compiling the database

Data obtained from routine process evaluation shall be regularly added to the database with a consequential recalculation of the database parameters.

A.5 Process Parameters

A.5.1 Parameters of a frequency distribution

The parameters which describe the process will generally be the parameters of a frequency distribution, or distributions, which includes the population mean, standard deviation (s.d.) and the 80th percentile. These parameters will be representative of data obtained from validation studies, initial processing and from routine process evaluation.

A.5.2 Validating parameters by reference

Data obtained from initial process studies shall be compared with the relevant national database, if there is one present, or with international microbiological criteria for products produced by similar processes, to validate the process. Microbiological criteria used to validate a process developed from experiments shall relate specifically to microbiological outcomes of the experiment approved by the Director-General.

A.6 Routine Process Evaluation

A.6.1 Application

Routine process evaluations shall be conducted according to the sampling plan required by any standard for products, byproducts, processes or the environment described in any manual or Industry Standard relating to their production or export certification.

A.6.2 Indicator organisms

Unless otherwise specified, routine process evaluations shall assess the general process hygiene and potential for enteric pathogens.

(a) Aerobic plate counts shall be used to evaluate the general process hygiene.

(b) *Escherichia coli* shall be used to assess the potential for the presence of enteric pathogens.

(c) The procedures for taking samples and the methods for analysis shall comply with the requirement of the approved laboratory.

A.6.3 Review of data

The new data shall be compared with the process parameters derived from the appropriate in-house database. The new data shall be compared against in-house standards using means and standard deviations, two or three class sampling plans, or appropriate trend analysis techniques.

A.7 Process Failure Evaluation

Process failure relates to circumstances where the process failed to comply with the operating parameters defined in the documented system which could result in an increased proliferation of bacteria or an increase in bacterial contamination of products/byproducts.

A.7.1 Sampling plan to be approved

Where it is necessary to evaluate the usability of products in the event of a process failure, the sampling plan and acceptance criteria shall be approved by the Director-General.

A.7.2 Process failure report

The sampling plan will depend on the circumstances of the failure. A full description of the circumstances shall be forwarded to the Director-General. The information shall include but is not necessarily restricted to:

- the process and the nature of the product or byproduct;
- the normal operating parameters for the process;
- the parameters operating for the duration of the process failure;
- the actions that were taken at the time of the failure; and
- the time taken to stabilise the defaulting state and restore preservation of the product.

A.8 Specific Pathogens

A.8.1 Application

Evaluating products or byproducts for the presence of specific pathogenic organisms shall be performed in the following circumstances:

- whenever it is specifically required by a processing criterion;
- whenever it is a certification requirement of a particular market;
- whenever it is recommended for the production of a type of food or particular method of preservation;
- whenever it is considered to be in the national good, e.g. to gain recognition that New Zealand's food hygiene controls are equivalent to the requirements of importing countries.

Note: Any consideration under the last point is to be determined in consultation with the industry.

A.8.2 Sampling

The sampling plans and sampling methods used for investigating specific pathogens in products or byproducts shall be consistent with the specific requirements of the production criteria, markets or type of food.

A.8.3 Approved laboratory

All pathogen analyses shall be performed in a laboratory that is participating in a quality assurance scheme that has been approved by the Director-General, e.g.

MILAB. Refer also to [Manual 15]. The laboratory procedures and analytical methods shall conform to the requirements of the quality assurance scheme.

A.8.4 Handling samples

The procedures for taking samples, handling and transporting the samples to a laboratory for analysis shall be detailed by the laboratory.

A.8.5 Compiling a database

The results of all pathogen evaluations shall be compiled into a database specific to the species of pathogen and the type of product or byproduct.

Appendix B. Chemistry

Scope

This section is limited to the evaluation of the chemical characteristics of products and byproducts as a consequence of their production and does not include evaluations performed under the National Chemical Residue Programme.

B.1 Outcome

The chemical characteristics of products and byproducts shall be used as an indication of their conformity with compositional standards and the potential for an adverse food safety outcome. Validation and verification of the chemical characteristics of products and byproducts shall be based on approved methodologies.

B.2 General Principles

B.2.1 Application

The chemical characteristics of any product or byproduct shall be evaluated where:

(a) in any New Zealand or foreign regulation, there is a standard description for a name, a type or a specific property of any product or byproduct; and/or

(b) the preservation of a product or byproduct is dependent on a particular chemical substance.

B.2.2 Standard descriptions

Standard descriptions shall include, but are not restricted to:

(a) specifically named products, e.g. corned beef, ground beef, ham, hamburger;

(b) types of products, e.g. mechanically separated meat;

(c) specific properties of products or byproducts e.g. nutritional content, nutritional claims, health claims.

B.2.3 Foreign and New Zealand standards

The standard descriptions for products intended for export may not necessarily be contained in Manual 12. Legal requirements relating to food standards in the

intended markets shall be consulted for the appropriate descriptions of products. The description of products intended for the domestic market are outlined in current New Zealand food regulations.

B.2.4 Laboratories

All chemical analyses shall be performed in a laboratory that is participating in a quality assurance scheme that has been approved by the Director-General, e.g. MILAB. Refer also to [Manual 15].

(a) The laboratory procedures and analytical methods shall conform to the requirements of the quality assurance scheme.

(b) If the laboratory quality assurance scheme does not have a requirement for an analytical method, then analyses shall be performed by methods that are currently accepted by the intended market and appropriate for the nature of the product or byproduct.

B.2.5 Handling samples for analysis

The procedures to be used by the Licensee for taking samples, handling and transporting the samples to a laboratory for analysis shall be detailed by the laboratory.

B.2.6 Sampling protocol

The sampling protocol used for validation purposes shall be appropriate to the nature of the product, or byproduct, and the distribution of the analyte(s) of concern.

B.2.7 Sampling for on-line verification

Sampling and testing for the purposes of on-line verification may include methods and analytical services which provide real time results and do not necessarily involve approved laboratory schemes, subject to:

(a) the method being calibrated against a fully validated analytical method if the result is a quantitative measure of an analyte;

(b) the measuring instruments being calibrated if the method results in a quantitative or qualitative measure of a characteristic of the product or byproduct which is not an analyte;

(c) formulation of products and byproducts conforming to documented procedures and the measuring instruments being calibrated.

B.2.8 Disposition of non-conforming standard descriptions

Any product or byproduct that does not conform to a standard description may be satisfactorily disposed of under the following conditions:

(a) the non conformance does not relate to any analyte that is present in amounts that could result in an intoxication;

(b) the product or byproduct conforms to a standard description in an alternative market, in which case the product or byproduct may be disposed of in that market;

(c) the product or byproduct may be reworked in order to adjust the level of non-conforming analytes provided:

(i) reworking will not result in any biological, chemical or physical outcome likely to adversely affect food safety,

(ii) the material and the process are of a nature that will allow reworking to occur,

(iii) conformance with a standard description is validated before release of the reworked material.

B.3 Additives

Additives are substances which are added to products to achieve a particular technical outcome and are substances which are not normally consumed on their own.

B.3.1 Levels of additives

The level of additive in any product intended for any market shall not exceed standards that are prescribed in the legal requirements relating to food standards of that market.

B.3.2 Validating additive levels

Where additive levels are prescribed, the level of additive in a product shall be validated in a laboratory that is participating in a quality assurance scheme approved by the Director-General.

B.3.4 Verifying additive levels

Verification activities may include the use of in-line control methods described in IS 8: Appendix B.2.7, in addition to validation as required in IS 8: Appendix B.3.2.

B.4 Preservatives

Preservatives may include additives, salt, spices and other biological substances.

Where any chemical substance is added to a product in order to achieve preservation, the level of the chemical in the final product shall be evaluated. The level of any chemical preservative shall not exceed any limits that may be prescribed in New Zealand legislation, in respect of products intended for the domestic market, or foreign legislation, in respect of exported products.

Appendix C. Physical Measurements

C.1 Outcome

The physical characteristics of products, byproducts and processes shall be used as an indication of preservation and the potential for an adverse food safety or regulatory outcome. Validation and verification of the physical characteristics of products, byproducts and processes is to be based on appropriate procedures.

C.2 Definitions

Physical characteristics include physical contamination, specific size or weight of meat, physical state of the product including temperature, water activity and pH.

C.3 General Principles

C.3.1 Application

The physical characteristics of a product, byproduct or process shall be evaluated where any particular characteristic is:

(a) critical to the preservation of the product; or

(b) critical to conforming with any criteria set out in New Zealand or foreign legal requirements.

C.3.2 Sampling procedures

The sampling procedures and methods for evaluating any physical characteristics shall conform to criteria contained in any product, byproduct, process or market requirement specified in any manual or processing standard recognised as valid.

C.3.3 Measuring instruments or personnel

All instruments, devices or personnel used to evaluate any physical characteristic shall be calibrated according to IS 8: Section 7.

C.3.4 Non-conformity

Any product, byproduct or process that does not conform to any standard or limitation for a physical characteristic required by any criteria may be reworked, provided:

(a) reworking will not result in any biological, chemical or physical outcome likely to adversely affect food safety;

(b) there is no regulatory prohibition or limitation on the distribution of reworked material;

(c) the material and the process are of a nature that will allow reworking to occur; and

(d) conformity with a compositional standard or standard product description is validated before release of the reworked material.

C.4 Temperature

C.4.1 Application

Any temperature that specifically relates to a food safety or a regulatory outcome in the production or preservation of products or byproduct shall be monitored.

C.4.2 Heat treatments

The temperature of any heat process that is designed to control microbial agents shall be monitored. This includes, but is not limited to, cooking, canning of products and the rendering of meals.

(a) The initial heat values shall be validated or, in the case of standard processes, the heat values for the process shall have been validated.

(b) The heat values that are achieved during processing shall be routinely monitored to verify replication of the validated process. Where validated heat values have been described in terms of time and temperature, these parameters shall be monitored during verification.

Note: Where heat values have been validated based on complex measurements involving particle flow rates and particle size, re-validation may only be necessary if there is any significant alteration to the equipment or process. In these instances the validated operating parameters shall be routinely monitored during verification.

C.4.3 Refrigeration temperatures

C.4.3.1 The temperature of any cooling or tempering process that is designed to limit the proliferation of residual or contaminating microbial agents shall be monitored. This includes the cooling of cooked or heated products, post-slaughter management, equilibration of chilled products, tempering and thawing of refrigerated products.

C.4.3.2 Where the potential for microbial proliferation in the cooling process has been validated, and described in terms of time and temperature, the process parameters of time and temperature shall be monitored to verify the process outcomes.

C.4.4 Preservation temperatures

The temperature of any refrigeration process that is designed to maintain a state of preservation of products shall be monitored.

C.4.5 Monitoring temperatures

Temperature shall be monitored at the site specified for the heating or cooling process or for the storage of refrigerated product.

(a) Where the temperature of the product or byproduct is monitored by directly measuring the product or byproduct, non-conformance shall be assessed as failing to achieve the specified temperature.

(b) Where the temperature of the product or byproduct is monitored by indirectly measuring the temperature of the heating or cooling medium, the temperature of the medium shall have been validated, and non conformance shall be assessed as failing to achieve the specification for the heating or cooling medium.

C.5 Water Activity (A)

C.5.1 Application

Where the preservation of a product, or byproduct, is dependent on reduced water activity, then the effectiveness of the preservation shall be validated by either:

(a) directly measuring the water activity;

(b) calculating water activity as a measure of added salt and conducting shelf life studies; or

(c) directly measuring moisture content and conducting shelf life studies.

The requirements of this section do not apply to surface drying of carcasses that may result during post slaughter management of cooling. Refer also to IS 6.

C.5.2 Verification of compliance

For verification of compliance with process controls, and the effectiveness of the process, indirect measures of water activity (e.g. levels of moisture or added salt) may be used, provided the methods have been calibrated against direct measurements of the water activity or valid shelf life studies.

C.6 Acidity (pH)

C.6.1 Application

Where pH is a critical factor in determining:

- the suitability of a type of process (e.g. high acid canned foods);
- the suitability of raw material (e.g. dark cutting or pale soft exudative meat (PSE)); or
- the effectiveness of fermentation,
- then pH shall be directly measured as part of the validation.

C.6.2 Verification of compliance

Direct or indirect measurements of pH may be used for routine verification activities where these are appropriate, e.g. inventory control and quality control of the formulation in the case of acidified products.

Appendix D. Sensory Tests

D.1 Outcome

Processing shall result in products which have the expected sensory characteristics of the type of product as determined by a competent person using recognised procedures.

D.2 Definitions

Deterioration is any statistically significant change in a sensory characteristic of a product that is detectable by an experienced test panel and affects the usability of the food.

Sensory characteristics includes taste and odours.

D.3 General Principles

D.3.1 Application

The sensory characteristics of a product shall be evaluated when there is evidence to suspect that deterioration has occurred through spoilage or contamination and products are still intended for human consumption.

(a) Spoilage includes microbial proliferation as a consequence of a failure to adequately preserve, or partially preserve, products.

(b) Contaminants includes air-borne contaminants, additives and processing aids, general production chemicals and lubricants.

D.3.2 Test methods

An evaluation of the sensory characteristics shall be performed by or under the supervision of a competent person. The test panels shall be experienced in the recognition of the normal sensory characteristics of the products under test. Test methods shall include control samples and the results shall be statistically valid.

D.3.3 Sampling protocol

The sampling plan, sampling procedures, handling and transport methods shall be detailed by the competent person.

Factors to consider in designing a sampling plan are:

(a) the nature of the deterioration (e.g. spoilage or contaminant);

(b) the distribution of the deteriorating effect and the types of product involved, including species of product; and

(c) the nature and the extent of any protective barriers, including the application of any form of preservation.

D.3.4 Hazard identification

The competent person shall determine the nature and extent of any health hazard associated with the deterioration and should limit test methods to those that are not expected to place the test panel at risk.

D.3.5 Disposition of deteriorated products

The disposition of deteriorated product shall be approved by the Director-General.

Appendix E. Statistical Techniques

E.1 Outcome

The data obtained from measurements used to validate and verify process outcomes shall be reliable, accurate, appropriately analysed and capable of detecting process variation.

E.2 Definitions

Control parameters are the parameters, or numerical target values and tolerances, that are to be used in process monitoring. They may be derived from industry specifications, process parameters or both. Where control parameters are based on assumptions, such as "worst case" scenarios or log counts that have a normal distribution, the assumptions shall be verified or demonstrated by appropriate references.

Process monitoring is the method used to detect changes in process parameters and to detect non-conforming product or byproduct.

Process parameters are a description of the observed characteristics of a process under normal operating conditions. They are normally obtained from direct measurement and relate to operating conditions, e.g. the average and range of temperatures, or mean and standard deviation of log-transformed plate counts.

Sampling plan is a description of the procedures and methods for obtaining data, including a sampling frequency, sampling sites, a quantity of sample, numbers of samples, methods of measurement.

Special investigation includes experiments and investigations of non-conforming production.

Validation, in relation to statistical techniques, is estimating values of process parameters and confirming that they fall within acceptable ranges based on relevant process standards.

Verification, in relation to statistical techniques, is confirming the values of process parameters and check assumptions made in deriving control parameters. Verification may not always entail the special collection of data, but may be based on data collected during routine process monitoring activities.

E.3 General Principles

Validation or verification of any process outcome is dependent on the quality of the data that is obtained. In general, information about a process or product/byproduct is based on a small number of samples from the population or lot. As the number of samples increases, the precision of estimates based on that sample also increases. Any conclusion from the analysis of the data will be a conclusion based on the samples. If the conclusion about the samples is to be extrapolated to the population or lot, the samples must be representative of the lot.

E.3.1 Application

Any data used for the purposes of validating or verifying a process shall have been obtained using an appropriate method and from a sampling plan yielding data that is representative of the process, product/byproduct or lot of product/byproduct. The circumstances under which the data were obtained should be clearly identified in the manner described in IS 8: Appendix E.4.

E.3.2 Documented sampling plan

The sampling plan shall be documented. Verification activities shall include determining compliance with the sampling plan.

E.3.3 Validating conformity of a process

A process shall be considered validated if process parameters imply conformity with relevant standards. Assumptions required to demonstrate this conformity must be consistent with known characteristics of equivalent processes or published scientific principles. The parameters shall be estimated with sufficient precision to demonstrate conformity.

E.3.4 Verifying conformity of a process

Verification activities will include the evaluation of data from routine process monitoring.

(a) Process monitoring may be considered verified if:

  (i) the method of collecting data conforms to the methods specified in the relevant sampling plan; and

  (ii) there is evidence of appropriate action being taken whenever data falls outside the appropriate ranges specified in the control parameters.

(b) Process control may be considered verified if the data lie within the appropriate ranges specified by the control parameters.

(c) Control parameters may be considered verified if:

(i) any assumptions under which they were derived are documented and verified; and

(ii) they have been demonstrated to conform with any relevant process standards, or have been derived using valid statistical and other methods to meet relevant production criteria or in-house standards, and are consistent with process parameters established during validation.

E.3.5 Analysis of data

All data shall be analysed using statistical methods that are appropriate to the type of data and the nature of the circumstances.

E.4 Data

E.4.1 Selection of samples

The design of any sampling plan will be based on assumptions about the distribution within the product/byproduct, or over space or time, of the particular characteristic to be measured.

E.4.1.1 Where any characteristic is not uniformly distributed in the product/byproduct, or lot of product/byproduct, then the basis for the sampling plan shall be included in the documentation.

(a) When any process description includes a specification for sampling, as in the case of routine microbiological evaluation of carcasses, the specified sampling plan shall be followed.

(b) Where any process criteria is based on a "worst case scenario", as in the case of physical characteristics of post-slaughter management, the sampling plan shall reflect sampling sites representative of the worst case.

(c) When any product standard is based on a maximum tolerance of a characteristic, as in the case of chemical characteristics of a manufactured product involving large, whole tissue meat components, the sampling plan shall reflect a sample size equivalent to the smallest package.

E.4.1.2 Where any characteristic is uniformly distributed in the product/byproduct, or lot of product/byproduct, then the sampling plan shall reflect requirements for sampling according to generally accepted criteria, should they exist for the product, type of product/byproduct or process.

E.4.1.3 Where any sampling plan requires samples to be obtained at random then random sampling methods shall be used.

(a) The sampling plan shall specify the particular random factor, e.g. random time in the case of a continuous process, random site in the case of a spatial distribution of characteristic, or random unit in the case of a lot of product/byproduct of a defined number of units.

(b) The random sampling plan shall be determined and documented before sampling starts. Sampling must conform to the documented plan.

(c) Random sampling methods include the use of random sample tables, random number generators and raffle techniques.

E.4.2 Numbers and frequency of samples to be taken

In any sampling plan, the frequency of sampling and the numbers of samples determines the precision of estimate based on the sample and probability of adverse variations in product quality going undetected. Sampling frequency and numbers will reflect the risk attached to an adverse food safety or regulatory outcome.

E.4.2.1 *Specified sampling plans*

Where any general criteria for processing includes a sampling plan which defines sampling frequency and a sample number, then the specification shall be followed, provided process control is verified. A general criteria for processing may also include reference to a sampling plan customarily used for similar processes. In these cases the food safety and regulatory outcomes of the similar process are to be validated as comparable.

E.4.2.2 *Unspecified sampling plans*

Where general criteria for processing do not exist, or do not include a sampling plan, then the sampling frequency and/or sample numbers shall be based on the maximum acceptable prevalence or level of the particular characteristic determined by its assessed severity in relation to a food safety or regulatory outcome.

E.4.2.3 *Sampling in high risk situations*

In the case of non-conforming product or byproduct, and where the risk attached to an adverse food safety outcome is assessed as high, the sampling plan shall be based on the 95% probability of detecting one case of the particular characteristic when the prevalence of that particular characteristic is at the maximum acceptable level.

E.4.3 Data checking

E.4.3.1 All data shall be reviewed to identify aspects of the data set which may differ from the basic assumptions about expected process outcomes.

E.4.3.2 *Count data*

Where measured data is involved, the review should include:

(a) the construction of a frequency distribution to check any distributional assumption, e.g. log-normal distributions;

(b) an examination for trends where data is collected over time; and

(c) checking for possible outliers as described in IS 8: Appendix A.4.6.

E.4.3.3 *Subjective data*

Where subjective data is involved, the data sheets should be checked for complete responses - non-responses or failures to identify a characteristic could unfairly bias the process outcomes.

E.4.3.4 *Unexpected variations*

Sampling and test methods and procedures shall be thoroughly reviewed when data differs markedly from the basic assumptions about the expected process outcomes.

E.5 Process Parameters

E.5.1 Validating process parameters

Data obtained from validation studies shall be compared to generally accepted criteria for the process or to criteria that have been specifically designed to meet particular requirements and have been approved by the Director-General. Appropriate statistical methods for comparative testing shall be applied.

E.5.2 Deriving control parameters

The control parameters at any appropriate control point shall be derived from the process parameters and any relevant production criteria. They shall be defined in the documentation.

E.5.3 Defining control parameters

The parameters shall define target values and tolerances, i.e. control limits and tolerances.

(a) Control parameters may specify target values, e.g. the central value in a distribution.

(b) Tolerances may relate to a range about a single figure, e.g. as the case of room temperatures, or they may be represented by such indicators as a

warning or action limit on a control chart, or a maximum allowable number of defective samples in an acceptance sampling plan.

E.5.4 Application of risk assessment

Where appropriate, the principles of risk assessment shall be applied in the derivation of process parameters.

E.6 Applied Statistics

The aim of routine process monitoring is to detect when the characteristics of concern for food safety or regulatory outcomes exceed any tolerance established for that characteristic but, more importantly, to detect situations which may lead to the adverse outcomes. By applying statistical techniques, monitoring schedules and sampling and acceptance plans can be developed to detect and/or assure outgoing quality levels (AQL's) for quantifiable attributes of production.

E.6.1 Monitoring schedule

Where no monitoring and control schedule has been specified in any process standard, for the purpose of verification activities, a schedule shall be developed for each process using appropriate statistical techniques.

E.6.2 Sampling and acceptance plans

E.6.2.1 Standard tables for sampling and acceptance plans, relative to expected and maximum permissible levels of defect, may be used, e.g. Dodge and Romig sampling plans, boning room reinspection plans, refer to IS 6: Appendix I.

E.6.2.2 *Lot plans*

Lot plans may be used for on-line monitoring; in these cases the production of a lot will occur over a period of time. The data should be checked for trends to determine if there is any change in the process parameters over the time taken to produce the lot. The inspection of samples drawn from the lot may be done throughout the production of the lot or after the lot has been produced.

(a) If inspection is performed throughout the production of the lot, the system of selecting samples shall be determined on a random time basis.

(b) If inspection is performed after the production of the lot, the system of selecting samples shall be determined on a random number basis.

(c) Any action relating to the acceptance criteria shall be applied to the whole lot.

E.6.2.3 *Modifying sampling plans*

Standard on-line plans, including Cusum plans, shall be applied as specified in the sampling plan. Modifications to any standard on-line plan that is used to verify a food safety or regulatory outcome shall be carried out by a statistician. The modifications shall be approved by the Director-General.

E.6.3 Trend analysis

Routine process monitoring data shall be presented in such a manner that process deviation can be readily detected and non-conformance is obvious. Appropriate statistical quality control methods of assembling and presenting data should be applied in this regard.

Range and mean charts, Cusum charts and V masks are all useful methods of displaying data and detecting trends.

Appendix F. Predictive Modelling

F.1 Outcome

Appropriate quantitative data shall be used for validation purposes when predictive modelling techniques are used to design or verify process outcomes.

F.2 Definitions

Predictive models will include, but are not restricted to, thermal performance, water activity and microbiological outcomes.

F.3 General Principles

F.3.1 Validating process parameters

Where any process parameters are designed according to a predicted process outcome, the outcome in real terms shall be validated using methods that generate quantitative data appropriate to the modelled parameters.

F.3.2 Verifying process outcomes

Predicted process parameters that have been appropriately validated may be used for routine process monitoring and for process verification purposes.

F.3.3 Calibrating predicted process parameters

When process modelling techniques are used as verification tools, the predicted process parameters shall be calibrated using the same methods employed for validation.

(a) Calibration shall be performed at least annually.

(b) Calibration shall also be performed whenever the process parameters are changed or modified including any change to factors that influence those parameters, e.g. increase in the carcass heat load in a chiller, changing or modifying retorts, etc.

F.4 Predictive Microbiology

F.4.1 Models appropriate to micro-organisms

Any mathematical model used for process design or verification activities shall be appropriate for the organism(s) of concern, the microbial growth factors and sensitive at the microbial growth surfaces of concern.

F.4.2 Limitation on predictive microbiology

Any predicted microbial outcome is not expected to be an accurate estimate of microbial numbers and shall not be used to quantify a microbiological outcome.

F.4.3 Designing process parameters

Mathematical models that predict microbial proliferation may be used to design process parameters.

(a) The factors included in the calculations, such as temperature, water activity, pH, nitrite or any other microbial growth-limiting factor, shall be separately validated using conventional methods.

(b) A quantitative microbiological outcome, using tests for appropriate species of microbial indicators, shall be established as a process outcome. However, in the case of canning, qualitative incubation tests are appropriate.

(c) Validation studies shall not use microbial inoculation techniques without the approval of the Director-General.

F.4.4 Process verification

Dynamic models that progressively calculate a microbial outcome from continuous data inputs may be used in part, for verification activities.

(a) The unit of measurement obtained from such models shall be used as a process index rather than a microbial count number.

(b) The data shall be obtained from reference points that have been standardised for the type of model and type of process. If the reference points are not an industry standard then they shall be standardised during process validation studies.

(c) The standardised reference points shall be documented as the appropriate process control parameters.

F.5 Temperature Models

Temperature modelling will include calculations for refrigeration performance and thermal processing.

F.5.1 Application

Temperature modelling should be used for the design of any temperature-dependent process.

(a) The refrigeration requirements for any premises should be determined against the expected process outcomes relative to the production volume of the premises.

(b) The refrigeration requirements for any product should be calculated from the specifications for processing outlined in any process standard.

(c) The thermal processing requirements for any product should be calculated from the specifications for processing outlined in any process standard.

(d) The thermal processing requirements for any byproduct should be calculated from specifications for their production outlined in any regulatory standard.

F.5.2 Validation of modelled parameters

Any calculated requirement for refrigeration or thermal processing of any product or byproduct shall be validated using appropriate methods of temperature measurement. When validated, the refrigeration or thermal processing shall be performed in a manner that accurately reflects the designed parameters of the refrigeration or thermal device.

F.5.3 Documented process parameters

When validated, the design parameters shall be documented as the appropriate process control parameters.