



# Accredited Evaluator Interim Application Pack

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

This document contains the requirements for the:

- generic accredited evaluator; and
- accredited evaluator with an activity endorsement.

## Background

The Accredited Evaluator Interim Application Pack contains the necessary information for a person to make an application to the Director, Animal Products for accreditation as an evaluator. For additional information about the role of the evaluator and the evaluation itself refer to the Evaluator's Guide, available on the NZFSA website.

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

An accredited evaluator without an activity endorsement in an area relevant to the RMP under evaluation will be expected to obtain technical input from another accredited evaluator or technical expert for any aspect of the programme that is outside her/his competency. It is recognised that the decision to obtain this input is not always clear cut. If the evaluator is in doubt, they should contact the NZFSA.

This application process is an interim measure. Over the past year the NZFSA has developed three NZQA unit standards associated with the development and evaluation of RMPs. These standards are:

- 19514 "Explain the Application of HACCP Principles";
- 19515 "Explain development and Implementation of Risk Management Programmes under the Animal Products Act";
- 19516 "Explain Evaluation and Evaluate a Risk Management Programme under the Animal Products Act".

Steps have been taken in this version of the application pack to incorporate these new NZQA unit standards as we move towards a finalised evaluator accreditation standard. A more rapid move to a permanent standard is being hampered by the availability of training providers and so it is not possible at this stage to make the new NZQA unit standards compulsory. The accredited evaluator will be assessed under this interim system and may be required to be reassessed once the standard has been finalised.

For the generic accreditation, where the applicant chooses to answer the questions in this pack rather than completing the relevant NZQA unit standard, every question must be answered to a satisfactory degree. The answers will be assessed according to the following ratings: competent, further evidence required or not yet competent. The NZFSA reserves the right to seek additional information from the applicant wherever necessary. This may include examples of work undertaken.

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

## Documentation Checklist

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

### Generic Accredited Evaluator

- Completed Accredited Person application form (AP7);
- Completed form for the consent to disclosure of convictions;
- 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.

# 1. Generic Accreditation

Where the applicant chooses to answer the questions below rather than completing the relevant NZQA unit standard, every question must be answered to a satisfactory degree. The applicant must add and sign the declaration given on page 6 to their written answers.

## Part 1: Understanding of the APA

### Either:

Provide a copy of the NZQA record of learning, or a certificate from the relevant industry training organisation as evidence of having obtained NZQA unit standard 19515 “Explain development and Implementation of Risk Management Programmes under the Animal Products Act”.

### Or answer the following questions:

1. What are the objects of the Animal Products Act 1999 (APA)?
2. Describe the four main controls of the risk management system under the APA and how they relate to each other. This should include RMPs, regulated control schemes, overseas market access requirements and duties.
3. Describe the interface of the APA<sup>1</sup> with the following legislation:
  - Food Act 1981;
  - Meat Act 1981 (Meat Regulations 1969, Fish Export Processing Regulations 1995, Game Regulations 1975);
  - Medicines Act 1981;
  - Agricultural Compounds and Veterinary Medicines Act 1997;
  - Dairy Industry Act 1952.
4. What legislation specifically defines which operators must have a RMP?
5. Outline the transition dates for existing operators that are transferring operations to the APA. Include the transition dates by operator type in your answer.
6. Outline each component of a RMP as listed in the figure “Components of a risk management programme” (Risk Management Programme Manual). Using scenario(s) you are familiar with, provide examples of what you would expect to see in a RMP for each component. Ensure that all specific legal requirements as provided for in the Animal Products (Risk Management Programme Specifications) Notice 2000 (or subsequent amendments) have been addressed in your answer for each component.

In relation to risk factors, list the four risk factors that must be considered by the operator when developing a RMP and describe the difference between hazards and other risk factors. Provide an example of a processing operation that would require:

- hazards to human health;
  - hazards to animal health;
- to be addressed in the RMP.

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<sup>1</sup> Consider the Acts which amend the APA and the Animal Products (Ancillary and Transitional Provisions) Act 1999.

Also provide eight different examples of risk factors:

- one for each of the 3 hazard categories for both human and animal health (6); and
- one for wholesomeness (1); and
- one for false or misleading labelling(1).

In relation to product outcomes, provide eight specific examples of product outcomes, one for each of the risk factors listed above.

7. Describe the options for incorporation or alignment of overseas market access requirements with the RMP and the effect on the evaluation and the RMP itself.
8. List and provide a brief overview of all of the animal products regulations and specifications relevant to RMPs. Include a description of regulation 10 of the Animal Products (Ancillary and Transitional Provisions) Regulations 2000 (AP(A&TP) regs). Comment on the legal status of the regulations and specifications in relation to the RMP.
9. For secondary processors of animal products intended for human consumption, describe the possible regulatory options available to address food safety. Include RMPs, FSPs and the Food Hygiene Regulations 1974 in your answer and a brief description of how these programmes may interface within a premises.
10. Describe the role of resources in developing a RMP including all resources outlined in the figure “Resources to assist in risk management programme development” (Risk Management Programme Manual). Ensure that your answer clarifies the legal standing of each of these resources and discuss why some resources are more likely to be used than others.
11. Describe the application of regulation 11 of the AP(A&TP) regs and its impact on the evaluation of a RMP. Describe those components of the RMP that must still be evaluated if this transitional provision has been used.
12. Describe the value of harmonising risk management approaches within the following NZFSA business groups: dairy, animal products and processed foods and retail sale, and the goal in relation to harmonisation of RMPs, PSPs and FSPs<sup>2</sup>. Include in the description the intention in terms of evaluation and verification of the various programmes.

## **Part 2: Validation**

1. Responsibilities:
  - (a) Explain who is responsible for validation.
  - (b) Explain the options available if the skills to undertake validation do not exist within the business.
2. Timing:
  - (a) Explain when validation and revalidation must be done.
  - (b) Give examples of situations when complete validation and incomplete validation are likely.
3. Complete validation:
  - (a) Describe the two key components of validation.
  - (b) What justification would you expect to see documented in a RMP for the selection of each product outcome?

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<sup>2</sup> Refer to the NZFSA website at <http://www.nzfsa.govt.nz/policy-law/harmonisation/> and “Implementation of the Generic Approach to Risk-based Management Plans”.

- (c) Where there are no product outcomes 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 validation of product outcomes, giving examples of the validation evidence that could be collected.
  - (e) Describe the validation of supporting systems, giving examples of the validation evidence that could be collected.
  - (f) Describe the validation of CCPs, giving examples of the validation information that could be collected.
  - (g) Discuss how (d), (e) and (f) above interrelate.
  - (h) Describe the validation required when an operator implements a process or procedure directly from a code of practice, compared to an operator developing their own procedures (e.g. a novel process).
  - (i) Describe how validation information should be presented for evaluation.
  - (j) Describe how the evaluator documents that they are satisfied that validation is complete.
4. Incomplete validation:
- (a) Describe how much validation is expected for incomplete validation and how the lack of some information is managed.
  - (b) Describe the two main components of a validation protocol and the importance of each.
  - (c) Describe how the evaluator documents that they are satisfied that the validation protocol is adequate.
  - (d) Describe how incomplete validation 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 validation and registration of the fully validated RMP.
  - (g) Describe how the evaluator documents that a RMP has been completely validated.
5. 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 validation information and the impact that the timing of the registration has on product disposition.

### Part 3: HACCP

1. Provide a copy of the NZQA record of learning, or a certificate from the relevant industry training organisation as evidence of having obtained either 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 active use of that unit standard in the last two years, in any of the following ways<sup>3</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

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<sup>3</sup> If you are unable to provide the required evidence, contact the NZFSA to discuss assessment options.

- (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.

#### **Part 4: Audit**

##### **Either:**

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

##### **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 accreditation that will require the audit qualification to be obtained within a specified timeframe (e.g. up to 6 months from the date of accreditation).

#### **Part 5: 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 accredited evaluator questions supplied have been prepared by me and are all my own work.

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

## 2. Activity Endorsement

A 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 a 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 associated with the particular process and the technology,
- detailed aspects of current industry norms<sup>4</sup>;
- the implementation of the technology or industry norm and that this has been properly completed by the operator;
- the acceptability of the evidence that had been provided by the operator to validate a process that is different to an industry norm.

A person applying for accreditation with an activity endorsement must provide sufficient information to demonstrate their level of competence. This information will be assessed on a case by case basis.

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 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 initial accreditation if you want to add activities to your accreditation.

### A. General<sup>5</sup>

1. Please 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:  
Please supply evidence of training and other qualifications relevant to the activity endorsement being sought.
3. Technical knowledge:
  - (a) What type of product(s) is/are produced in this area of activity?
  - (b) What type of production technology (process, equipment, preservation system etc.) is employed in this area of activity?
  - (c) 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.
  - (d) What resources that you are aware of describe or outline the currently accepted industry norms for this type of processing?

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<sup>4</sup> the term 'industry norm' includes industry standards (ISs, IAISs), codes of practice & GMP as described in authoritative texts and technical publications.

<sup>5</sup> specific examples may be used at any time to illustrate the points made.

- (e) 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.
  - (f) What, in your experience, presents the greatest difficulty to industry in applying industry norms, provide specific examples in relation to the selected activity.
  - (g) 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.
  - (h) 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.
  - (i) 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 accreditation, a total of two referees only may be supplied, provided their knowledge of the applicant is sufficient to cover both the generic accreditation and the activity endorsement.
  5. If this document does not accompany your initial application to become an accredited evaluator, please add and sign the declaration given on page 6 to your written answers.

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

Any person evaluating a 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.

For assessment in this activity the applicant must provide:

- evidence of having passed one of the above courses; and
- a résumé of relevant experience; and
- the information required to meet point 4 of Part A above.

### 3. Administrative Requirements

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

The documentation must cover the following:

1. How confidentiality in relation to information, operations and activities they come in contact with will be managed. The applicant must ensure that proprietary rights are protected.
2. The provisions for the storage and traceability of all relevant documentation associated with the evaluation process. Documentation, excluding the evaluation report, must be retained for at least 4 years.
3. How independence and conflict of interest will be managed. The evaluator must be free of any commercial, financial, management and other pressures (other than that associated with the evaluation) from those to whom the service is provided, and must have procedures that describe how the results of an evaluation will not be affected by external influences. 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 a 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 or other accredited evaluator to be used in an evaluation.

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