Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Risk Management Programme Manual

For Animal Product Processing

A guidance document issued by the Ministry for Primary Industries

New Zealand Government

Title

Guidance Document: Risk Management Programme Manual

About this document

The guide has been developed to assist animal product businesses to develop and operate their RMP.

Related Requirements

(1) Animal Products (Requirements for Risk Management Programme Outlines) Notice 2008

(2) Animal Products (Risk Management Programmes Specifications) Notices 2008

Document history

Previous Version Date	Current Version Date	Section Changed	Change(s) Description
October 2009	November 2017	All	New format and branding. Additional information on validation.

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Contents

Page

1 Purpose

The Risk Management Programme (RMP) Manual has been prepared by the Ministry for Primary Industries (MPI) to help you as an animal product business operator to develop and operate your RMP. The manual provides answers to the following types of questions:

- What is an RMP?
- Who needs an RMP?
- What resources are available to help you develop an RMP?
- What do you need in an RMP?
- How do you get an RMP evaluated and registered?
- How do you operate and amend an RMP?

2 Background

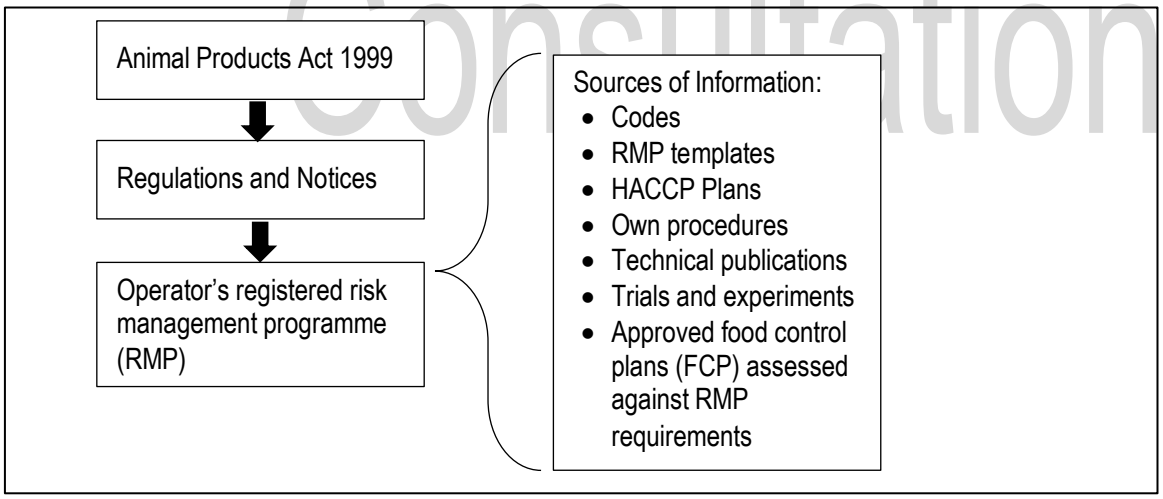
MPI is accountable for food/animal product control in New Zealand and for the implementation and overall performance of the regulatory framework. This has been established to define MPI's responsibilities as a regulator, the responsibilities of recognised agencies and persons, and you as the animal product business operator.

You as operators of animal product businesses must take responsibility for producing suitable animal material and products that are fit for their intended purpose. Animal product businesses should not rely on MPI or recognised agencies and persons to ensure the delivery of safe and suitable animal products.

2.1 The Animal Products Act framework

The Animal Products Act 1999 (APA) sets up New Zealand's legal framework for processing animal material and products that all operators must comply with (as described in Figure 1: Animal Products Act Framework below).

Figure 1: Animal Products Act framework



The APA and its subordinate legislation are administered by MPI. The risk management system under the APA provides for:

- the management of identified risk factors to ensure that products are fit for their intended purpose (for human or animal consumption); and
- facilitating access to overseas markets.

The risk management system comprises four main types of controls:

- Risk Management Programmes (RMPs);
- Regulated Control Schemes (RCS);
- export requirements; and
- the imposition of authorisations and duties on various persons.

Each of these is explained in the following clauses 2.1.1 to 2.1.4.

Regulations under the APA can be found by searching for 'Animal Products regulations' on the New Zealand Legislation website.

You can find a list of APA Notice by searching for 'Animal Products Act Notices' on the MPI website.

2.1.1 Risk Management Programmes (RMPs)

(Part 2 of the APA)

An RMP is a documented programme designed to identify and control risk factors in relation to the production and processing of certain animal materials and products. This is to ensure that the resulting animal product or material is safe and suitable. The RMP is based on the principles of Hazard Analysis and Critical Control Points (HACCP).

There are four types of risk factors:

a) risks from hazards to human health;
b) risks from hazards to animal health;
c) risks from false or misleading labelling; and
d) risks to the wholesomeness of animal material or product.

The first two points are collectively known as "hazards". The second two are known as "other risk factors".

To find out what is required to be included in an RMP, APA s17 must be read in conjunction with:

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

2.1.2 Regulated Control Schemes (RCS)

(Part 3 of the APA)

A regulated control scheme (RCS) is a scheme developed by MPI to manage risks, where:

- RMPs would not be feasible or practicable;
- it is more efficient for the government to run the programme; or
- it is needed to meet the market access requirements of foreign governments.

Examples of regulated control schemes include the Animal Products (Regulated Control Scheme – Contaminant Monitoring and Surveillance) Regulations 2004, and the Animal Products (Regulated Control Scheme – Bivalve Molluscan Shellfish) Regulations 2006.

2.1.3 Export requirements

(Part 5 of the APA)

There are general requirements for export (GREX) that apply to all exporters of animal materials or animal products. The exported products must meet New Zealand standards and comply with any additional requirements set by destination countries or markets (these are called Overseas Market Access Requirements (OMARs)) [APA 7].

It is your choice whether or not to include export requirements in your RMP (for animal products and dairy). For example, operations that are geared for markets such as the EU or the US may choose to incorporate OMARs into their RMP. You must comply with the overseas requirements for the countries that you are exporting to, regardless of whether you incorporate them as part of the RMP [APA 60(1)].

2.1.4 Imposition of authorisations and duties

(Part 8 of the APA)

MPI can recognise agencies and persons to carry out certain functions and activities (e.g. evaluation and external verification of RMPs). MPI maintains a public register for all recognised agencies and persons on the MPI Registers and lists webpage and you can find them by searching for the following lists:

- Animal Products Recognised people – evaluators;
- Animal Products Recognised people – verifiers;
- Dairy laboratories – recognised agencies;
- Dairy – recognised agencies;
- Recogsnied Laboratory Programme (RLP) Laboratories.

In addition, the APA imposes duties on key persons. These are the:

- RMP operators (see Part 8.1 RMP operator's duties and section 16 of the APA);
- exporters (see section 51 of the APA);
- recognised agencies (see section 101 of the APA); and
- recognised persons (see section 103 of the APA).

If these persons do not comply with their respective duties, the APA allows for a number of measures to be taken. This can include increased external verification of RMPs, suspension or deregistration of RMPs, deregistration of exporters and removal of recognition of agencies or persons. In addition, those who commit offences under the APA are liable to be prosecuted, and if found guilty, could be fined and/or even imprisoned.

2.2 Businesses requiring an RMP

See Appendix C: Businesses Requiring RMPs for details of the types of businesses that require an RMP.

2.3 Businesses not requiring an RMP

See Appendix D: Businesses Not Requiring RMPs for details of the types of businesses that do not need an RMP.

2.4 RMP configurations

You can develop an RMP as a stand-alone programme for each:

a) type of animal material or product;
b) type of process or operation; or
c) premises or place.

An RMP may also cover one or more materials, products, processes, operations, places or premises.

An RMP may be developed for a single business or cover multiple businesses.

2.4.1 Single-business RMPs

(Section 12(3) and 12(4) of the APA)

Single-business RMPs can be:

a) single-site, with one RMP (this is the simplest form of RMP);
b) single-site, with more than one RMP (this is useful if the operations are split in a logical way, but the overall cost to the business of registration and evaluation of the RMPs would be higher);
c) multi-site, with one RMP (this is useful if all sites operate in a similar manner. It may be necessary to add site-specific details to parts of the RMP. You must be aware that changes to the RMP may impact on all of the sites that have been included); and
d) multi-site, each with more than one RMP (this is complex and should be avoided unless there are logical reasons for such an arrangement. It would add to the overall cost to the business of registration and evaluation of the RMPs).

The number of RMPs you will need depends on the complexity of the operation and how practical it is to maintain and manage each one. Multiple RMPs give you flexibility if one area of operation is substantially changed in the future, or one RMP is suspended or deregistered. Export requirements may limit the ability to use multi-site options e.g. EU-listed premises (apart from dairy) must have separate RMPs for each physical location.

2.4.2 Multi-business RMPs

(Section 17A of the APA)

An RMP may apply to more than one business, upon approval by the Director-General (D-G). A multi-business RMP is only appropriate for businesses that have similar operations and where all operators have agreed to operate under one RMP. The legal requirements for RMPs also apply to multi-business RMPs [RMP Specs 4(2)].

You must apply for approval of a multi-business RMP when applying for registration, or when applying to amend an existing RMP. Approval of a multi-business RMP will require you to demonstrate that:

a) the RMP is appropriate to all businesses or part-businesses that it covers;
b) you will have sufficient control, authority and accountability for all matters covered by the RMP in relation to other businesses or part-businesses subject to its coverage; and
c) you have obtained the consent or otherwise taken into account the views of any person whose business or part-business is covered by the RMP.

Approval may be given subject to conditions. Approval will normally relate to specific businesses, but may relate to a type of business, premises or place if such a “general approval” provides negligible risk to human or animal health.

2.5 Relationship between the APA and other legislation

2.5.1 Food Standards Code

The Food Standards Code sets out the standards relating to labelling, composition and contaminants of food available in New Zealand and Australia. The Food Standards Code is developed by Food Standards Australia New Zealand (FSANZ).

The Food Standards Code will apply regardless of whether operations are managed under a food control plan (FCP) under the Food Act 2014 or an RMP. This means that all RMP operators must comply with the Code.

You can access the Food Standards Code here: http://www.foodstandards.govt.nz/code/Pages/default.aspx.

2.5.2 Food Act 2014

The Food Act 2014 introduced a risk-based and outcome-focused approach to managing food safety. Food businesses that are higher risk from a food safety point of view will operate under more stringent food safety requirements and checks (i.e. an FCP) than lower-risk food businesses (i.e. national programme).

Businesses who are doing secondary processing of animal products with a domestic focus can operate under the Food Act 2014.

Operating under an RMP

(Section 32 of the APA)

Some animal product businesses do not need to operate under an RMP but may still choose this over other options such as an FCP. Choosing to operate under an RMP can allow you to more easily take advantage of future export opportunities for animal products. However an RMP can only be used if the processing involves animal materials or animal products.

Once an RMP is registered for a secondary processor (e.g. honey extractors, dual operator butchers, etc.) MPI will notify the relevant territorial authority. This is in addition to other notifications required for a registered RMP.

Operating under an FCP registered as an RMP

(Section 34 of the APA)

If your business currently operates under an FCP, you may wish to register your FCP as an RMP so that it can be operated under this system on an intermittent basis only. This may be an option if you only occasionally intend to process animal product for export under the RMP and the rest of the time operate under the FCP. You must meet any OMARs applicable to your business while operating the RMP for export purposes.

You must notify MPI of the decision to operate under an RMP on an intermittent basis when applying for registration [RMP Spec 5(5)]. When operating the RMP, the requirements under the APA apply, including any conditions specified by MPI. During this time, the FCP requirements do not apply.

MPI will decide whether verification will be carried out under the APA or the Food Act or both. You can change your mind at any time and withdraw your application to operate under an RMP.

MPI will notify the relevant territorial authority once the RMP is registered. This is in addition to other notifications required for a registered RMP.

2.5.3 Agricultural Compounds and Veterinary Medicines Act 1997

All agricultural compounds imported, manufactured, sold or used in New Zealand must be authorised under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and its regulations.

The production of petfood in New Zealand is legislated under both the APA and ACVM. For example:

a) the primary processing of animal products for petfood (e.g. slaughter and dressing of mammals and birds) is covered by the APA and an RMP is required for these operations; and
b) the labelling of manufactured petfood is covered under ACVM.

2.5.4 Medicines Act 1981

Clause 5 of the Animal Products (Exemptions and Inclusions) Order 2000 exempts secondary processors of animal products that are a medicine or a related product under the Medicines Act from the requirement to have an RMP and to meet Parts 2 to 4 of the APA.

If an official assurance under the APA is required for the medicine or related product then an RMP is required. Dietary supplements containing animal products will need to comply with the APA and the Dietary Supplements Regulations 1985. It is the sponsor's (the person legally responsible for placing the product on the market) responsibility to ensure the product is made to an acceptable quality, is safe to use and complies with the law.

3 Resources for developing an RMP

MPI has developed various resources to assist you when developing your RMP:

a) Risk Management Programme Manual (this manual);
b) Codes, templates and RMP models;
c) guidance documents;
d) HACCP plans;
e) other procedures;
f) peer-reviewed scientific information;
g) predictive models; and
h) food control plans (FCP).

Writing your own RMP requires specialist skills, particularly in relation to HACCP application and the identification and analysis of risk factors. You should seek external assistance (see Part 3.8 RMP Consultants) if your own resources or skills are limited.

3.1 Codes, templates and RMP models

MPI has approved Codes, templates and RMP models under the APA that meet regulatory requirements which an RMP can be based on. These documents usually cover good operating practice (GOP), HACCP application and other RMP requirements. If you follow approved Codes, templates or RMP models it will:

- assist you to use current best practice or acceptable industry practices and procedures;
- assist you to address the relevant regulatory requirements within your RMP; and
- simplify the evaluation (where an evaluation is required) and external verification of RMPs that are based on the approved document.

MPI approved Codes, templates and RMP models can be found by searching for 'Operational Codes' on the MPI website.

3.1.1 Codes

A Code of Practice or Operational Code (Code) is a document which reflects agreed industry practice and provides information on how to meet regulatory requirements. A Code may incorporate an RMP template and/or model.

Parts of the Code that are directly applicable to your business may be incorporated into your RMP by reference. If you follow the recommendations in the Code you will only need to comply with the requirements, rather than having to prove the validity of the procedures.

3.1.2 Templates

A template is a simplified RMP form with prompts for each mandatory requirement and areas which can be tailored to the operation, e.g. a "fill in the gaps" document.

In most cases, if your RMP is fully based on an approved template, the requirement for evaluation will be waived. Refer to the Waiver of the Requirement to Provide a Copy of an Independent Evaluation Report for more details.

3.1.3 RMP models

A model is an incomplete RMP that will need to be tailored to your specific products, processes and premises. The extent of this will vary depending on how applicable the model is to your business.

Generic RMP models have been produced by MPI, in consultation with various industry working groups. The models show how the principles of HACCP can be applied and how RMP components could be written for various processes (e.g. slaughter and dressing, cutting and boning operations for cattle, farmed deer, sheep and bobby calves, etc.).

Usually the generic RMP models are based on New Zealand requirements only. However some RMP models do incorporate OMARs for specific countries - in these cases OMARs will be clearly differentiated from the New Zealand requirements. This usually happens when a significant number of processors export to the same country.

3.2 Guidance documents

MPI has developed various guides that operators may find useful:

- What is Validation? provides information on validation concepts;
- How to determine the shelf life of food can help operators determine the shelf life of their products and how to apply the appropriate date marking; and
- *Listeria* Factsheets and guidance provide information on *Listeria* and key good operating practices for the management of *Listeria* in the processing environment.

3.3 HACCP plans

Hazard Analysis and Critical Control Point (HACCP) is an internationally recognised system used to identify and manage food safety hazards. HACCP can be used throughout all stages of the food chain, from primary production to final consumption. The application of HACCP principles in a risk-based management programme such as RMPs is compulsory and is one way of satisfying hazard analysis for FCPs.

MPI has developed HACCP guidance and generic HACCP plans to assist RMP operators:

- Standardisation of Hazard Analysis and Critical Control Point (HACCP); and
- MPI Hazard Database has searchable information on food safety hazards that is reasonably likely to occur in New Zealand, including applicable regulatory limits and actions operators can take to control the hazards.

3.4 Other procedures

You may have access to documented food control or quality assurance systems that meet customer requirements (e.g. ISO 9001, FSSC 22000, etc.). It is likely that relevant parts of these documented systems can be incorporated into the RMP by reference and do not conflict with any regulatory requirements. You will need to make sure that RMP components that are not covered by these systems are added to complete your RMP.

3.5 Peer-reviewed scientific information

You may use scientific literature published in reputable journals (i.e. peer reviewed and appropriately referenced) as a basis for establishing or justifying certain procedures and criteria used in your RMP. The use of this type of information is only appropriate if the conditions or variables considered in the scientific study are applicable to the process(es) covered by the RMP.

3.6 Predictive models

You can use predictive models to establish product and process parameters. A predictive model is a computer-based software programme that considers the various factors affecting a particular reaction, operation or activity (e.g. growth or decline of foodborne microorganisms in food, a chemical deterioration, etc.).

These models are valuable tools to support hazard analyses, develop critical limits and to evaluate the effect of process deviations. They may also be used to predict the effectiveness of corrective actions but should not be used in isolation from other resources. Parameters used in predictive models should match process parameters, otherwise estimates are likely to be misleading.

Examples of some models:

- Pathogen Modelling Programme;
- Food Spoilage & Safety Predictor;
- ComBase;
- *E. coli* inactivation in fermented meats model developed by Tom Ross; and
- Process Hygiene Index (PHI) - the approximation of the potential bacterial growth that can occur during the cooling of meat products from slaughter until the meat has cooled to 7°C.

3.7 Food control plans

(Section 32 of the APA)

You may use a registered FCP as a basis for an RMP but it will need to be evaluated reviewed to ensure RMP requirements that are not covered by the FCP are met e.g. requirements in Notices (HC Specs) under the APA.

3.8 RMP consultants

If you choose to use a consultant to help develop your RMP, it is best to choose one who has relevant industry experience and is either a recognised person (i.e. evaluator or verifier) or otherwise experienced with the APA and RMP requirements.

You can find the list of RMP consultants by searching for 'RMP consultants' on the MPI website under registers and lists.

Note that the consultants on this list are not accredited by MPI and MPI has not carried out any investigation into the qualifications, experience or abilities of any persons listed. The inclusion of a consultant on the MPI list does not constitute an endorsement or recommendation by the New Zealand government or MPI and, before employing the services of a consultant, you need to do the normal due diligence you would when contracting any service provider or tradesperson.

If a recognised person is acting as a consultant to help with the development of your RMP, he/she will not be able to verify or evaluate your RMP within certain timeframes as outlined in the Independent Evaluation and Verification of Risk Management Programme Statement of Policy.

4 RMP development

Often a team approach is advantageous when developing an RMP due to the range of expertise, perspectives and experiences. Members of this team should be selected based on their responsibilities, knowledge and experience of:

- products and relevant processes;
- hazards relevant to the scope of the RMP; and
- food safety practices and principles.

You will need to understand the application of HACCP principles in order to be able to develop and implement an RMP. If this expertise is not available in-house, MPI recommends getting advice from a consultant, or a member of staff to undertake the appropriate training.

4.1 RMP responsibilities

Table 1: RMP Tasks and Responsibilities explains the tasks that need to be completed during the development and implementation of an RMP and who is responsible for each task.

Table 1: RMP tasks and responsibilities

Task	Who is responsible	What the task involves
Development	Operator	Develop the RMP
Validation	Operator	Perform checks and validate the RMP
Evaluation	Operator	Hiring a recognised evaluator to evaluate the RMP
	Recognised Evaluator	Evaluating and reporting on the validity of the RMP
Registration	Operator	Name the recognised RMP verifying agency that has indicated it is willing to verify the RMP
	Operator	Apply to MPI to register the RMP
	MPI	Registers the RMP
Operation	Operator	Contracting a recognised verifier for verifying the registered RMP
	Operator	Implementing and operating the registered RMP
	Operator	Operator verification
	Operator	Application for registration of significant amendments to existing RMP
Verification	Verifier	External verification
Notification	Operator	Notify certain matters to MPI
Cessation	Operator or MPI	• Surrender of the RMP registration • Suspension or de-registration of RMP registration • Voluntary suspension of RMP or part of RMP

4.2 RMP components

The RMP should include components shown in Table 3: Components of an RMP that are appropriate to your products and operation. Components must be documented in writing.

Table 2: Components of an RMP

Component	Part Reference
Operator, business and RMP identification	4.3
List of RMP documents	4.4
Management authorities and responsibilities	4.5
Scope of the RMP	4.6
Animal material and animal product description	4.7
Process description	4.8
Supporting systems	4.9
Application of HACCP	4.10
Identification and control of risks to wholesomeness	4.11
Identification and control of risks from false and misleading labelling	4.12
Validation	4.13
Provision for verification activities and verifier rights	4.14
(Applicable to Dual Operator Butchers only) Additional requirements in relation to homekill and recreational catch providers	4.15

Each of these components are discussed below.

4.3 Operator, business and RMP identification

4.3.1 RMP operator

(Section 17 of the APA)

Your RMP must specify the name and address (including the electronic address, if available) of the operator. The operator may be a company, a partnership or a sole trader. If the operator is a company, then the name must exactly match the details given at the Companies Office, and you must provide your New Zealand Business Number (NZBN), which can be found on your registration from the Companies Office. If the operator is a partnership or a sole trader then the name(s) of the business owner(s) must be given.

You, the operator, have the ultimate responsibility for ensuring that the RMP is effective. You, or the business itself must be resident in New Zealand as defined in section YD 1 or YD 2 (excluding section YD 2(2)) of the Income Tax Act 2007 and you, together with business directors and managers must be fit and proper persons to operate an animal product business.

Definition of 'fit and proper'
A fit and proper person must not have any conviction for an offence, in relation to fraud, dishonesty or negligence, whether in New Zealand or overseas, in regard to running a business of the type covered by the APA.

4.3.2 Businesses covered by the RMP

The name(s) of the business(es) or part-businesses covered under the RMP must be given in their legally correct form. Where there is only one business under the RMP and the business details have already been given as part of the operator details (see Part 4.3.1 RMP Operator) then no further information is required. If the business trades under another name, this must also be provided.

4.3.3 RMP identifier

For non-dairy operators the RMP identifier is a combination of the Business Identifier (see Part 4.3.3.1 Business Identifier) and RMP Number (see Part 4.3.3.2 RMP Number).

For dairy operators the RMP identifier is the Business identifier. Dairy operators must also nominate a Unique Location Identifier (ULI) (see Part 4.3.3.3 Unique Location Identifier).

A unique RMP identifier is to be applied to each RMP (see Table 3: Examples of Identifiers for examples). The unique RMP identifier will appear on the registration documentation for the RMP.

Table 3: Examples of identifiers

Business Identifier	RMP Number	Unique Location Identifier (ULI)
BUS111	01	000
BUS111	02	001
BUS111	03	002

4.3.3.1 Business identifier (business ID)

A unique business ID is needed for each premises or physical location that the RMP applies to. The ID is a number or number/letter combination of at least 3 and not more than 10 characters with at least one numeric character and no leading zeros. You will need to confirm the availability of the business ID with MPI. The business identifier is not be the same as any exporter's registration number.

Further information
For the purposes of carcass brands, inspection legends and carton seals, there is a physical limit of 6 characters.

You should also consider overseas market access requirements (OMARs) when selecting your business identifier, e.g. EU-listed premises must have individual business IDs for each premises. Where appropriate, the business identifier will be used by MPI for country listing purposes and may be used by you for animal product labelling and identification. Any change to an ID must be reflected in updated packaging and country listings. Certain country listings may take 6 - 12 weeks to update, therefore any product produced under the RMP with a new ID may not be eligible for export to the affected countries until country listings have been updated. Once your business ID has been established, it will be used for any future RMP registration applications.

You can check availability of business IDs on the list of registered RMPs by searching for 'RMP register' on the MPI website.

IDs from RMPs that are no longer registered are not available.

4.3.3.2 RMP number (Non-dairy only)

You may operate one or more RMPs under a business ID. Non-dairy operators will need to assign a consecutive two digit RMP number (01-99), to each new RMP. Any amendments to the RMP will need to be identified using the appropriate RMP number to ensure traceability.

4.3.3.3 Unique Location Identifier (Dairy only)

For the purposes of traceability and certification, dairy operators (excluding farm dairy or transport operators) must nominate a unique identifier for **each location** specified in the RMP [RMP Specs 5(3)]. The ULI will appear on the registration documentation for each registered RMP. If the RMP only covers processing at one location the ULI can be the same as the RMP identifier.

You can check the availability of ULI on the MPI website under registers and lists:

a) Dairy - Manufacturing unique location identifiers; and
b) Dairy - Stores unique location identifiers.

4.3.4 Operator, business and programme identification

MPI recommends that information covered in Part 4.3 Operator, business and RMP identification is located at the start of the RMP. Figure 2: Example of RMP Details gives an example the way the information can be presented.

Figure 2: Example of RMP details

Business Identifier:

RMP No:

Unique Location Identifier/s (dairy only):

Name of Operator:

Postal Address of Operator:

Physical Address of Operator:

Electronic Address of Operator:

Name of Business (if different to operator):

Address of Business (if different to operator):

4.4 List of RMP documents

You must develop a list of all the documents that make up the RMP and indicate the date or version of the current documents [RMP Spec 12]. It is not sufficient to name the RMP as a single document without providing further detail. Components of an RMP are shown in Table 2: Components of an RMP.

It is recommended that the list(s) are located near the start of the RMP to make it easy to find the various components. A contents page may be used to meet this requirement (if sufficient details are included), such as Table 4: Example of an RMP Document List.

Table 4: Example of an RMP document list

					Only for multi-businesses
Document Title	**Section Number**	**Section Title**	**No of Pages**	**Version - Date**	**Businesses it Applies to**
Manual A Supporting Systems	3	Cleaning and Sanitation	10	1 - 01/01/2017	All
Manual B					E only
Manual C					All but E

Where only parts of a document are included in the RMP, you should clearly show which parts are included and which are not. This needs to be shown in the RMP document list by referencing those parts of the document that are included or excluded (whichever is easiest).

4.5 Management authorities and responsibilities

(Sections 19(a), 19(b), 22(1) (b) and 22(1) (c) of the APA)

4.5.1 Day-to-day manager of the RMP

You must nominate a person who is responsible for the day-to-day management of the RMP (by name, position or designation) [RMP Spec 15(1)]. This is the person who:

- is the authorised "management representative" for all aspects of the RMP; and
- will deal with MPI over any RMP issues.

This person may be the operator, a senior operational manager, a quality/technical manager or person with similar competencies, authorities and responsibilities.

The day-to-day manager should ensure that he/she is familiar with the RMP and has:

- knowledge in food safety of relevant animal products and hygienic procedures and practices;
- knowledge of regulatory requirements, including responsibilities, related to the effective implementation of the RMP;
- technical knowledge and experience in the particular product/process; and
- able to liaise and communicate effectively with personnel and MPI.

It is acceptable to have more than one day-to-day manager provided their areas of responsibility are clearly documented in the RMP.

MPI recommends that you also identify a back-up person and document how this person is assigned to cover during periods when the day-to-day manager is unavailable.

MPI will need to be notified when the day-to-day manager is changed (see Part 7.6.2).

4.5.2 Evidence of sufficient control and consent for a multi-business RMP

(Section 17A of the APA)

For multi-business RMPs, you must provide evidence that there is sufficient control over the other businesses or part-businesses that it covers, and that you have the consent of those business owners [APA 17A(2)]. Examples of possible evidence include a signed contract or written correspondence between the parties.

4.6 Scope of the RMP

(Sections 12 (3) and 12 (4) of the APA)

The scope describes what is included in, and where necessary what is excluded from, an RMP. You should consider the physical and operational aspects of the RMP when determining your RMP configuration.

4.6.1 Physical boundaries

The physical boundaries are one of the main determinants of the scope of your RMP. You must include a description of the physical boundaries to which the RMP applies [RMP Spec 5(1)]. This can include facilities, equipment, worker amenities, external environment, processing, storage, support areas and even those areas not routinely used.

You can show the physical boundaries in a diagram or site plan of the premises, mobile premises or vessel. An example of a RMP site plan is included in Appendix I: Example of RMP Site Plan. Wherever possible, this should be drawn to scale and have enough detail to be able to readily identify any changes to the boundary. You should include any shared premises (both sites and buildings) and any remote buildings or people living on site.

For multi-business RMPs, you may provide alternative details instead of the physical boundaries for each business, premises or place if agreed with MPI. For example multiple farm dairies operating under a single RMP may have their physical boundaries identified by the operator by assigning an identifier that is specific to each farm dairy and recording its location or address on a register.

If you operate a mobile premises you should show the physical boundaries using a diagram or plan of the vehicle. Ensuring that all appropriate facilities are available at all sites where the premises operates remains your responsibility.

Transport operators can meet the requirement to provide the physical boundaries by maintaining an up-to-date list of the vehicles covered by the RMP.

4.6.2 Clarification of RMP scope

(Section 13 of the APA)

A RMP must consider all relevant sources of potential risk factors that may affect the animal material, animal product, operations or directly associated things within the physical boundaries of the RMP [RMP Specs 5(4)].

Only foods containing animal products can be regulated under the APA. Other foods must be regulated under a FCP or national programme under the Food Act 2014. At present this may require some businesses to register under both Acts.

Exclusions from RMP

You must document:

- any animal material, animal product or food excluded from your RMP;
- the alternative regime under which they are regulated, e.g. another RMP, an FCP/ national programme under Food Act, ACVM Act or Medicines Act; and

- how you will manage the interfaces between the regimes [RMP Spec 5(5)].

When explaining how the interfaces are managed you should clarify:

- the extent of the operation that is under each regime, e.g. by describing the point at which the process changes regimes, rooms used under the different regimes etc; and
- how the other operations impact on the RMP, e.g. shared facilities and equipment.

Shared facilities

If your RMP includes shared facilities, you must document:

- the activities taking place that are not covered by the RMP and the times when these activities occur;
- who is responsible for these activities;
- how the interfaces are managed, e.g. by complete cleaning, physical separation etc; and
- the authorities and accountabilities for resolving issues associated with that activity [RMP Spec 5(6)].

Example of records include:

- a contract stating who is responsible for maintaining specific buildings or equipment;
- how issues are raised; and
- the time frames for satisfactory resolution.

4.7 Animal material and animal product description

(Section 17(1) (c) and 17(2) (c) of the APA)

Your RMP must include a description of the animal material and product it covers [RMP Spec 6(1)]. Table 5: Examples of Product Description gives an example of how this information can be presented (note it is not an exhaustive list).

Table 5: Examples of product description

Requirements	Example 1	Example 2	Example 3
Product	Raw sheep carcasses, cuts, trimmings	Shell eggs	Pasteurised Hard Cheese
Intended consumer	General public	General public	General public
Intended use	• Further processing into manufactured products, retail products, food service items • To be cooked before consumption	• To be cooked before consumption	• Ready to eat
Regulatory limits[1] (additional regulatory limits may apply)	None	• HC Specs 13.38 - 13.43 • Food Standards Code 2.2.2	Maximum limit for[2]: • *Salmonella* spp. ND/25g • *L. monocytogenes* ND/25g • Coagulase positive *Staphylococci* (*S. aureus*) 1000cfu/g • *B. cereus* 1000cfu/g • *E. coli* 100cfu/g 72°C for 15 sec[3]
Operator-defined limits	*To be defined by the operator*	*To be defined by the operator*	*To be defined by the operator*
Other product details	• Packaging and labelling as per company specification (refer to document xx)[4] • Frozen to -12˚C	• Have been candled and packed • To be stored at or below 15˚C with best before date of 35 days from date of lay	• Food Standards Code 2.5.4

4.7.1 Animal material or product entering or leaving RMP

All of the animal materials or products entering and leaving the RMP must be documented including those intended for human consumption, animal consumption, industrial use and waste [RMP Spec 6(1) and (2)].

They may be described individually or in groups, providing the grouping does not compromise the identification and analysis of hazards and other risk factors. Grouping is normally based on having similar inputs, process steps and intended purpose.

[1] If limits exist, then operator must also document actions to be taken when limits are not met.
[2] Limits obtained from DPC1: Animal Products (Dairy): Approved Criteria for General Dairy Processing.
[3] Limit obtained from DPC 3: Animal Products (Dairy): Approved Criteria for the Manufacturing of Dairy Material and Product.
[4] This could be a reference to a company document where the packaging specification is located.

The name or type of animal materials or products required under clause 6(2) of the RMP Spec can be addressed by using a descriptor of the product such as raw, cooked, fermented, dried, canned, smoked, frozen, chilled, etc.

4.7.2 Intended purpose

You must document the intended use of the animal material or product and if appropriate, identify any specific consumer groups, for example:

- human consumption: infants, elderly, pregnant women, immuno-compromised individuals; and
- animal consumption: pets, zoo animals, farmed animals [RMP Spec 6(3)].

Clause 6 (3)(b) of the RMP Spec requires you to document whether the animal materials or products requires further processing, additional preparation by the final consumer or is ready to eat. You should include further details where known e.g. further processing may be described as canning, pasteurisation, drying, etc.

4.7.3 Limits

You must document, in relation each animal material or animal product described in Part 4.7.1, any relevant regulatory limits and any operator-defined limits in relation to:

a) risks from hazards to animal or human health;
b) risks from false or misleading labelling or representation; and
c) risks to the wholesomeness of animal material or animal product [RMP Spec 7].

Regulatory and operator-defined limits define the suitability for processing of animal material or fitness for intended purpose of animal product. Limits that are essential for food safety should be considered when determining critical control points (CCPs) for your process and may result in a CCP or may be adequately covered by GOP.

Examples of regulatory and operator-defined limits can be found in Appendix E: Examples of Limits.

4.7.3.1 Regulatory limits

A regulatory limit is a measurable regulatory requirement that is critical to the fitness for intended purpose of animal material or animal product e.g. microbiological or chemical limits, pasteurisation parameters for milk, cooking times and temperatures for a ham, etc.

Examples of some relevant legislation include:

- Animal Products Notices;
- Australian New Zealand Food Standards Code; or
- Food Standards Notices under Food Act 2014 (including the Maximum Residue Limit Notice).

4.7.3.2 Operator-defined limits

Operator-defined limits are measurable limits that are established by you to manage the fitness for intended purpose of your products. These are limits that are essential for food safety but have not been set in legislation for the specific product or risk factor of concern.

Examples of operator-defined limits are:

- intrinsic parameters of the final product (e.g. pH, moisture content, water activity, etc.);
- microbiological criteria defining the maximum acceptable level of a hazard in a product for food safety. An example is the absence of *C. botulinum* in shelf-stable low acid canned product;

- maximum levels of physical hazards (e.g. foreign material such as metal, bone, glass, etc.); or
- maximum levels of chemical hazard.

You must have evidence to demonstrate that the operator-defined limits you have selected are appropriate to your product, considering its intended use, intended consumer and expected handling after leaving the RMP [RMP Spec 7]. Evidence to justify the selection and level of operator-defined limits may include:

- approved Codes, templates and RMP models (see Part 3.1 Codes, Templates and RMP Models);
- peer-reviewed scientific information (see Part 3.5 Peer-reviewed Scientific Information);
- predictive models (mathematical modelling) (see Part 3.6 Predictive Models);
- scientific information from a person or organisation known to be competent (e.g. the Compendium of Microbiological Criteria for Food issued by FSANZ);
- international standards or journal articles; or
- previous validation studies or historical knowledge on performance of the control measure. You must ensure that the conditions (e.g. raw materials, relevant hazards, combination of control measures, intended use or distribution, etc.) in your particular operation do not differ from the conditions under which the control measure was previously validated.

Referring to that source should be adequate justification if the parameter is taken directly from one of the above sources. If not, you will need to prove that the selected parameter is valid. You may use data from your own experiments or trials (e.g. pilot tests of the process, etc.).

4.7.4 Actions to be taken when limits are not met

You must document the actions that will be taken (e.g. restoration of control, product disposition, preventative action, etc.) if any limits are not met (e.g. *L. monocytogenes* is detected in cooked cured meat, metal is detected in product, etc.) [RMP Spec 8]. You will need to include any response specified by MPI (e.g. increased sampling, rework or disposition) or by an Animal Products Officer.

4.7.5 Other product details

You may also include other details in the product description where appropriate e.g. requirements for post-mortem examination, packaging, storage, shelf-life, labelling, etc.

4.8 Process description

You must document every process or operation carried out under your RMP, including:

a) all inputs;
b) the main activities or steps; and
c) all outputs [RMP Spec 9].

The simplest way to describe your process is to use process flow diagrams showing all:

a) inputs;
b) activities or steps; and
c) outputs.

These diagrams provide the foundation for hazard and other risk factor identification and hazard analysis.

Inputs can include:

- animal materials or animal products e.g. raw milk, live sheep, red meat, fish, eggs, honey, etc.;
- other ingredients e.g. starch, water, salt, spices, etc.;

- additives or processing aids e.g. preservatives, antioxidants, colourings, gaseous packing agent, etc.; and
- packaging.

Your flow diagrams must include the main activities or steps in the process, e.g. any rework, recycling or multiple processing stream, etc. [RMP Specs 9]. If you are submitting an RMP outline for registration, inclusion of key process parameters e.g. processing times and temperatures, will assist MPI to assess your RMP and minimise the amount of further information that may be requested.

Outputs (all animal materials or animal products leaving your RMP) must be shown irrespective of their intended use, e.g. human consumption, animal consumption, industrial/technical use or waste, etc. [RMP Specs 9].

4.9 Supporting systems

Supporting systems includes good operating practices (GOP) that are designed to ensure animal materials or animal products are consistently produced safely and suitably. GOP can be referred to as good manufacturing practice (GMP), good hygienic practice (GHP) or supporting systems such as Standard Operating Procedures (SOPs), Sanitation Standard Operating Procedures (SSOPs), or operator pre-requisite programmes (OPRP).

You must document procedures to ensure animal material or product is fit for its intended purpose and that it complies with any relevant legislative requirements. These procedures must cover:

a) good operating practice (GOP);
b) all matters set out in sections 17(2) and 17(3) of the Act;
c) any corrective action procedures that are to be applied in the event of loss of control, including:
    i) how control will be restored;
    ii) how any affected animal material or animal product will be identified, controlled or disposed of; and
    iii) any measures to be taken to prevent recurrence of the loss of control [RMP Spec 11].

4.9.1 Areas covered in supporting systems

You must ensure that your supporting systems meet all relevant regulatory requirements or other related approved criteria. You should document all procedures that are necessary for your operation, this is likely to include but is not limited to the following topics:

- document control and record keeping;
- personnel health and hygiene;
- personnel competencies and training;
- operator verification and notification;
- corrective actions;
- design, construction and maintenance of buildings, facilities and equipment;
- repairs and maintenance;
- cleaning and sanitation;
- receipt of incoming materials for processing;
- allergen management;
- packaging;
- inventory control and traceability;
- calibration of measuring equipment;
- labelling and identification;
- control of maintenance compounds;
- pest control;

- control of processing operations;
- non-complying products and recall;
- waste management;
- storage;
- transport; and
- *Listeria* requirements for processors of certain ready-to-eat animal products.

In many cases, MPI has incorporated requirements into sector specific Codes. It is recommended that you consult these documents when developing your supporting systems.

4.9.2 Recommended documentation layout of each supporting system

MPI recommends that the documented procedures to contain the following:

a) purpose and scope;
b) general requirements and procedures;
c) procedures covering:
    i) control measures (see Part 4.9.2.1 Procedures for process control);
    ii) monitoring (see Part 4.9.2.2 Procedures for monitoring);
    iii) corrective action (see Part 4.9.2.3 Corrective action procedures); and
    iv) operator verification (see Part 4.9.2.4 Operator verification procedures).
d) records; and
e) references to other relevant documents.

Sufficient detail should be given in the procedures systems to ensure that managers and staff know what to do to assist in personnel training and to ensure clear understanding by other people (e.g. verifiers and recognised evaluators, etc.).

4.9.2.1 Procedures for process control

Process control procedure should include:

- the procedures for each process step, including rework;
- instructions necessary to make the product correctly (what, when, where, how and by whom); and
- any parameters and the limits for those parameters at each process step (e.g. pH during curing, time and temperature requirements for cooking, etc.).

4.9.2.2 Procedures for monitoring

Monitoring procedures should include the:

- identification of the person(s) or position(s) responsible for carrying out the monitoring;
- method of monitoring;
- acceptable criteria(s) or limit(s);
- frequency and sampling regime (must be appropriate to ensure consistent process control); and
- records to be kept.

4.9.2.3 Corrective action procedures

Your corrective action procedures should include:

- the identity of the person(s) or position(s) responsible for carrying out the corrective action;
- procedures for how control is restored;

- procedures for the control and disposition of non-complying product (e.g. checking the product back to the last compliant result, etc.);
- any action necessary to prevent reoccurrence;
- escalation of the response if preventative action fails; and
- the records to be kept including;

  – the actions taken;
  – any investigations carried out; and
  – the disposition of the affect product.

4.9.2.4 Operator verification procedures

You must document operator verification procedures that are carried out to check that your RMP has been implemented effectively, monitoring is occurring and appropriate corrective actions are taken when limits are not met [RMP Spec 16(1)]. Your operator verification procedures should include the:

- the identity of the person(s) or position(s) responsible for carrying out operator verification activities;
- when ongoing operator verification is to be carried out;
- how it will be done;
- follow-up action to be taken if a non-compliance is detected; and
- the records to be kept.

Operator verification includes activities such as:

- internal (verification) audits;
- confirming that regulatory and operator defined limits are met (e.g. product testing, confirming the effectiveness of hygiene and sanitation programmes, etc.);
- checking compliance to specifications (e.g. ingredient testing, etc.);
- conducting reality checks; and
- reviewing the RMP.

Further details on how to carry out operator verification is described in Part 4.17 Operator Verification.

Note
It is important that operators understand the purpose of monitoring and verification to confirm the RMP can consistently produce animal products that are fit for their intended purpose. Operator verification is a common problem area and will be checked as part of your Performance Based Verification (PBV) visits.

4.9.3 Document control

(Sections 17 (1) (a) of the APA)

Every document or part of a document that makes up a RMP must be:

(a) legible;
(b) dated or marked to identify its version;
(c) authorised prior to use, either directly or within the document control system, by:

  i) the operator;
  ii) the day-to-day manager of the programme; or
  iii) a person nominated to do so in the programme's document control system; and

d) available in a readily accessible form when required to any person with responsibilities under the programme [RMP Spec 19(1)].

There is flexibility in how you can document your RMP. You may reference documents such as Codes, HACCP plans or other documented procedures rather than reproducing them in your RMP, although in most cases some tailoring would be expected. The referenced documents then become part of the RMP. When only parts of a referenced document apply, you should show which parts of the document are included in or excluded from the RMP. You can do this by:

- using different formats for parts (e.g. bolding, highlighting, using boxes, colour-coding, etc.); or
- describing those parts that are excluded (e.g. all references to animal welfare, OMARs, etc.).

You should ensure that the format used for the RMP is user friendly for relevant personnel, the evaluator and recognised verifiers.

An operator must retain (by archive or otherwise) for four years, one copy of all obsolete documents from a registered risk management programme in a manner that protects the documents from damage, deterioration or loss, and prevents confusion with current documents [RMP Spec 19(3)].

An operator must ensure that the registered RMP, all reference material relating to the RMP, and any archived documents are readily accessible, or can be retrieved and made available within two working days of any request to:

a) recognised persons;
b) animal product officers;
c) the Director-General; and
d) persons authorised by the Director-General [RMP Spec 19(4)].

All documents relevant to your RMP must be made available to MPI, recognised evaluators or verifiers as necessary [RMP Spec 19(4)].

Definition of 'made available'
'Made available' means that no matter where the documents are stored, they can be mailed, couriered, faxed, emailed or transferred by other means within 2 working days.

4.9.3.1 Authorisation of documents

All RMP documents must be authorised by a person with appropriate authority before the RMP is registered and after any amendments are made [RMP Specs 19(1)(c)].

Authorisation can be done either by signing each page of the RMP or by some other way described in the document control system e.g.:

- signing a detailed document list or contents page that shows the current dates or versions and number of pages of each document or part-document; or
- electronic signatures so long as there are sufficient controls on access to passwords and authorisation codes.

4.9.3.2 Amendments

You must document procedures in your RMP for effective document control of the documents that form the risk management programme including how:

a) significant and minor amendments will be made to the RMP so that the programme is current and reflects the actual operation;
b) the amendments, or the nature of the amendments to the programme will be identified or described;
c) documents are authorised prior to issue and use; and

d) all amended parts of the RMP will be removed from use and replaced with the current versions at all locations to which it has been distributed without unnecessary delay after authorisation and, where necessary, after registration in accordance with section 25 of the Act [RMP Spec 19(2)].

These should include procedures for:

- identifying the need for an amendment;
- documenting the amendment;
- deciding if the amendment is significant with appropriate justification and if significant;
- if an amendment is significant, proceeding with evaluation and registration described later in this manual;
- authorising and issuing the amendment and removing obsolete documents; and
- implementing the amendment.

Information
For determining a significant amendment refer to:
- RMP Specs (22); or
- Appendix G: Guidance on Difference between Significant and Minor Amendments of this manual.

Examples of ways to indicate amended parts of an RMP are:

- increasing the version number of amended pages or sections;
- placing a line in the margin of relevant pages showing where amendments have been made;
- highlighting or otherwise changing the format of the amended sections; or
- describing the changes in an amendment page or register.

4.9.4 Record keeping

(Section 159 and 160 of the APA)

An operator must include record keeping procedures in the RMP to ensure that all records necessary to demonstrate compliance with the documented programme are:

a) legible; and
b) stored for four years, or for the shelf life of the product to which the records relate (whichever is longer) in a manner which protects the records from damage, deterioration or loss; and
c) can be retrieved and made available to persons referred to in subclause (3) of the RMP Spec within two working days of any request [RMP Spec 20(1)].

Records relating to the RMP's monitoring, corrective action and operator verification activities must include:

a) the date and where appropriate the time of the activity;
b) a description of the results of the activity; and
c) a means to identify the person or persons who performed the activity [RMP Spec 20(2)].

An operator must make all records relevant to the RMP available to the following persons on request:

a) recognised persons;
b) animal product officers;
c) the Director-General; and
d) persons authorised by the Director-General [RMP Spec 20(3)].

4.9.4.1 Electronic records

Where records are kept electronically, the operator should ensure that:

- electronic records cannot be altered without authorisation;
- any alterations are noted;
- records cannot be lost or damaged for the required time; and
- records are accessible to relevant personnel (e.g. internal auditor, recognised verifier, etc.).

4.9.5 Identification and competencies of responsible persons

You must identify the responsible persons where relevant within the RMP, these persons include:

a) day-to-day manager of the RMP (see Part 4.5.1);
b) authoriser(s) of the RMP (see Part 4.9.3.1);
c) persons responsible for key tasks (see Part 4.9.5.1); and
d) persons requiring specific mandatory competencies (see Part 4.9.5.3) [RMP Specs 15(1) and (2)].

For effective implementation of the RMP, the responsible persons and back-up personnel should have an appropriate level of competency e.g. in the application of HACCP principles and knowledge of the RMP, etc. You may do this through a variety of on-the-job training, training courses, observing and asking questions or e-learning modules.

The following competency standards are available from the New Zealand Qualifications Authority (NZQA):

a) 12315 "Supervise a seafood processing operation under a HACCP System";
b) 12316 "Coordinate development, and discuss implementation and verification of a HACCP plan for a seafood processing operation";
c) 12624 "Monitor a meat processing operation under a HACCP System" (expiring in 2018);
d) 12625 "Supervise a meat processing operation under a HACCP System" (expiring in 2018);
e) 12626 "Coordinate the development and verification of a HACCP plan or application for a meat processing operation" (expired);
f) 19514 "Explain the application of HACCP principles";
g) 19515 "Explain risk management programmes under the Animal Products Act 1999" (expired);
h) 16667 "Coordinate the development and verification of a HACCP plan in the dairy industry"(expiring in 2019);
i) 18407 "Explain the workplace application of HACCP in the dairy industry" (expiring in 2019);
j) 28264 "Implement a HACCP system in a food processing operation";
k) 28265 "Develop, implement and review a HACCP application for a food processing operation; or
l) any other qualification acceptable to MPI.

4.9.5.1 Persons responsible for key tasks

You should document the person(s) responsible by name, position or designation, for carrying out the following key tasks (including any within supporting systems):

- control activities, including those at CCPs (e.g. calibration tasks, purchasing approved chemicals, setting critical parameters on equipment, etc.);
- monitoring activities (e.g. at CCPs, pre-operative checks, temperature checks, etc.);
- corrective actions (e.g. restore control, product disposition, prevent recurrence, etc.);
- operator verification activities (e.g. record checks, internal audits, RMP review, etc.); and
- recall.

The task assignments will depend on the complexity of the operation. In simple operations, one person may be responsible for all of the activities. In more complex operations several people may be responsible for different parts of the programme.

You may designate these responsibilities to different people at different times e.g. by roster, etc. These designations should be well documented, including who is responsible for ensuring the appropriate actions

take place. You should also document how back-up personnel are assigned to cover for holidays and absences.

4.9.5.2 Competencies of responsible persons

Once you have identified the responsible persons, you must document the required competencies for carrying out their tasks effectively and keep training records for each staff member with responsibilities under the RMP showing that the competencies have been met and maintained [RMP Specs 15(2) and (3)]. An example of how you could do this is shown in Table 6: Competencies of Responsible Persons.

Table 6: Competencies of responsible persons

Person	Authorities and responsibilities	Training, knowledge or experience
Operator of RMP	Legal representative for the RMP (see Part 4.3 Operator, Business and RMP Identification)	Has a good understanding of relevant regulatory requirements under the APA including operator duties and the Food Standards Code (if applicable)
Day-to-day manager(s) of the RMP (including any deputies)	Responsible for the day-to-day management of the RMP (see Part 4.5.1 Day-to-day Manager of the RMP)	Has: • knowledge in food safety of relevant animal products and hygienic procedures and practices • knowledge of regulatory requirements, including responsibilities, related to the effective implementation of the RMP • technical knowledge and experience in the particular product/process (e.g. appropriate technical competencies, etc.) • able to liaise and communicate effectively with personnel and MPI
RMP authoriser(s)	Signs off the RMP documents and any amendments to the documents (see section Part 4.9.3.1)	Same as for the day-to-day manager of the RMP but only in relation to the part(s) of the RMP they are responsible for authorising
Person(s) undertaking document checks and validation RMP	Confirms that the RMP is appropriate, complete, complies with legal requirements, and is implemented effectively	Same as for the day-to-day manager of the RMP but only in relation to the part(s) of the RMP they are responsible for confirming
Persons responsible for control activities	See Part 4.8, 4.9, 4.10 and 4.11	Has thorough knowledge of: • the relevant operations, processes and systems in the RMP; • the control measures for each activity they are responsible for and how to recognise loss of control; and • the appropriate response when there is a loss of control
Persons responsible for monitoring activities	See Part 4.9.2.2 and 4.10.7	• Same as for persons responsible for control activities • Monitoring procedures for each activity they are responsible for • Relevant NZQA Unit Standard qualifications

Person	Authorities and responsibilities	Training, knowledge or experience
Persons responsible for corrective action activities	See Part 4.9.2.3 and 4.10.8	• Same as for persons responsible for monitoring activities • Corrective action procedures for each activity they are responsible for • Ability to identify product non-conformances. • Relevant NZQA Unit Standard qualifications
Operator verification activities	See Part 4.9.2.4, 4.9.6 and 4.10.9.	• Same as for day-to-day manager of the RMP • Operator verification procedures for each activity they are responsible for • Ability to interpret records and results. This may be demonstrated by appropriate internal audit training
Recall Manager	See Part 4.9.9	• Has a thorough understanding of recall policies and procedures • Relevant NZQA Unit Standard qualifications
Specific mandatory competencies	See Part 4.9.5.3	• The required competencies are mandated in legislation

4.9.5.3 Persons required to have specific mandatory competencies

There are some mandatory competency requirements for people who are responsible for certain specific operations or activities e.g. those who are responsible for supervising canning operations, etc. These mandatory competencies are listed in the:

- Part 5 and Schedule 3 of the Animal Products Notice: Specifications for Products Intended for Human Consumption;
- Clause 3.16 and Schedule 2 of the Animal Products Notice: Specifications for Products Intended for Animal Consumption; and
- Clause 15 Competency Requirements for Validators of the Animal Products (Dairy) Approved Criteria for the Manufacturing of Dairy Material and Products (DPC3).

4.9.6 Operator verification

You must document an operator verification system in your RMP with the following details:

a) the activities to be performed in relation to the RMP and their frequency;
b) any actions to be taken when all or part of the RMP is not effective; and
c) any recording and reporting requirements [RMP Spec 16(1)].

Operator verification is the application of methods, procedures, tests and other checks to confirm that the RMP:

- is consistently producing animal material or product that is fit for its intended purpose;
- is applicable to the operations carried out;
- will continue to comply with all legislative requirements; and
- will continue to be operated as written (or appropriate amendments are made as the process changes).

Operator verification activities may include:

- review of monitoring records to confirm that the required checks (including CCP monitoring) are carried out;
- confirming limits and/or parameters continue to be met;
- product tests and review of product testing results;
- review of corrective action records to ensure that defects, non-compliances or non-complying products are being identified and that the appropriate actions are taken or a plan is in place to rectify the deficiencies within specified timeframes;
- confirming that procedures have been reassessed after an event to ensure that corrective and preventative actions are effective;
- review of the HACCP system and its records (e.g. review of deviation and product disposition, confirmation that CCPs are kept under control, etc.);
- internal audits of all aspects of the RMP (e.g. reality checks, matching documented systems with physical observations, ensuring that all shifts are covered and talking to key personnel, etc.); and
- periodic review of the whole RMP.

Operator verification activities records should include the following information:

- the identity of the person(s) or position(s) who will carry them out;
- when, where, and how (i.e. methods) they will be carried out;
- the frequency of operator verification activities;
- monitoring is occurring according to the written procedures and is effective;
- actions to be taken if deficiencies are found (i.e. if CCPs are not operating correctly, procedures are not being followed, a non-compliance occurs, etc.); and
- records to be kept to show that verification has been done as planned.

Ideally the person carrying out operator verification activities should be independent of the processes being verified i.e. they should not check their own work. In small operations this may not always be possible.

It is important that you identify non-compliances within your RMP and that these are dealt with appropriately, rather than being picked up by your recognised verifier. Operator verification can be viewed as 'marking your own work' – if you are not picking up your mistakes and rectifying them, it is an indication there is a lack of operator control and your current operator verification activities are inadequate and should be reviewed.

4.9.7 Notification requirements

Your RMP must document a procedure for notifying MPI of any of the following changes:

a) name or position or designation of the person(s) responsible for the day-to-day management of the RMP; and
b) any emerging, new or exotic biological hazards or new chemical hazards that come to the operator's attention [RMP Spec 13 (1) and (2)].

Your RMP must document a procedure for notifying the verifying agency in charge of verifying your RMP, of the following issues:

a) any significant concern about the fitness for intended purpose of animal material or animal product;
b) where the cumulative effect of minor amendments necessitates the registration of a significant amendment to the programme as provided in section 25 of the Act;
c) where the RMP is no longer considered to be effective; and
d) where the premises identified as being used by the programme are not or no longer suitable for use [RMP Spec 13 (3)].

When you notify MPI or the recognised agency, you must do so in writing and without unnecessary delay [RMP Spec 13].

4.9.8 Corrective action for unforeseen circumstances

You must document in your RMP any corrective action procedures for unforeseen circumstances (e.g. flooding, etc.) [RMP Spec 11(2)]. You should document who is responsible for nominating a suitably skilled person to manage these corrective actions. The suitably skilled person may be different for each scenario depending on the skills needed. He/she is responsible for:

- identification, retention and assessment of non-complying product (e.g. review of relevant processing records, analyses to be undertaken, inspection of animal material or animal product, expert advice, literature review, etc.)
- product disposition[5] as appropriate to the nature of the problem and the intended use of the product (e.g. rework, reject, release under restricted conditions, regrade for alternative use where permitted under the RMP, etc.); and
- reporting to the recognised verifier including:
  - a description of the problem and the affected animal material or product;
  - a summary of the assessment made;
  - the decision on the disposition of the animal material or product; and
  - any actions taken to prevent recurrence of the non-compliance.

4.9.9 Recall procedures

(Section 17 (2) (c) and 85 of the APA)

In the event that non-complying animal materials or products are produced, you should take appropriate corrective actions and determine the disposition of affected products. If the non-compliance is detected before any of the affected products are released for distribution, it will be a trade level recall. However, if some or all of the products are in the distribution chain or with the consumer, you may need to initiate a consumer level recall to recover the products as quickly as possible.

You must document recall procedures where, due to the nature of the product, it is possible for your product to be recalled [RMP Spec 14 (1)]. Your business may not require a recall procedure if your product is intended to be consumed immediately e.g. a takeaway, etc. However you will still require procedures in place as you may be part of another business's recall e.g. you may need to remove recalled stock from shelves and return it to the manufacturer, etc.

You must document in your RMP a recall procedure which includes:

a) the criteria for deciding when a recall will be initiated;
b) how retrieval and disposition of the relevant animal material or animal product will be managed; and
c) a system for notifying the following MPI as soon as possible [RMP Specs 14].

The decision to recall product should be based on whether or not the product is fit for its intended purpose, considering both safety and suitability issues. You must withdraw the product if it is deemed to be no longer safe or suitable. You may decide to withdraw product if it is safe and suitable, but does not meet non-regulatory (commercial) requirements. In this case a formal recall is not required.

MPI has created a guide to assist you in developing recall procedures: Recall Guidance Material Version 4. The following should be considered when you are developing a recall plan:

[5] Exception reporting and disposition of non-conforming dairy material and dairy product must be undertaken as outlined in Animal Products Notice: Disposal of Non-conforming Dairy Material or Dairy Product.

- the purpose of the product recall;
- roles and responsibilities of people involved in the recall (e.g. the recall team, etc.);
- the business recall policy;
- the decision to recall;
- risk assessment;
- the scope of recall;
- notifications (e.g. to MPI, within the distribution chain or consumers, etc.);
- testing and review of recall procedures (e.g. mock recall, etc.);
- recall documentation;
- review of recall effectiveness.

You should ensure your recall plan is periodically tested using a 'trial run' or mock recall exercise. This can be considered as a validation of the product recall plan. It is recommended that product recall plans be validated annually (or more frequently if appropriate) and the effectiveness reviewed.

4.10 Application of HACCP

(Section 17(3) of the APA)

The HACCP approach is based on the expectation that supporting systems are effectively implemented prior to the application of HACCP principles.

You must apply HACCP principles to your process (including all inputs) [APA 17(3)]. This ensures a systematic approach to the identification, analysis and control of hazards. The principles of HACCP as defined by Codex are:

(1) Conduct a hazard analysis;

(2) Determine the critical control points (CCPs);

(3) Establish critical limits;

(4) Establish a system to monitor the control of the CCP;

(5) Establish the corrective action when monitoring indicates that a particular CCP is not under control;

(6) Establish verification procedures; and

(7) Establish documentation concerning all procedures and records relevant to the HACCP principles and their application

The application of HACCP principles must be documented [RMP Spec 20]. The person or people assigned to this task should have the appropriate knowledge and skills regarding HACCP and the particular processes.

You must review your application of HACCP whenever there are changes in the product, process and/or premises [RMP Spec 11].

Table 7: Hazard Identification for Inputs and Table 8: Hazard Analysis and CCP Determination Template are examples of how you can document the application of HACCP principles.

4.10.1 Types and sources of hazards

A hazard is described as a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse human or animal health effect. Hazards can be:

a) **biological**, includes microorganisms (e.g. *Salmonella* spp., *L. monocytogenes,* etc.), parasites (e.g. *Taenia saginata,* etc.) and biotoxins[6];
b) **chemical**, includes heavy metals, pesticides and veterinary medicines. Some food additives may also be hazardous if present in excessive or toxic amounts (e.g. nitrite, etc.); or
c) **physical**, includes objects in food that may cause illness or injury (e.g. glass, metal fragments, stones, bone slivers, shotgun pellets, etc.).

You should not confuse the source or cause of the hazard (e.g. faecal contamination, etc.) with the hazard itself (e.g. enteric pathogens, etc.) as again this may impact on the selected control measures.

4.10.2 Hazard identification and analysis

The hazard identification and analysis must be documented, this includes any uncontrolled hazards [RMP Spec 10 and 11] (see Part 4.10.4 for more information). Hazards may occur as a result of:

a) an input (e.g. an additive, ingredient, etc.);
b) the process itself (e.g. a process step may be the source of the hazards or may increase the level of an existing hazard, etc.); or
c) contamination from other sources (e.g. personnel, water, air, pests, wastes, processing equipment, etc.).

You should only consider hazards that are "**reasonably likely to occur**" in your hazard identification.

Definition of 'reasonably likely to occur'
"Reasonably likely to occur" means that:
- the particular hazard is known to occur in the particular food based on scientific reports, industry or company results, Codes and information from MPI; and
- the hazard is known to occur in New Zealand or if using imported ingredients, is known to occur in those ingredients (care should be taken when considering overseas information).

You may use generic HACCP plans or RMP models developed by MPI or others as a basis for your hazard identification. You should also consider whether there are additional hazards that are reasonably likely to occur for your specific product, process and operation. This is particularly important for unusual or novel products (e.g. placentas, glands, etc) where information may not be readily available and will require you to carry out your own research.

Hazards may be identified as groups based on their common characteristics, source and/or control e.g. enteric pathogens in beef trimmings, marine biotoxins in shell fish, chemical residues in fresh meat, enteric pathogens in raw milk, etc. However certain hazards that require specific controls must be explicitly identified. Some examples are listed below:

- *Campylobacter* in raw chicken and raw milk;
- *Staphylococcus aureus* in cooked ham;
- *Listeria monocytogenes* in certain ready-to-eat products;
- tutin toxin in honey;
- the pesticide 1080 in possums; or
- metal fragments in meat and bone meal.

[6] Biotoxins could instead be listed under chemical hazards. Either approach is acceptable.

You should avoid vague descriptions of hazards. For example, "foreign objects in a manufactured meat product" or "foreign matter in a dairy product" should not be used as it does not clearly identify the hazard (e.g. metal, bone, plastic, etc.) which may require different control measures.

Identification of hazards from inputs

You should identify the hazards that are reasonably likely to occur for each input. Typically supplier quality assurance programmes are the most practical way to manage certain hazards. The assurance programme places reliance on your supplier to control certain hazards to known levels and identifies those that may still be present (therefore may need to be controlled by your process). Any supplier quality assurance programme should be documented in the RMP and may include:

- agreed material specifications or procedures;
- supplier declarations for live animals;
- certificates of analysis for ingredients;
- supplier audits; or
- periodic testing of incoming materials.

Hazard identification from inputs can be presented in a table, as shown in Table 7: Hazard Identification for Inputs below.

Identification of hazards at each process step

In addition to identifying hazards from inputs, you should identify the hazards that are introduced to the product as a consequence of applying the process step itself. You can do this by performing hazard identification for each process step.

The potential impact of the process step on any existing hazard should also be considered during hazard analysis.

Identification of hazards associated with other sources

You should also identify any hazards associated with other sources, e.g. personnel, water, air, pests, wastes, processing equipment, etc. These hazards are best controlled by supporting systems.

Hazard analysis

Once you have identified the relevant hazards, you will need to analyse whether the level of hazard is potentially acceptable or unacceptable based on the information available to the food business operator. You can obtain this information from your ingredient suppliers or operator, regulatory or client testing programmes.

There are many risk assessment tools to help you conduct your hazard analysis:

- **risk ranking** – explains the approach to prioritising food safety risks and lists all the documents that relate to this process;
- **risk profiles** – MPI has published some risk profiles relevant to food or hazard, you can find them by searching for 'risk profiles' on the MPI website; or
- **quantitative and qualitative risk assessment** – evaluating the probability and severity of foodborne illnesses as a result of these hazards.

Table 7: Hazard identification for inputs

Inputs	Description/Specifications	Biological hazard (B)	Chemical hazard (C)	Physical hazard (P)
Beef cuts and trimmings	• Sourced from company with a registered RMP • Chilled or frozen as per company specification • Boneless cuts	Enteric pathogens, e.g. *Campylobacter jejuni*, *Clostridium* spp., Salmonella spp., Pathogenic *E. coli* (e.g. STEC), etc.	Chemical residues	• Bone • Metal
Raw milk	• Sourced from farm dairy with registered RMP • Chilled storage	• Non-spore forming pathogens e.g. *Salmonella spp*, *Listeria* monocytogenes, *Campylobacter*, Pathogenic *E. coli* (STEC), Mycobacterium bovis (TB), etc. • S. aerus Staphlococcal enterotoxin • Spore forming pathogens e.g. *Bacillus cereus*, *C. perfringens*, etc.	Chemical residues from milking animal, e.g. antibiotics, etc. Environmental contaminants e.g. pesticides, ag compounds heavy metals, maintenance compounds, etc.	• Glass • Metal
Walnuts	• Supplier approved programme • Supplier specifications	None[7]	None	Walnut shell
Salt	• Food grade	None	None	None
Spices	• Decontaminated	Spore forming organisms, e.g. Bacillus cereus, *Clostridium* spp., etc.	Chemical residues, e.g. herbicides, fumigant, etc.	Stones
Egg pulp	• Pasteurised • Frozen • Meets clauses13.39 to 13.43 of HC Spec • Meets Standard 1.6.1 and 2.2.2 from Food Standards Code	None	None	Egg shell
Bivalve molluscan shellfish	• Raw shucked (prior to testing as per clauses 14.13 – 14.34 of HC Spec) • Sourced from registered RMP	• *E. coli* spp. (STEC) • Salmonella spp.	Marine biotoxins	Shell
Plastic bag (packaging)	• Suitable as food contact material (HC Spec Part 7). • Protected from contamination	None	None	None

[7] "None" means hazards are not reasonably likely to occur because they are not associated with the input or it is controlled through supplier agreements.

4.10.3 Identification of control measures

Once you have identified and analysed the relevant hazards, you should determine the control measures for each hazard at every process step. A control measure is any action or activity that is applied to:

- control the initial level of the hazard (e.g. testing and rejection of unacceptable ingredients, good animal production practices, etc.);
- prevent an unacceptable increase of the hazard (e.g. chilling, reduction of water activity, use of preservatives, acidification, etc.); and
- reduce or eliminate the hazard (e.g. pasteurisation, commercial sterilisation, use of antimicrobial agents, trimming, washing, etc.).

4.10.4 Uncontrolled hazards

If control measures do not exist at any of the steps in the process or are inadequate to control a particular hazard to the required level, you should:

- redesign the process or add other control measures to control the hazard; or
- leave the hazard uncontrolled when it is appropriate to do so considering the intended use of the product and clearly indicate this in the documented hazard analysis.

There must be sufficient documentation to support your decision to leave the hazard uncontrolled and clearly indicated in the hazard analysis [RMP Spec 10]. You should also consider whether you need to inform a further processor, retailer or consumer about the uncontrolled hazard so that food safety can be assured prior to consumption.

4.10.5 Critical Control Point (CCP) determination

You must document the justification for each identified critical control point (CCP) [RMP Spec 11(3)]. Justification can be evidence such as historical records, technical publications, Codes or information provided by MPI.

A CCP is a step in the process (or a combination of process steps) at which control of one or more hazards is applied and is essential for food safety (e.g. meeting any regulatory or operator-defined limits relating to specific hazards(s) in your product, etc.).

When determining if control is essential at a particular step, you should consider the:

- degree of hazard control that is achieved at the step in relation to meeting the acceptable level of hazard;
- likelihood of failure to control the hazard at that step; and
- consequence of a failure to control the hazard at that step considering the intended use and consumer (i.e. risk to health).

Generally essential steps are those that are specifically designed to eliminate the hazard or reduce it to an acceptable level.

You should have a systematic process to hazard identification and analysis and CCP determination for every process covered by the RMP. Tools that may be used to help with your assessment include decision trees (Figure 3: Decision Tree for Hazard Analysis and CCP Determination) and table (Table 8: Hazard Analysis and CCP Determination Template). These tools have been adapted from the Codex decision tree for use by the animal products industry.

When you identify a CCP, the remaining HACCP principles must be applied (see Part 4.10.6 to Part 4.10.11).

If no CCPs have been identified, it is expected that the control of hazards at key steps can be adequately addressed by the supporting systems, but verification, documentation and record-keeping procedures will still need to be applied (see Part 4.10.9 and Part 4.10.11).

Figure 3: Decision tree for hazard analysis and CCP determination

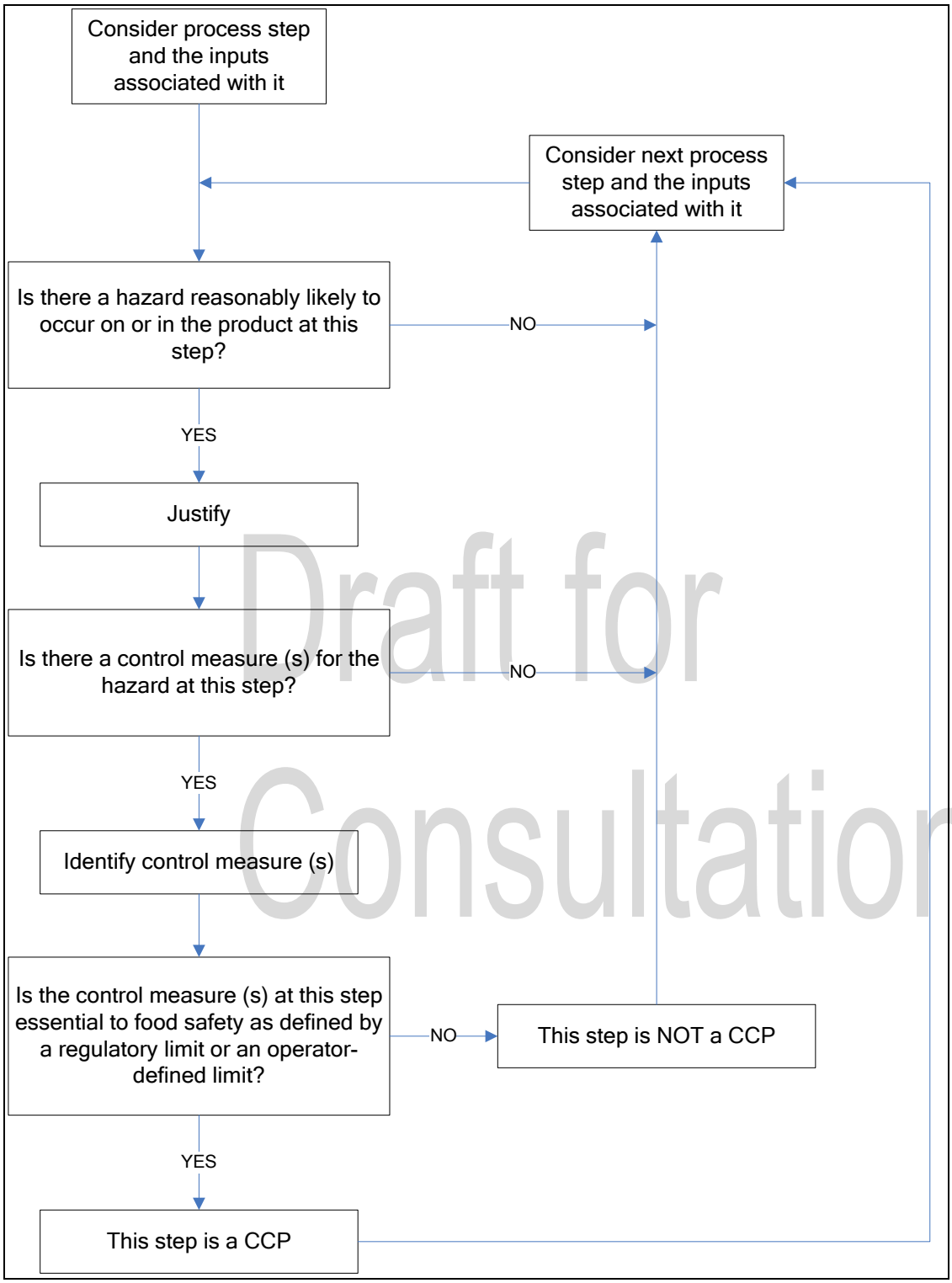


Table 8: Hazard analysis and CCP determination template (includes an example of receiving honey supers)

Process step	**Inputs**	**Hazard reasonably likely to occur on or in the product at this step**	**Justification**	**Q1. Is there a control measure(s) for the hazard at this step?** If yes, identify the control measure and then answer Q2. If no, consider hazard at next step.	**Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit or operator-defined limit?** If yes, this step is a CCP. If no, this step is not a CCP.	**CCP No.**
Receiving	Supers	B – bacterial pathogens	Bacterial spores (e.g. *Bacillus spp*, *Clostridum spp*) are likely to occur	No	No	
		C – tutin toxin	Reported incidence of tutin in NZ honey	Yes – supplier statements confirming beekeeper controls and options 1-5 (from Food Standard: Tutin in Honey 2016)	Yes	1
		C – Chemical residues	Residues may occur in honey	Yes – supplier statements confirming beekeeper controls	No	

To clarify the use of Table 8, each column is discussed in Table 9 Further Explanation for Headings of Table 9 below. You should go through the series of questions for each step in the process. The hazard analysis must show any hazard that is still there or uncontrolled at the end of the process [RMP Spec 10]. Examples of the use of this table can be found in a number of MPI Codes. Some HACCP applications can be found in RMP templates.

Table 9: Further explanation for headings of Table 8

Column 1	**Process step**	Each process step should be written in column 1 in the order that they occur in the process as shown in the process flow diagram.
Column 2	**Inputs**	All inputs added at the particular step should be indicated in column 2. This should align with the process flow diagram.
Column 3	**Hazard identification**	The hazards reasonably likely to occur at each process step should be identified considering: • hazards introduced by inputs at that step; • hazards introduced or transferred as a consequence of applying the process step itself (e.g. metal from mincers); • hazards carried over in the product from the previous step; and • any adverse impact of process step on existing hazards (e.g. growth of microorganisms).
Column 4	**Justification**	A brief justification for each identified hazard should be provided. This should include the identification of the source or cause of the hazard. Justification may include: • company experience and records; • peer-reviewed scientific literature; • surveys; • industry reports; • HACCP plans; • MPI Codes, templates and RMP models; and • other MPI guidance documents.
Column 5	**Identification of control measures**	You should identify the control measure(s) for each hazard. The procedures to be followed for all control measures should be documented in the RMP (e.g. in supporting systems, etc). The document number or title of the particular supporting systems that contains the relevant procedures should be given in this table to help with evaluation, verification and review of your RMP. Hazards that are not completely eliminated at a step should be carried forward to the next step to ensure that the impact of any succeeding step is considered. In particular, bacterial hazards should be carried over to succeeding steps since there is potential for their growth. Hazards that are unlikely to be affected by succeeding process steps (i.e. the hazard will not grow or increase) do not need to be carried forward to the next steps in the hazard analysis table to reduce repetition. However, the hazard must be reintroduced to the table at the step that it is controlled, or it must be shown at the last process step, as either remaining in the product or as uncontrolled. For example, if a chemical hazard is not controlled, changed any further nor removed and is still present at the final step in the process, it does not need to be recorded at each step as a 'hazard reasonably likely to occur on or in the product at this step', but does need to be written into the row at the final process step where it is still likely to occur (i.e. present).
Column 6	**CCP determination**	Decide whether or not a step is a CCP by determining if the control at that step is essential, by itself or in combination with other steps, to achieve any regulatory limit or operator-defined limits for the specific hazard(s). If there is no regulatory limit or operator-defined limit, there is no CCP.

Other CCPs that may be identified

You may be required to identify other CCPs in your process to satisfy an overseas market access or customer requirement. No further justification for the identification of these CCPs is necessary, however, they should be clearly identified as market access CCPs, or customer requirements to ensure their appropriate external verification. The recognised agency will verify the effectiveness of any market access CCP against the relevant OMAR.

4.10.6 Establishing critical limits

You must define and justify critical limit(s) for each CCP [RMP Spec 11(3)].

A critical limit is a criterion which separates acceptability from unacceptability at a CCP. Critical limits should be:

- measurable;
- linked to meeting a regulatory limit or operator-defined limit related to food safety; and
- parameters that can be monitored in short term, real time and on an on-going basis.

You should validate your critical limits to show that the CCP is appropriate and can consistently achieve the specified level of control. You should document the:

- parameters to be checked (e.g. pasteurisation time and temperature, etc.);
- limit for each parameter (e.g. 72°C for 15 seconds, etc.); and
- justification for each limit (e.g. a regulatory limit specified in the HC Specs, etc.).

4.10.7 Establish CCP monitoring

You must document monitoring procedures that will be applied for each critical limit [APA 17(3) (d)]. These should include:

- identity of the person or position responsible for monitoring at that CCP;
- monitoring method;
- monitoring frequency and sampling regime; and
- records to be kept.

Monitoring can be continuous (e.g. using an automatic measuring and recording device, etc.) or based on an established frequency or statistical sampling plan. The frequency of monitoring should be adequate to ensure the consistent control at that CCP. Other factors to consider when establishing frequency includes:

- the nature of the product;
- the likelihood of being unable to meet the limits;
- the cost of monitoring;
- the ability to retrieve all product since the last compliant CCP monitoring result;
- the consequence of failure (including risk to human health); and
- expected corrective actions (especially with respect to product disposition).

4.10.8 Establish corrective actions

You must document corrective action procedures and ensure they are implemented when a critical limit is not met [APA 17(3)(e) and RMP Spec (11(2)(c)]. Corrective action procedures should include:

- identity of the person(s) or position(s) responsible for carrying out the corrective action;
- procedures for how control is restored;

- procedures for control and disposition of non-complying product (e.g. checking the product back to the last compliant result;
- any action necessary to prevent re-occurrence;
- escalation of the response if preventative action fails; and
- records to be kept including:

  – the actions taken;
  – any investigations carried out; and
  – the disposition of the affect product.

4.10.9 Establish operator HACCP verification procedures

You must document operator HACCP verification procedures that will be carried out to ensure:

- the CCP is operating effectively;
- CCP monitoring is occurring according to the written procedures and is effective; and
- appropriate corrective action is taken when critical limits are not met [APA 17(3)(f) and RMP Spec 16].

Operator verification procedures should include:

- identity of the person or position responsible for ongoing operator verification;
- procedures and methods for operator verification activities to be undertaken;
- when and how often operator verification activities will be carried out;
- follow up actions to be taken if:
  – operator verification identifies that the CCP is not operating correctly;
  – procedures are not being followed; or
  – a non-compliance occurs; and
- records to be kept.

Examples of operator HACCP verification should also include:

- review of changes to inputs, processes or products and impact on the HACCP system;
- HACCP training records; and
- review of the effectiveness of the HACCP system.

These verification procedures may form part of RMP operator verification (see Part 4.9.6).

4.10.10 Confirming the application of HACCP

You should check the application of HACCP after completing the hazard analysis and CCP determination, initially and when reviewing the HACCP system. The following should be considered:

- Are all the regulatory limits accounted for in the HACCP application?
- Are the operator-defined limits appropriate and achievable?
- Are the identified CCPs essential to meeting the regulatory limits or operator-defined limits for particular hazard(s)?
- Are the critical limits appropriate and achievable?
- Can the critical limits be monitored effectively and in real time?
- Are all the identified hazards adequately controlled by supporting systems and/or a CCP(s)? If not, do you need to modify the process or add other control measures?
- Are there any uncontrolled hazards? If so, are you required by legislation to control it/them to a specified level?

- do you need to consider redesigning the process/product?
- do you need to inform a further processor, retailer or consumer about the uncontrolled hazard so that food safety can be assured prior to consumption (e.g. by providing feedback to suppliers, notifying further processing, or cooking/handling instructions, etc.).

4.10.11 Establish HACCP documentation and records

You must document all matters relating to the application of HACCP in your RMP (i.e. all of Part 4.10 Application of HACCP) [APA 17(3) (g)]. This includes:

- appropriate reference to scope, product description and process description; and
- all evidence and justifications for the decisions made.

Records must be kept to be able to demonstrate that the HACCP part of the RMP has been implemented and continues to be operated effectively [RMP Spec 20(1)]. Examples of records can include:

- critical limits validation records;
- CCP monitoring records;
- CCP corrective action records; and
- HACCP verification records.

4.11 Identification and control of risks to wholesomeness

(Section 4 of the APA)

Wholesomeness means that the product does not contain or have attached to it, enclosed with it, or in contact with it; anything that is offensive, or whose presence would be unexpected or unusual in product of that description.

In other words if a consumer would think "yuck" then it is likely that this is a wholesomeness risk factor. This is greatly dependent on the:

- intended use;
- intended consumer;
- nature of the product; and
- packaging / identification of the product.

Application of HACCP principles is not required for risks to wholesomeness but MPI recommends that you systematically assess each input and step in the process to identify and control any wholesomeness risk factors.

4.11.1 Identification of risks to wholesomeness

You must identify any risks to wholesomeness that are reasonably likely to occur within your process for each animal material or animal product or group of materials or products [AP Reg 6(1)]. This can be based on:

- an industry Code;
- your knowledge/experience of your product and process (including a review of internal records and reports); and
- any customer/consumer complaints.

Opinions about what is offensive, unexpected or unusual will vary. Common sense should be used to determine any problems that would be offensive, unexpected or unusual. See Table 10: Examples of Risks to Wholesomeness and their Controls.

Table 10: Examples of risks to wholesomeness and their controls

Product	Wholesomeness risk factor	Examples of control measures	Supporting system (put actual doc no. and/or title)
Whole chickens	• feathers	• correct set up of plucker • inspection of birds	Doc. xx
Hamburger patty	• bones	• supplier assurance programme • bone eliminator	Doc. xx
Milk (farm dairy operator)	• foreign or objectionable matter (insects, faeces, dirt or dust)	• ensure teats are clean • filter milk • bulk milk tank secure from environmental contamination • lidded vats closed at all times except from emptying milk until cleaning complete	Doc. xx
Shell eggs	• roundworms	• worming programme for free-range hens	Doc. xx
Mussel meat	• pea crabs	• inspection and removal	Doc. xx
Honey	• fermentation	• control of moisture content control • heating	Doc. xx
Canned corned beef	• plastic	• inspection of raw meat blocks, and removal • use of coloured liners	Doc. xx
Meat	• spoilage	• temperature control • hygienic practices	Doc. xx

4.11.2 Controls for risks to wholesomeness

Where you have identified a risk to wholesomeness, you must establish and document the control measures (see Table 10: Examples of Risks to Wholesomeness and their Controls for examples) and all other matters required by clause 11(2) of the RMP Spec.

The control measures may be documented within process control procedures, supporting system or a specific wholesomeness supporting system. If the control measures are documented in different parts of the RMP, MPI recommends that you explain this clearly and provide references to the relevant controls for each identified risk factor. An example of how this can be done is shown in Table 10: Examples of Risks to Wholesomeness and their Controls.

You are not required to set operator-defined limits for wholesomeness risk factors but you may if you wish to do so. Where an operator-defined limit has been set you must document actions to be taken if those limits are not met [RMP Spec 7 and 8].

4.12 Identification and control of risks from false or misleading Labelling

All animal products must meet legislative requirements related to labelling including:

- the Animal Product Regulations 2000, regulations 8 and 19;
- the Animal Products (Dairy) Regulations 2005, regulations 18 and 19;
- the Food Regulations 2015, regulations 149 - 152;
- Part 1.2 of the Australia New Zealand Food Standards Code;
- Part 8 of the Animal Products Notice: Specifications for Products Intended for Human Consumption;
- Part 4 of the Animal Products Notice: Specification for Products Intended for Animal Consumption Notice; and
- the Agricultural Compounds and Veterinary Medicines Act 1997.

When identifying risk factors, you should consider the type of animal material and/or product, its intended use and the requirements of systems to authenticate claims (e.g. species, composition, active ingredients, organics, free range, GM free, claims of effectiveness, etc.) and specific consumer groups (e.g. religious groups, people with allergies, etc.).

Application of HACCP principles is not required for risks from false or misleading labelling.

If products are intended for export, you should ensure the OMARs are met.

4.12.1 Identification of risks from false or misleading labelling

You must identify risk factors associated with false or misleading labelling that are reasonably likely to occur for each animal material or product or group of materials or products [AP Reg 6(1)]. This can be based on:

- an industry Code;
- knowledge or experience of your product and process (including from review of internal records and reports); and
- any customer/consumer complaints.

For simple products and processes, there may be little opportunity for these risk factors to occur. A common sense approach should identify those risk factors that are reasonably likely to occur for the operation. See Table 11: Examples of Risks from False or Misleading Labelling and their Controls.

Table 11: Examples of risks from false or misleading labelling and their controls

Labelling Risk Factor	Likely Cause	Control Measures	Supporting Systems (put actual doc no. and/or title)
Incorrect design (label content/format)	• Lack of research into label content • Using inaccurate or incomplete information	• Conduct adequate research • Checks on label design • Sign-off before release to processing	Doc. xx
Incorrect claims	• Lack of research into research to back claims • Limited understanding of the requirements around claims	• Conduct adequate research to support claims made • Understand the requirements around making claims	Doc. xx
Process deficiencies resulting in the	• Errors in processing, e.g. wrong product flow, inadequate separation, etc.	• Training and supervision • Processing procedures	Doc. xx

Labelling Risk Factor	Likely Cause	Control Measures	Supporting Systems (put actual doc no. and/or title)
product not matching its label	• Wrong formulation • Cross-contamination from equipment with unwanted ingredients, e.g. peanuts (allergens), etc. • Inputting wrong information into labeller, e.g. species, etc. • Wrong packaging materials • Changes in raw materials or suppliers (e.g. inadequate supplier quality assurance procedures, etc.)	• Formulation control procedures • Clean down • Order of processing • Compliance to raw material specifications • Material tracking • Inventory control • Label checks	

4.12.2 Control of Risks from False or Misleading Labelling

Where you have identified a risk to false or misleading labelling, you must establish and document all control measure(s) (see Table 11: Examples of Risks from False or Misleading Labelling and their Controls) and any other matters required by clause 11(2) of the RMP Specs.

The control measures may be documented within process control procedures, supporting systems or a specific labelling supporting system. If the control measures are documented in different parts of the RMP, MPI recommends that this is explained clearly with references to the relevant controls for each identified risk factor. An example of how this can be done is shown in Table 11: Examples of Risks from False or Misleading Labelling and their Controls.

You are not required to set operator-defined limits for false or misleading labelling risk factors, however, you may if you wish to do so. Where an operator-defined limit has been documented you must document actions to be taken if those limits are not met [RMP Specs 7 and 8].

4.13 Validation

You must confirm that the RMP is effective to produce safe and suitable animal material or products [RMP Spec 18(1)]. Where there is insufficient evidence to demonstrate the effectiveness of the RMP before it is registered, you must develop a protocol (a plan) to show how the evidence will be collected and analysed, and how the animal material or product will be disposed of [RMP Spec 18(1) (b) (ii)].

You must follow any conditions specified on the registration (i.e. timeframes for completion of the protocol) unless otherwise agreed with the recognised evaluator or MPI.

See Part 5.2 Validation for more detail on RMP validation.

Further information from Statement of Policy: Operator Responsibilities during Registration of a RMP (Version 1)

(1) Documentation checks and validation

The operator must check, prior to the registration of a RMP or a significant amendment to a registered programme, that the:

a) documentation is complete and complies with all relevant legislative requirements;

b) premises and equipment are ready to operate in accordance with the programme and other legislative requirements; and
c) RMP will be capable of consistently producing animal material or animal product that is fit for intended purpose.

4.14 Provision for verification activities and verifiers rights

(Sections 17 (4) of the APA)

You must make provisions in your RMP for verification activities and verifiers rights [RMP Spec 17]. You can do this by copying or referencing clause 17 of the RMP Spec into your RMP (this has reproduced below for your reference).

Clause 17 of the RMP Specs

(1) Taking into account the duties imposed on an operator under section 16(1)(e) of the Act and the requirement in section 17(4) of the Act, a risk management programme must include provisions allowing recognised risk management programme verifiers to have the freedom of access to carry out their verification functions and activities, including provisions allowing —

(a) such freedom to access premises, places, or facilities covered by a risk management programme as is necessary to enable a recognised risk management programme verifier to carry out his or her functions and activities; and
(b) such access to documents, records, and information that relate to a risk management programme as is necessary to enable a recognised risk management programme verifier to carry out his or her functions and activities; and
(c) such access to things (including containers and packages) that are used in connection with producing and processing animal material and animal products under a risk management programme as is necessary to enable a recognised risk management programme verifier to carry out his or her functions and activities; and
(d) such access to animal material, animal product, equipment, packages, containers, and other associated things used in processing animal material and animal product under a risk management programme as is necessary to enable a recognised risk management programme verifier to carry out his or her functions and activities(including identifying and marking any of those things); and
(e) such freedom to examine and take samples (for the purpose of analysis or retention) of animal material, animal product, or any other outputs, substance, or associated thing which has been, is, or may be used in contact with, or in the vicinity of animal material or animal product being produced or processed under a risk management programme as is necessary to enable a recognised risk management programme verifier to carry out his or her functions and activities.

(2) By way of explanation, in the case of a significant risk to the fitness for intended purpose of animal product or suitability of animal material for processing, a recognised risk management programme verifier may —

(a) recommend to the operator that processing under the risk management programme be temporarily interrupted; and
(b) recommend to the operator that any affected animal product that may not, or no longer, be fit for its intended purpose be detained; and
(c) recommend to an Animal Product Officer that the officer exercises his or her powers of interruption of operations under section 89 of the Act which (in the case only of the powers under section 89(b) and (c)) may be exercised by the Animal Product Officer over the phone if he or she considers that appropriate.

You must get written confirmation from a recognised verification agency indicating that they have agreed to provide verification services for your RMP [APA 20(2) (c)]. This is typically a letter which is considered to be part of the RMP and must be submitted with other documentation for registration.

You are responsible for contracting and paying for the services of a recognised verifier. All recognised verifying agencies are listed on the MPI website under registers and lists:

- Animal products (excluding dairy) verification agencies; or
- Dairy – recognised agencies.

See Part 8.3 External Verification for further details.

4.15 Additional requirements in relation to homekill and recreational catch for dual operator butchers

(Section 71 of APA)

A dual operator butcher (DOB) is a retail butcher who:

- is listed by the D-G as a homekill or recreational catch service provider; and
- processes homekill or recreational catch at the same premises or place as the retail butcher processes or trades in regulated animal product.

MPI has developed some guidance to assist DOB on interpreting the phrase “same premises or place”: Homekill: Activities occurring at the “same premises or place”.

DOBs must have a registered RMP before trading regulated animal product (see definition in Appendix A: Glossary of Terms) to ensure that any such product is fit for its intended purpose [APA 71(1)(c)].

In addition to the components required for a normal RMP, a DOB RMP must include:

- the identification and control of the risk factors introduced to the regulated product from homekill or recreational catch that is processed in the same place;
- control measures to ensure that homekill and recreational catch products are processed and stored separately from and are not mistaken for regulated animal products and do not enter trade (except for rendering as permitted under APA s69(3)(b)); and
- control measures to ensure that product from the business is not exported [APA 71(1) (d)].

A DOB must also document specific inventory control measures to comply with the Animal Product Notice: Homekill and Recreational Catch Service Provider Records and Information which gives the minimum requirements for record-keeping and traceability of homekill products.

MPI has developed an RMP template to assist in the preparation of DOB RMPs. This template has been approved so RMPs that are fully based on it do not need to be evaluated prior to registration. Search for ‘DOB RMP template’ on the MPI website.

5 Checks and validation

(Section 16, 17 (2) (b) and 20 of the APA)

Once you have developed your RMP, you should check that it contains all the required information before sending into MPI for registration. Refer to Table 12: Summary of Document Checks and Validation of the RMP for a list of checks you should perform prior to registering your RMP. These checks are explained in detail below.

In most cases these checks will provide sufficient evidence and you should make any existing compliance records available to the evaluator during RMP evaluation. However, where additional evidence may be required (refer to Appendix F: Procedures and Processes Requiring Validation), a protocol on how you will collect the evidence must be provided to the evaluator during evaluation [RMP Spec 18].

Further information from Statement of Policy: Operator Responsibilities during Registration of an RMP (V1)

(1) Documentation checks and validation
The operator must check, prior to the registration of an RMP or a significant amendment to a registered programme, that the:

(a) documentation is complete and complies with all relevant legislative requirements;
(b) premises and equipment are ready to operate in accordance with the programme and other legislative requirements; and
(c) RMP will be capable of consistently producing animal material or animal product that is fit for intended purpose.

Table 12: Summary of document checks and validation of the RMP

What to look for	Evidence required	When is the evidence required	Is a protocol needed?
RMP documentation checks			
• is complete • complies with all relevant legislative requirements	• RMP document • the use of a checklist is **recommended** to indicate where the relevant legislative requirements have been addressed within the RMP	Before applying for registration of RMP	N/A
Premises and equipment checks			
• ready to operate • meets the requirements of all relevant legislative requirements	• actual design and construction of premises is complete • equipment is available and ready to operate • commissioning reports and calibration certificates for certain equipment (e.g. retort, drier, etc.)	• before applying for registration of RMP, unless a pre-assessment procedure is followed • before or after registration of RMP	N/A Yes, if commissioning after registration
Supporting systems checks			

What to look for	Evidence required	When is the evidence required	Is a protocol needed?
• achievement of supporting system requirements	Records of compliance to: • documented procedures (e.g. monitoring records, internal audit reports); and • measurable support system requirements (e.g. product load-out temperatures)	• before or after registration • any existing evidence should be made available to the evaluator before registration	A protocol is not required for most supporting system operations See Appendix F: Procedures and Processes Requiring Validation for those operations that would require a protocol
Validating the RMP			
• setting the regulatory and operator-defined limits • product characteristics related to food safety and shelf stability • process parameters • GOP is effectively implemented	• limits are appropriately chosen for the process (e.g. from AP Notices, industry agree criteria, etc.) • records of compliance to relevant critical limits, regulatory and operator-defined limits • data from previous validation studies • results from microbial modelling and lethality calculations	Before or after registration	The operator must provide a written protocol for collection of evidence at the time of registration

5.1 Checks

5.1.1 RMP documentation

Before you apply for RMP registration, you should check that all of the required components of an RMP:

- are documented and complete; and
- meets all relevant legislative requirements, including any regulatory limits (you can do this by systematically checking it against the legislation).

To assist the evaluation process (refer to Part 6: Evaluation) it is recommended that you prepare a checklist of the relevant legislation and references where these requirements are addressed in the RMP.

5.1.2 Premises and equipment are ready to operate

You must ensure that the design and construction of premises and equipment are complete [RMP Spec 16(1)(d)]. All equipment necessary for the processes described in the RMP must be available, ready to start processing and have been viewed by the evaluator as part of the evaluation before registration of the RMP.

Certain equipment (e.g. retorts, rendering driers, pasteurisers, chillers, etc.) may be required to be validated. If this is to be done after registration, then the equipment validation must be included in the protocol [RMP Spec 18] (see Part 5.4 Validation After Registration). Operators should summarise the validation work into a report and make this available to the evaluator.

5.1.3 Demonstration of compliance with supporting systems

You must demonstrate that the RMP meets regulatory requirements for supporting systems [AP Reg 11]. Supporting systems such as hygiene and maintenance, personnel health, approved chemicals or water quality that meet these requirements should be documented in the RMP.

5.2 Validation

Validation is the process of collecting evidence (e.g. scientific technical information or records) to show that your RMP is capable of consistently producing the **desired outcome** (i.e. to produce animal materials or products that are fit for their intended purpose). An RMP that is not properly validated cannot provide assurances that hazards are effectively managed.

Validation can be completed either before you register your RMP (you will need to give your full RMP and the validation report/evidence to your evaluator to be evaluated) or after the RMP has been registered (provided a protocol was developed and evaluated).

You may use a technical expert or a consultant to undertake validation study, including preparing the validation report and where necessary a protocol.

MPI has developed more guidance on validation, you can find it by searching for 'What is Validation?' on the MPI Website. Further guidance on validation requirements for specific processes can be found in MPI Codes.

5.2.1 Protocol

When there is insufficient evidence to demonstrate the effectiveness of the RMP at the time of applying for registration (e.g. for a new businesses or a new process, etc.) you must document a protocol for how you will collect evidence [RMP Spec 18]. The protocol will need to be submitted to the evaluator as part of the RMP evaluation and to MPI when applying for registration.

The protocol must contain:

- details of the evidence required and how it is to be collected;
- a proposal for the disposition of animal material or product produced during implementation of the protocol; and
- a timeframe for completion of the protocol [RMP Specs 18(1) (b)].

You may use a consultant to design and document the protocol or parts of it e.g. to design sampling plans or to confirm the capability of complex machinery such as retorts and rendering dryers, etc. You may base your validation protocol on the information suggested as per sections 1-6 of Table 14: Suggested Content of a Validation Report.

Once the RMP is registered, you must follow the protocol and any conditions imposed by MPI for registration and collect evidence over the stated period [APA 16(1) (a)]. If the protocol needs to be changed e.g. because the design is not practical or proposed process is not producing valid results, you will need to discuss this with your evaluator, and if required, provide them with further document to support agreed changes.

The recognised verifier will check that the protocol is being following and completed during any verification visit.

Once you have completed your protocol, you should prepare a report of the results you have collected and submit this to the evaluator for assessment (see Part 5.2.5 Validation Report for what to include).

5.2.2 Desired outcomes

This is shown in Table 13: Example of Desired Outcomes to be Achieved and Possible Evidence.

Table 13: Example of desired outcomes to be achieved and possible evidence

Examples of desired outcomes	Examples of evidence
Setting regulatory limits and operator-defined limits (e.g. product characteristics, acceptable level of hazards in a product is achieved, process parameters, etc.).	New Zealand food legislation: • APA Notices • Food Standards Code Operator-defined limits: • Codes • internationally recognised standards • published scientific literature • industry agreed criteria • own validation research and trials
Product characteristic related to food safety and shelf stability (e.g. pH, moisture content, water activity, etc.). This can be an acceptable level of hazard in a product e.g. microbiological criteria, maximum levels of chemical residues or metal contaminants, etc.	• data from previous or current validation studies (including experiments such as challenge trials) • monitoring records of a control point (CP)
Process parameters (e.g. pasteurisation time and temperature, thermal process lethality such as 6-log reduction in *Listeria monocytogenes* or cooling rate, etc.)	• equipment commissioning reports • equipment calibration reports or certificates Existing businesses and processes (provided no changes have been made to the process): • data from previous or current validation studies (including experiments such as challenge trials) • monitoring records of a control point (CP) New businesses or processes: • microbial modelling • lethality calculations • data from validation studies (including experiments such as challenge trials) • trials to show process parameters (e.g. time and temperature) are met during commercial operation
Supporting Systems are effectively implemented	• records generated for each supporting system (e.g. training and cleaning records, etc.)

Note that validation is often not simply running trials in your process. It involves designing a robust experiment with a statistically valid sampling plan and how you will analyse your data to determine if the desired outcomes have been achieved.

For new processing equipment, the use of manufacturer specifications or performance claims is unlikely to be sufficient for validation (especially for equipment that is used to deliver a critical processing step e.g. thermal processing, high pressure processing, etc.). You will need to obtain evidence from experimental trials to validate that new machinery is functioning as intended.

5.2.3 Validation, operator verification and monitoring

There is often confusion between validation, operator verification and monitoring.

Validation confirms that product is fit for its intended purpose.

Monitoring and verification both take place after the validation has been completed.

They are tools to check that the RMP is being implemented as written and procedures are being followed, or that equipment is operating as intended i.e. confirming you are doing what you planned to do.

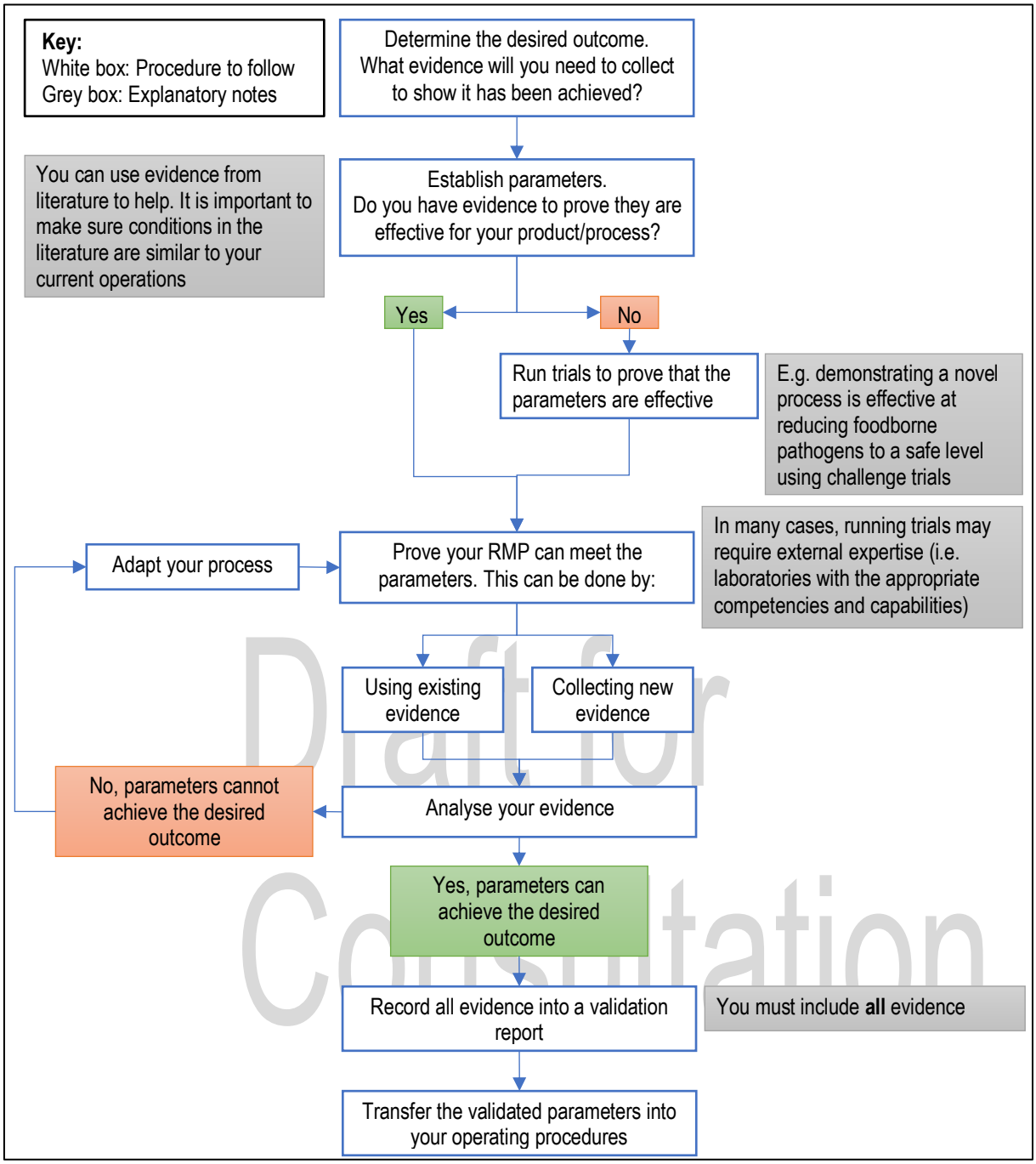
Operator verification can be observing personnel as they monitor control points, or reviewing records to show the limits have been met. Monitoring of control measures is an on-going activity to make sure the process is functioning as intended e.g. collecting 'real-time' measurements such as temperature data.

5.2.4 Validation procedure

Figure 4: Flowchart of Steps to Validation guides you through the steps recommended for validation. You should develop a clear purpose, and plan how the evidence will be collected and analysed (a protocol). Perform trials and carry out the relevant data analysis. When you have the evidence to show your process can achieve the desired outcome, it is recommended that you write a validation report (see Part 5.2.5).

You may need to revalidate whenever there is a change that could affect the control of hazards (e.g. new equipment, raw materials, control measures, etc.), or if new scientific or regulatory information becomes available. You may also need to revalidate when there is a system failure or if non-conformances indicate the current control measures are ineffective.

Figure 4: Flowchart of steps to validation



5.2.5 Validation report

Table 14: Suggested Content of a Validation Report gives some examples of what you can include in your validation report.

Table 14: Suggested content of a validation report

Sections	Suggested Headings	Examples of what to include
1	**Scope and Purpose of the validation** What am I trying to validate?	• what is the desired outcome? Are you trying to show that a product or process parameter is being met, or that supporting systems are effective? • what are the regulatory or operator-defined limits to be met? • any product characteristics (e.g. water activity, formulation, pH, etc.) • the process (e.g. pasteurisation, Ultra High Temperature (UHT), high pressure processing, etc.) and any process parameters • GOP(s) to be validated (e.g. cleaning, etc.)
2	**Competencies**	• person responsible for validation and any required competencies • any training for personnel working on the process line (e.g. plant personnel, plant managers, etc.) prior to starting validation? • are you relying on external or in-house technical expertise?
3	**Equipment**	• identify the equipment to be validated • commissioning reports • calibration reports or certificates • maintenance schedule
4	**Criteria against which effectiveness will be determined**	• regulatory or operator-defined limits (e.g. product characteristics, acceptable level of hazards in a product or process parameters) • GOP requirements e.g. water testing, effectiveness of cleaning and sanitation
5	**Trial Design**	Either: • do you have any previous data, records or reports to demonstrate what you are trying to validate is effective? Make sure the data is collected under your current processing conditions Or: • trial design: – equipment set-up – any specific trial conditions you need to meet – worst-case operating conditions (e.g. maximum loading, throughput, essential services, seasonal variations, shifts) – what data will be collected – any other variables that need to be considered • sampling design: – types of sample – number of samples to be collected, how often, any replicates? Your sampling plan should be **statistically valid** – location of sampling sites – sensitivity of your method, repeatability and consistency • method of analysis: in-house, external (accredited or non-accredited method)?
6	**Product disposition**	• how the product resulting from the trials is to be disposed of (e.g. test and release, rework, downgrading or dumping, etc.)
7	**Results**	• overview of the data collected (raw data should be included in the appendices) • analysis or interpretation of the data (**outliers should not be discarded** without good justification) • repeated testing of the same product until desired results are obtained is not acceptable • confirmation product disposition has occurred as planned

Sections	Suggested Headings	Examples of what to include
8	**Conclusion**	• have the desired outcomes been met? Does the evidence support the conclusions made? If not, you will need to adapt your trial design • have validated parameters been transferred to operating procedures?

Validation trial design

When designing a validation trial that will involve measuring, counting, or evaluating a process or product parameter, you should consider the "quality of the data" that will be collected and its appropriateness for use. If poor quality data is collected then this could profoundly affect the value of a trial or survey and in some cases invalidate the results of a trial or experiment.

It is important to consider the following when you are designing your sampling plan:

- bias and how they can be managed (i.e. a non-random or direct effect caused by factors(s) such as errors)
- accuracy (i.e. recording a measurement count that is very close to the actual value); and
- precision or repeatability (i.e. achieving consistent measurements).

You should determine what is you acceptable level of failure and the confidence interval you want from your results. For example if your acceptable level of failure is 1 failure in *n* number of samples, it is generally accepted to test *3n* of products to achieve a confidence interval of 95%.

Uncontrolled parameters

When conducting a validation trial, there may be parameters that are out of your control. These factors may influence the collected results hence affect the validity of your experimental results e.g.:

- environmental changes (such as fluctuations in temperature and/or humidity, changes in water used for sterilisation of equipment);
- different operators handling the samples; and
- alternating between different suppliers that have different raw material specifications.

To manage these uncontrolled factors, you should design your validation trials with the following fundamental principles of experimental design in mind:

- control (to test the product without any treatment to minimise experimental bias);
- randomisation of your trials (e.g. performing the trials in a randomised order to minimise potential bias or judgement, etc.);
- replication (e.g. repeating trials to obtain confidence that your results are a true representation, etc.); and
- reducing noise (i.e. controlling as much as possible, the varying conditions in the experiment, etc.).

If any significant parameters weren't controlled during the validation trials, you should explain why they were not (or could not be) controlled and how this may impact the results. Risk assessment may be necessary to decide the significance of uncontrolled parameters.

Microbiological challenge testing

A microbiological challenge test should be designed to demonstrate that the desired outcomes (e.g. 6-log reduction in a particular microorganism) have been achieved. Operators should account for the specific product and packaging characteristics as well as environment factors (e.g. uncontrolled parameters, etc.) to ensure the results obtained are valid. For example, a microbiological challenge test can demonstrate the commercial sterility achieved and maintained by the proposed treatment. This may be done by using

surrogate microorganisms (e.g. *Clostridium sporogenes*, etc.) in place of pathogenic target microorganisms (e.g. *Clostridium botulinum*, etc.) that have a similar resistance to the sterilisation process. An ideal surrogate is a strain of the pathogenic microorganisms that retains all other characteristics except for its pathogenic nature. Federal Drug Administration (FDA) recommends multiple specific surrogates for the target pathogens should be included in the challenge study.

You should determine the inoculation methods that is most appropriate to your process (e.g. spot inoculation or spray inoculation, etc.), the inoculation load (e.g. sufficient to be able to count the number of survivors after the sterilisation process, etc.) and the location of the inoculations (e.g. locations that are the 'worst-case' scenario, etc.).

Microbiological challenge tests require a lot of expertise and planning, it is strongly suggested to discuss with a food safety consultant prior to starting.

5.2.6 Amendments to the RMP

You may need to revalidate whenever there is an amendment to your RMP. If the change affects the control of hazards (e.g. new equipment, raw materials or control measures), or new scientific or regulatory information becomes available, you may be required to revalidate certain aspects of your RMP.

Any changes to your validation procedure will require a notification to your evaluator and MPI (see Part 8.4.3).

5.2.7 Common validation mistakes

The following table lists some of the common mistakes people make when carrying out validation. Remedial actions have been suggested.

Table 15: Common validation mistakes and corresponding remedial actions

Mistakes	Remedial actions
Omitting data that does not appear to be logical or only reporting data that fits within the critical limits (e.g. outliers)	Results cannot be excluded simply because it does not fit the expected pattern. You should analyse these results critically as they may indicate areas of improvement in your written procedures, process parameters, GOP etc. You must have a written justification based on known facts if you are going to exclude certain data points i.e. transcription errors, or sampling errors.
Failing to set up a 'worst case' scenario	When you design the protocol, you must take into consideration how the process will perform when the processing parameters are at its limits (i.e. greatest chance of failure). If a process is able to achieve its limits even when operating under these less favourable conditions, then all products made during normal production will most probably achieve the limits too.
Not enough replications	The trial design should be statistically valid, i.e. have a suitable number of samples so the results are reliable and repeatable. The number of replicates required will depend on the experimental design.
Not using enough or suitable measuring equipment	Any equipment used to make a critical limit reading should have a suitable accuracy and be calibrated for consistency.

6 Evaluation

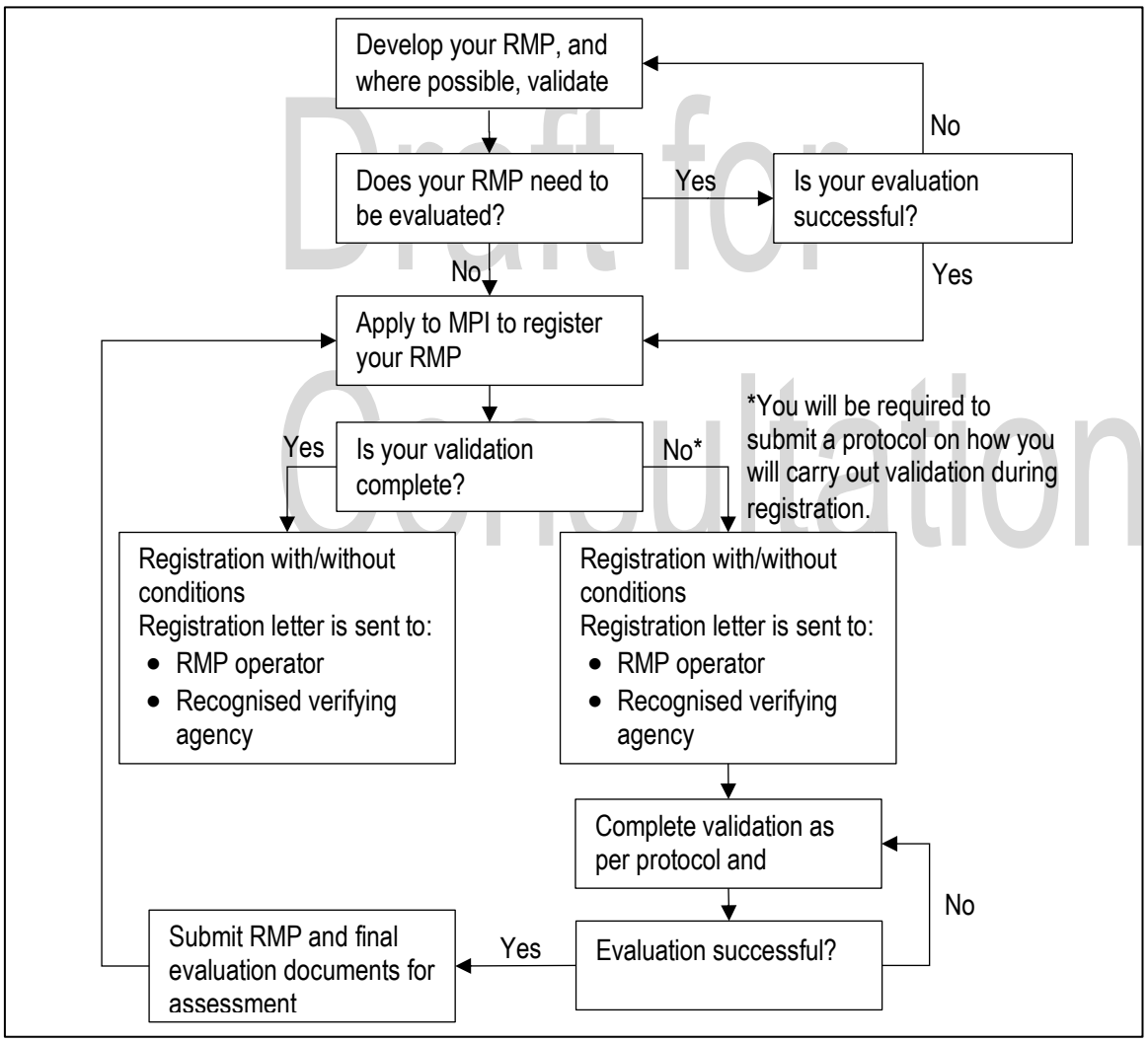
(Section 20 of the APA)

Evaluation is the independent assessment of your RMP to ensure that it meets requirements and when implemented, will produce animal material and product that is fit for its intended purpose. Evaluation is necessary for most RMPs, however the D-G may waive or modify the requirement for evaluation if:

a) your RMP is based on a template, model, or certain Codes approved under section 12(3A) of the APA (for a list of RMP templates for which evaluation has been waived see: Waiver of the Requirement to Provide a Copy of an Independent Evaluation Report);
b) your RMP is a multi-business RMP approved by the D-G in accordance with section 17A of the APA; or
c) the risks to human or animal health is such that an on-site assessment is considered not necessary [RA Notice 28(5)].

Once your RMP has been recognised as valid by a recognised evaluator, it can then be recommended to MPI for registration. The evaluator will prepare an evaluation report for you. This has been summarised in Figure 5 Evaluation and Registration Process.

Figure 5: Evaluation and registration process



You can search for the following guidance documents on evaluation on the MPI website:

- Recognised Evaluators of Non-dairy Risk Management Programmes;
- How to Evaluate Non-dairy Risk Management Programmes;
- Animal Products (Dairy) Conditions for Recognition; or
- Dairy Operational Guidelines and Approved Criteria.

6.1 Evaluation of non-dairy RMPs

6.1.1 Selection of a recognised evaluator

You will need to contract an independent evaluator recognised under the APA to evaluate your RMP. You should check the evaluator you chose has the required competencies (e.g. an activity endorsement, etc.). In some cases it is mandatory to use an evaluator with the appropriate activity endorsement, e.g. low acid canned foods, or dairy heat treatment. The evaluator may obtain technical assistance from technical experts or other recognised evaluators as necessary.

A list of all recognised evaluators and their activity endorsements is available on the MPI website: http://mpi.govt.nz/news-and-resources/resources/registers-and-lists/.

You cannot use the same person to develop and evaluate your RMP as this would be a conflict of interest.

You are responsible for costs associated with evaluation.

6.1.2 Desk-top assessment

The evaluator will carry out a desk-top review of all RMP documentation to ensure that your RMP is complete, meets all the relevant regulatory requirements and that the proposed controls will deliver animal material and product that is fit for its intended purpose.

If you intend to submit an RMP outline for registration the evaluator will check that the outline accurately reflects the content of the full RMP. This may occur at the premises or at some other location and typically occur prior to the on-site assessment.

6.1.3 On-site assessment

In order to undertake an evaluation and prepare the evaluation report, the recognised evaluator must conduct an on-site assessment that must include assessing the appropriateness of the RMP against the physical boundaries, design and construction of the premises or place and the operations described in the programme [RA Notice 28(1)].

The on-site assessment must be performed when the premises and equipment are ready to operate in accordance with the RMP and legislative requirements [RA Notice 28(2)]. If your premises is not operational at the time of evaluation (e.g. in the case of a new premises or new process), you must make reasonable attempts to demonstrate or explain normal operation.

The on-site assessment may be performed by a technical expert when agreed in writing by the D-G [RA Notice 28(3)].

Despite sub-clause (1), when undertaking an evaluation of an amendment to a risk management programme, the recognised evaluator may decide that an on-site assessment is not necessary and must give the reasons for that decision in the evaluation report [RA Notice 28(4)].

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

An on-site assessment must be conducted as part of the evaluation for a new RMP registration.

During the on-site assessment the recognised evaluator will:

- conduct a reality check of your operation against the documented RMP;
- confirm that the scope of your RMP is appropriate (include checking the physical boundaries);
- check the design and construction of your facilities and equipment and confirm that they are suitable and ready to operate (note: dairy evaluators will get this information from heat treatment and premises evaluation reports);
- check GOP to ensure that the RMP is capable of delivering animal material or product that is fit for its intended purpose;
- review the application of HACCP principles (e.g. your HACCP plan, etc.);
- talk to key personnel (including managers) to ensure an acceptable level of understanding of the RMP; and
- check relevant documents and records, including any validation evidence to support determination of the appropriateness of the RMP.

An on-site assessment may require more than one visit. In many cases the initial on-site assessment will highlight a range of issues still to be addressed (e.g. constructional issues), which may require further on-site assessments. A follow-up evaluation may be required when the RMP is incompletely validated at the time of registration.

In the case of mobile premises, fishing vessels or transporters, the on-site assessment may be done at the home base or home port. Where practicable, you should demonstrate the normal operations during the on-site assessment.

If your RMP covers a number of businesses or sites, depending on the nature of operations, the evaluator may only need to visit selected sites. The evaluator must consult MPI regarding this prior to the on-site assessments to determine whether this is acceptable.

6.1.4 Resolving RMP deficiencies

It is your responsibility to resolve any deficiencies identified by the evaluator. If changes are made, you should check whether any consequential changes to the RMP are necessary to ensure consistency e.g. to other procedures, GOP, the document list, version numbers etc.

If your RMP is found to be unsatisfactory, the evaluator may provide you with feedback in general terms stating where it is deficient. To ensure impartiality and independence is maintained, the evaluator must not provide solutions to the deficiencies if they wish to remain as your evaluator.

6.2 Evaluation of dairy RMPs

Evaluation of dairy RMPs must be completed in as per Part 9 of the Animal Products (Dairy Processing Specifications) Notice 2011. Evaluation must be undertaken by an evaluator recognised under the Animal Products Notice (Dairy Recognised Agencies and Persons Specifications 2017.

Evaluation of dairy RMPs is conducted in the same manner as evaluation of non-dairy RMPs. In addition, the dairy evaluator must evaluate heat treatment and premises reports as part of the evaluation process, as per clause 38(3) of the Animal Products (Dairy Processing Specifications) Notice 2011.

6.3 Reporting and registration documentation

When your RMP is satisfactory, the evaluator will endorse the RMP (or the outline) and prepare an evaluation report proposing any conditions to be applied by MPI upon registration. The evaluation report is only valid for 6 months and for this reason you should apply for registration as soon as possible after evaluation. The evaluation must be repeated if this timeframe is exceeded.

Submit the evaluation report, the endorsed RMP (or outline) and any other required documents to MPI with your application for registration.

6.4 Validation after registration

If your RMP is incompletely validated at the time of registration (i.e. certain aspects of the RMP may be validated but the remainder will be completed after the RMP is registered) you will need to develop a protocol or procedure before registration on how you will carry out the remaining validation work. More details on what to include in a protocol can be found in Part 5.2.1. Registration can be granted with the need to complete the validation as a condition of registration.

You must complete the validation in accordance with your protocol and provide a validation report to the evaluator on the work carried out and any significant amendments as a result of that work.

The validation report and any significant RMP amendments will be evaluated and this may require an on-site assessment. Deficiencies should be resolved in accordance with Part 6.1.4.

The final evaluation report is prepared once the evaluator is satisfied that validation is complete. Forward this report, together with any endorsed RMP amendments to MPI to satisfy the registration conditions.

6.5 Evaluation of significant amendments

If a significant amendment is made to your RMP, it must be submitted for evaluation and registration. The evaluation must involve all parts of the RMP that are affected by the amendment. The degree to which a part will need to be re-evaluated will depend on the degree it has been modified. You should update the RMP to include all new systems and procedures necessary to operate the amendment and ensure that personnel are aware of the changes and know what to do.

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. The evaluator must provide reasons in the evaluation report where an on-site assessment has not occurred.

When the amendment is considered acceptable, an evaluation report will be prepared. For details of amendments that are considered to be significant, refer to Appendix G: Guidance on Difference between Significant and Minor Amendments of this manual.

7 Registration

(Sections 19 and 22 of the APA)

Once the RMP has been developed and evaluated, you apply to MPI for it to be registered. Your RMP must be registered with MPI before commencing operations for trade [APA 3(1)(a)].

You should allow sufficient time to develop and evaluate your RMP before registration and make sure all RMP documentation is complete and that the premises and equipment are ready to operate. The time necessary to register your RMP may take up to 20 working days depending on the complexity and size of your operation and the extent and suitability of existing documentation. MPI has developed guidelines on the application process of registering an RMP.

MPI may request further information as part of your application. Your application will lapse if the information is not supplied within 6 months from the date of request, or within an extended date as agreed with MPI.

In some instances where an RMP assessment is complex or takes longer than anticipated, MPI will request payment of an additional assessment fee. This relates to the additional time involved in assessing your application and is calculated on an hourly basis.

Once the RMP assessment is complete, you will be emailed to confirm that your RMP has been registered, and MPI will supply you with the following documents after registration:

- an email approval notification on the day of registration that operators can commence operations on that day;
- a written letter confirming registration;
- a notice of registration;
- a notice of conditions if applicable (legal requirements that you must comply with); and
- an authorised copy of the registered RMP or outline.

Your RMP verifying agency will be provided with copies of these documents. The original authorised documents will be held by MPI.

Once a RMP is registered, the registration details will be put on the public RMP registers which can be found on the Registers and lists MPI webpage by searching for the following:

- Animal Products (non-dairy) RMPs; or
- Dairy RMPs.

If MPI is not satisfied your RMP has not meet all the requirements under the APA, the registration may be refused (see Part 7.3 Refusal to Register for more details).

It is your responsibility to ensure you comply with any RMP conditions within any specified timeframes. If the condition timeframe is exceeded, MPI may apply additional conditions, or the registration may be revoked.

7.1 Application for registration

You must use the right application form when you are registering your RMP. See below for a list of the application forms:

- AP4: Risk Management Programme Registration;
- AP5: Registration of Risk Management Programme under New Operator;
- AP6: Registration of Amendment to Risk Management Programme;

- AP50: Registration of a Minor Amendment; and
- AP55: Registration of RMP under Special Circumstances.

You can search the above forms on the MPI website by typing the relevant AP number in the search bar.

The application form will prompt you to include all other information that will be required for registering the RMP, including:

- the endorsed RMP or RMP outline (see section Part 7.1.1);
- the independent evaluation report (no more than 6 months old) if required (see section Part 6.3 Reporting and registration documentation) (for dairy processors the evaluation report may include heat treatment and/or premises evaluation reports, if required);
- confirmation that the recognised RMP verifying agency has agreed to verify the RMP (see section Part 4.14 Provision for verification activities and verifiers rights);
- the application fee; and
- AP49: Principle Categories of Processing tables.

The person who signs the declaration on the application form must have the appropriate authority to act on your behalf.

7.1.1 RMP documents to be submitted for registration

The entire endorsed RMP or an RMP outline must be submitted to MPI for registration [APA 20(2) (a)]. The outline must include the following details:

- operator, business and RMP identification;
- management authorities and responsibilities,
- physical boundaries of the RMP;
- RMP scope;
- animal material and product description;
- regulatory and operator-defined limits;
- process description;
- validation evidence or the protocol to carry out validation;
- list of RMP documents; and
- statement of verification from a recognised verification agency[RMP Outline 4(1)].

For multi-business RMPs, additional information on the key management personnel for each premise and must provide sufficient evidence to support the RMP is able to cover all of the processes at every site [RMP Outline 4(2)].

7.1.2 Electronic applications vs hard copy applications

MPI prefers email applications. If you submit documents electronically they should be in Microsoft Word, PDF or a format agreed with MPI prior to submission. If your document file size is too large to email, contact approvals@mpi.govt.nz to request a ShareFile link. ShareFile enables secure, convenient file sharing with MPI.

If you submit your application as a hard copy via the post or courier, please ensure you retain copies of the documents you've sent to MPI for your own records.

Whether your application is emailed or posted, please choose one or the other – submitting a mix of emailed and posted documents to MPI will likely cause delays in processing your application.

7.2 Pre-registration assessment

MPI can pre-assess the RMP documentation before the premises construction is complete.

This is intended to assist in the registration process and may reduce the time taken for RMP registration once the premises is complete.

This option is limited to situations where:

- an evaluation is required;
- the RMP documentation is complete and has been evaluated by the evaluator;
- the documentation is unlikely to change prior to registration; and
- the premises construction is at a stage of 'practical completion'.

Upon pre-assessment, the evaluator prepares an interim report. You must submit this report together with the application documentation to MPI for assessment. Any changes that are required prior to registration of the RMP can then be made and the application put on hold until the on-site assessment of the completed premises has occurred.

MPI will proceed with your registration once:

- the construction is complete;
- the on-site evaluation assessment has occurred; and
- the final evaluation report is updated and submitted.

See Pre-Registration Assessment of Risk Management Programme Documentation Statement of Policy for more information.

7.3 Refusal to register

(Section 23 of the APA)

You will be notified in writing if MPI declines to register your RMP, clearly stipulating the reasons. You will be given a reasonable opportunity to make written submissions or be heard in respect of the notification to decline registration (i.e. within 20 working days or as agreed).

Under Section 162 of the APA, you may apply for a review of the decision if a person other than the D-G makes the original decision to decline registration of your RMP. However, if the D-G makes the original decision, there is no right of review.

Your application for review should be in writing and state the reasons why you consider that the original decision was inappropriate. This should be provided to the D-G within 30 days of the original decision being notified.

The review will be carried out by the D-G or a designated person not involved in the original decision.

The D-G's decision is final and subject to judicial review.

7.4 Completion of validation

If your RMP is incompletely validated during registration, you must carry out validation as per your protocol within the conditions of your registration (e.g. specified timeframes, etc.). The validation will need to be evaluated and the recognised evaluator will confirm your RMP is valid in the evaluation report.

You must forward this report to MPI along with any other required documents as evidence [RMP Spec 18 (1)].

MPI will carry out an assessment of the documents and notify you in writing of the outcome of the assessment and any changes to the RMP conditions.

7.5 Registration of significant amendments

Where you make a significant amendment to your RMP under section 25 of the APA, you must register the amendment with MPI using form AP6: Registration of Amendment to Risk Management Programme [RMP Spec 21]. This must be accompanied by:

a) the RMP pages affected by the amendment with the changes clearly identified;
b) where appropriate, the protocol in accordance with clause 18 (1)(b) of the RMP Spec [RMP Spec 21]; and
c) the evaluation report confirming the validity of the RMP [RA Notice 30(1)].

The process for registering a significant amendment is the same as for initial registration of the RMP. Refer to section Part 8.4.1 for more information. For explanation on what is a significant amendment please refer to Appendix G: Guidance on Difference between Significant and Minor Amendments.

7.6 Change of registration details

(Section 24 and 25 of the APA)

You must notify MPI of any of the following changes to your RMP [RMP Spec 13].

7.6.1 Change in operator or operator name only

Where a change in "operator" or "operator name" is the only change to your registered RMP, you should complete application form AP5: Registration of Risk Management Programme under a New Operator (e.g. a change of the company name, a change to the (number of) members of a partnership, or a change in the names of directors).

In the event of the operator's death, bankruptcy, receivership, or liquidation, a new registration must be made using the application form AP55: Registration of RMP under Special Circumstances.

7.6.2 Change in day-to-day manager of an RMP

When there is a change to the name, position or designation of the person(s) responsible for the day-to-day management of the RMP, you must notify MPI of this change using the AP50: Registration of a Minor Amendment application form [RMP Spec 13(1)]. This is not a significant amendment to your RMP.

7.6.3 Change in recognised agency

You must notify MPI as soon as possible of a change in the recognised verifying agency using form AP60: Change of Recognised Agency for Verification Purposes. This is not a significant amendment of your RMP [APA 16(2)].

7.7 Multi-business RMP registration

If you are registering a multi-business RMP, the process is essentially the same as for a single business RMP. This includes the need for an evaluation, if required. The documents submitted differ slightly. MPI must be satisfied that the requirements in Section 17A of the APA have been met before the RMP is registered.

8 Operating the registered RMP

This section summaries the operators' responsibilities once the RMP is registered.

You can only commence processing product for trade from the date your RMP is registered. You are required to operate in accordance with your RMP and must comply with any conditions specified upon your registration [APA 16(1)]. It is illegal to operate outside the scope of your RMP.

When implementing the registered RMP, you must control hazards and other risk factors associated with the product and the process on an ongoing basis [APA 17(3)].

8.1 RMP operator's duties

The operator of an RMP has the following duties:

a) to ensure that the operations of your business do not contravene the relevant requirements of the APA, including the requirements set out in your RMP;
b) to ensure that your RMP is consistent with the requirements of regulations and specifications under the APA;
c) to adequately implement and resource all operations under your RMP, including provision for the instruction, competency and supervision of personnel to ensure the delivery of product that is fit for intended purpose;
d) to ensure that the capability and capacity of your premises, facilities, equipment and personnel are adequate to deliver product that is fit for intended purpose; and
e) to give the recognised verifying agency such freedom and access to carry out their functions and activities under the APA [APA 16(1)].

If you fail to meet your duties, you will be in breach of APA (Part 10 of APA). This may result in:

- interruption of operations;
- prohibition on use of process or equipment;
- increased external verification of the RMP;
- product disposal;
- recalls;
- suspension or deregistration of the RMP; and
- prosecution where appropriate.

8.2 Conflict between RMP and Regulations or Specifications

Where there is any conflict between documented requirements of a registered RMP and requirements of regulations or notices made under the APA, the requirements of the Regulations or Notices will prevail [APA 30].

8.3 External verification

The verification requirements (carried out by the recognised verifier) for non-dairy RMPs where the product does not require official assurances for export is prescribed by the Verification 2005 Statement of Policy or search for the term on the MPI website.

For dairy RMPs where the resulting product does not require official assurances for export, the verification system is described in the DPC3 Approved Criteria for the Manufacturing of Dairy Material and Product 2010.

An RMP that produces animal product for export (including dairy) that requires an official assurance, must follow the verification requirements prescribed by the Animal Products Notice: Export Verification Requirements 2016 and the Animal Products Export Verification Programme.

The verification frequency will depend on your level of compliance with the registered RMP and any applicable export requirements (i.e. is performance based). If your operation complies with the RMP and is consistently effective, the verifier may be able to reduce the frequency of verification. A higher frequency will be applied if the RMP is not being implemented correctly. More frequent verification may also be required if the business is exporting.

8.4 Amendments to the RMP

If you amend your RMP for any reason, the amendment will either be classified as significant or minor. MPI has provided some guidance on the difference between significant and minor amendments in Appendix G: Guidance on Difference between Significant and Minor Amendments.

You may consult a recognised evaluator or a technical expert to assist in making amendments to your RMP. In addition, if your product is intended for export, MPI strongly recommends that you discuss proposed amendments with your verifier to identify any potential market access implications.

You must identify any amendments made to your RMP as described in the document control section of your RMP. Validation must be conducted where necessary for every amendment.

The operator must notify MPI of any amendments to the RMP [RMP Spec 13(3)]. See Part 8.4.3 for more details.

8.4.1 Significant amendments to the RMP

You must apply to register the significant amendment where any change, event or other matter means that the RMP:

- is no longer appropriate, or will no longer be appropriate to the animal material or product, processes, or premises or place covered by the RMP; or
- otherwise impacts, or will impact, on the fitness for intended purpose of the animal product concerned or the content of the RMP as required under section 17 (1) of the APA [APA 15(1)].

Criteria for a significant amendment is set out in Section 25 of the APA and clause 22 of RMP Specs. This is reproduced below for your reference.

RMP Specs *22 Significant amendments to the risk management programme*

(1) The following activities that result in changes to the risk management programme require registration as an amendment in accordance with section 25 of the Act (except where they are done on a trial basis and the affected animal material or animal product is not traded):

a) making major alterations to the processing facilities or equipment which may impact on fitness for intended purpose of the animal material or animal product.
b) relocating processing operations to a new physical address (except where this is already permitted for mobile premises and vessels):
c) processing animal material or animal product that is not covered by the risk management programme, except:

i) where the product and process are similar, and
ii) a documented risk factor identification and hazard analysis has shown that all risk factors associated with that animal material or animal product are already adequately addressed by the risk management programme:

d) setting up a new process or process modification that is not covered by the risk management programme, except:

i) where the process or process modification is similar to existing processes, and
ii) a documented risk factor identification and hazard analysis has shown that all risk factors associated with that process are already adequately addressed by the risk management programme:

e) making any other changes that introduce new risk factors, or adversely impact on existing risk factors:
f) merging two or more registered risk management programmes:
g) splitting a registered risk management programme into two or more risk management programmes:or
h) adding a business to a multi-business risk management programme except where the Director-General's approval under section 17A of the Act applies to a type of business, premises or place rather than to specific businesses.

Significant amendments can be validated prior to registration, or after if a protocol was submitted during registration. Validation of the significant amendment should be carried out within the specified timeframe per registration conditions.

You must apply for registration of the amendment before any changes, events, or other matters where this is known in advance. In all other cases you must apply for registration of the amendment as soon as practicable [APA 25(2)]. If you do not comply with registration requirements for a significant amendment to your RMP, you will be in breach of the APA. Depending on the circumstances this could result in:

- suspension of the RMP;
- de-registration of the RMP; or
- prosecution.

8.4.2 Minor amendments to RMPs

(Section 26 of the APA)

Minor amendments can be made without evaluator or MPI involvement.

If you decide an amendment is minor, you should ensure sufficient written evidence is available to support this decision e.g.:

- a full description of the amendment (including details of any planned construction or alterations); and
- evidence that RMP Spec 22 has been considered.

If the changes are editorial (e.g. to improve the clarity of a procedure or to correct typographical errors) no evidence is required.

If you are making multiple minor amendments, it may be considered a significant amendment, if the combined effect of the changes make the RMP no longer appropriate. You should discuss with your verifier to see if this is applicable.

All minor amendments will be checked by the recognised verifier as part of their verification activities.

8.4.3 Notifications to MPI

To ensure the registration details shown on the RMP public register are up-to-date and accurate, some changes require notification to MPI. If there is a change in any of the following details, you should notify MPI of the change using the AP50: Registration of a Minor Amendment application form. Changes may include:

- surrender of the RMP;
- change of postal address and/or contact details;
- change in trading name;
- change of responsible person i.e. day-to-day manager (this is not a change in operator or operator's name – see section Part 7.6.2);
- removal or certain additions of product categories; or
- any other changes.

Make sure you attach any relevant documentation to assist with the amendment.

9 Ceasing Registration of an RMP

The section provides guidance for when you cease operating your RMP or your business is removed from the coverage of a multi-business RMP. If only a part of your RMP ceases operation, you should consider any impact on the parts of your RMP that is still operating.

You will need to give consideration to the control and disposition of any remaining animal material and animal product.

9.1 Surrender of registration

Where you choose to surrender your registered RMP (permanently as opposed to seasonal closure) you must notify the D-G in writing [APA 29(1)].

You (or where appropriate a liquidator, receiver, executor, or other successor to title of the operator) must, within 30 days of cessation:

a) notify MPI in writing (the AP50: Registration of a Minor Amendment form may be used for this), and include how any remaining animal material or product covered by the registered RMP will be dealt with;
b) surrender the notice of registration to MPI; and
c) notify the recognised (verifying) agency [APA 29 (2)].

This applies to multi-business RMP's you should notify MPI of your business details and provide evidence in writing that you have the consent of the person whose business it affects. However, if MPI has approved an alternative means by which businesses that make up the multi-business RMP had been approved, no notification is necessary, so long as the conditions of registration are met.

You must notify MPI of how to deal with any remaining animal material or product covered by the RMP and MPI may:

a) approve or agree to the proposal; and
b) direct you to take appropriate actions to deal with any affected animal material or product and use Animal Product Officers or other MPI employees to act on their behalf. All associated costs will then be recovered from you [APA 29 and 82].

You should make sure that eligibility documents for official assurances are raised for all animal product that you intend to export prior to surrender of your RMP. You will not be able to raise any eligibility documents after surrendering your RMP.

MPI will notify the relevant territorial authority [APA s32] when a surrender involves a secondary processor who has elected to operate under an RMP rather than under the Food Act regime, if necessary.

9.2 Suspension of registration

(Section 27 of the APA)

9.2.1 Suspension by MPI (mandatory suspension)

MPI may suspend part of, or the whole operation (including one or more businesses under a multi-business RMP) under a registered RMP for a period of up to 3 months if there are reasonable grounds to believe that the:

- RMP may not be or is no longer effective; or

- animal product produced under the RMP does not meet the requirements of the APA.

MPI must notify the recognised verifying agency of any suspension of an RMP and record the suspension on the public register [APA 27 (5)].The suspension may be notified in the Gazette [APA 27 (6)].

You will be given a written notice of the suspension specifying the following:

- the reason for the suspension;
- the period of the suspension;
- the date and time of commencement of the suspension (which may not be earlier than the date and time of notification);
- the operations to which the suspension applies; and
- any conditions or requirements in relation to the suspension [APA 27(3)].

Where a person acting under the delegated authority of the D-G suspends any operations, you may seek a review of the suspension by applying in writing to MPI within 30 days of notification [APA s162].

MPI may direct you to take appropriate action to deal with any affected animal material or product or may use animal product officers or other MPI employees to act on their behalf. All costs associated with this will be recovered from you [APA s82].

The period of suspension may be extended for an additional 3 months if there are reasonable grounds. MPI must notify you in writing of an extension to the period of suspension before the expiry of the original suspension. However, this extension can only take place after you have been notified of the proposed extension and the reasons for it and have had a reasonable opportunity to respond [APA 27 (4)].

9.2.2 Suspension by operator (voluntary suspension)

RMP operators may suspend all or any operations under the RMP for a minimum of 3 months and a maximum of 12 months. You must notify MPI of the suspension using AP50: Registration of a Minor Amendment application form.

Businesses that produce or process animal products requiring an official assurance for export, and who choose to suspend operations are still subject to the Animal Products Notice: Export Verification Requirements 2016 clauses 3.1(6) & (7) require that the registered operation(s) still undergo verification audits while operations are suspended. For example, for bee products export operations, the registered operation(s) will still be required to undergo 6 monthly audits.

MPI is also able to impose conditions and requirements in respect of the implementation and operation of the suspension and it is likely that voluntary suspensions will be imposed with a condition requiring a verification audit prior to restarting.

MPI must notify the recognised verifying agency of any suspension of an RMP and record the suspension on the public register [APA 27(5)].

9.3 Deregistration of the RMP

(Section 28 of the APA)

MPI may deregister an RMP or remove any animal product business from the coverage of a multi-business RMP if:

- repeated suspensions have occurred;
- a serious failure of operations has occurred;

- the fitness for intended purpose of the animal product is in doubt;
- you are not considered fit to continue operating your RMP; or
- your RMP has ceased to be relevant to your current operations.

Oral or written notice of the intention will be given to you (giving reasons) where MPI intends to deregister your RMP or remove your business from the coverage of a multi-business RMP. You will be given the opportunity to respond.

The date that deregistration or removal takes effect will be given by MPI. The deregistration date must not be earlier than the date of notification. Notification of deregistration or removal will also be given to your recognised verifying agency. MPI may notify any deregistration in the Gazette.

If a person acting under the delegated authority of the D-G deregisters your RMP or removes your business from the coverage of a multi-business RMP, you may seek a review of the decision by applying in writing to MPI within 30 days of notification (section 162 of the APA).

MPI may direct you to take appropriate action to deal with any affected animal material or product or may use animal product officers or other MPI employees to act on their behalf. All costs associated with this will be recovered from you (APA s82).

Appendix A: Glossary of terms

Act means the Animal Products Act 1999 unless otherwise stated

amendment means any change or event or other matter that:

a) means that the programme is no longer appropriate, or will no longer be appropriate to the animal material or product, processes or premises or place covered by the programme; or
b) otherwise impacts, or will impact, on the fitness for intended purpose of the animal product concerned or the content of the RMP

animal means any member of the animal kingdom and includes:

a) any mammal, bird, finfish, shellfish, reptile, amphibian, insect or invertebrate; and
b) any other creature or entity that is declared by the Minister by notice in the Gazette to be an animal for the purposes of this Act; but does not include a human being

animal consumption (see human or animal consumption)

animal material means any live or dead animal, or any tissue or other material taken or derived from an animal

animal product, or product means any animal material that has been processed (other than simply transported or stored in such a way as not to involve any alteration to its nature) for the purpose, or ultimate purpose, of consumption or other use by humans or animals

animal product business means a business undertaking that, for reward or for the purposes of trade:

a) produces or processes animal material or product; or
b) exports animal material or product

animal product officer, or officer, means a person appointed as an animal product officer under section 78 of the APA and includes the Director-General

animal product standard, or standard, means a standard prescribed by regulations and specifications that specifies the criteria that must be met to determine fitness for intended purpose of any class or description of animal product

audit means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives

business (see animal product business)

business identifier means a unique identification code, selected by the operator for a premises covered by an RMP

consumption (see human or animal consumption)

contaminant means any substance or thing which:

a) is undesirable, potentially harmful, or unexpected in a particular product or process; and
b) is or may be present in, or in contact with, animal material or animal product

control (noun) means the state wherein correct procedures are being followed and standards and other applicable criteria are being met

control (verb) means to take all necessary actions to ensure and maintain compliance with standards and other applicable criteria

control measure means any action and activity that can be used to prevent or eliminate an animal product related hazard or other risk factor, or to reduce it to an acceptable level

corrective action means any action to be taken when the results of monitoring indicate a loss of control

critical control point means a step at which control can be applied that is essential to prevent or eliminate a hazard or reduce it to an acceptable level, as described in section 17(3)(b) of the Act

critical limit means a criterion which separates acceptability from unacceptability at a critical control point, and includes acceptable parameters as described in section 17(3)(c) of the Act

Director-General (D-G) means the Chief Executive of the Ministry for Primary Industries or such other Ministry as has, with the authority of the Prime Minister, for the time being assumed responsibility for the administration of the APA 1999

day-to-day manager means the person identified in a risk management programme either by name, position or designation as being responsible for the day-to-day management of that programme

document (verb) means to include in writing in the RMP

dual operator butcher, or dual operator (DOB), means a retail butcher who:

a) is listed by the Director-General as a homekill or recreational catch service provider; and
b) processes homekill or recreational catch at the same premises or place as the retail butcher processes or trades in regulated animal product

evaluation means the process of independent assessment of the validity of an RMP for the purposes of providing an independent evaluation report as required under section 20(2) (b) of the Act

evaluator means a person recognised under section 103 of the Act to perform risk management programme evaluation functions and activities

exporter means a person who exports any animal material or product from New Zealand that is included in the coverage of the APA 1999

external verification means the process of verification of activities conducted under a risk management programme by a recognised verifier

farm dairy means a place where milking animals are milked on a permanent or temporary basis; and

(1) subject to paragraph (2), includes:

a) any stockyard, milking yard, feed yard, silo pad, or other construction associated with or involved in the activity of extracting milk from milking animals; and
b) any place where milk from the milking animals is first collected, filtered, deposited, cooled, stored, or treated for transport or for further processing; but

(2) does not include any place where any further processing takes place, or transport to that place

farm dairy operator means the person in charge of operations at a farm dairy, including the extraction of milk from milking animals

finfish includes all species of finfish of the Classes Agnatha, Chondrichthyes, and Osteichthyes, at any stage of their life history, whether living or dead (Fisheries Act 1996)

fish includes all species of finfish and shellfish, at any stage of their life history, whether living or dead (Fisheries Act 1996)

fit for intended purpose the phrase, used in relation to any animal product, that has been processed in accordance with the requirements of a registered RMP under the APA 1999, means that by reason of animal material or product having had the relevant risk factors managed and meeting any relevant animal product standards and associated specifications, the product is suitable for the purpose for which the product is specifically stated or could reasonably be presumed to be intended having regard to its nature, packaging, and identification

food:

(1) In this Food Act, unless the context otherwise requires, food:

a) means anything that is used, capable of being used, or represented as being for use, for human consumption (whether raw, prepared, or partly prepared); and
b) includes—

i) seeds, plants, or plant material intended for human consumption, including seeds that are intended to be sprouted and consumed as sprouts, but not other seeds, plants, or plant material intended for planting; and
ii) live animals intended for human consumption at the place of purchase; and
iii) live animals intended for human consumption that are sold in retail premises; and
iv) any ingredient or other constituent of any food or drink, whether that ingredient or other constituent is consumed or represented for consumption on its own by humans, or is used in the preparation of, or mixed with or added to, any food or drink; and
v) anything that is or is intended to be mixed with or added to any food or drink; and
vi) chewing gum, and any ingredient of chewing gum, and anything that is or is intended to be mixed with or added to chewing gum; and
vii) anything that is declared by the Governor-General, by Order in Council made under section 393, to be food for the purposes of this Act

food control plans (FCP) is a plan designed for a particular food business to identify, control, manage and eliminiate or minimise hazards or other relevant factors for the purpose of achieving safe and suitable food, taking into account:

a) each type of food that the food business trades in;
b) each type of process or operation that is applied to the food; and
c) each place in which the food business trades in food

good operating practice (GOP) (including good agricultural practice, good hygienic practice and good manufacturing practice) means documented procedures relating to practices that:

a) are required to ensure animal material and animal product are fit for intended purpose; and
b) are appropriate to the operating circumstances

general requirements for export (GREX) advises of requirements that are required to be met to allow for export that are not country specific

HACCP means a system which identifies, evaluates and controls hazards that are significant for food safety

HACCP plan means a document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration

hazard means a biological, chemical, or physical agent that:

a) is in or has the potential to be in animal material or product, or is or has the potential to be a condition of animal material or product; and
b) leads or could lead to an adverse health effect on humans or animals

hazard analysis means the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan

homekill means an animal that is killed or processed by its owner for the use or consumption of the owner, or by a person who is listed as a homekill or recreational catch service provider under section 76 of the Act

homekill product is product for the use or consumption of the animal owner including his or her family or household or farm workers and must not be traded (includes barter, supply as part of a service, public prize or reward etc)

homekill or recreational catch service provider means a person who is listed as a homekill or recreation catch service provider by the Director-General, who may kill or process for reward, for the owner, hunter or harvester of the animal, any animal or animal material that is homekill or recreational catch without needing to have, or to comply with a registered RMP

human or animal consumption used in relation to any animal product, means that the product is intended to be eaten, or taken orally, or administered parenterally, or applied topically

input means any animal material, animal product, additive, processing aid, ingredient, packaging, or other associated thing where that associated thing is contained within, attached to, enclosed with, or in contact with, the animal material or animal product

internal audit (or internal verification audit) means a systematic examination of RMP processes/procedures to ensure compliance to requirements:

c) by obtaining factual evidence (e.g. records, visual inspection (reality check, etc.); and
d) carried out by an independent/impartial suitably skilled auditor

in writing means printed, typewritten, or otherwise visibly represented, copied, or reproduced, including by fax or email or other electronic means

MPI means the Ministry for Primary Industries

monitor means the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a critical control point is under control

multi-business RMP means an RMP where approval is given under section 17A of the APA for that programme to apply to more than one business

non-complying (non-compliance) means any material or product or input that fails to comply with regulatory requirements

non-comforming (non-conformance) means any material or product or input that is suspected or known not to meet operator defined limits/criteria

officer (see animal product officer)

official assurance means a general statement to a foreign government or its agent that, in respect of any animal material or product:

a) specified processes have been completed under the Act; or
b) the animal product meets the relevant standards set under the Act; or
c) the processing system used meets any market access requirements of the importing country, which New Zealand has agreed to meet; or
d) the situation in New Zealand, in relation to any matter concerning animal material or animal product is as stated in the assurance

operator in relation to an animal product business, means the owner or other person in control of the business

operator-defined limit means a measurable limit established by a risk management programme operator to manage the fitness for purpose of animal material or animal product

operator verification means the application of methods, procedures, tests and other checks by an RMP operator to confirm the ongoing:

a) compliance of the RMP with the legislative requirements;
b) compliance of the operations within the RMP as written; and
c) applicability of the RMP to the operation;

and forms part of confirmation as described in section 17(3) (f) of the Act

output means animal material or animal product resulting from an operation undertaken under an RMP

overseas market access requirements (OMAR) means export requirements specific to an identified overseas market or markets

parenterally means administering a substance to a human or animal by a route other than orally or topically

place or premises includes any building, conveyance, craft, fishing vessel, or structure; and includes any land, water, or other area where animals or animal material are produced or may be present

process includes kill, slaughter, dress, cut, extract, manufacture, pack, preserve, transport and store

protocol contains:

a) details of the evidence to be collected to demonstrate the effectiveness of the RMP; and
b) a proposal for the disposition of animal material or animal product until the effectiveness of the programme has been demonstrated

readily accessible means that no matter where documents are stored, they can be mailed, couriered, faxed, emailed or transferred by other means within the time period stated

recognised agency in relation to any function or activity means a person or body recognised by the Director-General under section 103 of the Act for the purpose of performing that function or activity. This will include the management and supply of recognised persons to perform specialist functions and activities for the purposes of the Animal Products Act, including evaluation and verification functions and activities

recognised verifier means a person recognised under Section 103 of the Act to verify operations that are subject to a risk management programme, regulated control scheme, standards and specifications, or export requirements

recreational catch is a hunted or harvested wild animal for the hunter's or the hunting party's own consumption or use

registered exporter means an exporter currently registered by the Director-General under Part 5 of the Act as eligible to export animal material and products. Where a registered exporter is based overseas, this includes the New Zealand Agent or representative of that exporter

registered risk management programme means an RMP that is currently registered by the Director-General under Part 2 of the Act (see risk management programme)

regulated animal product means animal material or product that is processed or has been or is required to be processed, according to the requirements of an RMP and/or regulated control schemes (or of the Food Act Regime); and does not include any homekill or recreational catch product

regulated control scheme (RCS) means a programme which is imposed by the Director-General to manage risks where RMPs would not be feasible or practicable or where it is more efficient for the government to run the programme or it is needed to meet the market access requirements of foreign governments

regulatory limit means a measurable regulatory requirement that is critical to fitness for intended purpose of animal material or animal product

rendering means the breaking down of animal tissues into constituent fat and protein elements, whether by the application of heat and pressure or otherwise

retail butcher includes any type of butcher engaged in retail trade in regulated animal products

risk means a function of the likelihood and severity of an adverse health effect on the consumer as a result of exposure to a hazard.

risk factors means:

a) risks from hazards to animal or human health;
b) risks from false or misleading labelling; and
c) risks to the wholesomeness of animal material or product

risk management programme (RMP) is a programme designed to both identify and control, manage, and eliminate or minimise hazards and other risk factors in relation to the production and processing of animal material and animal products, in order to ensure that the resulting animal product is fit for intended purpose. An RMP established under the APA, 1999 may also encompass as a component, food safety programmes (or part thereof) established under the Food Act Regime

secondary processor (non-dairy only) means a person who, for reward (other than as an employee) or for purposes of trade, processes animal product at any stage beyond its primary processing (See Appendices C and D: Businesses requiring and not requiring RMPs)

shellfish includes all species of the phylum Echinodermata and phylum Mollusca and all species of the Class Crustacea at any stage of their life history, whether living or dead (Fisheries Act, 1996)

shelf life means the period nominated by the operator during which a product maintains its fitness for intended purpose under specified conditions

single-business risk management programme means an RMP covering a single business

standard (see animal product standard)

step means a point, procedure, operation or stage in the food chain, including raw materials, from primary production to final consumption

suitability covers aspects of product integrity other than food safety such as aesthetic defects, composition, and labelling

topically means applying a substance externally to a part of the body of a human or animal

trade means sell for human or animal consumption or use; and includes:

a) selling for resale (including as a constituent part of another article) for human or animal consumption or use;

b) offering or attempting to sell, or receiving for sale, or having in possession or exposing for sale, or sending or delivering for sale, or causing or permitting to be sold, offered, or exposed for sale;
c) barter;
d) supplying an article under a contract, together with other goods or services or both, in consideration of an inclusive charge for the article and the other goods or services;
e) supplying an article where there is a statutory responsibility to supply;
f) offering as a public prize or reward, or giving away for the purpose of advertisement or in the furtherance of any trade or business; and
g) every other method of disposition for valuable consideration.

uncontrolled hazard means a hazard which has been identified in a hazard analysis for a particular process or product, and for which the operator has no control measures available, and there is no mandatory requirement to control that hazard

unique location identifier means a unique identification code to indicate the location or premises within a risk management programme (dairy only)

validate means the process by which evidence is obtained to demonstrate that animal material or animal product will be fit for intended purpose, through the achievement of any regulatory limit or operator-defined limit

verification includes the ongoing checks carried out by recognised verifiers to determine whether:

a) operations that are subject to an RMP, regulated control scheme, standards or specifications are in compliance with the requirements of the programme or of the APA; and
b) animal material or products for whose export an official assurance is required have been produced or processed in a way that meets the requirements for the official assurance

wholesomeness in relation to any regulated animal product, means that the product does not contain or have attached to it, enclosed with it, or in contact with it anything that is offensive, or whose presence would be unexpected or unusual in product of that description

wild animal means an animal that:

a) is a kind that occurs in the wild or in the sea; and
b) is not, immediately before its taking or capture, owned by any person

Appendix B: Abbreviations

ACVM:	Agricultural Compounds and Veterinary Medicines Act 1997
AP Reg:	Animal Products Regulations 2000
APA:	Animal Products Act 1999
D-G:	Director-General
CCP:	Critical Control Point
COP:	Code of Practice or Code
DOB:	Dual Operator Butcher
GOP:	Good Operating Practice
HACCP:	Hazard Analysis and Critical Control Point
ISO:	International Organisation for Standardisation
MPI:	Ministry for Primary Industries
NZQA:	New Zealand Qualifications Authority
OMAR	Overseas Market Access Requirement
RA:	Recognised Agency
RA Notice:	Animal Products (Recognised Agencies and Persons Specifications) Notice 2015
RCS:	Regulated Control Scheme
RMP:	Risk Management Programme
RMP Outline:	Animal Products (Requirements for Risk Management Programme Outlines) Notice 2008
RMP Spec:	Animal Products (Risk Management Programmes Specifications) Notice 2009

Appendix C: Businesses requiring RMPs

You must operate under a registered RMP if you are producing or processing animal material or animal product (subject to the exclusions described in Appendix D: Businesses Not Requiring RMPs) if one of the following applies to you (section 13 of the APA):

a) primary processors of animal material;
b) secondary processors of animal products intended for human or animal consumption, except to the extent that they are subject to the Food Act regime;
c) retail butchers who are dual operator butchers; or
d) other persons specified by Order in Council under section 15 of the APA as requiring to operate under an RMP.

C.1 Primary processors (including dairy processors)

(Section 4 of the APA)

Because the term 'primary processor' determines who must have an RMP, the term is specifically defined in the APA (copied below).

***Primary processor** means a person who, for reward (otherwise than as an employee) or for purposes of trade:*

a) slaughters and dresses mammals or birds; or
b) dresses mammals or birds that are killed wild animals or are killed as if they were wild animals; or
c) removes or extracts or harvests any animal material from live animals for the purpose of processing for human or animal consumption; or
ca) is a dairy processor; or
d) in the case of-

- *i) finfish or shellfish, or animal material derived from finfish or shellfish; or*
- *ii) a mammal or bird, or animal material derived from a mammal or bird, if in the opinion of the Minister it is appropriate that the primary processing of that mammal or bird or animal material should extend beyond the matters referred to in paragraphs (1) and (2); or*
- *iii) any other animal, or animal material derived from any other animal, -*
- *iv) processes those animals or that animal material to the extent specified by the Minister by notice in the Gazette after appropriate consultation in accordance with section 163 and after having regard to the following matters;*
- *v) industry practice in relation to the animal material concerned*
- *vi) the degree of processing and number of processing operations required in relation to the animal material*
- *vii) the risk factors involved in processing the animal material*
- *viii) whether or not the processing of the animal material is or may be appropriately addressed by any legislative regime other than this Act*
- *ix) such other matters as the Minister considers relevant in the particular circumstances;*

but does not include hunters within the meaning of paragraph (2) of the definition of primary producer.

"Dairy processor" is included within the APA definition of "primary processor". The APA then defines dairy processor, as provided below. The result is that for dairy processors, primary processing extends to the point that the animal material is ready for sale or export. This is a later stage than for non-dairy processing.

***Dairy processor** means a person who, for reward (otherwise than as an employee) or for purposes of trade, carries out dairy processing; and:*
(a) includes:

i) a farm dairy operator:
ii) a transporter of dairy material from a farm dairy to a place of processing or manufacture:
iii) a transporter of dairy material from one place of processing or manufacture to another:
iv) an operator of any premises where dairy material is processed or manufactured or stored:
v) a transporter of dairy material to the place of export or sale for consumption or end use for purposes other than consumption:

(b) does not include persons (such as airline or shipping staff, stevedores, retailers, or wholesalers) handling the relevant product at the port of export or at the place of sale for consumption or use

Paragraph d) of the definition of primary processor within the APA allows additional processes to be added to the definition by Notice, where the definition within the Act is not clear enough for some industries. The Animal Products (Definition of Primary Processor) Notice 2000 defines the following persons as primary processors if they process for reward (otherwise than as an employee) or for purposes of trade:

e) a person who harvests and candles[8] eggs obtained from layer hens or other birds including quail, geese, ducks, ostriches and emus, where the eggs are intended for human or animal consumption;
f) a person who removes or extracts or harvests or undertakes drying, slicing, grinding or preserving of deer velvet;
g) a person who, in land based fish premises, carries out the first methodical assessment (this includes a visual check to ensure that the fish are in a satisfactory condition for processing to a product fit for human or animal consumption) of the suitability of the fish for processing is made, and the fish are processed. To clarify this general statement, the following operations carried out on-shore are included in primary processing (whether or not coupled with a methodical assessment of suitability for processing):
    i) the deheading, gutting, or filleting of finfish;
    ii) the tubing of squid;
    iii) the wet-storage, depuration, or shucking of shellfish;
    iv) the removing of roe from kina;
    v) the holding of crustaceans live (otherwise than in a marine farming operation), or their tailing;
    vi) in relation to fish to be sold whole or after processing at sea, any steps (including washing, chilling, freezing, or packing) taken to ensure their delivery to a buyer in good condition
h) a person who, in fish processing at sea, carries out any of the following operations:
    i) the filleting of finfish (but not their mere deheading, gutting, or scaling; and not including the filleting of fish that are to be consumed by the crew of the vessel concerned) i.e. factory vessels;
    ii) in respect of fish of any species processed at sea for the purposes of export that are not to be delivered to an on-shore primary processor, any other process normally applied to fish, including;
    iii) washing, chilling, freezing, and preserving;
    iv) deheading, gutting, scaling, and tubing;
    v) packing, transport, and storage.

[8] In this clause "candling" means the testing of eggs for freshness, fertility, or defects (by use of light, electronic means, or any other commercially accepted means).

C.2 Secondary processors of animal products

(Sections 13 and 32 of the APA)

All secondary processors of animal products intended for human or animal consumption must have an RMP, except where covered by the Food Act regime.

A secondary processor of animal products intended for export with an official assurance must have an RMP to comply with overseas market access or official assurance requirements.

Note: secondary processing is not applicable to dairy processing because all dairy processing is primary processing.

C.3 Dual Operator Butchers

(Section 71 of the APA)

Dual operator butchers (DOBs) are those butchers dealing in both homekill and retail meat at the same premises or place. They must have an RMP covering processing of their regulated product. There are also additional requirements for them to meet (see section 4.15 Additional Requirements in Relation to Homekill and Recreational Catch for Dual Operator Butchers.

C.4 Inclusions by Order in Council

You must develop and operate an RMP for the following operations if carried out for trade purposes in relation to any dairy, mammal or bird material or product, whether or not the product concerned is intended for human or animal consumption [Animal Products (Exemptions and Inclusions) Order 2000 (20)]:

a) rendering[9] operations;
b) blood-drying operations; or
c) technical grade dairy product[10] processed at the same place as dairy product for human or animal consumption, where that dairy product must be processed under an RMP or the technical grade dairy product is for export requiring an official assurance.

[9] In this regulation, "rendering" means the breaking down of animal tissues into constituent fat and protein elements, whether by the application of heat and pressure or otherwise.
[10] Technical grade dairy product means dairy product for sale or export that is not intended for human or animal consumption.

Appendix D: Businesses not requiring RMPs

(Section 13 of the APA)

The following persons are not required to have RMPs:

a) primary producers (e.g. sheep, beef, broiler farmers, etc.) of animal material;
b) transporters of animal material prior to primary processing;
c) secondary processors of animal products not intended for human or animal consumption (except if an official assurance is required for export);
d) listed homekill or recreational catch service providers (except dual operator butchers);
e) processors of dairy material or dairy products not intended for human or animal consumption except for technical grade dairy product manufactured in a human or animal consumption production facility (see additional criteria in Appendix C: Businesses Requiring RMPs;
f) those exempted by Order in Council made under section 9; and
g) those exempted by the Director-General under section 14.

D.1 Exemptions by Order in Council

The following persons are not required to have an RMP (Animal Products (Exemptions and Inclusions) Order 2000):

a) those operating fishing boats where the fish is not landed in New Zealand nor claimed to be a product of New Zealand;
b) those whose products are covered by the Medicines Act 1981 (except where required for official assurances);
c) those whose products are covered by the Agricultural Compounds and Veterinary Medicines Act 1997 (except for rendering and blood-drying operations, or where required for official assurances);
d) those who process certain dairy products that are consumed on the premises;
e) those who process certain dairy products that are food (e.g. multi-ingredients foods such as cakes, biscuits, soups and pastries, caffeinated or alcoholic drinks) except those who process multi-ingredient foods that consist principally of dairy products (see Appendix H: Determination of Principally Dairy), ice cream, or where required for Official Assurances;
f) those who are primary processing animal material for purposes other than human or animal consumption e.g. skinning and shearing;
g) those who process dairy material for the New Zealand or Australian market only, under a risk-based measure, but are not a farm dairy operator;
h) those who transport dairy material or dairy product for export without official assurance or for the New Zealand market;
i) those who process dairy material for animal consumption for the domestic market, if no other operations at the same premises require an RMP;
j) those who produce and process RCS raw milk;
k) a depot operator who stores RCS raw milk on behalf of farm dairy operators;
l) a transport operator who transports RCS raw milk on behalf of farm dairy operators;
m) those processing animal food in accordance with the Food Act regime, e.g. raw meat suitable for human consumption is sold by a supermarket delicatessen as petfood;
n) those who transport animal material or animal product (other than dairy material or dairy product) for animal consumption (except where required for Official Assurances);
o) those who have fish on a retail premises and fish is sold by a combination of retail and wholesale where the trader has a risked-based measure under the Food Act regime;
p) those who operate temporary holding and storage places for fish;
q) those who operate limited processing on registered limited processing fishing vessels;
r) those who process fish bait, fish berley, chum or ground bait;
s) those who operate certain tourists or charter fishing vessel and fishing guides;

t) those who harvest and provide limited processing of whitebait;
u) muttonbird primary processors;
v) certain primary processors of eggs (those with 100 or less female birds and who sell directly to the consumer – not through a third party);
w) airline holding facilities operators;
x) those who harvest, collect, store, grade or transport raw deer velvet;
y) apiarists who harvest, store and transport bee material or product; and
z) taxidermists (so long as no part of the animal is traded for human or animal consumption – except to rendering, and homekill and recreational catch services are not carried out on the same premises).

D.2 Exemptions by the Director-General

MPI may grant temporary exemptions under exceptional circumstances, under section 14 of the APA, from the requirement to have all or part of an RMP.

Appendix E: Examples of limits

Table 16: Example of limits for products for human consumption

Product	Regulatory Limits		Operator-Defined Limits	Controls
	Specifications	Food Standards Code		
RAW, NOT FURTHER PROCESSED				
Raw red meat and offal	Limits are set out in Part 3 of the Animal Products (Specifications for National Microbiological Database Programme) Notice 2016	----	Operator may define microbiological and defect levels	GOP
Poultry	*Salmonella* performance target, *Campylobacte*r performance target and Prevalence Performance Target for *Campylobacter* (limits in NMD Spec)	----	Operator may define microbiological and defect levels	GOP
MSM - red meat and poultry	----	----	Operator should define microbiological limits	GOP
Wetfish	----	Histamine level ≤ 200mg/kg	Operator should establish requirement for viable parasites to be absent, if known that fish is to be eaten raw	GOP
Bivalve molluscan shellfish other than scallops	*E. coli/g:* n=5 c=1 m=2.3 M=7	*E. coli/g:* n=5 c=1 m=2.3 M=7	----	GOP
Raw crustacean (not live)	----	Coagulase - positive staphylococci/g: n=5 c=2 m=10^2 M=10^3 *Salmonella*/25g: n=5 c=0 m=not detected in 25g SPC/g: n=5 c=2 m=5x10^5 M=5x10^6	----	GOP
	----	Specified additive levels (e.g. sulphur dioxide, sodium and potassium sulphites ≤ 100 mg/kg)	----	GOP

Product	Regulatory Limits		Operator-Defined Limits	Controls
	Specifications	Food Standards Code		
FURTHER PROCESSED				
Ready-to-eat food in which growth of *Listeria monocytogenes* can occur	----	Listeria monocytogenes/g: n=5 c=0 m=not detected in 25g	Operator must define lethality (e.g. 6D destruction of *Listeria monocytogenes*), or cooking time and temperature that will achieve required lethality	CCP-cooking
Ready-to-eat food in which growth of *Listeria monocytogenes* will not occur	----	Listeria monocytogenes/g: n=5 c=0 m=10^2cfu/g	----	
Casings	Water activity ≤ 0.83	Sulphur dioxide and sodium and potassium sulphites ≤ 500 mg/kg Ethyl lauroyl arginate ≤ 315 mg/kg	----	GOP
Raw meat & poultry products (e.g. patties, sausage, etc.)	----	Specified additive level (e.g. nitrate ≤ 125 mg/kg)	----	GOP if curing mix used. May be a CCP when nitrite added on its own
	----	----	Operator may define hazard levels (e.g. microbiological, physical hazard level, etc.)	GOP or CCP - metal detection
Cooked cured/salted meat	----	Coagulase - positive staphylococci/g: n = 5 c = 1 m = 10^2 M = 10^3 *Salmonella*: n=5 c=0 m=not detected in 25g	----	CCP – cooking
	----	Specified additive level (e.g. nitrite ≤ 125 mg/kg)	----	GOP if curing mix used. May be a CCP when nitrite added on its own
Heat treated meat paste and paté	----	*Salmonella*/g: n=5 c=0 m=not detected in 25g		CCP – Cooking

Product	Regulatory Limits		Operator-Defined Limits	Controls
	Specifications	Food Standards Code		
FURTHER PROCESSED				
	----	Specified additive level (e.g. nitrite ≤ 125 mg/kg etc.)	----	GOP if curing mix used. May be a CCP when nitrite added on its own
Uncooked comminuted fermented meats	----	Coagulase - positive staphylococci/g: n=5 c=1 m=10^3 M=10^4 *E. coli*/g: n=5 c=1 m=3.6 M=9.2 *Salmonella*/g: n=5 c=0 m=0	Operator must define pH and water activity	CCP - fermentation, maturation
	----	Sorbic acid and sodium, potassium and calcium sorbates ≤ 500mg/kg Primaricin (natamycin) ≤1.2mg/dm^2 Nitrite ≤500mg/kg	----	GOP if curing mix used. May be a CCP when nitrite added on its own
Cooked uncured meats (e.g. roast beef, chicken, etc.)	----	----	Operator must define microbiological levels (e.g. same as that for cooked cured meats, etc.)	CCP - cooking GOP post - cook handling
	----	Specified additive level	----	GOP.
Dried meat & poultry (e.g. jerky; freeze dried meat, etc.)	----	----	Operator should define microbiological levels, water activity and/or moisture content	CCP - drying/ cooking
	----	Specified additive level (e.g. nitrite ≤125 mg/kg, sorbic acid and sodium, potassium and calcium sorbates ≤1500mg/kg)	----	GOP if curing mix used. May be a CCP when nitrite added on its own

Product	Regulatory Limits		Operator-Defined Limits	Controls
	Specifications	Food Standards Code		
FURTHER PROCESSED				
Cooked crustacean	----	Coagulase - positive staphylococci/g: n=5 c=2 m=10^2 M=10^3 *Salmonella*: n=5 c=0 m=not detected in 25g SPC/g: n=5 c=2 m=10^5 M=10^6	Operator must define lethality	CCP – cooking
RTE processed finfish other than retorted (e.g. smoked fish, vacuum packaged cooked fish, manufactured fish products, etc.)		Histamine level ≤ 200mg/kg	----	GOP
Dried shelf stable fish	----	----	Operator should define water activity and/or moisture content	GOP
Fish or fish products with pH<4.6 (e.g. marinated mussels, etc)	----	----	Operator should define pH<4.6	CCP – acidification
Pasteurised egg	----	*Salmonella*/g: n=5 c=0 m=not detected in 25g	----	CCP – pasteurisation
Low acid canned foods	HC Specs 14.10	----	Commercially sterile by application of a 12D thermal process for *C. botulinum*	CCP – retorting
	----	Specified additive level (e.g. nitrites ≤50mg/kg, etc.)	----	GOP
Edible fat/oils	----	Specified additive level	----	GOP
Dried deer velvet	----	----	Operator should define water activity and/or moisture content	GOP
Honey	----	Moisture content ≤21% Reducing sugars ≥60%	----	GOP
	----	Tutin level ≤0.7mg/kg	----	

Table 17: Examples of limits for products for animal consumption

Product	Regulatory Limits	Operator-Defined Limits	Control
Raw meat and offal	----	Operator may define microbiological and defect levels	GOP
Dry rendered meals (e.g. meat and bone, blood)	Medium risk material: No vegetative pathogens, viruses and protozoa, and inactivate chemical substances that are harmful if consumed by animal [AC Specs 10.3(1)]	----	CCP - rendering or drying GOP post CCP
	----	Operator should define moisture content (e.g. ≤ 10%, etc.)	GOP
Heat treated, not shelf stable meat products that include offal (liver and lungs) of ruminants and pigs that are intended to be consumed by dogs without further processing (e.g. dog rolls, etc.)	No viable hydatids [Biosecurity Controlled Area Notice 294]	Operator may define microbiological levels	CCP – cooking
Dried meat products (e.g. jerky, etc.)	----	Operator should define water activity and/or moisture content	CCP - drying/ cooking
Low acid canned foods	----	Commercially sterile by application of a 12D thermal process for *C. botulinum*	CCP – retorting

Table 18: Examples of limits for dairy material and dairy products for human consumption

Product	Regulatory Limits			Operator-Defined Limits	Control
All dairy products for human consumption	All dairy products must be wholesome and not contain any foreign matter that constitutes a food safety hazard			Operator must define what constitutes a food safety hazard	GOP
	Dairy product must not exceed the following Product Safety Limits at any time during the product's shelf life (assuming the product is stored and handled according to manufacturer guidelines):				GOP
		General	Specific		
	Salmonella spp.	ND/25g	ND/250g		
	L. monocytogenes	ND/25g(4)	ND/25g		
	Coag. Pos. *Staphylococci*	1000/g	100/g		

Product	Regulatory Limits			Operator-Defined Limits	Control
	B. cereus	1000/g	100/g(5)		
	E. coli	100/g	10/g		
	E. sakazakii (Cronobacter spp.)	---	ND/300g		
	Further detail is contained in DPC1: Approved Criteria for General Dairy Processing.				
	Dairy material and dairy product must not contain chemical contaminants exceeding the limits specified in the Approved Criteria.				GOP
		Nitrate (mg/kg)	Nitrite (mg/kg)		
	Specified population (excluding ingredients1)	50	5		
	General population (and ingredients 1) – Milk powders	150	5		
	General population (and ingredients 1) – Protein Products	150	15		
All dairy products manufactured in NZ or for sale in NZ or Australia	Dairy products must comply with the microbiological limits in the Food Standards Code.			Operator may define additional microbiological levels for in-process or final product	
Dairy products manufactured in NZ or for sale in NZ	Dairy products must not contain any residues exceeding the limits specified in the Food Notice: Maximum Residue Levels for Agricultural Compounds 2017.			Operator may define additional residue limits	GAP on farm
Dairy products manufactured for export	Dairy products must not contain any residues exceeding the limits specified by Codex.			----	
Dairy products for sale in NZ	Levels of toxic trace metal should not exceed the limits specified in the Food Standards Code (refer to Volume Two Standard 1.4.1 Contaminants and Natural Toxicants). Further detail is contained in DPC1: Approved Criteria for General Dairy Processing.			----	
All dairy products for human consumption	Dairy product must comply with the food safety limits specified in fortification standards issued by Codex – refer to Codex Standard 72, 1981 "Infant Formula" and Codex Standard 156, 1987 "Follow-up Formula" (available on the Codex website) and the Food Standards Code.			----	

Appendix F: Procedures and processes requiring validation

Validation is the process of collecting evidence to show that the processes or steps in your RMP is effective in producing the desired outcome. You must validate these procedures when there are significant changes to your existing processes/products or new product/process is introduced [RMP Spec 18].

You must document a protocol for how you will collect the evidence when there is insufficient evidence to demonstrate the effectiveness of the RMP at the time of registration [RMP Spec 18]. The protocol will need to be submitted to the evaluator as part of the RMP evaluation and MPI when applying for registration.

The following tables gives a guide on GOP or processes that may need to be validated. Where no validation is required, this has been based on the assumption that procedures comply with a COP that is acceptable to MPI. Procedures that deviate from a COP may require additional validation.

Table 19: Supporting system

Procedures/operation	Unlikely to require validation	Likely to require validation	Comments
Design and construction of premises, facilities, equipment	√		
Water - Council supply	√		
Water - Other sources	√		Water requirements must already be met before RMP is implemented.
Water supply for fishing vessel	√		
Supply of process gases, compressed air	√		
Receipt, handling, storage of additives, processing aids, etc.	√		
Cleaning of facilities and equipment (normal circumstances)	√		
Cleaning of facilities and equipment (prior to switching to processing materials or products with stricter requirements)	√		E.g. alternating between manufacture of animal and human consumption products.
Cleaning (post-CCP areas for RTE products)		√	
Waste management	√		
Control of chemicals	√		
Health of personnel	√		
Pest control	√		
Repairs and maintenance of facilities and equipment	√		
Calibration of equipment and measuring devices	√		
Packaging (composition, use, handling)	√		
Labelling	√		

Table 20: Supply of Animal Material

Procedures/operation	Unlikely to require validation	Likely to require validation	Comments
Supply of animals (eligibility, locations, supplier statements, etc)	√		
Hygienic handling and dressing of killed mammals	√		Validation required if COP not used.
Cooling and transportation of killed mammals	√		
Supply of deer velvet	√		
Supply of fish	√		
Holding in animal material depots	√		

Table 21: Primary Processing of animal products

Procedures/operation	Unlikely to require validation	Likely to require validation	Comments
Farmed mammals, killed mammals, farmed birds, live possums			
Reception (animal health status, supplier statements)	√		
Identification and control of suspect animal material	√		
Ante-mortem and post-mortem examination	√		
Hygienic slaughter and dressing	√		Validation required if COP not used.
Washing of carcasses of mammals	√		
Cooling of poultry to 7°C		√	
Chilling or freezing below 7°C	√		
Chilled and frozen storage (maintenance)	√		
Capability of freezers/chillers when reducing temperature to preservation temperature		√	
Deer velvet			
Reception	√		
Fish products			
Reception	√		
Handling and processing	√		Histamine level is a required specification but it is not expected to be measured by the processor. Effectiveness can be demonstrated by compliance to established procedures.
Chilling and freezing to preservation temperature	√		
Capability of freezers and chillers	√		

Procedures/operation	Unlikely to require validation	Likely to require validation	Comments
Bivalve Molluscan Shellfish			
Reception	√		
Wet storage and depuration		√	Refer to HC Specs.
Shucking	√		
Heat Shocking (Listeriocidal)		√	Refer to HC Specs.
Chilling and freezing to preservation temperature	√		
Capability of freezers and chillers	√		
Eggs			
Whole Flock Health Scheme	√		
Reception of birds	√		
Pulping		√	
Bird management	√		
Harvesting and handling of eggs	√		
Washing of eggs	√		Protocol needed if criteria in MPI approved egg RMP template is not followed.
Candling and packing	√		
Storage	√		

Table 22: Secondary processing

Procedures/Operation	Unlikely to require validation	Likely to require validation	Comments
General			
Cleaning, sorting, grading of materials	√		
Cutting, boning, size reduction	√		
Thawing/tempering of meat and poultry	√		
Mixing, emulsification	√		
Honey and bee products			
Reception	√		
Handling, processing, packing	√		
Storage	√		
Handling material that may introduce allergens		√	Will need to show how the allergens will be controlled.
Thermal processing including Dairy			
Commercial sterilisation (aseptic, in container retorting)		√	
Pasteurisation		√	
Cooling of thermally processed product		√	Cooling is not critical for small products (e.g. cooked frankfurters). Protocol may not be necessary for such products.
Heat processing other than sterilisation and pasteurisation (i.e. non-lethal heating)	√		Heating for other technical reasons (e.g. grill marking of patties, heating of honey to reduce viscosity) does not require a protocol.
Drying		√	
Smoking			
Hot smoking		√	
Cold smoking of RTE products		√	
Cold smoking of products that require further cooking by the consumer	√		Smoking for flavour only does not require a protocol.
Cooling			
Chilling/freezing of mechanically separated meat	√		
Cooling of hot boned products to 7°C	√		
Salting, curing, brining	√		
Acidification			
Addition of acid for preservation (pH control) e.g. marinated mussels/fish		√	

Procedures/Operation	Unlikely to require validation	Likely to require validation	Comments
Addition of acid for flavour only	√		
Fermentation		√	
High pressure processing		√	
Extraction, expression	√		
Evaporation, concentration for preservation		√	
Rendering			
Rendering		√	Achievement of 90°C for 10 minutes must be confirmed for medium risk material. Requirement presently being reviewed.
Drying		√	
Refining of fats and oils	√		
Packing	√		
Capability of freezers/chillers when used for reducing temperature to preservation temperature		√	
Storage			
Refrigerated storage (cold store)	√		
Dry storage	√		
Transport			
Meat and meat products above 7°C		√	
Dairy, meat and meat products at or below 7°C	√		
Other products (non-refrigerated)	√		
Other product specific processors			
Cleaning and processing of green offal and runners	√		
Salting of casings	√		

Appendix G: Guidance on difference between significant and minor Amendments

Appendix G provides guidance and examples for RMP operators (animal products and dairy) on the difference between significant and minor amendments. This is intended as a guide only so will not cover every possible scenario and may not be a representative of every situation. Each amendment will be considered on a case by case basis. It may be necessary to consult with a recognised agency or MPI for further clarification.

If your change is a significant amendment under one clause of the Animal Products (Risk Management Programme Specifications) Notice 2008 and a minor amendment under another, then it is considered to be a significant amendment.

The registered scope and application of your RMP should be considered when deciding whether your change is a significant or minor amendment.

You should document the basis for the decision, including any advice received from recognised evaluators, verifiers, experts, writers or MPI, and make this available to recognised evaluators, recognised verifiers or MPI. Note that there may be situations where a recognised premises evaluator may be involved in signing off a project to expand or modify a premises but this may not result in a significant change to the RMP.

G.1 Major alterations to processing facilities or equipment

Making major alterations to the processing facilities or equipment which may impact on fitness for intended purpose of the animal material or animal product is considered a significant amendment to the RMP [RMP Spec 22(1) (a)].

Your justification should consider and include what is the potential for your change to adversely affect the fitness for purpose of your product? Consider the nature of your process (e.g. enclosed vs. exposed product, etc.).

Examples of Significant Amendments	Examples of Minor Amendments
Changes that can alter the processing environment temperature and humidity and the introduction of new hazards.	Altering floor layouts in standard hygiene areas.

G.1.1 Altering the physical boundaries of the RMP

In general, **increasing the physical boundaries** is a significant amendment. However, where the increase in boundary does not introduce new hazards and/or affect processes, the amendment may be considered minor. You need to provide a written justification to the recognised verification agency detailing why the increase in boundary is not considered a significant amendment and obtain their agreement before submitting the minor amendment to MPI. MPI will want to see confirmation of the agreement from your verification agency, so make sure you include this with your AP50: Registration of a Minor Amendment form.

Where the **physical boundaries of the RMP are reduced** this would be minor, unless the change adversely impacts on the RMP. Regardless of whether the change in physical boundary is significant or minor, you should notify the recognised agency and provide an updated site plan.

G.1.2 Removal of buildings/facilities

Your justification should include consideration of:

- what consequential changes are needed as a result of removing the buildings/facilities e.g. if processing activities are moved to a new building, are any alterations needed to ensure its suitability for this type of processing?
- are any new hazards or other risk factors introduced as a result of altered process flows, new environmental conditions etc.?

Examples of Significant Amendments	Examples of Minor Amendments
Removal of facilities/equipment that prevents essential processes from being carried out, e.g. removal of a blast freezer.	Removal of redundant or disused facilities/buildings.

G.1.3 Construction of new buildings and facilities

When deciding whether building construction is a significant or minor amendment you should consider:

- whether the construction results in duplication of existing processes;
- any impact on the existing buildings, facilities or operations; and
- any change to the physical boundaries.

Examples of Significant Amendments	Examples of Minor Amendments
Construction of a new store, new processing room, new filleting room etc. where this is not a duplication of an existing operations or facilities.	Construction of a new facility where it can be shown that it will not introduce risks to existing processes and products.
Construction on a new site.	Construction of a new cold store where the RMP includes a process for cold storage.

G.1.4 Building and facility alterations

Your justification should consider:

- the extent of alterations needed;
- the impact of the alterations on the process and operations, e.g. changes to process flow; new process steps;
- whether the alterations will change the use of the existing facilities, room or area; or
- whether the change impacts on the effectiveness of a CCP.

Examples of Significant Amendments	Examples of Minor Amendments
Reconfiguration or reconstruction of a processing area where there has been a substantial change to the process or a new hazard or risk is identified.	Reconfiguration or reconstruction of a processing area where it can be shown that the process has not changed and no new hazard or risk has been identified.
An accumulation of minor changes which together would be the equivalent of a significant amendment.	Minor alterations to processing facilities such as: • repairs and maintenance; • changes to equipment layout to improve process flows where this does not introduce new hazards; • introduction of a new production line, which duplicates an existing line within an existing area;

Examples of Significant Amendments	Examples of Minor Amendments
	• equipment changes to bag sealing or to allow halal slaughter; • alterations to stable ingredient (e.g. salt) storage, or alterations to animal holding facilities; and • changes to essential services where this does not introduce new hazards.
Changing the use of a room from a lower standard to a higher standard, e.g. support facility to a process room, pet food to human consumption, raw to cooked, or becoming part of a critical hygiene area, except where the RMP already contains buildings or facilities of a similar higher standard.	Construction in non-processing areas such as amenities, support facilities and engineering facilities, but not to change them to a higher standard of use.
Changing the use of a room so that it becomes part of a Critical Hygiene Area, except where the RMP already contains buildings or facilities included in the Critical Hygiene Area.	A new heat treatment facility where the RMP already contains similar facilities.
A new heat treatment facility where the RMP does not contain similar facilities.	

G.1.5 New processing equipment

Your justification should include consideration of:

- the process for installation, commissioning and/or validation, location, hygiene, maintenance etc.;
- what the equipment will be used for e.g. whether it is used for a process step that is essential for food safety, etc.;
- how the new equipment may affect the process flow; or
- whether the new equipment duplicates existing equipment.

Examples of Significant Amendments	Examples of Minor Amendments
New processing equipment that is essential for food safety e.g.: • new technology, e.g. high pressure processing, filtration as a microbiocidal step; • new equipment used for heat shocking mussels for listeriocidal effect; • adding or reducing plates in a pasteuriser; or • alterations to pasteuriser flow rates.	New processing equipment that is not essential for food safety e.g.: • new conveyor belts; • new mixers, blenders; or • new cutting equipment i.e. new cheese curd cutting machine. Note: Blenders for dairy based infant formula is considered a significant amendment
New processing equipment that can be detrimental to food safety if not set up and operated correctly e.g.: • new type of machine for mechanically separating meat; or • new type of egg washing system.	A new retort that is the same make and model as an existing retort covered by the existing RMP.
A new retort that is a different make and model to any existing retorts covered by the existing RMP.	

Examples of Significant Amendments	Examples of Minor Amendments
Major changes to rendering equipment e.g. changing from batch well cookers to continuous low temperature cookers, etc.	

G.2 Relocating processing operations

Relocating process operations to a new physical address (except where this is already permitted for mobile premises and vessels) is a significant amendment [RMP Spec 22(1) (b)].

G.3 New animal material or animal product

Processing animal material or animal product that is not covered by the RMP is a significant amendment, except:

a) where the product and process are similar, and
b) documented risk factor identification and hazard analysis has shown that all risk factors associated with that animal material product are already adequately addressed by the RMP [RMP Spec 22(1) (c)].

G.3.1 Primary processing of a new animal material

Primary processing of a new animal material not currently covered by the RMP is considered a significant amendment except as agreed by MPI [RMP Spec 22(1) (c)]. Such agreement may require you to notify MPI of changes so that accurate registration information can be maintained.

Animal Material	Significant Amendment	Minor Amendment and Notification to MPI
• Ostriches / emus. Mammals including: • Alpacas / llamas; • Bobby calves; • Buffaloes / bison / cattle hybrids; • Cattle; • Chamois; • Deer; • Horses / other equines; • Pigs; • Possums; • Rabbits / hares; • Sheep / goats. • Thar; or • Wallabies.	Changing between animal materials bulleted in column 1. Changing from farmed to non-farmed (e.g. wild / game estate/ farmed gone feral, etc.) and vice versa.	Changing between sheep and farmed goats. Changing between non-farmed types (i.e. from wild to game estate or to farmed gone feral or vice versa).
• Finfish / squid & other cephalopods / eels / paua / kina, crabs / non bivalve molluscan shellfish; • Crustaceans; • Bivalve molluscan shellfish (BMS).	Changing between animal materials bulleted in column 1 except as listed in column 3. Adding live rock lobsters when the RMP already covers live fish	Changing within a bullet in column 1. Adding live fish when the RMP already covers live rock lobster. Changing from farmed to non-farmed species and vice versa.

Animal Material	Significant Amendment	Minor Amendment and Notification to MPI
	(no processing) if tailing needs to be considered.	Adding paua or kina when the RMP already covers crustaceans or bivalve molluscan shellfish.
• Chickens / pouisson / fowl / ducks / geese / pheasants / quail / guinea fowl; • Turkey; • Layer hens.	Changing between animal materials bulleted in column 1. Changing from farm to non-farm and vice versa.	Changing within a bullet in column 1.
• Whole shell eggs.	Changing between farm methods (e.g. caged, barn, free range, etc.) for harvesting.	Changing between farm methods (e.g. caged, barn, free range, etc.) for other operations. Change of bird type, e.g. chicken to duck, etc.
• Deer velvet.	N/A.	N/A.

G.3.2 Adding a dairy material or product to the RMP

Processing of a new dairy material not currently covered by the RMP is considered a significant amendment except as agreed by MPI [RMP Spec 22(1) (c)]. Such agreement may nevertheless require you to notify MPI of changes so that accurate registration information can be maintained.

Examples of Significant Amendments	Examples of Minor Amendments
• Moving processing equipment to new premises	Addition of operator defined finished product limits to RMP
• Addition of a dairy powder operation where RMP does not already cover the production of powder products.	Addition of other dairy powders where operation already covers production of powder products (e.g. addition of blending whey products to an RMP covering blending of milk powders, speciality, etc.)
• Addition of sensitive population group to intended consumer in RMP	Changes to test pieces used for CCP (x-ray or metal detection), increasing sensitivity
• Addition of raw milk processing of a different species to an existing dairy RMP e.g. addition of caprine, ovine or cervine milk to existing RMP only covering bovine milk, etc.	Change in named responsible persons
• Addition of heat treatment of a different species to an existing RMP e.g. ovine milk to existing RMP of heat treatment of caprine milk.	

G.3.3Secondary processing of a new animal product (within process categories already covered by RMP)

New animal products may be able to be added to your RMP without the need for a significant amendment. In this case a minor amendment would be made to the RMP and MPI notified. To decide if a significant amendment is required, refer to AP49: Processing Categories Tables.

To use the categories table, turn to the secondary processing sections. Each process category (listed in the left hand column) to be undertaken with the new animal product must be considered.

The types of animal product for each process category are specified across the table. The rules for using the table are:

- addition of a new animal product described in a white box is a significant amendment;
- addition of a new animal product described in a shaded box, where the RMP only covers animal products described in a white box is a significant amendment; and
- addition of a new animal product described in a shaded box where the RMP covers at least one other animal product described in another shaded box is a minor amendment which requires notification to MPI.

Where the amendment would be considered significant under any process category being undertaken a significant amendment must be registered.

An example of secondary processing amendment to an RMP

An operator with a registered RMP covering boning/cutting of red meat for human consumption wishes to amend their RMP to cover boning/cutting of poultry carcasses for human consumption.
The process category to be considered is boning/cutting. Refer to the secondary processing for human consumption table within the categories table, part of this is copied below:

SECONDARY PROCESSING FOR HUMAN CONSUMPTION

Process Category	Animal material or product							
Acidification	Red meat	Poultry	Fish	BMS	Hides & skins	Eggs		
Aseptic processing	Red meat	Poultry	Fish	BMS	Paua	Bee Products	Eggs	
Blending / Mixing	Red meat	Poultry	Fish	BMS	Gelatine	Bee Products	Deer Velvet	Eggs
Boning / Cutting	Red meat	Poultry	Ostrich & Emu	Fish	BMS			
Collection	Red meat	Poultry	Fish	BMS	Foetal blood	Foetal tissue	Beeswax	Hides and skins (refer rules)

The RMP will already cover red meat for the boning/cutting process category. Since this appears in a shaded box, addition of poultry (also in a shaded box) can be made as a minor amendment with notification to MPI.

Note: You would also need to consider whether other factors, e.g. construction, would make the change a significant amendment by working through the other sections of this appendix.

G.3.2 Processing of animal material or animal product for a different consumer

Includes for example:

- changing from human to animal consumption or vice versa; or
- changing from general consumers to specific at risk groups where your RMP does not ensure that product is fit for this new intended purpose, e.g. infants, immuno-compromised people.

Your justification should include consideration of the intended purpose that your RMP currently covers.

Examples of Significant Amendments	Examples of Minor Amendments
• Where the RMP only covers processing for animal consumption and the operator wants to start processing for human consumption. • Where the RMP only covers processing for general consumption and the operator wants to start processing for susceptible population consumption.	If all product is produced to human consumption standards according to the RMP, but the operator now wants to down grade to animal consumption (e.g. petfood, etc). Note that risks involved in production of animal feed will need to be managed in the RMP. Management of loss stream product needs to be considered as a product output.

G.4 New process or process modifications

Setting up a new process or process modification that is not covered by the RMP is always a significant amendment, except:

a) where the process or process modification is similar to existing processes, and
b) a documented risk factor identification and hazard analysis has shown that all risk factors associated with that process are already adequately addressed by the RMP [RMP Spec 22(1) (d)].

G.4.1 Where an existing process flow does not adequately describe the new/amended process

Your justification should include consideration of:

- what has changed in the new process – are the steps that are essential for food safety being altered?
- does the process align with an industry Code e.g. do critical product parameters align with those specified in an approved Code?

Examples of Significant Amendments	Examples of Minor Amendments
Where a less severe preservation step is proposed, e.g. reduction in cooking temperatures, higher water activity for a dried product, etc.	Altering a drying process but still achieving the critical product parameter for water activity.
Making the process less effective, e.g. extending holding times at temperatures that allow growth of pathogens or slower cooling rate for a cooked product, except where the operator can demonstrate that they still meet the relevant criteria in an approved COP.	Different thermal process where operator can demonstrate that they still meet the relevant criteria in an approved COP.
Changing from cold boning to hot boning except where the operator can demonstrate that they still meet the relevant criteria in an approved COP.	Making a new flavour in an existing line of products, e.g. a range of soups containing the same or similar animal products; or the same or similar animal products containing different sauces or marinades etc.
Where processing of ready-to-eat product is to occur and the RMP does not cover this.	A new thawing/tempering process that complies with a recognised Code e.g. IS6 Tempering and thawing of cheese.

Examples of Significant Amendments	Examples of Minor Amendments
Addition of a CCP e.g. using a new type of preservation such as drying etc., not currently covered under the RMP.	Removal of a control point that had been incorrectly designated a CCP.
Removal of a CCP e.g. removing a pathogen kill step, changing from hot smoked mussels process, where hot smoking is a listeriocidal step, to cold smoking which is not a listeriocidal step, etc.	Removal of an external storage silo.
Changing from in-container sterilisation to aseptic processing in a cannery.	DOB or meat processors wanting to sell meat at stalls/farmers market can add a clip-on RMP template.
Amendment to process flow e.g. additional filters fitted that affect flow rates to heat treatment equipment, etc.	Addition of transport to a processing facility.
Processes for loading out product above the maximum critical preservation (loadout) temperatures specified in clauses 13.9, 13.17, 13.25, 13.32, 13.37 of the HC Specs. This may be significant for either the consigning or the receiving RMP or both.	Addition of retail shop to RMP site plan e.g. for a RMP processing honey.
Blending/additions to honey (e.g. powders or flavourings/syrups, bee venom, etc.) is a significant amendment if the new process is not already covered by the RMP. The current COP does not cover adding ingredients into honey, so evaluation will be required.	If the RMP is already evaluated and registered to cover addition of ingredients (e.g. flavouring, such as lemon flavoured honey) into honey, it is not a minor amendment and no notification is needed.

G.4.2 Changes to processing categories in the registration details

Adding new categories of processing not currently covered by the RMP is almost always a significant amendment. This applies whether the product is intended for human or animal consumption.

Refer to Application Form AP49: Processing Categories Tables for the complete list of process categories. Process categories are listed in the left hand column.

Adding a new process category i.e. moving between rows is in general a significant amendment, however some exemptions apply so discuss with your recognised agency to clarify.

Examples of Significant Amendments	Examples of Minor Amendments
Adding a brining process step to a cheesemaking operation that did not previously cover brining.	Adding non-refrigerated storage to a store that previously only covered refrigerated storage.

G.5 New risk factors or adverse impact on existing risk factors

Making any other changes that introduce new risk factors, or adversely impact on existing risk factors is a significant amendment [RMP Spec 22(1) (e)].

G.6 Merging RMPs

Merging two or more registered RMPs is a significant amendment [RMP Spec 22(1) (f)].

G.7 Splitting an RMP

Splitting a registered RMP into 2 or more RMPs is always a significant amendment [RMP Spec 22(1) (g)].

G.8 Adding a business to a multi-business RMP

Adding a business to a multi-business RMP except where the Director-General's approval under section 17A of the Act applies to a type of business, premises or place rather than to specific businesses is a significant amendment [RMP Spec 22(1)(h)].

Examples of Significant Amendments	Examples of Minor Amendments
Where the new business is being added to a multi-business RMP that is approved for specific businesses.	Where the new business is being added to a multi-business RMP that that is approved for a type of business, premises or place.

Appendix H: Determination of principally dairy

MPI considers the following points when determining whether a product is considered principally dairy under the APA and processing must be covered by an RMP.

(1) MPI requires receipt of any relevant specification/recipe, with a list of ingredients with the percentage of each by weight or volume, to make a determination as to whether the product consists 'principally of dairy'.

(2) Generally, if the total percentage of all dairy in the product is greater than or equal to the percentage of all other ingredients combined, the product will consist principally of dairy.

(3) However other factors are also taken into consideration such as:

a) the characterising ingredient of the food and nature of the food, for example lactose as an inert carrier in tabletted products;
b) dilution and concentration through processing; and
c) any other relevant factor.

(4) Please note this determination does not take into account any applicable export requirements.

See Appendix D: Businesses Not Requiring RMPs.

Notes:

"**Dairy product"** means – (a) animal material that, having originally been dairy material, - (i) has been delivered to the place of sale for consumption or for end use for purposes other than consumption;

"**Dairy processing**" means - All processing activities in relation to dairy material; and includes …

(e) the manufacture of products, including milk, butter, cream, milk-fat products, cheese, processed cheese, whey cheese, dried milks, milk-based infant formula, evaporated milks, condensed milks, whey, whey powder, whey products, casein, milk protein products, ice- cream, low dairy fat ice-cream-like products, yoghurt, other fermented milks, dairy desserts, lactose, and colostrum products:

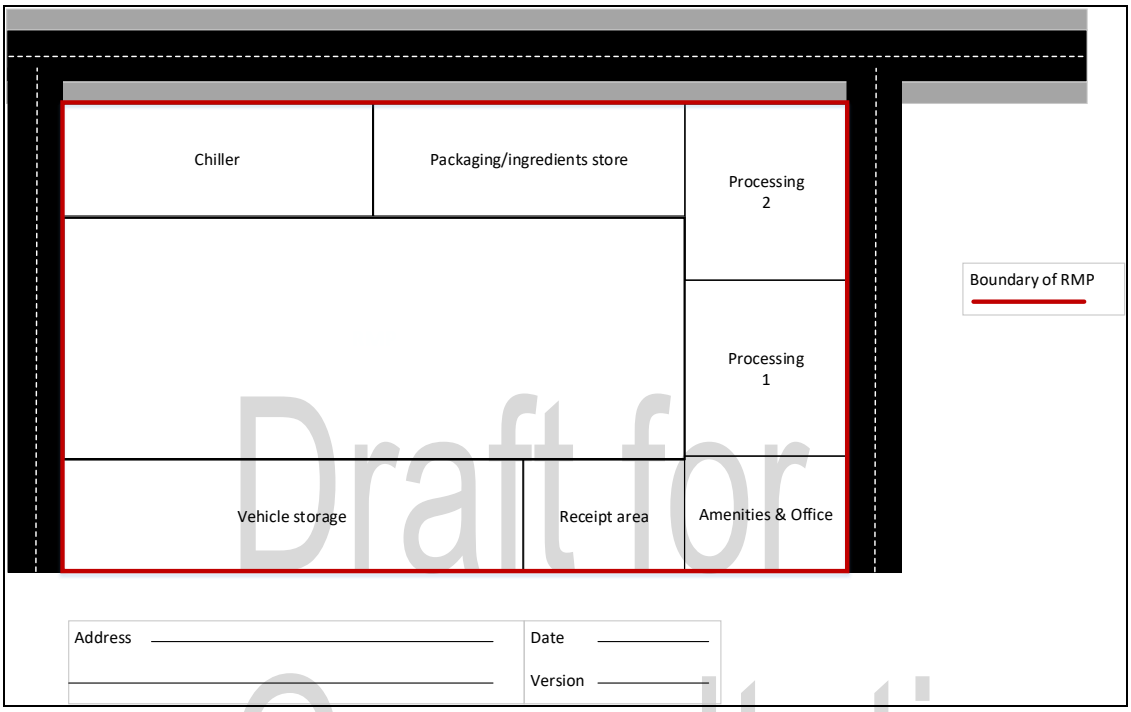
(h) further processing of dairy material that was previously dairy product with or without the addition of other material (including food, ingredients, additives, or processing aids as defined in the Food Standards Code), including reprocessing, repacking, reconstitution with water, and recombination of dairy products with or without water to make any dairy products.

Appendix I: Example of RMP site plan

The following figures are some examples of how the RMP site plan can show the RMP boundary and how new areas can be shown for significant amendments.

The site plan should also indicate any excluded areas, e.g. areas within the boundary that come under another RMP, or are subject to the Food Act regime, etc. The site plan should include the name, address, the version (dated) and the boundary.

Figure 6: Example site plan



Appendix J: Validation examples

Further examples of validation can be found in the Codex Guidelines for the Validation of Food Safety Control Measures CAC/GL69-2008.

J.1 Biological hazards

Example 1: Limit for a biological hazard (e.g. absence of *Listeria monocytogenes* in 25g of packaged heat treated meat paste).

(1) Conduct a hazard identification and analysis. Think about the following:

a) What sort of packaging will you be using? Is it going to promote the growth of specific pathogenic bacteria?
b) Do you know the bacterial count on your incoming raw materials?

(2) Identify the regulatory limit appropriate to the hazard and the product. Determine the appropriate performance criteria (e.g. log reduction, etc.) or process parameters (e.g. time and temperature profiles, etc.) required to achieve the regulatory limits.

Consider other microbiological hazards associated with your product and process and whether they have a regulatory limit and or/similar control measures that may be able to be validated together.

Reference New Zealand or international literature that confirms the chosen performance criteria or process parameters are capable of and appropriate to achieving the regulatory limit. Resources that may be useful in obtaining information on validation:

i) Codes (e.g. Further Processing, etc.); and
ii) MPI Science reports (e.g. Standardising D and Z values for cooking raw meat).

(3) You can also determine your own performance criteria and process parameters by the following steps:

a) establish the incoming microbiological load of the pathogen, unless already well established within food sector;
b) establish the required reduction of microbiological pathogens to meet regulatory limit for the product;
c) develop a process to meet product requirements (you will need to establish the key process parameters that are critical to achieving your regulatory limit); and
d) run trials to prove the key process parameter can achieve the required reduction in microbiological pathogens (e.g. challenge trials, predictive modelling with experimental data, lethality calculations).

(4) Develop process to meet performance criterion (including establishment of key process parameters).

(5) Prove you can achieve the required regulatory limit by:

a) collecting new evidence (e.g. running trials to during commercial operation conditions, etc,); and
b) using existing evidence (e.g. data from previous validation studies, monitoring records of a control point, predict modelling such as the Tom Ross Model for UCFM products, etc.).

(6) Analyse your evidence. If your process is unable to achieve the required regulatory limit, adapt your process (e.g. check your lethality calculations and extend your processing time, etc,) and repeat step (4) above until you can achieve the regulatory limit.

J.2 Chemical hazards

Example 2: Limit for a chemical hazard (e.g. 10mg/kg sulphite in dried apricots, 125µg/200ml Vitamin A in vitamin fortified milk powders, the level of histamine in fish or fish products must not exceed 200 mg/kg, etc.).

(1) Identify the regulatory limit appropriate to the hazard and the product.

(2) Reference any New Zealand or international literature that confirms that the chosen measures are capable of and appropriate for achieving the regulatory limit.

Literature searches may assist in validation using MPI or international information, e.g. temperature controls to limit toxin development, chemical degradation curves, processing losses, etc.

(3) Where the chemical is an additive, calculate the ingoing level from all sources/ingredients, expected losses during processing and final product levels of chemical. Consider the impact of either manual or automated delivery systems on accuracy and homogeneity of mixing.

(4) Prove achievement of the regulatory limit. Samples (taken from commercial production runs) must be tested or achievement demonstrated by other acceptable means to MPI e.g. histamine, etc.

(5) Where sampling occurs, it is recommended that 3-5 production batches are tested taking:

a) at least 3 samples per batch of homogenous material; or
b) at least 8 samples per batch of non-homogenous material.

J.3 Evidence to justify operator-defined limits

You must decide whether an operator-defined limit is needed for any of the hazards identified during the HACCP application. Operator-defined limits should only be considered if there is no regulatory limit for that hazard and control of that hazard is essential for food safety. E.g. setting a limit for water activity in dried product, a microbiological limit for RTE product where there is no limit in the legislation, etc.

You must document the basis for selection of an operator-defined limit, including:

- where the limit came from (e.g. industry or MPI COP, literature, an overseas regulatory agency, own trials, etc.);
- what hazard and food the limit applies to;
- why the limit is set at the particular level; and
- provide evidence to show the limit has been appropriately set.