Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Evaluation Manual

For evaluating Risk Management Programmes which do not cover dairy products

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Title

Guidance Document: Evaluation Manual

About this document

This document provides guidance to recognised non-dairy evaluators on the evaluation of risk management programmes (RMPs) other than those covering dairy.

Related Requirements

The requirements to which this Guidance Document relates are:

- Animal Products Act (1999)
- Animal Products (Risk Management Programme Registration – Required Part) Regulations 2020
- Animal Products (Recognised Agencies and Persons Specifications) Notice 2015
- Animal Products (Risk Management Programme Specifications) Notice 2008
- Animal Products (Risk Management Programme Specifications Amendment and Requirements for Risk Management Programme Outlines Revocation) Notice 2020
- Animal Products Notice: Specifications for Products Intended for Human Consumption 2019
- Animal Products Notice: Specifications for Products Intended for Animal Consumption 2017
- Food Standards Code

Document history

Version date	Section changed	Change(s) description
April 2007	All	General update include new formatting and branding
March 2020	5.1	Additional information from the Evaluator's Manual General update

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Disclaimer

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1 Purpose

This guidance document provides information for recognised non-dairy evaluators on how to evaluate Risk Management Programmes (RMPs) which do not cover dairy products.

2 Background

An evaluation is the independent assessment of an RMP to ensure:

- the RMP meets the requirements of the Animal Products Act 1999 (APA); and
- when implemented, the RMP will produce animal materials that are suitable for processing and animal products that are fit for their intended purpose.

When applying to register an RMP, businesses are required to submit a copy of an independent evaluation report (unless the requirement is waived) that recognises the validity of the RMP and recommends it for registration [APA s20].

3 An evaluation can only be carried out by a recognised evaluator.

To be recognised, a person must meet the requirements set out in Part 8 of the APA, particularly sections 103 and 105. The Director-General (D-G) must be satisfied that he/she is "a fit and proper person" to carry out evaluation. Note that as a recognised evaluator you are accountable to the D-G when carrying out your evaluation activities [APA 112IA]. How to interpret this document

General requirements and guidance information are differentiated in this document.

A regulatory requirement is identified by having a citation at the end of the relevant sentence or clause and the specific legislation from which the requirement is derived. The word "**must**" is often used to indicate its mandatory status. For example, all inputs, including raw materials, ingredients, additives and packaging must be handled, processed, and stored in a manner that minimises any potential contamination or deterioration [AP Reg 9].

The abbreviations used for legislation citied in this document are:

APA	Animal Products Act 1999
AP Reg	Animal Product Regulations 2000
AP Reg 2020	Animal Products (Risk Management Programme Registration – Required Part) Regulations 2020
HC Spec	Animal Products Notice: Specifications for Products Intended for Human Consumption 2019
AC Spec	Animal Products Notice: Specifications for Products Intended for Animal Consumption 2017
RA Notice	Animal Products (Recognised Agencies and Persons Specifications) Notice 2015
RMP Spec	Animal Products (Risk Management Programme Specifications) Notice 2008
RMP Amended Spec 2020	Animal Products (Risk Management Programme Specifications Amendment and Requirements for Risk Management Programme Outlines Revocation) Notice 2020

In many cases the mandatory requirements have been paraphrased or reworded using examples for context. You should refer to the cited legislation for the actual wording of the legal requirement.

Guidance information, indicated by "**should**", provides explanatory information, examples or options for achieving a particular outcome or requirement. Operators may use alternative methods or measures to those set out in the guidance information provided they do not in any way compromise supporting systems (refer to the section 4.9 Supporting Systems in the RMP Manual for more information) and the achievement of the requirements.

4 General requirements for evaluation

An evaluation includes:

- a desk-top assessment of the RMP; and
- for new RMPs, must also include an on-site assessment (unless an exemption has been granted) [RA Notice 28(1)].

The evaluation assesses all components of the RMP, including all processes, supporting and any blank record forms that may be incorporated by reference into the RMP.

If the operator intends to submit an RMP outline for registration, you will need to check that it accurately reflects the content of the full RMP.

You are responsible for the full assessment of the RMP, but you must seek technical input from other recognised evaluators or technical experts for any aspect of the RMP that is outside your competency [RA Notice 25(1)].

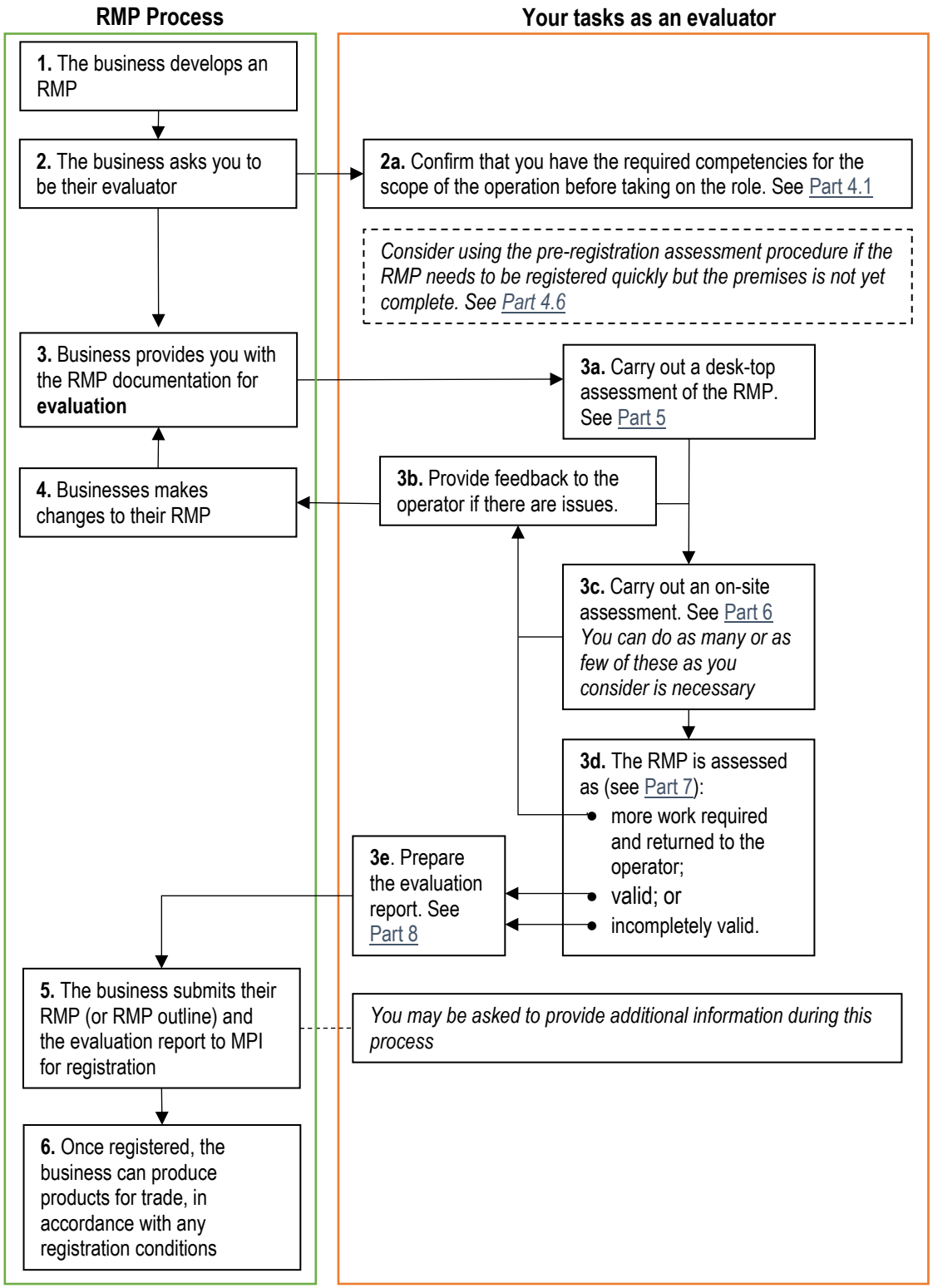
Upon completion of a successful evaluation, you will prepare an evaluation report for the operator that recommends the RMP for registration. A technical expert or other recognised evaluators may assist with evaluation and provide a supporting report.

A recognised evaluator is contracted to and paid for by the operator as it is a user pays system.

If during an evaluation, you are prevented from performing your role, or non-compliances are identified that the operator refuses to rectify, you must inform MPI as soon as practicable [RA Notice 23 and 24].

See Figure 1: The General Evaluation Process for a flowchart on how the evaluation fits with the RMP development process.

Figure 1: The General Evaluation Process



4.1 Pre-evaluation considerations

You will need to consider the following factors before agreeing to take on the role:

- **Do you have the appropriate sector knowledge?** You may consider using a technical expert for those areas you are unsure of. You should inform the operator if any technical expert or other recognised evaluator is used in an evaluation.
- **How will you deal with a conflict of interest?** You must be free of any commercial, financial, management and other pressures (other than that associated with the evaluation) that may impact on your ability to perform your role impartially. This also applies to any technical experts that you sub-contract work to. For further information see Appendix 1: Conflict of Interest and Independence.
- **How will you manage and store confidential information?** You will need to ensure that proprietary rights are protected. All records (e.g. correspondence with MPI, operators, technical experts) must be kept under secure conditions and in a way that will minimise deterioration [RA Notice 9].

4.2 Evaluation checks

When performing an evaluation, you should be aware of the requirements in relation to:

- compliance with the APA;
- any interface with RMPs which cover dairy;
- export requirements as part of the RMP (e.g. overseas market access requirements (OMARs));
- compliance with the Food Standards Code;
- any interface with Food Control Plans; and
- compliance with other legislation.

The above points have been expanded upon in the following parts.

4.2.1 Compliance with the APA

You will need to evaluate the RMP against all relevant APA legislation. When you recommend the RMP for registration, it indicates that this check has been done.

Legislation is often amended, so it is important to keep up-to-date. You can subscribe to the MPI website notification system to be notified when any consultations are carried out and when changes are made.

The APA and AP? Regulations, including full details of amendments, can be viewed on the New Zealand Legislation website. Animal Products Notices can be viewed on the MPI website or by searching for 'Animal Products Act Notices'.

4.2.2 Interface with RMPs which cover dairy

RMPs may cover both dairy and non-dairy materials and products. You can evaluate an RMP which includes dairy only if you are recognised to do so, as detailed under the Animal Products Notice: Dairy Recognised Agency and Recognised Persons Specifications.

If you are presented with an RMP that contains both 'principally dairy' and non-dairy animal materials and/or products, you may need to consider if 2 separate evaluations are needed, or if a dairy evaluator is needed as a technical expert. Refer to Appendix H: Determination of Principally Dairy in the RMP manual for more the definition of 'principally dairy'.

4.2.3 Export requirements as part of the RMP

Including export requirements (such as general export requirements or OMARs) into the RMP is optional. You are only required to evaluate the RMP against the New Zealand standard and ensure the RMP will produce suitable animal material and animal product that is fit for its intended purpose.

If export requirements are included in the RMP, these will be the procedures that the business must follow to be compliant with their RMP (i.e. they would need to meet both the New Zealand standard and export requirements).

4.2.4 Compliance with the Food Standards Code (FSC)

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

If you identify a non-compliance with the Code, you should let the operator know.

4.2.5 Interface with Food Control Plans (FCPs)

The evaluation of an FCP that is to be registered as an RMP must follow the same procedure as a complete RMP evaluation [APA s32]. To be able to evaluate FCPs, you must be recognised under the Food Act 2014.

MPI has developed a guidance document Can I include non-animal product foods in a Risk Management Programme? to provide options to RMP businesses who want to manage food safety of non-animal products within an RMP. Food businesses can include appropriate components of a FCP or National Programme (NP) that manages food safety under an RMP. Under certain circumstances this may include non-animal product foods.

4.2.6 Compliance with other legislation

When you evaluate the RMP, you will not be required to assess it against other legislation. It is the operator's responsibility for compliance with the requirements of all other legislation (e.g. the Building Act 2004, the Health and Safety at Work Act 2015).

If you identify a non-compliance with other legislation, you should let the operator know.

4.3 Evaluation against MPI Operational Codes, templates or RMP models

You should be very familiar with the content of MPI approved Operational Codes (also known as Codes of Practice), templates or RMP models, especially for the sectors you are working with. Most operators will follow these documents but some may have their own procedures, which may need to be validated.

In the case of approved RMP templates, a waiver from an evaluation usually applies (refer to the Waiver of the Requirement to provide a Copy of an Independent Evaluation Report). An evaluation would only be required if the scope of the operation does not align with the approved template, or if the RMP has been tailored to better reflect the operation. In this case the evaluation should be limited to the activities that fall outside the scope of the approved RMP template, or those aspects of the RMP that have been changed.

You will need to ensure the operator has validated any aspects of the RMP that have been tailored (where necessary), or that they have a protocol to describe how validation will be carried out after registration of the RMP.

MPI Operational Codes, templates or RMP models can be found on the MPI website or by searching for 'Codes of Practice'.

4.4 Evaluation against other documents

Other credible technical resources can be used to assist with evaluation. These can be particularly useful if the RMP covers new or emerging processes or products. For example:

- Codex Alimentarius International Food Standards;
- standards and guidance developed by other regulatory authorities, e.g. Canadian Food Inspection Agency, US Food and Drug Administration, US Department of Agriculture, European Commission, or the Australian jurisdictions (e.g. NSW Food Authority);
- non-MPI industry Codes of Practice;
- technical publications;
- peer reviewed scientific literature; or
- predictive models (e.g. Pathogen Modelling Programme, Food Spoilage & Safety Predictor, ComBase).

4.5 Evaluation of multi-business RMPs

A multi-business RMP (MBRMP) is a programme that is applied to more than one business. When evaluating a MBRMP, Section 17A of the APA requires the operator to have sufficient control, authority, and accountability for all matters covered by the RMP. The operator must maintain full records of the agreement(s) made with the other businesses [RMP Spec 20].

If a premises needs listing for export purposes, it cannot 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 their own RMP. However, this would not prevent operators from using the same RMP and having their own registration.

When you are evaluating a MBRMP, the same information is required but details must be provided for each business. For more information about what you need to consider when evaluating MBRMPs, see Appendix 3: Evaluation of multi-business RMPs.

4.6 Evaluation of significant amendments

A significant amendment to the RMP will need to be evaluated and registered [APA 25]. Your evaluation should focus on those parts of the RMP that are affected by the amendment, including any updates to supporting systems (e.g. GOP, cleaning and sanitation, process control etc.) (refer to the Section 4.9 of the RMP Manual for more information).

An on-site assessment may or may not be required depending on the nature of the amendment and whether it involves the physical premises. An on-site assessment would be expected for most significant amendments involving design and construction of the premise. You must provide reasons in the evaluation report if an on-site assessment was not carried out [RA Notice 28(4)].

An evaluation report must be prepared and include the appropriate recommendations, conditions and statements [RA Notice 31(1)].

4.7 Pre-registration assessment

To assist operators, MPI can pre-assess the RMP documentation before the premises construction is complete. Pre-registration can occur in situations where the RMP documentation is complete and unlikely to

change prior to registration, and the premises construction is at a stage of 'practical completion' (refer to the section 7.2 of the RMP manual for more information).

You will need to prepare an interim evaluation report that the operator will submit together with the RMP documentation to MPI for the pre-assessment. The documentation will be assessed by MPI and any changes needed prior to registration can be made by the operator. The application will then be put on hold until the final on-site assessment of the completed premises has occurred and at that time following the final on-site assessment, you can finalise the evaluation report for the operator. Provided there are few (if any) changes to the RMP documentation, the time to complete registration may be reduced and the operator can begin processing.

If the operator is using this approach to assist in the registration process, you will need to state this in your evaluation report.

5 Desk-top assessment

The desk-top assessment requires you to assess that the RMP is complete and meets the requirements of the APA and subordinate legislation.

You will need to check the RMP has the required information and can manage all of the hazards and other risk factors identified. Refer to Table 1: Example of desk top checks and the RMP manual for information to check for during a desk-top assessment.

If there are any problems are identified during the desk-top assessment, provide feedback to the operator but not the solutions.

Table 1: Example of desk top checks

RMP Content	Evaluator checks
Operator, business and RMP identification [APA 17] • Name of RMP operator; • Postal and physical address of operator; • Business covered by the RMP; • RMP identifier; and • Business ID.	All information is provided and correct.
List of RMP documents [RMP Spec 12]	Documents have correct version control. All documents are listed, including record forms. Documents clearly indicate if they are included or excluded from the RMP.
Management authorities and responsibilities [RMP Spec 15(1)] • Day-to-day manager of the RMP; and • Evidence of sufficient control and consent for a multi-business RMP.	Day-to-day manager of the RMP have the appropriate competency requirements. Name, position or designation of back-up day-to-day RMP manager is documented.
Scope of RMP [APA 12] • Physical boundaries; and • RMP Scope (any exclusions and shared facilities).	The site plan is complete and to scale. Shared facilities or any exclusions from the RMP are identified. Shared facilities are managed effectively and procedures are documented. Interface between different regulatory regimes can be managed effectively and are documented.
Animal material and animal product description [APA 17(1)] • Animal material or animal product entering or leaving RMP; • Intended purpose; • Limits (regulatory limits and operator-defined limits); • Actions to be taken when limits are not met; and • Other product details.	Everything that is received and processed under the RMP is documented (AP49 form should be used). Intended purpose of the products are documented. All relevant regulatory requirements (e.g. Animal Products Regulations and Notices, FSC) are addressed. Relevant regulatory and/or operator-defined limits have been identified. Operator-defined limits are justified with appropriate evidence. For potentially incompatible activities (e.g. products intended for general and vulnerable populations, or processing raw and ready-to-eat products), you need to determine the controls are adequate to manage the interface. Consider:

RMP Content	Evaluator checks
	• process flows; • the potential for cross-contamination; • cleaning and sanitation between activities; • management of personnel to ensure adequate separation; • traceability; and • correct labelling. Physical separation may be the only acceptable control measure. RMP should not be recommended for registration until the incompatible activities have been addressed and the controls are adequate.
Process description [RMP Spec 9] • All inputs; • All outputs; and • Process flow diagrams.	All products within the RMP scope are captured accurately. Process flow is in correct order with no missing steps. Any rework steps are included. Products can only be grouped into single process descriptions if this would not adversely impact hazard identification and the development of control measures. Products and processes intended to be carried out in the future can only be included in the RMP if the equipment is: • ready to operate; and • validation is complete, or a validation protocol is documented and evaluated. Otherwise the products and processes should be included in the RMP at a later date, where necessary as a significant amendment.
Supporting systems [RMP Spec 11] • Refer to the section 4.9 Supporting systems in the RMP manual for the full list of supporting systems.	All relevant supporting systems for good operation of the RMP are included, appropriate and complete. Appropriate procedures are documented to manage cross-contamination (particularly important for allergens). Content of supporting system is tailored to the operation, personnel responsibilities and actions are clearly stated. If the operator has referenced rather than included sections from a Code of Practices, make sure the operator has read the relevant sections and the references are correct. If the operator has developed alternative procedures, they may need to validate their process and provide supporting evidence. Disposition procedures (including actions to prevent recurrence) for affected product in the event of non-compliance are documented. You may need to review evidence to confirm certain aspects of the supporting systems, e.g.: • water testing results; • training courses completed; • packaging guarantees; • capacity and capabilities of chillers and/or cookers; and • equipment calibration certificates.

RMP Content	Evaluator checks
	Supporting systems that form part of a registered RMP must be evaluated each time they are included in a new RMP. Operator will need to tailor the supporting system, and where necessary, re-validated for the new RMP.
Operator verification (included under supporting systems) [RMP Spec 16(1)]	operator verification is robust and sufficient for the business.
Recall procedures (included under supporting systems) [APA 17(2)]	A recall procedure must be included in the RMP, except where the product is intended to be consumed immediately. Refer to the guide Recall Guidance Material for more information on recall procedures.
Application of HACCP [APA 17(3)] • Hazard identification and analysis; • Identification of control measures; • Uncontrolled hazards; • Critical Control Point (CCP) determination; • Establish critical limits; • Establish CCP monitoring; • Establish corrective actions; • Establish operator HACCP verification procedures; • Confirming the application of HACCP; and • Establish HACCP documentation and records.	Evidence supporting HACCP identification and analysis is sufficient and technically correct. Risk factors identified and the corresponding control measures applied are appropriate. Adequate justification and evidence provided when a hazard is eliminated or reduced to an acceptable level at a particular step. Adequate explanation and justification for hazards that have been omitted, otherwise they will need to be included in the hazard analysis. If there is little published information about the hazards to human and/or animal health for materials being processed, the operator should do their own research. This needs to be completed to your satisfaction, otherwise the affected materials and products cannot be included in the RMP. Operator has correctly identified and justified CCPs at steps where control can be applied and are essential for food safety. Some processes may not have CCPs. For processes with no CCPs, check hazards can be effectively managed by the supporting systems. Defined critical limits are justified and can be monitored in real-time. HACCP principles (e.g. limits for parameters, monitoring, corrective action procedures, operator verification or records) are documented.
Identification and control of risks to wholesomeness [APA 17(2)]	Risk factors identified and the control measures applied are appropriate and documented in the RMP.
Identification and control of risks from false or misleading labelling [AP Reg 8 and 19]	Mandatory labelling requirements (e.g. FSC) are correctly identified in the RMP. Any false or misleading labelling risk factors that are reasonably likely to occur have been identified and the corresponding control measured applied are appropriate. Ingredients lists are accurate (including correct animal species and allergens). Check label claims (words or pictorial representations) are not false or misleading. The operator should have the verifiable information to support these claims.

RMP Content	Evaluator checks
	Safe handling and storage instructions are included on the label (where needed). Cooking instructions are valid. Shelf life is appropriate for the product and the date mark is accurate on the product's label. Documented procedures to ensure the correct packaging is applied to the product. Documented procedures to ensure new label designs are correct.
Validation [RMP Spec 18(1)] • Completed validation work; or • A validation protocol (e.g. an experimental plan) showing details of the evidence required, how it will be collected and a timeframe for the work to be done.	The operator needs to demonstrate the RMP is effective. Due to the complexities of validation and the large variations in approaches that may be, you will need to evaluate each RMP validation on a case-by-case basis. The operator should prepare a validation report. Check for the following: • appropriate data collection and analysis methods; • appropriate process parameters are selected; • data shows the process meets parameters; • data is directly applicable to the operation (i.e. they have not been altered since the validation); • data showing non-compliance have not been excluded; • compliance to GOP; • data from predictive models back up with actual measurements from the process; • reputable technical publications used; • skills of people involved in validation; • where necessary, accredited or recognised laboratories have been used; • appropriate and accurate data analysis; • adequacy of the results (repeated testing until desired results are obtained is not acceptable); • evidence supports the conclusions made; and • validated parameters have been transferred to the operating procedures. For the validation protocol, check for the following: • appropriate data collection and analysis methods; • reasonable timeframe to complete validation; and • how the animal material and animal product will be disposed of during the trial work. The operator may deviate from the protocol if it does not provide them with the correct information, however, the animal material or animal product made cannot be traded. If the operator intends to trade the product, the modified protocol will need to be re-evaluated but this does not need to be submitted to MPI for registration. You must keep a record of the protocol re-evaluation.
Provision for verification activities and verifiers rights [APA s77E)]	All verifiers rights are provided (clause 17 of the RMP Spec is included in the RMP).

RMP Content	Evaluator checks
	The operator must not add any further requirements that override these rights.

5.1 Use of technical expertise and other recognised evaluator

When you are evaluating any aspect of the RMP that is outside of your competency you must seek assistance from a technical expert or another recognised evaluator [RA Notice 25(1)]. The decision to seek input may not always be clear-cut, but ultimately you should have confidence in the final evaluation report recommendations. If you are in doubt, it is recommended to either obtain technical input or contact MPI to discuss further.

A record of the aspects of the evaluation that he or she is responsible for needs to be agreed upon and documented. The technical expert or other recognised evaluator will need to submit a supporting report indicating those aspects that they evaluated and whether they are valid. The supporting report will need to be included as part of your evaluation report [RA Notice 29 (1) (m)].

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, a supporting report [RA Notice 29(1) m)] and formal competency assessment is not required.

5.1.1 Competency assessment of technical experts

You will need to carry out a competency assessment of the technical expert to determine whether they are able to perform the task [RA Notice 25(2)]. This will need to be done before the work is carried out. This includes checking the technical expert has the required competencies (e.g. any mandatory qualifications for a sector), training and experience. The report of the competency assessment is to be included with your evaluation report [RA Notice 29(1) (n)].

Follow your quality system (see Table 6: Competencies of responsible persons in the RMP Manual) when assessing the competency of a technical expert and ensure that records are kept.

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; and
- experimental design.

6 On-site assessment

You must visit the RMP premises and conduct an on-site assessment when the premises and equipment are ready to operate in accordance with the document RMP [RA Notice 28(1) and (2)]. Before visiting the site you should have a clear understanding of the aspects of the RMP you wish to target.

When carrying out an on-site assessment, you should check:

- physical boundaries of the RMP is appropriately documented;
- design, construction and suitability of the facilities and equipment, including any shared facilities;
- operations align with the documented RMP (where practicable, the operator should demonstrate normal operations during the on-site assessment);
- all personnel have a good understanding of their responsibilities (e.g. managers have a good understanding of the RMP);
- process flows, inputs, outputs, packaging flows, personnel, waste, and essential services are appropriate for the operation and the types of products made;
- supporting systems are effective. If problems are identified, the operator should be instructed to review their systems until you are satisfied;
- HACCP principles have been applied effectively; and
- any evidence and records that are available to support your determination about the appropriateness of the RMP. If the documents weren't available during the on-site assessment, you can arrange to have them within an agreed timeframe with the businesses.

Initial on-site assessments sometimes highlight a range of issues that will need to be addressed (e.g. constructional issues). It is likely that multiple site visits may be needed.

You may need to keep records (e.g. photos, videos of processes, photocopies of documentation) to assist with writing your evaluation report. These records must be kept in accordance with the procedures that were assessed as part of your application for recognition [RA Notice 9].

If the premises is a fishing vessel or a mobile premises, the on-site assessment may be completed at the homeport or home base. You should question how operations will be carried out at other locations so that you can assess whether all hazards and other risk factors that are likely to occur have been considered and will be appropriately managed (e.g. water supply and availability of essential services).

The on-site assessment may be performed by a technical expert if agreed with MPI [RA Notice 28(3)].

6.1 Exemptions from on-site assessment

An on-site assessment is required for new RMPs unless an exemption has been granted by MPI in writing [RA Notice 28 (5)].

When you are evaluating a new RMP, an exemption from an on-site assessment may be considered if:

- it is part of a MBRMP (and an onsite evaluation has already occurred for one of the other businesses covered by the MBRMP);
- it is based on a COP, model or template approved under section 12(3A) of the Act; or
- the level of risk to human or animal health is such that an on-site assessment is considered not necessary [RA Notice 28(5)].

The exemption will need to be granted by MPI before the evaluation is completed. You should provide a written justification to MPI on why an exemption should be considered.

6.2 Amendments to an existing RMP

An on-site assessment may or may not be required depending on the nature of the amendment (significant or minor). You must provide reasons in the evaluation report if you decide an on-site assessment is not necessary [RA Notice 28(4)].

For significant amendments involving design and construction of the premises, an on-site assessment would be expected.

7 Outcome of evaluation

When you have completed your evaluation, the RMP may either be:

- recognised as valid and a recommendation for registration made, with or without conditions;
- recognised as incompletely confirmed as valid and a recommendation for registration made, with conditions; or
- returned to the operator for further work.

Each of these outcomes are discussed in Table 2: Outcome of evaluation and steps to take.

Table 2: Outcomes of evaluation and steps to take

Outcome of evaluation	Evaluator's actions	Content of the evaluation report
RMP recognised as valid and a recommendation made, with or without conditions.	Prepare an evaluation report if the operator has provided sufficient evidence that the RMP can produce animal material and/or animal product that is fit for its intended purpose. The operator will submit the evaluation report to MPI when applying to register their RMP.	• Outcomes of the evaluation; • Recommendation for the RMP to be registered; and • Any condition(s) that should be applied by MPI. Further details on what to include in the evaluation report is discussed in Part 8.
RMP recognised as incompletely confirmed as valid and a recommendation for registration made, with conditions.	If the operator was unable to completely validate their RMP, they can do this after registering their RMP, provided a validation protocol was submitted at the time of registration. You must be satisfied that the RMP **has the potential** to deliver suitable animal material and/or animal product that is fit for its intended purpose. Prepare an interim evaluation report.	• Outcome of the evaluation; • Recommendation for the RMP to be registered; and • Any condition(s) that should be applied by MPI (e.g. timeline of when the RMP will need to be fully validated, restrictions on the trade of animal material and/or product during the validation trials). The statement in clause 31(3)(b) of the RA Notice must be included in the evaluation report and this must be signed and dated.
Returned to operator for further work.	Provide feedback to an operator: • in the areas the RMP is deficient (e.g. when certain requirements have not been met); • on additional resources available (e.g. COP, modelling programmes, RMP consultants). Providing specific advice and solutions will be seen as being involved in the RMP design and development and a conflict of interest. Do not compromise your independence if you intend to carry out any subsequent evaluation of the same RMP. Refer to Appendix 1: Conflict of interest and independence.	Not applicable.

8 Evaluation report

Once you are satisfied with the RMP, you will need to prepare an evaluation report to recommend the RMP for registration (with or without conditions). The evaluation report provides MPI with a summary of your evaluation and the findings from the desk-top and on-site assessments conducted.

The evaluation report must contain the following [RA Notice 29, 30 and 31]:

- Name and recognition identifier of the recognised evaluator;
- RMP business identifier;
- Name and address of the operator;
- Details of the RMP premise (fixed premise, mobile premises or a fishing vessel);
- Type of animal material or animal product to which the RMP applies;
- Principal categories of processing carried out under the RMP;
- Description of other process operations and activities;
- Completion date and brief description of the on-site assessment conducted;
- If an on-site assessment was not conducted, give reasons for this decision;
- List all RMP documents that were evaluated;
- List the basic resources used to develop the RMP;
- Any component of an FCP that is not recognised as part of the RMP;
- Name and identifier of any other animal products recognised evaluators or technical experts used to provide supporting reports;
- The supporting reports prepared by any other animal products recognised evaluators or technical experts;
- Copy of the competency assessment of any other recognised evaluators or technical experts used;
- Confirmation that a verifying agency will be responsible for verification;
- Statement that the outcome of the evaluation is satisfactory;
- Any conditions that MPI should consider when registering the RMP;
- Endorsement of the RMP or RMP outline (by electronic means, initially or signing each page, or any other means);
- One of the signed statements from clause 31(3) of the RA Notice;
- Endorsement of the evaluation report (by electronic means, initially or signing each page, or any other means);
- In the case of a completely validated RMP: a description of the validation work completed and an assessment of the quality of the operator's conclusions;
- In the case of an incompletely validated RMP: a validation protocol describing any work still to be completed; and
- In the case of amendment: removal, if appropriate, of any conditions imposed on a registered RMP.

Endorsement is intended to provide greater confidence to MPI that the RMP and evaluation report have not been modified since the evaluation was completed. Electronic endorsements are further explained in Appendix 2: Electronic file endorsements.

Appendix 1: Conflict of interest and independence

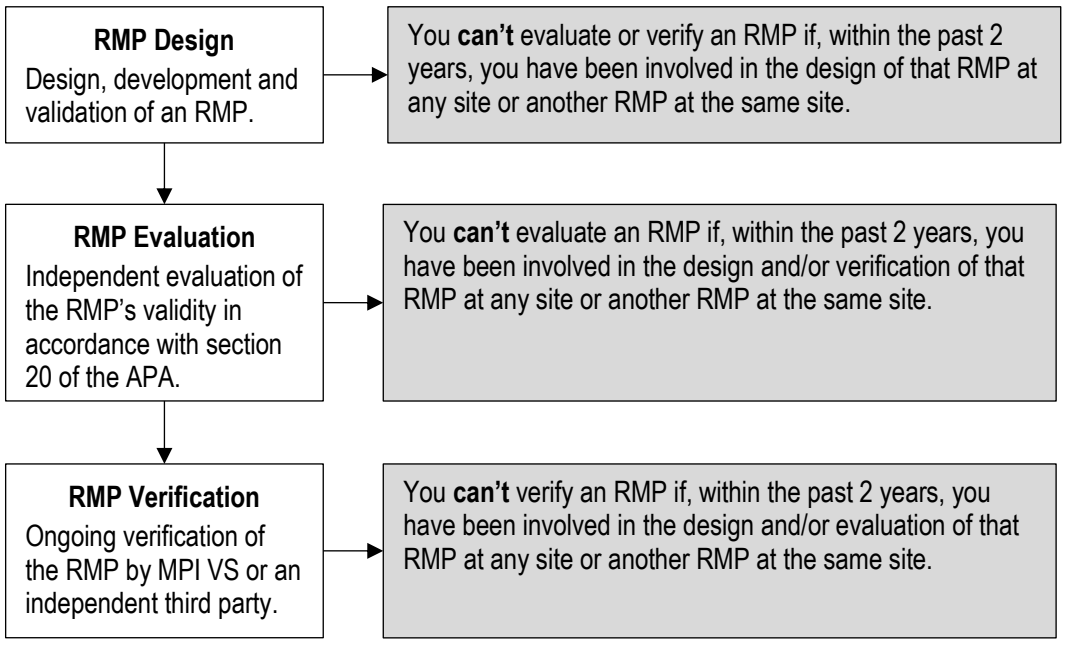
Conflict of interest may be defined as the loss of impartiality in an organisation's or individual's decisions or actions caused by conflicting interests in the outcome. Recognised evaluators need to be independent of any commercial, financial or other pressures from those to whom the service is provided (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 a recognised 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 a recognised evaluator and verifier may provide both functions, except that a verifier cannot verify an 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 is explained further in Figure 2: Evaluator and Verifier Independence.

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 2: Electronic file endorsements

Appendix 2.1: Operator requirements

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

- File name;
- Number of characters; and
- Last saved (date and time).

Example:

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

Appendix 2.2: Evaluator requirements

When you receive the electronic copy of the RMP from an operator, you must save the document with the required file name in the desired location. It is recommended that the document be password protected to prevent the document from being modified. Password protection will differ depending on the programme the document was created in. If password protection is used, you must not share the password to the operator. Where the RMP or RMP outline comprises a number of files the same password should be used for all these files.

The information in the footer of the document must be updated by the recognised 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; and
- Date modified.

The evaluation report must always reflect the exact properties of the file being endorsed.

File information must be identical on both the evaluation report and the RMP or RMP outline at the time of registration.

Appendix 3: Evaluation of multi-business RMPs

Table 3 Requirements for Various MRRMPs discusses what you should look out for when you are evaluating MBRMPs.

Table 3: Requirements for various MBRMPs

Requirements of RMPs	Type 1 MBRMPs	Type 2 MBRMPs	Type 3 MBRMPs
Description of each MBRMP	A single RMP covering more than one business, where each business conducts processing type operations (processing includes operations carried out at stores).	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).	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.
Operator, business and RMP identification	Operator must keep an up-to-date list of all businesses covered by the MBRMP (full legal name and physical address).		
List of RMP documents	All RMP documents must be developed for each business covered by the MBRMP. Clearly identify which documents apply to which businesses. List of RMP documents must indicate those that are common and those that relate to specific businesses. There may be some common documented systems if processing operations for each business are similar.		
Management authorities and responsibilities	Responsible persons must be clearly documented for each business. Include evidence of sufficient control, authority, accountability and consent for each business to be covered by the RMP (e.g. contract with each business, letter of consent for each business).		
Scope of RMP	Physical boundaries for each business must be provided, e.g. site plans for each business. Scope of operations and activities of each business must be clearly stated. If some businesses operate under another regulatory regime, this must be described in the MBRMP in accordance with clause 5(5) of RMP Specs. Each business will require an on-site assessment as part of evaluation. When new businesses are included, a significant amendment is required. If removing a	Including and removing businesses from the scope of the MBRMP is controlled by the operator. Inclusion of new businesses often involves a formal agreement between the business and the operator. A significant amendment is not required to do this. MPI does not hold a list of all businesses registered under that MBRMP.	Requirements of type 1 for each processing business and the requirements of type 2 for the supplying businesses.

Requirements of RMPs	Type 1 MBRMPs	Type 2 MBRMPs	Type 3 MBRMPs
	business, the operator will need to notify MPI.		
Animal material and animal product description	The scope of operations and the activities undertaken by each business must be clearly stated in the RMP. If a MBRMP is registered for a certain category of processing, animal material or animal 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 registered for one business, a significant amendment will be required to allow another business to commence that processing).	Clear identification of which details apply to which businesses. Operator-defined limits must be appropriate to each business. Evidence must be collected by each business or there must be clear justification for applying evidence from one business to another.	
Process Description	Inputs, outputs and process operations must be tailored to each business.		
Supporting Systems	Must indicate those procedures that are common and those that relate to specific businesses. Data to confirm that the control measures are effective and consistently achievable must be collected and analysed for each business.	Traceability of animal material and animal product is very important for operations of this nature and the documented system for this must be robust.	Requirements of type 1 for each processing business and the requirements of type 2 for the supplying businesses.
Operator Verification	Operator verification must be managed by a responsible person at each business and the recognised verifying agency treats each business as a separate RMP.	Tailored to each business as appropriate, e.g. identification of responsible personnel.	Requirements of type 1 for each processing business and the requirements of type 2 for the supplying businesses.

Requirements of RMPs	Type 1 MBRMPs	Type 2 MBRMPs	Type 3 MBRMPs
Recall Procedures	Tailored to each business as appropriate, e.g. identification of responsible personnel.		
Application of HACCP	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. Evidence used in the decision making process must be appropriate to each business. 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).	A full identification and analysis of hazards reasonably likely to occur must be conducted for all animal material and animal product within the scope of the MBRMP, including consideration of any hazards from the environment from which it has been taken. Must be tailored to each business where necessary (e.g. responsible personnel, methods for monitoring, corrective actions etc.). Data to confirm control measures are effective, consistently achievable must be collected and analysed for each business.	Requirements of type 1 for each processing business and the requirements of type 2 for the supplying businesses.
Identification and control of risks to wholesomeness	Identification and controls tailored to each business as appropriate.		
Identification and control of risks from false or misleading labelling	Identification and controls tailored to each business as appropriate.		
Provision for verification activities and verifier's rights	Must be clear in the document from the 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.	On-site verification of each business by the RMP operator is required to ensure that all businesses are operating in accordance with the RMP. The operator must document in the MBRMP the frequency of this verification and the procedures that will be followed.	Requirements of type 1 for each processing business and the requirements of type 2 for the supplying businesses.