Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Recognised Evaluators of Non-dairy Risk Management Programmes

A guide to gaining and maintaining recognition

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Title

Guidance Document: Recognised Evaluators of Non-dairy Risk Management Programmes

About this document

This guidance document contains the requirements for a person applying for recognition as a risk management programme evaluator (non-dairy) and to maintain recognition.

Related Requirements

The requirements to which this guidance document relates are:

- Animal Products (Fees, Charges, and Levies) Amendment Regulations 2015
- Animal Products (Recognised Agencies and Persons Specifications) Notice 2015
- Animal Products (Risk Management Programme Specifications) Notice 2008
- Animal Products (Requirements for Risk Management Programme Outlines) Notice 2008

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Disclaimer

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1 Purpose

This guide explains the requirements that must be met by a person applying for recognition as an evaluator of non-dairy risk management programmes (RMP), and to maintain recognition. Details about becoming a recognised evaluator of dairy RMPs can be found on the MPI website.

2 Background

Businesses that need to operate under a RMP under the Animal Products Act 1999 (APA) must register their programme with the Ministry for Primary Industries (MPI) before they can produce product for trade. An operator must submit an independent evaluation report (unless the requirement is waived) to the Director-General (DG) that recognises the validity of the RMP and makes a recommendation that it be registered.

An evaluation is a systematic assessment of an RMP. Its main purpose is to ensure that the RMP is appropriate, effective and meets the requirements of the legislation. An RMP evaluation can only be carried out by a person (i.e. an evaluator) who is recognised under the APA. Recognition is granted to evaluators to assist MPI in managing the risks associated with third party involvement in the process of registering RMPs. MPI needs to have confidence that the people performing this role have the required skills.

To be recognised, a person must meet the requirements set out in Part 8 of the APA, particularly sections 103 and 105. The DG must be satisfied that the applicant is "a fit and proper person" to perform the functions and activities concerned. The requirement to be "fit" relates to competencies and these stem from qualifications and/or experience. The requirement to be "proper" relates to a person's character. The following factors are taken into account when MPI assesses an application for recognition:

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

Clauses 15 and 16 of the Animal Products (Recognised Agencies and Persons Specifications) Notice 2015 detail the competency requirements that must be met by any person seeking recognition.

An evaluator is contracted to and paid for by the operator as it is a user pays system. The evaluator is responsible for the full assessment of the RMP but must seek technical input from other recognised evaluators or technical experts for any aspect of the RMP that is outside their competency.

A regulatory requirement is identified by having a citation at the end of the relevant sentence or clause, of the specific legislation from which particular requirement is derived from. In many cases, the mandatory requirements have been paraphrased. Operators should refer to the cited legislation for the actual wording of the legal requirement.

3 Abbreviations

APA
The Animal Products Act 1999

CCP
Critical Control Point

DG
Director-General

FCP
Food Control Plan

HACCP
Hazard Analysis and Critical Control Point

IANZ
International Accreditation New Zealand

ISO
International Organisation for Standardisation

JAS-ANZ
Joint Accreditation System of Australia and New Zealand

MPI
Ministry for Primary Industries

NZQA
New Zealand Qualifications Authority

RA Notice
Animal Products (Recognised Agencies and Persons Specifications) Notice 2015

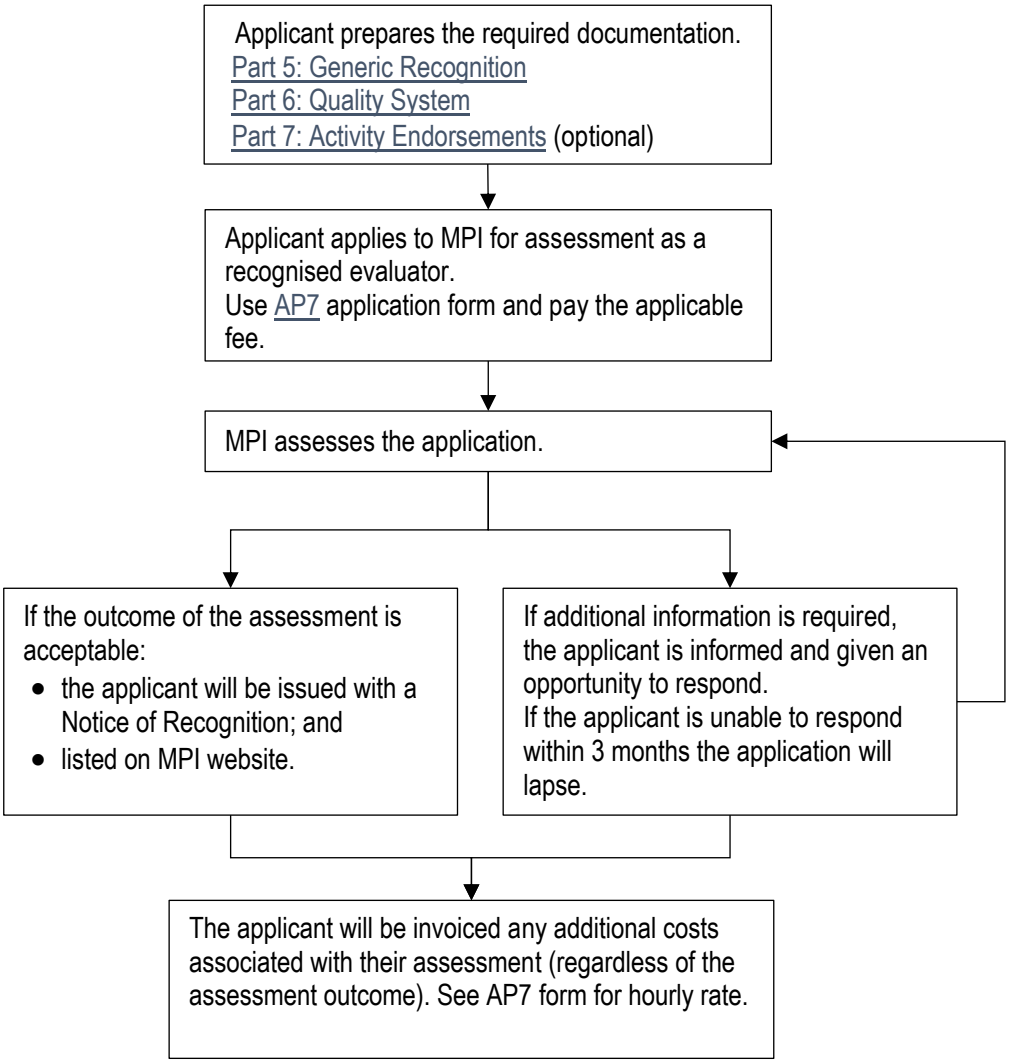
RMP
Risk Management Programme

RMP Specs
Animal Products (Risk Management Programme Specifications) Notice 2008

4 Application Procedure

The steps to becoming a recognised evaluator are outlined in figure 1 below.

Figure 1: Application procedure to becoming a recognised evaluator of non-dairy RMPs



An Application Checklist is attached in Appendix 1 for your reference.

Every effort will be made to ensure that the assessment is fair and transparent. However, if you are not satisfied with the outcome, section 162 of the APA provides for a review of the decision (see Part 4.4 for detail).

4.1 New Zealand Police Vetting

Under the APA, the DG must be satisfied that you are of an appropriate character and reputation to carry out evaluation. To allow MPI to check this, you need to complete and sign the "Vetting Service Request & Consent Form" which is attached to the AP7 application form.

The form provides MPI with written authority to obtain a report from the police of any convictions recorded. Convictions relating to crimes of dishonesty are 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.

4.2 Outcome of Assessment and Conditions of Recognition

If you meet the recognition requirements you will be issued with a Notice of Recognition. The Notice of Recognition means that you can evaluate RMPs for animal product sectors operating under the APA, other than those requiring a mandatory activity endorsement.

You must not take responsibility for, or sign any evaluation report until you have received this Notice of Recognition. You must retain the Notice of Recognition for the duration of your recognition. This must be returned to the DG if you stop being a recognised evaluator, or at any other time as may be requested by the DG.

Your recognition may be granted subject to conditions and the DG may by written notice, revoke, amend or add to any conditions applied and will notify you of the intention to do so. When acting as an evaluator, you must comply with any conditions of your recognition.

4.3 Fees

There are 3 fees associated with evaluator recognition:

a) application fee;
a) assessment fee; and
b) annual fee.

The application fee is paid when you submit your application and documentation to MPI.

An assessment fee is charged at the completion of the MPI assessment and this is calculated on an hourly rate for the time involved in assessing your application. You will be invoiced for the assessment fee and must pay this before your Notice of Recognition is issued. These fees must be paid regardless of the outcome of your assessment.

Each year you must pay a fee to maintain your recognition. Payment of this fee is your responsibility.

Refer the Animal Products (Fees, Charges, and Levies) Regulations 2007 for the applicable fees and charge out rates.

4.4 Right of Review

If you are not satisfied with a decision relating to the granting of your recognition, you may seek a review under section 162 of the APA.

4.4.1 Decision made by the DG

If the DG decides to refuse to grant your recognition you will be notified of this in writing, including the reasons for the decision. A summary of the information that was used to make the decision can be provided to you on request. You may make a written submission to the DG in an agreed timeframe, with the reasons why you think the decision should be overturned. The DG will review your submission and make a final decision. If the original decision is upheld, you will be notified in writing, including reasons, as soon as is practical (refer to section 109 of the APA).

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

4.4.2 Decision Made by a Person Acting Under Delegated Authority

If the decision to refuse recognition has been made by a person acting under delegated authority, you may seek a further review by the DG or a designated person who was not involved in the original decision. The application for review must be in writing and state the grounds on which you believe the original decision was not appropriate. Your submission must be made within 30 days of being notified of the refusal.

Your submission will be reviewed by MPI within 60 days. This may be extended a further 30 days on notification by the DG. You may be asked to provide additional information within a specified time. The time taken to supply this information is not included as part of the review period. The DG will notify you in writing, as soon as practicable, providing reasons if the decision to refuse recognition is upheld.

4.5 Public Register of Recognised Evaluators

MPI maintains a register of recognised evaluators (under section 112 of the APA). The register can be viewed on the MPI website www.mpi.govt.nz by searching for 'Evaluators'. The register lets the public, RMP operators and others know who is recognised to undertake evaluation, and any activity endorsements that have been granted. The register also facilitates compliance, audit and other supporting functions of MPI.

5 Generic Recognition

When applying for generic recognition as an evaluator you will need to provide written evidence that addresses the following requirements:

c) baseline skills and knowledge (Part 5.1);
d) knowledge of the APA (Part 5.2);
e) validation (Part 5.3);
f) HACCP (Part 5.4);
g) audit (Part 5.5); and
h) references (Part 5.6).

You must also have written procedures (a quality system, see Part 6) to deal with the processes and administration of an evaluation.

For some of these requirements, evidence that you have the required qualification is sufficient (e.g. an NZQA Unit Standard) or you can provide written answers to the questions posed. Make sure you include enough detail in your answers. For other requirements you will need to provide other documentation. MPI will assess your responses according to the following ratings:

- competent;
- further evidence required; or
- not yet competent.

When assessing your application, MPI may seek additional information, which may include examples of work you have carried out.

Each of the requirements listed above are expanded upon in the following sections.

5.1 Baseline Skills and Knowledge

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 appropriate to the role of the evaluator.

5.2 Knowledge of the APA

Either:

Provide a copy of your 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:

Provide written answers to the following questions:

(1) What are the objectives of the APA?

(2) Describe the relationship between RMPs and the other provisions for managing risks under the APA, including regulated control schemes, standards and specifications, and export requirements.

(3) Describe the relationship of the following legislation with the APA, and more particularly, its impact on a RMP evaluation:

a) Food Act 2014;

b) Food Standards Code;
c) Agricultural Compounds and Veterinary Medicines Act 1997;
d) Animal Welfare Act 1999;
e) Medicines Act 1981.

Explain whether you would evaluate requirements that fall under other legislation.

(4) What is a RMP?

(5) Which legislation specifically defines which operators must have a RMP?

(6) Outline each component of a RMP as listed in the figure 3A "Components of a risk management programme" of the RMP 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 in the following documents are addressed in your answer:

a) Animal Products (Risk Management Programme Specifications) Notice 2008;
b) Animal Products (Requirements for Risk Management Programme Outlines) Notice 2008;
c) Animal Products Act 1999 Statement of Policy: Operator Responsibilities during Registration of a Risk Management Programme (Version 1).

(7) List the 4 factors that must be considered by the operator when developing a RMP. Describe the difference between hazards and other risk factors. Provide an example of a processing operation that would require the following hazards to be addressed in the RMP:

a) hazards to human health; and
b) hazards to animal health.

(8) Provide 8 different examples of risk factors:

a) one for each of the 3 hazard categories for both human and animal health (6 in total); and
b) one for wholesomeness; and
c) one for false or misleading labelling.

(9) Give an example of a regulatory limit and/or an operator-defined limit for each of the hazards listed above and indicate whether the limit is regulatory or operator-defined.

(10) List and provide a brief overview of the Animal Products Regulations and Notices specific to non-dairy RMPs and comment on the legal status of them in relation to the RMP.

(11) For secondary processors of animal products intended for human consumption, describe the possible regulatory options available to address food safety. Include RMPs, Food Control Plans (FCP) and National Programmes in your answer and a brief description of how these programmes may interface within a premises.

(12) Describe the role of resources in developing a RMP (include all resources outlined in RMP Manual). Your answer should clarify the legal standing of each of these resources and discuss why some resources are more likely to be used than others. Make sure you include the MPI hazard data sheets and the hazard database in your answer.

(13) Describe the options for incorporation or alignment of overseas market access requirements (OMARs) with the RMP and the effect on the evaluation and the RMP itself.

(14) Explain what duties are and the duties that would apply to you as a recognised evaluator.

(15) Outline the evaluation process and what you need to assess when carrying out an evaluation, including what you would do if the RMP applied to more than one business.

(16) Outline the evaluation process for a significant amendment and how you would decide if an amendment is significant.

(17) What is, and how would you manage a conflict of interest?

(18) Describe when a technical expert or other recognised evaluator should be used, and how you would go about sourcing and using such a person.

(19) What must be included in the evaluation report and how is the report endorsed? Make sure you provide the legal reference for the contents of the evaluation report.

5.3 Validation

Provide written answers to the following questions:

(1) Responsibilities:

a) Explain who is responsible for validation.
b) Explain the options available if the skills to carry out validation do not exist within the business.

(2) Timing:

a) Explain when validation and re-validation must be done.
b) Give examples of situations when complete validation and incomplete validation are likely.

(3) Complete validation:

a) Describe the 2 key components of validation.
b) What justification would you expect to see documented in a RMP for the selection of each operator-defined limit?
c) Describe the validation of regulatory limits and operator-defined limits, giving examples of the validation evidence that could be collected.
d) Describe the validation of Good Operating Practice, giving examples of the validation evidence that could be collected.
e) Describe the validation of Critical Control Points, giving examples of the validation information that could be collected.
f) Discuss how (c), (d) and (e) above interrelate.
g) 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).
h) Describe how validation information should be presented for evaluation.
i) 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 2 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 the conditions mentioned in d).
f) Describe the process for completing 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.
c) Explain the operator's options in terms of the:

i) timing of registering the significant amendment and the collection of validation information; and
ii) impact that the timing of the registration has on product disposition.

5.4 HACCP

(1) Provide a copy of your NZQA record of learning, or a certificate from the relevant industry training organisation as evidence of having obtained at least one of the following NZQA unit standards:

a) 12626 "Co-ordinate the Development and Verification of a HACCP plan for a Meat Processing Operation";
b) 12316 "Co-ordinate the Development and Verification of a HACCP plan for a Seafood Processing Operation";
c) 19514 "Explain the Application of HACCP Principles";
d) 28265 "Develop, implement and review a HACCP application for a food processing operation";
e) 28264 "Implement a HACCP system in a food processing operation";
f) any other qualification acceptable to MPI.

(2) Provide evidence to demonstrate use of the unit standard in the last 2 years, in any of the following ways:

a) developing a HACCP plan in a RMP or custom FCP;
b) implementing a HACCP plan in a registered RMP or custom FCP, including operator verification activities;
c) verifying a HACCP plan in a registered RMP or custom FCP.

The evidence may be a summary report of your work including 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 2 references from senior management confirming that the involvement was of a satisfactory standard. A report on your work from an independent and qualified auditor may be used as an alternative to references from senior management.

Depending on the nature of the evidence supplied, a MPI assessor may discuss this further with you.

5.5 Audit

Either:

(1) Provide evidence of having a quality system audit qualification:

a) certified by a JAS-ANZ accredited personnel certification body or have attended a NZQA recognised audit course (e.g. a lead auditor course), or obtained a NZQA unit standard in auditing at level 6 or above;
b) if the audit qualification was completed more than 3 years previously, provide evidence to demonstrate a meaningful involvement in performing verification or evaluation over the intervening years or you must re-qualify.

Or (as an interim measure for up to 6 months from your date of recognition):

(1) If you do 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.

(2) Ensure that the following aspects of the audit process (sourced from ISO standard 19011 "Guidelines for auditing management systems") have been covered:

a) decide on the type of audit and standard against which audit is to be done;
b) notify the auditee;
c) obtain information prior to premises audit;
d) assess pre-audit information and if necessary target specific concerns;
e) select audit team;
f) brief the audit team;

g) visit premises and carry out entry meeting;
h) carry out audit;
i) carry out exit meeting and deliver conclusions;
j) write formal report;
k) follow up on non-conformances.

(3) A condition will be added to your recognition that will require your audit qualification to be obtained within 6 months (or other time as agreed with MPI) from the date of recognition.

(4) Please copy the following declaration at the end of your answers and sign and date it. MPI can accept scanned copies of signatures or electronic signatures.

Declaration:

I declare that the responses submitted to the Ministry for Primary Industries in response to the recognised evaluator questions supplied have been prepared by me and are all my own work.

Applicant Signature_____ Date_____/_____/_____

5.6 References

Give the names and contact details of 2 references who can provide information such as your job performance, work record, technical ability, personal attributes, character and reputation.

6 Quality System

As part of your application you should provide your written quality system (policies and procedures) that deals with:

a) traceability of the evaluation process and associated documentation;
b) confidentiality;
c) conflict of interest;
d) notifying MPI of certain things;
e) reporting certain things to MPI;
f) evaluation process;
g) assessment and use of technical experts.

If you are part of an organisation, the policies and procedures of the organisation can be submitted to fulfil this requirement. Once these policies and procedures have been assessed as part of your application, they must be followed for all evaluations [RA Notice 26(1)]. This includes ensuring that any sub-contractors you employ follow these procedures.

Any MPI audit of your competency as an evaluator will include an assessment of your compliance with these policies and procedures. It is important that these reflect your operation and are up-to-date.

6.1 Written Policies and Procedures

Please provide a copy of your written policies and procedures which address the following:

(1) How you will store and trace all relevant documentation associated with the evaluation, including records and any correspondence with MPI, operators, technical experts and any other businesses associated with the evaluation.

All documentation (including records and correspondence) must be retained for at least 4 years from the date of signing of the particular evaluation report and must be auditable [RA Notice 26 (2)]. This retention period applies even if you cease to work as a recognised evaluator[1].

Describe how your records will be kept under secure conditions in a manner that will minimise deterioration. You should also describe how documentation will be made available to the DG, an animal product officer or person authorised by the DG, upon request within 24 hours.

(2) How you will manage confidentiality in relation to information, operations and activities you come in contact with. You must ensure that proprietary rights are protected [RA Notice 26 (3)].

(3) How you will manage independence and conflict of interest. You 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 [RA Notice 26 (3)]. You must have procedures that describe how the results of an evaluation will not be affected by external influences.

The procedures should include how you will ensure that you or any person to whom you sub-contract work will not evaluate a RMP that you or the sub-contractor has been involved in the design, development, validation or verification, of within the time constraints as described in Appendix 2.

An exception to this applies if you have disclosed the conflict to MPI and MPI has been agreed in writing that the conflict can be managed. You must inform the operator if any technical expert of other

[1] If you cease to work as a recognised evaluator, arrangements should be made with MPI regarding record storage. Please contact MPI to discuss further.

recognised evaluator is to be used in an evaluation. Your procedures must describe how you would go about getting MPI agreement or notifying the operator in relation to these 2 scenarios.

(4) Your procedure for notifying MPI as soon as practicable and recommending any actions to be taken if you are prevented from performing an evaluation or exercising your duties and rights [RA Notice 23 (3)].

(5) Your procedure for reporting to MPI as soon as practicable and recommending any actions to be taken if you identify any uncorrected deficiency or non-compliance with any requirement under the APA when performing an evaluation and that you consider may:

a) result in exposure of humans or animals to an unacceptable level of hazard;
b) has the potential to jeopardise overseas market access; or
c) threaten the integrity of the official assurance system [RA Notice 24].

(6) Your procedure for notifying MPI if you leave or join a recognised agency or organisation that performs evaluation, including the name of the agency or organisation and the date that you left and/or joined it. Your procedure must ensure that MPI is notified before the move takes place. If you are no longer covered by a quality system as a result of this move, you will need to document policies and procedures to meet the requirements of this section [RA Notice 26(4)].

(7) The procedure for how you will carry out evaluations, including when a RMP is incompletely validated, and when evaluating a significant amendment. The procedure must include how you will obtain supporting reports from a technical expert with appropriate expertise, or another recognised evaluator (with the appropriate activity endorsement where required), for any aspect of the evaluation that is outside your expertise [RA Notice 25(1)].

(8) Your procedure for assessing the competency of any technical expert to whom you sub-contract evaluation work [RA Notice 25(2)]. This should include an assessment of the following information:

a) records of relevant training and qualifications;
b) résumé of relevant experience;
c) information relating to job performance, work record, technical ability and personal attributes relevant to the role sought, from at least one independent reference;
d) if being used for an activity with a mandatory competency requirement, evidence that the person meets the requirement (e.g. low-acid canned products); and
e) checking that there is no conflict of interest and independence will be maintained.

7 Activity Endorsements

Activity endorsements are used to identify evaluators' areas of specialist expertise. This information is available on the MPI public register of evaluators. A recognised evaluator with an activity endorsement is expected to have a high level of competence in the process or processes covered by that endorsement. You will need to be able to evaluate the complexities of a process and provide specialist knowledge to other recognised evaluators who do not have the same activity endorsement. An activity endorsement is required if you are evaluating a sector that has a mandatory competency requirement, e.g. low-acid canned foods, otherwise it is optional.

If you want to apply for an activity endorsement, you can select specific sectors or processes within a general or specific area. For example, you may want an activity endorsement for all types of rendering operations, or for a specific type of rendering. There are no restrictions on what activity endorsements you can be recognised for. You may seek one or more activity endorsements.

If seeking an activity endorsement you will need good knowledge and experience of:

- the process or technology;
- hazards and other risk factors associated with the particular product, process or technology;
- detailed aspects of current industry practice;
- installation and commissioning of the equipment, process or technology (if applicable);
- MPI Operational Codes, Codes of Practice, HACCP plans, generic models or other guidance in the selected area;
- reputable international standards and/or peer reviewed scientific information in the selected area (if available);
- how to assess the acceptability of the validation information provided by the operator.

To apply for recognition with an activity endorsement you will need to provide sufficient information to demonstrate your competence. The following are some examples of the types of activities that evaluators could receive an endorsement in:

- slaughtering, dressing, boning, cutting and size reduction of mammals and/or birds;
- egg layer farm or egg further processing;
- bee product processing;
- deer velvet processing;
- thermal processing of low-acid canned products;
- thermal processing of products other than low-acid canned foods;
- ready-to-eat product processing;
- further processing (e.g. high pressure processing);
- seafood primary processing;
- depuration of shellfish;
- rendering;
- tallow processing;
- animal feeds other than rendered products;
- biologicals processing.

MPI personnel with knowledge in the appropriate area(s) will assess the application. Input will be sought from external sources if the activity is outside the competencies of MPI personnel.

You can apply for an activity endorsement(s) as part of your initial application, or at any other time once you have been recognised.

7.1 General Requirements for an Activity Endorsement

For each activity endorsement you are applying for, you must provide written answers to the following questions [RA Notice 16]. Ensure that the answers are as complete as possible. If the information provided is sufficient to warrant further assessment, MPI will arrange an interview to discuss technical aspects of this activity. If not, you will be asked to provide more information or will be informed that insufficient information has been provided and that your application has been declined.

(1) Please state the activity you are seeking endorsement for (complete a separate response for each activity that you are applying for).

(2) Please supply any evidence of specialist training and qualifications relevant to the activity endorsement.

(3) Technical knowledge:

a) What type of product(s) is/are produced under this activity?
b) What type of production technology (process, equipment, preservation system etc.) is used for this activity?
c) List and discuss the features of this activity that need to be taken into account to minimise hazards to human or animal health and other risk factors.
d) What resources (that you are aware of) describe or outline the currently accepted industry practice for this activity?
e) Discuss the resources in d), commenting in particular on:

i) the practicality of implementing the industry practice;
ii) whether (amongst these resources) any 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 practice? Provide specific examples in relation to the selected activity.
g) Have you had practical experience with this activity, including:

i) the identification, analysis and control of hazards; and
ii) the validation of processing parameters, regulatory or operator-defined limits?

If yes, please provide examples.

h) If an operator chooses not to apply all or part of an industry practice, what validation evidence would you accept to demonstrate that the process will produce products that are fit for their intended purpose?
i) Are you knowledgeable in the principles of statistics and experimental design or would you seek the assistance of another person when dealing with validation of non-standard processes? Please explain your response.

(4) Supply the names and contact details of 2 references who can provide information such as your job performance, work record and technical ability relevant to the tasks to be performed.

(5) Where an activity endorsement is sought at the same time as a generic recognition, only 2 references may be supplied, provided their knowledge of you is sufficient to cover both the generic recognition and the activity endorsement.

7.2 Specific Activity Endorsement: Thermal Processing of Low-Acid Canned Products

(1) An evaluator of RMPs involving the thermal processing of shelf stable low-acid canned products for human or animal consumption must provide evidence of having passed at least one each of the Supervisors and the Qualified Persons courses:

Supervisors of low-acid canned products operations

a) Principles of Thermal Process Control, Acidification and Container Closure Evaluation, Massey University, New Zealand; or
b) Retort Supervisors Certification course, DWC FoodTech Pty Ltd, Australia; or
c) New Zealand Retort Supervisors and Process Control School, Food Processing Specialists Pty Ltd, Australia; or
d) another course acceptable to the DG.

AND

Qualified persons

a) Qualified Cannery Persons (Thermal Processing) Course, University of Western Sydney (Hawkesbury) Australia; or
b) Approved Persons Course for Thermally Processed Low-Acid Foods, DWC FoodTech Pty and CSIRO Australia; or
c) Introduction to the Fundamentals of Thermal Process Evaluation, Massey University, New Zealand (no longer available); or
d) another course acceptable to the DG.

(2) For assessment in this activity you must also provide:

a) a résumé of relevant experience; and
b) evidence of knowledge of current infrastructure and industry practice for the sector.

7.3 Specific Activity Endorsement: Aseptic Processing and Packaging Operations

(1) An evaluator of RMPs involving the aseptic processing and packaging of shelf stable low-acid products for human or animal consumption must provide evidence of having passed at least one each of the Supervisors and Qualified persons courses:

Supervisors of aseptic processing and packaging operations

a) Principles of Thermal Process Control, Acidification and Container Closure Evaluation, Massey University, New Zealand; or
b) another course acceptable to the DG.

AND

Qualified persons

a) Approved Persons Course for UHT Processing and Aseptic Packaging, DWC FoodTech Pty Ltd and CSIRO, Australia; or
b) another course acceptable to the DG.

(2) For assessment in this activity you must also provide:

a) a résumé of relevant experience; and
b) evidence of knowledge of current infrastructure and industry practice for the sector.

7.4 Specific Activity Endorsement: Depuration of Bivalve Molluscan Shellfish

(1) An evaluator of an RMP covering the depuration of bivalve molluscan shellfish must provide evidence of successfully completing at least one of the following courses:

a) SIS Training and Consulting Ltd Depuration Course, Solutions in Seafood Ltd, New Zealand;
b) Aquabio Consultants Depuration Training Course, Aquabio Consultants ltd, New Zealand; or
c) another course acceptable to the DG.

(2) For assessment in this activity you must also provide:

a) a résumé of relevant experience; and
b) evidence of knowledge of current infrastructure and industry practice for the sector.

8 Maintaining Recognition

MPI needs to have confidence that people who have been recognised to perform RMP evaluation keep up-to-date with developments under the APA and maintain their technical competency [RA Notice 23(2)]. It is your responsibility as a recognised person to make sure that the activities you perform as an evaluator are up to the expected standard. Opportunities should be taken to maintain and update your knowledge and skills.

To maintain your recognition you should:

- comply with any conditions of your recognition;
- receive an acceptable outcome from any compliance or systems audit carried out by MPI;
- conduct effective evaluations and prepare evaluation reports that accurately reflect the operation and the evaluation you have carried out;
- maintain and follow the procedures in your quality system;
- maintain your competency; and
- comply with the duties of recognised persons (section 103 of the APA).

If it is found that you have failed to meet the required competencies, or that your performance impacts negatively on the RMP or its ability to be registered, you will be notified of this.

If there is a serious deficiency in your performance, MPI may look into suspending and/or withdrawing your recognition. In these cases, the right of review will apply.

8.1 Compliance Audits

You may be subject to periodic compliance audits by MPI. The audit could involve:

a) a desk top assessment of your work;
b) observing you undertaking an on-site assessment; or
c) assessment of your compliance with the policies and procedures in your quality system.

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

8.2 Technical Competency

You are responsible for ensuring that your competence is maintained and improved upon. Aspects of this could be achieved through keeping up-to-date with the latest RMP developments, such as amendments to the legislation, new guidance documents, Codes of Practices, models and templates. It also involves keeping current with technical developments in the sectors you evaluate, including knowledge of validation of new or emerging technologies. Attendance at the Evaluator's Workshops is expected while technical conferences, seminars and training courses is encouraged.

A lot of information and tools are available to assist with this:

- feedback received during the registration of RMPs you have evaluated;
- food safety information on the MPI website - both requirements and guidance (e.g. new and amended Regulations and Notices, the *Listeria* guides);
- webinars from reputable organisations;
- e-Learning modules;
- attendance at national and international training course and conferences;
- accessing on-line literature and research including from overseas regulators, Codex and international research organisations; and

- microbiological modelling tools.

8.3 Renewal of Recognition

You must renew your recognition annually, or in accordance to the date on your Notice of Recognition [RA Notice 23(2)]. To renew your recognition, MPI will endeavour to notify you a month prior to when the renewal and annual fee is due or you must complete AP7 application form and pay the annual fee. Make sure you notify MPI if your contact details change so you continue to receive the renewal notification reminder.

If the renewal fee is not paid, continued activities as a recognised evaluator may be in breach of the APA. Any failure to pay the fee within 30 days of the due date may result in withdrawal of recognition under section 112N of the APA.

8.4 Additions or Changes to Recognition

8.4.1 Activity Endorsements

To amend your endorsed activities, submit a completed AP7 application form, together with the documentation required in Part 7 of this guide, to MPI. The application procedure described in Part 4 will apply. Fees are payable with each application.

If you want to remove an activity endorsement, please notify MPI in writing.

8.4.2 Substituted Notice of Recognition

Where the terms or conditions of recognition are varied, or your existing Notice has been damaged, lost, destroyed or contains a mistake, MPI may cancel the Notice of Recognition and issue a new one. A fee may apply.

Refer the Animal Products (Fees, Charges, and Levies) Regulations 2007 for the applicable fees.

8.4.3 Changes to Organisations

Moving from or joining an organisation for the purpose of evaluation will require you to notify MPI in writing. [RA Notice 26(4)].This enables MPI to track your movements and to check that you will continue to operate under an MPI assessed quality system. You will also need to notify MPI of the dates of cessation and commencement as appropriate.

If, as a result of a move you are no longer covered by a quality system you must submit your written procedures (to address the information required by Part 6) to MPI for assessment. This needs to occur within 4 weeks of leaving the organisation. You should not carry out new evaluations until these procedures have been submitted for assessment. If joining an organisation that has MPI assessed procedures, you must ensure that you conduct your evaluations in accordance with those procedures. Contact MPI to discuss further.

8.5 Suspension of Recognition

Under Section 112J of the APA, where there are reasonable grounds to believe that the performance of a person is unsatisfactory, the DG may suspend recognition for up to 3 months, with the option of extending for a further 3 months. In this case you will be required to provide MPI with a full list of the evaluations that are currently underway. The DG may impose conditions or requirements that must be satisfied for the suspension is to be lifted. You would be notified of this in writing.

If the decision to suspend recognition has been made by a person acting under delegated authority of the DG, the right of review process as described in Part 4.4 will apply.

8.6 Withdrawal of Recognition

Section 112N of the APA provides that where necessary, the DG may withdraw recognition. You would be notified of this in writing and would be required to provide MPI with a full list of the evaluations that are currently underway. The following circumstances would be considered grounds for withdrawal.

An evaluator:

a) is no longer fit and proper to undertake the activities for which recognition was granted; or
b) has failed to comply with any terms or conditions of recognition; or
c) has failed to meet any performance criteria specified by the DG; or
d) has failed to comply with the requirements of the APA.

If MPI plans to withdraw recognition, you will be given a reasonable opportunity to be heard and if the decision was made by a person acting under delegated authority of the DG, the right of review process as described in Part 4.4 would apply.

If your recognition is to be reviewed for withdrawal you would be required to:

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

8.7 Surrender of Recognition

You may surrender your recognition at any time by notifying MPI in writing. The surrender will take effect on a date you specify, or the date of receipt of the notice by the MPI. On surrender of your recognition, you must:

a) take all reasonable steps to notify all clients of the impending surrender; and
b) surrender your Notice of Recognition to the DG; and
c) retain your evaluation records for 4 years from the date of signing of the evaluation report, unless other arrangements have been made in writing with the DG.

Appendix 1: Application Checklist

The following lists the information that you must submit to MPI when applying for recognition as an evaluator. The information should be sent to the address at the top of the AP7 application form.

Generic Recognition (required)

□ Completed Recognised Person application form, including the form for the New Zealand Police vetting service of convictions (AP7);

□ Evidence of achieving NZQA standards (if any) (Part 5.1);

□ Written answers to the assessment questions and/or other required evidence and the signed declaration (Part 5.2-5.6);

□ Documentation to fulfil the quality system requirements (Part 6);

□ Application fee (as per AP7).

Activity endorsement (optional)

In addition to the above:

□ Documentation to fulfil the activity endorsement requirements (Part 7).

Appendix 2: Conflict of Interest and Independence

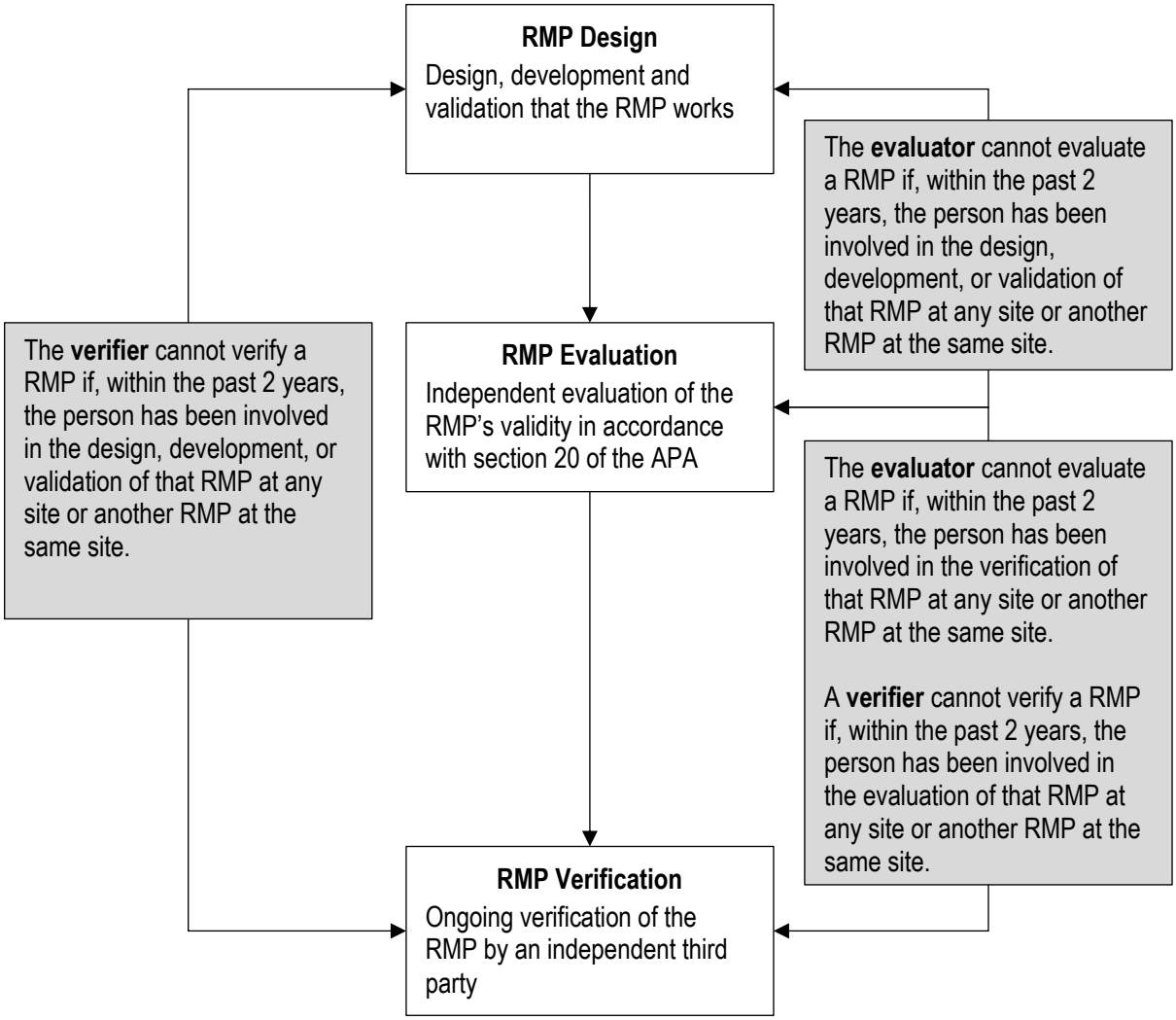
Conflict of interest may be defined as the loss of impartiality in an organisation's or individual's decisions or actions caused by conflicting interests in the outcome. An evaluator must ensure that they are independent of any commercial, financial or other pressures from those to whom the service is provided (other than for the purpose of providing that service) that may lead to a lack of independence from the RMP under evaluation.

In practice this means that an evaluator (or any other technical expert or specialist he or she may involve in the evaluation) cannot evaluate an RMP if, within the past 2 years, he or she has been involved in the design, development, validation or verification of that RMP at any site (i.e. physical location), or another RMP at the same site.

Individuals who are recognised as both an evaluator and verifier may provide both functions, except that a verifier cannot verify a RMP if, within the past 2 years, he or she has been involved in the evaluation of that RMP. These requirements do not prevent another person from the same organisation from providing the service on the same RMP, so long as independence is maintained. This has been explained further in figure 2.

For further information about managing conflict of interest and independence, refer to the MPI website: Independent evaluation and verification of risk management programmes.

Figure 2: Evaluator and Verifier Independence



Appendix 3: Use of Other Recognised Evaluators Technical Experts

During an evaluation you must get a supporting report from technical experts or other recognised evaluators for any aspect of the RMP that is outside your competency [RA Notice 25(1) and (2)]. The decision to seek input will not always be clear-cut but you must have confidence in the final evaluation report recommendations. If you are in doubt about whether additional technical input is required, it is recommended that you either obtain input or contact MPI to discuss further.

You can also get technical advice during an evaluation without having the person be formally responsible for completing part of the evaluation. In this case, neither a supporting report [RA Notice 29(1) m)] nor a formal competency assessment of the person is required.

Assessment of Competence of Other Recognised Evaluators and Technical Experts

If you use another recognised evaluator to provide a supporting report during the evaluation, you don't need to carry out a competency assessment, unless a specific competency is mandated. Where a mandatory competency is required the relevant activity endorsement will be sufficient evidence. If the evaluator does not have the required activity endorsement, you will need to confirm compliance with the competency specification [RA Notice 17] before he or she carries out the work.

If a technical expert is used to provide a supporting report, you must complete a competency assessment of that person before the work is carried out [RA Notice 29(1) n)] and if there is a mandatory competency, you must ensure that the technical expert meets the requirement.

You must follow your quality system (see Part 6) for assessing the competency of a technical expert. You are responsible for ensuring that the assessment is completed thoroughly and records of the assessment are kept. A copy of the competency assessment is to be included in the evaluation report. A record of the aspects of the evaluation that he or she is responsible for also needs to be agreed upon and documented.

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.