

**Evaluators' Manual  
for  
Risk Management  
Programmes**

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## **REVIEW OF EVALUATORS' MANUAL**

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MAF Food Assurance Authority will review this manual as necessary.

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

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**SUGGESTIONS FOR CHANGE: EVALUATORS' MANUAL**

<b>Evaluators' Manual</b>	
Name:	
Organisation:	
Address:	
Email:	
Phone:	Fax:
Section	Suggested Improvements
Signature:	Date:
Please post to: Programme Manager (Risk Management Programmes) Animal Products Group MAF Food Assurance Authority PO Box 2526 Wellington	Acknowledgement of receipt: Signature: Date:

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## **AMENDMENT RECORD**

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

Amendments to the manual can be identified by the version number in the page header.

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

<b>Amendment No:</b>	<b>Date</b>	<b>Entered by</b>
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# 1. Introduction

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## 1.1 LEGISLATION

The Animal Products Act regime is structured to comprise three main levels of law:

- Acts;
- Regulations;
- Specifications.

### 1. Acts

The two Acts that are relevant to animal products are:

- the Animal Products Act 1999 (the Act); and
- the Animal Products (Ancillary and Transitional Provisions) Act 1999.

### 2. Regulations

The Animal Products Regulations 2000 came into force on 20 November 2000 and relate to animal product standards and miscellaneous provisions.

The Animal Products (Ancillary and Transitional Provisions) Regulations 2000 came into force on 20 November 2000 and cover transitional matters. These regulations will expire on the close of 31 October 2002, if not sooner revoked.

### 3. Specifications

The specifications associated directly with the accredited evaluator are the “Animal Products (Accredited Evaluator Specifications) Notice 2000”.

***In this manual, these specifications are identified as text within a box as shown for this paragraph.***

The Acts, regulations and specifications are mandatory and have the force of law.

Note: all terms used in this manual have the interpretation as described in the Animal Products Act 1999, the Animal Products (Ancillary and Transitional Provisions) Act 1999 or any subordinate Regulations or Specifications.

For further information about the legislation, refer to the MAF Food website at [www.maf.govt.nz/animalproducts/legislation/](http://www.maf.govt.nz/animalproducts/legislation/)

## 1.2 ANIMAL PRODUCTS ACT

The Animal Products Act 1999 establishes a risk management system in order to:

- minimise and manage any risks to human or animal health arising from animal products; and
- facilitate the entry of animal material and products into overseas markets through the provision of official assurances.

The main control mechanism under the risk management system is an operator's individually designed and implemented risk management programme. These programmes must identify, control, manage, eliminate and/or minimise hazards and other risk factors in order to ensure that the resulting animal material is suitable for processing or the animal products is fit for intended purpose.

Prior to the commencement of operations under the Act, each risk management programme must be registered with MAF Food Assurance Authority.

Section 20 of the Act requires an operator seeking registration of a risk management programme to submit a copy of an independent evaluation report, that recognises the validity of the programme, to the Director-General of MAF. A person who is accredited as an evaluator under the Act must conduct the evaluation.

This manual details the competency requirements and accreditation process of a risk management programme evaluator and provides guidance for the evaluation.

## 1.3 REQUIREMENTS FOR EVALUATOR ACCREDITATION

To be accredited by the Director-General, a person must meet the requirements set out in Part 8 of the Act, particularly sections 101 and 107. The person must satisfy the Director-General that he or she is "a fit and proper person" to perform the functions and activities concerned.

The requirement to be "fit" relates to the competencies the person will be expected to have and these will stem from qualifications and/or experience. The requirement to be "proper" relates directly to the integrity of the person. The following factors will be taken into account in the assessment of the person:

- relevant competencies;
- character and reputation;
- ability to maintain an appropriate degree of impartiality and independence; and
- ability to maintain appropriate confidentiality, particularly in relation to commercially sensitive matters.

To be accredited<sup>1</sup> as an evaluator (generic) a person must meet a number of requirements, which include the competency specification and having documented procedures dealing with systems and administration.

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<sup>1</sup> The term "accreditation" or "accredited" has been applied in 2 different ways throughout this manual. The context will determine the appropriate interpretation. An individual may be accredited by the Director-General

Where a person has one or more particular areas of expertise, for example seafood primary processing, they may apply for an activity endorsement. An activity endorsement may be applied to the evaluator accreditation where the Director-General is satisfied that the person has demonstrated a satisfactory level of technical expertise in that activity. Wherever possible, the accredited evaluator is encouraged to gain activity endorsement(s), as this will assist the operator in selecting an appropriate evaluator, and the regulator during the registration of the risk management programme.

Regardless of the type of accreditation gained, the accredited evaluator must seek input from other accredited evaluators with the appropriate activity endorsements or technical experts<sup>2</sup> with the appropriate area of expertise, for any aspect of the evaluation that is outside their competency. An exception to this may apply if a code of practice, or risk management programme template etc. has been developed in consultation with, or agreed, to by MAF Food and which the accredited evaluator is evaluating the programme against.

During the transition period of the Act, the requirement that the accredited evaluator be subject to accreditation to ISO 17020 "General criteria for the operation of various types of bodies performing inspection", and a selection of supplementary criteria<sup>3</sup> is to be phased in. As an interim measure during this time, the accredited evaluator may commence evaluating risk management programmes prior to being subject to ISO 17020 accreditation.

#### **1.4 RISK MANAGEMENT PROGRAMME EVALUATION**

An evaluation involves a systematic assessment of the risk management programme's validity by an independent accredited evaluator. The evaluator will be contracted and paid by the operator. The evaluator is responsible for the risk management programme's complete assessment. However, evaluators must use the services of other accredited evaluators or technical experts for any aspect of the risk management programme that is outside their competency.

The risk management programme must be assessed against any relevant animal product regulations and specifications to ensure that the proposed operations will produce animal material that is suitable for further processing or animal product that is fit for intended purpose.

The accredited evaluator must evaluate the:

- completeness of the risk management programme against the requirements of the Act and the associated legislation;
- appropriateness and clarity of the scope of the risk management programme;
- completeness of the product description;

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as an accredited evaluator, or an individual, organisation or agency may be accredited by an accreditation body (e.g. IANZ) to ISO 17020.

<sup>2</sup> A "technical expert" is a person who is technically competent in certain area(s) as confirmed by the accredited evaluator through assessment of qualifications, training and experience, but are not themselves accredited.

<sup>3</sup> Any future reference to ISO 17020 throughout this document will be taken to include the supplementary criteria.

- appropriateness of the types and levels of outcomes (including ensuring that any animal product standards or specifications have been met);
- completeness and accuracy of the process description;
- completeness and appropriateness of hazard and other risk factor identification and analysis;
- completeness and appropriateness of the critical control points (including setting of critical limits), other controls, monitoring and corrective action procedures, operator verification activities and record keeping. (These are likely to be found both within the process control system and in supporting systems);
- adequacy and scientific basis of evidence provided to support the risk management programme;
- ability of the risk management programme to deliver the stated outcomes on an ongoing basis;
- effectiveness of recall procedures; and
- adequacy of document control systems.

During the transition period, the accredited evaluator must give due consideration to the transitional evaluation provisions of the Animal Products (Ancillary and Transitional Provisions) Regulations 2000 (Reg. 11).

At the completion of the evaluation, the accredited evaluator may recognise the risk management programme as valid (refer to section 7.1), or may return the programme to the operator for further work. Where the risk management programme is considered to be valid, the accredited evaluator must prepare an evaluation report for the operator.

The evaluation report summarises the outcomes of the evaluation and makes a recommendation to the Director-General that the programme should be registered, including any conditions that should be applied. Specifications detail the content of the evaluation report that is mandatory and endorsement(s) that must be applied by the evaluator. The operator must submit a copy of the independent evaluation report when they are making application to have their risk management programme registered.

Where a risk management programme is not of a satisfactory standard to be recognised as valid, the accredited evaluator should provide feedback to the operator explaining the areas where the programme is deficient. To ensure that impartiality and independence is maintained in cases where the evaluator may be involved in the further evaluation of that risk management programme, methods of rectifying any deficiency must not be provided. Otherwise this would involve the evaluator in the design and development of the risk management programme, hence compromising their independence.

This manual should be read in conjunction with the **Accredited Evaluator Interim Application Pack** (the Pack) (refer to Appendix 6) and the **Risk Management Programme Manual**. These documents are also available on the MAF Food website.

## 2. Evaluator Competency

### 2.1 GENERIC EVALUATOR COMPETENCY SPECIFICATION

The information in the following box details the competency specifications that must be met by any person wishing to be accredited as an evaluator.

**Specification clause:**

**5. Evaluator competency requirements**

- (1) Every applicant for accreditation under section 103 of the Act as an evaluator must have knowledge of—**
- (a) the object of the Animal Products Act 1999 and the relationship between risk management programmes and other provisions for managing risks under the Act, including regulated control schemes and overseas market access requirements; and**
  - (b) the relationship between risk management programmes and food safety programmes within the meaning of the Food Act 1981; and**
  - (c) the regulations and specifications relating to risk management programmes; and**
  - (d) the contents of and requirements for risk management programmes; and**
  - (e) the resources available to assist in risk management programme development; and**
  - (f) the risk factors to be considered when developing a risk management programme; and**
  - (g) the validation process and assessment of quality of evidence for a risk management programme; and**
  - (h) the evaluation requirements for recognised plans, processes and systems under regulation 11 of the Animal Products (Ancillary and Transitional Provisions) Regulations 2000, and other administrative transitional requirements; and**
  - (i) the relationship between the Animal Products Act 1999, the Animal Products (Ancillary and Transitional Provisions) Act 1999, regulations and specifications made under those Acts and other associated legislation, including the Meat Act 1981 and the Food Act 1981; and**
  - (j) the matters relating to hazards specified in section 17(3) of the Act in relation to risk management programmes.**
- (3) Every applicant for accreditation as an evaluator must have achieved a qualification in quality systems auditing granted by an organisation accredited by Joint Accreditation Systems of Australia and New Zealand (JAS-ANZ) or any other accreditation body recognised by JAS-ANZ for the purpose of certifying auditors in accordance with international norms.**

This specification forms part of the requirements of the *Accredited Evaluator Interim Application Pack* (refer to Appendix 6).

A person applying for accreditation must complete the requirements of the Pack.

## **2.2 ACCREDITED EVALUATOR TO BE OF AN APPROPRIATE CHARACTER AND REPUTATION**

The Director-General must be satisfied that the applicant is a proper person to carry out the function and activities concerned.

Given the importance of the role of the accredited evaluator and the need for maintenance of the integrity of the risk management system, the person must complete and sign a "Consent to Disclosure" form with their application. This will provide MAF Food with written authority to obtain a report from the police of any convictions recorded.

The Director-General will use this information to assist in determining whether the person has the necessary reliability and integrity to fulfil the evaluator's role under the Act. In this regard, convictions relating to crimes of dishonesty will be of particular relevance. Convictions for other types of offences may also be relevant depending on the type of offence, its severity and the length of time since conviction. Each case will be determined on its merits and the information will be kept confidential.

The applicant must also supply the names and contact details of a minimum of two referees with their application for the provision of information including that relating to character and reputation.

## **2.3 ACTIVITY ENDORSEMENTS**

The attainment of an activity endorsement is not mandatory for an accredited evaluator.

The purpose of an activity endorsement is to identify the specific areas of expertise of the evaluator and make this available to both the operator when selecting an evaluator and to persons involved in registering the risk management programmes.

An accredited evaluator without an activity endorsement in an area covered by the risk management programme will be expected to obtain technical input for any aspect of the programme that is outside their competency. Where this has not been obtained, it is likely that the evaluation report will be subject to greater scrutiny at the time of registration.

The specifications for activity endorsements have been split into two categories. Those that have no specific course or qualification etc. mandated by the Director-General, and those that have.

The following box details the specification that must be met by persons applying for an activity endorsement in any area where the Director-General has not mandated a specific competency requirement.

**Specification clause:**

**5. Evaluator competency requirements**

- (2) If seeking endorsement for a specific evaluation activity, the applicant must provide to the Director-General evidence of his or her—**
- (a) relevant qualifications, training and experience; and**
  - (b) compliance with any relevant competency specifications; and**
  - (c) knowledge of the infrastructure and operational norms of the relevant industry or industries.**

At this stage, the Director-General has only mandated a specific competency requirement for those persons evaluating a risk management programme involving the thermal processing of low-acid canned products for human or animal consumption. When applying for an activity endorsement in this area, the person must provide evidence of having passed a recognised course of instruction covering the fundamentals of thermal processing, including thermal processing calculations.

**Specification clause:**

**5. Evaluator competency requirements**

- (4) Any evaluation assessment of thermal processing operations for low-acid canned products for human or animal consumption must be undertaken by a person who has successfully completed one of the following courses—**
- (a) Qualified Cannery Person (Thermal Processing) Course, University of Western Sydney (Hawkesbury) Australia; or**
  - (b) Approved Persons Course for Thermal Processing of Low-Acid Foods, Food Science Australia, Werribee, Australia; or**
  - (c) Introduction to the Fundamentals of Thermal Process Evaluation, Massey University, Palmerston North, New Zealand.**

The Director-General may recognise alternative qualifications to those specified above.

It should be noted that if a technical expert or other accredited evaluator is used to provide a supporting report in this area, the evaluator must ensure that the person has obtained at least one of these qualifications prior to undertaking the work.

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## 3. Operational Competency Requirements

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### 3.1 ACCREDITED EVALUATOR TO BE ACCREDITED TO ISO 17020

It is MAF Food's intention to require accredited evaluators to be subject to ISO 17020 accreditation. This requirement is to be phased in during the transition period.

The need to have this requirement in place is to provide MAF Food with greater confidence and control over the evaluation process and to enhance the consistency in approach to the evaluation and its outcome among the various evaluators.

MAF Food is also in the process of harmonising the evaluation regimes between the animal products group and dairy group<sup>4</sup> within the Ministry, with the ultimate aim of allowing evaluators to move between the different regimes without having to meet any additional criteria (excluding any specific activity endorsement requirements).

It is intended that the accredited evaluator may demonstrate that they are subject to ISO 17020 accreditation either:

- (a) individually, as a sole trader; or
- (b) as part of an organisation; or
- (c) as part of a recognised agency that has been recognised by the Director-General for providing the evaluation function.

Supplementary criteria are being developed that must be met by the sole trader, organisation or recognised agency as part of gaining IANZ accreditation. Following are the criteria that have been developed to date and may be subject to change.

1. An accredited evaluator working as a sole trader or as part of an organisation will not need to be recognised as an agency under section 103 of the Act, or employed or engaged by a recognised agency under section 103.
2. An agency that is recognised under section 103 of the Act for certain functions (e.g. risk management programme verification) and that wishes to perform the function of evaluation, must be recognised under section 103 as an agency for this new function.
3. An evaluator that is accredited as a sole trader to ISO 17020 must be a signatory<sup>5</sup>. The signatory must notify the Director-General when changing contact details or if joining an organisation or recognised agency for the purpose of evaluation.
4. An accredited evaluator that works for an organisation or recognised agency that has been accredited to ISO 17020 may or may not need to be a signatory. The number of

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<sup>4</sup> The dairy group is currently in the process of implementing the ISO 17020 requirement for agencies involved in evaluation and verification.

<sup>5</sup> In this context a "signatory" means a person nominated by an agency or organisation and approved by IANZ as competent to take responsibility for specific types of functions and activities on behalf of that agency or organisation.

signatories within an organisation or recognised agency will be determined by IANZ in consultation with MAF Food and will depend on their size, the potential scope of the work to be performed and expected performance. In this case, the accredited evaluator must notify the Director-General when changing contact details or if joining another organisation or recognised agency for the purpose of evaluation.

### **3.2 INTERIM ADMINISTRATIVE REQUIREMENTS**

As an interim measure, an individual who is accredited as an evaluator for the purpose of the Act prior to receiving accreditation to ISO 17020 must have written procedures in place to deal with things such as confidentiality, independence and impartiality, traceability of the evaluation documentation and assessment of technical experts<sup>6</sup>.

The evaluator must ensure that any person to whom they subcontract evaluation work will also follow these documented procedures.

### **3.3 CONFLICT OF INTEREST AND INDEPENDENCE**

Conflict of interest may be defined as the loss of impartiality in an organisation's or individual's decisions or actions caused by conflicting interests in the outcome. In the case of an evaluator's conflict of interest, the policy applies only to the individual evaluator – not the organisation.

Any person carrying out an evaluation must ensure that they are independent of any commercial, financial or other pressure from those to whom the service is provided (other than for the purpose of providing that service) that may lead to a lack of independence from the risk management programme under evaluation.

In practice this means that an evaluator (or any other technical expert involved in evaluation of a risk management programme) cannot evaluate a programme if, within the past 2 years, they have been involved<sup>7</sup> in the design, development, operator validation or verification of that programme at any site (i.e. physical location), or another programme at the same site.

It is noted that there may be multiple programmes operating at one site, therefore provision of these functions for any one of those programmes would preclude the person concerned from providing evaluation functions at that site.

Individuals and organisations (including their employees and sub-contracted personnel) who are seeking accreditation to act as evaluators and/or verifiers may provide both functions, except that an individual verifier cannot verify a programme if, within the past 2 years, they have been involved in the evaluation of that programme. These requirements

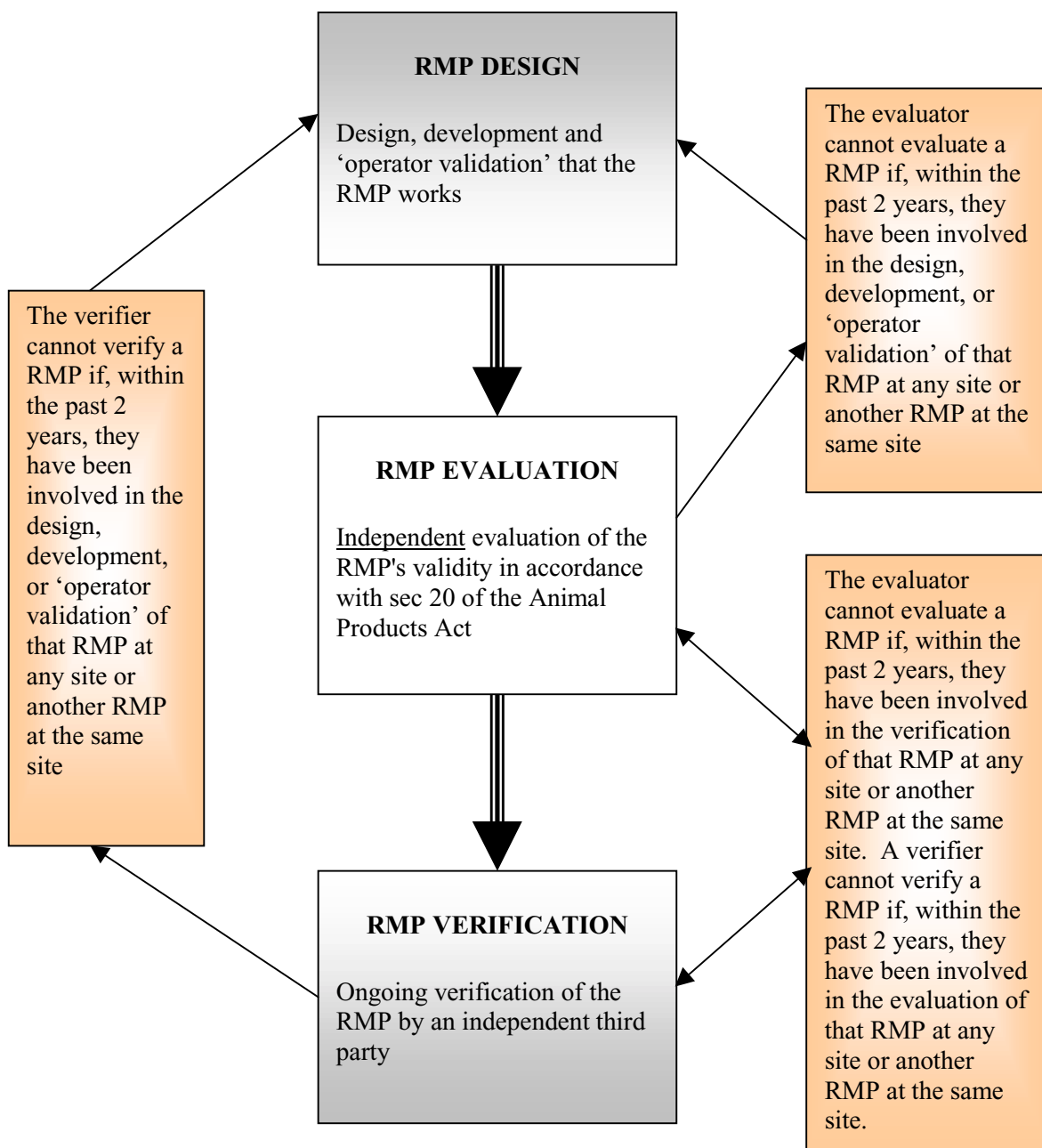
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<sup>6</sup> If the accredited evaluator is employed or engaged by an agency or organisation that has met these requirements, or are themselves accredited to ISO 17020 these procedures will be covered by that accreditation.

<sup>7</sup> Being "involved" in the design, development or validation of a risk management programme does not include the offering of advice.

do not preclude another person from the same organisation or agency from carrying out that function or activity on the same programme.

**Figure 1: MAF's Policy on Evaluator and Verifier Independence**



The verification function associated with overseas market access requirements (OMARs) is not subject to these same constraints if the OMARs are not included in the risk management programme. In this case verification of OMARs may be conducted by any person who is accredited for that purpose, regardless of any involvement that they may have had in the design, development, validation, evaluation or verification of a risk management programme.

The following box details the relevant specifications that have been developed to control confidentiality, impartiality and independence. Any person applying for accreditation as an evaluator must comply with these specifications. It is the responsibility of the evaluator to ensure that these specifications are applied to technical experts used in an evaluation.

**Specification clause:**

**6. Confidentiality**

- (1) The accredited evaluator must have documented procedures for maintaining appropriate confidentiality of information relating to operations and activities he or she comes into contact with during the course of carrying out evaluation functions and activities under the Act.**
- (2) The accredited evaluator must protect the proprietary rights of operators in relation to any information or thing he or she comes into contact with during the course of carrying out evaluation functions and activities under the Act.**

**7. Impartiality and independence**

- (1) The accredited evaluator must not have any commercial, financial or management relationship with those to whom he or she is providing an evaluation service (other than for the purpose of providing that service).**
- (2) The accredited evaluator must have documented procedures for avoiding any compromise of his or her impartiality and independence while carrying out evaluation functions and activities under the Act.**

### **3.4 EVALUATOR ACCOUNTABILITY AND RECORDS MANAGEMENT**

In many cases the professional judgement of accredited evaluators will be called upon when evaluating risk management programmes. They must take responsibility for the following factors during the evaluation of a risk management programme:

- exercising sound judgement;
- following the Act and any relevant regulations and specifications;
- conducting a full and effective evaluation of the risk management programme;
- any technical input received during the evaluation;
- recognising the validity of the risk management programme where appropriate; and
- any recommendations for conditions that should be applied by the Director-General during registration of the risk management programme.

The evaluator must keep fully auditable records of the evaluation (including copies of any relevant records generated by the technical expert) for a period of 10 years from the date of signing the evaluation report. This retention period applies even if the person ceases to work as an accredited evaluator.

The records must be kept under secure conditions in a manner that will minimise deterioration.

The responsibility for complying with this specification rests with the individual evaluator.

**Specification clause:**

**10. Records Management**

- (1) Every accredited evaluator must have documented procedures for storing and tracking all records of evaluations he or she has undertaken and any correspondence with the operator, technical experts and other accredited evaluators associated with those evaluations.**
- (2) The accredited evaluator must retain the documents specified in subclause (1) for at least 10 years from the date of signing the evaluation report.**
- (3) All records relating to evaluations must be auditable and be made available to the Director-General, an animal product officer or person authorised by the Director-General, as required.**

These specifications form part of the requirements of the *Accredited Evaluator Interim Application Pack* (refer to Appendix 6).

A person applying for accreditation must complete the requirements of the Pack.

## **4. Use of Technical Experts and Other Accredited Evaluators**

### **4.1 INPUT FROM TECHNICAL EXPERTS OR OTHER ACCREDITED EVALUATORS**

The accredited evaluator must seek input during the evaluation of a risk management programme for any aspect of the programme that is outside their competency. The accredited evaluator must have the ability to recognise and obtain additional technical input when required.

It is recognised that the decision to seek this technical input for the evaluation will not always be clear-cut. The accredited evaluator must have confidence in the final report recommendations that they submit to the operator. If the evaluator is in doubt about whether additional technical input is required, it is recommended that the input is obtained or that they contact MAF Food to discuss the issue further.

Following the provision of technical input, the other accredited evaluator or technical expert must prepare a supporting report for inclusion with the evaluation report (refer to section 4.3).

#### ***Specification clause***

#### ***4. Technical experts***

- (1) The accredited evaluator must obtain supporting reports from a technical expert with appropriate expertise, or another accredited evaluator with the appropriate activity endorsement, for any aspect of the risk management programme evaluation that is outside his or her expertise.***

### **4.2 ASSESSMENT OF COMPETENCE OF OTHER ACCREDITED EVALUATORS AND TECHNICAL EXPERTS**

Where another accredited evaluator is used to provide a supporting report, an activity endorsement in the relevant area will provide sufficient evidence that the person is competent to provide that information. In this case, the accredited evaluator will not be expected to undertake any competency assessment other than confirm the appropriate activity endorsement.

If a technical expert is used to provide a supporting report, the evaluator must have completed a competency assessment of that person prior to the work being undertaken.

The following specification applies to all persons applying for accreditation as an evaluator.

**Specification clause:**

**9. Technical experts**

- (2) The accredited evaluator must take all reasonable steps to ensure that any technical expert from whom a supporting report is obtained is competent to provide that supporting report.**
- (3) The accredited evaluator must have documented procedures for assessing the competency of any technical expert from whom a supporting report is obtained, which must include information relating to—**
- (a) the technical expert's relevant qualifications, training and experience; and**
- (b) compliance with any relevant competency specifications.**

These specifications form part of the requirements of the *Accredited Evaluator Interim Application Pack* (refer to Appendix 6).

A person applying for accreditation must complete the requirements of the Pack.

A copy of the documented competency assessment of any technical expert used in an evaluation must be included with that evaluation report. The evaluator will be responsible for ensuring that the competency assessment is completed in a full and thorough manner.

Examples of areas where technical input may be sought are listed below:

- sanitary design and construction;
- process design/flow;
- potable water - treatment systems, delivery systems;
- refrigeration design - capability, capacity, and management;
- quality control/assurance;
- statistics - assessment of quality of evidence;
- experimental design.

Refer to **Appendix 1**, Activity Endorsements, for further examples.

#### **4.3 SUPPORTING REPORTS FROM TECHNICAL EXPERTS OR OTHER ACCREDITED EVALUATORS**

The technical experts used in an evaluation are expected to complete their evaluation in the same manner as the accredited evaluator. The evaluation must be full and thorough.

The technical experts or other accredited evaluators must prepare a supporting report at the completion of their evaluation, the content of which should align with the requirements of the evaluation report, as appropriate (refer to section 9). The report should include a recommendation as to whether the part of the risk management programme evaluated is

valid, and any conditions that should be applied by the Director-General on registration of the programme.

Where the part of the risk management programme is not of a satisfactory standard to be recognised as valid and the technical expert or other accredited evaluator may be involved in future evaluation(s) of that same programme, they should provide feedback to the operator describing the areas where the programme is deficient but they should not become directly involved in the development of the risk management programme. Otherwise this would compromise their independence.

The accredited evaluator must include a copy, in full, of any supporting reports obtained during the evaluation with their evaluation report.

When an accredited evaluator signs off on an evaluation report, this provides confirmation to the Director-General that they are satisfied with any supporting reports that have been included. It is the responsibility of the accredited evaluator to ensure that supporting reports are of a reasonable standard. If there appears to be a lack of technical content or if the accredited evaluator has any reason to believe that the supporting report does not demonstrate an adequate evaluation of the relevant components of the risk management programme, the accredited evaluator must obtain further information.

It is recognised that the assessment of any supporting reports by the accredited evaluator can only occur relative to the degree of technical expertise of that person. However, failure to make this assessment and obtain further information where determined to be necessary, would be seen as a lack of due diligence.

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## 5. Evaluator Application Procedure

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### 5.1 INTERIM ASSESSMENT PROCEDURE

All documentation necessary to make an application for accreditation as an evaluator is detailed in the *Accredited Evaluator Interim Application Pack* (the Pack) (refer to Appendix 6). This is an interim procedure.

Where an activity endorsement is sought, MAF Food personnel with knowledge in the appropriate areas will assess the applicant. MAF Food may seek input from external sources where the endorsement activity is outside the competencies of its personnel.

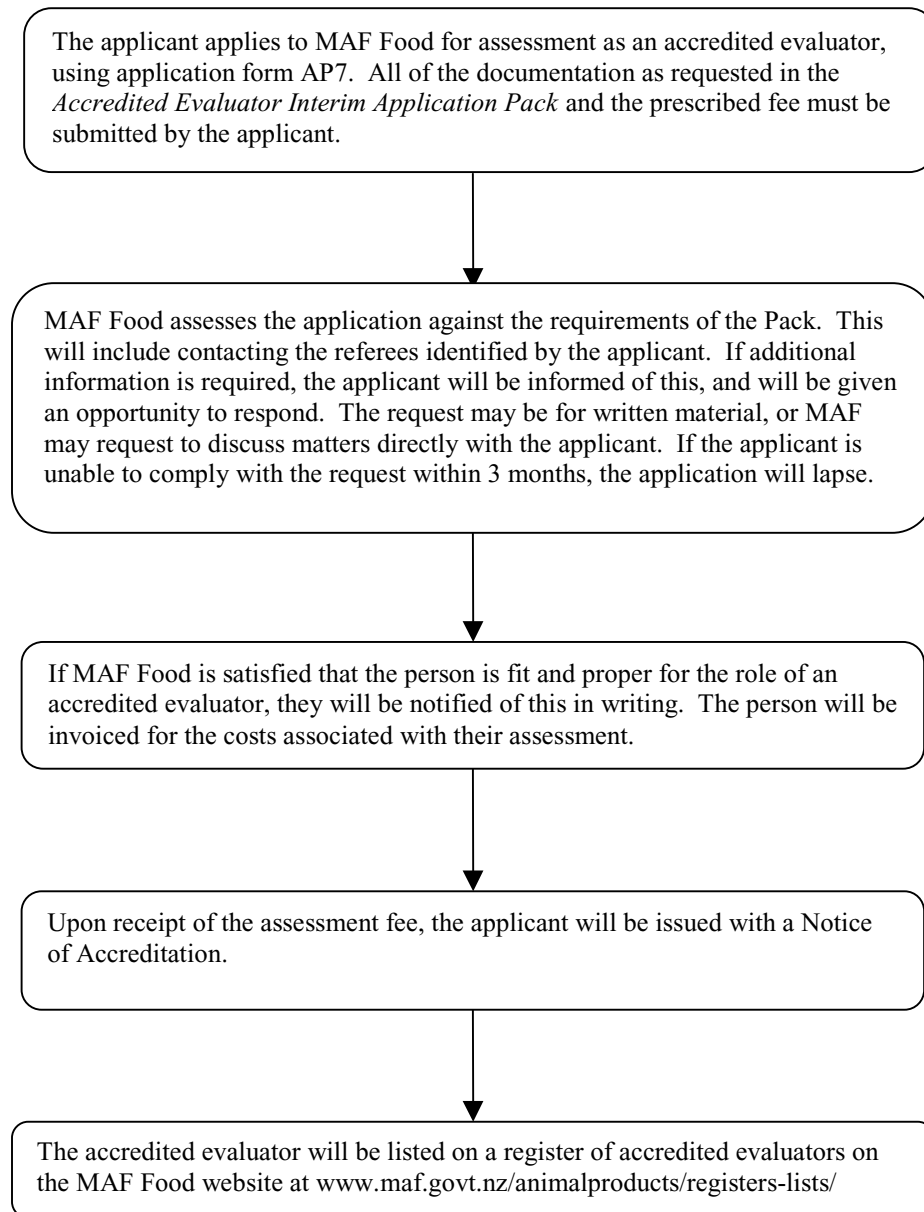
Owing to the interim nature of the assessment to be undertaken by MAF Food, it will be a requirement that the accredited evaluator be reassessed to the finalised standard once completed.

At the completion of the assessment, those persons who meet the requirements to be accredited as an evaluator will be issued with a Notice of Accreditation. The person must not take responsibility for, or sign an evaluation report until they have received this Notice. The Notice of Accreditation must be retained by the accredited evaluator for the duration of their accreditation, and must be returned to the Director-General on cessation of accreditation, or at any other time as may be requested by the Director-General.

If the applicant is dissatisfied with a decision relating to the granting of an accreditation, a review may be sought in accordance with section 162 of the Act (refer to section 5.3).

The following diagram illustrates the interim assessment procedure that will be followed by MAF Food.

## Figure 2: Interim Assessment Procedure



## 5.2 FEES

The applicant will be required to pay an application fee and an assessment fee (calculated on an hourly basis) for the time involved in assessing the application<sup>8</sup>. At the completion of the assessment, the applicant will be invoiced for the assessment fee and must pay this

<sup>8</sup> In certain circumstances, the Director-General may provide an estimate of the costs associated with the assessment prior to the assessment occurring, and in some circumstances, the applicant will be required to pay this fee prior to the processing of the application.

prior to the Notice of Accreditation being issued. This fee must be paid by the applicant regardless of the outcome of the application.

An annual fee must be paid in subsequent years to maintain accreditation. Payment of the annual fee is the responsibility of the accredited evaluator. If the annual fee is not paid, continued activities as an accredited evaluator may be in breach of the Act. Any failure to pay the appropriate fee within 30 days of the due date may result in withdrawal of accreditation under section 109 of the Act. MAF Food will endeavour to notify the accredited evaluator when the annual fee is due.

(Refer to Schedule 4, Animal Products (Ancillary and Transitional Provisions) Act for the fees and charge out rates).

### **5.3 RIGHT OF REVIEW**

#### **5.3.1 Decision made by the Director-General**

The Director-General may refuse to grant an accreditation. Where this occurs, the applicant will be notified of the intended decision in writing, including the reasons for the proposed refusal. A summary of the information that was used to make the decision will be provided to the applicant on request. The applicant may make a written submission to the Director-General within an agreed timeframe, stating the reasons why they believe the decision should be overturned. The Director-General will review the submission and make a final decision. Where the original decision is upheld, the applicant will be notified in writing, including reasons, as soon as is practical (refer to section 104 of the Act).

The Director-General's decision will be final unless determined otherwise in a court of law.

#### **5.3.2 Decision made by a person acting under delegated authority**

Section 162 of the Act provides that where the decision to refuse accreditation has been made by a person acting under delegated authority of the Director-General, the applicant may seek a further review by the Director-General or a designated person who has not been involved in the original decision.

The application for review must be in writing and must state the grounds on which it is believed the original decision was inappropriate. The submission must be made within 30 days of being notified of the refusal.

The submission will be reviewed by MAF Food within 60 days. This may be extended a further 30 days on notification of the applicant by the Director-General. The Director-General may request additional information to be provided within a specified time. The time taken to supply this information will not be included as part of the review period. As soon as is practicable, the Director-General will notify the applicant in writing, providing reasons where the decision to refuse accreditation is upheld.

## **5.4 REGISTRATION OF ACCREDITED EVALUATORS**

The Director-General will maintain a register of all accredited evaluators as provided for under section 112 of the Act. The register will be available for public viewing on the MAF Food website at [www.maf.govt.nz/animalproducts/registers-lists](http://www.maf.govt.nz/animalproducts/registers-lists)

The register informs members of the public and risk management programme operators of those individuals who are accredited to undertake the evaluation function, and the activity endorsements which have been granted where appropriate. The register also facilitates compliance, audit and other supporting administrative functions of MAF Food.

The register will contain the following information about accredited persons:

- name;
- contact details; and
- activity endorsements.

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## **6. Accreditation Requirements**

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### **6.1 CONDITIONS OF ACCREDITATION**

Accreditation may be granted subject to conditions. The Director-General may, by written notice revoke, amend or add to any conditions applied and will give notice to the evaluator of the intention to do so. When acting as an evaluator, the person must comply with the conditions of accreditation.

### **6.2 COMPLIANCE AUDITS**

Once accredited, evaluators must demonstrate ongoing competence in the evaluation of risk management programmes. The evaluator will be subject to ongoing periodic compliance audits by MAF Food.

### **6.3 MAINTENANCE OF ACCREDITATION**

To maintain accreditation the evaluator must:

- ensure that their knowledge of industry practices (as appropriate) and animal products regulations and specifications remains current;
- continue to develop and enhance their skills in the evaluation of risk management programmes;
- receive an acceptable outcome from any compliance audit;
- conduct effective evaluations and produce evaluation reports that accurately reflect the operation; and
- comply with any conditions of their accreditation.

If at any stage it is found that the accredited evaluator fails to meet the required competency specification, or that the performance of the accredited evaluator places the risk management system at risk, they will be notified of this. Where there is a serious deficiency in the performance of the accredited evaluator, the procedures pertaining to withdrawal of accreditation, including the right of review will apply (refer to section 6.6).

### **6.4 ADDITIONS OR CHANGES TO ACCREDITATION**

#### **6.4.1 Endorsement activities**

An evaluator who wants to amend their accredited activities must submit a completed application form AP7, together with the documentation as outlined in the Pack to the Director-General. They will then undergo an assessment in this new activity. The assessment procedure as described in section 5.1 will apply.

An accredited evaluator who wishes to remove an activity endorsement from their accreditation must notify the Director-General in writing.

#### **6.4.2 Substituted Notice of Accreditation**

Where the terms or conditions of accreditation are varied, or the existing Notice has become disfigured, dilapidated, lost, destroyed or contains a mistake, the Director-General may cancel an existing Notice of Accreditation and issue a new Notice. A fee will apply.

(Refer to section 111 of the Act, and schedule 4 of the Animal Products (Ancillary and Transitional Provisions) Act 1999 for details).

#### **6.5 CHANGES TO ORGANISATIONS**

When an accredited evaluator moves from or joins a recognised agency or organisation for the purposes of the evaluation, they must notify the Director-General in writing.

This is to enable the Director-General to track the movements of accredited evaluators and to ensure that they remain subject to the documented requirements relating to confidentiality, impartiality and independence, traceability of documentation and assessment of technical experts, or that they are covered by the ISO 17020 accreditation.

##### ***Specification clause:***

##### **8. *Changes to organisations etc***

***Prior to moving from, or joining a recognised agency or organisation that performs evaluation functions, the accredited evaluator must notify the Director-General of —***

- (a) the name of the recognised agency or organisation that the evaluator is joining; and***
- (b) the dates of cessation and commencement of engagement, as appropriate.***

#### **6.6 WITHDRAWAL OF ACCREDITATION**

Section 109 of the Act provides that where necessary, the Director-General may at any time withdraw an accreditation. The evaluator will be notified of this in writing. The following circumstances would be considered grounds for withdrawal:

- the person is no longer fit and proper to undertake the activities for which accreditation was granted;
- the person has failed to comply with any terms or conditions of the accreditation;
- the person has failed to meet any performance criteria specified by the Director-General; or

- the person has failed to comply with the requirements of the Act.

Where the Director-General plans to withdraw accreditation, the evaluator will be given a reasonable opportunity to be heard. If the decision to withdraw accreditation has been taken by a person acting under delegated authority of the Director-General, the right of review process as described in section 5.3 will apply.

The accredited evaluator must:

- take all reasonable steps to notify all clients of the impending withdrawal; and
- surrender their Notice of Accreditation to the Director-General on withdrawal of the accreditation.

## **6.7 SURRENDER OF ACCREDITATION**

The accredited evaluator may surrender their accreditation at any time by notice in writing to the Director-General. The surrender will take effect on the expiry of 3 months after the date of receipt of the notice by the Director-General. This time may be brought forward on approval by the Director-General.

On surrender of accreditation, the person must surrender their Notice of Accreditation to the Director-General (refer to section 110 of the Act).

## **6.8 EXPIRY OF ACCREDITATION**

Evaluator accreditation will expire at the end of three years from the date of issue and must be renewed at that time. The person will need to apply for re-accreditation and an assessment will be undertaken to ensure their competency is maintained. Details of the procedure will be made available as required. It is likely that the assessment will include a review of the reports produced by the accredited evaluator and of any compliance reports prepared about their performance.

## 7. Risk Management Programme Evaluation

### 7.1 OUTCOME OF AN EVALUATION

Following the evaluation of a risk management programme (including evaluation of amendments) the programme may either be:

- recognised as valid and a recommendation for registration made, with or without conditions; or
- recognised as incompletely validated and a recommendation for registration made, with conditions; or
- rejected pending further work.

### 7.2 GENERAL REQUIREMENTS

*Note: It is expected that standard auditing procedures will be followed in the evaluation of the programme. Details of these procedures will not be expanded upon in this document.*

The evaluator must address the following points, as appropriate:

- an evaluation must include a desk-top assessment of the risk management programme which may be conducted on or off-site as agreed between the evaluator and the operator;
- an evaluation must include all aspects of the operation including all supporting systems, taking into consideration the transitional provisions allowed for in regulation 11 of the Animal Products (Ancillary and Transition Provisions) Regulations 2000. Any programme or record that has been cross referenced within the risk management programme must be evaluated;
- where a risk management programme has been incompletely validated, the evaluator must undertake an on-site assessment prior to registration of the programme. The evaluator may also undertake a second on-site assessment at the completion of validation depending on the nature of the risk management programme;
- where the premises or place is a fishing vessel or a mobile premises, the on-site assessment may be completed at the home base or homeport. Where practicable, the operator should demonstrate the normal operations to the evaluator. The evaluator should ask questions covering operations at other locations to endeavour to check that all hazards and other risk factors that are likely to occur have been considered by the operator; and
- where an operator intends to submit an outline of the risk management programme to the Director-General when applying for registration, the evaluator must assess the outline document to ensure that it accurately reflects the risk management programme that it covers.

**Specification clause:**

**11. Preparing an evaluation report**

- (1) As part of the evaluation, the accredited evaluator must conduct an on-site assessment to assess the appropriateness of the risk management programme to the physical boundaries and the operations described in the programme.**
- (2) Despite subclause (1), when undertaking an evaluation of an amendment to a risk management programme, the accredited evaluator may decide that an on-site assessment is not necessary and must give the reasons for that decision in the evaluation report.**

At the completion of a successful evaluation (i.e. the risk management programme is to be recommended for registration) an evaluation report must be produced for the operator (refer to Section 8 for details of the report content).

Refer to **Appendix 2**, Points to Consider for Evaluation.

### **7.3 FEEDBACK ON UNACCEPTABLE RISK MANAGEMENT PROGRAMMES**

The evaluator must ensure that when providing feedback to an operator following the evaluation of an unsatisfactory programme that they do not compromise their independence. It is recognised that the amount and detail of information provided will in many cases depend on professional judgement.

The accredited evaluator should provide feedback to the operator explaining the areas where the programme is deficient. This feedback should be kept as generic as possible but where certain regulations or specifications, for example, have not been met these should be identified to the operator.

To ensure that impartiality and independence is maintained in cases where the accredited evaluator may be involved in the further evaluation of the risk management programme, methods of rectifying a deficiency must not be provided. Otherwise this would be seen as involving the evaluator in programme design and development and would prevent them from being involved in the evaluation of that programme for 2 years.

## **7.4 EVALUATION OF COMPLIANCE WITH THE ANIMAL PRODUCTS ACT AND OTHER LEGISLATION**

The risk management programme **must be** evaluated against the following:

- Animal Products Act 1999;
- Animal Products (Ancillary and Transitional Provisions) Act 1999;
- Animal Products Regulations 2000;
- Animal Products (Ancillary and Transitional Provisions) Regulations 2000;
- Animal Products (Exclusions and Inclusions) Order 2000;
- Animal Products (Definition of Primary Processor) Notice 2000;
- Animal Products (Specifications for Products Intended for Human Consumption) Notice 2000;
- Animal Products (Risk Management Programme Specifications) Notice 2000;
- Certain Technical Directives developed under the Meat Act and applied under the Act (transitional arrangement)<sup>9</sup>.

A recommendation by the evaluator for registration of a risk management programme will be taken to mean that this has been thoroughly completed.

It is not necessary to evaluate the risk management programme against any legislation other than that associated with the Act e.g. the Food Act 1981. It is the responsibility of the operator to ensure that the relevant requirements of other legislation are met.

The risk management programme should be evaluated against the following where appropriate:

- industry codes of practice<sup>10</sup>;
- technical publications;
- outcomes of trials and experimentation.

Further information on the resources available to the operator during the development of the risk management programme and subsequently for use during the evaluation is provided in section 2, Resources for developing a risk management programme, of the Risk Management Programme Manual.

## **7.5 EVALUATION OF OVERSEAS MARKET ACCESS REQUIREMENTS AS PART OF THE RISK MANAGEMENT PROGRAMME**

Overseas market access requirements (OMARs) are additional to risk management programme requirements.

Documentation may include OMARs and risk management programme components. If the OMARs form no part of the risk management programme, then they will not be validated, evaluated or registered as part of the programme.

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<sup>9</sup> Refer to Appendix 5 for a list of the applicable technical directives

<sup>10</sup> The operator is not obliged to follow an industry code of practice but if they do not, the validation of the programme may be subject to a more in-depth evaluation than those programmes that do conform to a code.

Where an operator makes the commercial decision to integrate OMARs into their risk management programme, either directly or by reference, these requirements will form part of the risk management programme. This integration may either be included in supporting systems, process controls or product outcomes.

Inclusion of an OMAR in the risk management programme means that it must be validated, evaluated and registered as part of the risk management programme. The evaluator must clearly understand what has been included, and assess the programme against any New Zealand animal products regulations and specifications, and any product outcomes specified by the operator, even if these have been included to meet an OMAR.

The resulting programme will be registered as meeting the New Zealand standard only. Once registered, this will be the programme that the company must operate to. An operator who fails to operate according to the registered programme will be non-compliant, even if the New Zealand standards and specifications have been met.

## **7.6 EVALUATION OF PREVIOUSLY RECOGNISED PROGRAMMES (TRANSITIONAL PROVISION)**

Existing animal product businesses that switch from operating under the Meat Act 1981 to operating under the Animal Products Act 1999 can incorporate existing recognised plans, systems or processes into their risk management programme under Regulation 11 of the Animal Products (Ancillary and Transitional Provisions) Regulations 2000.

This provision applies to any:

- (a) HACCP plan and supporting systems; or
  - (b) hazard identification and analysis process<sup>11</sup> and supporting systems;
- currently operating under the Meat Act 1981 and that has been recognised in writing by the Director-General or an authorised employee of the Ministry.

Evaluation of these recognised plans, system or processes in terms of sections 12 and 17 of the Animal Products Act is not required, provided they have not been subject to significant change since their recognition.

The applicable plans, systems or processes are those that have been recognised against the following standards:

- NZ Fishing Industry Agreed Implementation Standard 003.5 notified in the Fish Processing Circular 1995, including amendments up to March 2000, but excluding section 2.6 (mandatory market access requirements);
- OMAR 99/196 issued on 10 November 1999, reference 99/MISC/7, “Revised HACCP Standard for a HACCP Plan, HACCP competency Requirements and HACCP Implementation for US Listed Meat Processors”;

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<sup>11</sup> A hazard identification and analysis process means a process carried out by a business operating under the Meat Act regime, that having identified and analysed hazards (if any) the business has determined that no HACCP plan was necessary.

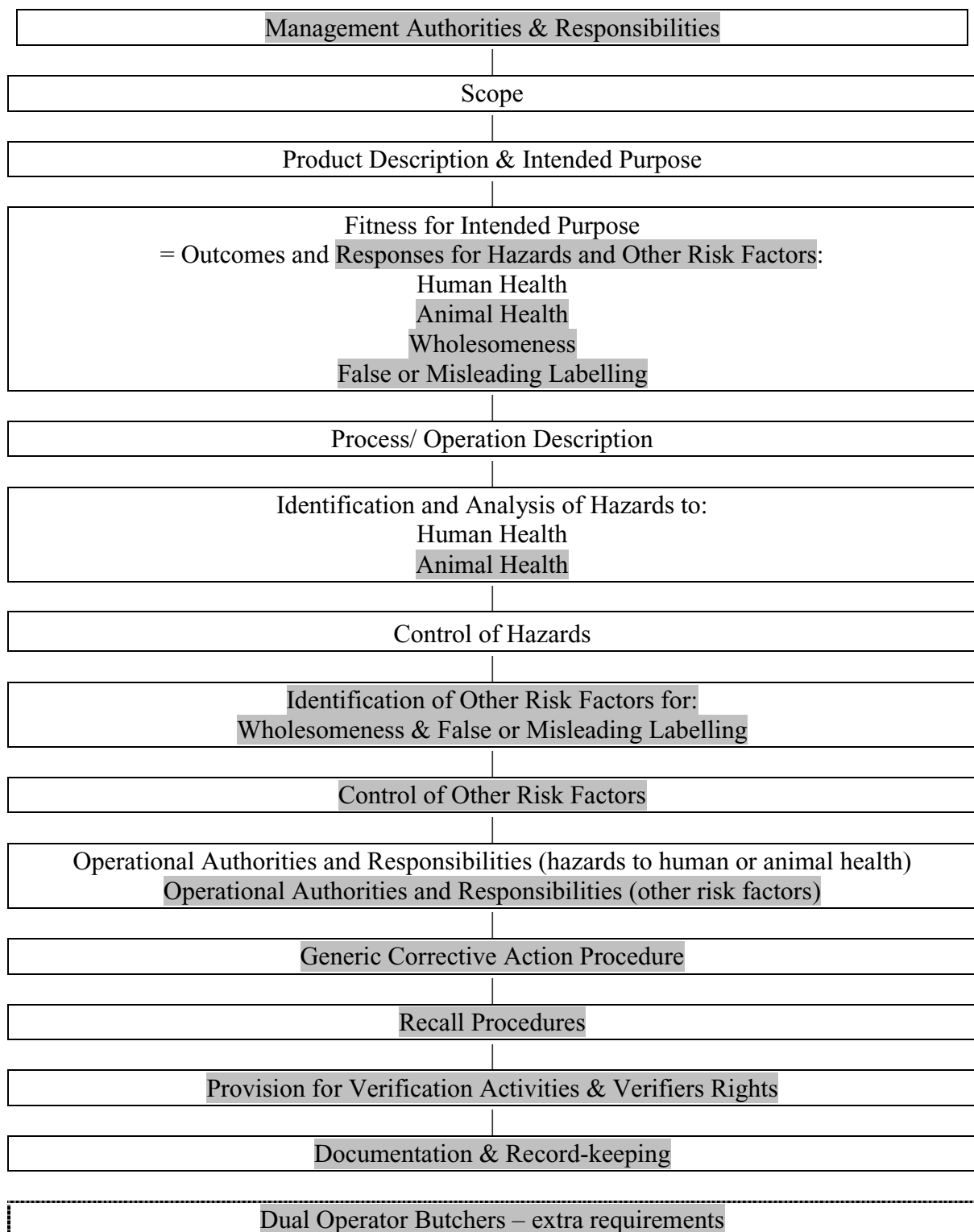
- NZ Venison Industry Standards Council, Reference No. VISC 1, issued on 27 January 2000 “ Industry Standard for a HACCP Plan, HACCP competency Requirements and HACCP Implementation”.

The applicable supporting systems are those that underpin or support a recognised HACCP plan or hazard identification and analysis process (e.g. good manufacturing or good hygiene practice programme or schedule relating to cleaning, staff training, document management or other matters). These are programmes that have been recognised against the Fish Export Processing Regulations 1995, or the New Zealand Meat Industry Standards Council or Venison Industry Standards Council agreed standards.

Where the risk management programme contains any of these recognised plans, systems or processes the evaluator should confirm that they have been formally recognised in writing and should check that the scope of these documents align with the scope of the risk management programme. The evaluation report must include a complete list of those plans systems or processes that have not been evaluated due to this transitional provision. The list should include the document name, version, date of recognition and the name of the person responsible for the recognition.

The following diagram illustrates those components of the risk management programme that still need to be evaluated once the transitional provisions have been taken into account.

**Figure 3: Components of a risk management programme still to be evaluated for previously recognised plans, processes or systems<sup>12</sup>**



<sup>12</sup> Those components that have been highlighted must be subject to a full evaluation.

Supporting systems that have been recognised in writing, but which do not underpin or support a recognised HACCP plan or hazard identification and analysis process are not eligible for this transitional provision and must be evaluated. Any new documentation is also not eligible for this provision and must be fully evaluated.

Any amendments to a registered risk management programme that had not been fully evaluated due to this transitional provision must be subject to a full evaluation prior application for registration of that amendment.

## **7.7 EVALUATION OF RECOGNISED SUPPORTING SYSTEMS THAT ARE USED IN A RISK MANAGEMENT PROGRAMME IN SUPPORT OF A NEW PROCESS OR PRODUCT**

Recognised supporting systems that underpin or support a recognised HACCP plan or hazard identification and analysis process under the Meat Act regime, but are used in a risk management programme to support a new process or new product must be evaluated. The degree of evaluation required will depend on the extent of direct application to the risk management programme.

An example of this may be a company licensed under the Meat Act who wants to extend their capabilities to other species. In this case the operator may have existing recognised supporting systems in place under the Meat Act, but must develop a risk management programme for the new species. The supporting systems in this case will not be eligible for the transitional provision and will need to be evaluated. The degree of evaluation required will be determined by the evaluator based on the extent and nature of the changes, if any, made to the supporting systems to accommodate the new species. If many or significant changes were needed, the programmes must be fully evaluated. However, if the operator is able to demonstrate that few changes have been made, the evaluation may involve a simple assessment to ensure that the systems are valid for the new species.

## **7.8 EVALUATION OF OPERATOR VALIDATION**

Owing to the complexities of the validation process, and the large variation in approaches that may be taken by the operator, specific guidance on how the evaluator should approach the evaluation of the validation data cannot be provided. The evaluator must make each evaluation on a case-by-case basis.

The basic requirements of operator validation are:

- confirming that the documentation is complete, including ensuring that all the components of the risk management programme and any relevant animal products regulations and specifications have been met; and
- demonstration that the risk management programme consistently achieves the defined outcomes.

The evaluator must ensure that the operator has validated each of the outcomes. This may be through final product testing, validation of critical control points (within the process or supporting systems) and /or validation of other controls. Validation may be through, but not limited to the following:

- the provision of evidence that the operation is run in accordance with any agreed codes of practice;
- the use of historical data, that is directly applicable to the operation documented in the risk management programme;
- evidence from technical publications that justifies the outcomes, together with evidence that the operation is run in accordance with the technical publications;
- trials and experimentation; and
- predictive modelling backed up with data from the actual process.

The evaluator may need to check a range of issues associated with the validation, such as:

- compliance with the criteria detailed in any agreed codes of practice;
- validity of any technical publications used;
- the relevance of the tests used;
- sampling techniques and analysis methodology;
- sampling regime, including confirmation that sufficient data has been collected to validate the outcome;
- confirmation that validation actually occurred and is legitimate;
- where necessary, confirmation that competent people or suitably skilled people have been used in the development and validation of the risk management programme;
- where necessary, confirmation that MILAB laboratories, registered for the required analyses, or laboratories with persons who are accredited as signatories for the required analyses have been used;
- appropriateness and accuracy of the data analysis;
- appropriateness of the conclusions drawn; and
- confirming that in practice, the process is operated in accordance with the validated process.

For microbiological outcomes, in general, the use of microbiological levels as provided for in the Ministry of Health “Microbiological Reference Criteria for Food” guideline will not be acceptable. These levels are intended to provide an indication of when food may be unsafe and as such microbiological outcomes set by industry should be lower than these. The operator will need to have considered any further processing or handling that the animal material or animal product is likely to receive in setting the outcomes.

## **7.9 OPERATOR USE OF CONSULTANTS (TECHNICAL EXPERTS) AS PART OF VALIDATION**

In some cases the operator may have used consultants (technical experts) to validate certain aspects of a risk management programme that are at the limits of the competency of the accredited evaluator.

Where this has occurred, the need to obtain input from another technical expert or other accredited evaluator to evaluate those aspects of the programme is at the discretion of the evaluator.

If the evaluator has:

- satisfied themselves that the consultant (technical expert) had an acceptable level of competence to perform the task (using the documented procedures for determining the competency of a technical expert); and
- a reasonable understanding of the validation provided and is satisfied with the recommendations made;

he/she may accept that that component of the programme has been adequately validated. A copy of the competency assessment of the consultant must be included with the evaluation report.

Alternatively, the accredited evaluator may choose to obtain a supporting report from another accredited evaluator or a technical expert for that aspect of the programme.

## **7.10 FALSE OR MISLEADING LABELLING RISK FACTORS**

The evaluator must check that the operator has applied the principles of HACCP and has identified and controlled any risk factors from false or misleading labelling. This will include the labelling procedures in place to ensure that the labels will not contain anything that is false or misleading, for example:

- ingredient listings;
- claims;
- the use of correct species;
- safe handling and storage instructions;
- systems to ensure that new label designs are correct;
- regulatory information;
- controls to prevent cross-contamination (particularly important in the area of allergens); and
- discrepancies between product and packaging etc.

Compliance with other labelling legislation such as the Food Regulations 1984 or the Fair Trading Act 1986 need not be evaluated.

## **7.11 WHOLESOMENESS RISK FACTORS**

The evaluator must check that the operator has applied the principles of HACCP and has identified and controlled any wholesomeness risk factors. Such risk factors may have been identified by:

- customer or consumer complaints;
- other external feedback e.g. audits;
- internal records; or
- experience;

and may include factors such as spoilage (taste, odour, appearance) or extraneous matter.

If the operator has not identified any wholesomeness risk factors as reasonably likely to occur there must be sufficient validation information to support this statement.

Refer to the Risk Management Programme Manual for further information to assist in the evaluation of labelling and wholesomeness risk factors.

## **7.12 VERIFIERS RIGHTS**

The evaluator must confirm that all rights of the verifier as provided for in the Animal Products (Risk Management Programme Specifications) Notice 2000 have been included in the risk management programme, and that the operator has not changed the intent of the specifications, or added further requirements that over ride these rights.

## **7.13 EVALUATION OF SUPPORTING SYSTEMS USED IN MULTIPLE RISK MANAGEMENT PROGRAMMES**

Supporting systems that form part of a number of a registered risk management programmes must be evaluated each time a new risk management programme is submitted for evaluation. The fact that a supporting system has been registered as part of a previously registered programme is not sufficient to allow automatic registration.

This evaluation may be simply to ensure that the supporting system is valid for the new risk management programme or may be an in-depth evaluation of the system. This will be at the discretion of the evaluator and will depend on factors such as involvement in any previous evaluations where the programme was recognised as valid, or the nature of the supporting system.

## **7.14 RECOGNITION OF VALIDITY**

Where the operator has completed the validation of the risk management programme and has provided sufficient evidence to satisfy the accredited evaluator that the programme will deliver animal material that is suitable for further processing and/or animal product that is fit for intended purpose, the programme must be recognised as valid. The evaluation report must make this recommendation and include any proposed conditions to be applied by the Director-General on registration of the programme. The statement as detailed in clause 13(3)(a) of the Animal Products (Accredited Evaluator Specifications) Notice 2000 must be added to the evaluation report (refer to section 8.2).

## **7.15 RECOGNITION OF AN INCOMPLETELY VALIDATED PROGRAMME**

### **7.15.1 Initial evaluation**

An incompletely validated risk management programme refers to a programme for which there is inadequate evidence to demonstrate ongoing achievement of outcomes. This will generally occur with new businesses, processes or products.

Prior to registration of a risk management programme or amendment, the programme may be operated on a trial basis. The resulting animal material or product must not be traded

(as defined in section 2 of the Act, including bartering and rendering) but may only be disposed of by burning or burying.

To allow an operator to register a risk management programme and begin processing so as to complete the validation process, and to have the option of trading the animal material or product (provided any conditions imposed by the Director-General are met), the operator may request that the programme be evaluated for recognition of the incompletely validated programme. This option is only available where a programme is complete other than for the required validation data and is ready to implement.

In this case the evaluator must evaluate:

- the documentation to ensure that it is complete;
- any evidence provided by the operator to indicate that the risk management programme is capable of achieving established outcomes;
- the operator's protocol outlining the means by which the data will be collected in a scientifically sound and statistically valid manner for the completion of validation, e.g. experimental protocol, trials, data collection and analysis; and
- the operator's protocol setting out the proposal for the disposition of animal material or product produced during the validation.

The accredited evaluator must be satisfied that the programme is potentially capable of operating effectively and producing animal material that is suitable for further processing or animal product that is fit for intended purpose.

An evaluation for recognition of an incompletely validated programme requires the evaluation report to include recommendations for any conditions to be applied by the Director-General on registration of the programme. The conditions may include:

- a requirement that the programme be fully validated within a specified time frame; or
- restrictions on trade of the animal material or product resulting from the validation trials.

The statement as detailed in clause 13(3)(b) of the Animal Products (Accredited Evaluator Specifications) Notice 2000 must be added to the evaluation report (refer to section 8.2).

It is recognised that in some cases the validation protocol, registered as part of the risk management programme, will fail to deliver the required information. Should the operator deviate from the registered validation protocol, but the resulting animal material or product be burnt or buried, this would not be considered to be a variance to the protocol that would need to be re-evaluated. If however, the operator needs to alter the protocol and has the intention of disposing of the animal material or product in a manner other than burning or burying, the modified protocol will need to be submitted for evaluation.

### **7.15.2 Re-evaluation following completion of validation of the risk management programme**

Once the operator has completed the validation of the risk management programme in accordance with the validation protocol, the programme must be resubmitted for evaluation to obtain recognition of its validity.

In this case, the evaluator must assess the output from the validation work and determine whether there is sufficient, meaningful evidence to confirm that the programme is valid. The evaluator must also reassess any aspect of the programme that has been modified as a result of the validation.

For those risk management programmes that are considered to be valid, the evaluation report must include recommendations, where appropriate, for:

- any conditions that have been applied during the validation period to be removed (where appropriate); and
- any additional conditions to be applied to the validated programme.

The statement as detailed in clause 13(3)(c) of the Animal Products (Accredited Evaluator Specifications) Notice 2000 must be added to the evaluation report (refer to section 8.2).

Refer to the Risk Management Programme Manual, for further details on validated and incompletely validated programmes.

## **7.16 RISK MANAGEMENT PROGRAMME AMENDMENTS**

When an amendment<sup>13</sup> is made to a risk management programme, those parts of the programme affected by the amendment must be submitted for evaluation. Once again, this process may involve either the recognition of validity or the recognition of an incompletely validated programme.

The operator need only submit those sections of the risk management programme that impact on the amendment under evaluation. However, where the evaluator considers that other aspects of the programme will be affected, they should request further information from the operator. The evaluator should follow the same procedure as used for a full evaluation but must decide on a case-by-case basis whether an on-site assessment is necessary, providing reasons in the evaluation report where an on-site assessment is not conducted.

An evaluation report must be prepared for those risk management programme amendments that are to be recommended for registration. The evaluation report must comply with the requirements detailed in section 8 (as applicable to the nature of the amendment) and contain the appropriate recommendations, conditions and statements as specified.

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<sup>13</sup> Refer to sections 25 and 26 of the Act for a description of an amendment and updates of minor amendments. The Risk Management Programme Manual also contains a discussion of risk management programme amendments and updates.

## **7.17 EVALUATION OF FOOD SAFETY PROGRAMMES**

The evaluation of any food safety programme that is to be registered as a risk management programme must follow the same procedure as for a risk management programme evaluation.

## 8. Evaluation Report and Reporting Requirements

### 8.1 REPORT CONTENT

The following specification details the mandatory requirements of the evaluation report. The accredited evaluator must provide further information in the evaluation report as appropriate to the risk management programme.

#### **Specification clause:**

#### **12. Contents of evaluation reports**

**Every evaluation report must include—**

- (a) the name of the accredited evaluator and his or her accreditation identifier; and**
- (b) the name and address of the operator of the risk management programme; and**
- (c) the types of animal material and animal product to which the risk management programme applies; and**
- (d) the principal categories of processing carried out under the risk management programme; and**
- (e) a brief description of the processing activities and other operations and activities covered by the risk management programme; and**
- (f) the location, physical boundaries and type of premises or place to which the risk management programme applies; and**
- (g) the identification of all documents that comprise the risk management programme which were reviewed during the evaluation; and**
- (h) the basic resources used in the development of the risk management programme, including the use of codes of practice, the degree of application of the codes, and whether any new and innovative processing methods are involved; and**
- (i) the identification of any recognised HACCP plan and supporting systems, or any recognised hazard identification and analysis process and supporting systems that has been recognised by the Director-General or a duly authorised employee of the Ministry, in accordance with regulation 11 of the Animal Products (Ancillary and Transitional Provisions) Regulations 2000; and**
- (j) the identification of any approved food safety programme within the meaning of the Food Act 1981 that is to be recognised as part of the risk management programme; and**

- (k) the completion date of the initial on-site assessment, or in relation to the evaluation of an amendment, if the evaluator decided that an on-site assessment was not necessary, the reason for that decision; and**
- (l) the name and identifier of any accredited evaluators and the name of any technical experts used to provide supporting reports during the evaluation of the risk management programme; and**
- (m) a full copy of any supporting reports prepared by any technical expert or accredited evaluator during the evaluation of the risk management programme; and**
- (n) a copy of the competency assessment of technical experts as described under clause 9(3); and**
- (o) a statement of whether the evaluation is for the registration of a validated or incompletely validated risk management programme, or an amendment; and**
- (p) a statement of whether in the accredited evaluator's opinion the risk management programme has been adequately validated, or whether the protocol that has been documented to complete the validation process and the disposition of any animal material or animal product produced during the validation process, is acceptable.**

The Risk Management Programme Manual provides a template that may be followed by the operator to control the version of each document that comprises the risk management programme. Where this has been provided, confirmation by the evaluator that the details are correct and signing a copy of this document will be a satisfactory method of achieving paragraph (g) for the purposes of the evaluation report. Where the operator has not prepared a version control document, the evaluator will be required to do so. A similar list is required to fulfil paragraph (i).

Refer to **Appendix 3** for an example of an evaluation report cover page.

## **8.2 EVALUATOR RECOMMENDATIONS, ENDORSEMENTS AND STATEMENTS**

The accredited evaluator must include a recommendation that the risk management programme or incompletely validated risk management programme should be registered and any conditions that should be applied. These requirements also apply to evaluation reports prepared for amendments to risk management programmes.

### **Specification clause:**

#### **13. Evaluator recommendations, endorsements and statements etc**

- (1) The accredited evaluator must recommend to the Director-General—**

- (a) whether the risk management programme or amendment to a programme, is suitable for registration; and**
- (b) the conditions, if any, that the Director-General should consider imposing on the registration of the incompletely validated or validated risk management programme, including conditions relating to the commencement of operations under section 22(2) of the Act; and**
- (c) the removal, if appropriate, of any conditions imposed on a registered risk management programme prior to the completion of validation.**

The accredited evaluator must endorse the risk management programme or the risk management programme outline document, as appropriate. The endorsed version of the programme will be the document that is submitted by the operator when applying for registration of the programme.

Where the document is to be submitted by the operator in hard copy for registration, each page of the document is to be initialled or signed by the evaluator. This should be in a colour other than black. It is also recommended that a numbering system be employed so that the completeness of the documentation can be checked.

If the operator intends to submit the risk management programme in an electronic format, refer to **Appendix 4** for the means acceptable to the Director-General by which the evaluator is to endorse the electronic file.

The evaluation report must be endorsed in the same manner as specified for the risk management programme.

The endorsement is intended to provide greater confidence to the Director-General that the risk management programme or evaluation report has not been modified since the evaluation.

**Specification clause:**

**13. Evaluator recommendations, endorsements and statements etc**

- (2) The accredited evaluator who signs the evaluation report must endorse the risk management programme or the outline documentation to confirm that it accurately represents the programme evaluated, by—**
  - (a) using electronic means acceptable to the Director-General; or**
  - (b) initialling or signing each page of the hard copy of the risk management programme or any other means acceptable to the Director-General.**

The evaluation report must contain one of the following statements as appropriate to the nature of the evaluation. The statement must also be applied where the report is for the purposes of an amendment.

**(3) All evaluation reports must contain one of the following statements, as appropriate—**

**(a) Statement for the purposes of complete validation**

**I confirm that a full assessment of the risk management programme or amendment to the risk management programme {title, date and identified by version} has been undertaken.**

**I am satisfied that this programme or amendment to this programme complies with the requirements imposed by or under the Animal Products Act 1999 and the relevant provisions of the Animal Products (Ancillary and Transitional Provisions) Act 1999.**

**Name:**

**Signed:**

**Date:**

**(b) Statement for the purposes of incomplete validation**

**I confirm that an evaluation of the incompletely validated risk management programme or amendment {title, date and identified by version} has been undertaken.**

**I also confirm that the operator has a satisfactory documented protocol to complete the validation process including any requirements for the disposition of any animal material or animal product produced during the validation process.**

**Name:**

**Signed:**

**Date:**

**(c) Statement for the purposes of completion of validity**

**I confirm that an evaluation of the risk management programme or amendment {title, date and registration identifier}, which was incompletely validated, but has now been validated in accordance with the documented protocol, has now been undertaken.**

**I am satisfied that this programme or amendment complies with the requirements imposed by or under the Animal Products Act 1999 and the relevant provisions of the Animal Products (Ancillary and Transitional Provisions) Act 1999.**

**Name:**

**Signed:**

**Date:**

- (4) *The accredited evaluator, who will be held responsible for the accuracy of the information contained in the evaluation report, must sign the appropriate statement specified in subclause (3).***

## APPENDIX 1: Activity Endorsements

The following are examples of activity endorsements.

Evaluation of:

- *Slaughtering, dressing, boning, cutting and size reduction of mammals and birds*
- *Egg processing*
- *Bee product processing*
- *Deer velvet processing*
- *Thermal processing of low acid canned products*
- *Thermal processing- other than low acid canned products*
- *Ready-to-eat product processing*
- *Further processing (specify)\**
- *Seafood primary processing*
- *Depuration of shellfish*
- *Rendered product processing*
- *Tallow processing*
- *Animal foods other than rendered product processing*
- *Biologicals/ pharmaceutical processing*
- *Dual Operator Butchering*

*\*Other than those specifically listed (e.g. pH, water activity, other chemical preservation).*

## APPENDIX 2: Points to Consider for Evaluation

The accredited evaluator is encouraged to use the following list as guidance when evaluating a risk management programme. This is not an all-inclusive list as the accredited evaluator is expected to tailor the evaluation according to the nature of the risk management programme. Where applicable the relevant Animal Products (Risk Management Programme Specifications) Notice 2000 specification has been added as a reference.

<b>1. General / Scope</b>
<ul style="list-style-type: none"> <li>• Name of operator</li> <li>• Business address of operator</li> <li>• E-mail address of operator (optional)</li> <li>• Name, position or designation of the person responsible for the day-to-day management</li> <li>• Name of business</li> <li>• Physical address of premises</li> <li>• Set of premises or place that the risk management programme applies to</li> <li>• Postal address of the business</li> <li>• E-mail address of business</li> <li>• Web-site address of business</li> <li>• Set of processes or operations</li> </ul>
<b>2. Risk Management Programme Application (RMP Spec 5)</b>
<ul style="list-style-type: none"> <li>• Physical boundaries of the place covered by the programme</li> <li>• Extent of application of the risk management programme</li> <li>• Risk factors covered by the programme</li> <li>• Summary of materials and/or products being processed</li> </ul>
<b>3. Material or Product Description (RMP Spec 6)</b>
<ul style="list-style-type: none"> <li>• Intended purpose           <ul style="list-style-type: none"> <li>-intended use of animal material and/or products</li> <li>-intended consumer</li> </ul> </li> <li>• Important material and /or product characteristics</li> </ul>
<b>4. Material and Product Outcomes (RMP Specs 7 and 8)</b>
<ul style="list-style-type: none"> <li>• Outcomes for suitability for further processing or fitness for intended purpose</li> <li>• All relevant animal product regulations and specifications have been addressed</li> <li>• Each of risk factors addressed</li> <li>• Response in event that outcomes not met</li> <li>• Measurable parameter(s)</li> <li>• Supporting validation data</li> <li>• Consistent with hazard identification and analysis</li> </ul>
<b>5. Process Description (RMP Spec 9)</b>
<ul style="list-style-type: none"> <li>• Each process step documented</li> <li>• Accurate</li> <li>• Consistent with the scope of the risk management programme</li> <li>• Includes all process variations e.g. rework</li> </ul>

<b>6. Inputs (RMP Spec 9)</b>
<ul style="list-style-type: none"> <li>• Animal material and animal product</li> <li>• Additives</li> <li>• Processing aids</li> <li>• Other ingredients</li> <li>• Packaging</li> </ul>
<b>7. Outputs (RMP Spec 9)</b>
<ul style="list-style-type: none"> <li>• Animal material</li> <li>• Animal product</li> </ul>
<b>8. Identification of Hazards from Inputs and Process Steps (RMP Spec 10)</b>
<ul style="list-style-type: none"> <li>• Hazards to           <ul style="list-style-type: none"> <li>-Human health</li> <li>-Animal health</li> </ul> </li> <li>• Consider raw materials, other inputs, each processing step</li> <li>• Decision making process and supporting information documented</li> <li>• Hazard identification of inputs after supplier assurances</li> </ul>
<b>9. Supporting systems to Manage and Control Hazards from Inputs (RMP Spec 10)</b>
<ul style="list-style-type: none"> <li>• Supplier quality assurance programmes</li> </ul>
<b>10. Identification of Hazards from Sources other than Inputs and Process Steps (RMP Spec 10)</b>
<ul style="list-style-type: none"> <li>• Hazards to           <ul style="list-style-type: none"> <li>-Human health</li> <li>-Animal health</li> </ul> </li> <li>• Consider           <ul style="list-style-type: none"> <li>-internal environs</li> <li>-personnel</li> <li>-water</li> <li>-air</li> <li>-pests</li> <li>-equipment (including non-contact)</li> <li>-external environs</li> <li>-other</li> </ul> </li> </ul>
<b>11. Supporting Systems to Manage and Control Hazards other than Inputs and Process Steps (RMP Spec 10 and 11)</b>
<ul style="list-style-type: none"> <li>• Consider each supporting system</li> <li>• Sanitary design and essential services           <ul style="list-style-type: none"> <li>- Design and construction</li> <li>- Facilities</li> <li>- Equipment</li> <li>- Other essential services</li> </ul> </li> <li>• Premises hygiene and maintenance           <ul style="list-style-type: none"> <li>- Cleaning and sanitation</li> <li>- Waste management</li> <li>- Maintenance</li> <li>- Management of maintenance compounds</li> <li>- Pest control</li> </ul> </li> <li>• Personnel hygiene           <ul style="list-style-type: none"> <li>- Health</li> <li>- Personnel hygiene and behaviour</li> <li>- Protective clothing</li> </ul> </li> </ul>

<ul style="list-style-type: none"><li>• Competent personnel and training programmes<ul style="list-style-type: none"><li>- Identification of training needs</li><li>- Provision of training</li><li>- Maintenance of training</li><li>- Assessment of training effectiveness</li><li>- Training records</li></ul></li><li>• Packaging</li><li>• Labelling</li><li>• Traceability and control</li><li>• Calibration</li><li>• Non-complying animal material or animal product</li><li>• CCP and Non-CCP controls for supporting systems</li></ul>
<b>12. Other Risk Factor Identification and Analysis (RMP Spec 10)</b>
<ul style="list-style-type: none"><li>• Wholesomeness issues (customer/consumer complaints)</li><li>• Documentation in support of wholesomeness risk factors identified e.g. customer/consumer complaints, reports, records</li><li>• Consider spoilage e.g. taste, odour, colour, texture and extraneous materials</li><li>• False or misleading labelling risk factors</li><li>• Documentation in support of labelling risk factors identified e.g. customer/consumer complaints, reports, records</li><li>• Consider claims, ingredient listings, correct species, safe handling and storage instructions, systems for implementation of new labels, prevention of cross-contamination and discrepancies between product and packaging</li></ul>
<b>13. Hazard Analysis/CCP Determination/Controls (RMP Spec 10) (process and supporting systems)</b>
<ul style="list-style-type: none"><li>• Acceptable/unacceptable levels with respect to product outcomes (is there data to validate that the hazards/risk factors do or do not occur at unacceptable levels for each process step?)</li><li>• Justification for identification</li><li>• Control measures available</li><li>• Uncontrolled hazards identified and documented</li><li>• Consider basis for establishing control measures and application to operation e.g. code of practice</li><li>• Other controls (Non CCP)</li></ul>
<b>14. Other Risk Factor Controls (Process and Supporting System) (RMP Spec 11)</b>
<ul style="list-style-type: none"><li>• CCPs</li><li>• Other controls (Non-CCPs)</li></ul>
<b>15. Critical Limits (RMP Spec 11)</b>
<ul style="list-style-type: none"><li>• Parameters</li><li>• Target levels for each parameter</li><li>• Critical limits scientifically valid for the hazard/risk factor (e.g. regulatory critical limits, others)</li><li>• Data to validate that the control measures are effective, consistently achievable and relevant to outcomes</li></ul>

<b>16. Monitoring (CCPs and Non-CCPs) (RMP Spec 11)</b>
<ul style="list-style-type: none"><li>• Responsibilities for monitoring</li><li>• When</li><li>• Method</li><li>• Monitoring sufficient to ensure CCPs are under control, frequency statistically or performance based, related to the prevalence of the hazard/risk factor (CCPs only)</li><li>• Records</li></ul>
<b>17. Corrective Action Procedures (CCPs and Non-CCPs) (RMP Spec 11)</b>
<ul style="list-style-type: none"><li>• Responsibilities for taking corrective action</li><li>• Restoration of control</li><li>• Control and disposition of non-conforming product</li><li>• Action to be taken to prevent the problem from recurring (CCPs only)</li><li>• Escalating response if preventative action fails (CCPs only)</li><li>• Records</li></ul>
<b>18. Transitional Provisions (AP(A&amp;TP) Reg. 11.</b>
<ul style="list-style-type: none"><li>• Confirmation of recognition</li><li>• List of recognised programmes provided</li><li>• Responses when product outcomes not met</li><li>• All other components covered</li></ul>
<b>19. Generic Corrective Action Procedure (RMP Spec 13)</b>
<ul style="list-style-type: none"><li>• Responsibility for the procedure</li><li>• Procedure for identifying suitably skilled persons based on situation</li><li>• Means of identifying, retaining and controlling affected material or product</li><li>• Procedures for assessment of non-compliance and product disposition</li><li>• Records and reporting</li><li>• Notification of the animal products officer and risk management programme verifier</li></ul>
<b>20. Operator Verification (CCPs and Non-CCPs) (RMP Spec 17 and 24)</b>
<ul style="list-style-type: none"><li>• Responsibilities for validation/revalidation</li><li>• Responsibilities for ongoing operator verification</li><li>• Frequency of ongoing operator verification</li><li>• Method of ongoing operator verification</li><li>• Follow up action in event of non-compliance</li><li>• Records</li></ul>
<b>21. Operational Authorities and Responsibilities (RMP Spec 14)</b>
<ul style="list-style-type: none"><li>• Name, position or designation of personnel who perform monitoring</li><li>• Name, position or designation of personnel who perform corrective actions</li><li>• Name, position or designation of personnel who perform operator verification</li></ul>
<b>22. Recall Procedures (RMP Spec 26)</b>
<ul style="list-style-type: none"><li>• Identification and traceability<ul style="list-style-type: none"><li>- Inputs</li><li>- Work-in-progress</li><li>- Final Products</li></ul></li><li>• Responsibilities and authorities</li><li>• Risk assessment and decision to recall</li><li>• Communication and documentation</li><li>• Product recovery and disposition</li><li>• Corrective and preventative action</li></ul>

- Review of effectiveness
- Director-General notification

**23. Provision by the Operator for Verification Activities and Verifiers' Rights (RMP Spec 15)**

- Access to all parts of the premises or place and facilities within the boundaries of or relating to the risk management programme
- Access to all documentation, records and information relating to, or comprising, the risk management programme (including records held in electronic or other form)
- Freedom to examine all things necessary and open any containers, packages and other associated things to inspect their contents
- Freedom to identify or mark any animal material, animal product, equipment, package, container or other associated thing
- Freedom to
  - Examine and take samples of any animal material, animal product or any other input, substance, or associated thing which has been, is, or may be in contact with, or in the vicinity of, any animal material or animal product
  - test, or analyse, or arrange for the testing, or analysis of such samples
  - order retention of raw materials including animal material, ingredients, animal products, packaging or equipment pending testing results and decisions on disposition
- Authority where there may be significant risk to fitness for intended purpose of animal product or suitability for processing of animal material to detain any animal material and animal products or other relevant things in the event of non-compliance with the risk management programme
- Authority in cases of significant risk to fitness for intended purpose of animal product or suitability of animal material for processing to intervene and direct a temporary interruption of processing until the cause of the risk has been remedied
- View evidence of the willingness of the nominated verifying agency to undertake the role of verifying the risk management programme.

**24. Documentation and Record Keeping (RMP Spec 16)**

- Document retrieval system (including records)
- Records demonstrating compliance to be retained
- Adequate procedures for electronic records if applicable
- Storage conditions
- Documents
  - legible
  - in writing
- Document control
  - Document names
  - Version/issue date
  - Authorisation
  - References
  - Evaluation status
- Changes clearly indicated
- Endorsed
- Retention times

**25. Additional Requirements for Dual Operator Butchers**

- Separation of homekill and regulated meat
- Inventory control in relation to regulated product
- Hazard and other risk factor analysis considers impact of homekill operation on regulated meat.

## APPENDIX 3: Example Evaluation Report Cover Page

This form has been drafted to provide the evaluator with a means of recording the basic information required from the evaluation. This is an example only. The evaluator may extend this form to include other information where appropriate. This information would make up part of the evaluation report only.

<b>Requirement</b>	<b>Response</b>
Name of accredited evaluator:	
ID of accredited evaluator:	
Operator details:	
Types of animal material and/or animal product:	
Principal categories of processing:	
Brief description of the processing activities and other operations and activities:	
Location, physical boundaries and type of premises or place:	
Product outcomes:	
Basic resources used by the operator	

and the degree of application and/or identification of any novel processing undertaken:	
Full list of any HACCP / hazard ID (and supporting systems) which have been previously recognised by MAF, including date of recognition and ID of person responsible for recognition:	
Approval number and description of the scope of any approved Food Safety Programme that is to be recognised as part of the risk management programme:	
Completion date of the on-site assessment, or for an amendment where no on-site assessment was completed reason for that decision:	
Name and identifier of any other accredited evaluator and name of any technical experts used in the evaluation:	
Incomplete or full validation:	
Recommendations for any conditions to be imposed on registration:	
Recommendations for the removal of any conditions that had been imposed prior to completion of validation:	

The appropriate recommendation, statement and signature is to be included here, as described in Section 8.2.

**Inclusions and endorsement (as appropriate):**

- Supporting report(s)
- Competency assessment(s)
- List of documents reviewed and version control
- List of previously recognised plans, systems or processes
- Endorsement completed

## **APPENDIX 4: Electronic File Endorsements**

The following procedures for electronic endorsement are acceptable for the specified software packages:

### **A Microsoft Word (97 & 2000)**

#### ***Operator procedure***

(Note: where the operator has not completed this requirement, the evaluator must do so before continuing with the endorsement procedure).

1. Select 'Header and Footer' on the 'View' toolbar.
2. Go to the bottom of the page and click inside the footer Note: layout to be similar to the following example –

File name: RMP Procedure Endorsement.doc No. Characters: 4622 Last saved: 20/12/2000 10:00

3. Select 'Field' on the 'Insert' toolbar.
4. Under categories select 'Document Information', and then under field names select 'FileName' and ok.
5. Repeat, this time under field names select 'NumChars' and ok.
6. Under categories select 'Date and Time', and then under field names select 'Save Date' and ok.
7. Save document as per normal.

#### ***Evaluator procedure***

Once the operator has completed the above procedure evaluator to complete the following:

1. Select 'Save As' on the 'File' toolbar.
2. Under 'Options' insert a unique password<sup>1</sup> in 'password to modify', enter and reconfirm password.
3. Save with the required file name in desired location.
4. Double left click on the footer to access it.
5. Press 'Ctrl & A' on the keyboard (this highlights information in footer).
6. Right click on this highlighted information and select 'Update field'.
7. Close 'Header and Footer' box.
8. Select 'Save' on the 'File' toolbar.
9. Select 'Properties' on the 'File' toolbar.
10. Select 'Statistics' page and record the following 'modified:', 'pages:' and 'characters:' (not characters (with spaces):) from this page.
11. Select 'Close' on the 'File' toolbar. Note: if you are asked 'Do you want to save the changes..' ALWAYS select 'No'.
12. Record the file name, size and date modified of the file(s). This information can be obtained from either Windows Explorer or File / Open in Word.
13. The information from steps 10,12 and related password are then supplied to the Director-General directly either by mail, fax or email.

- <sup>1</sup> Note: (a) this password is case sensitive.  
(b) the evaluator must not divulge any password to the operator.  
(c) where the RMP or RMP outline comprises a number of Word files the same password should be used for all these Word files.

## **B Microsoft Excel (97 & 2000)**

### ***Operator procedure***

Not applicable.

### ***Evaluator procedure***

1. Select 'Save As' on the 'File' toolbar.
2. Under 'Options' insert a unique password<sup>2</sup> in 'password to modify', enter and reconfirm password.
3. Save with the required file name in desired location.
4. Select 'Close' on the 'File' toolbar.
5. Record the file name, size and date modified of the file(s). This information can be obtained from either Windows Explorer or File / Open in Excel.
6. This information and related password are then supplied to the Director-General directly either by mail, fax or email.

- <sup>2</sup> Note: (a) this password is case sensitive.  
(b) the evaluator must not divulge any password to the operator.  
(c) where a RMP or RMP outline comprises a number of Excel files the same password should be used for all these Excel files.

## **C PDF files created from Microsoft Word files with Adobe Acrobat 4.0**

### ***Operator procedure***

1. Complete steps 1 – 7 as described above under Microsoft Word / operator procedure for the source Word document.
2. In Word select 'Print' on the 'File' toolbar.
3. Change the printer to 'Acrobat PDF writer' and ok.
4. Save the pdf file in desired location.

### ***Evaluator procedure***

Once the operator has completed the above procedure, the evaluator is to complete the following:

1. In Acrobat select 'Open' on the 'File' toolbar.
2. Locate and open the pdf file that was created (refer above).
3. Select 'Save As' on the 'File' toolbar.

4. Choose the standard security method.
5. Enter a unique password<sup>3</sup> in 'change security options' and under the 'do not allow' heading enable all security features except printing. Note: no password is entered in 'open the document' section.
6. Save with the required file name in desired location.
7. Record the file name, size and date modified of the file(s). This information can be obtained from Windows Explorer.
8. This information and related password are then supplied to the Director-General directly either by mail, fax or email.

- <sup>3</sup> Note:
- (a) the evaluator must not divulge any password to the operator.
  - (b) where a RMP or RMP outline comprises a number of pdf files the same password should be used for all these pdf files.

## **APPENDIX 5: Transitional Arrangements**

From the date of commencement of Part 2 of the Animal Products Act 1999 conformity with the general guidelines listed below will be taken as compliance with the requirements of the Animal Products Act. Any person wishing to depart from any general guideline should first consult the Director, Animal Products, to ensure that the departure will not result in non-compliance with the Act.

### 1 Ante-mortem examinations

- a. Section 14.1 of Technical Directive 98/123 “Feral possums: New Zealand standards for procurement, processing and inspection.”.
- b. Technical Directive 98/180 “Poultry: ante- and post-mortem inspection” which specifically provides the ante-mortem provisions now forming part of PIPS5.
- c. “Ostrich and Emu Processing Standard 5” (OEPS5) ) - sections 2.2.3 - 2.2.5 and Appendices 1 and 2 -issued under cover of Technical Directive 99/46 “Ostrich and Emu Processing Standard 5”.

### 2 Post-mortem examinations

- a. Section 14.2 of Technical Directive 98/123 “Feral possums: New Zealand standards for procurement, processing and inspection”.
- b. Technical Directive 98/180 “Poultry: ante- and post-mortem inspection” which specifically provides the post-mortem provisions now forming part of PIPS5.
- c. “Ostrich and Emu Processing Standard 5” (OEPS5) ) - section 3.2.12 and Appendices A-3, A3.1 and A 3.2 - issued under cover of Technical Directive 99/46 “Ostrich and Emu Processing Standard 5”.

## **APPENDIX 6: Accredited Evaluator Interim Application Pack**



**Ministry of Agriculture and Forestry**  
Te Manatu Ahuwhenua, Ngaherehere

# Accredited Evaluator Interim Application Pack

The following requirements must be completed by any person seeking accreditation as an evaluator of risk management programmes under the Animal Products Act.

This pack contains the requirements for:

- the generic accredited evaluator; and
- those persons seeking an accredited evaluator activity endorsement.

November 2000

## Background

The Accredited Evaluator Interim Application Pack contains the necessary information for a person to make an application to the Director-General for accreditation as an evaluator. For additional information about the role of the evaluator and the evaluation itself refer to the Evaluator's Guide.

All evaluators must gain accreditation to the generic accredited evaluator competency specification, but may or may not seek an activity endorsement. The purpose of the activity endorsement is to identify the areas of expertise of the accredited evaluator and make this information available to both the operator and to persons involved in registration of risk management programmes.

An accredited evaluator without an activity endorsement in an area relevant to the risk management programme under evaluation will be expected to obtain technical input for any aspect of the programme that is outside their area of competency. It is recognised that the decision to obtain this input is not always clear cut. If the evaluator is in doubt, they should contact MAF Food.

Where the accredited evaluator has made the decision not to obtain additional technical input, the evaluation report will be subject to greater scrutiny at the time of registration.

The application for the evaluator to both the generic specification and the activity endorsement is a written exercise and is an interim measure. The generic accredited evaluator competency specification is to be further developed into a formal standard, and within a time set by the Director-General, the accredited evaluator assessed under the interim system will be required to be reassessed. The depth of the reassessment will depend on the final standard.

In addition to this, it has been proposed that the accredited evaluator be subject to ISO 17020 accreditation. The intention is to phase in this requirement during the transition period. Further information will be released on these requirements as it becomes available.

Every question within the "Assessment Questions for Accreditation as a Generic Evaluator" must be answered to a satisfactory degree by the applicant. The answers will be assessed according to the following ratings: competent, not yet competent or further evidence required. To assist the applicant, each question has been given a weighting as an indication of the level of detail that will be expected in the response. MAF reserves the right to seek additional information from the applicant if necessary. This may include examples of work undertaken.

Every effort will be made to ensure that the assessment is conducted in a fair and transparent manner. In the event that an applicant is dissatisfied with the outcome of this assessment process, section 162 of the Animal Products Act provides for a review of the decision.

## Accredited Evaluator Documentation Checklist

Please complete the following documentation and submit them together with the application fee to the address listed on the top of the application form.

### Generic Accredited Evaluator Competency Specification

- Completed Accredited Person application form (AP7);
- Completed form for the consent to disclosure of convictions;
- Written answers to the accredited evaluator assessment questions and the signed declaration;
- Documentation to fulfil the administrative requirements;
- Application fee.

### Activity endorsement

In addition to the above:

- Documentation to fulfil the activity endorsement requirements.

## Assessment Questions for Accreditation as a Generic Evaluator

This is an interim assessment process for an applicant seeking generic evaluator accreditation and as such, the applicant will be required to undergo a reassessment to the final generic accredited evaluator competency standard within a period of time as set by the Director-General.

The applicant must provide written answers to the following questions and submit them in hardcopy form together with the supporting documentation specified in the attached documentation checklist, to MAF Food Assurance Authority for assessment. Each question must be completed to a satisfactory degree. The applicant must add the declaration as given at the bottom of the question sheet to their written answers and complete and sign the declaration.

The Generic Accredited Evaluator Competency Specification and Interim Assessment Checklist has been provided as part of this pack as guidance to the approach that will be taken by MAF Food when assessing the submission. However it should be noted that certain aspects of the checklist are not relevant to this assessment.

<b>Part 1:</b>	<b>Weighting</b>
1. What are the objects of the Animal Products Act 1999 (the Act)?	2
2. Briefly describe the three main controls of the risk management system under the Act and how they relate to each other. (This should include reference to risk management programmes, regulated control schemes and overseas market access requirements).	4
3. Briefly describe the interface of the following legislation with the Animal Products Act, and the aspects of this other legislation that need to be taken into consideration during a risk management programme evaluation: <ul style="list-style-type: none"><li>• Food Act 1981; and</li><li>• Meat Act 1981 (Meat Regs 1969, Fish Export Processing Regs 1995, Game Regs 1975).</li></ul>	5
4. Briefly outline each component of a risk management programme as listed in figure 3a; Components of a risk management programme (Risk Management Programme Manual). Include a brief description of the impact of incorporating overseas market access requirements into the risk management programme.	15
5. Briefly outline the animal products regulations and specifications <sup>14</sup> pertaining to risk management programmes. Comment on the legal status of the regulations and specifications in relation to the risk management programme and its evaluation.	4
6. Briefly describe the relationship between risk management programmes and food safety programmes under the Animal Products Act. List the options available for secondary processors of animal products in relation to risk based management programmes. Include a brief description of how these programmes may interface within premises.	4
7. List the risk factors that must be considered by the operator when developing a risk management programme, with a brief description of each, and describe the difference between hazards and other risk factors.	4

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<sup>14</sup> All of these regulations and specifications are available on the MAF Food website at [www.maf.govt.nz/animalproducts](http://www.maf.govt.nz/animalproducts)

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|--|---|
| 8. Describe the role of resources in developing a risk management programme, including all resources outlined in figure 2a; Resources to assist in risk management programme development (Risk Management Programme Manual). Include a discussion on the resources most likely to be used and other resources. | 7 |
| 9. Describe the impact the Animal Products (Ancillary and Transitional Provisions) Regulations 2000 (Regulation 11), on the evaluation of the risk management programme.   | 5 |
| 10. Describe the object of the harmonisation project between MAF and MoH, and the goal in relation to harmonisation of risk management programmes, product safety programmes and food safety programmes <sup>15</sup> .  | 2 |

**Part 2:**

- |  |    |
|--|----|
| 1. Briefly describe the validation process of the risk management programme, including: <ul style="list-style-type: none"> <li>• The two key components of validation;</li> <li>• Who is responsible for carrying out the validation;</li> <li>• How validation should be applied;</li> <li>• The validation required when an operator, for example, implements a process or procedure directly from a code of practice compared to an operator developing their own procedures (e.g. a novel process); and</li> <li>• The difference between validation and incomplete validation and its impact on the evaluation report(s) and the registration process.</li> </ul> | 15 |
|--|----|

**Part 3:**

**Either:**

- |   |    |
|---|----|
| 1. Provide a copy of the NZQA record of learning, or a certificate from the relevant industry training organisation as evidence of having obtained either the NZQA standard 12626 or 12316; and | 35 |
| 2. Briefly describe how the HACCP principles are applied to risk factors other than hazards.  | 5  |

**Or:**

Answer the following questions using practical examples from your own experience. (Note: This is an interim option only and is not considered to be equivalent to the HACCP qualifications listed above. Part of any future competency specification will be the achievement of an NZQA HACCP standard acceptable to the Director-General).

- |   |   |
|---|---|
| 1. Describe the relationship between a HACCP plan and the supporting systems, and the significance of supporting systems as part of the risk management programme.  | 5 |
| 2. Describe the essential elements of a HACCP plan (consider the eleven elements in this answer, which includes the seven principles of HACCP, the scope, product description, process description and food safety objectives). | 6 |
| 3. Describe the elements of a HACCP plan that need to be documented.  | 3 |

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<sup>15</sup> Refer to the MAF Food website at [www.maf.govt.nz/Food/information/moh-maf/harmonisation/](http://www.maf.govt.nz/Food/information/moh-maf/harmonisation/) and "Implementation of the Generic Approach to Risk-based Management Plans".

4. Describe the elements of a HACCP plan that generate records. 3
5. Describe the animal product business activities that influence the implementation of a HACCP plan. 4
6. Describe the relevance of staff roles and responsibilities in relation to implementing a HACCP plan. 3
7. Describe the staff training that should be given to effectively implement and maintain a HACCP plan. 3
8. Describe what operator verification of a HACCP plan consists of. 4
9. Describe what issues need to be considered when reviewing a HACCP plan. The description should include significant changes, performance of the HACCP implementation, resourcing (including new staff) and the applicability of the documentation. 4
10. Briefly describe how the HACCP principles are applied to risk factors other than hazards. 5

**Part 4:**

**Either:**

1. Provide evidence of having an audit qualification in quality systems, that is granted by an organisation, accredited by JAS-ANZ (or any other accreditation body recognised by JAS-ANZ) for the purposes of certifying auditors in accordance with international norms. 20

**Or:**

2. If the applicant does not have an auditor qualification, contact MAF Food Assurance Authority (Programme Manager, (RMPs)) to discuss assessment.

**Part 5**

Please provide the names and contact details of 2 referees for the provision of information relating to job performance, work record, technical ability, personal attributes, character and reputation, relevant to the tasks to be performed.

**Declaration:**

I declare that the answers submitted to MAF Food Assurance Authority in response to the accredited evaluator questions supplied have been prepared by me and are all my own work.

Applicant Signature \_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_

## Accredited Evaluator with Activity Endorsement

A person applying to the Director-General, MAF Food Assurance Authority, for accreditation with an activity endorsement must provide sufficient information to demonstrate their level of competence. This information will be assessed on a case by case basis. These requirements are in addition to the generic competency specification.

### A. General

The applicant must:

1. Provide evidence of having obtained a qualification that is at least equivalent to level 5 within the NZQA framework, such as a bachelor degree. The qualification should have some relevance to the activity endorsement being sought.

The following are examples of possible qualification areas: meat technology, meat preservation, animal science, meat industry operations, seafood technology, food science, food technology, food engineering, biochemistry, chemical technology and biotechnology.

2. Supply records of training and other qualifications relevant to the activity endorsement being sought.
3. Supply a résumé of relevant experience. This may include practical work experience in the industry at a level where an appreciation of the effects of processing techniques on product safety would be gained.
4. Provide written evidence of having knowledge of the infrastructure and operational norms of the industry or industries for which the activity endorsement is being sought.
5. Supply the names and contact details of 2 referees for the provision of information relating to job performance, work record, technical ability, personal attributes, character and reputation, relevant to the tasks to be performed.

Note: Where an activity endorsements are sought at the same time as a generic accreditation, the applicant may supply the names of two referees only, provided their knowledge of the applicant is sufficient to cover the two areas (generic accreditation and activity endorsement(s)) where information will be sought.

### B. Specific Activity Endorsement: Thermal processing of low acid canned products

Any person evaluating a risk management programme involving the thermal processing of low acid canned products for human or animal consumption must provide evidence of having passed a course of instruction covering the fundamentals of thermal processing, including thermal processing calculations. The following courses have been approved to date to meet this requirement:

1. Qualified Cannery Persons (Thermal Processing) Course, University of Western Sydney (Hawkesbury);
2. Approved Persons Course for Thermal Processing of Low Acid Foods, Foods Science Australia, Werribee, Australia; and
3. Introduction to the Fundamentals of Thermal Process Evaluation, Massey University, New Zealand. (No longer available).

For assessment in this activity, the applicant need only provide evidence of having passed one of the above courses and must meet the requirements of sections 3 and 5 of Part A.

## Administrative Requirements

The following is an interim requirement that must be fulfilled by accredited evaluators who are not accredited for the evaluation function to ISO 17020. If accredited to ISO 17020 for the evaluation function, evidence of the accreditation is sufficient to fulfil the administrative requirements.

The applicant must submit to MAF Food Assurance Authority the written policies and procedures they have in place to deal with things such as conflict of interest, coercion or impartiality and traceability of the evaluation process and associated documentation. Where an individual is part of an organisation, the policies and procedures of the organisation may be submitted to fulfil this requirement.

The documentation must cover the following:

1. How confidentiality in relation to information, operations and activities they come in contact with will be managed. The applicant must ensure that proprietary rights are protected.
2. The provisions for the storage and traceability of all relevant documentation associated with the evaluation process. Documentation, excluding the evaluation report, must be retained for at least 10 years.
3. How independence and conflict of interest will be managed. The evaluator must be free of any commercial, financial, management and other pressures (other than that associated with the evaluation) from those to whom the service is provided, and must have procedures that describe how the results of an evaluation will not be affected by external influences.

The procedures should also ensure that the applicant or any person to whom work is sub-contracted will not evaluate a risk management programme that they have been involved in the design, development or verification of, within any specified time constraints. (Refer to the Animal Products Regulations 2000, Reg 24).

4. The process that will be followed to assess the competency of any technical expert to whom evaluation work is subcontracted. This should include an assessment of the following:
  - records of relevant training and qualifications;
  - résumé of relevant experience;
  - information relating to job performance, work record, technical ability and personal attributes relevant to the role sought, from at least one independent referee;
  - where a particular competency requirement has been specified by the Director-General for certain activities, evidence that the person meets the requirement (e.g. thermal processing of low acid canned products); and
  - independence.

# Generic Accredited Evaluator Competency Specification and Interim Assessment Checklist

Applicant Name: \_\_\_\_\_ Assessment Date: \_\_\_\_\_  
 \_\_\_\_\_

Assessor's Name(s): \_\_\_\_\_ Assessment result(\*):  
 C = Competent.  
 NYC = Not yet competent.  
 FER = Further evidence required.

Element 1 – Describe a risk management programme in relation to the Animal Products Act 1999 and the Animal Products (Ancillary and Transitional Provisions) Act 1999.

P.C	Evidence	Comments	Decision *C, NYC, FER
1.1	The applicant must describe the objects of the Animal Products Act 1999 (the Act).	Brief mention of the 2 objects of the Act. (Section 2 of the Act).	
1.2	The applicant must describe the key controls of the risk management system.	Must mention each of the following and their relationship if any to each other: <ul style="list-style-type: none"> <li>• Risk management programmes</li> <li>• Regulated control scheme</li> <li>• Overseas market access requirements.</li> </ul>	
1.3	The applicant describes the interface of other legislation with the Act, and must cover the following legislation: <ul style="list-style-type: none"> <li>• Food Act 1981; and</li> <li>• Meat Act 1981 (Meat Regs 1969, Fish Export Processing Regs 1995, Game Regs 1975).</li> </ul>	The applicant must be able to say whether the legislation mentioned impacts on the Act and risk management programmes or vice versa. Which legislation is affected by the Animal Products (Ancillary and Transitional Provisions) Regulations 2000 (AP(A&TP) Regs; which legislation disappears after November 2002. Key information sought is the impact of this other legislation on the evaluation process and how it should be dealt with during the evaluation.	
1.4	The applicant outlines the components required in a risk management programme. All components (described in section 3 of the Risk Management Programme Manual) must be outlined. Document control must be mentioned as part of record keeping. The applicant outlines the impact of incorporating overseas market access requirements into the risk management programme.	A description of each component is expected as per Fig 3a; Components of a risk management programme (Risk Management Programme Manual). Outlines the options for the incorporation or alignment of the overseas market access requirements (OMARs) with the risk management programme and the effect on the evaluation of incorporating OMARs into the risk management programme.	
1.5	The applicant outlines relevant animal products regulations and specifications pertaining to risk management programmes, giving examples of each.	Mentions the regulations and specifications with respect to product intended for human consumption and product not intended for human consumption (including rendering). Includes reference to Regulation 10 of	

P.C	Evidence	Comments	Decision *C, NYC, FER
		the AP(A&TP) Regs. How the regulations and specifications will be interpreted and applied during the evaluation of a risk management programme. The legal status of the regulations and specifications in relation to the risk management programme.	
1.6	The applicant describes the relationship between risk management programmes and food safety programmes under the Act. This description must include all options available to secondary processors processing animal products that are food in New Zealand in relation to risk based management programmes.	Most cover FSP recognition as part of the RMP. Options include: Election to have RMP in total; FSP and RMP intermittent use; Food Act regime in total. Mentions the impact of requiring official assurances.	
1.7	The applicant describes what risk factors must be considered when developing a risk management programme and the difference between hazards and other risk factors.	Must cover: Hazards to human health; Hazards to animal health; Risks to wholesomeness; and Risks from false or misleading labelling.	
1.8	The applicant describes the role of resources in developing a risk management programme. The description must cover all resources outlined in the Risk Management Programme Manual (regulatory requirements and other resources as per Fig 2a; Resources to assist in risk management programme development).	Mandatory resources to be used: Act, regulations, specifications. Optional resources to be used – Fig 2a of the Risk Management Programme Manual. The description will include the legal standing of these documents and the difference between resources most likely to be used and other resources.	
1.9	The applicant describes the impact of the AP(A&TP) Regs (Reg 11) on the evaluation of the risk management programme.	The description must include reference to all plans, processes and systems that are covered under reg. 11 of the AP(A&TP) Regs. The description must include the impact of this transitional provision on the evaluation, and must describe those aspects of the risk management programme that must still be evaluated.	
1.10	The applicant describes the object of the harmonisation work between MAF and the Ministry of Health in relation to the evaluation and verification/audit of risk based management programmes.	Must mention the ultimate aim of: <ul style="list-style-type: none"> <li>• Aligning the requirements for RMPs, PSPs and FSPs; and</li> <li>• Having a single evaluator or audit/verifier competency standard (with the exception of the additional requirements such as the activity endorsement) such that accredited/approved persons may perform their role across the various regimes.</li> </ul>	

Element 2: Describe the validation process and the assessment of quality of evidence for risk management programmes.

P.C	Evidence	Comments	Decision C, NYC, FER
2.1	<p>The applicant describes how the risk management programme is validated in terms of:</p> <ul style="list-style-type: none"> <li>• Completion of documentation; that it is complete and meets the requirements of the Act and any relevant standards and specifications;</li> <li>• Being capable of achieving established product outcomes; and</li> <li>• Being implemented and consistently delivering the expected product outcomes.</li> </ul> <p>The applicant describes the significance of the process and supporting systems with respect to validation.</p>	<p>Documentation check against mandatory requirements. Validation data is open to a case-by-case interpretation. The description must cover the fact that some supporting systems will require validation in their own right, e.g. water, and others will be assessed according to compliance with standards and specifications. For additional guidance on validation, refer to the Risk Management Programme Manual, the Fishing Industry Agreed Guidelines “A Guide to HACCP Systems in the Seafood Industry” and the MAF Food Assurance Authority “Guide to HACCP systems in the Meat Industry”.</p>	
2.2	<p>The applicant describes how incomplete validation of a risk management programme will be addressed. This description must cover:</p> <ul style="list-style-type: none"> <li>• the responsibilities of the operator when the programme is incompletely validated;</li> <li>• how incomplete validation affects the evaluation report;</li> <li>• how incomplete validation affects the registration process;</li> <li>• how conditions applied as a result of the registration process impact on the completion of validation;</li> <li>• how completion of validation is achieved;</li> <li>• how completion of evaluation is achieved; and</li> <li>• the requirements, if any, for information to be sent to MAF Food.</li> </ul>	<p>Operators responsibilities – Section 4.5; Incomplete Validation (refer to the Risk Management Programme Manual). In relation to incomplete validation must cover that the documentation will be complete except for the validation data; The programme will include the:</p> <ul style="list-style-type: none"> <li>• protocol covering collection of data;</li> <li>• proposal for disposition of product resulting from validation trials;</li> </ul> <p>Registration conditions; Evaluation report after validation is completed; Registration conditions may be altered following completion of validation.</p>	

Element 3: Discuss the application of the HACCP principles to the development and operation of a risk management programme.

P.C	Evidence	Comments	Decision C, NYC, FER
3.1	<p>The applicant describes the application of the HACCP principles to the development and operation of a risk management programme. All eleven elements must be described, complete with animal product business</p>	<p>If the applicant has one of the specified HACCP unit standards view qualification, and provides a description of how the principles of HACCP are applied to risk factors other than hazards.</p>	

P.C	Evidence	Comments	Decision C, NYC, FER
	<p>examples:</p> <ul style="list-style-type: none"> <li>• in relation to the range of risk factors;</li> <li>• in relation to section 17 the Act 1999</li> <li>• in relation to any relevant regulations and specifications.</li> </ul> <p>HACCP qualifications accepted to date:</p> <ul style="list-style-type: none"> <li>• NZQA standard 12626 “Co-ordinate the Development and Verification of a HACCP Plan for a Meat Processing Operation”; or</li> <li>• NZQA standard 12316, “Co-ordinate the Development and Verification of a HACCP Plan for a Seafood Processing Operation”</li> </ul>	<p>If the applicant does not have one of the specified unit standards, a full description of the application of the HACCP principles is required. (In the longer term a HACCP qualification will be required).</p> <p>Must mention the 11 elements of HACCP, which includes the seven principles of HACCP, the scope, product description, process description and food safety objectives.</p>	

**Element 4: Demonstrate use of a recognised audit qualification**

P.C	Evidence	Comments	Decision C, NYC, FER
4.1	<p>Audit qualification in quality systems that is granted by an organisation, accredited by JAS-ANZ (or any other accreditation body recognised by JAS-ANZ) for the purposes of certifying auditors in accordance with international norms.</p>	View qualification.	
4.2	<p>Ensure that the following aspects of the audit process (sourced from ISO standards 10011 - 1:1992; 10011 - 3:1992) have been covered:</p> <ul style="list-style-type: none"> <li>• Decide on the type of audit and standard against which audit is to be done;</li> <li>• Notify the auditee;</li> <li>• Obtain information prior to premises audit;</li> <li>• Assess pre-audit information and if necessary target specific concerns;</li> <li>• Select audit team;</li> <li>• Brief the audit team;</li> <li>• Visit premises and carry out entry meeting;</li> <li>• Carry out audit;</li> <li>• Carry out exit meeting and deliver conclusions;</li> <li>• Write formal report;</li> <li>• Follow up on non-conformances.</li> </ul>	Ensure that the applicant understands and appreciates MAF expectations re the auditor standards and components, as per list.	