



# Evaluators' Manual

for Risk Management Programmes  
Animal Product Processing Excluding Dairy

## Prelims

Amendment 2

April 2007

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## Disclaimer

### ***IMPORTANT DISCLAIMER***

Every effort has been made to ensure the information in this report is accurate.

NZFSA does not accept any responsibility or liability whatsoever for any error of fact, omission, interpretation or opinion that may be present, however it may have occurred.

### ***Website***

A copy of this document can be found at: <http://www.nzfsa.govt.nz/animalproducts/index.htm>

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# 1 Introduction

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## 1.1 Overview

An operation that requires a risk management programme (RMP) under the Animal Products Act (the Act) must have the programme registered with the New Zealand Food Safety Authority (NZFSA) prior to the commencement of processing.

Section 20 of the Act requires an operator seeking registration of an RMP to submit a copy of an independent evaluation report (unless the requirement is waived) to the Director-General that recognises the validity of the programme. A person who is recognised as an evaluator under the Act must conduct the evaluation. Evaluators are recognised by the Director-General to allow the NZFSA to manage the risk associated with third party involvement in the government process of registering RMPs.

This manual details the competency requirements and recognition process for a person to become a recognised RMP evaluator involved in evaluating animal material and animal product processing other than dairy, and provides guidance for the evaluation process. For further details of the requirements for operators of dairy RMPs refer to the NZFSA website:

[Dairy Requirements](#)

The NZFSA is reviewing New Zealand's domestic food regulatory programme – “The Domestic Food Review”. This is a wide ranging long-term project that represents the first major review of food controls in almost 30 years. Part of this process includes a review of the evaluation process with the aim of having a single competency for all evaluators regardless of the underpinning legislation, with ‘add-ons’ for certain processing types. Further, it has been proposed that all evaluators be part of a recognised agency that has International Accreditation New Zealand (IANZ) or Joint Accreditation Systems of Australia and New Zealand (JAS-ANZ) accreditation to ISO 17020 “General criteria for the operation of various types of bodies performing inspection”. It has been proposed that evaluation would only be required for more complex operations or for programmes that have not been developed based on approved codes of practice, templates or models. The outcomes of the “Domestic Food Review” will be phased in, and over time will be reflected in updates to this manual or replacement of this manual with alternative guidance material.

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The following sections provide an overview of the legislation that underpins RMPs and their evaluation under the Act. It also provides an overview of the different aspects of RMP evaluation.

## 1.2 Legislation

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

- Acts;
- Regulations;
- Notices (including specifications).

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

All legislation, including full details of any amendments can be accessed from the NZFSA website at the following: [Animal Products Legislation](#). As legislation is amended periodically it is critical that evaluators keep abreast of these amendments.

### Act

The Animal Products Act 1999 (the Act) is the key piece of legislation for animal products.

The Act 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 and provide official assurances.

### Regulations

The Animal Products Regulations 2000 provide animal product standards and miscellaneous provisions.

The Animal Products (Fees, Charges, and Levies) Regulations 2002 define the fees, charges and levies payable under the Act<sup>1</sup>.

### Notices (including specifications)

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<sup>1</sup> These regulations are currently being reviewed and may be subject to change.

A series of notices have been developed under the Act. Those of particular importance for RMPs and their evaluation are listed in section 7.2

***In this manual, the specifications relating directly to RMP evaluation are identified as bold italicised text within a box as shown for this paragraph. These specifications have been taken from the Animal Products (Recognised Agencies and Persons Specifications) Notice 2007.***

### Other information

Other information such as policy statements, codes of practice, templates and models are also on the NZFSA website and evaluators must also be familiar with these documents.

### 1.3 Requirements for Evaluator Recognition

To be recognised as an evaluator 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 is expected to have and these stem from qualifications and/or experience. The requirement to be “proper” relates directly to the integrity of the person.

The following factors are taken into account in the assessment of the person:

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

The person must meet a number of requirements, which include the competency specification and having documented procedures to deal with systems and administration. (Refer to sections 2 to 5 of this manual for further details of the requirements for recognition).

Where a person has one or more particular areas of expertise, for example seafood primary processing, they may apply for an activity endorsement. Also, some processing types have a mandatory competency requirement for evaluation (e.g. commercial sterilisation). An activity endorsement may be granted where the Director-General is satisfied that the person has demonstrated a satisfactory level of technical expertise in that activity. Wherever

possible, the recognised 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 RMP.

Regardless of the type of recognition gained, the evaluator must seek input from other recognised evaluators or technical experts<sup>2</sup> with the appropriate area of expertise, for any aspect of the evaluation that is outside their competency.

#### 1.4 Key Aspects of Evaluation

An evaluation involves a systematic assessment of the RMPs validity by an independent recognised evaluator who is working **on behalf of the Director-General** and therefore the NZFSA. The primary purpose of evaluation is to ensure that the RMP is suitable and effective and meets the requirements of the legislation. As it is a user pay system, the evaluator is contracted and paid by the operator. The evaluator is responsible for the complete assessment of the RMP. However, evaluators must use the services of other recognised evaluators or technical experts for any aspect of the RMP that is outside their competency.

At the completion of the evaluation, the evaluator may:

- a. recognise the RMP as valid; or
- b. return the RMP to the operator for further work.

Where the RMP is considered to be valid, the evaluator must prepare an independent 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. The operator must submit the independent evaluation report when they are making application to have their RMP registered.

Where an RMP is not of a satisfactory standard to be recognised as valid, the 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 the revised RMP, methods of rectifying any deficiency must not be provided. Otherwise this would involve the evaluator in the design and development of the RMP, hence compromising their independence.

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

## 2 Evaluator Competency

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### 2.1 Generic Evaluator Competency Specification

The following box details the competency specifications that must be met by any person seeking recognition as an evaluator.

**Specification clause:**

**18 General competencies for all verifiers and evaluators**

**1. Any person applying to be recognised for verification or evaluation must—**

- a. achieve a quality system audit qualification that is certified by a JAS-ANZ accredited personnel certification body or have attended a NZQA recognised audit course, or obtain a NZQA unit standard in auditing at level 6 or above; and**
- b. if the quality system audit qualification was completed more than three years previously, must be able to demonstrate a meaningful involvement in performing verification or evaluation over the intervening years or must complete re-qualification; and**
- c. be competent in performing audits; and**
- d. to the extent relevant to the person's evaluation or verification activities and the industry sector in which those functions are to be performed, demonstrate an understanding of the Act, including—**
  - i) the object of the Act and the relationship between risk management programmes and other provisions for managing risks under the Act, including regulated control schemes, standards and specifications, and export requirements; and
  - ii) the relationship between risk management programmes and food safety programmes under the Food Act 1981; and
  - iii) contents of, and requirements for, risk management programmes including the risk factors to be considered and the matters specified in

section 17 of the Act; and

- iv) the confirmation process and assessment of the quality of evidence for a risk management programme; and
- v) the role, responsibilities and duties of operators, exporters, recognised agencies, and recognised persons; and
- vi) the role and duties of the Director-General, official assessors, animal product officers, and authorised persons; and
- vii) the relevant regulations, export requirements, notices and specifications made under the Act; and
- viii) the relationship between the Act and other associated legislation, including the Food Act 1981; and

**e. hold at least a NZQA Level 4 qualification in animal health, public health, seafood technology, food engineering, food technology or other qualification or experience that will enable the Director-General to determine that the person is able to adequately and competently perform verification or evaluation; and**

**f. have general knowledge of the infrastructure and operational norms of the industry for which the evaluation or verification is going to be performed that will enable the Director-General to determine that the person is able to adequately and competently perform verification or evaluation in that industry.**

**2. Despite sub-clause (1)(a), a person may obtain their qualification in quality system auditing within 6 months (or such other period of time as agreed in writing by the Director-General) of becoming a recognised person, providing they meet the other requirements set out in sub clause (1)(c) to (f) as appropriate and any other requirements specified by the Director-General.**

## 2.2 NZQA Unit Standards

The NZFSA has developed three NZQA unit standards in the subjects of HACCP, RMPs and evaluation, as relevant to the Animal Products Act 1999.

The three standards are:

- 19514 “Explain the application of HACCP principles”;
- 19515 “Explain risk management programmes under the Animal Products Act 1999”;
- 19516 “Explain evaluation and evaluate a risk management programme under the Animal Products Act 1999”.

These unit standards are available on the NZQA website: [www.nzqa.govt.nz](http://www.nzqa.govt.nz) by clicking on qualifications framework then entering the unit standard number: 19514, 19515 or 19516 in the search framework box.

Assessment material is also available on the NZFSA website at: [Unit standard assessment material](#).

In addition to these, there are two other NZQA HACCP standards that are acceptable to the NZFSA instead of 19514. These are:

- 12626 “Coordinate the development and verification of a HACCP plan for a meat processing operation”; and
- 12316 “Coordinate the development and verification of a HACCP plan for a seafood processing operation”.

To be recognised as an evaluator, an applicant must be assessed as competent against unit standards **19514**, **12626** or **12316** and unit standard **19515**.

Unit standard **19516** is not currently a requirement for evaluator recognition, although completion of this is strongly recommended. The requirements covered by standard 19516 are addressed by additional questions in the Recognised Evaluator Application Pack in Appendix V of this manual.

### **2.3 Confirmation of Validity and HACCP**

In addition to completing the NZQA unit standards, the applicant must demonstrate further knowledge of HACCP and confirmation of validity under the Act. To do this, written responses to the questions on confirmation of validity (1.2) and HACCP (1.3) in the Recognised Evaluator Application Pack must be provided.

### **2.4 Audit**

The applicant must have evidence of obtaining a specified audit qualification at the time of making application for recognition or must obtain the qualification within six months of being recognised. In the latter case they must provide a written submission that describes all their relevant training and experience in auditing (see (1.4) of the Recognised Evaluator Application Pack). They must include information on the types of audits undertaken and their role. Emphasis should be given to the audits undertaken and experience gained in the previous three years. If the applicant has the qualification but has had no role in audit during the previous three years, he/she will need to be re-qualified.

### **2.5 NZQA level 4 Qualification or Equivalent**

The applicant must have evidence of holding at least a NZQA Level 4 qualification in animal health, public health, seafood technology, food engineering, food technology or other qualification or experience which is acceptable to the NZFSA.

### **2.6 Recognised Evaluator to be a “Proper Person”**

Under the Act, the Director-General must be satisfied that the applicant is of an appropriate character and reputation to carry out the function and activities concerned.

Given the importance of the role of the recognised 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 the NZFSA 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.

## **2.7 Activity Endorsements**

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

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

A recognised evaluator without an activity endorsement in an area covered by the RMP will be expected to obtain technical input for any aspect of the programme that is outside their competency.

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

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:***

***19 Activity endorsements for evaluators***

***If a person is seeking to be recognised as an evaluator with endorsements for specific evaluation activities, then their application for recognition must include a clear statement of the endorsements being sought and evidence of:***

***(a) relevant qualifications, training and experience; and***

***(b) current knowledge of the infrastructure and operational norms of the relevant industry; and***

***(c) current knowledge of the operational norms relevant for the endorsement being sought.***

Currently only two mandatory competency requirements have been set by the Director-General. These are for those aspects of RMPs relating to the evaluation of thermal

processing of low-acid canned products for human or animal consumption, and for the depuration of bivalve molluscan shellfish.

If applying for an activity endorsement in either of these areas, a person must provide evidence of having passed a recognised course of instruction. The Director-General may recognise alternative qualifications to those specified.

**Specification clause:**

**20 Additional competencies for evaluators and verifiers of low-acid canned products**

**(2) In addition to clauses 18 and 19, any person applying to be recognised to perform evaluation of thermal processing of low-acid canned products must hold at least one of the following qualifications—**

**(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; or**

**(3) The Director-General may accept alternative qualifications to those detailed in sub-clauses (1) and (2).**

**23 Additional competencies for evaluators and verifiers of the depuration of bivalve molluscan shellfish**

**In addition to clause 18, any person applying to be recognised to evaluate or verify bivalve molluscan shellfish depuration must be able to demonstrate technical knowledge of depuration requirements through successfully completing the Depuration Training Course conducted by the New South Wales Food Authority, or an alternative qualification agreed by the Director-General.**

It should be noted that if a technical expert or other recognised evaluator is used to provide a supporting report in this area, the evaluator must ensure that the person has met the requirements of clauses 20 or 23 prior to undertaking the work.

## 3 Operational Requirements

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### 3.1 Quality System

To be recognised as an evaluator for the purpose of the Act a person must develop a documented quality system to deal with issues such as confidentiality, independence and impartiality, traceability of the evaluation documentation and assessment of technical experts. Once these documented systems have been approved as part of the recognition process, they must be followed for all evaluations.

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

***Specification clause:***

***29 Additional requirements for recognised persons not subject to the management of a recognised agency***

***(1) A recognised person that is not subject to the management of a recognised agency must, in relation to the performance of their functions and activities under the Act,—***

***(a) establish and maintain an effective quality system, and document all relevant parts of that system;***

### 3.2 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 an organisation the evaluator may be part of.

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 RMP under evaluation.

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

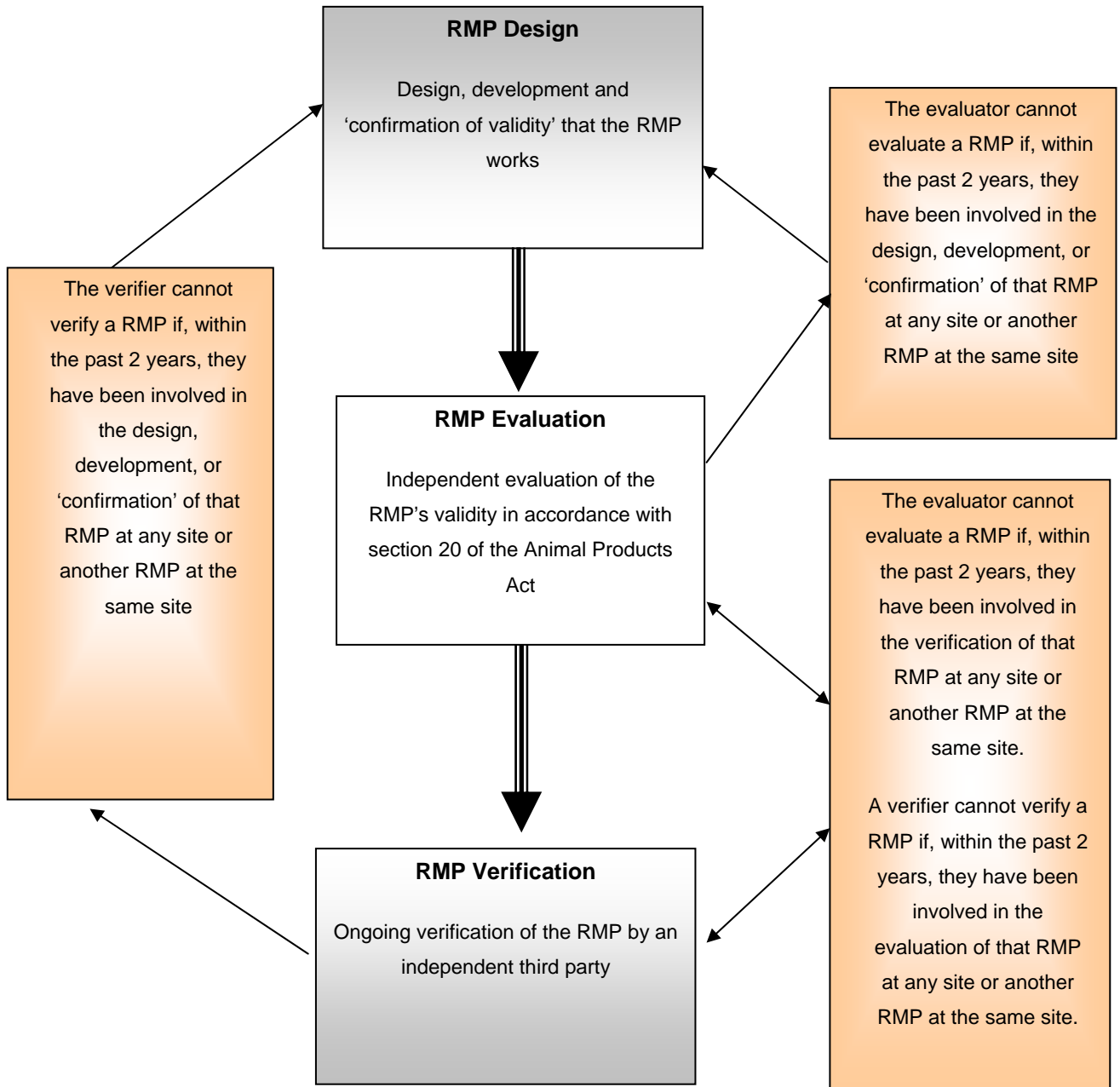
It is noted that there may be multiple programmes operating at one site, therefore provision of these functions for any one of those programmes would preclude the person concerned from providing evaluation functions at that site.

Individuals and organisations (including their employees and sub-contracted personnel) who are seeking recognition 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 do not preclude another person from the same organisation or agency from carrying out that function or activity on the same programme, so long as the independence is maintained.

The verification function associated with export requirements is not subject to these same constraints. Verification of export requirements may be conducted by any person who is recognised for that purpose, regardless of any involvement that they may have had in the design, development, confirmation of validity, evaluation or verification of that RMP.

For the full policy statement regarding conflict of interest and independence, refer to the NZFSA website: [Independent evaluation and verification of risk management programmes](#)

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



The following box details the specifications for confidentiality, impartiality and independence. Any person applying for recognition as an evaluator must have documented procedures as part of their quality system that describes how the specifications will be complied with. It is the responsibility of the evaluator to ensure that these procedures are complied with by any technical experts or other evaluators used in an evaluation.

**Specification clause:**

**29 Additional requirements for recognised persons not subject to the management of a recognised agency**

**(3) In addition to sub-clauses (1) and (2), if a person is recognised to perform evaluation and is not subject to the management of a recognised agency, then that person must—**

**(a) have documented procedures for maintaining appropriate confidentiality and protecting the proprietary rights of operators in accordance with section 107(d) of the Act; and**

**(b) not have any commercial, financial or management relationship with those to whom he or she is providing evaluation services (other than for the purpose of providing those services) unless specifically disclosed and agreed to by the Director-General; and**

**(c) have documented procedures to ensure impartiality and independence is not compromised while carrying out their functions and activities.**

### **3.3 Evaluator Accountability and Records Management**

In many cases the professional judgement of recognised evaluators will be called upon when evaluating RMPs. They must take responsibility for the following factors during the evaluation of an RMP:

- exercising sound judgement; and
- following the Act and any relevant regulations and specifications; and
- conducting a full and effective evaluation of the RMP; and
- any technical input received during the evaluation; and
- recognising the validity of the RMP where appropriate; and

- any recommendations for conditions that should be applied by the Director-General during registration of the RMP.

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 at least 4 years from the date of signing the evaluation report. This retention period applies even if the person ceases to work as a recognised evaluator<sup>3</sup>.

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 who must develop a documented quality system which describes how these specifications will be complied with.

**Specification clause:**

**29 Additional requirements for recognised persons not subject to the management of a recognised agency**

**(1) A recognised person that is not subject to the management of a recognised agency must, in relation to the performance of their functions and activities under the Act,—**

**(b) have documented procedures for storing and tracking all relevant records;  
and**

**(c) have documented procedures for storing and tracking any correspondence with the NZFSA, operators, technical experts, and other businesses associated with those functions and activities.**

**(2) A recognised person that is not subject to the management of a recognised agency must retain records and correspondence for at least 4 years from the date of signing the particular evaluation report concerned, and records and correspondence must be auditable and be made available to the Director-General, an animal product officer or person authorised by the Director-General, upon request within 24 hours.**

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<sup>3</sup> If a person ceases to work as a recognised evaluator, arrangements may be made with the NZFSA regarding record storage. Please contact the NZFSA to discuss further if this is the preferred option.

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### **3.4 Amendments to Approved Quality System Procedures**

Any significant amendments that are made to the evaluator's documented quality system that had been approved as part of the recognition process, must be submitted to the NZFSA for re-assessment and re-approval.

An amendment would be considered significant if it radically changes the way an evaluation is to be conducted or how documentation is to be managed. Amendments which are made to enhance the evaluation process would not be considered significant.

An NZFSA Compliance and Investigation Group (CIG) audit of an evaluator's competency will include an assessment of the evaluator's compliance against their approved procedures and the resulting evaluation documentation and reports (also see section 6.2).

## 4 Use of Technical Experts and Other Recognised Evaluators

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### 4.1 Input from Technical Experts or other Recognised Evaluators

The recognised evaluator must seek input during an evaluation for any aspect of the programme that is outside their competency. He/she must have the ability to recognise and obtain additional technical input when required.

The decision to seek this technical input will not always be clear-cut. The recognised 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 the NZFSA to discuss the issue further.

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

#### ***28 Requirements for recognised persons to perform evaluation***

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

### 4.2 Assessment of Competence of Other Recognised Evaluators and Technical Experts

Where another recognised evaluator is used to provide a supporting report no competency assessment is needed unless a specific competency is mandated. Where a specific competency is mandated an activity endorsement in the relevant area will provide sufficient evidence that the person is competent. If the person does not have the required activity endorsement, the evaluator will need to confirm compliance with the competency specification (i.e. clauses 20 or 23 of the Recognised Agencies and Persons specifications) before the work is undertaken.

If a technical expert is used to provide a supporting report, the evaluator must complete a competency assessment of that person before the work is undertaken, and where there is a

mandatory competency (clauses 20 and 23), must ensure that the technical expert complies with that specification.

Persons applying for recognition as an evaluator must document a quality system which describes how the following specification will be complied with. These procedures must be followed when assessing the competency of technical experts.

**Specification clause:**

**28 Requirements for recognised persons to perform evaluation**

***Any person recognised to perform evaluation, whether subject to the management of a recognised agency or not, must have documented procedures for assessing the required competencies, training and experience of any technical expert from whom a supporting report is obtained to ensure that only technical experts that are competent to provide the analysis and report required are used.***

The evaluator is responsible for ensuring that the competency assessment is completed in a full and thorough manner.

During the process of registering an RMP where a technical expert has been used, the NZFSA assessor will check that the documented competency assessment has been included with the evaluation report. In addition to this, any CIG audit of an evaluator's competency will include a review of this procedure and the resulting documentation and competency report(s).

Examples of areas where technical input may be sought are:

- 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 I, Activity Endorsements, for further examples.

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### **4.3 Supporting Reports from Technical Experts or other Recognised Evaluators**

Technical experts and other recognised evaluators used in an evaluation must complete their evaluation in a full and thorough manner.

If satisfied that the part of the RMP that they are responsible for assessing is acceptable, the technical expert or other recognised evaluator must prepare a supporting report at the completion of their evaluation. The content of the supporting report must meet the mandatory requirements of the evaluation report, as appropriate to the scope of the work (refer to section 9 for contents of the evaluation report). The report must include a statement that the part of the RMP evaluated is valid, and any conditions to be applied by the NZFSA at the time of registration.

If that part of the RMP is not acceptable and the technical expert or other recognised evaluator is to 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 should not become directly involved in the development of the RMP. Otherwise this would compromise their independence and prevent them from evaluating the revised document.

The recognised evaluator must include in full, any supporting reports obtained from the technical expert or other recognised evaluator, with their evaluation report.

It is the responsibility of the recognised evaluator to ensure that supporting reports are of an acceptable standard. If there appears to be a lack of technical content or if the recognised evaluator has any reason to believe that the supporting report does not demonstrate an adequate evaluation of the relevant components of the RMP, the evaluator must obtain further information. The evaluator's signature on the evaluation report provides confirmation to the NZFSA that they are satisfied with any supporting reports that have been included. It is recognised that the assessment of any supporting reports by the 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 necessary, would be seen as a lack of due diligence and could result in further investigation into competency by the NZFSA.

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## 5 Application Procedure

Amendment 2

April 2007

### 5.1 NZFSA Assessment

The following section describes the procedures that will be followed by the NZFSA when a person applies to be recognised as an evaluator. This procedure is being reviewed as part of the Domestic Food Review, and will be subject to change following the outcome of this.

All documentation necessary to make an application for recognition as an evaluator is detailed in sections 2, 3 and 4 and Appendix V "Recognised Evaluator Application Pack" of this Manual.

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

### 5.2 Outcome of Assessment

At the completion of the assessment, a person who meets the requirements to be recognised as an evaluator will be issued with a Notice of Recognition. The person must not take responsibility for, or sign any evaluation report until they have received this Notice. The Notice of Recognition must be retained by the recognised evaluator for the duration of their recognition, and must be returned to the Director-General on cessation of recognition, 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 recognition, a review may be sought in accordance with section 162 of the Act (refer to section 5.4).

### 5.3 Fees

There are three fees associated with evaluator recognition:

- a. application fee;
- b. assessment fee;
- c. annual fee.

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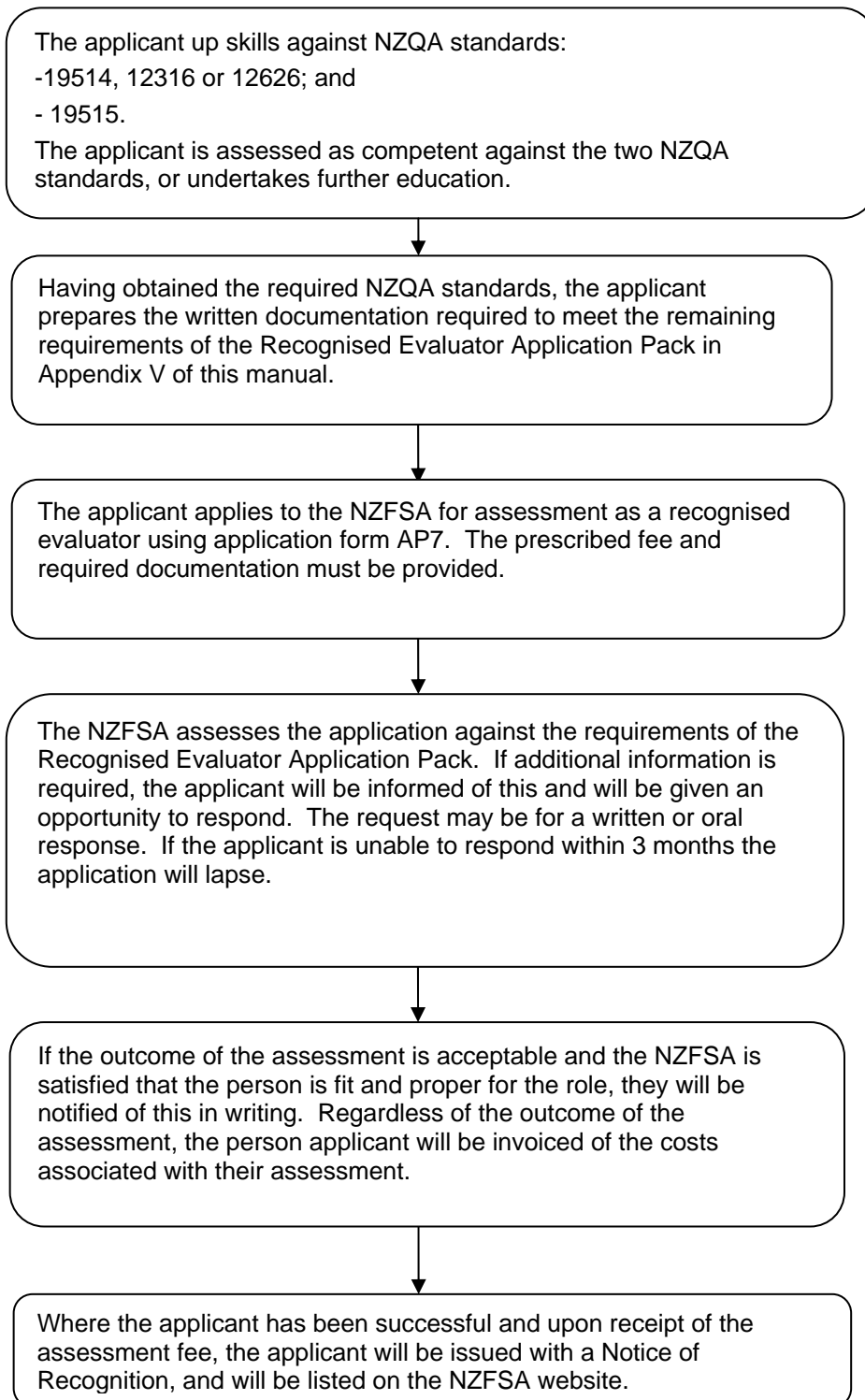
The applicant is required to pay an application fee when submitting their documentation and an assessment fee is charged at the completion of the NZFSA assessment, which is calculated on an hourly basis for the time involved in assessing the application. The applicant is invoiced for the assessment fee and must pay this prior to the Notice of Recognition being issued. This fee must be paid by the applicant regardless of whether the application has been successful.

An annual fee must be paid in subsequent years to maintain recognition. Payment of the annual fee is the responsibility of the recognised evaluator. If the annual fee is not paid, continued activities as a recognised 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 recognition under section 109 of the Act. The NZFSA will endeavour to notify the recognised evaluator when the annual fee is due.

Refer the Animal Products (Fees, Charges, and Levies) Regulations 2002 for the applicable fees and charge out rates.

The following diagram illustrates the assessment procedure followed by the NZFSA.

**Figure 2: Assessment Procedure**



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## **5.4 Right of Review**

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

The Director-General may refuse to grant recognition. 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.

### **5.4.2 Decision Made by a Person Acting Under Delegated Authority**

Section 162 of the Act provides that where the decision to refuse recognition 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 NZFSA within 60 days. This may be extended a further 30 days on notification to 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 recognition is upheld.

## 5.5 Registration of Recognised Evaluators

The Director-General maintains a register of all recognised evaluators as provided for under section 112 of the Act. The register is available for public viewing on the NZFSA website at [List of Recognised Evaluators](#).

The register informs members of the public and RMP operators of those individuals who are recognised 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 the NZFSA.

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## 6 Maintenance of Recognition

Amendment 2

April 2007

### 6.1 Conditions of Recognition

Recognition 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 recognition.

### 6.2 Compliance Audits

The evaluator will be subject to ongoing periodic compliance audits by the Compliance and Investigation Group (CIG) of the NZFSA.

The CIG audit will involve:

- a. a desk top assessment of the recognised evaluator, including assessment against their approved quality systems; and
- b. observation of the evaluator undertaking an on-site assessment as part of an RMP evaluation.

These audits form part of the system to ensure competency of recognised evaluators and the overall performance of the RMP evaluation system.

### 6.3 Maintenance of Competence

Evaluators have a responsibility to ensure that their competence is maintained and improved upon on an ongoing basis. This would occur through attendance at the Evaluator's Workshops and by keeping up to date with the latest RMP developments including amendments to the legislation, new manuals, approved COPs, models and templates. It also involves keeping abreast of technical developments in the specific industries for which the service is provided, including knowledge of the confirmation of validity that would be needed if implementing new technologies. Attendance at technical conferences, seminars and training courses is encouraged. Attendance at the Evaluator's Workshops is expected.

During the RMP registration process an NZFSA assessor may request further clarification from an evaluator and provide feedback where an RMP is deficient. This NZFSA feedback must be used by the evaluator as a means of training and further education. Repeated requests for similar information would be seen as a failure to maintain and improve on competence.

**Specification clause:**

**26 General requirements for recognised persons**

**(1) A recognised person must only perform those functions and activities listed in clause 17(2) that they have been recognised to perform.**

**(2) To maintain recognition, the person must—**

**(a) renew their recognition annually or at a frequency determined by the Director-General; and**

**(b) diligently carry out their functions and activities in accordance with the requirements of their recognition, including following any conditions imposed as part of the recognition; and**

**(c) maintain their level of competency;**

The evaluator must ensure that sufficient time and due diligence is applied to each evaluation. Workload must be managed to ensure that the evaluation is conducted to the degree and in the depth required to be satisfied that an RMP is valid. The evaluator must not cut corners on the evaluation with the expectation that it will be rectified by the NZFSA. This would be seen as a failure to comply with the duties of a recognised evaluator under the Act.

To maintain recognition the evaluator must:

- ensure that their knowledge of industry practices and animal products legislation remains current; and
- continue to develop and enhance their skills in the evaluation of RMPs; and
- receive an acceptable outcome from any compliance audit; and
- conduct effective evaluations and produce evaluation reports that accurately reflect the operation; and
- comply with the duties of recognised persons (section 107 of the Act); and

- comply with any conditions of recognition.

If at any stage it is found that the recognised evaluator fails to meet the required competency specification, or that the performance of the recognised evaluator impacts negatively on the risk management system, they will be notified of this. Where there is a serious deficiency in the performance, the procedures pertaining to suspension and withdrawal of recognition, and the right of review will apply (refer to sections 6.5 and 6.6).

## **6.4 Additions or Changes to Recognition**

### **6.4.1 Activity Endorsements**

An evaluator who wishes to amend their endorsed activities must submit a completed application form AP7, together with the documentation as outlined in the Recognised Evaluator Application Pack, Activity Endorsement, to the Director-General. They will then undergo an assessment in this new activity. The assessment procedure as described in section 5 will apply. Fees are payable with each application.

A recognised evaluator who wishes to remove an activity endorsement must notify the Director-General in writing.

### **6.4.2 Substituted Notice of Recognition**

Where the terms or conditions of recognition 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 Recognition and issue a new Notice. A fee will apply.

Refer the Animal Products (Fees, Charges, and Levies) Regulations 2002 for the applicable fees.

### **6.4.3 Changes to Organisations**

If a recognised evaluator moves from or joins an organisation for the purposes of evaluation, they must notify the NZFSA in writing. This is to enable the NZFSA to track the movements of recognised evaluators and to ensure that they remain subject to approved quality system procedures relating to confidentiality, impartiality and independence, traceability of documentation and assessment of technical experts as described in sections 3 and 4.

**Specification clause:****29 Additional requirements for recognised persons not subject to the management of a recognised agency**

**(4) A recognised evaluator that is not subject to the management of a recognised agency must, prior to moving from or joining a recognised agency or organisation that performs evaluation functions, 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.**

If a recognised evaluator joins a new organisation or leaves an organisation and begins working as an individual, it is their responsibility to continue to operate under NZFSA approved quality systems. Where the evaluator loses coverage under the approved quality systems as part of the move, he/she must develop and submit new systems to the NZFSA for approval. This must occur within 4 weeks of leaving the previous organisation. New evaluations should not commence until these systems have been written and submitted for approval. If joining an organisation that has an NZFSA approved quality system, the evaluator must ensure that they conduct all evaluations in accordance with those procedures.

## **6.5 Suspension of Recognition**

Section 108A of the Act provides that where there are reasonable grounds to believe that the performance of the person is unsatisfactory, the Director-General may at any time suspend recognition for up to three months, with the option of extending for a further three months. The evaluator will be required to provide the NZFSA with a full list of the evaluations that are currently underway. The Director-General may impose conditions or requirements that must be satisfied if the suspension is to be lifted. The evaluator will be notified of this in writing.

If the decision to suspend recognition has been taken by a person acting under delegated authority of the Director-General, the right of review process as described in section 5.4 will apply.

## 6.6 Withdrawal of Recognition

Section 109 of the Act provides that where necessary, the Director-General may at any time withdraw recognition. The evaluator will be notified of this in writing. The evaluator will be required to provide the NZFSA with a full list of the evaluations that are currently underway

The following circumstances would be considered grounds for withdrawal:

- the person is no longer fit and proper to undertake the activities for which recognition was granted; or
- the person has failed to comply with any terms or conditions of recognition; or
- 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 NZFSA plans to withdraw recognition, the evaluator will be given a reasonable opportunity to be heard. If the decision to withdraw recognition has been taken by a person acting under delegated authority of the Director-General, the right of review process as described in section 5.4 will apply.

The recognised evaluator must:

- take all reasonable steps to notify all clients of the impending withdrawal; and
- surrender their Notice of Recognition to the Director-General on withdrawal of the recognition.
- retain the evaluation records for 4 years from the date of signing of each evaluation report, unless other arrangements have been made in writing with the Director-General.

## 6.7 Surrender of Recognition

The recognised evaluator may surrender their recognition at any time by notice in writing to the NZFSA. The surrender will take effect on the expiry of 3 months after the date of receipt of the notice by the NZFSA. This time may be brought forward on approval by the NZFSA.

On surrender of recognition, the person must surrender their Notice of Recognition to the NZFSA (refer to section 110 of the Act).

The recognised evaluator must:

- take all reasonable steps to notify all clients of the impending surrender; and
- surrender their Notice of Recognition to the Director-General.
- retain the evaluation records for 4 years from the date of signing of the evaluation report, unless other arrangements have been made in writing with the Director-General.

### **6.8 Expiry of Recognition**

Evaluator recognition 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-recognition and an assessment will be undertaken to ensure their competency is maintained. The assessment will include a review of any compliance reports prepared about their performance.

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## 7 Risk Management Programme Evaluation

Amendment 2

April 2007

### 7.1 General Requirements<sup>4</sup>

During an evaluation, the evaluator must assess the following:

- the completeness of the RMP against the requirements of the Act and its subordinate legislation; and
- scope of the RMP, including ensuring that all animal materials, products, processes and areas that are required to be covered under that RMP have been captured. If any of these are missed, the operator would be operating illegally if producing those products or using those areas; and
- completeness of each product description; and
- inclusion of any relevant regulatory limits; and
- appropriateness of important product characteristics (IPCs), including ensuring that any animal product standards and specifications that are IPCs, have been met; and
- completeness and accuracy of each process description; and
- appropriateness of:
  - each hazard identification and analysis; and
  - 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); and
  - other risk factor identification and control (wholesomeness and false or misleading labelling); and

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<sup>4</sup> Note: It is expected that standard auditing procedures will be followed in the evaluation of the RMP. Details of these procedures will not be expanded upon in this document.

- adequacy of evidence provided to confirm the validity of the RMP or that there is an acceptable protocol for collection of any required evidence after registration; and
- effectiveness of recall procedures; and
- adequacy of document control systems and record keeping.

The evaluator must ensure that the following occurs:

- an evaluation must include a desk-top assessment of the RMP which may be conducted on or off-site as agreed between the evaluator and the operator; and
- unless an exemption has been granted, the evaluation of a new RMP must involve an on-site assessment. Evaluation of a significant RMP amendment may or may not involve an on-site assessment (at the discretion of the evaluator). Refer to section 7.9 for details of the requirements for on-site assessments; and
- an evaluation must include all aspects of the operation and all components of the RMP including all supporting systems. Any programme or record that has been cross referenced within the RMP must be evaluated; and
- where an operator intends to submit an RMP outline to the NZFSA, the evaluator must assess the outline to ensure that it accurately reflects the RMP; and
- at the completion of a successful evaluation (i.e. the RMP is to be recommended for registration) an evaluation report must be produced for the operator (refer to Section 9 for details of the report content); and
- the evaluator must endorse the RMP or RMP outline.

Refer to Appendices II and III for further guidance on the points to consider during an evaluation.

## **7.2 Evaluation of Compliance with the Animal Products Act and Subordinate Legislation**

The RMP must be evaluated against the relevant legislation as appropriate to its scope. This legislation is subject to amendment so the recognised evaluator must be familiar with the NZFSA website and keep abreast of the latest developments. All relevant legislation is on the NZFSA website: [Animal Products - Legislation](#) and it is recommended that evaluators sign on to the website to be notified of any changes.

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The legislation to be considered<sup>5</sup> is:

- Animal Products Act 1999; and
- Animal Products Regulations 2000; and
- Animal Products (Exclusions and Inclusions) Order 2000; and
- Animal Products (Definition of Primary Processor) Notice 2000; and
- Animal Products (Risk Management Programme Specifications) Notice 2003; and
- Animal Products (Specifications for Products Intended for Human Consumption) Notice 2004; and
- Animal Products (Specifications for Products Intended for Animal Consumption) Notice 2006; and
- Animal Products (Specifications for the Ante-mortem And Post-mortem Examination of Poultry Intended for Human or Animal Consumption) Notice 2005; and
- Animal Products (National Microbiological Database Specifications) Notice 2005; and
- Animal Products (Residue Specifications) Notice 2004; and
- Animal Products (Contaminant Monitoring and Surveillance) Notice 2006; and
- Animal Products (Specifications for the Ante-mortem and Post-mortem Examination of Mammals, Ostriches and Emus Intended for Human Consumption) Notice 2006; and
- Animal Products (Branding and Associated Requirements) Notice 2006; and
- Animal Products (Regulated Control Scheme-Bivalve Molluscan Shellfish) Regulations 2006; and
- Animal Products (Specifications for Bivalve Molluscan Shellfish) Notice 2006.

A recommendation by the evaluator for registration of an RMP will indicate compliance with all relevant legislation.

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<sup>5</sup> current at the time of writing

### **7.2.1 Interface with Dairy RMPs**

RMPs may be developed to cover both dairy and non-dairy animal materials and products. These are known as multi-sector RMPs. Evaluators who are recognised to evaluate non dairy RMPs are not currently permitted to evaluate dairy RMPs unless they are recognised under the dairy system. This is due to the different recognition requirements.

If presented with an RMP for evaluation which contains both dairy and non dairy animal materials and/or products it is likely that two separate evaluators will be needed<sup>6</sup>.

### **7.3 Evaluation of Compliance with the Food Standards Code<sup>7</sup>**

The Food Standards Code (FSC) contains standards for composition, labelling, substances added to food (e.g. additives and processing aids) and contaminants, and applies to all foods produced, or imported, for sale in Australia and New Zealand. RMP operators must comply with the relevant provisions of this Code (unless an exemption has been granted for specific export products under section 60B of the Act).

If during the course of an evaluation a non-compliance with other legislation is identified, this should be brought to the attention of the operator. However an RMP evaluation is not an assessment against this other legislation.

### **7.4 Evaluation of Compliance with Other Legislation**

It is the responsibility of the operator to ensure that the requirements of all other legislation (e.g. the Building Act 2004) are met. If during the course of an evaluation a non-compliance with other legislation is identified, this should be brought to the attention of the operator. However an RMP evaluation is not an assessment against this other legislation.

### **7.5 Evaluation against NZFSA Approved Codes of Practice, Templates or Models**

The NZFSA can approve Codes of Practice (COPs), templates or models under the Act. The approved documents provide industry agreed information on how to meet regulatory requirements and cover Good Manufacturing Practice (GMP), HACCP application and other

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<sup>6</sup> Work is commencing on the further harmonisation of dairy and non-dairy requirements.

<sup>7</sup> It should be noted that an NZFSA project is underway to address the incorporation of Food Standards Code requirements into RMPs.

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RMP requirements. Several approved documents are available on the NZFSA website.

These include the:

- Code of Practice: Processing of Bee Products; and
- Risk Management Programme Template for Dual Operator Butchers; and
- Egg Risk Management Programme Template; and
- Code of Practice for Cold and Dry Stores.

In most cases where an operator has chosen to develop an RMP fully based on an approved COP, template or model, a waiver from the requirement to have an independent evaluation applies.

An evaluation is only necessary if the scope of the RMP does not align with the approved document, or if tailoring to better reflect actual operations has occurred. In those cases the evaluation is limited to the activities that fall outside the scope of the approved document, or to those aspects of the RMP that have been tailored. The evaluation should follow normal procedures and for a new RMP registration requires an on-site assessment (unless specific exemption from the on-site assessment has been granted). The evaluator must ensure that the operator has confirmed the validity of any tailored parts or has a protocol to describe how this will occur.

It is expected that most operators, for which COPs, templates or models have been developed and approved, would operate in accordance with that document. For evaluators, the approved documents provide useful guidance on NZFSA expectations regarding the content of RMPs for these industries.

For details of the approval process refer to: [Approval of Templates, Models, Codes of Practice Statement Policy](#). To view the waivers from the need for an independent evaluation refer to: [Waiver of the Requirement to Provide a Copy of an Independent Evaluation Report](#).

## 7.6 Evaluation against Other Documents

Where there are no NZFSA approved documents covering a particular aspect of an RMP, the evaluator should refer to other credible technical resources for guidance e.g.:

- other industry codes of practice;
- technical publications;
- peer reviewed scientific information;
- predictive models.

Further information on the resources available to the operator during the development of the RMP and subsequently for use during the evaluation is provided in section 3, Resources for Developing an RMP, of the [Risk Management Programme Manual](#).

## 7.7 Evaluation of Certain RMP Components

The recognised evaluator must ensure that all required aspects of the operation have been adequately captured in the RMP. The following sections discuss particular aspects of an evaluation.

### 7.7.1 Scope

#### 7.7.1.1 Physical Boundaries

The physical boundaries must include all areas used in the RMP. It is recommended that the physical boundaries of the RMP be taken as the boundaries of the property, rather than the footprint of the buildings, as this would allow certain constructional alterations to be made within the boundaries at a later date without requiring a significant amendment to the RMP. The simplest method for identifying the physical boundaries of the RMP is by lines drawn on a site plan.

#### 7.7.1.2 Exclusions and Interfaces

Any buildings or facilities that are excluded from the RMP (e.g. as they operate under a different regulatory regime such as the Food Act or are under the control of another operator who has their own RMP) must be documented in the RMP and preferably, clearly identified on the site plan.

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Activities conducted by the operator but excluded from the scope of the RMP must be clearly documented in the RMP, including how the interfaces with those activities are managed. An example of this would be non-animal products being produced using similar or the same processes to the animal product processing, in an area within the scope of the RMP.

Information to be documented must include:

- responsible persons;
- definition of processing areas that are used for RMP and non-RMP operations;
- any risk factors that may be introduced by the non-RMP operations;
- whether the operations occur at the same time, are physically separated or are separated by distance, and how this is managed, including management of personnel;
- any particular cleaning and sanitation procedures etc. that must occur between operations, who is responsible and how this will be done.

Any activities conducted by another operator under their own RMP at the same site must also be clearly documented in the RMP, including how the interfaces with those activities are managed. An example of this may be one operator operating a day shift and another operating a night shift using the same processing areas. The information to be documented must include:

- responsible persons;
- activities occurring;
- definition of the areas used by the other operator;
- any risk factors that may be introduced by the other operation;
- if the operations occur at the same time, are physically separated or separated by distance, and how this is managed;
- any particular cleaning and sanitation procedures etc. that must occur between operations, who is responsible and how this will be done;
- how any disputes between the operators will be managed.

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## 7.7.2 Animal Materials and Product Description

### 7.7.2.1 Animal Materials or Products Entering or Leaving the RMP

All animal materials and products entering and leaving the RMP must be documented. The evaluator must confirm that everything the operator intends to receive and produce within the scope of the RMP is captured. For consistency, the categories as defined by the NZFSA should be used: [Principal Categories of Processing Table](#).

Any product or process that an operator intends to undertake in the future should not be documented within the scope of the RMP unless the equipment is ready to operate and a protocol has been documented that describes how the operation is to be confirmed as valid.

### 7.7.2.2 Intended Consumer and Intended Use

The intended consumer must be defined for all animal materials and products within the scope of the RMP based on the expected use. If product is made specifically for vulnerable groups, these must be considered.

Some operations may not be compatible. If an operator is producing for example:

- products for human and animal consumption; or
- products for the general population and vulnerable groups;

the evaluator must determine where these operations are occurring e.g. are the activities physically separate or are they occurring in the same place. If the operations are occurring in the same place the evaluator must assess whether the products and processing operations are compatible and whether there are sufficient controls in place to manage the interfaces. If operations are not compatible the RMP should not be recommended for registration unless they are physically separated. The evaluator must consider process flows, cross-contamination, cleaning and sanitation, personnel management, traceability, substitution and false or misleading labelling issues.

## 7.7.3 Evaluation of Regulatory Limits

At the time of writing no regulatory limits have been developed by the NZFSA. Until this occurs, nothing is required to be documented in the RMP for regulatory limits.

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#### **7.7.4 Evaluation of Important Product Characteristics**

Important product characteristics (IPCs) are measurable criteria that have been set by the operator and define what is to be achieved in the product. The RMP effectiveness is confirmed against these criteria. As part of the evaluation, the recognised evaluator must review the IPCs.

IPCs are not expected to be documented for animal materials or products that have not undergone further processing. However, for further processed products, particularly those that are ready to eat, IPCs are expected to be documented.

The IPCs must be developed to address relevant hazards and must be set at appropriate levels given the processing that has occurred and the intended use and consumer of the product. Microbiological IPCs are a measure of what is to be achieved within the scope of the RMP, rather than what is to be achieved at the end of the product shelf life. Product that is ready-to-eat, or is intended for an immuno-compromised consumer group, is likely to have lower microbiological limits than product that requires further cooking by the consumer. The operator must have evidence to justify how the IPCs have been set and this information should be used to assist in the evaluation. Sources of information used to assist in defining IPCs include the Food Standards Code, scientific publications, approved COPs, models or templates and the RMP Manual.

For microbiological IPCs, the use of the 'defective' limit from the Ministry of Health "Microbiological Reference Criteria for Food" guideline is not acceptable. These levels are intended to provide an indication of when product is at the end of its shelf life whereas the operator needs to consider any further processing or handling that the product is likely to receive once it leaves the premises as well as the product shelf life, when setting the IPCs. For further information on setting microbiological IPCs refer to [Microbiological limits](#)

#### **7.7.5 Other Product Details**

Where the operator has chosen to include other product details, these should be checked for appropriateness by the evaluator. Other product details are things that may be covered by specification or are details that the operator wants to clearly capture, but may not be measurable in the product and therefore would not be an IPC.

#### **7.7.6 Process Description**

The recognised evaluator must check the accuracy of the process description. It must be ensured that all steps are in the correct order, that there are no missing steps and that the start and finish of the process is consistent with the scope of the RMP. Any rework steps

must be included. Products should only be grouped into single process descriptions where it would not adversely impact on hazard identification and the development of control measures. All products required to be included in the RMP must be covered by a process description. The evaluator must conduct a reality check of the process description as part of the on-site assessment. If new processes are not yet operating, the operator will need to talk the evaluator through the process.

#### **7.7.7 Good Manufacturing Practice/Supporting Systems**

The recognised evaluator must check the appropriateness and completeness of the supporting systems. He/she must ensure that all specifications relevant to the supporting systems have been addressed. Refer to the RMP Manual (section 4.8.) for further details of supporting system content and coverage.

#### **7.7.8 Evaluation of Supporting Systems Used in Multiple RMPs**

Supporting systems that form part of a registered RMP must be evaluated each time they are included in a new RMP. It may be necessary for the operator to reconfirm the validity of the supporting system for the new RMP. The degree to which a previously evaluated supporting system will need to be re-evaluated will depend on how much modification it has undergone to make it applicable to the new RMP and the processes and products it is now supporting. The evaluator must be confident that the supporting systems provide adequate control and have sufficient detail that staff will know what to do under the new RMP. As the RMP is a new registration, an on-site assessment would be needed unless an exemption has been granted.

#### **7.7.9 Hazard Identification**

The operator must conduct a hazard identification for all animal materials and products within the scope of the RMP. Evidence generated by the operator to justify the decisions made should be used to assist in the evaluation. If novel materials or products are being processed for which there is little published information in relation to hazards to human and/or animal health, the operator is responsible for generating this information. If this has not occurred to the satisfaction of the recognised evaluator, affected materials and products must not be included within the scope of the RMP that is recommended for registration.

The evaluator must ensure that all hazards that are reasonably likely to occur have been identified. If an expected hazard has been omitted, the operator must justify the omission or where that is not possible, include it in the RMP. The recognised evaluator must ensure that the hazard rather than the source of the hazard is identified. The level of specificity of

hazard identification must be appropriate to the product and the process controls to be applied. First level hazard identification only is not acceptable. Examples of different levels of hazard specificity are given in the following table.

**Table 1: Hazard Specificity**

Hazard Type/ First level	Second level	Third level	Fourth level
<b>Biological</b>	Pathogenic Group (e.g. enteric, spore forming, toxin producing)	Salmonellae	<i>Salmonella typhimurium</i> DT104
<b>Chemical</b>	Pesticide, cleaning chemical, heavy metal, veterinary medicine	Specific chemical	
<b>Physical</b>	Metal, glass, wood, bone slivers, stones	Stainless steel	

The operator may only group materials or products for the purpose of hazard identification where it can be ensured that hazards for any particular material or product within the group will not be overlooked.

#### 7.7.10 Hazard Analysis

The evaluator must evaluate the adequacy of the analysis used to determine whether an identified hazard from a raw material or process step is likely to occur at unacceptable levels and whose elimination or reduction to acceptable levels is essential for food safety. The potential of each process step to introduce a hazard and its impact on existing hazards must be considered. If a hazard is eliminated or reduced to acceptable levels at a particular step, it must be clear how this has occurred and adequate justification must be given in the RMP to support the decisions made. The recognised evaluator should use the evidence generated by the operator to assist in the evaluation.

#### 7.7.11 Critical Control Points and Critical Limits

A CCP is a step at which control can be applied and is essential for food safety.

The evaluator must check that the operator has only identified CCPS at steps where control can be applied and is essential for food safety. It is a common problem that an operator either identifies too many CCPs, which are resource hungry in terms of monitoring etc. and are a distraction from the true CCPs, or they elect to have no CCPs, in which case those steps which are essential to food safety lack the appropriate degree of control.

The recognised evaluator must ensure that the operator has evidence to justify the decisions made and that the identification of CCPs is appropriate to the product and process.

Once identified as a CCP, the operator must have defined and justified the critical limit(s) which is the criterion which separates acceptability from unacceptability. Critical limits must be measurable and should be linked to the achievement of a regulatory limit or IPC. They must be parameters that can be monitored in a timely fashion to ensure consistent effectiveness of the CCP. A common problem is the selection of limits that cannot be monitored at the required frequency in real-time e.g. microbiological limits where the results are not available for 3 days.

Once CCPs and critical limits have been established, the operator must have documented the remaining HACCP principles. The evaluator must ensure that the content is specifically tailored to the operation and that the actions and responsibilities are clear. Generic statements are not acceptable. Proper disposition of affected product in the event of non-compliance must be included as well as actions to prevent recurrence.

#### **7.7.12 Other Controls**

The recognised evaluator must ensure that all other controls necessary for the satisfactory operation of the RMP are adequately documented, including limits for any parameters, monitoring, corrective action procedures, operator verification and records.

#### **7.7.13 Confirming Application of HACCP**

The recognised evaluator must ensure that this task has been adequately completed. Refer to section 4.9.10 of the [Risk Management Programme Manual](#) for further details of what needs to be checked.

#### **7.7.14 Risks from False or Misleading Labelling**

The evaluator must check that the operator has identified any risk factors that are reasonably likely to occur, associated with false or misleading labelling. Information used to identify risk factors may include COPs, models, templates, operator knowledge and experience, external audits, internal records or customer complaints. Consideration must be given to:

- inclusion of mandatory information; and
- correct and complete ingredient listings (including correct animal species); and
- truthfulness of any label claims; and

- inclusion of safe handling and storage instructions; and
- controls for cross-contamination (particularly important in the area of allergens); and
- discrepancies between product and packaging; and
- systems to ensure that new label designs are correct.

Where any false or misleading labelling risk factor has been identified, the operator must document control measures in the RMP. The evaluator must be satisfied that the risk factors identified and the control measures applied are appropriate.

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

Refer to section 4 of the Risk Management Programme Manual for further information on risks from false or misleading labelling.

#### **7.7.15 Risks to Wholesomeness**

The evaluator must check that the operator has identified any risks to wholesomeness that are reasonably likely to occur. Information used to identify risk factors may include COPs, models, templates, operator knowledge and experience, external audits, internal records or customer complaints.

Examples of risk factors include spoilage (taste, odour, appearance) or extraneous matter (e.g. feathers, non-rigid plastic).

Where any risk to wholesomeness has been identified, the operator must document control measures in the RMP. The evaluator must be satisfied that the risk factors identified and the control measures applied are appropriate.

Refer to section 4 of the Risk Management Programme Manual for further information on risks to wholesomeness.

#### **7.7.16 Verifiers Rights**

The evaluator must confirm that all rights of the verifier as provided for in the Animal Products (Risk Management Programme Specifications) Notice 2003 have been included in the RMP. The operator must not have changed the specifications, or added any further requirements that over ride these rights. This is easiest achieved by the operator referencing the relevant clause in the RMP.

## 7.8 On-site Assessment

An on-site assessment must be conducted as part of the evaluation for any new RMP registration. However, there are exceptions to this requirement as defined in the following specification. Where an evaluator seeks a specific exemption from an on-site assessment, he/she must contact the NZFSA and an exemption must be granted before the evaluation is completed. The reason for the exemption must meet one of the criteria provided for in the specification.

The following link provides examples of the exemptions that have been granted to date for certain classes or types of businesses: [Exemptions from on-site assessments](#)

An on-site assessment may be conducted at the discretion of the evaluator for significant amendments.

**Specification clause:**

**33 On-site assessment**

***(1) In order to undertake an evaluation and prepare the evaluation report, the recognised evaluator must conduct an on-site assessment that must include assessing the appropriateness of the risk management programme against the physical boundaries, design and construction of the premises or place and the operations described in the programme.***

***(2) The on-site assessment must be performed when the premises and equipment are ready to operate in accordance with the risk management programme and legislative requirements.***

***(3) The on-site assessment may be performed by a technical expert when agreed in writing by the Director-General.***

***(4) Despite sub-clause (1), when undertaking an evaluation of an amendment to a risk management programme, the recognised evaluator may decide that an on-site assessment is not necessary and must give the reasons for that decision in the evaluation report.***

***(5) Despite sub-clause (1), the Director-General may by notice in writing exempt a business or part of any business, or any type or class of business, from the requirement that an on-site assessment be conducted, where the premises, place, activity or class of activity is—***

***(a) covered by a multi-business risk management programme approved under***

**s 17A of the Act; or**

**(b) based on a template, model or code of practice issued under section 12(A) of the Act; or**

**(c) the level of risk to human or animal health is such that an on-site assessment is not considered necessary.**

**(6) Any exemption granted to a business or part of any business, or any type or class of business may be subject to conditions that the Director-General considers relevant and the business must comply with the conditions.**

The on-site assessment must include:

- A check of the extent of the physical boundaries of the RMP and the suitability of the facilities and equipment, including any shared facilities. All facilities and equipment necessary to operate the RMP must be in place and ready to operate at the time of the on-site assessment that is conducted for the purpose of the evaluation report.
- A check of the appropriateness of the design and construction of the premises;
- A “reality check” of the premises to ensure that the actual operations align with the documented RMP.
- A discussion with key personnel including managers to check that they are aware of the RMP and their responsibilities.
- A check of the process, material, product, personnel, waste, packaging flows and essential services to ensure that the RMP is capable of delivering animal material that is suitable for further processing or product that is fit for its intended purpose.
- A review of selected supporting systems, including any records generated. If problems are identified, further systems should be reviewed or the operator should be instructed to improve all systems for subsequent review.
- A review of the application of HACCP principles, including talking to personnel responsible for key tasks and a review of any records generated.
- A review of any confirmation evidence and records.

The on-site assessment must be well organised. The recognised evaluator must have a clear understanding of those aspects of the operation to be targeted during the assessment. It is recommended that checklists of the information to be reviewed be prepared in advance.

If the required documents are not available at the time of the visit, arrangements should be made to have these provided within an agreed timeframe.

If 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 during the on-site assessment. Questions about operations at other locations should be asked in an endeavour to check that all hazards and other risk factors that are likely to occur have been considered by the operator.

Often a single on-site assessment will not be sufficient. In many cases the initial on-site assessment will highlight a range of issues still to be addressed by the operator (e.g. constructional issues), which may require a further on-site assessment.

Concise records of the on-site assessment must be retained and may include photocopies of documents provided by the operator.

For an RMP that was incompletely confirmed as valid at the time of registration, the evaluator may decide that it is necessary to undertake a second on-site assessment when evaluating the completion of confirmation.

### **7.9 Evaluation of Export Requirements (including Overseas Market Access Requirements) as Part of the RMP**

Export requirements (including overseas market access requirements) are additional to RMP requirements.

Company documentation may include export requirements and RMP components. If the export requirements form no part of the RMP, then they will not be confirmed as valid, evaluated or registered as part of the RMP.

Where an operator makes the commercial decision to integrate export requirements into the RMP, either directly or by reference, these requirements will form part of the RMP.

Inclusion of an export requirement in the RMP means that it must be confirmed as valid, evaluated and registered as part of the RMP. The evaluator must assess the programme against any New Zealand animal products regulations and specifications. 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 regulations and specifications have been met.

## 7.10 Use of Pre-registration Assessment Policy Statement

To assist in the RMP registration process and reduce the time required for registration once premises construction is complete, the option of allowing for pre-assessment of the RMP documentation before the premises construction is complete, has been developed.

The use of the NZFSA policy statement is limited to situations where the RMP documentation is complete and is unlikely to change prior to registration, and the premises construction is at a stage of 'practical completion'. An interim report is prepared by the evaluator and submitted by the operator together with the required documentation to the NZFSA for assessment. Any changes to the RMP that are required prior to registration can then be made and the application put on hold until the on-site assessment of the completed premises has occurred.

Following the on-site assessment the evaluator produces the completed evaluation report and providing there are few, if any, changes to the documentation, the registration time is reduced and the operator could begin processing within days of construction being completed.

If the policy statement is being used to assist in the registration process this needs to be stated clearly in the interim evaluation report. The policy statement, including the contents of the interim report is available at: [Pre-registration assessment of risk management programme documentation](#).

## 7.11 Evaluation of Multi-business RMPs

There are three main types of multi-business RMPs (MBRMPs):

1. A single RMP covering more than one business, where each business conducts processing type operations (processing includes operations carried out at stores);
2. A single RMP covering more than one business where each business carries out harvesting or collection type operations (e.g. on-farm harvest of blood from live animals);
3. A single RMP covering one or more businesses that carry out harvesting or collection type operations which then feed into one or more businesses carrying out processing type operations.

Section 17A of the Act requires the operator of any MBRMP to have sufficient control, authority, and accountability for all matters covered by the programme in relation to the other businesses or part-businesses subject to its coverage and must have obtained the consent or otherwise taken into account the views of any person whose business or part-business is

to be covered by the programme. The evaluator must check that there is documentation in place between the various businesses and the operator to this effect.

For type 1 MBRMPs, the evaluator will need to note the following:

- all documentation that is required for a single business RMP must be present for each business covered by the MBRMP. There may be some common documents depending on the similarity of processing operations at the various businesses, but there are also likely to be a range of documented systems which are specific to each business.
- The list of documents that comprise the MBRMP must indicate which documents are common and which relate to specific businesses.
- Each business must be listed individually, giving the full legal name and physical address.
- The physical boundaries of each business must be provided, this is most simply done by providing site plans with the physical boundaries marked for each premises.
- In most cases, each business covered by the MBRMP will require an on-site assessment as part of the evaluation, i.e. each business is treated as though it were a single business RMP. If there is justification for a certain business to be exempt from an on-site assessment, the exemption needs to be approved by the NZFSA before the evaluation is completed. A written justification is required from the evaluator for an exemption to be granted (also see section 7.8).
- The scope of operations and the activities undertaken at each business must be clearly stated in the MBRMP.
- Responsible persons must be clearly documented for each business.
- It is likely that some or all of the premises also operate under another regulatory regime. This must be described in the MBRMP in accordance with clause 5(3) of the RMP specifications.
- It must be clear that when including new businesses into this type of MBRMP a significant amendment is required. If removing a business, the operator will need to notify the NZFSA.
- The operator must be aware of their duties, as described in section 16 of the Act in relation to the entire MBRMP.

- Operator verification must be managed by a responsible person at each business and the external verification policy treats each business as a separate RMP.
- If a MBRMP is registered for a certain category of processing, animal material or product for one business and another business is to commence that operation, this will nearly always require a significant amendment to the MBRMP. A clear statement of the operations conducted by each business in the MBRMP is required e.g. if thermal processing was evaluated at one business, but is to occur at another business, a significant amendment will be required to allow the other business to commence that processing.

For type 2 MBRMPs, the evaluator will need to note the following:

- The MBRMP is generally made up of the main RMP document which comprises all the components of an RMP, and procedures which describe how suppliers (businesses) are included and removed from the scope of the MBRMP.
- The list of documents that comprise the MBRMP must indicate which documents are common and which relate to specific businesses.
- The operator must keep an up-to-date list of all businesses covered by the MBRMP. This list must include the full legal name(s) of the businesses (instead of the RMP identifier) and their full physical address (instead of the physical boundaries). This information must be complete and accurate as this is the list that the MBRMP will be verified against.
- Including and removing businesses from the scope of the MBRMP is controlled by the operator. A significant amendment is not required to do this. The NZFSA does not hold a list of all businesses registered under that programme.
- Inclusion of new businesses often involves a formal agreement between the business and the operator and there must be documented procedures to be followed by the businesses when operating under the MBRMP.
- The scope of operations and the activities undertaken by each business must be very clearly stated in the RMP.
- A full identification and analysis of hazards reasonably likely to occur must be conducted for all animal material and product within the scope of the MBRMP, including consideration of any hazards from the environment from which it has been taken.

- Traceability of animal material and product is very important for operations of this nature and the documented system for this must be robust.
- On-site verification of each business by the operator is required to ensure that all businesses are operating in accordance with the documented procedures. The operator must document in the MBRMP the frequency of this verification and the procedures that will be followed.
- It should be noted that the MBRMP is only required to cover those operations that would by law require an RMP in their own right.
- The operator must maintain full records of the agreements between the businesses and the operator, and the operator must have sufficient control over all businesses.

Type 3 MBRMPs involve the requirements of type 1 for each processing business and the requirements of type 2 for the supplying businesses.

It should be noted that if a premises needs listing for export purposes, they will not be able to be registered as part of a MBRMP. This is because when listing a premises for export, each physical address must have a unique RMP identifier and therefore their own RMP. (Note, this would not prevent operators from using the same RMP, but these would need to be registered in their own right).

For further details on MBRMPs refer to the [Risk Management Programme Manual](#).

## **7.12 Evaluation of a Significant Amendment**

If a significant amendment is made to an RMP, it must be submitted for evaluation and registration. The evaluation must involve all parts of the RMP that are affected by the amendment. The degree to which a previously evaluated part will need to be re-evaluated will depend on how much modification it has undergone. The evaluator must be confident that the operator has updated the RMP to include all new systems and procedures necessary to operate the amendment and that staff will know what to do. It is likely that some supporting systems such as personnel health would not be affected by most amendments, but others such as cleaning and sanitation, training and calibration etc. may be. Most significant RMP amendments will require some tweaking of existing supporting systems and the evaluator should ensure that this has occurred.

An on-site assessment may or may not be required depending on the nature of the amendment and whether it involves the physical premises. For most significant amendments involving design and construction an on-site assessment would be expected.

In all cases reasons must be included in the evaluation report where an on-site assessment has not occurred.

The evaluation may be of a confirmed or incompletely confirmed significant amendment. If the RMP is incompletely confirmed a protocol will be required, the outcome of which is evaluated once the confirmation is complete.

An evaluation report must be prepared for those significant RMP amendments that are to be recommended for registration. The evaluation report must comply with the requirements detailed in section 9 and contain the appropriate recommendations, conditions and statements as specified.

For details of amendments that are considered to be significant, refer to Appendix G of the [Risk Management Programme Manual](#).

### **7.13 Evaluation at the Three Year Review**

Within one month of the three year anniversary of the RMP registration, the operator must have reviewed the RMP and provided evidence of this to the NZFSA.

To satisfy the review requirement, the operator has two options:

- to complete a RMP 3 year review form; or
- to obtain a full re-evaluation of the RMP by a recognised evaluator.

If an operator chooses to use the three year review form, there may be no involvement of the evaluator. However, if on completing the review form the operator identifies that they are operating outside the scope of the registered RMP (e.g. if a significant amendment is required) an evaluation of those aspects of the programme is required. The standard procedure for evaluating significant amendments must be followed and the evaluation report is submitted by the operator with the completed three year review form.

If the operator chooses the second option, an evaluation of the complete RMP occurs and follows the procedure for a full evaluation.

The three year review form is available on the NZFSA website at: [Three year review form](#)

### **7.14 Evaluation of Food Safety Programmes**

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

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### **7.15 Outcome of Evaluation**

Following the evaluation of an RMP (including evaluation of significant amendments) the programme may either be:

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

### **7.16 Feedback on Unacceptable RMPs**

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 recognised evaluator should provide feedback to the operator explaining the areas where the programme is deficient. Where certain regulations or specifications have not been met these should be identified to the operator.

To ensure that impartiality and independence is maintained in cases where the recognised evaluator may be involved in the further evaluation of the RMP, 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.

### **7.17 Obstruction or Non-compliance by the Operator**

If during the course of an evaluation, the evaluator is prevented from performing the evaluation, or non-compliances are identified which the operator refuses to rectify, the recognised evaluator must inform the NZFSA.

**Specification clause**

**26 General requirements for recognised persons**

**(3) When a recognised person is prevented from performing their functions and activities or exercising their duties and rights, that recognised person must,—**

**(b) whether subject to the management of a recognised agency or not, advise the NZFSA as soon as practicable recommending any actions to be taken as appropriate.**

**27 Requirements of recognised persons when non-compliance is detected**

**If in the course of performing their functions and activities, any recognised person detects any uncorrected deficiency or non-compliance with any relevant requirements under the Act, which the person considers may—**

- (a) result in exposure of humans or animals to an unacceptable level of hazard; or**
- (b) have the potential to jeopardise overseas market access; or**
- (c) threaten the integrity of the official assurance system;**

**the person must report that uncorrected deficiency or non-compliance as soon as practicable, to either the appropriate manager in the recognised agency, or the NZFSA in the event that the person is not managed by a recognised agency, and recommend any actions to be taken.**

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## 8 Evaluation of Confirmation of Validity

Amendment 2

April 2007

### 8.1 Confirmation of Validity

Confirmation of validity is the initial demonstration that the RMP meets all necessary requirements and that it is effective in consistently producing materials that are suitable for further processing or products that are fit for their intended purpose. A RMP may be completely confirmed as valid prior to registration (refer section 8.3) or certain aspects of the RMP may be confirmed as valid prior to registration with the remainder completed after registration (refer section 8.4).

Owing to the complexities of confirming the validity of an RMP, and the large variation in approaches that may be taken by the operator, the evaluator must make each evaluation on a case-by-case basis.

The basic requirements of confirmation of validity are:

- confirming that the documentation is complete, including ensuring that all the components of the RMP and all relevant animal products legislative requirements have been met;

This must be completed before the RMP is registered and will include a systematic check of the RMP against the relevant legislation. It is recommended that the evaluator develop a checklist to assist in this process.

- confirmation that the premises and equipment are ready to operate;

All equipment necessary to operate the process(es) within the scope of the RMP must be available and ready to operate before registration of the RMP. The evaluator must view these as part of the on-site assessment including assessment of all product, process, personnel and waste flows. If equipment commissioning is required for a critical process step, the evaluator will either review the evidence collected prior to registration of the RMP, or the commissioning methodology the operator intends to follow is to be included in the protocol.

- demonstration that the RMP is effective;

This will involve a review of all evidence collected by the operator which demonstrates that the RMP will consistently deliver material that is suitable for

further processing or product that is fit for its intended purpose including evidence that regulatory limits, IPCs and GMP/GHP are consistently met. This may occur before RMP registration or how the evidence will be collected is documented in the protocol.

Evidence may include measurable data such as results from product testing, critical control points and other process parameters, and may include records of compliance with documented procedures e.g.:

- historical data, that is directly applicable to the operation documented in the RMP (the evaluator would need to be satisfied that changes have not been made to the process since the data was collected that would make the data inapplicable);
- providing evidence that the operation is run in accordance with parameters defined in approved COPs, models or templates;
- providing evidence from technical publications to confirm that appropriate parameters have been selected, together with evidence that the operation is run in accordance with those parameters;
- providing evidence from scientifically sound trials and experimentation;
- providing evidence from predictive modelling which is backed up with data from the actual process.

The evaluator is likely to need to check a range of issues associated with the evidence provided, such as:

- validity of any technical publications used;
- relevance of the tests used;
- sampling techniques and analysis methodology;
- sampling regime, including confirmation that sufficient data has been collected to cover normal operating situations (shifts etc.);
- the work is legitimate (note: repeat testing until desired results are obtained is not acceptable);
- suitably skilled people have been used;
- where necessary, laboratories with the required accreditation or recognition for the analyses have been used;

- appropriateness and accuracy of the data analysis;
- appropriateness and accuracy of the conclusions drawn;
- in practice, the process is operated in accordance with the confirmed process.

For further details on confirming the validity of RMPs and protocols, refer to section 5 and Appendix F of the [Risk Management Programme Manual](#).

## **8.2 Operator Use of Consultants (Technical Experts) as Part of Confirmation of Validity**

In some cases the operator may have used consultants (technical experts) to confirm the validity of certain aspects of an RMP that are at the limits of the evaluator's competency.

Where this has occurred, obtaining input from another technical expert or other recognised evaluator to evaluate those aspects of the programme is strongly recommended.

If the evaluator has:

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

He/she may accept that the component of the programme has been adequately confirmed as valid. The evaluator must complete a competency assessment of the consultant and include the assessment report with the evaluation report.

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

## **8.3 Recognition of Complete Confirmation**

Where the operator has completed the confirmation of the RMP and has provided sufficient evidence to satisfy the recognised evaluator that the programme will deliver animal material that is suitable for further processing and animal product that is fit for its intended purpose prior to registration, the RMP 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. The statement as detailed in clause 36(3)(a) of the Animal Products (Recognised Agencies and Person Specifications) Notice 2007 must be included in the

evaluation report, and signed and dated by the recognised evaluator (refer to section 9 for report content).

## 8.4 Recognition of Incomplete Confirmation

### 8.4.1 Initial Evaluation

Where there is insufficient evidence to demonstrate the ongoing effectiveness of an RMP, it may be evaluated for recognition of incomplete confirmation. The evaluator must complete the desk-top assessment and the on-site assessment for a new RMP registration (unless an exemption has been granted) and be satisfied that the RMP is potentially capable of delivering animal material that is suitable for further processing or animal product that is fit for its intended purpose.

If a protocol is needed, the evaluator must check:

- the means by which the data will be collected in a scientifically sound and statistically valid manner for the completion of confirmation, e.g. experimental protocol, trials, data collection and analysis; and
- the proposal for the disposition of animal material or product produced while completing the confirmation of validity. This maybe holding and testing, release (with or without restrictions), rework or dumping.

The evaluator should also ensure that a reasonable timeframe (e.g. 3 months) for the completion of confirmation is included in the protocol. Refer to section 5.3.1 of the [Risk Management Programme Manual](#) for further guidance on protocols. All the headings listed in the RMP Manual should be addressed in the protocol. "Not applicable" should be written under the headings that are not relevant to the work to be undertaken.

The evaluation report is to include recommendations for any conditions to be applied by the NZFSA on registration of the programme. The conditions may include:

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

The statement as detailed in clause 36(3)(b) of the Animal Products ((Recognised Agencies and Person Specifications) Notice 2007 must be included in the evaluation report, and signed and dated by the recognised evaluator (refer to section 9 for report content).

In some cases the protocol, evaluated and registered as part of the RMP, will not provide the operator with the required information to confirm the validity of the programme. Should the operator deviate from the registered 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 (e.g. trade), the modified protocol will need to be submitted for evaluation. The re-evaluated protocol does not need to be submitted to the NZFSA for registration, but the evaluator must keep complete records of the protocol re-assessment.

#### **8.4.2 Re-evaluation Following Completion of Confirmation**

Once the operator has completed the confirmation of validity of the RMP or significant amendment in accordance with the protocol, the RMP must be resubmitted for evaluation to obtain recognition of its complete confirmation.

The evaluator must assess the output from the confirmation work and determine whether there is sufficient, meaningful evidence to confirm that the programme is valid. A technical expert may be required to assist with this assessment. The evaluator must also reassess any RMP documentation that has been significantly amended as a result of the confirmation work. An on-site assessment may be conducted if necessary to be satisfied that the programme is valid.

For those RMPs that are considered to be confirmed as valid, the evaluation report must include recommendations, where appropriate, for:

- any conditions that had been applied during the confirmation period to be removed (where appropriate); and
- any additional conditions to be applied to the confirmed programme.

The statement as detailed in clause 36(3)(c) of the Animal Products (Recognised Agencies and Person Specifications) Notice 2007 must be included in the evaluation report, and signed and dated by the recognised evaluator (refer to section 9.3 for report content).

## 9 Reporting Requirements

Amendment 2

April 2007

### 9.1 Evaluation Report Content

The following specification details the mandatory requirements of the evaluation report for a confirmed or incompletely confirmed RMP. The recognised evaluator should provide further explanatory information in the evaluation report as appropriate to the RMP. This specification also applies to evaluation reports of significant amendments.

**Specification clause:**

**34 Contents of an evaluation report**

**(1) Every evaluation report must include—**

**(a) the name of the recognised evaluator and his or her recognition identifier, and**

**(b) the business identifier; and**

**(c) the name and address of the operator of the risk management programme; and**

**(d) in the case of a risk management programme relating to the following places—**

**(i) a premises, the physical address of the premises; and**

**(ii) a mobile premises, any vehicle registration numbers, and the location at which the mobile premises is principally based; and**

**(iii) a fishing vessel, the physical address of the operator, the name of the fishing vessel, and the fisheries registration number; and**

**(e) the types of animal material and animal product to which the risk management programme applies; and**

**(f) the principal categories of processing carried out under the risk management programme; and**

***(g) a brief description of the processing activities and other operations and activities covered by the risk management programme; and***

***(h) in regard to the on-site assessment:***

***(i) the date and brief description of the on-site assessments conducted in accordance with clause 33; or***

***(ii) in the case of an exemption granted to a business or part of a business, a copy of the Director-General exemption; or***

***(iii) in the case of an evaluation of an amendment where the evaluator decided that an on-site assessment was not necessary, the reason for that decision; and***

***(i) a list of all documents (including the document name, version and date or other unique identifier, that will allow the relevant version to be identified on any date) that comprise the risk management programme, and were reviewed during the evaluation; and***

***(j) 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***

***(k) the identification of any food safety programme within the meaning of the Food Act 1981 that is to be recognised as part of the risk management programme; and***

***(l) the name and identifier of any other recognised evaluators and the name of any technical experts used to provide supporting reports during the evaluation of the risk management programme; and***

***(m) all supporting reports prepared by any technical expert or other recognised evaluator during the evaluation of the risk management programme; and***

***(n) a copy of the competency assessment of any technical experts used, including the supporting information obtained; and***

***(o) confirmation that the evaluator has viewed evidence that a specified verifying agency will be responsible for the verification functions and activities in relation to the risk management programme; and***

***(p) a statement in the case of an incompletely confirmed risk management programme, that the protocol that has been documented to complete the confirmation of validity of the risk management programme, and the disposition of any animal material or animal product produced during that process, is acceptable.***

***(2) In the case of a multi-business risk management programme, the evaluation report must detail the requirements of sub-clauses (1)(d) to (1)(p) for each business, as appropriate.***

For multi-business RMPs, the same information must be provided in the evaluation report, but details must be provided for each business that the RMP covers.

The [Risk Management Programme Manual](#), section 4.3 gives a template that may be used by the operator to control the version of each document that comprises the RMP. 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 (l) in the evaluation report.

## **9.2 Evaluator Confirmations, Endorsements and Statements**

The evaluation report must include a sentence indicating that the RMP is satisfactory and recommending any conditions to be considered by the NZFSA on registration. The following specification also applies to reports resulting from the evaluation of significant amendments.

**Specification clause:**

**36 Evaluator confirmations, endorsements and statements etc**

**(1) The recognised evaluator must include in the evaluation report—**

***(a) a statement that the outcome of the evaluation assessment is satisfactory and that the risk management programme as written is appropriate to the operation; and***

***(b) the conditions, if any, that the evaluator recommends that the Director-General impose on the registration of the incompletely confirmed or confirmed risk management programme, including conditions relating to the commencement of operations; and***

***(c) recommendation of the removal, if appropriate, of any conditions imposed***

***on a registered risk management programme.***

The recognised evaluator must endorse the RMP or the RMP outline. If provided in hard copy, each page is to be initialled or signed by the evaluator in a colour other than black. For a significant amendment, the amended pages must be endorsed, if provided.

If the operator intends to submit the RMP or outline in an electronic format, refer to Appendix IV for the means acceptable to the NZFSA by which the evaluator is to endorse the electronic file.

The evaluation report must be endorsed in the same manner as specified for the RMP or RMP outline.

Endorsement is intended to provide greater confidence to the NZFSA that the RMP and evaluation report have not been modified since the evaluation.

***Specification clause:***

***36 Evaluator confirmations, endorsements and statements etc***

***(2) The recognised evaluator who signs the evaluation report must endorse the risk management programme or the outline of the contents of the programme, or the amended pages of the risk management programme, 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***

***(c) any other means acceptable to the Director-General.***

The evaluation report must contain one of the following statements as appropriate to the type of evaluation conducted. The statements must also be applied when the report is for a significant amendment.

**Specification clause:**

**36 Evaluator confirmations, endorsements and statements etc**

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

**(a) Statement for the purposes of complete confirmation of validity**

***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.***

**Name**

**Signed**

**Date**

**(b) Statement for the purposes of incomplete confirmation of validity**

***I confirm that an evaluation of the incompletely confirmed 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 confirmation process including any requirements for the disposition of any animal material or animal product produced during the confirmation process.***

**Name**

**Signed**

**Date**

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

***I confirm that the risk management programme or amendment {title, date and***

***registration identifier}, which was incompletely confirmed has now been confirmed in accordance with the documented protocol, and that an evaluation 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.***

***Name***

***Signed***

***Date***

***(4) The recognised evaluator, who will be held responsible for the accuracy of the information contained in the evaluation report, must sign the appropriate statement specified in sub-clause (3), and endorse the report by—***

***(a) using electronic means acceptable to the Director-General; or***

***(b) initialling or signing each page of the hard copy of the report; or***

***(c) any other means acceptable to the Director-General.***

### **9.3 Evaluation Report Content Following the Completion of Confirmation**

The following specification details the mandatory requirements of the evaluation report following the completion of confirmation. The recognised evaluator should provide further explanatory information in the evaluation report as appropriate to the RMP. This specification also applies to reports resulting from evaluation of significant amendments.

The report should include a discussion of the confirmation work conducted by the operator and the evidence viewed on which the decision that the RMP was satisfactory was based. If the programme remains only partially confirmed as valid the report should clarify those aspects that have been completed and those that still need to be done. Where further work is required the protocol, if amended, will need to be re-evaluated.

If significant amendment(s) have been made to the RMP as a result of the confirmation work, the amendments must be evaluated and endorsed and the evaluation report must describe the significant amendments made, including if an on-site assessment was undertaken. The operator is required to provide these amended and endorsed pages (including the updated document list) as part of their submission to the NZFSA.

**Specification clause:****35 Contents of evaluation reports following completion of confirmation of validity**

**(1) An evaluation report confirming the validity of a registered risk management programme, must contain:**

**(a) the name of the recognised evaluator and their recognition identifier; and**

**(b) the business identifier; and**

**(c) the name and address of the operator of the risk management programme; and**

**(d) in the case of risk management programme relating to the following places—**

**(i) a premises, the physical address of the premises; and**

**(ii) a mobile premises, any vehicle registration numbers, and the location at which the mobile premises is principally based; and**

**(iii) a fishing vessel, the physical address of the operator, the name of the fishing vessel, and the fisheries registration number; and**

**(e) any changes to the list of documents made in accordance with clause 34 which were reviewed during the evaluation of the completion of confirmation work; and**

**(f) the name and identifier of any other recognised evaluators and the name of any technical experts used to provide supporting reports during the evaluation of the completion of confirmation work; and**

**(g) all supporting reports prepared by any technical expert or other recognised evaluator during the evaluation of the completion of confirmation work; and**

**(h) a copy of the competency assessment of any technical experts used; and**

**(i) a description of the confirmation work undertaken and an assessment of the quality of the operator's conclusions;**

**(j) in the event that the confirmation work has not been completed, a description of any work still to be completed in accordance with the protocol.**

**(2) In the case of a multi-business risk management programme, the evaluation report must detail the requirements of sub-clauses (1)(d) to (1)(j) for each business, as appropriate.**

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# APPENDIX I: Activity Endorsements

Amendment 2

April 2007

The following are examples of activities for which evaluators can receive endorsements:

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

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

## APPENDIX II - Points to Consider for Evaluation

Amendment 2

April 2007

Recognised evaluators are encouraged to use the following table when developing a checklist to assist in evaluating an RMP. This list is not all-inclusive as the evaluator is expected to tailor the evaluation to the RMP. Where applicable, the relevant Animal Products (Risk Management Programme Specifications) Notice 2003 specification clause, HC spec references and Food Standard Code references have been added. It is recommended that references to other relevant pieces of legislation are included in any tailored evaluator checklists.

Note: Appendix III gives additional requirements for multi-business RMPs.

<b>1. Operator, business and RMP Identification</b>
<ul style="list-style-type: none"><li>• Name of operator</li><li>• Postal address of operator</li><li>• Physical address of operator</li><li>• E-mail address of operator (optional)</li><li>• Names of businesses or part businesses covered by the programme if different to operator (legally correct)</li><li>• Address of business (if different to operator)</li><li>• Unique RMP identifier (Business identifier or alternative details where approved, RMP number)</li></ul>
<b>2. Management Authorities and Responsibilities (RMP spec 13)</b>
<ul style="list-style-type: none"><li>• Name, position or designation of the person responsible for the day-to-day management</li><li>• Name, position or designation of the person responsible for back-up day-to-day management</li></ul>

<ul style="list-style-type: none"> <li>• Competency of day-to-day manager and back-up day-to-day manager</li> </ul>
<b>3. Risk Management Programme Scope (RMP Spec 5)</b>
<ul style="list-style-type: none"> <li>• Physical boundaries of the place covered by the programme</li> <li>• All sources of potential risk factors considered?</li> <li>• Any animal material or product excluded? If yes, interface management documented</li> <li>• Any other person sharing the facilities? If yes, interface management documented</li> </ul>
<b>4. Material or Product Description (RMP Spec 6), Food Standards Code.</b>
<ul style="list-style-type: none"> <li>• Name and type of all materials and/or products entering and leaving the programme</li> <li>• Intended purpose</li> <li>• Intended consumer (human (including any specific consumer group), animal, industrial use, waste)</li> <li>• Intended use of animal material and/or products (further processing, additional consumer preparation, ready to consume)</li> </ul>
<b>5. Material and Product Regulatory Limits and IPCs (RMP Specs 6 and 7). Food Standards Code.</b>
<ul style="list-style-type: none"> <li>• Regulatory limits</li> <li>• Important material and /or product characteristics</li> <li>• All relevant animal product regulations and specifications addressed</li> <li>• Each risk factor considered</li> <li>• Supporting confirmation data</li> <li>• Consistent with hazard identification and analysis</li> <li>• Food Standards Code considered</li> </ul>
<b>6. Process Description (RMP Spec 9)</b>

<ul style="list-style-type: none"> <li>• All inputs, main activities or steps (including key processing parameters), all outputs</li> <li>• Accurate</li> <li>• Consistent with scope of the RMP</li> <li>• Includes all process variations e.g. rework</li> </ul>
<b>7. Inputs (RMP Spec 9). Food Standards Code.</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>8. Outputs (RMP Spec 9)</b>
<ul style="list-style-type: none"> <li>• Animal material</li> <li>• Animal product</li> <li>• Human consumption, animal consumption, industrial use, waste</li> </ul>
<b>9. GMP/ Supporting systems (RMP Spec 11), HC specs.</b>
<ul style="list-style-type: none"> <li>• System contains:</li> <li>• Purpose and scope</li> <li>• Authorities and responsibilities</li> <li>• Materials and equipment</li> <li>• Procedures (control measures, monitoring, corrective actions, operator verification, records/reports)</li> <li>• Regulations and specifications met?</li> <li>• Confirmation that systems are effective?</li> </ul>

Topics include:

- Design and construction
- Facilities
- Equipment
- Other essential services (water, air)
- Cleaning and sanitation
- Waste management
- Maintenance
- Management of maintenance compounds
- Pest control
- Personnel hygiene and behaviour
- Health
- Protective clothing
- Competent personnel and training programmes (Identification of training needs, provision of training, maintenance of training, assessment of training effectiveness, training records)
- Incoming materials (including supplier quality assurance programmes)
- Control of operations
- Product specific procedures
- Packaging
- Labelling
- Traceability and Inventory control
- Calibration
- Non-complying animal material or animal product

- External environs
- Transportation
- Other?
- All relevant animal product regulations and specifications addressed

#### **10. Hazard Identification (RMP Spec 10)**

- Identify hazards to
  - human health (products intended for human consumption)
  - animal health (products intended for animal consumption)
- Consider raw materials, other sources, each processing step
- Hazard identification of raw materials after supplier assurances
- Hazards reasonably likely to occur
- Hazards identified to appropriate level of specificity
- Hazards introduced at each process step
- Impact of each process step on existing hazards
- Decision making process and supporting information documented

#### **11. Hazard Analysis/CCP Determination/Controls/Critical limits (RMP Specs 10 and 11)**

- Systematic analysis
- Acceptable/unacceptable levels with respect to regulatory limits and IPCs? (is there data to validate that the hazards do/do not occur at unacceptable levels for each process step?)
- Control measures available
- Accurate 'carry over' of hazards to subsequent steps
- CCPs applied where control essential for food safety
- Justification for identification of CCPs

- CCPs for other reasons identified as such? (e.g. market access, customer requirement)
- Other controls (Non CCP)
- Identification of uncontrolled hazards. Are these acceptable?
- Measurable critical limits (parameters to be checked, limits, scientific justification for each limit, data to confirm that the control measures are effective, consistently achievable and relevant to regulatory limits or IPCs)
- Monitoring for each critical limit (person, method, frequency and sampling regime (sufficient to ensure CCPs are under control, frequency statistically or performance based, related to the prevalence of the hazard), records)
- Corrective actions for each critical limit (person, procedures for restoration of control, control and disposition of non-conforming product, preventative action, escalating response, records)
- Verification (person, methods, frequency, follow-up actions, records)
- HACCP application confirmed

**12. Identification and Control of Risks to Wholesomeness (RMP Specs 10 and 11)**

- Wholesomeness (considered spoilage, extraneous materials)
- Systematic identification
- Documentation in support of wholesomeness risk factors identified e.g. customer/consumer complaints, internal and external reports, records
- Appropriate controls where risk factors identified (including parameters, monitoring, corrective action)

**13. Identification and Control of Risks from False or Misleading Labelling (RMP Specs 10 and 11)**

- False or misleading labelling (considered ingredient listings, claims, composition, allergens, warnings for specific consumer groups, safe handling and storage instructions, systems for implementation of new labels, prevention of cross-contamination and discrepancies between product and labelling/packaging?)

- Systematic identification
- Documentation in support of labelling risk factors identified e.g. customer/consumer complaints, internal and external reports, records
- Appropriate controls where risk factors identified (including parameters, monitoring, corrective action)

#### **14. Corrective Action for Unforeseen Circumstances (RMP Spec 11)**

- Responsibility for the procedure
- Procedure for identifying suitably skilled persons based on situation
- Means of identifying, retaining and controlling affected material or product
- Procedures for assessment of non-compliance and product disposition
- Records and reporting
- Notification of the recognised RMP verifier

#### **15. Operator Verification (RMP Spec 14)**

- Responsibilities for confirmation/reconfirmation
- Responsibilities for each ongoing operator verification activity (RMP remains applicable, in compliance with legislation, implemented as written, producing product that is fit for its intended purpose)
- Defined frequency of each operator verification activity
- Method for each operator verification activity
- Follow up action in event of non-compliance
- Records

#### **16. Identification and Competencies of Responsible Persons (RMP Spec 13)**

- Name, position or designation of personnel who authorise the RMP
- Name, position or designation of personnel who perform key tasks including:
  - control activities

- monitoring
- corrective actions
- operator verification
- recall
  
- Name of person fulfilling any mandatory competency requirement
- Competencies of personnel required by bullets 1, 2 and 3
- Records demonstrating competencies met and maintained

#### 17. Recall Procedures (RMP Spec 12)

- Identification and traceability
  - Inputs
  - Work-in-progress
  - Final Products
- Responsibilities and authorities
- Risk assessment and decision to recall
- Communication and documentation
- Product recovery and disposition
- Corrective and preventative action
- Review of recall effectiveness
- Director-General and recognised RMP verifier notification
- Refer to section 4.14 of the RMP Manual and the following: [Recalls](#) for further information on the content of recall procedures.

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

- Specification copied directly into the RMP, or clause 15 referenced

- No additional statements added that undermine the specification
- Letter from recognised verifying agency agreeing to provide verification services for that RMP

#### 19. Document Control and Records (RMP Specs 16 and 17)

- Documents
  - legible
  - version controlled
  - authorised
- Document control
  - control of significant and minor amendments
  - version/issue date
  - authorisation
  - evaluation status, endorsement
- Records
  - Legible
  - Include date and time of activity, results, identification of responsible person
- Adequate procedures for electronic records if applicable
- Storage conditions
- Retention times for obsolete documents and records (4 years)
- Document retrieval system (including records), documents available

#### 20. Notification Requirements (RMP specs 26 and 27)

- Procedures to notify NZFSA and/or recognised RMP verifier of:
  - Emerging, new or exotic biological hazards or new chemical hazards
  - Any significant concerns about suitability of animal material or fitness for

intended purpose of animal product

- Significant amendments
- RMP no longer effective
- Premises no longer suitable
- Use of premises for which resulting risk factors not adequately considered

**21. List of RMP documents (RMP Spec 20)**

- Version controlled list of all documents that make up the RMP, including:
  - Supporting systems
  - Procedures
  - Site plans
  - Letter confirming external verification services will be provided
  - Blank record forms

**22. Confirmation of Validity (RMP Spec 18)**

- evidence; or
- protocol (all contents as per the RMP Manual, section 5.3.1 addressed)

# APPENDIX III: Additional Requirements for Multi-business RMPs

Amendment 2

April 2007

<b>1. Operator, business and RMP Identification</b>
<ul style="list-style-type: none"> <li>• Names of each business or part business covered by the programme (legally correct)</li> <li>• Address of each business</li> <li>• Unique RMP identifier or alternative details where approved by the NZFSA e.g. legally correct business name and address</li> <li>• Physical address of each business</li> <li>• E-mail address of each business (optional)</li> </ul>
<b>2. Management Authorities and Responsibilities (RMP spec 13)</b>
<ul style="list-style-type: none"> <li>• May provide alternative details for day-to-day manager for each business, premises or place where approved</li> <li>• Evidence of sufficient control or consent for each business to be covered by the RMP (e.g. contract with each business, letter of consent for each business)</li> </ul>
<b>3. Scope (RMP Spec 5)</b>
<ul style="list-style-type: none"> <li>• Plan showing the physical boundaries of each business or alternative details as approved by the NZFSA e.g. the full legal address of the properties covered if the RMP covers a number of supplier farms rather than processing businesses. Each site plan needed for multiple processing businesses</li> </ul>
<b>4. Material or Product Description (RMP Spec 6)</b>
<ul style="list-style-type: none"> <li>• Must be clear which details apply to which business e.g. business A processes 1, 2 and 3; business B process 1, 3 and 5 etc</li> </ul>
<b>5. Material and Product Regulatory Limits and IPCs (RMP Specs 6 and 7)</b>

<ul style="list-style-type: none"> <li>• IPCs must be appropriate to each business considering the risk factors identified</li> <li>• Evidence must be collected by each business or there must be clear justification for applying evidence from one business to another</li> </ul>
<b>6. Process Description (RMP Spec 9)</b>
<ul style="list-style-type: none"> <li>• Must be tailored to each business. Differences in inputs, outputs and processing operations must be captured</li> </ul>
<b>7. Inputs (RMP Spec 9)</b>
<ul style="list-style-type: none"> <li>• Must be accurate for each business</li> </ul>
<b>8. Outputs (RMP Spec 9)</b>
<ul style="list-style-type: none"> <li>• Must be accurate for each business</li> </ul>
<b>9. GMP/ Supporting systems (RMP Spec 11)</b>
<ul style="list-style-type: none"> <li>• Must be tailored to each business. Differences in methods of operation must be captured. Procedures must be what is actually occurring at each site</li> <li>• Data to confirm that the control measures are effective and consistently achievable must be collected and analysed for each business</li> </ul>
<b>10. Hazard Identification (RMP Spec 10)</b>
<ul style="list-style-type: none"> <li>• Must address all hazards at each site. Identification must be carried out by personnel with knowledge of each business included within the scope of the RMP to ensure that no hazards are overlooked</li> <li>• Evidence used in the decision making process must be appropriate to each business</li> <li>• Documentation for the decision making process must be retained for each business (the documentation may be the same for all businesses or there may be documentation which is business specific)</li> </ul>
<b>11. Hazard Analysis/CCP Determination/Controls/Critical limits (RMP Specs 10 and 11)</b>
<ul style="list-style-type: none"> <li>• Must be tailored to each business where necessary (e.g. responsible personnel, methods for monitoring, corrective actions etc)</li> <li>• Data to confirm control measures are effective, consistently achievable must be</li> </ul>

collected and analysed for each business
<b>12. Identification and Control of Risks to Wholesomeness (RMP Specs 10 and 11)</b>
<ul style="list-style-type: none"> <li>• Identification and controls tailored to each business as appropriate</li> </ul>
<b>13. Identification and Control of Risks from False or Misleading Labelling (RMP Specs 10 and 11)</b>
<ul style="list-style-type: none"> <li>• Identification and controls tailored to each business as appropriate</li> </ul>
<b>14. Corrective Action for Unforeseen Circumstances (RMP Spec 11)</b>
<ul style="list-style-type: none"> <li>• Tailored to each business as appropriate e.g. identification of responsible personnel</li> </ul>
<b>15. Operator Verification (RMP Spec 14)</b>
<ul style="list-style-type: none"> <li>• Tailored to each business as appropriate e.g. identification of responsible personnel</li> </ul>
<b>16. Identification and Competencies of Responsible Persons (RMP Spec 13)</b>
<ul style="list-style-type: none"> <li>• Tailored to each business as appropriate e.g. identification of responsible personnel</li> </ul>
<b>17. Recall Procedures (RMP Spec 12)</b>
<ul style="list-style-type: none"> <li>• Tailored to each business as appropriate e.g. identification of responsible personnel</li> </ul>
<b>18. Provision by the Operator for Verification Activities and Verifiers' Rights (RMP Spec 15)</b>
<ul style="list-style-type: none"> <li>• Must be clear in the document from recognised verifying agency that they are agreeing to provide verification services for all businesses covered by the RMP and that they are aware of the businesses this applies to</li> </ul>
<b>19. Document Control and Records (RMP Specs 16 and 17)</b>
<ul style="list-style-type: none"> <li>• Must be tailored to each business as appropriate e.g. identification of responsible personnel, procedures</li> </ul>
<b>20. Notification Requirements (RMP specs 26 and 27)</b>
<ul style="list-style-type: none"> <li>• Unlikely to require tailoring –identification of responsible personnel may need to be tailored</li> </ul>
<b>21. List of RMP documents (RMP Spec 20)</b>

- 
- Must identify which documents apply to which businesses

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## APPENDIX IV: Electronic File Endorsements

Amendment 2

April 2007

The following procedures are to be applied to all files submitted which are endorsed electronically.

### 1.1 Operator Requirements

Documentation being submitted for electronic endorsement must include the following information in the footer of the front page of the document.

- File Name
- Number of Characters
- Last Saved (date and time)

Example:

---

File Name: RMP Procedure.doc No Characters: 4622 Last Saved: 20/10/2006 10:30

---

### 1.2 Evaluator Requirements

On receipt of an electronic document from an operator the evaluator must save the document with the required file name in the desired location. The document must be password protected to prevent the document from being modified. Password protection will differ depending on the programme the document was created in.

The information in the footer of the document must be updated by the evaluator in the event that changes or alterations are made prior to submission.

Once evaluation is complete the evaluation report must document the following information from the RMP or RMP outline to which it relates to:

- File Name
- RMP Identifier
- Number of Pages
- Number of Characters (not with spaces)

- File Size
  
- Date Modified

Once finalised the evaluation report must be password protected prior to submission. The evaluation report must always reflect the exact properties of the file being endorsed.

**Notes:**

- a. the evaluator must not divulge any password to the operator.
  
- b. where the RMP or RMP outline comprises a number of files the same password should be used for all these files.
  
- c. File information must be identical on both the evaluation report and the RMP or RMP outline at the time of registration.

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# APPENDIX V: Recognised Evaluator Application Pack

Amendment 2

April 2007

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

This document contains the requirements for the:

- Generic recognised evaluator; and
- Recognised evaluator with an activity endorsement.

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## BACKGROUND

The Recognised Evaluator Application Pack contains the necessary information for a person to make an application to the NZFSA for recognition as an evaluator. For additional information about the role of the evaluator and evaluation refer to the Evaluator's Manual.

All evaluators must be recognised to the generic standard, but may seek an activity endorsement. The purpose of an activity endorsement is to identify the areas of expertise of the recognised evaluator and make this information available to both the operator and to persons involved in registration of risk management programmes (RMP).

In addition to the application fee, the applicant is charged on an hourly basis for the time involved in the NZFSA assessment of their application. This fee must be paid regardless of the outcome of the assessment. Refer to the Evaluator's Manual for details of the assessment process.

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.

## **DOCUMENT CHECKLIST**

Please complete the following documentation and submit to the address listed on the top of the application form (AP7).

### **Generic Recognised Evaluator**

- Completed Recognised Person application form (AP7);
- Completed form for the consent to disclosure of convictions;
- Evidence of achieving NZQA standards;
- Written answers to the assessment questions and/or the required evidence and the signed declaration;
- Documentation to fulfil the administrative requirements;
- Application fee (as per AP7).

### **Activity Endorsement**

In addition to the above:

- Documentation to fulfil the activity endorsement requirements.

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# 1. Generic Recognition

## 1.1 Understanding of the APA

Provide a copy of the NZQA record of learning, or a certificate as evidence of having obtained NZQA unit standard 19515 "Explain Risk Management Programmes under the Animal Products Act 1999".

## 1.2 Confirmation of Validity

Provide written responses to the following:

1. Responsibilities:
2. Explain who is responsible for confirmation of validity.  
Explain the options available if the skills to undertake confirmation of validity do not exist within the business.
3. Timing:
  - a. Explain when confirmation of validity and reconfirmation of validity must be done.
  - b. Give examples of situations when complete confirmation of validity and incomplete confirmation of validity are likely.
4. Complete confirmation of validity:
  - a. Describe the two key components of confirmation of validity.
  - b. What justification would you expect to see documented in an RMP for the selection of each important product characteristic?
  - c. Where there are no important product characteristics for certain hazards identified in the RMP or hazards that would normally be associated with a product of that nature, what justification would you expect to see?
  - d. Describe the confirmation of validity of important product characteristics, giving examples of the evidence that could be collected.
  - e. Describe the confirmation of validity of supporting systems, giving examples of the evidence that could be collected.
  - f. Describe the confirmation of validity of CCPs, giving examples of the evidence that could be collected.

- 
- g. Discuss how (d), (e) and (f) above interrelate.
  - h. Describe the confirmation of validity required when an operator implements a process or procedure directly from an approved code of practice, model or template, compared to an operator developing their own procedures (e.g. a novel process).
  - i. Describe how confirmation of validity information should be presented for evaluation.
  - j. Describe how the evaluator documents that they are satisfied that confirmation of validity is complete.
5. Incomplete confirmation of validity:
- a. Describe how much confirmation of validity is expected for incomplete confirmation and how the lack of some information is managed.
  - b. Describe the purpose and contents of a protocol.
  - c. Describe how the evaluator documents that they are satisfied that the protocol is adequate.
  - d. Describe how incomplete confirmation of validity impacts on the evaluation and the conditions of registration of the RMP.
  - e. Explain who recommends and who finalises these conditions.
  - f. Describe the process for completion of confirmation of validity and registration of the fully confirmed RMP.
  - g. Describe how the evaluator documents that an RMP has been completely confirmed as valid.
6. Amendments:
- a. Explain the role of the evaluator when a company makes a minor amendment to their RMP.
  - b. Explain the role of the evaluator when a company makes a significant amendment to their RMP and the operator's options in terms of the timing of the registration of the amendment for collection of confirmation evidence and the impact that the timing of the registration has on product disposition.

### 1.3 HACCP

1. Provide a copy of the NZQA record of learning, or a certificate as evidence of having obtained either of the following NZQA unit standards:
  - a. 12626 "Co-ordinate the development and verification of a HACCP plan for a meat processing operation"; or
  - b. 12316 "Co-ordinate the development and verification of a HACCP plan for a seafood processing operation"; or
  - c. 19514 "Explain the application of HACCP principles".
2. Provide evidence to demonstrate the active application of HACCP principles in the last two years, in any of the following ways<sup>8</sup>:
  - a. Development of a recognised HACCP plan or registered RMP; and/or
  - b. Implementation of a recognised HACCP plan or registered RMP, including all necessary internal verification activities; and/or
  - c. Recognition of validity or external verification of a recognised HACCP plan or a registered RMP

The evidence may be a summary report of the applicant's work documenting the company involved, product, process, time period, extent of involvement and responsibility (examples of HACCP plans or verification reports may be attached). This should be accompanied by at least two references from senior management confirming that the involvement occurred and was of a satisfactory standard.

As an alternative to the references from senior management, a report on the applicant's work from an independent and qualified auditor may be provided.

Depending on the nature of the evidence supplied, a NZFSA assessor may elect to discuss this information with the applicant.

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<sup>8</sup> If you are unable to provide the required evidence, contact the NZFSA to discuss assessment options.

## 1.4 Audit

### Either:

Provide evidence of having achieved a quality system audit qualification (such as the Lead Auditor Course) that is certified by a JAS-ANZ accredited personnel certification body (such as RABQSA International) or have attended a NZQA recognised audit course, or obtain a NZQA unit standard in auditing at level 6 or above.

If the quality system audit qualification was completed more than three years previously, provide evidence of a meaningful involvement in performing verification, audit or evaluation over the intervening years. If this is not possible, re-qualification is necessary.

### Or:

If the applicant does not have an auditor qualification, provide a detailed résumé of the training you have completed and the audit work you have undertaken to date and your role in that work. Ensure that the following aspects of the audit process (sourced from ISO standard 19011 "Guidelines for auditing management systems") have been covered:

- Decide on the type of audit and standard against which audit is to be done;
- Notify the auditee;
- Obtain information prior to premises audit;
- Assess pre-audit information and if necessary target specific concerns;
- Select audit team;
- Brief the audit team;
- Visit premises and carry out entry meeting;
- Carry out audit;
- Carry out exit meeting and deliver conclusions;
- Write formal report;
- Follow up on non-conformances.

A condition will be added to the recognition that will require the audit qualification to be obtained within a specified timeframe (e.g. up to 6 months from the date of recognition).

### **1.5. NZQA level 4 Qualification or Equivalent**

Provide evidence of holding at least a NZQA Level 4 qualification in animal health, public health, seafood technology, food engineering, food technology or other qualification or experience which is acceptable to the NZFSA.

### **1.6. Referees**

Please provide the names and contact details of two referees who can provide information such as your 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 the New Zealand Food Safety Authority in response to the recognised evaluator questions supplied have been prepared by me and are all my own work.

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

## 2. Activity Endorsement

An RMP evaluator with an activity endorsement is expected to have a high degree of technical knowledge of the type of process or processes covered by that endorsement. Such a person would be expected to evaluate the technical complexities of an RMP and determine whether it meets all of the requirements for that type of process. It is also expected that specialist knowledge and technical expertise could be provided to an evaluator who does not have the same activity endorsement. An activity endorsement can be limited to specific processes within a general process area e.g. it may include all rendering types or a specific type of rendering.

An evaluator with an activity endorsement is expected to have a thorough knowledge of:

- the process technology covered by the activity;
- hazards and other risk factors associated with the particular process and the technology and possible/normal control measures for each;
- detailed aspects of current industry norms<sup>9</sup>;
- the implementation of the technology or industry norm and that this has been properly completed by the operator;
- the acceptability of the evidence provided by the operator to validate a process that is different to an industry norm.

A person applying for recognition 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.

Please provide a written response to the following questions for **each** activity endorsement applied for. Please ensure that the answers are as complete as possible and do not be restricted by the questions. If the information provided is sufficient to warrant further assessment, NZFSA will arrange an interview with you to discuss technical aspects of this activity. If this is not the case, you will be asked to provide more information or will be

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<sup>9</sup> the term 'industry norm' includes, codes of practice, models, templates, industry standards (ISs, IAISs, PIPs, OEPs) & GMP as described in authoritative texts and technical publications.

informed that insufficient information has been provided and that your application for endorsement of the specified activity has been declined.

**Note:** this section may be completed in support your initial application to become an evaluator or at any time after your recognition if you want to add activities to your recognition.

## 2.1 General Activity Endorsement Questions<sup>10</sup>

1. State the activity for which you seek endorsement (complete a separate response for each activity that you are applying for).
2. Specialist qualification(s) or training in this activity:  
Supply evidence of training and other qualifications relevant to the activity endorsement being sought.
3. Technical knowledge:  
What type of product(s) is/are produced in this area of activity?
  - a. What type of production technology (process, equipment, preservation system etc.) is employed in this area of activity?
  - b. List and discuss the features of processing using this technology that need to be taken into account to avoid or minimise hazards to health or animal health.
  - c. What resources that you are aware of describe or outline the currently accepted industry norms for this type of processing?
  - d. Discuss these resources, commenting in particular on:
    - i) the practicality of implementing the industry norms,
    - ii) whether, amongst these resources, conflicting advice may be present,
    - iii) how would you deal with such a conflict.
  - e. What, in your experience, presents the greatest difficulty to industry in applying industry norms, provide specific examples in relation to the selected activity.

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<sup>10</sup> specific examples may be used at any time to illustrate the points made.

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- f. Have you had practical experience with this activity, including the identification and analysis of hazards and the validation of processing parameters? If yes, please provide detailed examples.
  - g. If the operator does not choose to adopt all or part of an industry norm, what quality of evidence would you accept as validation of the departure from the industry norm.
  - h. Are you knowledgeable about the principles of statistics and experimental design or would you seek the assistance of another person when confronted with validation of non-standard processes. If you consider yourself knowledgeable in this area, on what basis is this decision made?
4. Supply the names and contact details of 2 referees for the provision of information relating to job performance, work record and technical ability relevant to the tasks to be performed. Where an activity endorsement is sought at the same time as a generic Recognition, a total of two referees only may be supplied, provided their knowledge of the applicant is sufficient to cover both the generic Recognition and the activity endorsement.
  5. If this document does not accompany your initial application to become a Recognised evaluator, please add and sign the declaration given on page 6 to your written answers.

## **2.2 Additional Activity Endorsement Requirements for Specified Sectors**

### ***Thermal Processing of Low Acid Canned Products***

Any person evaluating an RMP 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) Australia;
2. Approved Persons Course for Thermal Processing of Low Acid Foods, Foods Science Australia, Werribee, Australia;
3. Introduction to the Fundamentals of Thermal Process Evaluation, Massey University, New Zealand. (No longer available);
4. Any other course approved by the Director-General.

### ***Depuration of Bivalve Molluscan Shellfish***

Any person evaluating an RMP involving the depuration of bivalve molluscan shellfish must be able to demonstrate technical knowledge of depuration requirements through successfully completing the Depuration Training Course conducted by the New South Wales Food Authority, or an alternative qualification agreed by the Director-General on a case by case basis.

The applicant must provide evidence of having passed an appropriate course of instruction.

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## 3. Operational Requirements: Quality System

The applicant must submit the written policies and procedures they have in place to deal with things such as confidentiality, 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:

- a. 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.
- b. 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 4 years.
- c. 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. Refer to the policy statement "Independent evaluation and verification of risk management programmes" available on the NZFSA website.

The procedures should also ensure that the applicant or any person to whom work is sub-contracted will not evaluate an RMP 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). The operator must be informed of any technical expert of other recognised evaluator to be used in an evaluation.

- d. 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;

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- 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.