Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Risk Management Programme Manual

For Animal Product Processing

December 2023

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 Act 1999

(2) Animal Products Regulations 2021 (version dated November 2021)

(3) Animal Products Notice: Production, Supply and Processing (version dated June 2022)

Document history

Version Date	Section Changed	Change(s) Description
October 2009	NA	NA
September 2018	All	New format and branding. Additional information on validation. Incorporated the following Statements of Policy: • Operator Responsibilities during Registration of a Risk Management Programme (Version 1); and • Pre-registration Assessment of Risk Management Programme Documentation.
August 2019	3.1.2	Removal of the guidance box in relation to the process of transitioning to a revised RMP template.
February 2020	7.1, 7.5 All 7.1 4.3.3.3, 7.1.1 3.2	Incorporated changes as per the RMP Regulations introduced as part of the Food Safety Law Reform Act (Regulatory Redesign). Updated clause references to the amended Animal Products Notice: Specifications for Products Intended for Human Consumption (issued 2019). Removed references to revoked Animal Products (Requirements for Risk Management Programme Outlines) Notice 2008 Incorporated References to Animal Products Notice: Risk Management Programme Specifications Amendment and Requirements for Risk Management Programme Outlines Revocation (issued 2020) Included links to guidance documents on validation. Included information about inclusion of non-animal products in an RMP.
November 2022		Incorporated changes as per the Animal Product Regulations 2021 and the Animal Products Notice: Production, Supply and Processing, introduced as part of the Food Safety Law Reform Act 2018. Removed references to expired APA instruments, introduced references to the new instruments, updated definitions. General structure of the guide has been updated to reflect other MPI documents to enable ease of reading and consistency (e.g., definitions moved to the start of the document). Guidance has been amended and where possible, simplified and consolidated. Some key changes include:

Version Date	Section Changed	Change(s) Description
		• more detail about electronic signatures • simplification of principally dairy determination information • RMP physical boundary guidance expanded • some appendices have been deleted, reordered, renamed and a new appendix added • guidance around minor and significant amendments has been amended. • validation guidance amended for more clarity, including validation of shelf life • guidance added around exemption from requirement from an on-site assessment during evaluation • updated guidance on changing from a single-business RMP to multi-business RMP • operator verification guidance amended • added guidance on whom to contact/notify at MPI, when required (Note that although every effort has been made to provide with the specific contact information where possible, please contact MPI at info@mpi.govt.nz if a specific email has not been provided) • clarified the relationship between supporting systems/GOP and HACCP • added guidance on including non-animal products in an RMP • RMP contents table has been updated
April 2023	3.2	Added link to a new guidance document 'Own-source water checklist and template water-use plan'
December 2023	3.2 4.11.9	Added link to a new guidance document 'Dairy Processors Template Water-use Plan' Corrected reference details

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Emblems, and Names Protection Act 1981 or would infringe such provision if the relevant use occurred within New Zealand. Attribution to the Ministry for Primary Industries should be in written form and not by reproduction of any such emblem, logo or Coat of Arms.

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1 Purpose

The Risk Management Programme (RMP) Manual has been prepared by the New Zealand Food Safety (NZFS) business unit of the Ministry for Primary Industries (MPI) as a step-by-step guide to help you as an animal product business operator to develop and operate your RMP. The manual provides answers to the following 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?

1.1 How to interpret the RMP manual

Regulatory requirements and guidance information are differentiated in this document.

A regulatory requirement is identified by having a citation at the end of the relevant sentence or clause in [square brackets] and the specific legislation from which the requirement has been taken. The word "**must**" is often used to indicate its mandatory status. For example: "The operator of a risk management programme must ensure that animal material, animal product, and other inputs are processed and handled in a way that manages and minimises their contamination and deterioration" [AP Reg 58(1)].

In some cases, the requirements have been paraphrased or reworded using animal material and product examples for context. Operators should refer to the cited legislation for the actual wording of the legal requirement. You should also check the current edition of the documents or references mentioned in this manual as they are amended from time to time. This Guidance may not reflect the latest amendments.

Guidance information, indicated by "**should**", provides explanatory information, examples or options for achieving a particular outcome or requirement. Operators may use alternative methods or measures to those set out in the manual, provided they do not compromise good operating practices and the achievement of the requirements. It is your responsibility as an RMP operator to ensure that all animal material and product is fit for its intended purpose.

1.2 Definitions

APA or **the Act** means the Animal Products Act 1999, unless otherwise stated

animal means any member of the animal kingdom, and includes:

a) any mammal, bird, finfish, shellfish, reptile, amphibian, insect or invertebrate:
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 the APA;

but does not include a human being [APA 4(1)]

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 [APA 4(1)]

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 [APA 4(1)]

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 [APA 4(1)]

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 [APA 4(1)]

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 [APA 4(1)]

control:

a) when used as a noun means the state wherein correct procedures are being followed and any established criteria are being met;
b) when used as a verb means to take all necessary actions to ensure and maintain compliance with established criteria and procedures (see Codex GPFH)

corrective action includes an action-

a) to restore control; or
b) to identify any affected animal material or animal product, and –
    i) ensure its fitness for intended purpose; or
    ii) manage its disposal; or
c) to prevent recurrence of a loss of control [AP Reg 3]

critical control point, in relation to a hazard of significance referred to in section 17(3)(b) of APA, means a point at which it is essential to use processes or procedures to control the hazard (whether by preventing or eliminating it, or reducing it to an acceptable level) [AP Reg 3]

critical limit means a criterion, observable or measurable, relating to a control measure at a critical control point that separates acceptability from unacceptability of animal material or animal product [AP Reg 3]

critical non-compliance means, in relation to a breach of a regulatory requirement, a breach that makes it reasonably likely that 1 or more of the following may occur:

a) animal or human health is adversely affected;
b) access to overseas markets is jeopardised;
c) the integrity of the official assurance system is threatened;
d) the integrity of test results is threatened [AP Reg 3]

Director-General (D-G) means the chief executive of the Ministry [APA 4(1)]

day-to-day manager means the person identified in a RMP either by name, or the position or designation as being responsible for the day-to-day management of that RMP as nominated by the owner or operator of the business

document (verb) means to include in writing in the risk management programme (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 under section 76 of APA; and
b) processes homekill or recreational catch at the same premises or place as the retail butcher processes or trades in regulated animal product [APA 4(1)]

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 APA

evaluator means a person or agency who is recognised under APA to carry out independent evaluations of the validity of RMPs and the validity of significant amendments to those programmes [AP Reg 3]

export requirements means requirements specified by the Director-General by notice under section 167(1) of APA, in relation to all or any class or description of animal material or animal product intended for export, if the Director-General is satisfied that the setting of the requirements—

a) is necessary or desirable for the purpose of facilitating access to overseas markets; or
b) is in accordance with the requirements of the relevant authority of the importing country, or can reasonably be expected to satisfy the requirements of the relevant authority of the importing country; or
c) is necessary or desirable to safeguard assurances provided by New Zealand [APA 60]

exporter means a person who exports any animal material or product from New Zealand, whether or not for reward or for purposes of trade; and, where an exporter registered under Part 5 of APA is based overseas, includes the New Zealand agent or representative of that exporter [APA 4(1)]

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 [APA 4(1)]

farm dairy operator means the person in charge of operations at a farm dairy, including the extraction of milk from milking animals [APA 4(1)]

finfish has the same meaning as in the Fisheries Act 1996 [APA 4(1)]

fish means finfish and shellfish [APA 4(1)]

fit for intended purpose, used in relation to animal product that has been processed in accordance with Parts 2 to 4 of APA, means that, by reason of animal material or product having had the relevant risk factors managed in accordance with Parts 2 and 3 of APA, and meeting any relevant animal product standards and any supplementary notices, 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 [APA 4(1)]

food in the Food Act, unless the context otherwise requires,

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 Food Act [Food Act 2014]

food control plan (FCP) is a plan designed for a particular food business to identify, control, manage and eliminate 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 [Food Act 2014]

game estate means a place within which animals are kept (whether all of the time or only some of the time), as if in the wild, for the purpose of providing opportunities for persons to hunt or catch them as recreational catch as if in the wild, being animals of a species, kind, or description specified for the purposes of section 65B of the APA by the Director-General by notice under section 167(1) of APA [APA 65B]

game estate animal means any of the following (see section 65B of APA):

a) any deer species (including, but not limited to, red deer, fallow deer, wapiti deer (elk), sika deer, white tail deer and sambar deer);
b) tahr;
c) chamois;
d) goats;
e) pigs;
f) wallabies;
g) buffalo;
h) sheep;
i) cattle [PSP Notice A1.3].

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 to which they relate

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

HACCP plan means documentation or set of documents, prepared in accordance with the principles of HACCP to ensure control of significant hazards in the food business (see Codex GPFH)

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

a) is in or has the potential to be in animal material or animal product, or is or has the potential to be a condition of animal material or animal product; and
b) leads or could lead to an adverse health effect on humans or animals [APA 4(1)]

hazard analysis means the process of collecting and evaluating information on hazards identified in raw materials and other ingredients, the environment, in the process or in the food, and conditions leading to their presence to decide whether or not these are significant hazards (see Codex GPFH).

homekill means an animal that is killed or processed by its owner, or by a person who is listed as a homekill or recreational catch service provider under section 76 of the APA, for the use or consumption of the owner [APA 4(1)]

homekill or recreational catch service provider means a person who is listed by the D-G, to kill or process homekill or recreational catch for reward, for the owner, hunter or harvester of the animal without needing to have, or to comply with a registered RMP [APA 4(1)]

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 [APA 4(1)]

input means any animal material, animal product, or anything (such as an additive, a processing aid, ingredient, or packaging) that is intended to be contained within, attached to, enclosed with, or otherwise in contact with, the animal material or animal product [AP Reg 3]

in writing means printed, typewritten, or otherwise visibly represented, copied, or reproduced, including by fax or email or other electronic means [APA 4(1)]

MPI means the Ministry for Primary Industries

monitor in the context of a HACCP Plan, 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-conforming, in relation to animal material or animal product, means any material or product that is known—

a) not to meet regulatory requirements; or
b) not to have been processed in accordance with regulatory requirements [AP Reg 3]

official assurance means a general statement to a foreign government or an agent of a foreign government, attesting that, as appropriate, any 1 or more of the following applies in respect of any animal material or animal product:

a) any specified process has been completed under the APA with respect to the animal material or product concerned;
b) the animal product concerned meets the applicable animal product standards and any supplementary notices;
c) any export requirements that are stated in the assurance have been met;
d) the situation in New Zealand, in relation to any matter concerning animal material or animal products, is as stated in the assurance [APA 61(2)]

operator in relation to an animal product business, means the owner or other person in control of the business [APA 4(1)]

operator-defined limit means a measurable limit established by a risk management programme operator to manage the fitness for intended purpose of animal material or animal product [AP Reg 3]

operator verification means **verification** carried out by an operator

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

overseas market access requirement (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 [APA 4(1)]

place 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 [APA 4(1)]

premises include:

a) all premises, places and facilities within the physical boundary of any relevant RMP; and
b) any vessel or other conveyance, and any mobile premises, used for harvesting or processing animal material or animal product, other than a transportation unit or animal material depot; and
c) the fixtures and fittings that form part of any premises [PSP Notice A1.3]

process includes kill, slaughter, dress, cut, extract, manufacture, pack, preserve, transport and store [APA 4(1)]

readily accessible in relation to documentation means that no matter where documents are stored, they can be transferred electronically, mailed, couriered, or transferred by other means within the time period stated

recognised agency means a person or group of persons recognised by the Director-General under section 101 or 102, and section 102 respectively of the APA for the purpose of performing specified functions or activities [APA 4(1)]

recreational catch means a wild animal that—

a) is killed, captured, taken, or harvested by a recreational hunter or fisher, or other person undertaking similar recreational activities (including a client hunter killing or catching an animal on a game estate, as if in the wild), for the use or consumption of the hunter, fisher, or other person in terms of section 68 of APA; and
b) is processed either by its catcher or by another person under section 69 of APA, and not in compliance with Parts 2 to 4 of APA [APA 4](1)]

registration number means a unique identification code, selected by the operator and confirmed by MPI for a premises covered by an RMP [AP Reg 5]

regulated control scheme (RCS) means a programme which is imposed by the D-G to manage risks where:

a) RMPs would not be feasible or practicable for the relevant risk factors to be managed; or
b) where it is more efficient for the government to run the programme or it may require statutory authority to manage the risk factors; or
c) the measures are additional to meet any export requirements [APA 4(1)]

regulatory limit means a measurable regulatory requirement that is critical to fitness for intended purpose of animal material or animal product [AP Reg 3]

required parts means those part of the RMP that must be submitted for registration if the operator is not submitting the entire RMP [see AP Reg 26 & 27]

rendering means the breaking down of animal tissues into constituent fat and protein elements, whether by the application of heat and pressure or otherwise [APA 4(1)]

retail butcher includes any type of butcher engaged in retail trade in regulated animal products [APA 4(1)]

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 animal product [APA 4(1)]

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 [APA 4(1)]

sanitise means to disinfect, or to otherwise reduce or maintain microbial contamination to or at a level that avoids the creation of a hazard, by the application of maintenance compounds or other things (such as steam or light) [PSP Notice A1.3(1)]

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 [APA 4(1)]

shellfish has the same meaning as in the Fisheries Act 1996 [APA 4(1)]

shelf life means the period nominated and validated 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

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

topically means applying a substance externally to a part of the body of a human or animal [APA 4(1)]

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; and

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; and
c) barter; and
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; and
e) supplying an article where there is a statutory responsibility to supply; and
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 [APA 4(1)]

uncontrolled hazard means a hazard that—

a) has been identified in a hazard analysis for the processing activity or animal material or animal product; and
b) is one for which the operator of the risk management programme has no control measure available; and
c) is not subject to any regulatory limit or operator-defined limit [AP Reg 16(2)]

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

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

validation protocol is a document that sets out how the operator will demonstrate that the RMP or aspects of the RMP are effective [AP Reg 34(2) & PSP Notice B1.3]

verification includes the application of methods, procedures, tests, and other checks conducted by a verifier to confirm—

a) in relation to a risk management programme or regulated control scheme—
    i) whether operations that are subject to the programme or scheme are being carried out in compliance with it; and
    ii) the applicability of the programme or scheme to the operations of the relevant animal product business; and
    iii) the effectiveness of the programme or scheme;
b) in relation to animal material or animal products for whose export an official assurance is required, whether the animal material or animal products have been produced or processed in a way that meets the requirements for the official assurance;
c) whether a regulated person has complied with a requirement imposed by or under APA [APA 4(1)]

verifier means a recognised person whose specified functions and activities include carrying out verification functions and activities [APA 4(1)]

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 [APA 4(1)]

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 [APA 4(1)]

Note - Any term or expression that is defined in the Animal Products Act 1999, Regulations and Notices made under those Acts and used, but not defined, has the same meaning as in those Acts, Regulations or Notices.

1.3 Abbreviations

ACVM Act:	Agricultural Compounds and Veterinary Medicines Act 1997
AP Reg:	Animal Products Regulations 2021
AP Reg amendment	Animal Products Amendment Regulations 2022
APA:	Animal Products Act 1999
D-G:	Director-General
CCP:	Critical Control Point
COP:	Code of Practice or Operational Code
Codex GPFH:	Codex Alimentarius Commission, General Principles of Food Hygiene, CXC 1-1969 (amended 2020)
DOB:	Dual Operator Butcher
FCP:	Food Control Plan
Food Act:	Food Act 2014
FSC:	Food Standards Code
GOP:	Good Operating Practice
HACCP:	Hazard Analysis and Critical Control Point
ISO:	International Organisation for Standardisation
MPI:	Ministry for Primary Industries
NMD Notice:	Animal Products Notice: National Microbiological Database Programme
NZFS:	New Zealand Food Safety
NZQA:	New Zealand Qualifications Authority
OMAR:	Overseas Market Access Requirement
PSP Notice:	Animal Products Notice: Production, Supply and Processing
RA:	Recognised Agency
RCS:	Regulated Control Scheme
RMP:	Risk Management Programme
EU:	European Union
US:	United States of America

2 Background

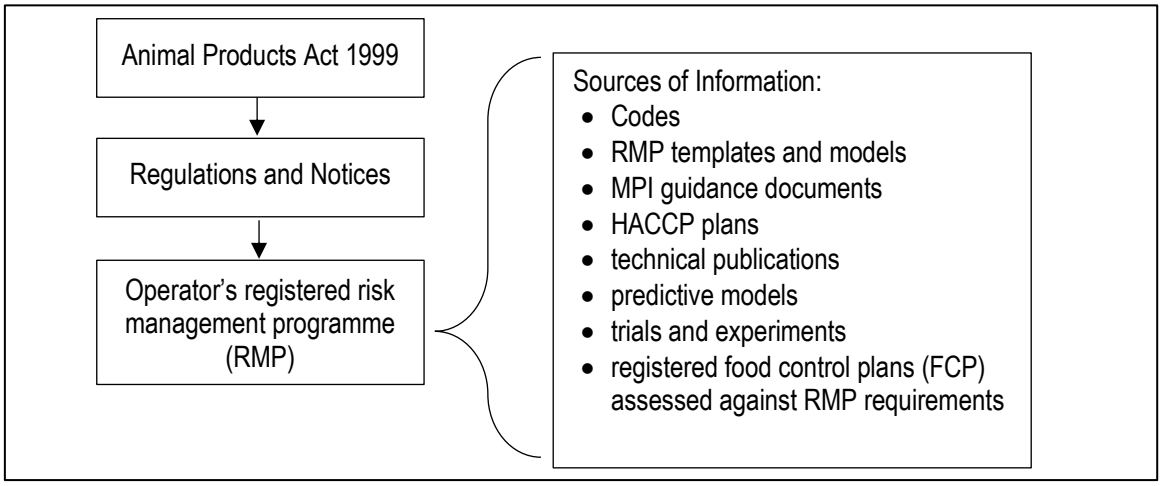
NZFS, a business unit within MPI, is accountable for food/animal product control in New Zealand and for the implementation and overall performance of the regulatory framework. The regulatory framework has been established to define MPI's responsibilities as a regulator, the responsibilities of recognised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

You, as operators of animal product businesses, are responsible for producing suitable animal material and products that are fit for their intended purpose. Animal product businesses must not rely on MPI or recognised agencies and persons to ensure the delivery of such 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 RMP operators must comply with (as described in Figure 1: Animal Products Act framework below). Check the New Zealand Legislation website for the latest version of the APA and the AP Regs.

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 animal materials and animal 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
- authorisations and duties on various persons.

Each of these is explained in sections 2.1.1 to 2.1.4 of this manual.

You can see the APA Notices here

2.1.1 Risk Management Programmes (RMP)

(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 animal materials and animal products. This is to ensure that the resulting animal product is fit for its intended purpose. The RMP is based on the principles of Hazard Analysis and Critical Control Points (HACCP).

There are four types of risk factors:

- risks from hazards to human health;
- risks from hazards to animal health;
- risks from false or misleading labelling; and
- risks to the wholesomeness of animal material or animal product.

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

To find out what is legally required to be included in an RMP, section 17 of the APA (Contents of and Requirements for Risk Management Programmes) must be read in conjunction with the:

- Animal Products Regulations 2021; and
- Animal Products Notice: Production, Supply and Processing

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 RCSs include:

- Animal Products (Regulated Control Scheme – Bivalve Molluscan Shellfish) Regulations 2006; and
- Animal Products Notice: Regulated Control Scheme – Bivalve Molluscan Shellfish for Human Consumption.
- Animal Products Notice: Regulated Control Scheme – Transport and Handling of Products for Export with an Official Assurance.

You should refer to the relevant RCS Regulation and/or Notice for the requirements you will need to meet. There may also be templates that you can use e.g. Regulated Control Scheme (RCS) Template for Transport of Animal Material and Product.

2.1.3 Export requirements

(Part 5 of the APA)

There are general export requirements 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 issued by Notice, either as general export requirements or market specific requirements (these are called Overseas Market Access Requirements (OMARs)) [APA 60 (1)]. Refer to the relevant Animal Product Notices (e.g. the Animal Products Notice: Official Assurances Specifications for Animal Material and Animal Products and the Animal Products Notice: Official Assurances Specifications for Dairy Material and Dairy Products) for the additional requirements you need to meet.

It is your choice whether to include procedures that describe how export requirements are met (e.g. OMARs) in your RMP unless the OMAR requires otherwise. Businesses that are geared for markets such as the EU or the US may choose to incorporate OMARs into their RMP. If you include export requirements in your RMP, these will be the procedures you must operate to, i.e. meet New Zealand Standards and export requirements to be compliant with the RMP.

For more information about the requirements for exporting animal product click this link: Requirements for exporting animal products

If you have any questions about exporting animal products, email exporterhelp@mpi.govt.nz for assistance.

2.1.4 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 verification of RMPs). A public register for all recognised agencies and persons is on the MPI Registers and lists webpage. You can find out who has been recognised for the different functions by searching for the following links:

- Evaluators;
- Verifiers;
- Dairy Specialists and Farm Dairy Assessors
- Animal products recognised agencies - including dairy; and
- Animal Product Recognised Laboratories – Recognised laboratories under APA

The APA also imposes duties on key persons. These are:

- RMP operators (see 8.1 RMP Operator's Duties of this manual and section 16 of the APA);
- exporters (see section 51 of the APA);
- recognised agencies (see section 112G of the APA); and
- recognised persons (see section 112H of the APA).

If duties are not complied with, the APA allows for a number of measures to be taken. This can include increased verification of RMPs by verifiers, 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 A: Businesses Requiring RMPs for details of the types of businesses that require an RMP.

2.3 Businesses not requiring an RMP

See Appendix B: Businesses Not Requiring RMPs for details of the types of businesses that do not need an RMP. Some of these businesses may instead be required to operate under a risk-based measure under the Food Act.

2.4 RMP configurations

You can develop an RMP as a stand-alone programme for each [APA 12]:

- type of animal material or animal product that the business produces or processes; and
- type of process or operation that is applied to the animal material or product; and

- set of premises or place in which the animal material or product is produced or processed.

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

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:

- single-site, with one RMP (this is the simplest form of RMP);
- 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);
- 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
- 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 may 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 a separate RMP for each physical location.

2.4.2 Multi-business RMPs

(Section 17A of the APA)

A single RMP may apply to more than one business, if approved under section 17A 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.

- 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. If you are interested in this option, contact MPI to discuss further.

2.5 Including non-animal products in an RMP

You may want to include non-animal products in your RMP. The guidance document - Can I include non-animal product foods in a Risk Management Programme? has been prepared by MPI to explain the options if you want to include other foods in your RMP.

2.6 Relationship between the APA and other legislation

2.6.1 Food Standards Code (FSC)

The Food Standards Code sets out the standards relating to labelling, composition and contaminants of food sold, processed or handled for sale or imported into 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 the Food Act or the APA.

You can access the Food Standards Code here.

2.6.2 Food Act 2014

The Food Act is a risk-based approach to managing food safety of food intended for human consumption. Food business operations that are higher risk from a food safety point of view 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 some types of animal product primary processing, and those carrying out secondary processing of animal products with a domestic focus can operate under the Food Act.

2.6.3 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.

2.6.4 Operating under an FCP registered as an RMP

(Section 34 of the APA)

If your business operates under an FCP, you may wish to register your FCP as an RMP so that it can be operated as an RMP under 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 general export requirements, export notices and OMARs applicable to your business while operating the RMP for export purposes.

Contact MPI Approvals at approvals@mpi.govt.nz if you intend to operate under an RMP on an intermittent basis when applying for registration [APA 34(1)].

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 surrender your RMP registration.

2.6.5 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 regulated under both the APA and ACVM Act. For example:

- 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
- the labelling of manufactured petfood is covered under the ACVM Act.

2.6.6 Medicines Act 1981

Regulation 258 of the AP Reg exempts secondary processors of animal products that are a medicine or a related product under the Medicines Act 1981 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 [AP Reg 258(3)].

2.6.7 Dietary supplements

If an official assurance under the APA is required for dietary supplements containing animal products, you will need an RMP and to comply with 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.

Further information can be found on the Medsafe website.

3 Resources for developing an RMP

MPI has developed various resources to help when developing your RMP. These can be found on the MPI website:

- Sector specific Operational Codes and RMP templates;
- Sector specific HACCP plans;
- Sector or topic specific guidance documents.

Additionally the following documents may be useful:

- peer-reviewed scientific information; and
- valid predictive models.

You will need to refer to the APA and any subordinate legislation for the regulatory requirements you must meet.

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 3.8 RMP Consultants) if you need specialist or technical help.

3.1 Codes and templates

Operational Codes, COPs, and RMP templates have been developed to assist businesses to meet regulatory requirements, and on which an RMP can be based. These documents usually cover good operating practice (GOP), HACCP application and other RMP requirements. If you follow the Operational Codes, COPs or RMP templates this 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 verification of RMPs by verifiers.

3.1.1 Operational Codes and COPs

An Operational Code is a document which reflects agreed industry practice and provides information on how to meet regulatory requirements. In most cases, an Operational Code is an updated version of a COP.

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

If you decided to incorporate the whole or part(s) of an Operational Code into your RMP, then the incorporated part(s) becomes mandatory (i.e. it is no longer a guide)

3.1.2 RMP Templates

An RMP template is a document with prompts for each mandatory requirement and includes areas that need to be filled in to describe your operation e.g. a “fill in the gaps” document. MPI have developed templates for select sectors only.

In most cases, if your RMP is fully based on a RMP template, the requirement for evaluation will be waived. Refer to the Waiver of the Requirement to Provide a Copy of an Independent Evaluation Report to check if a waiver has been given. If evaluation has not been waived, evaluation will still be required.

You can also use an RMP template as a basis for your own RMP, and make modifications. If any of the modifications you make are considered to be significant amendments, the parts modified will need to be evaluated.

3.2 MPI guidance documents

MPI has developed various guides that you may also find useful:

- What is Validation? provides information on validation;
- RMP Operator Resource Toolkit provides examples of RMP forms and procedures (you are free to modify these to your operation);
- Own-source Water Checklist and Template Water-use Plan (Non-dairy) can be used by non-dairy RMP operators to develop water-use criteria and a water-use plan when using own-source water;
- Dairy Processors Template Water-use Plan can be used by dairy processors to develop a water-use plan;
- *Listeria* Factsheets and Guidance provide information on *Listeria* and key good operating practices for managing of *Listeria* in your operation;
- How to Determine the Shelf Life of Food can help you determine shelf life and how to apply the date marking;
- Guidance for Dairy Manufacturers provides information to help dairy operators to complete their RMPs or FCPs.

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. Applying HACCP principles when developing a RMP is mandatory [APA section 17].

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

- Hazard Analysis and Critical Control Point web page;
- Standardisation of Hazard Analysis and Critical Control Point (HACCP) describes MPI's approach to HACCP and has information on how to apply HACCP Principles;
- 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; and
- Sector specific HACCP applications.

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.). You can incorporate by reference the relevant parts of these documents into your RMP, as long as they 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 FCP as a basis for an RMP, but it will need to be evaluated by a recognised evaluator to ensure requirements of the APA are met prior to RMP registration.

3.8 RMP consultants

Sometimes it is useful to seek specialist advice to help develop your RMP. If you choose to use a consultant, it is best to choose one who has relevant industry experience or is otherwise experienced with the APA. You should check their reputation online and ask for references from customers who got the same or similar work done.

You should also be clear about the type of advice you are seeking e.g. do you need food safety information on a specific animal product, or do you need advice on how to meet the food labelling requirements? You should look for a consultant that will help you understand what to do, and why.

You can find the list of RMP consultants on the MPI website by searching for 'Hiring a food consultant'.

However, you should note that the **consultants on this list are not approved 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 (e.g. evaluator or a verifier) is acting as a consultant to help with the development of your RMP, they will not be able to evaluate or verify your RMP within certain timeframes [AP Reg 74 & 84]:

a) an evaluator who was involved in the design or development of an RMP or a significant amendment to that programme must not evaluate the programme for a period of 2 years after the date on which the programme or amendment is registered, unless the D-G agrees otherwise in writing [AP Reg 74].

b) an evaluator must not use a technical expert for the purposes of AP Regs 77(3) or 81(3) if the technical expert was also involved in the design or development of that programme or the amendment being evaluated, for a period of 2 years after the date on which the programme or amendment is registered, unless the D-G agrees otherwise in writing.
c) a verifier must not verify an RMP that they previously evaluated, or for which they evaluated a significant amendment, for a period of 2 years after the date of the evaluation, unless the D-G agrees otherwise in writing [AP Reg 84].

4 RMP development

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

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

An understanding of the application of HACCP principles is needed to be able to develop and implement an RMP. If this expertise is not available in-house, MPI recommends staff undertake HACCP training or get advice from a consultant.

You cannot produce animal material or product for traded before your RMP is registered, so you need to make sure you allow sufficient time to develop and have your RMP evaluated before registration. This can take many months.

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	References to sections of the RMP Manual
Development	Operator	Develop the RMP	Section 4
Checks & Validation	Operator	Perform checks and validates the RMP	Section 5
Evaluation	Operator	Hire a recognised evaluator to evaluate the RMP	Section 6
	Recognised Evaluator	Evaluate and report on the validity of the RMP	Separate guidance document: Evaluation Manual
Registration	Operator	Contract a recognised RMP verifying agency to confirm they will verify the RMP	Section 4.16
	Operator	Apply to MPI to register the RMP	Section 7.1
	MPI	Registers the RMP	
Operation	Operator	Implement and operate the registered RMP	Section 8

Task	Who is responsible	What the task involves	References to sections of the RMP Manual
	Operator	Verification by operator of RMP	Section 4.11.14 Section 4.12.10.2
Verification	Recognised Verifier	External verification by recognised verifier	Section 8.3
Amendment and Notification	Operator	Amendments to the RMP - Certain changes are registered by MPI or notified to MPI	Section 8.4
	Operator	Application for registration of significant amendments to existing RMP	Section 7.5
Cessation	Operator or MPI	Surrender of the RMP registration Suspension of RMP operations De-registration of RMP registration	Section 9

4.2 RMP components

The RMP must include the components that are appropriate to your products and operation shown in Table 2: Components of an RMP.

Table 2: Components of an RMP

Component	Section 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
Limits	4.8
Other product details	4.9
Process description	4.10
Supporting systems/Good Operating Practices (including but not limited to procedures for corrective actions for foreseen as well as unforeseen type loss of control, recall, operator verification, notification, document control and records)	4.11
Application of HACCP	4.12
Identification and control of risks to wholesomeness	4.13
Identification and control of risks from false and misleading labelling	4.14
Validation of RMP effectiveness	4.15
Provision for verification activities	4.16
Additional requirements for homekill and recreational catch providers *(Applicable to Dual Operator Butchers only)*	4.17

Each of these components are discussed below.

4.3 Operator, business and RMP identification

4.3.1 RMP operator

(Section 17, 19(a), 22(1)(b) and 22(1)(c) of the APA)

Your RMP must specify the name and address (including the electronic address, if available) of the business owner or operator whose programme it is. 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 or dishonesty, whether in New Zealand or overseas, in regard to running a business of the type covered by the APA [APA 22(1)(b)].

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 4.3.1 RMP Operator) then no further information is required. If the business trades under another name, this must also be provided [AP Reg 5(a)].

4.3.3 RMP identifier

For non-dairy operators, the RMP identifier is a combination of the Registration number (see 4.3.3.1 Registration number) and RMP Suffix (see 4.3.3.2 RMP Suffix).

For dairy operators, the RMP identifier is the Registration number. Dairy operators must also nominate a Unique Location Identifier (ULI). (See 4.3.3.3 Unique Location Identifier).

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

Table 3: Examples of identifiers

Registration number	RMP Suffix	Unique Location Identifier (ULI)
BUS111	01	123
BUS111	02	1234
BUS111	03	567

4.3.3.1 Registration number

The registration number 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 can indicate in your application the registration number you want to use, but will need to confirm the availability of the business registration number with MPI. Alternatively, MPI will assign a registration number. The registration number is not to be the same as any exporter's registration number, or an ID used for any other approval under the APA.

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 registration number, e.g. EU-listed premises must have individual registration numbers for each premises. Where appropriate, the registration number will be used by MPI for country listing purposes and may be used by you for animal product labelling and identification. Any change to a registration number 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 registration number may not be eligible for export to the affected countries until country listings have been updated. Once your registration number has been established, it will be used for any future RMP registration applications.

You can check availability of registration numbers on the MPI website by searching for 'Registered Risk Management Programmes'.

Registration numbers from RMPs that are no longer registered are not available.

4.3.3.2 RMP suffix (relevant to Non-dairy only)

Most RMPs have 01 as the default RMP suffix. In rare instances, you may decide to operate one or more RMPs under a registration number. Non-dairy operators will be assigned a consecutive two digit RMP suffix (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)

Operators of premises used for dairy manufacture or storage of dairy material or product must be assigned a unique location identifier (ULI) by MPI for **each location** specified in the RMP, and the ULI must be included in the RMP [AP Reg 5(d), PSP Notice D3.2(1)]. The ULI will appear on the registration documentation for each registered RMP. If the RMP only covers processing at one location the ULI should ideally be the same as the RMP identifier. An operator may request a specific ULI, but MPI will determine the ULI assigned, and may decline a request for various reasons, including potential confusion with other premises or RMP IDs, or another request for the ULI has already been received.

You can check the availability of Dairy ULIs on the MPI website by searching for 'Register of Dairy Unique Location Identifiers'.

4.3.4 Operator, business and programme identification

MPI recommends that information covered in 4.3 Operator, Business and RMP Identification is located at the start of your RMP.

Figure 2: Example of RMP details gives an example of the way the information can be presented.

Figure 2: Example of RMP details

Registration number: 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 have a list of all the documents that make up your RMP and indicate the date or version of the documents at the time of registration of the RMP or any significant amendment to the RMP [AP Reg 24(3) & (4), & 27(c)]. You will also need a method of identifying the current version of all documents that make up the RMP [AP Reg 24(3) & (4)]. These lists may be one and the same.

A contents page may be used to meet this requirement (if sufficient details are included). An example is given in 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 on registration**	**Amendment record version-date**	**Businesses it Applies to**
Manual A Supporting Systems	3	Cleaning and Sanitation	10	1 – 01/01/2022	2 – 01/07/22	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 or excluded by referencing those parts of the document that are included or excluded (whichever is easiest).

4.5 Management authorities and responsibilities

(Section 17 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 position, or name and position) [AP Reg 5(b)].

This is the person who:

- is the authorised management representative for all aspects of RMP;
- will deal with MPI over any RMP issues; and
- will be present at verification visits.

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

The operator must ensure the day-to-day manager is familiar with the RMP and has:

- knowledge in food safety of relevant animal materials and 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 your 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 7.6.2 Change in Day-to-day Manager of an RMP).

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

(Section 17A of the APA, AP Reg 28)

A person applying to MPI for approval of a multi-business RMP to apply to another business must provide the following information:

- written evidence that, once registered, the operator of the multi-business risk management programme will have sufficient control, authority, and accountability for all matters covered by the programme in relation to each business;
- written evidence that the person applying for approval has obtained the consent or otherwise taken into account the views of any person whose business is to be covered by the programme.

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, AP Reg 6 &7)

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. All animal material or animal product and the processes or activities covered by the RMP are to be included in the scope.

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 [AP Reg 6]. This must include facilities, equipment, personnel amenities, external environment, processing, storage, support areas used under the RMP and must also include any areas not routinely used.

You can show the physical boundaries on a diagram or site plan of the premises, mobile premises or vessel. An example of a RMP site plan is included in Appendix F: Example of an RMP Site Plan. Wherever possible, this should be drawn to scale and have enough detail to be able to readily allow the identification of any changes to the boundary. You should identify any shared premises (both sites and buildings) and any remote buildings or people living on site. Property boundaries can be used for the physical boundaries rather than the footprint of the buildings. This may allow for possible constructional changes to be made at a later date without requiring a significant amendment to the RMP. However, what is included in the physical boundaries of the RMP will be subject to verification.

Ideally, the boundary should be a continuous line, rather than multiple boundaries (or "bubbles") under the same RMP with no designated pathway between the boundaries. If isolated bubbles are used to signify boundaries, product cannot be moved between these areas nor can any other item used under the RMP (i.e. cleaning products). If product is moved between the spaces outside of an RMP boundary with no designated path, it may lose its export eligibility.

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 multi-business 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 [PSP Notice D2.2(5)].

If you operate a mobile premises ensuring that all appropriate facilities are available at all sites where the premises operates is 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 17(1) & (2) of the APA)

An RMP must be developed taking into account all relevant sources of potential risk factors that may affect the animal material, animal product, operations or directly associated things when a person uses areas within the physical boundaries of the RMP for any activity that is not covered by the programme.

Exclusions from RMP

You must document:

a) any animal material, animal product or food that is within the physical boundaries, but is excluded from your RMP;

b) the alternative regime under which they are regulated, e.g. another RMP, an FCP or national programme under Food Act, ACVM or Medicines Act;
c) how the interfaces between the regimes will be managed; and
d) the authorities and accountabilities for resolving issues associated with those activities (e.g. any disputes between the operators) [AP Reg 7].

When explaining how the interfaces are managed, you should clarify:

- the names or positions of the people responsible for managing the interface;
- clear identification of the processing areas that are used for RMP and non-RMP activities;
- any hazards or wholesomeness risk factors that may be introduced by the non-RMP activities and relevant control measures;
- the extent of the operation that is under each regime (e.g. by describing the point at which the process changes regimes);
- how RMP and non-RMP activities are separated (e.g. occur at the same time, physically separate or separate by time and/or distance) and how this is managed (including managing personnel); and
- any particular procedures that must occur in between RMP and non-RMP operations (e.g. cleaning and sanitation).

Shared facilities

If your RMP includes shared facilities (e.g. facilities that are shared with another business) you must document:

- the areas within the RMP that are shared;
- the activities taking place that are not covered by the RMP, and the times when these activities occur;
- any hazards or wholesomeness risk factors that may be introduced by the other activities and relevant control measures;
- how the shared facilities are managed, e.g. by complete cleaning, physical separation etc.;
- the names or positions of people responsible for managing the interface; and
- the authorities and accountabilities for resolving issues associated with those activities (e.g. any disputes between the operators) [AP Reg 7].

Example of records include:

A contract stating who is responsible for maintaining specific buildings or equipment and if problems occur, how these issues are raised, with the time frames for satisfactory resolution of these issues.

4.7 Animal material and animal product description

(Section 17(1)(c) of the APA & AP Reg 8)

Your RMP must include a description of the animal material and product it covers. Table 5: Examples of Product Description shows how this information can be presented.

Table 5: Examples of product description

Requirements	**Example 1**	**Example 2**	**Example 3**
Product	Raw sheep carcasses, cuts, trimmings	Table Eggs	Pasteurised Liquid Milk made from raw cows milk
Intended consumer	General public	General public	General public

Requirements	Example 1	Example 2	Example 3
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	None	Maximum microbiological limits[2]: • *Salmonella* spp. not detected in n=5 x 25 g • *L. monocytogenes* not detected in n=5 x 25 g • *Coagulase Positive Staphylococci* (*S. aureus*) 1000 cfu/g • *B. cereus* 1000 cfu/g • *E. coli* 100 cfu/g
			Chemical maximum limits: • Inhibitory Substances 0.006 IU/ml benzyl penicillin equivalent [PSP Notice] • Codex Maximum Residue Limits for Veterinary Drugs • Codex Extraneous Residue Limits • Food Standards Code Chapter 1.4.1
			Processing related limit: • 72°C for 15 sec[3]
			Action Limits: • Chlorate 0.1mg/kg
Operator-defined limits	*To be defined by the operator*	*To be defined by the operator e.g. for* *Salmonella* Enteritidis	*To be defined by the operator, including:* • Wholesomeness and physical hazards
Other product details	• Packaging and labelling as per company specification	• Have been candled, are visibly clean and packed • To be stored at or below 15°C with best	• Food Standards Code Standard 2.5.1 • Shelf life and storage conditions

[1] If limits exist, then elsewhere in the RMP the operator must also document actions to be taken when limits are not met.

[2] Limits obtained from Table 4 in the PSP Notice.

[3] Limit obtained from PSP Notice. Other time/temperature combinations could be used.

Requirements	Example 1	Example 2	Example 3
	(refer to document xx)[4] • Frozen to -12°C	before date of 35 days from date of lay • PSP Notice Chapter J	

4.7.1 Animal material or product entering or leaving the physical boundaries of the RMP

All of the animal materials or products entering or leaving the physical boundaries of the RMP must be documented by their name or type, including those intended for human consumption, animal consumption, industrial or other use [AP Reg 8].

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.

The name or type of animal materials or products required under AP Reg 8 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 consumer of the animal material or product that leaves the RMP, including whether it is intended for:

a) human consumption: e.g. general population, infants, elderly, pregnant women, immuno-compromised individuals;
b) animal consumption: e.g. pets, zoo animals, farmed animals; or
c) some other purpose e.g. Industrial or technical use (e.g. laboratory media) [AP Reg 8(c)].

AP Reg 8(c) requires you to document the intended use of the animal material or product an whether it 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.

4.8 Limits

You must document, in relation to each animal material or animal product described in 4.7.1 Animal Material or Product Entering or Leaving the physical boundaries of the RMP, any relevant regulatory and any operator-defined limits [AP Reg 11] in relation to:

- risks from hazards to animal or human health;
- risks from false or misleading labelling or representation; and
- risks to the wholesomeness of animal material or animal product.

Regulatory and operator-defined limits define the fitness for intended purpose of animal material or 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 C: Examples of Limits.

[4] This could be a reference to a company document where the packaging specification is located.

4.8.1 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, etc.

Examples of some relevant legislation include:

- Animal Products Act Notices;
- Australia New Zealand Food Standards Code; or
- Food Standards Notices under the Food Act (including the Food Notice: Maximum Residue Levels for Agricultural Compounds).

4.8.2 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 hazards.

Operator-defined limits are not generally expected for raw animal products that have not undergone further processing, however, there are exceptions to this, e.g. the PSP Notice requires processors of mechanically separated meat to set operator-defined limits for the process hygiene indicators of aerobic plate count and *E. coli*.

When setting operator-defined limits, you should consider the process, shelf life, intended use and intended consumer of the product. Products that are ready-to-eat or are intended for vulnerable populations may have lower microbiological limits than products that are to be processed further or require cooking by the consumer. Keep in mind that the microbiological limits are a measure of what is to be achieved when the product leaves the RMP, rather than at the end of its shelf life, and so you may set these lower than the limits applied at the point of sale or consumption.

You will need to show that the operator-defined limit(s) you have selected are appropriate to your product, considering its intended use, intended consumer and expected handling after leaving the RMP. You must retain the information justifying each operator-defined limit [AP Reg12].

Evidence to justify the selection and level of operator-defined limits may include:

- Operational Codes, COPs and RMP templates (see 3.1 Codes and Templates);
- peer-reviewed scientific information (see 3.5 Peer-reviewed Scientific Information);
- predictive models (mathematical modelling) (see 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); or
- international standards or journal articles.

Referring to the source from which you have taken your operator-defined limits 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 validation data from your own trials, validation studies or historical knowledge/data on performance of the control measure. Refer to Part 5 of this manual.

4.8.3 Actions to be taken when limits are not met

You must document the actions that will be taken if any regulatory or operator-defined limits are not met [AP Reg13]. Actions will include restoration of control, production disposition, corrective actions and preventative actions. The actions need to include any specific responses prescribed by Animal Product Notices (e.g. increased sampling, reprocessing, downgrading or disposal).

4.9 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.

4.10 Process description

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

a) all inputs; including rework; and
b) the main activities or steps; and
c) all outputs that are animal material or animal product [AP Reg 9].

The simplest way to describe your process is to use process flow diagrams.

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 should include the main activities or steps in the process, e.g. any rework, recycling or multiple processing stream, etc. If you are submitting the 'required parts' of an RMP 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 are to be shown irrespective of their intended use e.g. human consumption, animal consumption, industrial/technical use or waste.

4.11 Supporting systems/Good Operating Practices (GOP)

Supporting systems include GOP, as described in Part 2 of the AP Regs, that are designed to ensure animal materials or animal products are consistently produced that are fit for their intended purpose. GOP is an overarching term and includes several interacting components such as good manufacturing practice (GMP), good hygienic practice (GHP) and good agricultural practice (GAP). Supporting systems may also be referred to Standard Operating Procedures (SOPs), Sanitation Standard Operating Procedures (SSOPs), or pre-requisite programmes (PRPs). For ease of use the terms supporting systems and GOP are used in this manual interchangeably.

General guidelines:

- The development, implementation and maintenance of GOP are necessary to support the processing of animal material and product that is fit for its intended purpose at all stages in an operation, from

reception through to the final product. GOP assist in managing hazards and other risk factors in animal material or animal product.

- GOP manages many sources of hazards and other risk factors to animal material or animal product and should ensure that they are processed in an environment in which the presence of contaminants is minimised. Properly applied GOP provides the foundation for effective application of HACCP principles.

These procedures must meet the requirements of AP Reg 10 and cover:

- good operating practices (GOP) [AP Reg Part 2];
- the matters set out in sections 17(2) and 17(3) of the APA;

4.11.1 Areas covered by supporting systems

You must ensure that your supporting systems meet all relevant regulatory requirements and include all procedures that are necessary for your operation [AP Reg 10 & Part 2]. This is likely to include, the following list. Note that not all regulatory requirements have been listed below and that the regulatory requirements will be amended from time to time. It is your responsibility to ensure that you have accessed and incorporated the most recent requirements into your procedures.

- design, location, construction of premises, places, facilities, equipment and essential services [AP Reg 42; PSP Notice Part C1];
- operation of premises etc. [AP Reg 43];
- operation of essential services including lighting, ventilation & process gases [AP Reg 45; PSP Notice C1.25 - C1.27];
- water [AP Reg 46; PSP Notice Part C1 subpart 4];
- waste management [AP Reg 47; PSP Notice Part C1 subpart 3];
- calibration of measuring equipment & monitoring equipment [AP Reg 48; PSP Notice C1.10];
- cleaning and sanitising procedures [AP Reg 50; PSP Notice C1.6];
- maintenance [AP Reg 51; PSP Notice C1.7];
- use of maintenance compounds [AP Reg 53; PSP Notice C1.8];
- pest control [AP Reg 54; PSP Notice C1.12];
- personal hygiene, health of persons, and clothing & equipment [AP Reg 55; PSP Notice Part C2];
- personnel competencies and training [AP Reg 19 & 20];
- corrective action procedure for managing unforeseen circumstances (i.e. unforeseen types loss of control) [AP Reg 18(2) and 18(3)];
- verification by operator [AP Reg 22];
- record keeping and document control and record keeping [AP Reg 23 & 24];
- notification requirements;
- reporting requirements [AP Reg 25];
- allergen management;
- labelling and identification [AP Reg 66; PSP Notice Part C3];
- packaging and packing [AP Reg 68; PSP Notice Part C3];
- non-conforming products [AP Reg 70; PSP Notice Part C6];
- traceability [AP Reg 103];
- recall [AP Reg 105];
- receipt of incoming materials [AP Reg 134];
- control of processing operations [AP Reg 58];
- transport [PSP Notice Part C5];
- product specific procedures (e.g. environmental pathogen monitoring) [PSP Notice Part D3];
- *Listeria* requirements for processors of certain ready-to-eat animal products [PSP Notice Part L3].

In many cases, MPI has incorporated requirements into sector-specific Operational Codes. It is recommended that you use these documents to help develop your supporting systems.

4.11.2 Recommended content of each supporting system

The procedures must be appropriate to the operation and contain sufficient detail to enable people with responsibilities (e.g. staff, managers) to know what to do, to assist in personnel training and to ensure clear understanding others (e.g. verifiers and evaluators, etc.). Written procedures should be simple and easy to understand for all personnel. We recommend that your procedures contain the following:

- purpose and scope;
- general requirements and procedures;
- procedures covering:
  - control measures (see 4.11.3 Procedures for Process Control)
  - monitoring (see 4.11.4 Procedures for Monitoring GOP);
  - corrective action (see 4.11.5 Procedures for corrective actions); and
  - verification by the operator (see 4.11.7 Procedures for operator verification of GOP)
- records; and
- references to other relevant documents.

The RMP Operator Resource Toolkit was developed to assist you to develop your RMP. The toolkit contains example forms and procedures that can be modified to suit your operations.

4.11.3 Procedures for process control

Process control procedures 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
- sufficient detail including any critical measurements at each process step (e.g. pH during curing, time and temperature requirements for cooking, etc.).

After the identification of hazards and their control measures in the HACCP plan, the control measures are determined to be controlled by GOP or at CCPs (for significant hazards) in the HACCP plan.

Caution should be exercised to ensure accurate translation of validated control measures for the control of significant hazards at CCPs from the HACCP plan to process control procedures (operation, monitoring, corrective action and operator verification).

The process control procedures for a CCP are likely to be more detailed than for control measures that are managed by GOP.

4.11.4 Procedures for monitoring

You need to monitor your GOP procedures to ensure that they are properly implemented and effective. The frequency of monitoring will depend on the purpose of the GOP procedure and the impact on the animal material or product's fitness for intended purpose.

Monitoring procedures should include the:

- identification of the person(s) or position(s) responsible for carrying out the monitoring [AP Reg 19];
- method of monitoring;
- acceptable criteria(s) or limit(s);
- frequency and sampling regime (must be appropriate to ensure consistent control); and
- records to be kept.

Refer to section 4.12.8 of this manual for monitoring of critical limits at CCP in the HACCP system.

4.11.5 Procedures for corrective actions

As part of your GOP procedures, you must document the specific corrective actions that will be taken if the results of monitoring of the GOP procedure indicates that there has been a loss of control (for example, monitoring indicates that your cleaning and sanitation procedures have not been effective). You need to document how control will be restored; how any affected animal material and animal product will be identified, managed, or disposed of will, and the action to be taken to prevent the problem from recurring [AP Reg 18].

Your corrective action procedures, should include:

- the identity of the person(s) or position(s) responsible for carrying out the corrective action [AP Reg 19];
- root cause analysis of the non-conformance (if needed);
- procedures for how control is restored;
- procedures for the control & disposition of non-conforming product (e.g. checking the product back to the last compliant result, etc.);
- any action necessary to prevent reoccurrence of a loss of control
- escalation of the response if corrective action fails;
- follow-up that the corrective actions and preventative actions taken have been effective; and
- the records to be kept including;
  - the actions taken;
  - any investigations carried out; and
  - the disposition of the affected product.

Refer to section 4.12.9 of this manual for corrective action to be undertaken when monitoring results indicate a loss of control at CCP in the HACCP system.

4.11.6 Corrective action procedure for unforeseen circumstances

You must have a corrective action procedure that will be followed when a problem occurs for which a specific corrective action has not been documented in the RMP. This includes things like natural disasters or fire, but may also include smaller points of failure that may impact on the fitness for intended purpose of animal material and product.

The procedure must specify how you will identify person(s) with the skills suitable to manage the event, and the records kept in relation to the loss of control and the corrective actions taken [AP Reg 18(2) & (3)]. The appropriate person may be different for each scenario depending on the skills needed.

The identified person is responsible for aspects such as:

- identification, retention and assessment of non-conforming 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
- records and reporting to the verifier or verifying agency about any loss of control that adversely affects the suitability of animal material for processing or the fitness for intended purpose of animal product [AP Reg 36(1)].

[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 and PSP Notice Part D1.

4.11.7 Procedures for operator verification

You must undertake operator verification to check that the GOP procedures have been implemented effectively, monitoring is occurring where planned, and that appropriate corrective actions are taken when requirements are not met.

Note:
Operator verification is often an area that is not done as frequently or as thoroughly as it should be. It is important that these procedures are well developed and implemented. Your operator verification is commonly checked as part of your verification by verifier.

For additional guidance for development and implementation of operator verification procedures, refer MPI Guidance Document: Operator Verification.

Your procedures for operator verification should specify the responsible persons by name or position, activities to be performed, their frequency, actions when verification shows that GOP is not effective and matters to be recorded or reported [AP Reg 19].

Procedures for operator verification must include:

a) regularly checking that all procedures for managing risk factors are appropriate, effective, and consistent with the regulatory requirements;
b) regularly checking that records are generated as required by the RMP and contain all required information to demonstrate GOP is effective;
c) regularly checking whether staff are following the documented procedures, including any validated parameters; and
d) checking, after any significant amendment to the RMP has come into effect, that all parts of the supporting systems that may be affected by the amendment are effective and properly implemented [PSP Notice B1.1].

Refer to section 4.12.10 of this manual for operator verification in relation to HACCP and section 4.11.14 for operator verification of the RMP.

4.11.8 RMP documents and procedures for document control

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

Every document or part of a document that makes up an 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; or
    ii) the day-to-day manager of the programme; or
    iii) a person nominated to do so in the programme's document control procedures.
d) available in a readily accessible form when required by any person with responsibilities under the programme [AP Regs 24, 31, 32 & 33].

The operator of a RMP must have an up-to-date version of the RMP [AP Reg 31(1)].

There is flexibility in how you can document your RMP.

You should ensure that the format used for the RMP is user friendly for relevant personnel, the verifier and evaluator. The D-G can require you to amend your RMP if it is not clear enough [APA 26A].

If a RMP document (e.g. a GOP procedure) has become obsolete, it needs to be archived. You will need to keep a copy of the document for the longer of:

a) 4 years; or
b) the shelf life of the animal material or animal product to which the RMP relates.

They need to kept in a manner that will protect them from damage and deterioration, and prevents confusion with documents currently making up the RMP [AP Reg 32].

The registered RMP, all reference material relating to the RMP, and any archived documents must be readily accessible and made available within 2 working days of any request to:

a) a recognised person or agency;
b) an animal product officer;
c) the Director-General; and
d) persons authorised by the Director-General [AP Reg 33].

4.11.8.1 Authorisation or "sign-off" of documents

All RMP documents must be authorised by a person with appropriate authority (e.g. day-to-day manager of the RMP or the person or position assigned the responsibility) before the RMP is registered and after any amendments are made [AP Reg 19 & 24(6)].

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

An electronic signature must:

a) identify the person who has signed the document;
b) indicate the person who signed the document is approving the information in the document (for example by placing the electronic signature at the end of the information in the document);
c) be reliable given the purpose and circumstances for which it is required; and
d) not be altered, or if it can be altered, any alteration must be able to be identifiable.

4.11.8.2 Amendments

Your document control procedures for effectively controlling of all RMP documents must include how:

a) significant and minor amendments will be made so that the RMP is current and reflects the actual operation;
b) amendments, or the nature of the amendments 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 version at all locations without unnecessary delay after authorisation and, where necessary, after registration of a significant amendment [AP Reg 24(1) & (2)].

These should also include procedures for:

- documenting the amendment in a legible manner (Twink™ should not be used);
- deciding if the amendment is significant with appropriate justification;
- if an amendment is significant, proceeding with evaluation and registration described later in 8.4.1 Significant Amendments to your RMP;

- if an amendment is minor (with or without notification to MPI), follow with procedures described in 8.4.2 Minor Amendments to RMPs;
- implementing the amendment.

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;
- describing the changes in an amendment page or register.

4.11.9 Record keeping

(Section 77H and 77G of the APA)

Records are the evidence which demonstrate your compliance with the RMP. Record keeping procedures must ensure that all records necessary to demonstrate compliance with the RMP are:

a) legible; and
b) stored for 4 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 within two working days of any request [AP Reg 23 & 33]

Any records relating to monitoring, corrective action, and operator verification must:

a) specify when the activity occurred (including the date);
b) give a description of the results of the activity; and
c) identify who performed the activity [PSP Notice B1.2].

All records relevant to the RMP must be made 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 [AP Reg 33].

Refer to Part 5.2.5 of this manual for the additional requirements for the retention of records and information resulting from validation.

4.11.9.1 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 people.

4.11.10 Competencies and skills

Where MPI have set specific training or knowledge requirements in law, these are referred to as "competencies". If specific competencies have not been set, it is up to you to identify the skills needed to perform a task or role.

4.11.11 Persons responsible for key tasks

[AP Reg 19]

You need to include in your procedures, the people by position, or name and position, responsible for carrying out the following key tasks (including any within supporting systems) and any competencies or skills to carry out those tasks:

- sign-off on documents that make up part of the programme before they are implemented;
- monitoring at a critical control point;
- corrective actions (e.g. restore control, product disposition, prevent recurrence, etc.);
- operator verification (e.g. record checks, internal audits, RMP review, etc.);
- recalls; and
- any other key tasks that are specified as such in a supplementary notice.

The task assignments will depend on the complexity of the operation. In simple operations, one person may be responsible for all of the tasks. In more complex operations, several people may be responsible for different tasks. You may designate these responsibilities to different people at different times, e.g. by roster, etc. You should also document how back-up personnel are assigned to cover for holidays and absences.

4.11.12 Mandatory competencies

There are some mandatory competency requirements for people who are responsible for certain operations or activities under an RMP. Some of these mandatory competencies are found in the following locations in the PSP Notice:

- PSP Notice Part D3, D3.19(3)(b) Validation of defined heat treatments;
- PSP Notice Part F3, subpart 5: Ante-mortem and post-mortem examiners;
- PSP Notice Part H2, H2.6 Competency of personnel processing fish for human consumption;
- PSP Notice Part H3, H3.24 Competency requirements for BMS depuration;
- PSP Notice Part L1 Thermal processing of low-acid commercially sterilised product; and
- PSP Notice Part L3, L3.6 Competencies of personnel (*Listeria* requirements for processors of certain ready-to-eat animal products).

If a staff member has completed a course or unit standard that has expired or is no longer available, as long as the course is listed in the relevant Notice this will still be acceptable. You will need to ensure that the knowledge gained from these competencies are maintenance on a regular basis.

4.11.13 Suitable skills

You must ensure that anyone carrying out a task that could affect the animal material or product fitness for intended purpose is suitably skilled. To do this you must:

- identify the tasks which are considered “key tasks”;
- document the required skills needed to carry out the tasks effectively and how they will be achieved and maintained; and
- keep training records for each staff member [AP Reg 20].

For example, people responsible for HACCP development and implementation should have appropriate skills in the application of HACCP principles and knowledge of the RMP. This may be done through a variety of on-the-job training, training courses[6], observing and asking questions or e-learning modules [AP Reg 20].

An example of how you could do this is shown in Table 6: Skills of responsible Persons.

[6] The New Zealand Qualifications Authority (NZQA) provide the framework for competency standards and courses in various manufacturing or primary processing sectors.

Table 6: Skills of responsible persons

Person	Authorities and responsibilities	Training, knowledge or experience
Operator of RMP	Legal representative for the RMP (see 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 4.5.1 Day-to-day Manager of the RMP)	Has thorough knowledge of: • food safety of relevant animal materials and animal products and hygienic procedures and practices • regulatory requirements, including responsibilities, related to the effective implementation of the RMP • particular product/process (e.g. appropriate technical competencies, etc.) and relevant experiences 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 4.11.8.1 Authorisation or "sign off" of documents)	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) responsible for application of HACCP or part of the HACCP team	Confirms that the HACCP principles have been properly applied and if a plan is relevant has been appropriately implemented	The relevant level of HACCP expertise
Person(s) undertaking document checks and validation RMP	Confirms that the RMP is appropriate, complete, effective, 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 validating. For example, persons validating aspects of an RMP should be skilled in that aspect (cook-chill, pathogen monitoring etc).
Persons responsible for control activities	See 4.11.3 Procedures for process control, 4.12 Application of HACCP and 4.13 Identification and Control of Risks to Wholesomeness	Has thorough knowledge of: • relevant operations, processes and systems in the RMP • control measures for each activity they are responsible for and how to recognise loss of control • appropriate response when there is a loss of control
Persons responsible for monitoring activities	See 4.11.4 Procedures for Monitoring and 4.12.8 Establish CCP Monitoring and 4.13 Identification and Control of Risks to Wholesomeness	• 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 4.11.5 Corrective Action Procedures; 4.11.6 Corrective action procedures for unforeseen circumstances, 4.12.9 Establish Corrective Actions and 4.13 Identification and Control of Risks to Wholesomeness	• Same as for persons responsible for control activities • Corrective action procedures for each activity they are responsible for • Ability to identify product non-conformances • Relevant NZQA Unit Standard qualifications
Verification by operator	See Part 4.11.7 Procedures for Operator Verification, 4.11.14 Operator verification of RMP and 4.12.10.2 Operator verification (HACCP) procedures	• 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 • Effecting corrective actions if needed
Persons responsible for recall	See 4.11.18 Recall Procedures	• Thorough understanding of recall policies and procedures, including carrying out the mock recalls • Relevant NZQA Unit Standard qualifications

4.11.14 Operator verification of the RMP

Operator verification of the entire RMP are the checks carried out to confirm that the RMP is accurate, effective and properly implemented. Well developed and implemented operator verification procedures will 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;
- continues to comply with all legislative requirements; and
- continues to be operated as written (or appropriate amendments are made as the process changes).

Your operator verification procedures should include:

- activities to be performed (e.g., internal audits, reality checks), and the activities' frequency;
- 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 and reporting, as appropriate.

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 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.

Also see Section 4.11.7 Operator Verification of GOP and 4.12.10 Operator Verification (HACCP).

For additional guidance for development and implementation of operator verification procedures, refer MPI Guidance Document: Operator Verification.

4.11.15 Notification and reporting requirements

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

a) position, or name and position of the person(s) responsible for the day-to-day management of the RMP (notify MPI Approvals at approvals@mpi.govt.nz); and

b) any emerging, new, or exotic biological hazards or new chemical hazards that come to the operator's attention [AP Reg 25 & 37].

An emerging, new, or exotic biological or new chemical hazard can be thought of as something that is not in our hazard database, or that has not historically been seen in your product sector. RMP operators are usually best placed to identify any emerging, new or exotic biological hazards or new chemical hazards and to notify them to the MPI as soon as practicable after its discovery, so that appropriate actions can be taken.

Please notify such events to: animal.products@mpi.govt.nz with the subject line "**Notification to MPI of emerging, new, or exotic biological hazard or chemical hazard".**

Your RMP must also document a procedure for notifying your verifier or verifying agency, of any of the following issues:

a) any significant concern about the fitness for intended purpose of animal material or animal product; or
b) where the RMP is no longer considered to be effective; or
c) where the premises identified as being used by the programme is not or no longer suitable for use; or
d) where anything within the physical boundaries of the programme is used for additional purposes or by other persons not covered by the programme and the RMP has not adequately considered relevant hazards or other risk factors relating to that use; and the programme has not adequately considered relevant hazards or other risk factors relating to that use; or
e) there has been a critical non-compliance by the operator; or
f) any loss of control that occurs is due to unforeseen circumstances and adversely affects the suitability of animal material for processing or the fitness for intended purpose of animal product [AP Reg 25 & 36].

When you notify your verifier or agency, you must do so in writing and without unnecessary delay [AP Reg 36]. The information should also be provided in a form that is easy to access, understand and interpret.

4.11.16 Traceability and recall procedures

(Section 77B and 77C of the APA, AP Reg Part 5)

Your RMP must include procedures for tracing and recalling animal material or animal products including conducting simulations or mock recalls to confirm their effectiveness.

4.11.17 Traceability

[AP Reg 103 & 104]

RMP operators must implement traceability procedures that enable animal material and animal product to be traced from the supplier to the operator, and from the operator to the next recipient in the supply chain (other than the final consumer). Procedures must also enable you to identify and locate animal material and animal product while it is with the physical boundaries of your operation.

This information must be sufficient to allow an effective recall to be carried out if required.

If a request is made by the D-G or an animal product officer to provide traceability information, you must be able to provide the information in a readily accessible format within 24 hours after the request, or within any reasonable shorter period specified in the request.

4.11.18 Recall Procedures

In the event that non-conforming animal materials or products are produced, you should take appropriate corrective actions and determine the disposition of affected products. If the non-conformance is detected before any of the affected products are released for distribution, it will be a trade level recall. However, if 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 [AP Reg 105]. Your business may not require a recall procedure if your product is intended to be consumed immediately, e.g. a takeaway.

Your recall procedure must include:

a) the criteria for deciding when a recall will be initiated;
b) how retrieval and disposition of the animal material or animal product will be managed;
c) a system for notifying MPI (the D-G or animal product officer) of a recall within 24 hours [AP Reg 106], and the verifier as soon as possible without unnecessary delay [AP Reg 36]; and
d) how you will provide the following details to the D-G or animal product officer in a readily accessible format within 24 hours after the recall [AP Reg 106(2)]:
    i) the animal material or animal product affected by the recall; and
    ii) the reason for the recall.

You must notify MPI at food.recalls@mpi.govt.nz

You can find a guide to assist you in developing recall procedures on the MPI website by searching for 'Recall Guidance'.

4.11.19 Simulated/mock recall

[APA Section 77B, AP Reg 107 & 108]

You must ensure your recall plan is periodically tested using a 'simulated' or mock recall exercise. The simulation must demonstrate the effectiveness of the operator's traceability and recall procedures. The simulated recall must be carried out at least every 12 months after a previous simulated recall or after a genuine recall, if the recall demonstrated the traceability and recall procedures to be effective. Your recall procedure should state when you will carry out each simulated recall.

4.11.20 Validation of Supporting systems/GOP

You must demonstrate that your RMP meets regulatory requirements with GOP (e.g. hygiene and maintenance, personnel health, approved chemicals, water quality).

Refer to section 5 of this manual and Appendix D for those supporting systems that are likely to require validation.

4.12 Application of HACCP

(Section 17(3) of the APA)

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 application of HACCP is based on the expectation that supporting systems are effectively implemented prior to applying the HACCP Principles.

The Principles of HACCP as defined by Codex Alimentarius are:

(1) Conduct a hazard analysis and identify significant hazards. Identify control measures;

(2) Determine the Critical Control Points (CCPs);

(3) Establish validated critical limits for each CCP;

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

(5) Establish the corrective actions to be taken when monitoring indicates a deviation from a critical limit at a CCP has occurred (i.e. a particular CCP is not under control);

(6) Validate the HACCP plan and then establish procedures for verification to confirm that the HACCP system is working as intended; and

(7) Establish documentation concerning all procedures and records appropriate to these principles and their application.

For further guidance on HACCP, refer to the following:

- Hazard Analysis and Critical Control Point;
- Standardisation of Hazard Analysis and Critical Control Point (HACCP); and
- Codex GPFH.

The application of HACCP principles must be documented. 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 [APA 16].

4.12.1 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:

- **biological**, includes microorganisms (e.g. *Salmonella* spp., *L. monocytogenes,* etc.), parasites (e.g. *Taenia saginata,* etc.) and biotoxins[7];
- **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.); and
- **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 this may impact on the selected control measures.

4.12.2 Conduct a hazard analysis

Hazard analysis consists of identifying potential hazards and evaluating them to determine which are significant to your operation (refer to Codex GPFH for guidance).

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

The hazard identification and analysis must be documented, this includes any uncontrolled hazards [AP Reg 14 &16] (see 4.12.4 Uncontrolled Hazards for more information). Hazards may occur as a result of:

- an input (e.g. an ingredient, additive, etc.);
- the process itself (e.g. a process step may be the source of a hazard or may increase the level of an existing hazard, etc.); or
- 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, COPs 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 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 shellfish, 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* (Lm) in certain ready-to-eat products;
- tutin toxin in honey;
- the pesticide 1080 in possums; or
- metal fragments in meat and bone meal.

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 and 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.

You can use the hazard database on the MPI website to assist with identifying 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. *Listeria monocytogenes* (Lm), *Campylobacter*, Pathogenic *E. coli* (STEC), *Mycobacterium bovis* (TB), Salmonella, coagulase positive Staph aureus • Spore forming pathogens, e.g. *Bacillus cereus*	• Chemical Residues from feed, agricultural compounds, veterinary medicines, and maintenance compounds etc. • Environmental contaminants	• Glass • Metal etc.
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	None	None	Egg shell
Bivalve molluscan shellfish	• Sourced from registered grower	• *E. coli* spp. (STEC) • *Salmonella* spp. • *Vibrio spp.*	Marine biotoxins	Shell
Plastic bag (packaging)	• Suitable as food contact material [AP Reg 68] • Protected from contamination	None	None	None

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.

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 you. You can obtain this information from your ingredient suppliers, 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 on the MPI website by searching for 'Food Risk Profiles'; or
- **quantitative and qualitative risk assessment** – evaluating the probability and severity of foodborne illnesses as a result of these hazards.

4.12.3 Identification of control measures

Once you have identified and analysed the relevant hazards, you should determine the control measures for each hazard at each 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.).

(for guidance refer to Codex GPFH)

4.12.4 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 [AP Reg 16]. You should also consider whether you need to inform a further processor, retailer or consumer (such as by providing cooking instructions on the label) about the uncontrolled hazard so that food safety can be assured prior to consumption.

4.12.5 Determine the Critical Control Points (CCPs)

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.). You must determine whether there are any CCPs in your process.

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 use 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 4.12.7 Establishing validated critical limits for each CCP).

If no CCPs have been identified, operator verification, documentation and record keeping is still required (see 4.12.10 Establish Operator HACCP Verification Procedures.

You must document the justification for each identified critical control point (CCP) [AP Reg 15]. Justification can be evidence such as historical records, technical publications, Operational Codes, COPs or information provided by MPI.

Figure 3: Decision tree for hazard analysis and CCP determination

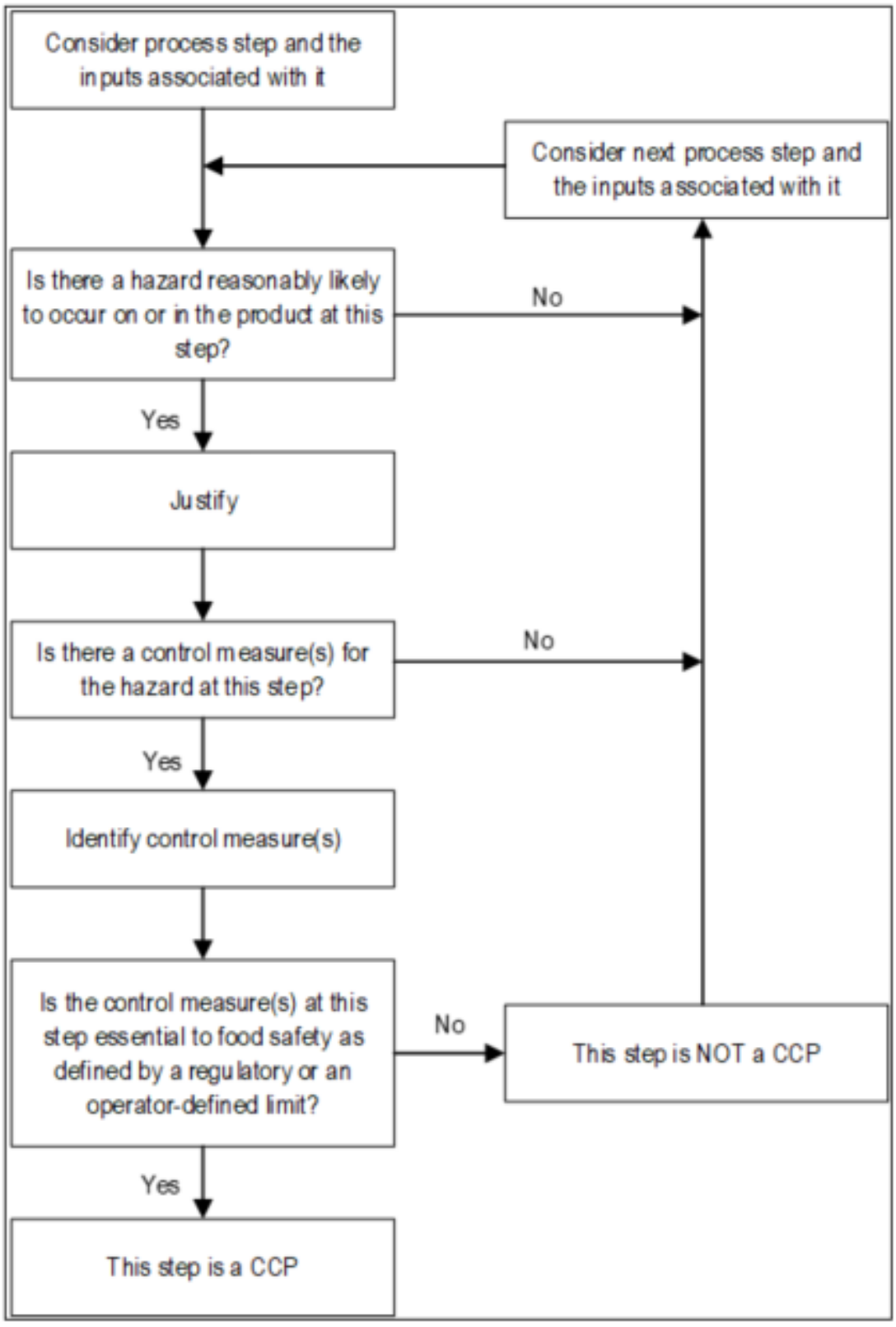


Table 8: Hazard analysis and CCP determination template (includes an example of receiving honey supers)

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 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.*, *Clostridium spp.*) are likely to occur	No	No	
		C – tutin toxin	Reported incidence of tutin in NZ honey	Yes – harvest declaration 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 – harvest declarations confirming beekeeper controls	No	

To clarify the use of Table 8, each column is discussed in Table 9: Further Explanation for Headings of Table 8 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 [AP Reg 16]. Examples of the use of this table can be found in a number of MPI COPs. Some HACCP applications can be found in RMP templates.

Table 9: Further explanation of headings in 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 Operational Codes, COPs, templates; 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 system 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 or 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 or operator-defined limits for the specific hazard(s). If there is no regulatory or operator-defined limit, there is no CCP. Note: not all regulatory limits require a CCP, for example APC and *E. coli* limits specified for process control.

4.12.6 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 verifier will verify any market access CCP against the relevant OMAR.

4.12.7 Establishing validated critical limits for each CCP

You must define and justify critical limit(s) for each CCP [AP Reg 15].

A critical limit is a criterion, observable or measurable, relating to a control measure at a critical control point (CCP) that separates acceptability from unacceptability of animal material or animal product [AP Reg 3].

Critical limits should be:

- linked to meeting a regulatory 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 must document the:

a) parameters to be monitored (e.g. pasteurisation time and temperature, etc.); and
b) limit for each parameter (e.g. 72°C for 15 seconds, etc.); and
c) justification for each critical limit [AP Reg 15].

You must show that they are consistently capable of controlling the hazard to an acceptable level [APA 17(2)b & AP Reg 34].

For guidance, refer to section 5.2 Validation of this manual and Codex GPFH - Establish validated critical limits for each CCP.

Validation of control measures is also further described more fully in the Codex document - Guidelines for the Validation of Food Safety Control Measures (CXG 69 – 2008).

4.12.8 Establish CCP monitoring

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

- identity of the person(s) or position(s) 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 that provide results in real-time) 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 include:

- 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).

Limits that cannot be monitored at the required frequency in real-time are not appropriate, e.g. microbiological limits where the results may not be available for a number of days (this would be considered verification rather than a monitoring activity).

Monitoring records must as a minimum [PSP Notice B1.2(1)]:

a) specify when the activity occurred (including the date); and
b) give a description of the results of the activity; and
c) identify who performed the activity.

4.12.9 Establish corrective actions

You must document corrective action procedures and ensure they are implemented when monitoring indicates a critical limit at a CCP is not met [APA 17(3) and AP Reg 10(3)c)].

Corrective action procedures should include [AP Reg 18(1)]:

- identity of the person(s) or position(s) responsible for carrying out the corrective action;
- procedures for how control is restored;
- procedures for identifying, managing or disposition of non-conforming product (e.g. checking the product back to the last compliant result);
- any action necessary to prevent re-occurrence of a loss of control;
- escalation of the response if preventative action fails;
- follow-up that corrective actions taken have been effective; and
- records to be kept including [PSP Notice B1.2]:
  - a description of the results of the activity (e.g. the actions taken, any investigations carried out, the disposition of the affect product); and
  - specifying when the activity occurred (including the date); and
  - identifying who performed the activity.

Disposal of non-conforming dairy material or dairy product
The disposal of non-conforming dairy material or dairy product is specified in the Animal Products Notice: Disposal of Non-conforming Dairy Material or Dairy Product.

4.12.10 Validation of the HACCP plan and Operator Verification (HACCP) Procedures

4.12.10.1 Validation of the HACCP plan

Validation is necessary to ensure that the HACCP plan is capable of controlling the significant hazards relevant to the animal product business and produces animal product that is fit for its intended purpose.

You should check the application of HACCP after completing the hazard analysis and CCP determination initially and when reviewing the HACCP system, to ensure plan is and remains effective. 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 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.)?

Refer to section 5 of this manual and Codex GPFH for guidance on validation

4.12.10.2 Operator verification (HACCP) procedures

You must document procedures for operator verification to confirm that the HACCP system is working effectively on an ongoing basis. These include procedures to verify that the CCPs are operating effectively, monitoring is occurring as written and that appropriate corrective actions are taken when critical limits are not met.

The procedures should include:

- identity of the person(s) or position(s) responsible for operator verification;
- how operator verification will be carried out;
- frequency;
- follow-up actions to be taken if:
  - the CCP is not operating correctly;
  - procedures are not being followed; or
  - a non-compliance occurs; and
- records to be kept [PSP Notice B1.2].

These verification procedures may form part of GOP and/or RMP operator verification.

4.12.11 Establish HACCP documentation and record keeping

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

- appropriate reference to RMP scope, product description and process description;
- any changes made to the HACCP plan; and
- all evidence and justifications for the decisions made.

Records must be kept to demonstrate that the HACCP application has been implemented and continues to be operated effectively [AP Reg 23; PSP Notice B1.2]. Examples of records can include:

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

4.12.12 Common HACCP mistakes

MPI has identified some common problems among food businesses when they conduct their HACCP analysis, along with suggested actions on how to reduce these mistakes. This is discussed in Table 10: Common HACCP Mistakes.

Table 10: Common HACCP mistakes

Common HACCP mistakes	Actions you can take to minimise these mistakes
Step(s) where a hazard is eliminated or reduced to an acceptable level is not clearly identified	Make sure all processing steps are identified in the process flow diagram, and this is reflected in the Hazard analysis and CCP Determination table
Hazards being carried through the entire analysis even when they have been removed by a particular process step	Make sure all processing steps are identified in the process flow diagram, and this is reflected in the Hazard analysis and CCP Determination table
Hazards disappearing without a clear step in the process where the control has been applied	Review your HACCP plan to identify which control measures are relevant to the hazard of concern
Identifying too many CCPs. This can be resource intensive and a distraction from the true CCPs	Follow through Figure 3: Decision Tree for Hazard Analysis and CCP Determination to identify the relevant CCPs Look for COPs, RMP templates relevant to your animal product as a reference
Relevant CCPs have not been identified so the steps essential to food safety lack the appropriate level of control	Follow through Figure 3: Decision Tree for Hazard Analysis and CCP Determination to identify the relevant CCPs Look for COPs or RMP templates relevant to your animal product as a reference

4.13 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.

4.13.1 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 14]. This can be based on:

- an industry Operational Code or COP;
- your knowledge or 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 11: Examples of Risks to Wholesomeness and their Controls.

Table 11: Examples of risks to wholesomeness and their controls

Product	Wholesomeness risk factor	Examples of control measures
Whole chickens	• feathers	• correct set up of plucker • inspection of birds
Hamburger patty	• bones	• supplier assurance programme • bone eliminator
Milk (farm dairy operator)	• foreign or objectionable matter (e.g. 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
Whole shell eggs	• roundworms	• worming programme for free-range hens
Mussel meat	• pea crabs	• inspection and removal
Honey	• fermentation	• control of moisture content control • heating
Canned corned beef	• plastic	• inspection of raw meat blocks, and removal • use of coloured liners
Meat	• spoilage	• temperature control • hygienic practices

4.13.2 Controls for risks to wholesomeness

Where you have identified a risk to wholesomeness, you must establish and document the control measures (see Table 11: Examples of Risks to Wholesomeness and their Controls for examples) and all other matters required by APA 17(2), and AP Reg 10 & 18 for the scope of procedures.

The control measures may be documented within process control procedures, supporting systems or a specific wholesomeness supporting system. If the control measures are documented in different parts of the RMP, we recommend 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 11: Examples of Risks to Wholesomeness and their Controls.

You are not required to set operator-defined limits for wholesomeness risk factors, however, 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 [AP Reg 11 - 13].

4.14 Identification and control of risks from false or misleading labelling

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

- the Animal Product Regulations 2021, Part 2, subpart 7 and 246;

- the Food Regulations 2015, regulations 149 – 152;
- Part 1.2 of the Australia New Zealand Food Standards Code;
- PSP Notice Part C3; 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, genetically free (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.

4.14.1 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 animal product, or group of materials or products [AP Reg 14]. This can be based on:

- an industry Operational Code or COP;
- your 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 12: Examples of risks from false or misleading labelling and their controls below.

Table 12: Examples of risks from false or misleading labelling and their controls

Labelling Risk Factor	Likely Cause	Control Measures
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
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
Process deficiencies resulting in the product not matching its label	• Errors in processing, e.g. wrong product flow, inadequate separation, etc. • Wrong formulation • Cross-contamination from equipment with unwanted ingredients, e.g. peanuts, 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.	• Training and supervision • Processing procedures • Formulation control procedures • Clean down • Order of processing • Compliance to raw material specifications • Material tracking • Inventory control • Label checks

4.14.2 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 12: Examples of Risks from False or Misleading Labelling and their Controls) and any other matters required by APA 17(2), and AP Reg 10 & 18 for the scope of procedures.

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 12: 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 [AP Reg 11-13].

4.15 Validation of RMP effectiveness

You must have evidence to validate the effectiveness of the RMP, when it is necessary to demonstrate that it is capable of consistently producing animal material or animal product that is fit for its intended purpose [AP Reg 34(1)].

Refer to section 5 of this manual for more detail on RMP validation.

4.16 Provision for verification activities

(Section 77E of the APA)

Before you apply for registration of the RMP, you must get written confirmation from a recognised verifying agency indicating that they will verify your RMP [AP Reg 26(1)(a)]. This is typically a letter and must be submitted with your other documentation for registration.

You are responsible for contracting and paying for the services of a verifier.

You can find a list of recognised verifying agencies on the MPI website from “Agency name or NZBN’ or the “Search Agency” tool

See 8.3 Verification by recognised verifier for further details about verification.

4.17 Additional requirements 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 (unregulated product) at the same premises or place as the retail butcher processes or trades in regulated animal product.

MPI has developed guidance to assist DOBs 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 to ensure that any such product is fit for its intended purpose [APA 71(1)(c)].

In addition to the components required for a standard 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 69(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 Products Notice: Homekill and Recreational Catch Service Provider Records which gives the minimum requirements for record keeping and traceability of homekill products.

You can find the DOB RMP template on the MPI website. This template has been approved, and a waiver has been granted so RMPs that are fully based on it do not need to be evaluated by a recognised evaluator prior to registration.

5 Checks and validation

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

Once you have developed or amended your RMP, you should check that it contains all the required information and meets the regulatory requirements. You need to check that:

- RMP documentation is complete and complies with all relevant legislative requirements;
- premises and equipment are ready to operate in accordance with RMP procedures and other legislative requirements; and
- the RMP is capable of consistently producing animal material or animal product that is fit for its intended purpose.

Refer to Table 13: Summary of Document Checks and Validation of the RMP for a list of checks you should perform prior to having your RMP or significant amendment evaluated. In most cases these checks will provide sufficient evidence and you should make any existing compliance records available to the evaluator during evaluation.

If validation information is required and is collected before registration of the RMP, this will need to be provided to your recognised evaluator. If evidence needs to be collected after your RMP is registered, a validation protocol on how you will collect the evidence must be provided to the evaluator.

Table 13: Summary of document checks and validation of the RMP

What to look for	Evidence required	When is the evidence required	Is a validation 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 evaluation 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 evaluation 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			
• achievement of supporting system requirements	Records of compliance to: • documented procedures, e.g. monitoring records, internal audit reports; and	• before or after registration • any existing evidence should be made available to	A protocol is not required for most supporting systems See Appendix D: Procedures and

What to look for	Evidence required	When is the evidence required	Is a validation protocol needed?
	• measurable support system requirements, e.g. product load-out temperatures	the evaluator before registration	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, FSC etc. • records of compliance to relevant critical limits, regulatory and operator-defined limits • validation information from previous validation studies or trials • results from microbial modelling and lethality calculations	Before or after registration	Yes, if validation after registration.

5.1 Checks

5.1.1 RMP documentation

Before you have your RMP evaluated, you should check that all of the required components of your RMP:

- are documented and complete; and
- meet all relevant legislative requirements, including any regulatory limits (i.e. by systematically checking it against the legislation).

To assist the evaluation (refer to 6 Evaluation) it is recommended that you prepare a checklist of the relevant legislation and references to 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. All equipment necessary for the processes described in your RMP must be available, ready to start processing and can be viewed during the on-site assessment (unless exempt, see 6.1.4 for details) by the recognised evaluator as part of the evaluation [AP Reg 78].

Certain equipment (e.g. retorts, rendering driers, pasteurisers, chillers, etc.) may need to be validated. If this is to be done after registration, then the equipment validation must be included in your validation protocol [AP Reg 34] (also see 6.3 Evaluation after completing validation).

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 animal products that are fit for their intended purpose). An RMP that is not properly validated cannot provide

assurances that hazards and other risk factors are effectively managed. Validation maybe completed before and/or after RMP registration [AP Reg 34] .

There are two distinct elements to validation:

- The scientific or technical justification that demonstrates that the designed process can control the identified hazard.
- Gathering evidence (wherever possible under productions conditions) to demonstrate the system can perform as expected.

Validation many range from running simple trials on your process to designing robust trials with a statistically valid sampling plan and analysing your data to determine if the desired outcomes have been achieved. For new processing equipment, relying on manufacturer specifications or performance claims is unlikely to be sufficient (especially for equipment that is used to deliver a critical processing step, e.g. thermal processing). You will need to obtain evidence to validate that new machinery is functioning as intended.

You may also use a technical expert/consultant to undertake the validation or to help prepare the protocol.

Specific animal products (e.g. infant formula) may have additional validation requirements, please refer to the relevant Animal Products Notices for these requirements or Operational Codes for additional guidance.

5.2.1 Validation procedure

You can find the validation guide 'What is Validation?' on the MPI website. Validation examples are included in Appendix E: Validation Examples.

5.2.2 Desired outcomes of validation

This is shown in Table 14: Example of Desired Outcomes to be Achieved and Possible Evidence.

Table 14: Example of desired outcomes to be achieved and possible evidence

Examples of desired outcomes	Examples of evidence
Setting regulatory and operator-defined limits, e.g. product characteristics, acceptable level of hazards in a product is achieved, process parameters, etc. Note – A common mistake is for RMP operators to set inappropriate operator-defined limits. It is a requirement to justify how these limits have been set to ensure this has been given sufficient consideration e.g. if you set a limit for *Salmonella* spp. - why have you selected this pathogen and the limit?	New Zealand food legislation: • APA Notices • Food Standards Code (FSC) Operator-defined limits: • Operational Codes, COPs • internationally recognised standards • published scientific literature industry agreed criteria Referring to the 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 must ensure that the conditions (e.g. raw materials, relevant hazards, combination of control measures, intended use or distribution, etc.) in your operation do not differ from the conditions under which the limit or control measure was validated in sources above.
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.	• data from previous or current validation studies (including experiments such as challenge trials) • monitoring records of a control point (CP)

Examples of desired outcomes	Examples of evidence
microbiological criteria, maximum levels of chemical residues or metal contaminants, etc.	
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 • heat treatment validation reports (by a recognised person or suitably qualified person) • data from previous or current validation studies (including experiments such as challenge trials) • trials to show process parameters, e.g. time and temperature, and flow rate are met during commercial operation • monitoring records of a critical control point (CCP)
Shelf life (Note - Food must meet the requirements of the Food Standards Code, Standard 1.2.5)	• own shelf-life studies • historical information on similar or related food products • challenge studies • predictive modelling • Operational Codes, COPs • published scientific literature • a combination of these approaches For further detailed information, refer to the MPI guide: How to Determine the Shelf Life of Food available on MPI Website.
Supporting Systems are effectively implemented	• records generated for each supporting system, e.g. training and cleaning records, water test results, water checklist, etc.

5.2.3 Protocol for validation

When there is insufficient evidence to demonstrate the effectiveness of the RMP before registration (e.g. for a new businesses or a new process, etc.) and the validation information is necessary under AP Reg 34(1), you must document a validation protocol for how you will collect the evidence. The protocol will need to be submitted to the evaluator as part of the evaluation and to MPI when applying for registration.

If a validation protocol is developed, it must contain:

- details of the evidence required and how it is to be collected;
- a proposal for the disposition of animal material or animal product produced during implementation of the protocol;
- the estimated time frame for completion of the validation [AP Reg 34(2)];
- the aspects of the RMP to be validated (including any criteria or limits to be met);
- any competencies for persons undertaking validation;
- details of the information required to demonstrate the effectiveness of the aspect of the RMP to be validated, including how evidence is to be collected and analysed; and
- any other trial design features and conditions [PSP Notice B1.3(2)].

Once the RMP is registered, you must follow the protocol and any conditions imposed by MPI at registration. Refer to section 6.3 of this manual.

5.2.4 Trial design

5.2.4.1 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. If poor quality data is collected then this could affect the value of a trial or experiment and in some cases invalidate the results.

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

- Variability of raw materials and processing;
- bias and how it can be managed (e.g. the impact of non-random sampling);
- accuracy (i.e. ensuring a measurement is as close as possible to the actual value); and
- precision or repeatability (i.e. achieving consistent measurements).

5.2.4.2 Uncontrolled parameters

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

- environmental changes (e.g. fluctuations in temperature and/or humidity);
- different personnel handling the samples; and
- alternating between different suppliers that have different raw material specifications.

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

- have controls (e.g., test the product without any treatment to minimise experimental bias);
- randomise your trials (e.g. run your trials in a random order to minimise potential bias);
- replication (e.g. repeat trials to increase confidence that your results are a true representation); and
- controlling the conditions of the experiment as much as possible.

If any significant parameters weren't controlled during the validation trials, this needs to be highlighted in the validation report

5.2.4.3 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 a process will achieve the required inactivation. If carried out in a commercial production setting, this may be done by using surrogate microorganisms, in place of pathogenic target microorganism.

Microbiological challenge tests require a lot of expertise and planning, it is recommended that you discuss this with an expert in challenge trials prior to starting. Typically, this form of validation is suited to research environments rather than commercial processing operations.

5.2.5 Records of validation information

You must keep your validation information and records for the lifetime of the process or activity to which it relates (i.e. as long as the process or activity is in operation), until it is re-validated or new records are created.

If the process, activity or product ceases, or new validation information is created, the obsolete validation information and records must be archived for another 4 years or for the shelf life of the animal material or

animal product it relates to, whichever is longer [AP Reg 32 & PSP Notice B1.2(2)]. Updates to the validation information should be kept together for easy reference and readily accessible.

Table 15: Expectations for validation information, gives some examples of what you can include in your validation report to meet the requirements of PSP Notice B1.3(1).

Table 15: Expectations for validation information

Section	Requirement in Notice	Suggested examples of what to include
1	**The aspect of the RMP that the validation relates to** What am I trying to validate?	• what is the desired outcome? • Are you trying to show validation of an operator-defined or regulatory limit, CCP, CL is being met, or that supporting systems are effective?
2	**Any persons with required competencies involved in validation**	• person(s) responsible for validation and any required competencies • are you relying on external or in-house technical expertise? • any training for personnel working on the process line prior to starting validation trials?
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 • any product characteristics, e.g. water activity, formulation, pH, etc. • the process and any process parameters, e.g. pasteurisation, Ultra High Temperature (UHT), high pressure processing, etc. • GOP requirements, e.g. water testing, effectiveness of cleaning and sanitation
5	**How the validation information was generated and the evidence and its analysis demonstrating the effectiveness of the process or activity**	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 e.g.: • run trials (consider trial design, equipment set-up, any specific trial conditions you need to meet e.g. worst-case operating conditions), any other variables that need to be considered • what data will be collected • sampling design (consider types of samples, number of samples to be collected, location of sampling sites, how often, replicates). Your sampling plan should be **statistically valid** • method of analysis: in-house, external (accredited or non-accredited method, sensitivity of your method, repeatability and consistency)

Section	Requirement in Notice	Suggested examples of what to include
		• Note repeated testing of the same product until desired results are obtained is not acceptable
6	**The findings from the validation (i.e. results)**	• 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)
7	**Conclusion, including any amendments to the process or activity / RMP**	• 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?
8	**Where validation information has been collected under a validation protocol**	• confirmation that adequate animal material or animal product disposition has occurred (e.g. Animal Products Notice: Disposal of Non-conforming Dairy Material or Dairy Product)
9	**If a validation protocol was developed, the validation information must include**	• the contents of the validation protocol (see section 5.2.3 of this manual)

5.2.6 Amendments to the RMP

You must re-validate whenever there is an amendment to your RMP or if new scientific or regulatory information becomes available [AP Reg 34] that would invalidate the previous validation information. In the case of a significant amendment to your RMP, this can be something that results in a change in the control of hazards within your RMP (e.g. new equipment, raw materials, critical control points, critical limits etc.). You may also need to re-validate when there is a system failure or if non-conformances indicate the current control measures are ineffective.

5.2.7 Common validation mistakes

Table 16 Common Validation Mistakes and Corresponding Remedial Actions lists some common mistakes made during validation. Remedial actions have been suggested.

Table 16: 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 consider how the process will perform under the worst-case conditions that you will encounter during commercial processing If a process is effective when operating under these conditions, then all products made during normal production will most probably achieve the limits too. It is important that you properly assess what "worst case" means, as sometimes this is not obvious.

Mistakes	Remedial actions
Not enough replicates	The trial design should be statistically valid, i.e. have a suitable number of runs so the results are reliable and repeatable. The number of replicates required will depend on the experimental design
Not using suitable measuring equipment	Any equipment used to make critical measurements should have a suitable accuracy and be calibrated

6 Evaluation

(Section 20 of the APA)

Evaluation is the independent assessment of your RMP to ensure that it meets the requirements and when implemented, is capable of producing animal material and animal 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:

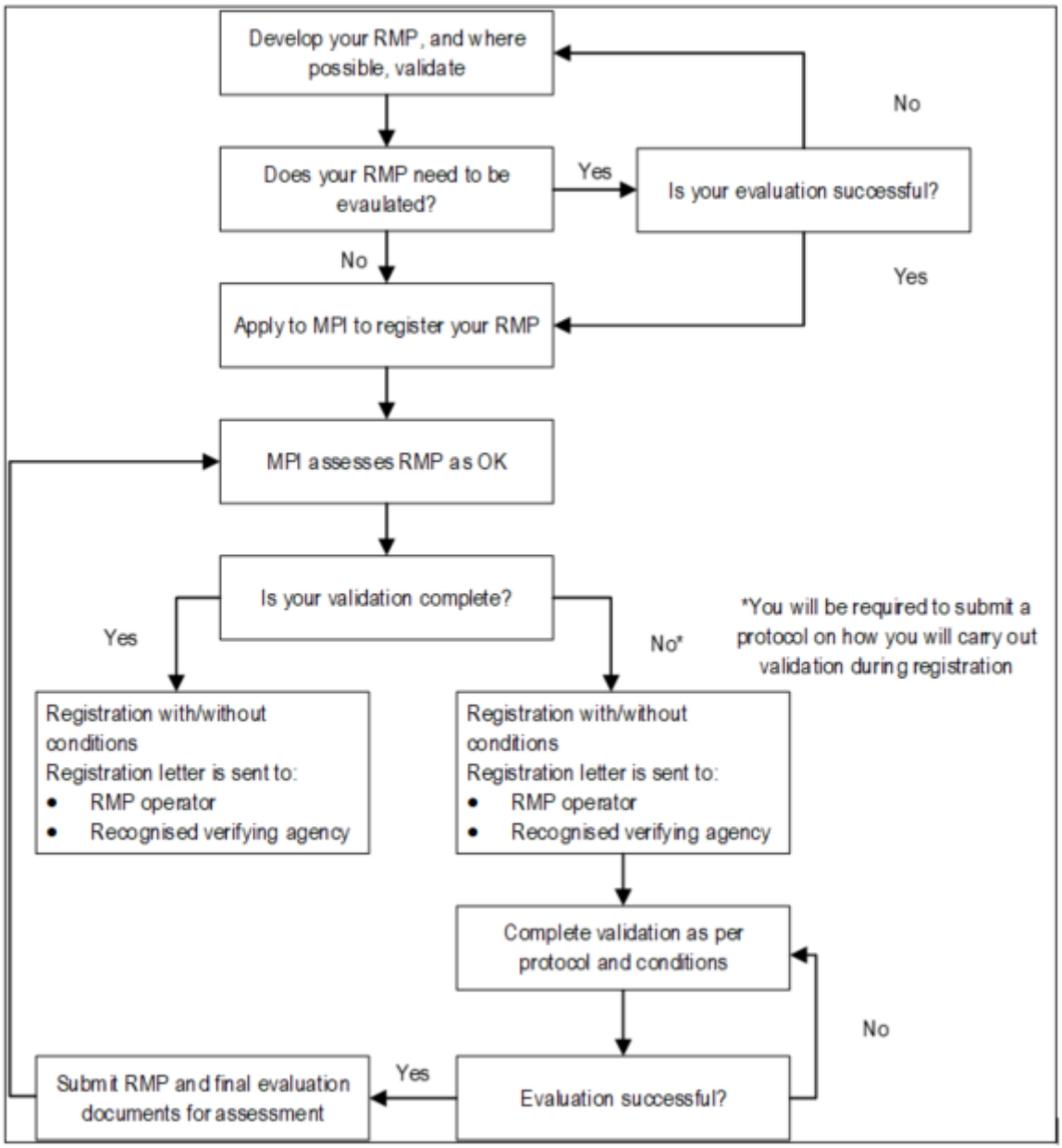
a) your RMP is based on a template for which evaluation has been waived see: Waiver of the Requirement to Provide a Copy of an Independent Evaluation Report);
b) your RMP is a multi-business RMP approved by the D-G in accordance with section 17A of the APA; or
c) the risks to human or animal health is such that an evaluation is considered not necessary [AP Reg 29].

Once your RMP has been assessed as valid by an evaluator, it can then be recommended to MPI for registration. The evaluator will prepare an evaluation report for you. This process has been summarised in Figure 4 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;
- Evaluation Manual (For evaluating Risk Management Programmes which do not cover Dairy Products;
- Guidance Document - Dairy: Recognition of Agencies and Persons; and
- Dairy Operational Guidelines and Approved Criteria (Approved criteria (for reference only, as these are now withdrawn), codes of practice, and guidance for dairy).

Figure 4: Evaluation and registration process



6.1 Evaluation of RMPs

6.1.1 Selection of a recognised evaluator

You will need to contract a recognised evaluator to evaluate your RMP. You should check the evaluator has skills and knowledge appropriate to your operation. In some cases, it is mandatory to use an evaluator who has been recognised for certain activities, e.g. low-acid canned foods; general dairy manufacture [PSP Notice Tables 24 & 25]. The evaluator may also obtain technical assistance from technical experts or other recognised evaluators as necessary e.g.: for dairy heat treatment evaluation.

You can find a list of recognised evaluators and their activities on the MPI website by selecting 'RMP Evaluation' under Recognition Function and clicking 'Search Person'. You can also select an activity to narrow down the options.

You cannot use the same person to develop and evaluate your RMP within a period of 2 years (unless the Director-General agrees otherwise in writing), as this would be a conflict of interest (refer to AP Reg 74). The same rules apply to any technical expert used in the evaluation (i.e. they cannot have been involved in the development of the RMP for a period of 2 years).

You are responsible for costs associated with evaluation.

6.1.2 Evaluations of RMPs that cover both dairy and non-dairy

RMPs may cover both dairy and non-dairy material and products. The evaluator can evaluate an RMP which includes dairy only if they are recognised to do so, as detailed under the PSP Notice. If an evaluator is presented with an RMP that contains both 'principally dairy' and non-dairy animal materials and/or products, they may need to consider if 2 separate evaluations are needed, or if a dairy evaluator is needed to support the lead RMP evaluator. Refer to the guidance procedure for principally dairy determinations in Section 10: Principally dairy determination for multi-ingredient foods of this (RMP) manual for definition of 'principally dairy'.

6.1.3 Desk-top assessment

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

If you intend to submit only "Parts" of your RMP for registration, your evaluator will also check that the parts of RMP provided to them accurately reflect the content of the full RMP [AP Reg 27] (see section 7.1.1 of this manual for details of the Parts that must be submitted).

This desk-top assessment may occur at the premises or at some other location and typically occurs prior to the on-site assessment.

6.1.4 On-site assessment

When an RMP is to be first registered, the evaluator must conduct an on-site assessment to assess the appropriateness of the RMP against the physical boundaries, design and construction of the premises or place and the operations described in the programme [AP Reg 78]. You may be exempt from the need for an on-site assessment under AP Reg 79 if certain criteria are met, for example if the level of risk to human or animal health is such that an on-site visit is unnecessary. In this case, the evaluator applies to MPI for the exemption and provides justification as to why they believe an on-site assessment is not necessary.

The on-site assessment for the purpose of the evaluation report must be performed when the premises and equipment are ready to operate. If your premises is not operational at the time of evaluation (e.g. if it is a new premises or new process), you must make reasonable attempts to demonstrate or explain normal operation.

When carrying out an evaluation of a significant amendment to an RMP, the evaluator may decide that an on-site assessment is not necessary and must give the reasons for that decision in the evaluation report [PSP Notice N3.4(1)(e)]. An exemption is not needed in this case. (Also see section 6.4 of this manual).

During the on-site assessment the 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 the GOP and supporting systems to ensure that the RMP is capable of delivering animal material or animal product that is fit for its intended purpose;
- review the application of HACCP principles, e.g. your HACCP plan;
- talk to key personnel (including managers) to ensure an acceptable understanding of the RMP; and
- check relevant documents and records, including any validation.

More than one on-site assessment may be required. 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.

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. If it is an evaluation to register an RMP, the recognised evaluator will need to apply to MPI for an exemption from the on-site assessment for the sites that will not be visited.

6.1.5 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 not satisfactory, the evaluator may provide you with feedback in general terms stating where it is deficient. To ensure impartiality and independence is maintained, the evaluator cannot provide solutions to the deficiencies if they wish to remain as your evaluator.

6.2 Evaluation report

When your RMP is satisfactory, your evaluator will prepare an evaluation report, including any conditions to be applied by MPI upon registration. You will need to provide your evaluation report as part of the registration documentation and as it is only valid for 6 months, you should apply for registration as soon as possible after you receive your report. The evaluation must be repeated if this timeframe is exceeded.

The evaluation report will meet the requirements in AP Reg 75 and PSP Notice N3.4 and N3.5.

6.3 Evaluation after completing validation

If your RMP was incompletely validated at the time of registration you must complete the validation in accordance with your protocol and provide the validation information and any amendments to the RMP as a result of that work to your evaluator. These will be evaluated and may require an on-site assessment. Deficiencies should be resolved in accordance with 6.1.5 Resolving RMP Deficiencies of this manual.

The evaluator will prepare a supplementary evaluation report once satisfied that validation is complete. The contents of the report are in PSP Notice N3.4(4). You must then provide this report, together with any RMP amendments to MPI to satisfy the registration conditions.

6.4 Evaluation of significant amendments

If a significant amendment is made to your RMP, you will need to update the RMP to include all new systems and procedures necessary to operate the amendment and ensure that staff are aware of the changes and know what to do. This must then be evaluated and registered.

The evaluator will assess 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 to which it has been modified. 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 significant amendment is satisfactory, the evaluation report will be prepared by the evaluator.

You will need to provide your evaluation report as part of the registration documentation and as it is only valid for 6 months and so you should apply for registration as soon as possible after you receive your report. The evaluation must be repeated if this timeframe is exceeded.

The evaluation report will meet the requirements in AP Reg 75 and PSP Notice N3.4 and N3.5.

Refer to AP Reg 30 for details on the kinds of amendments to an RMP that require registration as a significant amendment and Appendix G: Guidance on Difference between Significant and Minor Amendments of this manual.

7 Registration

(Sections 19 and 22 of the APA and AP Reg Part 1, subpart 2)

Once your RMP has been evaluated, apply to MPI Approvals at approvals@mpi.govt.nz for it to be registered. Your RMP must be registered with MPI before you can start producing animal material or product that can be traded [APA 3(1)(a)].

MPI will aim to process applications within 10 working days. Complexity, quality and size of an application may affect this timeframe. MPI has developed guidance about the Application process – New or Amended RMP. During the applications process MPI may request further information to make sure all requirements are met. 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 require an additional assessment fee. This 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 the following documents will be attached:

- a letter confirming registration;
- a notice of registration;
- a notice of conditions if applicable (additional legal requirements that you must comply with); and
- a copy of the registered RMP or required parts of the RMP.

Your RMP verifying agency will also 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 register (Registered Risk Management Programmes). It is your responsibility to ensure you comply with any RMP conditions. If a condition timeframe is exceeded, MPI may apply additional conditions, or the registration may be revoked.

If MPI considers that your RMP has not met the requirements, or an operator does not meet the criteria for registration, registration may be refused (see 7.3 Refusal to Register for more details).

7.1 Application for registration

You must use the correct application form when you are applying to register your RMP. See below for a list of the application forms:

- AP4: Registration of Risk Management Programme;
- AP5: Registration of Risk Management Programme under New Operator;
- AP6: Registration of Amendment to Risk Management Programme;
- AP50: Minor Update to Risk Management Programme Details; and
- AP55: Registration of RMP under Special Circumstances.

You can find these forms on the MPI website by typing the relevant AP form number into the search bar.

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

- the entire RMP or RMP required parts (see 7.1.1 RMP “required parts” to be submitted for registration);
- validation protocol (if there is one);

- the evaluation report (no more than 6 months old) if required (see 6.2 Evaluation report) (for dairy processors, the evaluation report may include heat treatment and/or premises evaluation reports, if required);
- confirmation that the recognised agency has agreed to verify the RMP (see 4.16 Provision for Verification Activities);
- the application fee; and
- AP49: Processing Categories 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 "required parts" to be submitted for registration

You have the option of submitting either your entire RMP or just the "required parts" for registration [APA 20(2)(a)]. If you chose to submit the 'required parts' only, these are specified in AP Reg 27 and includes:

- name and address (including the electronic address, if available) of the operator and the business(es) covered by the programme [APA 17(1)b & c];
- identification of —

  a) the animal material or animal product being produced or processed; and
  b) the premises or place to which the programme applies; and
  c) any other businesses to which the programme applies (if it does not apply only to the business of the person applying for registration) [APA17(1) b & c];

- the trading name (if applicable) of the business [AP Reg 5];
- the position, or name and position, of the person responsible for the day-to-day management of the programme [AP Reg 5];
- the registration number or other unique identifier of the programme, when available [AP Reg 5];
- any unique location identifier (ULI) of the premises or place (dairy only) [AP Reg 5 & PSP Notice D3.2];
- the location and type of premises or place covered by RMP including [AP Reg 5] —

  a) its physical address; or
  b) if the premises are mobile, the location where the premises are based principally; or
  c) if the premises are a vehicle, any vehicle registration number and the location where the vehicle is based principally; or
  d) if the premises are a craft or fishing vessel, the name of the craft or fishing vessel, the physical address of the operator of its RMP, and (if applicable) the fishing vessel registration number under the Fisheries Act 1996

- physical boundaries of the RMP [AP Reg 6];
- description of any other activities occurring within the physical boundaries [AP Reg 7];
- animal material and animal product and intended use [AP Reg 8];
- process description (including all inputs, all outputs and the main activities or steps) [AP Reg 9];
- all relevant regulatory and operator-defined limits [AP Reg 11];
- identification and justification of CCPs & critical limits [AP Reg 15];
- the hazard identification and management information required by section 17 (3)(a) to (c) of the APA (described in 4.12.2 – 4.12.7);
- list of all the documents that comprise the RMP, including the date or version of each document [AP Reg 26 & 27].

For multi-business RMPs, the information listed above, specific to each business must be identified. Where a large number of businesses are covered by the multi-business RMP, providing information about the document or recording system where this information is kept may be sufficient, but should be checked with MPI.

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 MPI Approvals at 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.

Please choose either electronic or hard copy submission. Submitting a mix of emailed and posted documents to MPI will likely cause delays in processing your application.

7.2 Pre-registration assessment of RMP documentation

Substantial work is involved in developing an RMP, and where a business is also constructing new facilities, the work required is even greater. MPI requires time to complete the registration process and this can be prolonged if problems are encountered with the application, which can be frustrating for the operator, evaluator and MPI.

A pre-registration assessment of RMP documentation is an option available for businesses with premises at a stage of 'practical completion'. This is to assist with the registration process and to reduce the time required to complete the registration once premises construction is complete.

'Practical completion'
'Practical completion' requires the exercise of judgement, but the principle is that the construction of the building envelope, services and equipment should be substantially complete to the point where the facility is ready for engineering commissioning.

The use of this option is limited to situations where the:

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

This option cannot be used when the RMP documentation is not complete, i.e. an operator cannot use this option to have documentation assessed in a piecemeal fashion.

7.2.1 Pre-registration assessment procedure

The following summarises the pre-registration procedure to be followed.

(1) The operator completes all RMP documentation:

   a) this will include the validation protocol; and
   b) all design and construction requirements must have been finalised and construction is at a stage of 'practical completion'.

(2) The operator contracts an evaluator to undertake the evaluation:

   a) this will involve a desk-top assessment to ensure the RMP documentation is complete and likely to deliver animal material or product that is fit for intended purpose;
   b) the evaluator may choose to undertake an on-site assessment at this time, as this may be useful in highlighting any design and construction issues which need resolution. However, as the construction is not complete, a further on-site assessment for the purposes of the evaluation report will be necessary; and

c) if satisfied, the evaluator will prepare an interim evaluation report, the contents of which will meet PSP Notice N3.4(1) (a-c) (except d-f) & N3.4(2). The evaluator will need to clearly state that this is an interim evaluation report and indicate any areas of the RMP that are still incomplete.

(3) The operator will submit the interim evaluation report, the RMP documentation and the application forms (including the applicable fee) to the D-G for pre-assessment.

(4) The D-G will assess the documentation (within 10 working days wherever possible):

a) the operator will make any amendments that are required as a result of the assessment; and
b) the application will be put on hold by MPI until the construction and on-site assessment is completed.

(5) Once the construction is complete, the operator will arrange for the evaluator to complete the on-site assessment.

(6) Once satisfied, the evaluator completes the evaluation report as required by AP Reg 75 and PSP Notice N3.4 and 3.5. Any amendments to pre-assessed RMP documentation that have been made as a result of the completion of the evaluation must be highlighted in the RMP by the operator and in the evaluation report by the evaluator.

(7) The operator submits all remaining information to the D-G for completion of the registration process. If the RMP is satisfactory, the RMP will be registered without delay:

a) when significant changes have been made to the RMP, the original assessment will have to be repeated and there may be little reduction in the time required to complete the registration; and
b) the operator will be charged for all the time involved in the assessment of the RMP (including initial assessment and any re-assessments).

7.3 Refusal to register

(Section 23 of the APA)

You will be notified in writing if MPI refuses 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 refuse registration (i.e. within 10 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 refuse 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 Condition close-out after completion of validation

If your RMP was incompletely validated when registered (i.e. if you had developed a validation protocol), it would've included a condition requiring validation to be completed. After you have completed your validation you must forward the evaluation report along with any other required documents as evidence to MPI Approvals at approvals@mpi.govt.nz. MPI will then assess the documentation and notify you in writing of the outcome of the assessment and any changes to your RMP conditions (see section 6.3 of this manual).

7.5 Registration of significant amendments

Where you make a significant amendment to your RMP, under section 25 of the APA you must apply for registration of the amendment with MPI Approvals at approvals@mpi.govt.nz using form AP6: Registration of Amendment to Risk Management Programme [AP Reg 29]. This must be accompanied by:

a) the entire RMP with the changes clearly identified; or
b) the "required parts" of the RMP (see section 7.1.1 of this manual) with the changes clearly identified; and
c) the evaluation report (no more than 6 months old), unless this requirement is waived under APA s 20, AP Reg 29(3)); and
d) a validation protocol, if validation information under AP Reg 34(1) is necessary and is not available before the application for registration.

The process for registering a significant amendment is the same as for initial registration of the RMP. Refer to 8.4.1 Significant Amendments to your RMP for more information. For an explanation of what is a significant amendment refer to AP Reg 30 and Appendix G: Guidance on Difference between Significant and Minor Amendments.

7.6 Change of registration details

(Section 16, 24 and 25 of the APA)

You must notify MPI Approvals at approvals@mpi.govt.nz of any of the following changes to your RMP [AP Reg 37].

7.6.1 Change in operator or operator name only

Registration of an RMP may not be transferred to a different operator. Where a change in "operator" or "operator name" is the only change to your registered RMP, 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: 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 Approvals at approvals@mpi.govt.nz of this change using the AP50: Minor Update to Risk Management Programme Details application form [AP Reg 37]. This is not a significant amendment to your RMP.

7.6.3 Change in recognised agency

You must notify MPI Approvals at approvals@mpi.govt.nz as soon as possible of a change in your 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. For a multi-

business risk management programme, the operator of the programme must also provide the following information:

a) evidence in writing that the operator will have sufficient control, authority, and accountability for all matters covered by the programme in relation to the businesses; and
b) evidence in writing that the operator has obtained the consent or otherwise taken into account the views of any person whose business is to be covered by the programme [AP Reg 28].

MPI must be satisfied that the requirements in Section 17A of the APA has been met before the RMP is registered.

8 Operating your RMP

This section summaries your 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.

8.1 RMP operators' duties

You have the following duties as an RMP operator:

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 notices under the APA;
c) to adequately implement and resource all operations under your RMP, including providing 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 for your operation's throughout and to deliver product that is fit for intended purpose; and
e) to give the 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 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 the Act, Regulations or Notices

Where there is any conflict between your registered RMP and requirements under the APA, the requirements under the APA prevail [APA 30].

8.3 Verification by recognised verifier

The verification requirements for RMPs are in part 4 of the AP regulations. These requirements are expanded on in the Animal Products Notice: Production, Supply and Processing in Chapter M, and include the verification frequencies.

The frequency at which your RMP will be verified will depend on your level of compliance with your registered RMP and, if exporting, any applicable export requirements. If your operation complies with your 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 your business is exporting and your product requires official assurances. Please refer to clauses M1.3 and M1.5 of the PSP Notice for additional information on the verification steps that may apply to different official assurance export business(es) and moving up or down verification steps.

8.4 Amendments to the RMP

You must amend your RMP and apply for registration where any change, event, or other matter means that it [APA 25]:

a) 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 as required under section 17 of APA.

If you amend your RMP for any reason, the amendment will be classified as significant or minor. AP Reg 30 specifies the kinds of amendments that require registration as a significant amendment under section 25 of the APA. To determine if an amendment is significant or minor, MPI has provided some guidance in Appendix G: Guidance on the Difference between Significant and Minor Amendments.

You may also consult your verifier, an evaluator or a technical expert for advice. Additionally, 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.

Transitional arrangements

Until 1 November 2023, an amendment made to an RMP registered before 1 July 2022 solely to meet the requirements of the new animal product regulations and notices are considered minor amendments and don't need to be registered with MPI [AP Reg Schedule 1(2)].

8.4.1 Significant amendments to your RMP

(Section 25 of the APA)

A significant amendment to your RMP will need to be evaluated by an evaluator prior to being registered with MPI (unless the requirement for evaluation is waived). The evaluation is to make sure the changes to the amended RMP still meets regulatory requirements and will produce animal material and animal product that is fit for its intended purpose.

If the significant amendment needs to be validated, this can be done either before or after registration of the amendment. As is the case when initially registering your RMP, will require a validation protocol if this is to occur after registration.

For a significant amendment, your application will need to include the information in section 7.5 of this manual.

You must apply for registration of the significant amendment as soon as practicable [APA 25(2)]. If you do not comply with registration requirements when you significantly amend 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. For a minor amendment, you will need to document and keep the following evidence on file:

- a description of the change;
- written justification detailing why the change is not considered a significant amendment; and
- if you have sought advice from a recognised evaluator, verifier, technical expert or MPI to determine the amendment as minor.

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 a number of minor amendments, it may be considered a significant amendment if 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 verifier as part of their verification.

8.4.3 Notifications to MPI

[APA 26]

To ensure the registration details shown on the RMP public register are up-to-date and accurate, some changes should be notified to MPI. Notify MPI Approvals at approvals@mpi.govt.nz of the changes using the AP50: Minor Update to Risk Management Programme Details application form. See the form for details on which changes can be notified. Make sure you attach any relevant documentation to assist with the amendment.

9 Ceasing operations or 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 are still operating.

You will need to give consideration to the control and disposition of any remaining animal material and animal product that may be in your possession on removal of your registration.

9.1 Surrender of registration

If you decide to surrender your 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 Approvals at approvals@mpi.govt.nz in writing (the AP50: Minor Update to Risk Management Programme Details form may be used for this), and include how any remaining animal materials or animal products covered by the RMP will be dealt with;
b) surrender the notice of registration to MPI Approvals at approvals@mpi.govt.nz; and
c) notify your recognised verifying agency [APA 29(2)].

When you notify MPI of a surrender and include how you intend to deal with any remaining animal material or animal product covered by the RMP and MPI will either:

a) approve or agree to the proposal; or
b) direct you to take appropriate actions to deal with any affected animal material or animal 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 32] when a surrender involves a secondary processor who has elected to operate under an RMP rather than under the Food Act, if necessary.

9.2 Suspension of operations

(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 will 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:

a) the reason for the suspension;
b) the period of the suspension;
c) the date and time of commencement of the suspension (which may not be earlier than the date and time of notification);
d) the operations to which the suspension applies; and
e) 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 162].

MPI may direct you to take appropriate action to deal with any affected animal material or animal 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 82].

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, 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 Approvals at approvals@mpi.govt.nz of the suspension using AP50: Minor Update to Risk Management Programme Details application form.

a) An operator who suspends operations under subsection 4A of APA 27 must give the Director-General a notice in writing stating — the date on which the suspension starts, which must be a date after the date of the notice; and
b) the date on which the suspension ends; and
c) which operations are suspended; and
d) how the operator intends to deal with any affected animal material or product [APA 27(4)B].

Businesses that process animal products, and who choose to temporarily cease operations, are still subject to PSP Notice M1.7. This requires that the RMP may still undergo verification with the limited verification scope to cover the activities that continue (e.g. storing of animal products) and the verifier may apply a higher verification step. It is expected that the operator should advise the verifier or verifying agency before resuming other processing activities.

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 prior to restarting.

MPI will notify the verifying agency of any suspension of an RMP [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. Notification of deregistration or removal will also be given to your 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 [APA 162].

MPI may direct you to take appropriate action to deal with any affected animal material or animal 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 82].

10 Principally dairy determination for multi-ingredient food

If you manufacture, process, or sell products that contain dairy, MPI has developed guidance: Procedure for Principally Dairy Determinations to help you determine whether a multi-ingredient food is considered to be a dairy product under New Zealand Standards. This includes products such as tablets, supplements, and fortified foods that contain dairy ingredients. This guidance is provided to help manufacturers to make the determination.

MPI encourages operators to do their own determinations, or discuss this with their verifier.

If clarification is required (e.g. for difficult situations or when an operator and verifier disagree), MPI can be contacted for a principally dairy determination by completing the Principally Dairy Determination Form and submitting it to MPI by emailing Animal.Products@mpi.govt.nz, making sure you have included the formulation, product name, list of ingredients and label. Mock-up or proposed artwork is accepted if the product is still in the development phase. Any additional proposed marketing material is also helpful, or links to websites with information about the product.

Appendix A: 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 B: Businesses Not Requiring RMPs) if one of the following applies to you [APA 13]:

- primary processors of animal material;
- secondary processors of animal products, except to the extent that they are subject to the Food Act;
- retail butchers who are dual operator butchers; or
- other persons specified by Order in Council under section 15 of the APA;
- producers of chicken as specified by AP Reg 40A as per the AP Reg amendment 2022.

A.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 in italics).

***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 a) and b); or
iii) any other animal, or animal material derived from any other animal -

processes those animals or that animal material to the extent specified by the Minister by notice (see subsection (4) after consultation in accordance with section 163 and after having regard to the following matters;

iv) industry practice in relation to the animal material concerned;
v) the degree of processing and number of processing operations required in relation to the animal material;
vi) the risk factors involved in processing the animal material;
vii) whether or not the processing of the animal material is or may be appropriately addressed by any legislative regime other than this Act;
viii) 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 goes for retail sale or export.

***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 -

i) persons (such as airline or shipping staff or stevedores) handling dairy material at the port of export:
ii) Wholesalers of other persons (other than retailers) handling dairy material at the place of sale for consumption or use: or
iii) retailers doing any or all of the following at the place of sale for consumption or use:

A) handling dairy material:
B) dividing or combing dairy material into smaller or larger quantities: or
C) repackaging dairy material

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:

a) 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;
b) a person who removes or extracts or harvests or undertakes drying, slicing, grinding or preserving of deer velvet;
c) 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; or
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

d) 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;

[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).

iv) deheading, gutting, scaling, and tubing; or
v) packing, transport, and storage.

A.2 Secondary processors of animal products

(Sections 13 and 32 of the APA)

All secondary processors of animal products intended for human consumption must have an RMP, unless they operate under the Food Act.

Some secondary processors of animal products intended for animal consumption may be exempt from RMP requirements if they meet certain conditions. More information on this can be found here.

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

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

A.3 Dual Operator Butchers

(Section 71 of the APA)

Dual operator butchers (DOBs) are butchers who deal with both homekill (unregulated meat not for trade) and retail meat (regulated meat) at the same premises or place. They must have an RMP covering processing of their regulated product and describe how they will ensure a clear separation between processing and of the product itself between homekill and regulated meat. There are also additional requirements for them to meet (see 4.17 Additional Requirements in Relation to Homekill and Recreational Catch for Dual Operator Butchers).

A.4 Specific requirement to operate under an RMP

The following processing must be carried out under an RMP [AP Reg 39 & 40]:

a) rendering[9] and blood-drying operations in relation to mammal and bird material or product that is not intended for human consumption;
b) 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] "rendering" means the breaking down of animal tissues into constituent fat and protein elements, whether by the application of heat and pressure or otherwise [APA 4(1)]
[10] Technical grade dairy product means dairy product for sale or export that is not intended for human or animal consumption [AP Reg 40(2)].

Appendix B: Businesses not requiring RMPs

(Section 13 of the APA)

The following persons are not required to have RMPs:

a) certain exemptions for operators from requirements to have registered RMP in respect of the operations specified in Schedules 2 and 3 of the AP Reg, some of which are mentioned below.

B.1 General and product specific inclusions and exemptions

The following persons are not required to have an RMP. Some operators will instead need to operate under a risk-based measure under the Food Act regime. These have been marked * in the list below:

a) those operating fishing boats where the fish is not landed in New Zealand nor claimed to be a product of New Zealand [AP Reg 262];
b) those whose products are covered by the Medicines Act 1981 (except where required for official assurances) under the conditions as outlined in AP Reg 258;
c) those who process certain dairy products that are consumed on the premises* [AP Reg schedule 2, section 15];
d) 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 (see Section 10: Principally Dairy determination for multi-ingredient food), ice cream, or where required for official assurances [AP Reg schedule 2, section 16];
e) those who are primary processing animal material for purposes other than human or animal consumption (but excluding technical grade dairy products requiring official assurances), e.g. skinning and shearing [AP Reg Schedule 3, section 2];
f) those who process dairy material for the New Zealand or Australian market only* and elect to operate under a Food Act risk-based measure but excluding farm dairy operators [AP Reg schedule 2, section 12];
g) those who transport dairy material or dairy product for export without official assurance or for the New Zealand market* (Food Act risk-based measure such as NP1 applies for transport of food for human consumption) [AP Reg schedule 2, section 12] ;
h) those who manufacture or store dairy material for animal consumption for the domestic market, if no other operations at the same premises require an RMP [AP Reg schedule 2, section 13];
i) registered RCS farm dairy operators who produce and process RCS raw milk (raw drinking milk) [AP Reg schedule 2, section 14];
j) a registered RCS depot operator who stores RCS raw milk (raw drinking milk) on behalf of farm dairy operators [AP Reg schedule 2, section 14];
k) a transport operator who transports RCS raw milk on behalf of farm dairy operators [AP Reg schedule 2, section 14];
l) those processing animal food in accordance with the Food Act, e.g. raw meat suitable for human consumption is sold by a supermarket delicatessen as petfood* [AP Reg schedule 3, section 1];
m) those who transport animal material or animal product (other than dairy material or dairy product) for animal consumption for export without official assurances or for the domestic market. [AP Reg schedule 3, section 5];
n) those who have fish on a retail premises and fish is sold by retail or a combination of retail and wholesale, where no fish from those premises are exported* [AP Reg schedule 2, section 2];
o) those who operate temporary holding and storage places for fish [AP Reg schedule 2, section 4];
p) those who operate limited processing on registered limited processing fishing vessels [AP Reg schedule 2, section 5];
q) those who process only fish bait, fish berley, chum or ground bait [AP Reg schedule 2, section 6];
r) those who operate certain tourists or charter fishing vessel and fishing guides [AP Reg schedule 2, section 3];

s) those who harvest and provide limited processing of whitebait, sells for consumption or processing [AP Reg schedule 2, section 7];
t) muttonbird primary processors [AP Reg schedule 2, section 9];
u) certain primary processors of eggs (those with 100 or less female birds and who sell directly to the consumer – not through a third party) [AP Reg schedule 2, section 1];
v) airline holding facilities operators [AP Reg schedule 3, section 3];
w) those who harvest, collect, store, grade or transport raw deer velvet [AP Reg schedule 2, section 10];
x) apiarists who harvest, store and transport bee material or product [AP Reg schedule 2, section 11];
y) taxidermists (so long as no part of the animal is traded for human or animal consumption – except to rendering operations under an RMP, and homekill and recreational catch services are not carried out on the same premises) [AP Reg schedule 3, section 4];
z) primary processing of fish, other than BMS, that are caught at fishing competitions and sold by auction, for cultural, benevolent, philanthropic, or charitable purposes if they comply with certain conditions as outlined in AP Reg schedule 2, section 8; and
aa) further petfood processing i.e. secondary processing of animal material or animal product intended for cats or dogs under certain conditions as outlined in AP Reg schedule 2, section 17.

B.2 Exemptions from RMPs

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

Appendix C: Examples of limits

For guidance purposes only, some examples of limits are given below. You should also check the current edition of the documents or references (mentioned here) as they are amended from time to time.

Table 17: Example of limits for products for human consumption

Product	Regulatory Limits		Operator-defined Limits	Controls
	Notice	Food Standards Code		
RAW, NOT FURTHER PROCESSED				
Raw red meat and offal	Limits are set out in Part 3 of the NMD Notice	----	Operator may define microbiological and defect levels	GOP
Poultry	*Salmonella* Performance Target, *Campylobacter* Performance Target and Prevalence Performance Target for *Campylobacter* (limits in NMD Notice)	----	Operator may define microbiological and defect levels	GOP
Mechanically separated meat (MSM) - red meat and poultry	----	----	Operator must define microbiological limits for aerobic plate count and *E. coli* [PSP Notice L2.3(6)]	GOP
Wetfish	----	Histamine level ≤ 200 mg/kg	Operator must establish a requirement for viable parasites to be absent, if it known that fish is to be eaten raw	GOP
Bivalve molluscan shellfish for consumption in raw state other than scallops	*E. coli/g:* n=5 c=1 m=2.3 M=7 [PSP Notice H3.5]	*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 25 g SPC: n=5 c=2 m=5x10^5 /g M=5x10^6 /g	Operator should establish limit for marine biotoxins if likely to be harvested from contaminated waters	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 25 g	If heat treated operator may 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=10^2 cfu/g	----	
Casings	Water activity ≤ 0.83 [PSP Notice F3.36]	Sulphur dioxide and sodium and potassium sulphites ≤ 500 mg/kg	----	GOP
Sausage and sausage meat containing raw, unprocessed meat	----	Sulphur dioxide and sodium and potassium sulphites ≤ 500 mg/kg Ethyl lauroyl arginate ≤ 315 mg/kg	----	GOP
Processed 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
Packaged cooked cured/salted meat	----	*Coagulase Positive Staphylococci*/g: n=5 c=1 m=10^2 /g M=10^3 /g *Salmonella*: n=5 c=0 m=not detected in 25 g	----	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

Product	Regulatory Limits		Operator-defined Limits	Controls
	Specifications	**Food Standards Code**		
FURTHER PROCESSED				
Packaged heat-treated meat paste and paté	----	*Salmonella*/g: n=5 c=0 m=not detected in 25 g		CCP – Cooking
	----	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[11]	----	*Coagulase Positive Staphylococci*/g: n=5 c=1 m=10^3 M=10^4 *E. coli*/g: n=5 c=1 m=3.6/g M=9.2/g *Salmonella*/g: n=5 c=0 m=0/25 g	Operator must define pH and water activity.	CCP – fermentation, maturation
	----	Sorbic acid and sodium, potassium and calcium sorbates ≤ 1500mg/kg Primaricin (natamycin) ≤ 1.2 mg/dm^2 Nitrite ≤ 500 mg/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

[11] For more information on uncooked comminuted fermented meats (UCFM) please refer to the UCFM Standard.

Product	Regulatory Limits		Operator-defined Limits	Controls
	Specifications	**Food Standards Code**		
FURTHER PROCESSED				
Dried meat & poultry (e.g. jerky; freeze dried meat, etc.)	----	----	Operator should define microbiological levels (e.g. *Salmonella, Staphylococcus,* STEC), 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 ≤ 1500 mg/kg)	----	GOP if curing mix used. May be a CCP when nitrite added on its own
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 25 g SPC/g: n=5 c=2 m=10^5 M=10^6	Operator must define lethality	CCP – cooking
Ready-to-eat processed finfish other than retorted (e.g. smoked fish, vacuum packaged cooked fish, manufactured fish products, etc.)		Histamine level ≤ 200 mg/kg	----	GOP
Dried shelf stable fish	----	----	Operator should define water activity and/or moisture content	GOP
Fish or fish products with pH<4.4 (e.g. marinated mussels, etc.)	----	----	Operator should define pH<4.4	CCP – acidification
Processed egg product	----	*Salmonella*/g*:* n=5 c=0 m=not detected in 25 g (***processed***, in relation to egg product, for the purposes of Schedule 27 of FSC, means pasteurised or subjected to an equivalent treatment)	----	CCP – pasteurisation

Product	Regulatory Limits		Operator-defined Limits	Controls
	Specifications	Food Standards Code		
FURTHER PROCESSED				
Low-acid canned foods	----	----	Commercially sterile by application of a 12D thermal process for *C. botulinum*	CCP – retorting
	----	Specified additive level (e.g. nitrites ≤ 50 mg/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 ≤ 0.7 mg/kg	----	

Table 18: 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
Rendered products	Does not contain biological hazards (such as vegetative bacteria, viruses, protozoa) or chemical substances at levels potentially harmful to animals that will consume the product [PSP Notice L2.2]	----	CCP – rendering or drying GOP post-CCP
	----	Operator should define moisture content	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 19: Examples of limits for dairy material and dairy products for human consumption

Further detail on dairy limits can be found in PSP Notice D1.3 - D1.7 and the Food Standards Code. You should also check any other Notices and OMARs that may be relevant to your product and situation.

Product	Regulatory Limits			Operator-defined Limits	Control
All dairy products for human consumption	Dairy product must not exceed the following Microbiological 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 5x25g	ND 250g ND 60x25g (infant formula products and foods for special medical purposes)		
	L. monocytogenes	ND 5x25g 100 cfu/g (applies only to ready-to-eat dairy product in which growth of L. monocytogenes will not occur)[12]	ND 5x25g ND 10x25g (infant formula products and foods for special medical purposes)		
	Coag. Pos. *Staphylococci*	1000 cfu/g	100 cfu/g 10 cfu/g (infant formula products)		
	B. cereus	1000 cfu/g	100 cfu/g		
	E. coli	100 cfu/g	10 cfu/g		
	Cronobacter spp.	NA	ND 30x10g IF(infant formula) 0-6 months		
	Dairy material and dairy product must not contain chemical residues and contaminants exceeding the limits specified in the PSP Notice D1.4.				GOP

[12] as defined by the Food Standards Code, Standard 1.6.1 clause 4

Product	Regulatory Limits			Operator-defined Limits	Control
		Nitrate (mg/kg)	**Nitrite** (mg/kg)		
	Powdered formula for infants and young children up to 36 months (excluding dairy ingredients)	50	5		
	Milk powders (including ingredients for dairy product intended for infants and young children but excluding buttermilk powder) - General population	150	5		
	Protein Products (including dairy ingredients) – General population	150	15		
	Buttermilk powder	150	20		
All dairy products	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 must not contain any residues exceeding the limits specified in the Food Notice: Maximum Residue Levels for Agricultural Compounds			Operator may define additional residue limits	GAP on farm
	Levels of contaminants and toxins should not exceed the limits specified in the Food Standards Code (refer to Standard 1.4.1 Contaminants and Natural Toxicants) Further detail is contained in PSP Notice Chapter D				
All infant formula and follow-up infant formula for human consumption	Refer to Food Standards Code			----	

Appendix D: Procedures and processes requiring validation

Validation is the process of collecting evidence to show that your RMP is effective in producing the desired outcome. You must validate your procedures and processes when first developed, when there are significant changes to your existing processes/products or when new products/processes are introduced [AP Reg 34].

The following tables provides guidance 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 validation.

Table 20: Supporting system

Procedures/operation	Unlikely to require validation	Likely to require validation	Comments
Design and construction of premises, facilities, equipment	✓		
Untreated water - town 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	✓		Evidence to show that PSP Notice C1.27 is met.
Receipt, handling, storage of additives, processing aids, etc.	✓		
Cleaning of facilities and equipment (normal circumstances)	✓		Evidence to show that cleaning and sanitation is effective. May be achieved through ongoing monitoring and verification.
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. Evidence maybe needed e.g. management of *Listeria monocytogenes* if processing certain RTE products.
Cleaning (post-CCP areas for ready-to-eat products)		✓	
Waste management	✓		
Control of chemicals	✓		
Health of personnel	✓		
Pest control	✓		May be achieved through ongoing

Procedures/operation	Unlikely to require validation	Likely to require validation	Comments
			monitoring and verification.
Repairs and maintenance of facilities and equipment	✓		
Calibration of equipment and measuring devices	✓		Evidence to show that calibration under PSP Notice C1.10 is met.
Packaging (composition, use, handling)	✓		Evidence that packaging is suitable [AP Reg 68, PSP Notice C3.5].
Labelling	✓		

Table 21: Supply of Animal Material

Procedures/operation	Unlikely to require validation	Likely to require validation	Comments
Supply of animals (eligibility, locations, supplier declarations, 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 22: 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 declarations)	✓		
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 cooler than 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 specified in FSC but it is not expected to be measured routinely, but periodic verification likely. Effectiveness also demonstrated by compliance to established procedures.
Chilling and freezing to preservation temperature	✓		
Capability of freezers and chillers	✓		
Bivalve Molluscan Shellfish			
Reception	✓		
Wet storage and depuration		✓	Refer to PSP Notice Part H3 subparts 2 and 3
Shucking	✓		
Heat shocking if used for pathogen inactivation (e.g. *L. monocytogenes, Vibrio* spp.)		✓	Refer to PSP Notice, H3.8
Chilling and freezing to preservation temperature	✓		

Procedures/operation	Unlikely to require validation	Likely to require validation	Comments
Capability of freezers and chillers	✓		
Eggs			
Whole Flock Health Scheme	✓		
Reception of birds	✓		
Pulping		✓	
Pasteurisation		✓	
Bird management	✓		
Harvesting and handling of eggs	✓		
Washing of eggs	✓		Needed if criteria in MPI approved RMP Template for Harvesting, Candling, or Packing Eggs is not followed
Candling and packing	✓		
Storage	✓		

Table 23: Secondary processing

Procedures/Operation	Unlikely to require validation	Likely to require validation	Comments
General			
Cleaning, sorting, grading of materials	✓		
Cutting, boning, size reduction, mechanical separation	✓		Mechanical separation may require validation
Thawing/tempering of meat and poultry	✓		Validation required if COP not used
Mixing	✓		
Honey and bee products			
Reception	✓		
Handling, processing, packing	✓		Validation of blending equipment used to reduce tutin levels likely to be needed
Storage	✓		
Handling material that may introduce allergens		✓	Will need to show how the allergens will be controlled

Procedures/Operation	Unlikely to require validation	Likely to require validation	Comments
Thermal processing			
Commercial sterilisation (aseptic, in container retorting)		✓	
Pasteurisation and thermisation		✓	
Cooling of thermally processed product		✓	Cooling is not critical for small products that cool rapidly (e.g. cooked frankfurters). Validation may not be necessary for such products.
Heat processing other than sterilisation, thermisation 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 validation but time in danger zone to be managed.
Drying		✓	
Smoking			
Hot smoking		✓	
Cold smoking of ready-to-eat products		✓	
Cold smoking of products that require further cooking by the consumer	✓		Smoking for flavour only does not require validation but time in danger zone to be managed.
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		✓	
Addition of acid for flavour only	✓		
Fermentation		✓	
High pressure processing		✓	
Extraction, expression	✓		

Procedures/Operation	Unlikely to require validation	Likely to require validation	Comments
Evaporation, concentration for preservation		✓	
Rendering			
Rendering		✓	Achievement of 90°C for 10 minutes must be validated for medium risk material
Drying		✓	
Refining of fats and oils		✓	
Packing	✓		May require validation if necessary for food preservation, e.g. seal integrity, MAP
Storage			
Refrigerated storage (cold store)	✓		
Dry storage	✓		
Transport			
Meat and meat products above 7°C		✓	
Meat and meat products at or cooler than 7°C	✓		
Other products (non-refrigerated)	✓		
Other product specific processors			
Cleaning and processing of green offal and runners	✓		
Salting of casings	✓		

Appendix E: Validation examples

Further examples of validation can be found in the Codex Guidelines for the Validation of Food Safety Control Measures (CAC/GL69-2008).

E.1 Biological hazards

Example 1: Limit for a biological hazard (e.g. absence of *Listeria monocytogenes* in 25 g 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 any 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:

a) OCs, COPs, Guidance Documents (e.g. Further Processing, etc.); and
b) 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 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.

E.2 Chemical hazards

Example 2: Limit for a chemical hazard (e.g. 10 mg/kg sulphite in dried apricots, 125 µg/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.

E.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 ready-to-eat product where there is no limit in the legislation, etc.

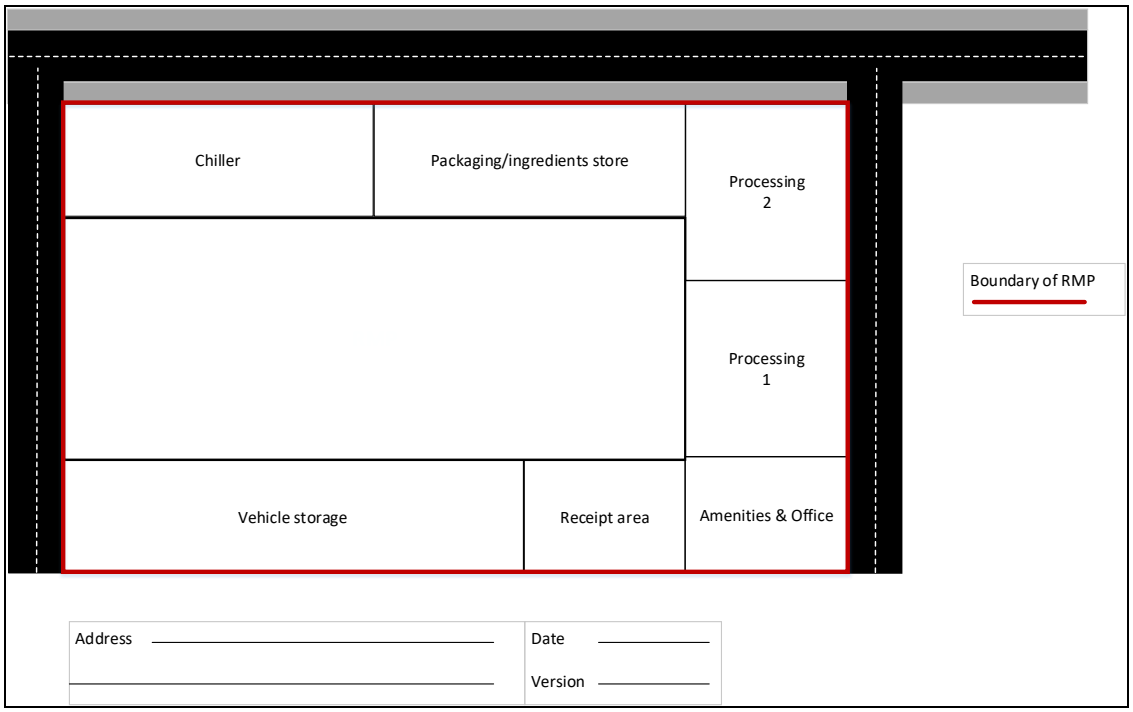
You must document the basis for selection of an operator-defined limit, including:

- 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.

Appendix F: Example of an RMP site plan

Figure 5 is an example of a site plan showing how the RMP boundary can be displayed. 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, etc. The site plan should include the name, address, the version (dated) and the boundary.

Figure 5: Example site plan



Appendix G: Guidance on the difference between significant and minor amendments

For guidance purposes only, this section provides some examples on the difference between significant and minor amendments. This guide cannot cover every possible scenario and may not be representative of every situation. Each amendment will need to be considered on a case by case basis.

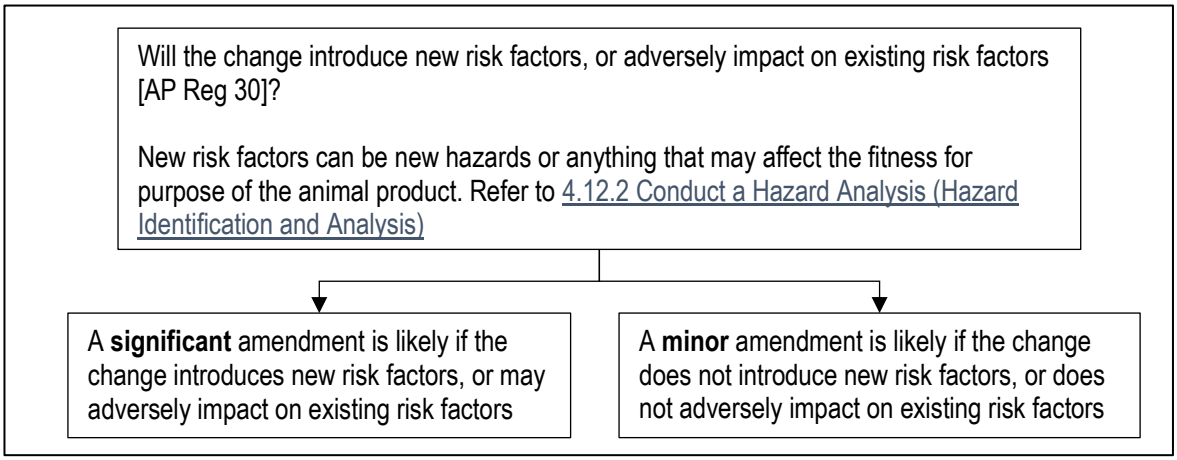
It is your responsibility to document the justification to determine whether an amendment is significant or minor.

If clarification is required (e.g. for difficult or unclear situations), it is recommended you discuss with your verifier or a suitably qualified technical expert. If you require assistance from MPI Approvals approvals@mpi.govt.nz to make a determination, ensure you include the documented justification and any verifier/expert support with your request.

Determining whether an amendment is significant or minor

Regulation 30 of AP Reg has a list of what is considered a significant amendment to the RMP. To help you determine if an amendment is significant or minor, you can use the following guiding principles:

Figure 6: Guiding principles to determine between a significant or minor amendment to your RMP



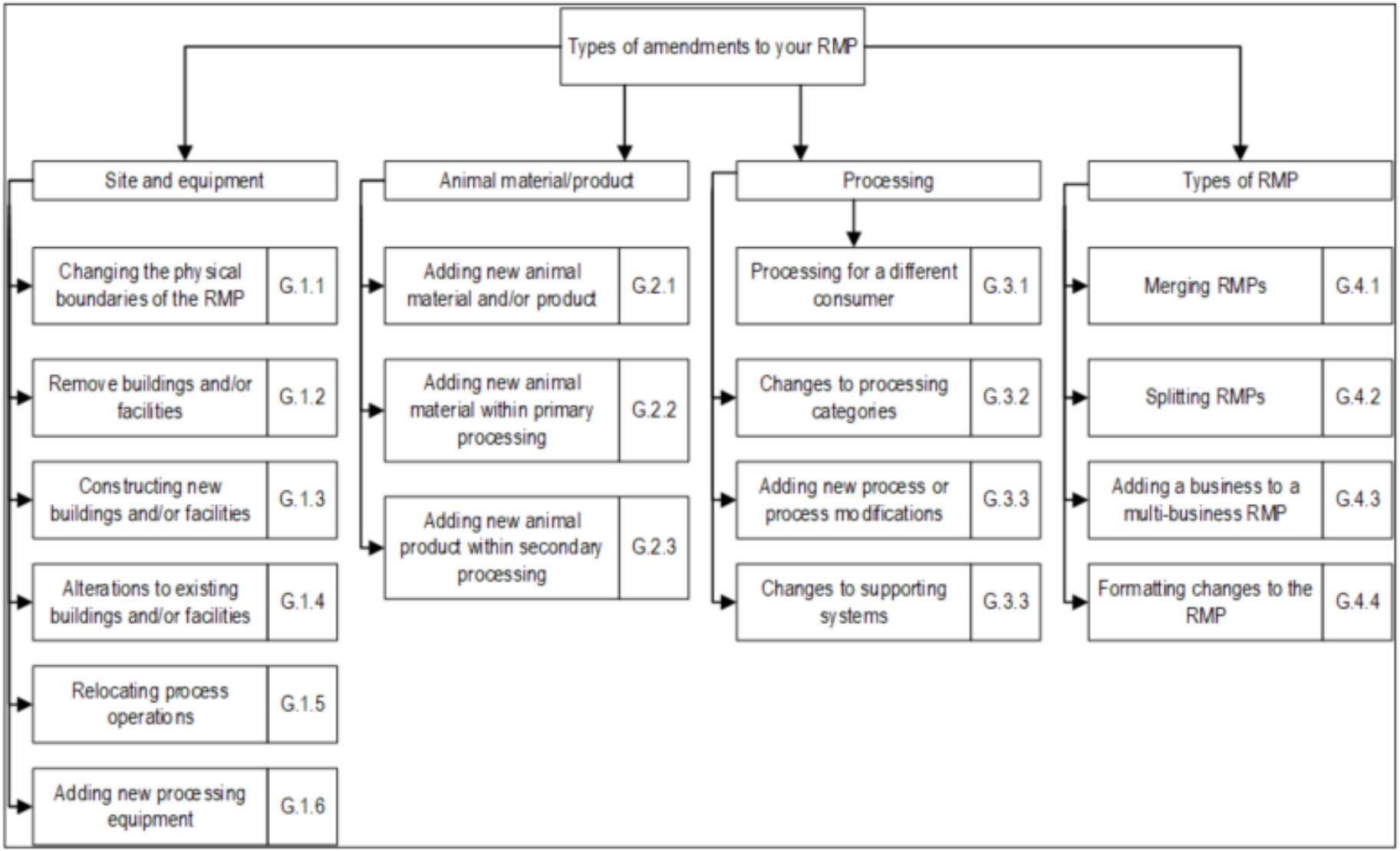
To assist with the guiding principle above, you should consider the following questions:

- will the change introduce new biological, chemical or physical hazards? Do they need to be controlled?
- will the change affect an existing CCP? If yes, how will this be managed?
- will the change mean hazards may be present at a higher concentration such that the current controls are no longer effective?
- will the change result in changes to existing processes, procedures or documented systems? These will need to be updated and communicated to the staff;
- do you need to re-validate your process? If yes, do you have a validation protocol?
- will the product be affected by exposure to the new hazards (e.g. is it exposed, or enclosed in packaging)?

You should refer to 8.4 Amendments to the RMP on the procedures to following when making a change to your RMP and the information that should be documented. Sections 8.4.1 Significant Amendment to your RMP and 8.4.2 Minor Amendment to RMPs goes into detail on what sort of information to include to support the significant and minor amendments respectively.

Use Figure 6: Breakdown of the Type of Amendments and Corresponding Section of Appendix G to determine which section of Appendix G you should read for the type of amendment you want to make. Each section gives examples of significant and minor amendments.

Figure 7: Breakdown of the types of amendments and the corresponding section of Appendix G



G.1.1 Changing 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.

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

Examples of Typical Significant Amendments	Examples of Typical Minor Amendments
Increasing the RMP boundary to include a new processing premises	Decreasing the RMP boundary to remove a disused or redundant part of the factory
	Increasing the RMP boundary to include a container load-out area

G.1.2 Removal of buildings and/or facilities

When deciding whether removal of buildings/facilities is a significant or minor amendment, you should consider:

- what consequential changes are needed as a result of removing the buildings and/or facilities?
- if as a consequence, processes are moved to other existing facilities, are any new hazards or other risk factors introduced as a result of altered process flows, new environmental conditions, etc.?

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

G.1.3 Construction of new buildings and/or 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, operations or essential services (e.g. water, electricity, etc.); and
- any change to the physical boundaries of the RMP.

Examples of Typical Significant Amendments	Examples of Typical 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	Inclusion of an additional raw milk silo
Construction on a new site	Construction of additional dry storage where the RMP covers dry storage and there are existing dry storage facilities

G.1.4 Alterations to existing buildings and/or facilities

When deciding whether alterations to existing buildings/facilities is a significant or minor amendment, you 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, etc.;
- whether the alterations will change the use of the existing facilities, room or area; and
- whether the change impacts on the effectiveness of a CCP.

Examples of Typical Significant Amendments	**Examples of Typical Minor Amendments**
Changes that can alter the processing environment and impact on ability to control temperature and/or humidity, so new hazards are introduced or existing hazards not controlled to same extent. For example: major changes to the temperature and humidity for packing rooms used for dry powder packing	Small changes in temperature or humidity that do not introduce new hazards
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; • equipment changes to bag sealing; • changing slaughter methods to halal; • alterations to shelf-stable ingredients storage; • alterations to animal holding facilities; or • changes to essential services where this does not introduce new hazards or impact on the ability to control existing hazards
Changing the use of a room from a lower hygiene standard to a higher hygiene standard, e.g. support facility to a process room, petfood to human consumption, raw to cooked, or becoming part of a critical hygiene area	Construction in non-processing areas such as amenities, support facilities and engineering facilities, but not to change them to a higher standard of use
Any changes to dairy heat treatment equipment and processes	Removal of a storage silo
	Altering floor layouts in standard hygiene areas
	Addition of a separate retail shop selling honey within the physical boundaries of an RMP processing honey

G.1.5 Relocating process operations

Relocating process operations to a new physical address (except where this is already permitted for mobile premises and vessels) is a significant amendment [AP Reg 30].

G.1.6 Adding new processing equipment

When deciding whether new processing equipment is a significant or minor amendment, you should consider:

- 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 Typical Significant Amendments	Examples of Typical 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 listericidal 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, e.g. cheese curd cutting machine Note: Addition of blenders for dry dairy products 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	A new type of egg washing system (parameters would be subject to any necessary validation)
A new retort that is a different make and model to any existing retorts covered by the existing RMP	A new retort that is the same make and model as an existing retort covered by the existing RMP (would still be subject to validation by the qualified canner)
Any change to dairy defined heat treatment equipment	
Major changes to rendering equipment, e.g. changing from batch well cookers to continuous low temperature cookers, etc.	A new jet coder being installed on an existing packing line

G.2.1 Adding new animal material or animal product

Processing animal material or animal product that is not covered by the existing 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 [AP Reg 30].

Examples of Typical Significant Amendments	Examples of Typical Minor Amendments
Processing of a new dairy material not currently covered by the RMP where new hazards are introduced	Processing of a new dairy material not currently covered by the RMP, where the dairy material and product are similar and the process is the same, and no new hazards are introduced.
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.

Examples of Typical Significant Amendments	Examples of Typical Minor Amendments
	addition of blending whey powders to an RMP covering blending of milk powders.
Addition of raw milk processing of a different species to an existing RMP, e.g. addition of goat, sheep or deer milk to existing RMP only covering cow milk, etc.	
Addition of dairy heat treatment of a different species to an existing RMP, e.g. sheep milk to existing RMP of heat treatment of caprine milk	
Reducing testing frequencies or relaxing a test limit	Increasing testing frequencies or tightening a test limit

G.2.2 Adding new animal material within primary processing (non-dairy only)

Primary processing of a new animal material not currently covered by the RMP is usually considered a significant amendment. Where an amendment is not significant, you can notify MPI Approvals at approvals@mpi.govt.nz of some minor amendments so that accurate registration information can be maintained.

Column 1	Column 2	Column 3
Animal Material	**Significant Amendment**	**Minor Amendment and Notification to MPI**
• Ostriches/emus • Alpacas/llamas • Bobby calves • Buffaloes/bison/cattle hybrids • Cattle • Chamois • Deer • Horses/other equines • Pigs • Possums • Rabbits/hares • Sheep/goats • Thar • Wallabies	Changing between animal materials bulleted in column 1 (case by case basis for wild animals) Changing from farmed to non-farmed (e.g. wild/game estate/farmed gone feral, etc.) and vice versa	Changing between sheep and goats Changing between non-farmed types (i.e. from wild to game estate or to farmed gone feral or vice versa) Addition of a wild deer when the RMP already processes farmed deer and other wild mammals
• Fish other than Bivalve molluscan shellfish (BMS) (i.e. finfish, non BMS shellfish, crustaceans) • Bivalve molluscan shellfish (BMS)	Changing between animal materials bulleted in column 1 except as listed in column 3	Changing within a bullet in column 1 Adding live BMS processing if already covers fish, but not if wet storing or depurating the live BMS Changing from farmed to non-farmed species and vice versa Adding paua or kina if already covers BMS

Column 1	Column 2	Column 3
Animal Material	**Significant Amendment**	**Minor Amendment and Notification to MPI**
• Chickens/ poussin/ fowl/ ducks/ geese/ pheasants/ quail/ guinea fowl • Turkey • Layer hens	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 within a bullet in column 1
• Table eggs		Changing between farm methods (e.g. caged, barn, free range, etc.) for harvesting if using the RMP Template for Harvesting, Candling, or Packing Eggs. Change of bird type e.g. chicken to duck, etc.
• Deer velvet	N/A	N/A

G.2.3 Adding new animal product within secondary processing (non-dairy only)

Some new animal products can 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 Approvals at approvals@mpi.govt.nz can be 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 should 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 can be notified to MPI Approvals at approvals@mpi.govt.nz

Where the amendment would be considered significant under any process category 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 animal 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 Approvals at approvals@mpi.govt.nz

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.3.1 Processing for a different consumer

Your written justification should consider:

- the intended consumer currently covered by your RMP; and
- if changing from general consumers to specific at-risk groups, does your RMP ensure that product is fit for this new intended purpose, e.g. for infants, elderly, pregnant women or immuno-compromised people.

Examples of Typical Significant Amendments	Examples of Typical Minor Amendments
Where the RMP only covers processing for animal consumption and the operator wants to start processing for human consumption	If all product is produced to human consumption standards according to the RMP, but the operator now wants to divert to animal consumption e.g. petfood Note: that risks involved in production of animal feed will need to be managed in the RMP. Management of a loss stream product needs to be considered as a product output. Notify the verifier and MPI Approvals at approvals@mpi.govt.nz
Where the RMP only covers processing for consumption by the general population and the operator wants to start processing for susceptible population consumption	
	The addition of 'industrial use' or inedible products (e.g. hides and skins) to an existing registered RMP, including those that use the Stores RMP Template.

G.3.2 Changes to processing categories

Adding new categories of processing not currently covered by the RMP is almost always a significant amendment.

Refer to application form AP49: Processing Categories Tables for the complete list of primary and secondary process categories. Process categories are listed in the left hand column.

Examples of Typical Significant Amendments	Examples of Typical 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
	Addition of transport to a processing facility

G.3.3 Adding new process or process modifications

Setting up a new process or process modification that is not covered by the current 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 [AP Reg 30].

When the existing documentation does not adequately describe the new/amended process, you should consider:

- what has changed in the new process?
- have the steps that are essential for food safety altered? Can they still manage the hazards to the appropriate level?
- does the process or critical product parameters align with what is specified in a COP (refer to 3.1.1 Operational Codes and COPs)? If not, do you have the evidence to support you the parameters are appropriate for your product?

Examples of Typical Significant Amendments	Examples of Typical Minor Amendments
Making the process less effective e.g. extending storage 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	Altering a drying process but still achieving the critical product parameter for water activity
Changing from cold boning to hot boning, unless the operator is following the relevant criteria in the Operational Code: Post Slaughter Activity, Red Meat Code of Practice Chapter 9 (COP 9) Boning processes outside those covered under COP 9 are considered a significant amendment	Different thermal process where operator can demonstrate that they still meet the relevant criteria in an approved COP A new thawing/tempering process that complies with COP 9
Where processing of ready-to-eat product is to occur and the RMP does not cover this	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.

Examples of Typical Significant Amendments	Examples of Typical Minor Amendments
Addition of a CCP that requires the process to be revalidated e.g. using a new type of preservation such as drying that is not currently covered under the RMP	Tempering and thawing of cheese
Changes to a CCP or amendments to the process flow, e.g. additional fitted filters that affect flow rates to heat treatment equipment, etc.	Addition of operator defined finished product limits to the RMP
Removal of a CCP e.g. removing a pathogen kill step, changing from hot smoked mussels process, where hot smoking is a listericidal step, to cold smoking which is not a listericidal step, etc.	Changes to test pieces used for CCP (x-ray or metal detection) with increasing sensitivity
	Re-designation of a control measure as a CCP as it was incorrectly identified
Blending/additions to honey (e.g. bee venom, etc.) if the new process is not already covered by the RMP where new hazards are introduced	
New process e.g. 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
Egg shelf life extensions e.g. beyond 35 days for whole eggs for a specific export or domestic market requirement	

G.3.4 Changes to supporting systems

When deciding whether alterations to current supporting systems (cleaning and sanitation, pest control, etc.) is a significant or minor amendment, your written justification should consider:

- the extent of changes to be made to your supporting systems;
- do the changes need to be validated?; and
- the impact of the alterations on the process and operations, e.g. changes to process flow, new process steps, etc.

Examples of Typical Significant Amendments	Examples of Typical Minor Amendments
Changes to the water treatment facility that may introduce new hazards and/or affect processes that are essential for food safety	
	Change pest management contractor or cleaning contractor
Reducing swabbing points to an existing dairy environmental testing programme	Adding swabbing points to an existing environmental testing programme
	Expanding the number of microorganisms monitored for
Changes to the dairy environmental testing programme that may affect verification of the effectiveness of the *Listeria* control measures	Swapping suppliers for the same cleaning solution (e.g. like for like). Changing a brand of cleaning chemical if it is like for like

G.4.1 Merging RMPs

Merging two or more registered RMPs is a significant amendment [AP Reg 30].

G.4.2 Splitting an RMP

Splitting a registered RMP into two or more RMPs can be done via a significant amendment [AP Reg 30]; or alternatively will require a new application for the new RMP and a minor amendment application for removal of certain activities from the existing RMP.

G.4.3 Changing from a single-business to a multi-business RMP

Changing an RMP from a single-business RMP to a multi-business RMP is a significant amendment [AP Reg 30].

G.4.4 Adding a business to a multi-business RMP

Adding a business to a multi-business RMP except where the D-G's approval under section 17A of the APA applies to a type of business, premises or place, rather than to specific businesses, is a significant amendment. Adding a farm onto an existing multi-business farm dairy RMP is a minor amendment.

G.4.5 Formatting changes to the RMP

Formatting changes to the RMP are unlikely to be a significant amendment to the RMP.

However, multiple minor amendments to an RMP that have an effect on the fitness for intended purpose of animal material or animal product, or on the validity of the programme would be a significant amendment [AP Reg 30].

An example of a minor amendment is:

a) when the entire RMP has been reviewed, re-ordered and reformatted with no content change; and
b) updates to legislation references are made.