Risk Management
Programme Manual
for Animal Product Processing
# Table of Contents

Prelims .................................................................................................................................................. 2

1  **Overview of RMP Manual** ........................................................................................................ 7
1.1  RMP Manual 2009 .................................................................................................................. 7
1.2  The New Zealand Food Safety Authority Approach to Food Safety .................................. 7
1.3  The Animal Products Act Framework .................................................................................. 8
1.4  Businesses Requiring an RMP .......................................................................................... 13
1.5  Businesses Not Requiring an RMP .................................................................................. 13
1.6  RMP Configurations .......................................................................................................... 13
1.7  Relationship between the Animal Products Act and Other Acts .................................. 15

2  **Resources for Developing an RMP** ...................................................................................... 18
2.1  Introduction .......................................................................................................................... 18
2.2  The Animal Products Act 1999 and Associated Legislation ............................................. 19
2.3  Codes of Practice, Templates and Models ........................................................................ 19
2.4  Dairy Operational Guidelines ............................................................................................. 21
2.5  HACCP Plans ...................................................................................................................... 21
2.6  Generic RMP Models .......................................................................................................... 21
2.7  Existing Procedures ................................................................................................................ 22
2.8  Peer-Reviewed Scientific Information ................................................................................ 22
2.9  Predictive Models ................................................................................................................ 22
2.10  Approved Food Safety Programmes ................................................................................ 23

3  **RMP Development** ............................................................................................................. 24
3.1  Introduction ............................................................................................................................ 24
3.2  Operator, Business and RMP Identification ....................................................................... 26
3.3  List of RMP Documents ...................................................................................................... 29
3.4  Management Authorities and Responsibilities ................................................................. 30
3.5  Scope of the RMP ................................................................................................................ 31
3.6  Animal Material and Animal Product Description ............................................................ 34
3.7  Process Description .............................................................................................................. 40
3.8  Good Operating Practice/Supporting Systems ................................................................... 41
3.9  Application of HACCP (Identification, Analysis and Control of Hazards to Human or Animal Health) .................................................................................................................. 45
3.10 Identification and Control of Risks to Wholesomeness ................................. 59
3.11 Identification and Control of Risks from False or Misleading Labelling ........... 62
3.12 Identification and Competencies of Responsible Persons ............................... 64
3.13 Corrective Action for Unforeseen Circumstances ............................................. 68
3.14 Recall Procedures ............................................................................................ 70
3.15 Validation ......................................................................................................... 71
3.16 Operator Verification ....................................................................................... 72
3.17 Notification Requirements ................................................................................ 73
3.18 Provision for Verification Activities and Verifiers Rights ............................... 74
3.19 Document Control .......................................................................................... 76
3.20 Requirements for Records ............................................................................... 78
3.21 Specific Requirements for Dual Operator Butchers .......................................... 79

4 Checks and Validation .......................................................................................... 81
4.1 Introduction ....................................................................................................... 81
4.2 Checks ............................................................................................................... 84
4.3 Validation .......................................................................................................... 85
4.4 Development and Implementation of the Protocol ............................................ 88
4.5 Validation Examples .......................................................................................... 91
4.6 Amendments to the RMP .................................................................................. 94

5 Evaluation ............................................................................................................ 95
5.1 Introduction ....................................................................................................... 95
5.2 Selection of Recognised Evaluator ................................................................... 96
5.3 Evaluation Prior to RMP Registration ............................................................... 97
5.4 Reporting and Registration Documentation ..................................................... 98
5.5 Validation after Registration ............................................................................ 98
5.6 Evaluation of Significant Amendments .......................................................... 99
5.7 Linkage between Evaluation and Registration ................................................ 100

6 Registration ......................................................................................................... 101
6.1 Introduction ..................................................................................................... 101
6.2 Application for Registration ............................................................................ 101
6.3 Assessment and Registration .......................................................................... 104
6.4 Compliance with RMP Registration Conditions ............................................. 106
6.5 Refusal to Register ........................................................................................... 106
6.6 Completion of Validation ................................................................................ 106
6.7 Registration of Significant Amendments ....................................................... 107
6.8 Change of Registration Details ....................................................................... 107
6.9 Multi-Business RMP Registration ................................................................. 108

7 Operating the Registered RMP ............................................................................ 109
7.1 Introduction .......................................................................................................109
7.2 Operator’s Duties ..............................................................................................109
7.3 Conflict between RMP and Regulations or Specifications...........................110
7.4 External Verification ........................................................................................111
7.5 Amendments to the RMP ................................................................................111
8 Ceasing Registration of an RMP..........................................................................115
8.1 Introduction .......................................................................................................115
8.2 Surrender of Registration ................................................................................115
8.3 Suspension of Registration ..............................................................................116
8.4 Deregistration of the RMP ...............................................................................117
9 Appendix A: Glossary of Terms ..........................................................................119
10 Appendix B: Abbreviations ................................................................................130
11 Appendix C: Businesses Requiring RMPs ..........................................................131
11.1 Primary Processors (Including Dairy Processors) .........................................131
11.2 Secondary Processors of Animal Products ....................................................134
11.3 Dual Operator Butchers ..................................................................................135
11.4 Inclusions by Order in Council .......................................................................135
12 Appendix D: Businesses Not Requiring RMPs ...................................................136
12.1 Exemptions by Order in Council .....................................................................136
12.2 Exemptions by the Director-General ..............................................................138
13 Appendix E: Examples of Limits .........................................................................139
14 Appendix F: Procedures or Steps that Require Data as Evidence for
Demonstrating Effectiveness ....................................................................................152
14.1 General Requirements .................................................................................153
14.2 Supply of Animal Material .............................................................................154
14.3 Primary Processing .........................................................................................154
14.4 Secondary Processing ....................................................................................156
15 Appendix G: Guidance on Difference between Significant and Minor
Amendments ..............................................................................................................159
15.1 Major Alterations to Processing Facilities or Equipment ...............................159
15.2 Relocating Processing Operations ..................................................................163
15.3 New Animal Material or Animal Product ......................................................163
15.4 New Process or Process Modifications ..........................................................168
15.5 New Risk Factors or Adverse Impact on Existing Risk Factors ......................170
15.6 Merging RMPs ..............................................................................................171
15.7 Splitting RMP ...............................................................................................171
15.8 Adding a Business to a Multi-Business RMP ................................................171
16 Appendix H: Determination of Principally Dairy ...............................................172
RMP Help Desk

Do I need a Risk Management Programme (RMP)?

What is required for an RMP?

How do I apply to register an RMP?

Contact: MPI Approvals
Phone: 04 894 2550

E-mail: Approvals@mpi.govt.nz

Obtaining Other Information

All resources mentioned in this manual are available on the New Zealand Food Safety Authority (NZFSA) web site at http://www.nzfsa.govt.nz/animalproducts/index.htm.

To obtain hard copies of NZFSA Animal Products publications, please use the Contact link at the bottom of this page.
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This manual shall be reviewed as necessary by the New Zealand Food Safety Authority. Suggestions for alterations, deletions or additions to this manual, should be sent, together with reasons for the change, any relevant data and contact details for the person making the suggestion, to:

Assistant Director (Production and Processing)
New Zealand Standards Group
New Zealand Food Safety
PO Box 2835
Wellington
Telephone: 04 894 2500
Facsimile: 04 894 2643
1 Overview of RMP Manual

This section explains how risk management programmes (RMPs) fit within the framework of the Animal Products Act 1999 (APA) and gives an overview of RMP requirements.

1.1 RMP Manual 2009

This manual has been prepared by the New Zealand Food Safety Authority (NZFSA) to help you as the operator of an animal product business to develop and operate your RMP. The RMP Manual 2009 incorporates the amendments to RMP specifications, and now includes dairy materials and products1. The types of questions addressed by this manual are:

- What is an RMP?
- Who needs an RMP?
- What information is available to help you develop an RMP?
- What is needed in an RMP?
- How do you get an RMP evaluated and registered?
- What are the key things about operating an RMP?

1.2 The New Zealand Food Safety Authority Approach to Food Safety

The New Zealand Government has placed priority on maintaining and improving food safety. NZFSA was established with this in mind.

NZFSA is ultimately accountable for food/animal product control in New Zealand and for the implementation and overall performance of the regulatory framework. NZFSA uses a regulatory model to define its own responsibilities as the regulator and the responsibilities of recognised agencies and persons and you as an animal product business operator. While

1 For the purposes of the RMP Manual, animal material and animal product includes dairy material and dairy product.
NZFSA sets standards, a key principle of this model is that operators of animal product businesses take responsibility for producing safe and suitable products that are fit for their intended purpose. Animal product businesses must not rely on NZFSA or recognised agencies and persons to ensure the delivery of safe and suitable animal products — you must take this responsibility yourself.

1.3 The Animal Products Act Framework

The risk management system under the APA 1999 provides for:

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

- facilitating access to overseas markets.

The risk management system comprises four main types of controls: RMPs, regulated control schemes, export requirements, and the imposition of authorisations and duties on various persons. Each of these is explained in succeeding sections.

1.3.1 RMPs

(Part 2 of the Animal Products Act)

An RMP is a documented programme designed to identify and control hazards and other risk factors in relation to the production and processing of certain animal material and animal products, to ensure that the resulting animal product is fit for its intended purpose.

1.3.1.1 Hazards and other risk factors

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 product.

2 Some primary processors may have “animal materials” as their “final product”. 
The first two are collectively known as “hazards”. The second two are known as “other risk factors”.

The RMP requirements stated in Part 2 of the APA must be read in conjunction with:

- the Animal Products (Risk Management Programme Specifications) Notice 2008
- the Animal Products (Requirements for Risk Management Programme Outlines) Notice 2008; and

These expand on the requirements in the Act.

1.3.2 Regulated Control Schemes

(Part 3 of the Animal Products Act)

A regulated control scheme is a scheme developed by NZFSA and imposed by the Director-General to manage risks, where:

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

1.3.3 Export Requirements

(Part 5 of the Animal Products Act)

There are general requirements that apply to all exporters. In addition to these, there may be specific technical requirements imposed by importing countries. While NZFSA endeavours to minimise such requirements through negotiation with importing countries, certain overseas market access requirements remain. These requirements are additional to the New Zealand standard on which an RMP is based.

It is your choice whether or not to include overseas requirements in your RMP. Operations that are geared for markets such as the EU or the US may choose to incorporate overseas requirements in their RMP. Operations that are mainly trading in New Zealand may exclude them, as it could be too onerous to have these requirements as part of their normal operation. It should be noted however that you must still comply with the overseas requirements for the countries that you are exporting to, regardless of whether you choose to incorporate them as part of the RMP.

1.3.4 Imposition of Authorisations and Duties

(Part 8 of the Animal Products Act)

The APA provides for the recognition by NZFSA of agencies and persons to undertake certain functions and activities (e.g. evaluation and external verification) important to the management of RMPs.


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

- operators of RMPs (see 7.2 of this manual and section 16 of the Animal Products Act)
- exporters (see section 51 of the Animal Products Act)
- recognised agencies (see section 106 of the Animal Products Act); and
- recognised persons (see section 107 of the Animal Products Act).
If these persons do not comply with their duties, the Act allows for a number of measures to be taken as appropriate. These include increased external verification of RMPs, suspension or deregistration of RMPs, deregistration of exporters, removal of recognition of agencies and removal of recognition of persons. In addition, those who commit offences under the Act are liable to be prosecuted, and if found guilty, would be subject to the imposition of fines and/or terms of imprisonment.

### 1.3.5 RMP Responsibilities

Table 1A explains the tasks that need to be done during the development and implementation of an RMP and the responsibilities of the various people involved.
Table 1A: RMP Responsibilities

<table>
<thead>
<tr>
<th>Tasks</th>
<th>Responsibility</th>
<th>Section to refer to:</th>
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<tbody>
<tr>
<td><strong>Development</strong></td>
<td></td>
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<tr>
<td>• Development of the RMP</td>
<td>• Operator</td>
<td>Sections 2 and 3 of this manual</td>
</tr>
<tr>
<td>• Checks and validation of the RMP</td>
<td>• Operator</td>
<td>Section 4 of this manual</td>
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<tr>
<td><strong>Evaluation</strong></td>
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<tr>
<td>• Hiring an evaluator to evaluate the RMP</td>
<td>• Operator</td>
<td>Section 5 of this manual</td>
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<tr>
<td>• Evaluating and reporting on the RMPs validity</td>
<td>• Recognised evaluator</td>
<td>Evaluator’s manual and specification</td>
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<tr>
<td><strong>Registration</strong></td>
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<tr>
<td>• Naming the recognised RMP verifying agency that has indicated it’s willingness to verify the registered RMP</td>
<td>• Operator</td>
<td>Section 6 of this manual</td>
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<tr>
<td>• Application for the registration of the RMP</td>
<td>• Operator</td>
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<td>• Registration of the RMP</td>
<td>• Director, Approvals</td>
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<tr>
<td><strong>Operation</strong></td>
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<td>• Contracting verification services to be used for verifying the registered RMP</td>
<td>• Operator</td>
<td>Section 7 of this manual</td>
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<tr>
<td>• Implementation of the registered RMP</td>
<td>• Operator</td>
<td></td>
</tr>
<tr>
<td>• Specific operational duties</td>
<td>• Operator</td>
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</tbody>
</table>
1.4 **Businesses Requiring an RMP**

See Appendix C for details of the types of businesses that require an RMP.

1.5 **Businesses Not Requiring an RMP**

See Appendix D for details of the types of businesses that do not need an RMP.

1.6 **RMP Configurations**

An RMP may be developed as a stand-alone programme for each:

- type of animal material or product
- type of process or operation; or
- premises or place.
An RMP may also relate to one or more materials, products, processes, operations, places or premises.

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

### 1.6.1 Single-business RMPs

*(Sections 12(3) and 12(4) of the Animal Products Act)*

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 give you flexibility if one area of operation is substantially changed in the future, or one RMP is suspended or deregistered. Export requirements may limit the ability to use multi-site options, e.g. EU-listed premises (apart from dairy) must have separate RMPs for each physical location (refer to Section 3 for more information on RMP identification).

### 1.6.2 Multi-business RMPs

*(Section 17A of the Animal Products Act)*

A registered RMP may apply to more than one business, if this is approved by the Director-General. This is only appropriate for businesses that have similar operations and where all operators have agreed to operate under one RMP.

Approval of a multi-business RMP will require you to demonstrate that:
the programme is appropriate to all businesses or part-businesses that it covers

that you will have sufficient control, authority and accountability for all matters covered by the programme in relation to other businesses or part-businesses subject to its coverage; and

you have obtained the consent or otherwise taken into account the views of any person whose business or part-business is covered by the programme.

You must apply for approval of a multi-business RMP either when applying for registration of the RMP under section 20 of the APA, or when applying to amend an existing RMP under section 25(3) of the APA.

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.

**AP (RMP Specifications) Notice 2008 clause 4(2):**

*For the avoidance of doubt, references to a ‘risk management programme’ relate to both a ‘multi-business risk management programme’ and a ‘single-business risk management programme’ except where a specific reference is made to either.*

This clause clarifies that the legal requirements within the specifications also apply to multi-business RMPs.

### 1.7 Relationship between the Animal Products Act and Other Acts

#### 1.7.1 Food Act 1981

The Food Act's provisions relating to composition and labelling, including those found in the Food Standards Code, apply regardless of whether operations are managed under a food safety programme (FSP), RMP or the Food Hygiene Regulations. This means that RMP operators must comply with the Food Standards Code.

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3 Dairy processors do not have the option of operating under the Food Hygiene Regulations. When operating under the Food Act, they must have an approved FSP.
1.7.1.1  Election to operate under an RMP

*(Section 32 of the Animal Products Act)*

Although your business may not be required to operate under an RMP you may still choose this option over other available options (e.g. FSP, or Food Hygiene Regulations). Choosing to operate under an RMP when it is not compulsory allows you to more easily take advantage of future export opportunities. However the RMP option can only be taken up if the processing involves animal materials or animal products.

In addition to other notifications required for a registered RMP, the Director, Approvals, will notify any relevant territorial authority of your choice, once the RMP is registered.

1.7.1.2  Election to operate under a Food Safety Programme registered as an RMP

*(Section 34 of the Animal Products Act)*

If your business currently operates under an FSP, you may wish to have your FSP registered as an RMP to be operated on an intermittent basis. This may be an option if you only occasionally intend to process product for export. You must be aware of and implement any overseas market access requirements applicable to your business while operating the RMP for export purposes.

All requirements relating to an RMP and its application for registration, apply to this election.

You must notify the Director, Approvals, of the decision to operate under an RMP on an intermittent basis at the time of registration.

When operating the RMP the requirements of the APA apply, including any conditions specified by the Director, Approvals. During this time, the Food Safety Programme requirements do not apply.

The Director, Approvals, will decide whether verification will be carried out under the APA or the Food Act or both.

You can change your mind at any time and withdraw your application to operate under an RMP.

In addition to other notifications required for a registered RMP, the Director, Approvals, will notify any relevant territorial authority of the election, once the RMP is registered.
1.7.2 **Agriculture Compounds and Veterinary Medicines Act 1997 (ACVM Act)**

The primary processing of animal products for pet food, e.g. slaughter and dressing of mammals and birds is covered by the APA and an RMP is required for these operations.

Clauses 7 and 8B of the Animal Products (Exemptions and Inclusions) Order 2000 exempts the secondary processing of animal products, or the processing of dairy material (provided there are no other RMPs at the same place) and that are covered by the ACVM Act, from the requirement to have an RMP. However, if an official assurance under the APA is required then you must develop and register an RMP.

1.7.3 **Medicines Act 1981**

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

If an official assurance under the APA is required for the medicine or related product then an RMP is required.
2 Resources for Developing an RMP

2.1 Introduction

This section discusses the various resources that you can use when developing your RMP.

The main resources that are available are:

1. this RMP Manual
2. the Animal Products Act 1999 and associated legislation (see 2.2)
3. codes of practice, templates and models (see 2.3)
4. dairy operational guidelines (see 2.4)
5. HACCP Plans (see 2.5)
6. generic RMP models (see 2.6)
7. existing procedures (see 2.7)
8. peer-reviewed scientific information (see 2.8)
9. predictive models (see 2.9); and
10. approved food safety programmes (see 2.10).

The development of tailor-made RMPs requires special skills, particularly in relation to HACCP application and the identification and analysis of risk factors.

You should seek external assistance if your own resource or skill level is limited. If you elect to use a consultant, you should choose one who has relevant industry experience and is either a recognised person (e.g. evaluator or verifier) or otherwise experienced with the APA and RMP requirements. If a recognised person is acting as a consultant then that person will not be able to verify or evaluate your RMP within certain time frames. This requirement is explained in the ‘Independent Evaluation and Verification of Risk Management Programmes’ Statement of Policy. This statement was written for non-dairy operators, but can also be applied to dairy operators.
2.2 The Animal Products Act 1999 and Associated Legislation

The Animal Products Act 1999 and its associated legislation are administered by the New Zealand Food Safety Authority. The legislation provides the regulatory requirements that all operators must comply with. The APA regime includes the following types of legislation:

- Acts
- Regulations
- Orders in Council
- Notices (including specifications)
- Standards (e.g. Food Standards, and Animal Product Standards made under notice)
- Directions
- Approved Criteria (for dairy material and product only).

Of particular importance when developing an RMP are the two sets of RMP specifications (see section 1.3.1.1). Excerpts from the RMP specifications are included throughout this manual.

To view the relevant legislation go to:

http://www.nzfsa.govt.nz/animalproducts/legislation/index.htm (non-dairy operators)


2.3 Codes of Practice, Templates and Models

An RMP may be based on NZFSA templates, models, or codes of practice, where these are available.

These are defined as:

1. A Code of Practice (COP):
   Is a document which reflects agreed industry practice and provides information on meeting regulatory requirements.

2. Template:
   A simplified RMP form with prompts for each mandatory requirement. (A “fill in the gaps” document).
3. Model:
   A completed RMP that can be used as an example for replication in part or in whole.

A COP may incorporate a template and/or model. Any references in this manual to COP also apply to templates and models.

2.3.1 COPs, Templates and Models Approved under the APA

NZFSA may approve COPs, templates and models that meet regulatory requirements. These documents are expected to cover Good Operating Practice (GOP), HACCP application and other RMP requirements. NZFSA approved COPs, templates and models are available at:

- Dairy:

- Other Animal Products:

2.3.2 Advantages of Approved COPs, Templates and Models

If you follow an approved COP, template or model it will:

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

You will still need to tailor your RMP to suit your specific animal product business. The extent of this will vary depending on the applicability of the approved document to your business.

Parts of approved COPs, templates or models that are directly applicable to your business may be incorporated into your RMP by reference.

If you follow the recommendations in the COP you will only need to demonstrate consistent compliance with the requirements, rather than having to prove that the requirements are valid in the first place.
In most cases, if your RMP is fully based on an approved COP, template or model the requirement for evaluation will be waived.

2.4 Dairy Operational Guidelines

These guidelines were developed within the dairy industry and when followed will assist you to meet the legislative requirements.


2.5 HACCP Plans

RMPs are based on the application of HACCP principles. NZFSA developed HACCP guidance and generic HACCP plans to assist meat and seafood operators. These documents are available at http://www.nzfsa.govt.nz/animalproducts/haccp/index.htm.

For the dairy sector, HACCP guidance is available at:

HACCP plans for products intended for human consumption only address hazards to human health. You must ensure that hazards to animal health and other risk factors (i.e. risks to false or misleading labelling, wholesomeness) are also addressed in your RMP, where appropriate.

Exporters must consider the impact of overseas market access requirements that relate to their HACCP plans (e.g. mandated Critical Control Points (CCPs)) when a plan is incorporated into an RMP. For certain markets such as the US, the components of the HACCP plan need to be easily identified so that this is clear to any overseas reviewers.

2.6 Generic RMP Models

Generic RMP models have been produced by NZFSA, in consultation with various industry working groups. The models show how the principles of HACCP can be applied and how RMP components could be written for various processes including:

- slaughter and dressing, and cutting and boning operations for cattle, farmed deer, sheep and bobby calves
- processing of half-shell mussels
- processing of hot smoked mussel meat
• processing of oysters

• processing of finfish.

These models are not complete RMPs. If used, you must tailor your RMP to your specific products, processes and premises.

In general, generic RMP models are based on New Zealand requirements only. However, some RMP models do incorporate overseas market access requirements for specific countries. This usually happens when a significant number of processors export to the same country. In such cases the RMP model clearly identifies the market access requirements to differentiate them from New Zealand requirements.

2.7 Existing Procedures

You may have access to documented food control or QA systems that meet customer requirements, e.g. ISO 9001. It is likely that relevant parts of these documented systems can be incorporated into the RMP by reference where the meet and do not conflict with any regulatory requirements. You must ensure that RMP components that are not covered by these systems are added to complete your RMP.

2.8 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.

2.9 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; chemical deterioration.

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

An example of a predictive model commonly used in the New Zealand meat industry is the model for estimating Process Hygiene Index (PHI). This model provides an 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.

2.10 Approved Food Safety Programmes

(Section 32 of the Animal Products Act)

You may use an approved FSP as a basis for an RMP but it will need to be revised to ensure RMP requirements that are not covered by the FSP are met. This includes the identification of risk factors other than hazards to human health, i.e:

- risks from hazards to animal health (where relevant)
- risks from false or misleading labelling
- risks to the wholesomeness of animal material or animal product.
3 RMP Development

3.1 Introduction

(Section 17 of the Animal Products Act)

This section provides guidance on designing an RMP.

3.1.1 RMP Development Expertise

Understanding the application of HACCP principles is essential to develop and implement an RMP. If this expertise is not available in-house, NZSFA recommends that competent external advice is sought, or a member of staff undertakes appropriate training. A team approach offers the benefit of a range of expertise, different perspectives and experience. The members of this team should be selected on the basis of their responsibilities, knowledge and experience of the products, processes and hazards relevant to the scope of the RMP, and knowledge of the principles and practice of producing food safely.

3.1.2 RMP Development Time

If you want to register an RMP by a certain date, it is your responsibility to allow sufficient time for development, evaluation and registration. The time necessary will depend on the complexity and size of your operation and the extent and suitability of existing documentation.

3.1.3 RMP Components

The RMP should include those components shown in Figure 3A that are appropriate to the product and operation. Components must be documented in writing.
Figure 3A: Components of an RMP

<table>
<thead>
<tr>
<th>Component</th>
<th>Section Reference:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operator, Business and RMP Identification</td>
<td>3.2</td>
</tr>
<tr>
<td>List of RMP Documents</td>
<td>3.3</td>
</tr>
<tr>
<td>Management Authorities and Responsibilities</td>
<td>3.4</td>
</tr>
<tr>
<td>Scope of the RMP</td>
<td>3.5</td>
</tr>
<tr>
<td>Animal Material and Animal Product Description⁴</td>
<td>3.6</td>
</tr>
<tr>
<td>Process Description</td>
<td>3.7</td>
</tr>
<tr>
<td>Good Operating Practice / Supporting Systems</td>
<td>3.8</td>
</tr>
<tr>
<td>Application of HACCP (Identification, analysis and</td>
<td>3.9</td>
</tr>
<tr>
<td>control of Hazards to Human or Animal Health)</td>
<td></td>
</tr>
<tr>
<td>Identification and Control of Risks to Wholesomeness</td>
<td>3.10</td>
</tr>
<tr>
<td>Identification and Control of Risks from False and</td>
<td>3.11</td>
</tr>
<tr>
<td>Misleading Labelling</td>
<td></td>
</tr>
<tr>
<td>Identification and Competencies of Responsible</td>
<td>3.12</td>
</tr>
<tr>
<td>Persons</td>
<td></td>
</tr>
<tr>
<td>Corrective Action For Unforeseen Circumstances</td>
<td>3.13</td>
</tr>
<tr>
<td>Recall Procedures</td>
<td>3.14</td>
</tr>
<tr>
<td>Validation</td>
<td>3.15</td>
</tr>
<tr>
<td>Operator Verification</td>
<td>3.16</td>
</tr>
<tr>
<td>Notification Requirements</td>
<td>3.17</td>
</tr>
<tr>
<td>Provision for Verification Activities &amp; Verifier</td>
<td>3.18</td>
</tr>
<tr>
<td>Rights</td>
<td></td>
</tr>
<tr>
<td>Document Control</td>
<td>3.19</td>
</tr>
<tr>
<td>Requirements for Records</td>
<td>3.20</td>
</tr>
<tr>
<td><strong>Dual Operator Butchers – extra requirements</strong></td>
<td>3.21</td>
</tr>
</tbody>
</table>

Each of these components is discussed in succeeding sections.

⁴ Note that for the purposes of the RMP Manual, animal material and animal product includes dairy material and dairy product.
3.2 Operator, Business and RMP Identification

3.2.1 RMP Operator

(Section 17 of the Animal Products Act)

Your RMP must specify the name and address (including the electronic address, if available) of the operator. The operator may be a company, a partnership or a sole trader. If the operator is a company, then the name must exactly match the details given at the Companies Office. 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 OE1 or OE2 of the Income Tax Act 1994, and you, together with business directors and managers must be fit and proper persons to operate an animal product business.

3.2.2 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 section 3.2.1) then no further information is required.

If the business is a company, then the name must exactly match the details given at the Companies Office. If the business is a partnership or a sole trader operation then the name(s) of the business owner(s) must be provided. If the business trades under another name, this must also be provided.

3.2.3 Business Identifier

A unique business identifier is needed for each premises or physical location that the RMP applies to.

5 A fit and proper person must not have any conviction for an offence, in relation to fraud, dishonesty or negligence, whether in New Zealand or overseas, in regard to running a business of the type covered by the APA.
• The identifier must be a number or number/letter combination of at least 3 and not more than 10 characters with at least one character as a number and no leading zeros. The business identifier must not be the same as any exporter’s registration number. You should also consider overseas market access requirements when selecting your business identifier, e.g. EU-listed premises must have individual business identifiers for each premises. Where appropriate, the business identifier will be used by NZFSA for country listing purposes and may be used by you for animal product labelling and identification.

• For multi-business RMPs, you may provide alternative details instead of giving an identifier for each business, premises or place. The alternative used must be approved by NZFSA.

In relation to exports, any change to an identifier must be reflected in updated packaging and country listings. Certain country listings may take 6 - 12 weeks to update, therefore any product produced under the RMP with a new ID may not be eligible for export to the affected countries until country listings have been updated. Once your business ID has been established, it will be used for any future RMP registration applications.

You can check availability of identifiers on the list of registered RMPs at the following links:


or


3.2.4 RMP Number (Non-dairy only)

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

6 For the purposes of carcass brands, inspection legends and carton seals, there will be a physical limit of 6 characters.

7 This provides links to a list of currently registered RMPs only. Identifiers from RMPs that are no longer registered are also not available for your use. You will need to confirm availability with NZFSA.
3.2.5 RMP Identifiers

For dairy operators the RMP Identifier is the Business Identifier. For non-dairy operators the RMP Identifier is a combination of the Business Identifier and RMP Number.

A unique RMP identifier is to be applied to each RMP (see Table 3B for an example). The unique RMP identifier will appear on the registration documentation for the RMP.

3.2.6 Unique Location Identifier (Dairy only)

AP (RMP Specifications) Notice 2008 clause:

5 Scope of a risk management programme
(3) A risk management programme that covers dairy processing (other than a farm dairy or the transport of dairy material) and includes more than one location, must contain a unique location identifier for each location identified within the risk management programme.

For the purposes of traceability and certification, you must nominate a unique identifier for each location specified in the RMP. The unique location identifier (ULI) will appear on the registration documentation for each registered RMP. If the RMP only covers processing at one location the ULI can be the same as the RMP identifier.

You can check the availability of Unique Location Identifiers at:
http://www.nzfsa.govt.nz/dairy/registers-lists/reg-fac.htm or

Table 3B: Examples of Identifiers

<table>
<thead>
<tr>
<th>Business Identifier</th>
<th>RMP Number</th>
<th>Unique Location Identifier (ULI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUS111</td>
<td>01</td>
<td>000</td>
</tr>
<tr>
<td>BUS111</td>
<td>02</td>
<td>001</td>
</tr>
<tr>
<td>BUS111</td>
<td>03</td>
<td>002</td>
</tr>
</tbody>
</table>

3.2.7 Operator, Business and Programme Identification

NZFSA recommends that information covered in section 3.2 is located at the start of the RMP. Figure 3C gives an example of one way that this information may be presented.
Figure 3C: Example of RMP Details

<table>
<thead>
<tr>
<th>Business Identifier:</th>
</tr>
</thead>
<tbody>
<tr>
<td>RMP No (non dairy only):</td>
</tr>
<tr>
<td>Unique Location Identifier/s (dairy only):</td>
</tr>
<tr>
<td>Name of Operator:</td>
</tr>
<tr>
<td>Postal Address of Operator:</td>
</tr>
<tr>
<td>Physical Address of Operator:</td>
</tr>
<tr>
<td>Electronic Address of Operator:</td>
</tr>
<tr>
<td>Name of Business (if different to operator):</td>
</tr>
<tr>
<td>Address of Business (if different to operator):</td>
</tr>
</tbody>
</table>

3.3 List of RMP Documents

**AP (RMP Specifications) Notice 2008 clause:**

**12 Document list**

*(1) A risk management programme must contain a list of all documents that comprise the programme with their date or version at the time of registration of the programme or any significant amendment to that programme.*

*(2) For multi-business risk management programmes, the document list must also specify, where necessary, which documents relate to which business.*

You must develop list(s) of all the documents that make up the RMP, including the components shown in Figure 3A. The list(s) should include supporting systems, procedures, site plans, letters confirming that external verification services will be provided, and blank record forms and any referenced documents. It is not sufficient to name the RMP as a single document without providing further detail.
It is recommended that the list(s) be located at the start of the RMP to make it easy to find the various components. A contents page may be used to meet this requirement (if sufficient details are included). Table 3D gives an example of one way to format a document list.

Table 3D: Example of an RMP Document List

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Section Number</th>
<th>Section Title</th>
<th>No of Pages</th>
<th>Version - Date</th>
<th>Only for multi-businesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual A Supporting Systems</td>
<td>3</td>
<td>Cleaning and Sanitation.</td>
<td>10</td>
<td>1 - 2/3/08</td>
<td>All</td>
</tr>
<tr>
<td>Manual B</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>E only</td>
</tr>
<tr>
<td>Manual C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>All but E</td>
</tr>
</tbody>
</table>

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

3.4 Management Authorities and Responsibilities

(*Sections 19(a), 19(b), 22(1) (b) and 22(1) (c) of the Animal Products Act*)

3.4.1 Day-to-day Manager of the RMP

You must nominate a person who is responsible for the day-to-day management of the RMP by name, position or designation. This is the person who:

- is the authorised “management representative” for all aspects of the RMP
- will deal with NZFSA over any RMP issues.

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

The day-to-day manager must ensure that:

- the RMP is appropriate, complete, complies with legal requirements, and is implemented as written
• significant amendments are made and registered in accordance with section 25 of the Act; and

• notifications and minor amendments are made, as appropriate.

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

NZFSA 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.

NZFSA must be notified when the day-to-day manager is changed (see section 6.8.2).

3.4.2 Evidence of Sufficient Control and Consent for a Multi-business RMP

(Section 17A of the Animal Products Act)

For multi-business RMPs, you must provide evidence that your operation has sufficient control over the other businesses or part-businesses that it covers, and that you have the consent of those business owners. Examples of possible evidence include:

• a signed contract

• written correspondence between the parties.

3.5 Scope of the RMP

(Sections 12 (3) and 12 (4) of the Animal Products Act)

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 (see section 1.6).

3.5.1 Physical Boundaries

AP (RMP Specifications) Notice 2008 clause:

5 Scope of a risk management programme
(1) A risk management programme must contain a description of the physical boundaries to which the risk management programme applies.
(2) The physical boundaries of a farm dairy may be documented in the risk
management programme by assigning a farm dairy identifier to each farm dairy and maintaining a register showing the physical location of each farm dairy.

The physical boundaries are one of the main determinants of the scope of your RMP. You must include all aspects of the operation (e.g. facilities, equipment, worker amenities, external environment, processing, storage and support areas) even those not routinely used, in the physical boundaries.

You can show the physical boundaries in a diagram or site plan of the premises, mobile premises or vessel. Wherever possible, this should be drawn to scale and should have a level of detail so that any changes to the boundary can be readily identified.

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

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

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

3.5.2 Clarification of RMP Scope

(Section 13 of the Animal Products Act)

AP (RMP Specifications) Notice 2008 clause:

5: Scope of a risk management programme

(4) A risk management programme must contain consideration of all relevant sources of potential risk factors that may affect the animal material, animal product, operations or directly associated things within the physical boundaries of the risk management programme.

(5) For the purposes of section 17(1)(b)(ii) of the Act, a risk management programme must specify whether any animal material, animal product or food that is within the physical boundaries of the risk management programme, is excluded because it is covered under a different risk management programme or a different regulatory
regime, and if so clearly explain how the interfaces are managed.

(6) If a person other than the risk management programme operator uses areas inside the physical boundaries of the risk management programme for any activity not covered by the risk management programme, a risk management programme must address the interfaces with this activity to ensure that the effectiveness of the programme is not compromised, and the operator must document in the risk management programme the authorities and accountabilities for resolving issues associated with that activity.

Only foods containing animal products can be regulated under the APA. Other foods must be regulated under:

- a FSP under the Food Act 1981; or
- the Food Hygiene Regulations 1974 (also under the Food Act).

3.5.2.1 Exclusions

You must document:

- any animal material, animal product or food excluded from your RMP
- the alternative regime under which they are regulated, e.g. another RMP, Food Act regime, ACVM Act regime or Medicines Act 1981
- how you will manage the interfaces between the regimes.

When explaining how the interfaces are managed you should clarify:

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

3.5.2.2 Shared facilities

If your RMP includes shared facilities, you must document:

- the activities taking place that are not covered by the RMP and the times when these activities occur
- who is responsible for these activities
• how the interfaces are managed, e.g. by complete cleaning, physical separation etc; and

• the authorities and accountabilities for resolving issues associated with that activity, e.g. a contract stating who is responsible for maintaining specific buildings or equipment, how issues are raised and the time frames for satisfactory resolution etc.

3.6 Animal Material and Animal Product Description

(Section 17(1) (c) and 17(2) (c) of the Animal Products Act)

Your RMP must include a description of the animal material and animal product to which it applies. An example of how this information may be presented is given in table 3E (see section 3.6.6).

3.6.1 Animal Material or Product entering or leaving RMP

**AP (RMP Specifications) Notice 2008 clause:**

6 Animal material and animal product description
(1) For the purposes of section 17(1)(c) of the Act, a risk management programme must specify the name or type of all animal materials or animal products entering the physical boundaries of the risk management programme.

(2) A risk management programme must specify the name or type of all animal materials or animal products leaving the physical boundaries of the risk management programme.

All of the animal materials or animal products entering or leaving the RMP must be documented including those intended for human consumption, animal consumption, industrial use and waste.

They may be described individually or in groups in a manner that will 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 animal products required under Clause 6(2) of the RMP spec can be addressed by using a descriptor of the product such as raw, cooked, fermented, dried, canned, smoked, frozen, chilled etc.
3.6.2 Intended Purpose

AP (RMP Specifications) Notice 2008 clause:

6 Animal material and animal product description
(3) A risk management programme must specify the intended use of each animal material or animal product described in clause 6(2) when it leaves the physical boundaries of the risk management programme, including —
(a) whether the material or product is intended for human or animal consumption, and
(b) whether the material or product —
   (i) is to be subject to further processing; or
   (ii) requires additional preparation by the final consumer; or
   (iii) is ready to eat or consume.

3.6.2.1 Intended consumer

You must document the intended use of the animal material or animal product and if appropriate identify any specific consumer groups e.g:

- human consumption: infants, elderly, immuno-compromised individuals (YOPI)
- animal consumption: pets, zoo animals, farm animals.

3.6.2.2 Intended use

Clause 6 (3)(b) of the RMP spec requires you to document whether your product requires further processing or is ready to consume and may include further details where known, e.g. further processing may be described as canning, pasteurisation, drying etc.

---

8 For RMPs that only maintain animal materials or animal products in the condition that they received them from another RMP, e.g. stand-alone stores, it is acceptable to state that this information is covered by the supplier’s RMP(s).

9 See previous footnote.
3.6.3 Limits

Regulatory and operator-defined limits define the suitability for processing of animal material, or fitness for intended purpose of animal product. The effectiveness of the RMP can be validated against these criteria.

Limits that are essential for food safety should be considered at CCP determination and may result in a CCP or may be adequately covered by GOP (see section 3.8).

**AP (RMP Specifications) Notice 2008 clause:**

7 Limits

A risk management programme must, in relation to each animal material or animal product described in clause 6(2), specify any relevant regulatory limits and any operator-defined limits in relation to —

(a) risks from hazards to animal or human health; and

(b) risks from false or misleading labelling or representation; and

(c) risks to the wholesomeness of animal material or animal product.

8 Actions when limits are not met

A risk management programme must specify the actions to be taken if the limits in clause 7 are not met.

3.6.3.1 Regulatory limit

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. pasteurisation parameters for milk or cooking times and temperatures for a ham.

Regulatory limits must be documented in the RMP and must be met.

You must consider all relevant legislation including

- Animal Products Specifications Notices e.g. Animal Products (Specifications for Products Intended for Human Consumption) Notice clause 121 for raw harvested bivalve molluscan shellfish;

- Australian New Zealand Food Standards e.g. Standard 1.6.1 Microbiological Limits for Food and Standard 1.3.1 Food Additives.

Regulatory limits for dairy products can be found in the relevant Approved Criteria. Examples of regulatory limits are given in Appendix E.
3.6.3.2 **Operator-defined limits**

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

Examples of possible operator-defined limits are:

- intrinsic parameters of the final product (e.g. pH, moisture content or water activity)
- 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 rubber, fibres, metal, bone); and
- maximum levels of chemical hazards.

You must demonstrate that the operator-defined limits are appropriate to your product, considering its intended use, intended consumer and expected handling after leaving the RMP\(^\text{10}\). Evidence to justify the selection and level of operator-defined limits may include:

- approved COPs, Templates & Models (see section 2.3.1)
- peer-reviewed scientific information (see section 2.8)
- predictive models (mathematical modelling) (see section 2.9)
- scientific information from a person or organisation known to be competent
- international standards or journal articles
- previous validation studies or historical knowledge on performance of the control measure. You must ensure that the conditions (e.g. raw materials, relevant hazards, combination of control measures, intended use or distribution) in your particular

---

\(^{10}\) The Microbiological Reference Criteria issued by the Ministry of Health relates to criteria at the end of shelf life. For this reason, it may be inappropriate to use these criteria in the RMP as they may be too high for use at the point of release from an RMP. For guidance on this and other microbiological limits that are commonly used for finished products see [http://www.nzfsa.govt.nz/processed-food-retail-sale/fact-sheets/which-micro.htm](http://www.nzfsa.govt.nz/processed-food-retail-sale/fact-sheets/which-micro.htm)
operation do not differ from the conditions under which the control measure was previously validated.

If the parameter is taken directly from one of the above sources, then referring to that source should be adequate justification.

If the parameter is not taken directly from one of the above sources, then you will need to prove that the selected parameter is valid. You may use data from your own experiments or trials. Examples of this approach are laboratory trials and pilot tests of the process.

Examples of operator-defined limits are given in Appendix E.

3.6.4 Actions to be Taken when Limits are not Met

**AP (RMP Specifications) Notice 2008 clause:**

8 **Actions when limits are not met**

A risk management programme must specify the actions to be taken if the limits in clause 7 are not met.

You must document the actions that will be taken (restoration of control, product disposition and preventative action) if any limits are not met e.g. *Listeria monocytogenes* is detected in cooked cured meat or metal is detected, including any response specified by NZFSA e.g. DPC1: Approved Criteria for General Dairy Processing, 17 Disposal of Non-conforming Dairy Material or Dairy Product.

3.6.5 Other Product Details

You may also include other animal material and animal product details in the product description where appropriate, e.g. requirements for post-mortem examination, packaging, storage, shelf-life and/or labelling.
### 3.6.6 Examples of Animal Material and Animal Product Descriptions

**Table 3E: Examples of Product Description**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Example 1</th>
<th>Example 2</th>
<th>Example 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product.</strong></td>
<td>Raw sheep carcasses, cuts, trimmings.</td>
<td>A grade shell eggs.</td>
<td>Cheese.</td>
</tr>
<tr>
<td><strong>Intended consumer.</strong></td>
<td>General public.</td>
<td>General public.</td>
<td>General public.</td>
</tr>
<tr>
<td><strong>Intended use.</strong></td>
<td>Further processing into manufactured products, retail products, food service items To be cooked before consumption.</td>
<td>May be cooked or consumed raw.</td>
<td>Ready to eat.</td>
</tr>
<tr>
<td><strong>Regulatory limits</strong></td>
<td>None.</td>
<td>None.</td>
<td>Maximum limit (Approved Criteria DPC1).</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><em>Salmonella</em> spp. ND/25g.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><em>L. monocytogenes</em> ND/25g.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Coagulase positive <em>Staphylococci</em> (<em>S. aureus</em>).</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1000cfu/g.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><em>B. cereus</em> 1000cfu/g.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><em>E. coli</em> 100cfu/g.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>72°C for 15 sec.</td>
</tr>
<tr>
<td><strong>Operator-defined limits.</strong></td>
<td>None.</td>
<td>None.</td>
<td>None.</td>
</tr>
<tr>
<td><strong>Other product details.</strong></td>
<td>Packaging and labelling as per company specification (refer to document xx)(^{12}). Frozen to -12°C.</td>
<td>HC Specification 107. FSC standard 2.2.2. Have been candled and packed. Shelf life. To be stored at or below 15°C.</td>
<td>FSC Standard 2.5.4.</td>
</tr>
</tbody>
</table>

---

11 If limits exist, then operator must also document actions to be taken when limits are not met.

12 This could be a reference to a company document where the packaging specification is located.
3.7 Process Description

**AP (RMP Specifications) Notice 2008 clause:**

9. Description of the process or operation

A risk management programme must specify every process or operation carried out under that programme, including -

(a) all inputs; and

(b) the main activities or steps; and

(c) all outputs.

The simplest way to describe your process is to use process flow diagrams showing all inputs, activities or steps, and outputs. These diagrams provide the foundation for hazard and other risk factor identification and hazard analysis.

Inputs include:

- animal materials or animal products, e.g. raw milk, live sheep, red meat, fish, eggs, honey
- other ingredients, e.g. starch, water, salt, spices
- additives / processing aids, e.g. preservatives, antioxidants, colourings, gaseous packing agent; and
- packaging.

You should show the main activities or steps in the process including any rework or recycling, and multiple processing streams. Key process parameters should also be included in the process flow, e.g. processing times and temperatures. This is especially important if you will be submitting an RMP outline for registration. This will assist NZFSA to assess your RMP and minimise the amount of further information that may be requested to clarify the effectiveness of your RMP.

Outputs include all animal materials or animal products leaving your RMP and should be shown irrespective of their intended use, e.g. human consumption, animal consumption, industrial/technical use and waste.
3.8 Good Operating Practice/Supporting Systems

AP (RMP Specifications) Notice 2008 clause:

11 Control of hazards and other risk factors
(1) A risk management programme must contain sufficient procedures to ensure that
—
(a) animal material or animal product subject to the risk management programme is fit for its intended purpose and that it complies with the programme; and
(b) legislative requirements (including regulatory limits) are met.
(2) The procedures referred to in subclause (1) must cover —
(a) good operating practice; and
(b) all matters set out in sections 17(2) and 17(3) of the Act; and
(c) any corrective action procedures that are to be applied in the event of loss of control, including —
(i) how control will be restored; and
(ii) how any affected animal material or animal product will be identified, controlled or disposed of; and
(iii) any measures to be taken to prevent recurrence of the loss of control.

3.8.1 Background

Good operating practice (GOP) includes the practices and procedures designed to ensure consistent production of products that are fit for their intended purpose.

GOP includes several interacting components, such as good hygienic practices (GHP), effective process control and other quality assurance systems.

GOP is typically documented in supporting systems.  

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13 Good Operating Practice includes Good Manufacturing Practice (GMP) and Good Hygienic Practice (GHP).

14 These systems may also be referred to as Standard Operating Procedures (SOPs), Sanitation Standard Operating Procedures (SSOPs), GMP procedures and pre-requisite programmes.
3.8.2 GOP Covered in Supporting Systems

You should document GOP that are necessary for your operation. A good place to start is to ensure you document all procedures required under the Animal Products (Specifications for Products Intended for Human Consumption\(^\text{15}\)) Notice or the Animal Products (Dairy Processing Specifications) and related Approved Criteria. This is likely to include but is not limited to systems covering:

a. design, construction and essential services
b. premises hygiene and maintenance
c. health and hygiene of personnel
d. competency of personnel
e. calibration
f. packaging
g. labelling
h. inventory control and traceability
i. chemicals
j. pest control
k. supply of animal material
l. incoming materials
m. control of operations, hygienic techniques and process control
n. product specific procedures
o. storage
p. transportation; and
q. recall.

\(^{15}\) Or alternatively, consider the Animal Consumption specifications - depending on the intended consumer for products made.
3.8.3 Contents of Supporting Systems

You must ensure that supporting systems meet all relevant regulatory requirements. In many cases NZFSA has developed sector specific COPs. It is recommended that you consult these documents when developing these systems.

NZFSA recommends that supporting systems contain the following:

1. Purpose and scope
2. Authorities and responsibilities
3. Materials and equipment (where appropriate)
4. Procedures covering:
   a. control measures – see section 3.8.3.1
   b. monitoring – see section 3.8.3.2
   c. corrective action – see section 3.8.3.3; and
   d. operator verification – see section 3.8.3.4.
5. Recording / reporting; and
6. References to other relevant documents.

Sufficient detail must be given in the supporting systems to ensure that managers and staff know what to do, to assist in staff training and to ensure clear understanding by other people such as the external verifiers and recognised evaluators.

3.8.3.1 Procedures for control of operations

You must document:

- the procedures for each process step, including rework

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16 For procedures relating to other supporting systems e.g. premises hygiene and maintenance, refer to the COP developed by NZFSA for the various sectors.
• instructions necessary to make the product correctly (what, when, where, how and by whom); and

• any parameters and the limits for those parameters at each process step (e.g. pH during curing, time and temperature requirements for cooking).

3.8.3.2 Monitoring procedures

You must document procedures for monitoring control measures and applicable limits. Monitoring procedures should include the:

• identify of the person or position responsible

• method of monitoring

• acceptance criteria or limit

• frequency and sampling regime if applicable; and

• records to be kept.

The frequency of monitoring must be appropriate to ensure consistent process control.

3.8.3.3 Corrective action procedures

You must document corrective action procedures which are implemented when a non-compliance to documented procedures and/or failure to achieve a limit is identified. Your corrective action procedures should include:

• the identity of the person or position responsible

• procedures for restoration of control

• procedures for control and disposition of non-complying product, including checking of product back to the last good result

• any action necessary to prevent reoccurrence

• escalating response if preventative action fails; and

• records of all of the above.
3.8.3.4 **Operator verification procedures (also see 3.16)**

You must document operator verification procedures which ensure that GOP has been implemented effectively, monitoring is occurring and that appropriate corrective action is taken when limits are not met. Operator verification includes activities such as internal audits, achievement of regulatory and operator defined limits e.g. product testing, effectiveness of hygiene and sanitation programmes e.g. environmental testing, compliance to specifications (e.g. ingredient testing) and reviews of the RMP. These procedures should include:

- the identity of the person or position responsible
- procedures for when ongoing operator verification is to be carried out
- procedures for how it will be done
- follow up action to be taken if non-compliance is detected; and
- how the above activities are recorded.

3.9 **Application of HACCP (Identification, Analysis and Control of Hazards to Human or Animal Health)**

*(Section 17 (3) of the Animal Products Act)*

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**AP (RMP Specifications) Notice 2008 clause:**

10 **Identification of risk factors and analysis of hazards**

*In addition to the requirements in sections 17(2) and (3) of the Act, a risk management programme must specify any uncontrolled hazards that are likely to be present in animal product leaving the physical boundaries of the risk management programme and the operator must be able to justify that this is appropriate considering the intended use of the product.*

11 **Control of hazards and other risk factors**

(1) A risk management programme must contain sufficient procedures to ensure that —

(a) animal material or animal product subject to the risk management programme is fit for its intended purpose and that it complies with the programme; and

(b) legislative requirements (including regulatory limits) are met.

(2) The procedures referred to in subclause (1) must cover —
(a) good operating practice; and
(b) all matters set out in sections 17(2) and 17(3) of the Act; and
(c) any corrective action procedures that are to be applied in the event of loss of control, including —
   (i) how control will be restored; and
   (ii) how any affected animal material or animal product will be identified, controlled or disposed of; and
   (iii) any measures to be taken to prevent recurrence of the loss of control;

(3) A risk management programme must specify the following for each identified critical control point —
(a) the justification for its identification; and
(b) the critical limits to be met and the justification for those limits.

You must apply HACCP principles to your process. This ensures a systematic approach to the identification, analysis and control of hazards. The principles of HACCP, as defined by Codex are:

1. Conduct a hazard analysis
2. Determine the critical control points (CCPs)
3. Establish critical limits
4. Establish a system to monitor the control of the CCP
5. Establish the corrective action when monitoring indicates that a particular CCP is not under control
6. Establish verification procedures
7. Establish documentation concerning all procedures and records relevant to the HACCP principles and their application

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

You are only required to apply the HACCP principles to the actual process, including all inputs to the process.

The application of HACCP principles must be documented. The person or people assigned to this task must have the appropriate knowledge and skills regarding HACCP and the particular processes.
You must review your application of HACCP whenever changes in the product, process and/or premises are made.

### 3.9.1 Types and Sources of Hazards

A hazard is described as biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

- biological hazards include microorganisms (e.g. *Salmonella spp.*, *Listeria monocytogenes*), parasites (e.g. *Taenia saginata*) and biotoxins. ¹⁷
- chemical hazards include heavy metals, pesticides and veterinary medicines. Some food additives may also be hazardous if present in excessive or toxic amounts (e.g. nitrite).
- physical hazards are objects in food that may cause illness or injury. Some examples are glass, metal fragments, stones, bone slivers and shotgun pellets.

Hazards may occur as a result of:

- an input
- the process itself; or
- contamination from “other sources”, such as personnel, water, air, pests, wastes or processing equipment.

### 3.9.2 Hazard Identification and Analysis

#### 3.9.2.1 Hazard identification

You should only consider hazards that are “reasonably likely to occur” in your hazard identification. 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 NZFSA; and

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¹⁷ Biotoxins could instead be listed under chemical hazards. Either approach is acceptable.
the hazard is known to occur in New Zealand (care should be taken when considering overseas information).

You may use generic HACCP plans or generic RMPs as a basis for your hazard identification but you must then 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 such as placentas and glands.

Hazards may be identified by group based on their common characteristics, source and/or control. Examples include: enteric pathogens in beef trimmings, marine biotoxins in shellfish, chemical residues in fresh meat, enteric pathogens in raw milk.

However, certain hazards that require specific controls must be explicitly identified. Examples of these hazard / product combinations include: Campylobacter in raw chicken, Staphylococcus aureus in cooked ham, Listeria monocytogenes in ready-to-eat smoked fish, tutin toxin in honey, the pesticide 1080 in possums, Salmonella in raw milk, and 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) which may require different control measures.

You must be careful not to mix up the source or cause of the hazard (e.g. faecal contamination) and the hazard itself (e.g. enteric pathogens).

3.9.2.2 Identification of hazards from inputs

You should identify the hazards that are reasonably likely to occur for each input.

Supplier quality assurance programmes are typically the most practical way to manage the hazards in incoming raw materials and ingredients. Supplier quality assurance programmes may include; agreed material specifications, supplier declarations for live animals, certificates of analysis for ingredients, supplier audits, and periodic testing of incoming materials. Supplier specifications and procedures should be documented in the RMP.

Hazard identification may be presented in a table, as shown in Table 3F.
Table 3F: Hazard Identification for Inputs

<table>
<thead>
<tr>
<th>Inputs</th>
<th>Description/specification</th>
<th>Biological hazard (B)</th>
<th>Chemical hazard (C)</th>
<th>Physical hazard (P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beef cuts and trimmings.</td>
<td>Sourced from company with a registered RMP.</td>
<td>Enteric pathogens, e.g. Campylobacter jejuni, Clostridium spp., Salmonella spp., E. coli spp.</td>
<td>Chemical residues.</td>
<td>Bone Metal.</td>
</tr>
<tr>
<td></td>
<td>Chilled or frozen as per company specification.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Boneless cuts.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raw milk.</td>
<td>Sourced from farm dairy with registered RMP.</td>
<td>Non-spore forming pathogens e.g. Salmonella, Listeria, E. coli, Mycobacterium bovis (TB).</td>
<td>Chemical residues from cow, e.g. antibiotics, pesticides, heavy metals.</td>
<td>None.</td>
</tr>
<tr>
<td></td>
<td>Chilled storage.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walnuts.</td>
<td>Supplier approved programme.</td>
<td>None^18.</td>
<td>None.</td>
<td>Walnut shell.</td>
</tr>
<tr>
<td></td>
<td>Supplier specifications.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salt.</td>
<td>Food grade.</td>
<td>None.</td>
<td>None.</td>
<td>None.</td>
</tr>
<tr>
<td>Spices.</td>
<td>Decontaminated.</td>
<td>Spore forming organisms, e.g. Bacillus cereus, Clostridium spp.</td>
<td>Chemical residues, e.g. herbicides, fumigant.</td>
<td>Stones.</td>
</tr>
<tr>
<td></td>
<td>Frozen.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Meets Food Stds Code, Std 2.2.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sourced from registered RMP.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plastic bag (packaging).</td>
<td>Suitable as food contact material (HC</td>
<td>None.</td>
<td>None.</td>
<td>None.</td>
</tr>
</tbody>
</table>

^18 “None” means hazards are not reasonably likely to occur because they are not associated with the input or it is controlled through supplier agreements.
3.9.2.3 Identification of hazards at each process step

You should identify the hazards that are introduced into the product as a consequence of applying the process step itself. The potential impact of the process step on any existing hazard should also be considered during hazard analysis. Hazard analysis should be done for each step.

3.9.2.4 Identification of control measures

You should identify any control measures for each identified hazard at each process step.

A control measure is any action or activity that is applied to:

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

3.9.2.5 Uncontrolled hazards

**AP (RMP Specifications) Notice 2008 clause:**

10 Identification of risk factors and analysis of hazards

In addition to the requirements in sections 17(2) and (3) of the Act, a risk management programme must specify any uncontrolled hazards that are likely to be present in animal product leaving the physical boundaries of the risk management programme and you must be able to justify that this is appropriate considering the intended use of the product.

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:
• consider redesigning the process or adding 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 this decision, and the uncontrolled hazard must be clearly indicated in the hazard analysis. You should also consider whether you need to inform a further processor, retailer or consumer about the uncontrolled hazard so that food safety can be assured prior to consumption.

3.9.3 Critical Control Point (CCP) Determination

You should determine whether there are any CCPs in your process.

A CCP is a step in the process at which control of one or more hazards is applied and is essential for food safety.

To decide whether or not a step is a CCP, you need to determine if the control at that step is essential (by itself or in combination with other steps) to achieve any relevant regulatory limit or operator-defined limit relating to specific hazard(s).

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

• the degree of hazard control that is achieved at the step

• likelihood of failure; and

• consequence of control failure 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 approach to hazard analysis and CCP determination for each process covered by the RMP. This must be documented including justification for the hazards and CCPs identified. Justification may be based on information such as historical records, technical publications, COPs or information provided by NZFSA.

Tools that may be used include decision trees and tables that provide a series of questions to guide the user through the decision-making process. The decision tree and/or table
currently used by NZFSA has been adapted from the Codex decision tree for use by the animal products industry (see Figure 3G and Table 3H).

When you identify a CCP, the remaining HACCP principles must be applied (see 3.9.4 - 3.9.8). When there are no CCPs identified, verification, documentation and record-keeping still need to be applied (see sections 3.9.7 and 3.9.8).

3.9.3.1 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 must be clearly identified as market access CCPs, to ensure their appropriate external verification. The Recognised Agency will verify the effectiveness of any market access CCP against the relevant OMAR.
Figure 3G: Decision Tree for Hazard Analysis and CCP Determination

Consider process step and the inputs associated with it

Is there a hazard reasonably likely to occur on or in the product at this step?

YES

Justify

NO

Is there a control measure (s) for the hazard at this step?

YES

Identify control measure (s)

NO

Is the control measure (s) at this step essential to food safety as defined by a regulatory limit or an operator-defined limit?

YES

This step is a CCP

NO

This step is NOT a CCP

Consider next process step and the inputs associated with it
### Table 3H: Hazard Analysis and CCP Determination Template

<table>
<thead>
<tr>
<th>Process step.</th>
<th>Inputs.</th>
<th>Hazard reasonably likely to occur on or in the product at this step.</th>
<th>Justification.</th>
<th>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.</th>
<th>Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit or operator-defined limit? If yes, this step is a CCP. If no, this step is not a CCP.</th>
<th>CCP No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

To clarify the use of Table 3H, each column is discussed below. You should go through the series of questions for each step in the process. The hazard analysis must show any hazard that is uncontrolled at the end of the process. Examples of the use of this table can be found in a number of NZFSA Codes of Practice. See the Meat Code of Practice for one example.

**Column 1 - Process step**

Each process step should be written in column 1 in the order shown in the process flow diagram.

**Column 2 – Inputs**

All inputs 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
- 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 be based on company experience and records, scientific literature, surveys, industry reports, COPs, generic HACCP plans and other NZFSA guidance documents.

Column 5 – Question 1: Identification of control measures

You should identify the control measure for each hazard. The procedures for all control measures must be documented in the RMP (e.g. in supporting systems). The document number or title of the particular supporting system should be given in this table to facilitate verification and RMP review.

Hazards that are not completely eliminated at a step should be considered at the next step to ensure that the impact of succeeding steps is considered. In particular, bacterial hazards should be carried over to succeeding steps since there is potential for their growth.
Hazards unlikely to be affected by succeeding process steps (i.e. will not grow or increase), such as chemical residues and parasites, do not need to be carried over to each step 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, if it is uncontrolled.

**Column 6 - CCP determination**

Decide whether or not a step is a CCP by determining if the control at that step is essential, by itself or in combination with other steps, to achieve any regulatory limit or operator-defined limits for the specific hazard(s). If there is no regulatory limit or operator-defined limit, there is no CCP.
3.9.4 Establishing Critical Limits

You must define and justify critical limit(s) for each CCP. A critical limit is a criterion which separates acceptability from unacceptability at a CCP.

Critical limits must be measurable and linked to the achievement of a regulatory limit or operator-defined limit related to food safety. They should be parameters that can be monitored on an on-going basis to ensure consistent effectiveness of the process step to achieve the specified level of control.

You must document the:

- parameters to be checked
- limit for each parameter; and
- justification for each limit.

3.9.5 Establish CCP Monitoring

You must document monitoring procedures for each critical limit. These should include the:

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

Monitoring could be continuous (e.g. using an automatic measuring and recording device), or based on an established frequency or statistical sampling plan. The frequency must be adequate to ensure consistent control. Other factors to consider when establishing the frequency include: the nature of the product, the likelihood of failing the limits, the cost of monitoring, the consequence of failure (including risk to human health), and expected corrective actions (especially with respect to product disposition).

3.9.6 Establish Corrective Action

You must document corrective action procedures and ensure they are implemented when a critical limit is not met. Corrective action procedures should include:
• the identity of the person or position responsible for taking corrective action

• procedures for restoration of control

• procedures for control and disposition of non-complying product, including checking of product back to the last good result, where possible

• action to prevent a reoccurrence

• escalating response if preventative action fails; and

• records to be kept.

### 3.9.7 Establish Verification Procedures

You must document verification procedures to ensure that the CCP is implemented effectively, monitoring is occurring as written and that appropriate corrective action is taken when critical limits are not met. These procedures should include:

• the identity of the person or position responsible for ongoing operator verification

• procedures for operator verification activities to be undertaken

• frequency of operator verification activities

• follow up action to be taken if non-compliance occurs; and

• records to be kept.

These verification procedures may form part of operator verification (see section 3.16).

### 3.9.8 Establish HACCP Documentation and Records

You must document all matters relating to the application of HACCP within your RMP. Suitable records must be kept to be able to demonstrate that the HACCP part of the RMP has been implemented effectively, e.g. CCP monitoring records, CCP corrective action records and HACCP verification records.

### 3.9.9 Confirming the Application of HACCP

You should check the application of HACCP after completing the hazard analysis and CCP determination. The following should be considered:
• are the operator-defined limits appropriate and achievable?

• are the identified CCPs essential to comply with the regulatory limit(s) or operator-defined limits for particular hazard(s)?

• are the critical limits appropriate and achievable?

• can the critical limits be monitored effectively?

• are all the identified hazards adequately controlled by GOP 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).

3.10 Identification and Control of Risks to Wholesomeness

(Section 4 of the Animal Products Act)

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 NZFSA recommends that you systematically assess each input and step in the process to identify and control any wholesomeness risk factors.

It is unlikely that any risks to wholesomeness will be identified for animal materials or products intended for animal consumption.
### 3.10.1 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. This can be based on:

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

Opinions about what is offensive, unexpected or unusual will vary. Common sense should be used to determine any problems that would be offensive, unexpected or unusual. See Table 3I for examples of likely risks to wholesomeness.

#### Table 3I: Examples of Risks to Wholesomeness and their Controls

<table>
<thead>
<tr>
<th>Product</th>
<th>Wholesomeness Risk Factor</th>
<th>Examples of Control Measures</th>
<th>Supporting System (put actual doc no. and/or title)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole chickens.</td>
<td>Feathers</td>
<td>Correct set up of plucker. Inspection of birds.</td>
<td>Doc. xx</td>
</tr>
<tr>
<td>Milk (farm dairy operator).</td>
<td>Foreign or Objectionable Matter (insects, faeces, dirt or dust).</td>
<td>Ensure teats clean. Filter milk. Bulk milk tank secure from environmental contamination, lidded vats closed at all times except from emptying milk until cleaning complete.</td>
<td>Doc. xx</td>
</tr>
<tr>
<td>Shell eggs.</td>
<td>Roundworms</td>
<td>WORMING PROGRAMME FOR FREE-RANGE HENS.</td>
<td>Doc. xx</td>
</tr>
<tr>
<td>Mussel meat.</td>
<td>Pea crabs</td>
<td>Inspection and removal.</td>
<td>Doc. xx</td>
</tr>
<tr>
<td>Honey</td>
<td>Fermentation</td>
<td>Control of moisture content control. Heating.</td>
<td>Doc. xx</td>
</tr>
<tr>
<td>Meat</td>
<td>Spoilage</td>
<td>Temperature control. Hygienic practices.</td>
<td>Doc. xx</td>
</tr>
</tbody>
</table>
3.10.2 Controls for Risks to Wholesomeness

**AP (RMP Specifications) Notice 2008 clause:**

11 Control of hazards and other risk factors
(1) A risk management programme must contain sufficient procedures to ensure that
...
(2) The procedures referred to in subclause (1) must cover —
(a) good operating practice; and
(b) all matters set out in sections 17(2) and 17(3) of the Act; and
(c) any corrective action procedures that are to be applied in the event of loss of control, including —
(i) how control will be restored; and
(ii) how any affected animal material or animal product will be identified, controlled or disposed of; and
(iii) any measures to be taken to prevent recurrence of the loss of control;

Where you have identified a risk to wholesomeness, you must document:

- the control measures (see Table 3I for examples); and

- all other matters required by clause 11(2) of the RMP spec as listed above.

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, NZFSA recommends that you explain this clearly and provide references to the relevant controls for each identified risk factor. An example of how this can be done is shown in Table 3I.

**AP (RMP Specifications) Notice 2008 clause:**

7 Limits
A risk management programme must, in relation to each animal material or animal product described in clause 6(2), specify any relevant regulatory limits and any operator-defined limits in relation to —
(a)...
(c) risks to the wholesomeness of animal material or animal product.
8 Actions when limits are not met
A risk management programme must specify the actions to be taken if the limits in clause 7 are not met.
You are not required to set operator-defined limits for wholesomeness risk factors. However, you may 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.

3.11 Identification and Control of Risks from False or Misleading Labelling

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

- the Animal Product Regulations 2000, regulations 8 and 19
- Part 7 of the current Animal Products (Specifications for Products For Human Consumption) Notice
- Parts 1.1A and 1.2 of the Australia New Zealand Food Standards Code
- Part 1 of the Food (Safety) Regulations 2002; and where applicable
- the Animal Products (Specifications for Products Intended for Animal Consumption) Notice; and
- the Agricultural Compounds and Veterinary Medicines Act 1997.

When identifying risk factors, you should consider the type of animal material and/or product, its intended use and the requirements of:

- systems to authenticate claims, e.g. species, composition, active ingredients, organics, free range, GM free, claims of effectiveness; and
- specific consumer groups, e.g. religious groups, people with allergies.

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

If products are intended for export, you should ensure the requirements of the relevant market are met.

3.11.1 Identification of Risks from False or Misleading Labelling

You should 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. This can be based on:

- guidance in industry COPs
• knowledge / experience of your product and process (including from review of internal records and reports); and

• customer 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 3J for examples of likely risks to false or misleading labelling.

**Table 3J: Examples of Risks from False or Misleading Labelling and Their Controls**

<table>
<thead>
<tr>
<th>Labelling Risk Factor</th>
<th>Likely Cause</th>
<th>Control Measures</th>
<th>Supporting system (put actual doc no. and/or title)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect design (label content/format)</td>
<td>Lack of research into label content Using inaccurate or incomplete information</td>
<td>Conduct adequate research Checks on label design Sign-off before release to processing</td>
<td>Doc. xx</td>
</tr>
<tr>
<td>Process deficiencies resulting in the product not matching its label</td>
<td>Errors in processing, e.g. wrong product flow, inadequate separation Wrong formulation Cross contamination from equipment with unwanted ingredients, e.g. peanuts (allergens) Inputting wrong information into labeller, e.g. species Wrong packaging materials Changes in raw materials or suppliers (i.e. inadequate supplier quality assurance procedures)</td>
<td>Training and supervision Processing procedures Formulation control procedures Clean down Order of processing Compliance to raw material specifications Material tracking Inventory control Label checks</td>
<td>Doc. xx</td>
</tr>
</tbody>
</table>

### 3.11.2 Control of Risks from False or Misleading Labelling

*AP (RMP Specifications) Notice 2008 clause:*

11 Control of hazards and other risk factors

(1) A risk management programme must contain sufficient procedures to ensure that …

(2) The procedures referred to in subclause (1) must cover —

(a) good operating practice; and

(b) all matters set out in sections 17(2) and 17(3) of the Act; and
(c) any corrective action procedures that are to be applied in the event of loss of control, including —
   (i) how control will be restored; and
   (ii) how any affected animal material or animal product will be identified, controlled or disposed of; and
   (iii) any measures to be taken to prevent recurrence of the loss of control;

Where you have identified a risk to false or misleading labelling you must establish control measure(s) for them. You should document procedures to control each risk factor including all matters required by cause 11(2) of the RMP spec.

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, NZFSA 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 3J.

AP (RMP Specifications) Notice 2008 clause:

7 Limits
A risk management programme must, in relation to each animal material or animal product described in clause 6(2), specify any relevant regulatory limits and any operator-defined limits in relation to —
(a)…
(b) risks from false or misleading labelling or representation; and
8 Actions when limits are not met
A risk management programme must specify the actions to be taken if the limits in clause 7 are not met.

You are not required to set operator-defined limits for false or misleading labelling risk factors. However, you may 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.

3.12 Identification and Competencies of Responsible Persons

AP (RMP Specifications) Notice 2008 clause:

15 Identification and competency of responsible persons
(1) A risk management programme must specify the identity (either by position,
(designation or name) of—
(a) the day-to-day manager of the risk management programme; and
(b) those persons authorising all or part of the risk management programme on behalf of the operator in accordance with clause 19(1)(c); and
(c) those persons performing key tasks under the risk management programme including monitoring, corrective action, and operator verification activities.

(2) A risk management programme must specify the competencies needed by the persons identified under subclause (1) to enable the effective operation of the risk management programme.

(3) A risk management programme must provide for the keeping of records, in an easily accessible form, demonstrating that the competencies documented under subclause (2) have been achieved and maintained.

3.12.1 Identification of Responsible Persons

You must identify responsible persons at appropriate places within the RMP in any format that suits the operation. These persons include:

- day-to-day manager of the RMP (see section 3.4.1)
- authoriser(s) of the RMP (see section 3.19.2)
- persons responsible for key tasks (see section 3.12.1.1); and
- persons requiring specific mandatory competencies (see section 3.12.1.2).

For effective implementation of the RMP, the responsible persons and back-up staff must have an appropriate level of competency in the application of HACCP principles and knowledge of the RMP. You may do this by on-the-job training, have the responsible persons attend training courses and/or may have them assessed against relevant competency standards, e.g. those available from the NZ Qualifications Authority. The available NZQA standards include:

a. 12315: Supervise a seafood processing operation under a HACCP System
b. 12316: Coordinate the development and verification of a HACCP plan for a seafood processing operation
c. 12624: Monitor a meat processing operation under a HACCP System
d. 12625: Supervise a meat processing operation under a HACCP System
e. 12626: Coordinate the development and verification of a HACCP plan for a meat processing operation

f. 19514: Explain the application of HACCP principles

g. 19515: Explain development and implementation of RMPs under the APA

h. 16667: Coordinate the development and verification of a HACCP plan in the dairy industry

i. 18407: Explain the workplace application of HACCP in the dairy industry

3.12.1.1 Persons responsible for key tasks

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

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

The task assignments will depend on the complexity of the operation. In simple operations, it may be that one person is responsible for all of the activities. In a more complex operation, several people are likely to be responsible for different parts of the programme. You may designate these responsibilities to different people at different times, e.g. by roster. If this is the case, then the method of designation must be documented, including who is responsible for ensuring that this happens. You should also document how back-up personnel are assigned to cover for holidays and absences.

3.12.1.2 Persons required to have specific mandatory competencies

There are some mandatory competency requirements for persons who are responsible for certain specific operations / activities, for example those who are responsible for supervising canning operations. These mandatory competencies are listed in the:
3.12.2 Competencies of Responsible Persons

Once you have identified the responsible persons, you must document their required competencies for carrying out their tasks effectively. An example of how you could do this is shown in Table 3K.

You must keep training records for each staff member with responsibilities under the RMP.

Table 3K: Competencies of Responsible Persons

<table>
<thead>
<tr>
<th>Person</th>
<th>Authorities and responsibilities</th>
<th>Training, knowledge or experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operator of RMP</td>
<td>Legal representative for the RMP (see section 3.2)</td>
<td>Has a good understanding of relevant regulatory requirements under the APA including operator duties and the Food Standards Code (for human consumption)</td>
</tr>
<tr>
<td>Day-to-day manager(s) of the RMP (including any deputies)</td>
<td>Responsible for the day-to-day management of the RMP (see section 3.4.1)</td>
<td>Has:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- a thorough understanding of RMP requirements, e.g. through experience in developing an RMP or by meeting an appropriate RMP NZQA (New Zealand Qualifications Authority) Unit Standard</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- appropriate technical competencies, e.g. relevant scientific, food technology or food safety qualifications which may be demonstrated by meeting an appropriate HACCP coordinator NZQA Unit Standard</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- a complete knowledge of the operations, processes and systems that are included in the RMP, e.g. through on the job training</td>
</tr>
<tr>
<td>RMP authoriser(s)</td>
<td>Signs off the RMP documents and any amendments to the documents (see section 3.19)</td>
<td>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</td>
</tr>
<tr>
<td>Person</td>
<td>Authorities and responsibilities</td>
<td>Training, knowledge or experience</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Person(s) undertaking document checks and validation RMP</td>
<td>Confirms that the RMP is appropriate, complete, complies with legal requirements, and is implemented effectively</td>
<td>Same as for the day-to-day manager of the RMP but only in relation to the part(s) of the RMP they are responsible for confirming</td>
</tr>
<tr>
<td>Persons responsible for control activities</td>
<td>See sections 3.8, 3.9, 3.10 and 3.11</td>
<td>Has thorough knowledge of: - the relevant operations, processes and systems in the RMP, - the control measures for each activity they are responsible for and how to recognise loss of control and - the appropriate response when there is a loss of control</td>
</tr>
<tr>
<td>Persons responsible for monitoring activities</td>
<td>See sections 3.8 and 3.9</td>
<td>Same as for persons responsible for control activities. They may also have an appropriate supervisor NZQA Unit Standard</td>
</tr>
<tr>
<td>Persons responsible for corrective action activities</td>
<td>See sections 3.8, 3.9 and 3.13</td>
<td>Same as for persons responsible for monitoring activities. They also must have the ability to identify product non-conformances. A supervisor and/or HACCP coordinator NZQA Unit Standard would be appropriate for this role</td>
</tr>
<tr>
<td>Operator verification activities</td>
<td>See sections 3.8, 3.9 and 3.16</td>
<td>Same as for day-to-day manager of the RMP. They also must have the ability to interpret records and results. This may be demonstrated by appropriate internal audit training</td>
</tr>
<tr>
<td>Recall Manager</td>
<td>See section 3.14</td>
<td>Has a thorough understanding of Recall policies and procedures. They may also have an appropriate HACCP coordinator NZQA Unit Standard</td>
</tr>
<tr>
<td>Specific mandatory competencies</td>
<td>See section 3.12.1.2</td>
<td>The required competencies are mandated in legislation</td>
</tr>
</tbody>
</table>

3.13 Corrective Action for Unforeseen Circumstances

**AP (RMP Specifications) Notice 2008 clause:**

11 Control of hazards and other risk factors

(1) A risk management programme must contain sufficient procedures...

(2) The procedures referred to in subclause (1) must cover —

(c) any corrective action procedures that are to be applied in the event of loss of control, including —
(iv) where the loss of control is due to unforeseen circumstances and there is no specific corrective action already documented, nomination of a suitably skilled person to manage the corrective action, recording of the issue and corrective actions taken, and reporting of such matters to the recognised risk management programme verifier without unnecessary delay.

In addition to the corrective actions for non-compliances to documented procedures and parameters, you must also document in your RMP, corrective action procedures for unforeseen circumstances, for example if there is a fire in part of the premises or flooding occurs. This should include documenting who is responsible for nominating a suitably skilled person 19 to manage these corrective actions. The suitably skilled person is responsible for:

a. identification, retention and assessment of non-complying product (including as appropriate a review of relevant processing records, analyses undertaken, inspection of animal material or animal product, expert advice, literature review etc)

b. product disposition20 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); and

c. reporting to the recognised verifier including:

i. a description of the problem and the affected animal material or animal product

ii. a summary of the assessment made

iii. the decision on the disposition of the animal material or animal product; and

iv. any actions taken to prevent recurrence of the non-compliance.

19 The actual person should not be nominated until a problem occurs, as the skills needed will depend on the nature of the problem. This person may be a staff member or may be an external consultant with expertise relevant to the situation. This person should not be the recognised verifier of the RMP as this would create a conflict of interest during verification.

20 Exception reporting and disposition of non-conforming dairy material and dairy product must be undertaken as outlined in DPC1: Animal Products (Dairy) Approved Criteria for General Dairy Processing.

3.14 Recall Procedures

*(Section 17 (2) (c) of the Animal Products Act)*

**AP (RMP Specifications) Notice 2008 clause:**

14 Recall of animal material or animal product

(1) For the purposes of section 17(2)(c) of the Act where, due to the nature of the animal material or animal product it is possible to recall it from trade, distribution or consumers, a risk management programme must contain a recall procedure, including —

(a) the criteria for deciding when a recall will be initiated; and

(b) how retrieval and disposition of the relevant animal material or animal product will be managed.

(2) A risk management programme must contain a system for notifying the following people as soon as possible when animal material or animal product is recalled from trade, distribution or from consumers because it is not or may not be fit for its intended purpose —

(a) the Director-General; and

(b) the recognised risk management programme verifier or recognised risk management programme verifying agency.

There may be times when non-complying animal material or animal product is produced. If the non-compliance is detected before any of the affected products are released for distribution or sale, you should take appropriate corrective actions to fix the problem and determine the proper disposition of affected products. However, if some or all of the products are in the distribution chain or with the consumer, then you may need to initiate a product recall to recover the products as quickly as possible. Your decision to recall product should be based on whether or not the product is fit for its intended purpose, considering both safety and suitability issues. 21

You must document recall procedures where, due to the nature of the product, it is possible for your product to be recalled. The exception is where your product is intended to be

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21 You may decide to withdraw product if it is safe and suitable, but does not meet non-regulatory (commercial) requirements. In this case a formal recall is not required.
consumed immediately. Your recall procedure should cover voluntary recalls, and recalls required by the Director-General, under section 85 of the APA 1999.

You should include the following when establishing your recall procedures:

   a. a system to identify and trace all inputs, work-in-progress and final products
   b. responsibilities and authorities for recalls, including recall management and notification to the Director-General and the recognised RMP verifying agency
   c. media statements, including a draft recall notice
   d. criteria for deciding whether a recall is necessary (i.e. impacts on fitness for intended purpose)
   e. communication and documentation, including notification to the Director-General and the recognised verifying agency
   f. product recovery and disposition
   g. corrective and preventive action; and
   h. review of recall effectiveness.

Guidance documents which may assist you to develop appropriate recall procedures are available on the NZFSA website: Food Recalls for Manufacturers.


3.15 Validation

See section 4 for more detail on validation.

AP (RMP Specifications) Notice 2008 clause:

18 Document checks and validation
(1) A risk management programme or any significant amendment to a risk management programme, where necessary, must contain —
(a) evidence to demonstrate the effectiveness of the risk management programme; or
(b) a protocol containing —
   (i) details of the evidence to be collected to demonstrate the effectiveness of the risk management programme, and
(ii) a proposal for the disposition of animal material or animal product until the effectiveness of the programme has been demonstrated.

You must confirm that the RMP is valid. Where there is insufficient evidence to demonstrate the effectiveness of the RMP, you may need to develop a protocol. You must adhere to the timeframes for completion of the protocol unless otherwise agreed with the recognised evaluator or NZFSA.

3.16 Operator Verification

AP (RMP Specifications) Notice 2008 clause:

16 Operator verification
(1) A risk management programme must specify an operator verification system including —
(a) the activities to be performed in relation to the risk management programme, and their frequency; and
(b) any actions to be taken when all or part of the risk management programme is not effective; and
(c) any recording and reporting requirements.
(2) A risk management programme must contain a mechanism for ensuring that, wherever possible, persons carrying out operator verification are independent of the activities being verified.

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

- is still applicable to the operation
- remains in compliance with all legislative requirements
- continues to be implemented as written; and
- is producing material suitable for processing or product fit for its intended purpose.

Ongoing operator verification activities may include:

- review of monitoring records
- product tests
- review of non-conformance and corrective action records
• calibration checks

• internal audits; and

• periodic review of the complete RMP.

You should document the verification activities including:

• when, how, and where they will be carried out

• the identity of the person(s) or position who will carry them out

• actions to be taken if deficiencies are found; and

• records to be kept to show that verification has been done as planned.

You must define the frequency of verification activities, which may be performance based and vary for different parts of the RMP.

Ideally persons 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.

3.17 Notification Requirements

AP (RMP Specifications) Notice 2008 clause:

13 Notifications
(1) A risk management programme must contain a procedure for notification of the Director-General in writing, without unnecessary delay, of any change to the name or position or designation of the person(s) responsible for the day-to-day management of the programme.

(2) A risk management programme must contain a procedure for notification of the Director-General of any emerging, new or exotic biological hazards or new chemical hazards that come to the operator's notice in relation to the programme as soon as practical after their discovery.

(3) A risk management programme must contain a procedure for notifying the recognised risk management programme verifying agency in writing, without unnecessary delay, of the following issues relating to the operation of the programme —

(a) any significant concern about the fitness for intended purpose of animal material
or animal product:

(b) where the cumulative effect of minor amendments necessitates the registration of a significant amendment to the programme as provided in section 25 of the Act:
(c) where the risk management programme is no longer considered to be effective:
(d) where the premises identified as being used by the programme are not or no longer suitable for use:
(e) where anything within the physical boundaries of the programme is used for additional purposes or by other operators and the programme has not adequately considered relevant hazards or other risk factors.

You must have documented procedures for how you notify NZFSA or the recognised RMP verifying agency of the requirements in clause 13.

3.18 Provision for Verification Activities and Verifiers Rights

(Sections 17 (4) of the Animal Products Act)

**AP (RMP Specifications) Notice 2008 clause:**

17 Allowing verifiers to carry out verification functions and activities

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

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

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

You must make provision in the RMP for verification activities and verifiers rights, as described in the specification above. You can do this by copying the specification directly into the RMP or by referencing clause 17 of the Animal Products (Risk Management Programme Specifications) Notice 2008.

You must also get written confirmation from a recognised RMP verifying agency indicating that they have agreed to provide verification services for your RMP. This is typically a letter which is considered to be part of the RMP and must be submitted with the other documentation required for registration.

You are responsible for contracting the services of a recognised verifier. All recognised verifying agencies are listed on NZFSA web site

http://www.nzfsa.govt.nz/animalproductsregisters-listsrecognised-agencies/index.htm (non-dairy) and


See section 7.4 for further details about external verification.
3.19  Document Control

3.19.1  General

(Sections 17 (1) (a) and (d) of the Animal Products Act)

AP (RMP Specifications) Notice 2008 clause:

19 Document control

(1) Every document or part of a document that makes up a risk management programme must be —
(a) legible; and
(b) dated or marked to identify its version; and
(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 system; and
(d) available in a readily accessible form when required to any person with responsibilities under the programme.

(2) A risk management programme must contain procedures for effective document control of the documents that form the risk management programme including how —
(a) significant and minor amendments will be made to the risk management programme so that the programme is current and reflects the actual operation; and
(b) the amendments, or the nature of the amendments to the programme will be identified or described; and
(c) documents are authorised prior to issue and use; and
(d) all amended parts of the risk management programme will be removed from use and replaced with the current versions at all locations to which it has been distributed without unnecessary delay after authorisation and, where necessary, after registration in accordance with section 25 of the Act.

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

(4) An operator must ensure that the registered risk management programme and all reference material relating to the risk management programme, and any archived documents are readily accessible, or can be retrieved and made available within two
You must document all components of the RMP. You should ensure that the format used for the RMP is user friendly for relevant staff, the evaluator and external verifiers.

There is flexibility in how you can document your RMP. You may reference documents such as a Code of Practice, HACCP plan or other documented procedures rather than reproducing them in the RMP. These documents then become part of the RMP. When only parts of a referenced document apply to your RMP, you must show which parts of the document are included in or excluded from the RMP. You can do this by:

- using different formats for parts, e.g. bolding, highlighting, using boxes, colour-coding; or
- describing those parts that are excluded, e.g. all references to animal welfare or overseas market access requirements.\(^\text{22}\)

All documents relevant to your RMP must be made available to evaluators, verifiers and regulators, as necessary. **Made available** means that no matter where the documents are stored, they can be mailed, couriered, faxed, emailed or transferred by other means within 2 working days.

### 3.19.2 Authorisation of Documents

All your RMP documents must be authorised by a person with appropriate authority before the RMP is registered and after any amendments are made. This must be done by a person with appropriate authority as required by the RMP Specifications 2008 clause 19(1)(c).

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

- signing a detailed document list or contents page that shows the current dates or versions and number of pages of each document or part-document; or

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\(^{22}\) Inclusion of an export requirement into the RMP, either directly or by reference, means that it must be evaluated against the NZ standard and registered as part of the RMP. Once registered, the company must comply with the RMP. It is recommended that these requirements are not integrated into the RMP.
• appropriate electronic means so long as there are sufficient controls on access to passwords, authorisation codes, electronic signatures.

3.19.3 Making Amendments

Your document control procedures must explain how you make a significant or minor amendment. These should include procedures for:

• identifying the need for an amendment

• documenting the amendment

• deciding if the amendment is significant (as per Section 25 of the APA and as clarified in the RMP Specs 2008 clause 22 and Appendix G of this manual), with appropriate justification and if significant, proceeding with evaluation and registration described later in this manual

• authorising and issuing the amendment and removing obsolete documents; and

• implementing the amendment.

3.19.4 Identification of Amendments

You must document how amendments to the RMP are identified. Examples of ways to indicate amended parts of an RMP are:

• increasing the version number of amended pages or sections

• placing a line in the margin of relevant pages showing where amendments have been made

• highlighting or otherwise changing the format of the amended sections; or

• describing the changes in an amendment page.

3.20 Requirements for Records

(Sections 159 and 160 of the Animal Products Act)

AP (RMP Specifications) Notice 2008 clause:

20 Requirements for records
(1) An operator must include record keeping procedures in the risk management programme to ensure that all records necessary to demonstrate compliance with the documented programme are —
   (a) legible; and
   (b) stored for four years, or for the shelf life of the product to which the records relate (whichever is longer), in a manner which protects the records from damage, deterioration or loss; and
   (c) can be retrieved and made available to persons referred to in subclause (3) within two working days of any request.

(2) Records relating to the risk management programme’s monitoring, corrective action and operator verification activities must include —
   (a) the date and where appropriate the time of the activity; and
   (b) a description of the results of the activity; and
   (c) a means to identify the person or persons who performed the activity.

(3) An operator must make all records relevant to the risk management programme available to the following persons on request —
   (a) recognised persons; and
   (b) animal product officers; and
   (c) the Director-General; and
   (d) persons authorised by the Director-General.

3.20.1 Electronic Records

Where records are kept electronically, you must document the systems to manage access to files and ensure appropriate back-ups are made. You must also ensure that:

- electronic records cannot be altered without authorisation
- any alterations are noted; and
- records are accessible to relevant personnel (e.g. internal auditor, verifier).

3.21 Specific Requirements for Dual Operator Butchers

(Section 71 of Animal Products Act)

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

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

DOBs must have a registered RMP before trading regulated animal product (see definition in appendix A) to ensure that any such product is fit for its intended purpose.

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

• the identification and control of the risk factors introduced to the regulated product from homekill or recreational catch that is processed in the same place

• control measures to ensure that homekill and recreational catch products are processed and stored separately from and are not mistaken for regulated animal products and do not enter trade (except for rendering as permitted under APA s69(3)(b)); and

• control measures to ensure that product from the business is not exported.

A DOB must also document specific inventory control measures to comply with the Animal Product (Homekill and Recreational Catch Service Provider Records and Information) Specifications, which gives the minimum requirements for record-keeping. This can be found at the following web site:


NZFSA has developed an RMP template to assist preparation of DOB RMPs. This template has been approved so RMPs that are fully based on it do not need to be evaluated prior to registration. See http://www.nzfsa.govt.nz/animalproducts/subject/dual-butcher/index.htm for the template and other useful resources.
4 Checks and Validation

4.1 Introduction

This section discusses what you need to do once you have developed your RMP. You must check that the:

- RMP documentation is complete and complies with all relevant legislation under the APA
- premises and equipment are ready to operate; and
- RMP will be capable of consistently producing animal material or animal product that is fit for its intended purpose.

To demonstrate that the RMP will be capable of consistently producing animal material or animal product that is fit for its intended purpose, you must show that GOP requirements are being met. If there are regulatory and or operator-defined limits applicable to your product or process, you may also need to validate the RMP to confirm its effectiveness to consistently achieve those limits.

If there is insufficient evidence to demonstrate the effectiveness of the RMP at the time of application for registration (e.g. for new businesses or new process), you may need to document a protocol for the collection of evidence, refer to section 4.4.

The requirements for checks and validation are summarised in Table 4A and explained in detail in the following sections.

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23 Currently validation may operate slightly differently for dairy operators in that engineers may be used as part of the process. It is intended that this be aligned with the non-dairy requirements with any amendment to the specification for recognised agencies and persons.
Statement of Policy: Operator Responsibilities during Registration of an RMP (V1)

(1) Documentation checks and validation

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

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

(b) premises and equipment are ready to operate in accordance with the programme and other legislative requirements; and

(c) RMP will be capable of consistently producing animal material or animal product that is fit for intended purpose.

AP (RMP Specifications) Notice 2008 clause:

18 Document checks and validation

(1) A risk management programme or any significant amendment to a risk management programme, where necessary, must contain —

(a) evidence to demonstrate the effectiveness of the risk management programme; or

(b) a protocol containing —

(i) details of the evidence to be collected to demonstrate the effectiveness of the risk management programme, and

(ii) a proposal for the disposition of animal material or animal product until the effectiveness of the programme has been demonstrated.
Table 4A: Summary of Requirements for Demonstrating Effectiveness of the RMP

<table>
<thead>
<tr>
<th>Requirements for demonstrating effectiveness of the RMP</th>
<th>Evidence for demonstrating effectiveness of the RMP</th>
<th>When is the evidence required</th>
<th>Is a protocol needed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Checks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. RMP documentation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• is complete; and</td>
<td>• RMP document;</td>
<td>Before application for registration of RMP</td>
<td>NA.</td>
</tr>
<tr>
<td>• complies with all relevant legislative requirements</td>
<td>• the use of a checklist is recommended to indicate where the relevant legislative requirements have been addressed within the RMP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Premises and equipment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ready to operate</td>
<td>Actual design and construction of premises is complete; equipment is available and ready to operate</td>
<td>Before application for registration of RMP</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>Commissioning reports for certain equipment (e.g. retort, drier)</td>
<td>Before or after registration of RMP</td>
<td>Yes, if commissioning after registration</td>
</tr>
<tr>
<td>c. GOP check</td>
<td>Records of compliance to:</td>
<td>Before or after registration</td>
<td>A protocol is not required for most GOP operations</td>
</tr>
<tr>
<td>Achievement of GOP requirements</td>
<td>• documented procedures (e.g. monitoring records, internal audit reports); and</td>
<td></td>
<td>See Appendix F for those operations that would require a protocol</td>
</tr>
<tr>
<td></td>
<td>• measurable GOP requirements (e.g. product load out temperatures)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

24 Also see section 6.3.1 Pre-registration Assessment, for the pre-assessment procedure of RMP documentation before the premises is complete.
### Checks

#### RMP Documentation

You must check that all of the required components of an RMP have been documented and are complete. You must also check that the RMP documentation meets all relevant legislative requirements including any regulatory limits and GOP requirements contained within specifications or approved criteria, by systematically checking it against the legislation. This must be completed before the application for registration of the RMP.

To assist the evaluation process (refer section 5) it is recommended that you prepare a checklist that lists the relevant legislation and references where these requirements are addressed in the RMP.

#### Premises and Equipment are Ready to Operate

You must ensure that the design and construction of premises and equipment meets the requirements of the APA. The premises must be complete and all equipment necessary for the processes described in the RMP must be available, ready to start processing and have been viewed by the evaluator as part of the evaluation before registration of the RMP.

Certain equipment (e.g. retorts, rendering driers, pasteurisers) may require commissioning by a competent person. If this activity is to be done after registration, then the
commissioning must be included in the protocol (see section 4.4). A commissioning report should be made available to the evaluator when required.

### 4.2.3 Demonstration of Compliance with GOP Requirements

You must demonstrate that the RMP meets regulatory requirements for GOP. Procedures for meeting these requirements should be documented in the supporting systems, e.g. hygiene and maintenance, personnel health, approved chemicals, water quality. In most cases the checks referred to in section 4.2 will be sufficient evidence but in some cases data will be needed (refer to Appendix F for those supporting systems that require data as evidence for demonstrating effectiveness). Where this is needed you should make any existing compliance records available to the evaluator and if such evidence is not available during the evaluation (e.g. new processes or operations), a protocol will be required (see section 4.4).

### 4.3 Validation

You must provide evidence to demonstrate that when the RMP is implemented as documented, the criteria defining the product’s fitness for intended purpose, and particularly the regulatory limits and operator-defined limits are consistently met.

This will generally involve product testing and/or the measurement of process parameters.

Where available, historical data may be used to show that a process is consistently able to meet the criteria (e.g. microbiological databases, final product testing results). An advantage of using historical data, particularly if it has been collected over a long period, is that product/process variability due to factors such as season, raw material sources, and work shifts will be reflected in the results.

When using historical data, consider how applicable it is to the process covered by the RMP as it may have been collected for a different purpose and under different conditions. For example, if raw materials have changed or if the data collection methodology has changed it may be inappropriate to use historical data to validate current procedures.

You must consider the following when undertaking validation:

- any hazards that may already be controlled by the supplier when establishing incoming hazard levels
- the use of calibrated equipment when any critical measurements are taken
- statistical sampling of each batch for a number of batches, including inputs as well as final product
- the use of challenge tests 25 where appropriate
- if there is high variability within the operation then more sampling will be required to ensure that the process design is capable of dealing with all variables likely to be encountered
- if initial test results are unsatisfactory (i.e. outside an acceptable limit) it is not acceptable to simply retest the same batch or the same product samples until a satisfactory result is achieved.

You may use an external competent person (e.g. consultant) to undertake validation including preparing the validation report and where necessary a protocol.

### 4.3.1 Achievement of Regulatory Limits

You must collect evidence to demonstrate that the relevant regulatory limits are being met.

Regulatory limits may be expressed as product requirements (such as water activity), performance criteria (such as a certain log reduction of a pathogen) or process parameters (such as thermal processing parameters). See section 3.6.3.1 for a further explanation of regulatory limits. The type of data required will depend on how the regulatory limit has been expressed. If a regulatory limit is expressed as the level of hazard in a final product, then results of end product testing will be needed. If the limit is expressed as a process parameter, then measurements of the particular process parameter will be expected.

If there is insufficient evidence when applying for RMP registration, you must provide a protocol that describes how data will be collected to demonstrate achievement of the regulatory limit (see section 4.4).

Further guidance on validation requirements for specific processes can be found in NZFSA COPs. For example, guidance on the validation of uncooked comminuted fermented meats is given in the Guidelines for the Production of Uncooked Comminuted Fermented Meat (UCFM) Products, and guidance on the validation of further processing operations for non dairy products is given in the Further Processing code of practice.

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25 Challenge testing generally involves subjecting a product with a known level of hazard to the intended process to determine whether the required hazard reduction is achieved.
4.3.2 Achievement of Operator-defined Limits

To demonstrate the achievement of an operator-defined limit, you must first collect evidence to demonstrate that this limit has been appropriately set for that product, and then you must provide evidence that it will be met.

Operator-defined limits may be expressed as product requirements (such as pH), performance criteria (such as a certain log reduction of a pathogen) or process parameters (such as cooking parameters to ensure a specified microbiological level is achieved). See section 3.6.3.2 for a further explanation of operator-defined limits. The type of data required will depend on how the operator-defined limit has been expressed. If an operator-defined limit is expressed as the level of hazard in a final product, then results of end product testing will be needed. If the limit is expressed as a process parameter, then measurements of the particular process parameter will be expected.

If there is insufficient evidence when applying for RMP registration, you may need to provide a protocol that describes how data will be collected to demonstrate achievement of the operator-defined limit (see section 4.4).

A protocol is not required when the evidence only involves demonstrating compliance to documented procedures (i.e. no data is collected). A protocol is also not required for any operator-defined limits related to wholesomeness.

4.3.3 Resources to Assist in Validation

The following resources may be used to assist in the validation process, either when demonstrating the appropriateness of a limit or when collecting evidence to demonstrate that a limit will be met:

- references from reputable scientific literature etc (e.g. COPs, international standards, journal articles)
- mathematical modelling programmes.
- previous validation studies or historical knowledge on performance of the control measure. For this to be possible you must ensure that the conditions (e.g. raw materials, relevant hazards, combinations of control measures, intended use, distribution) in their particular operation do not differ from the conditions under which the control measure was previously validated
- validation trials and experimentation
• challenge testing
• NZFSA COPs

4.4 Development and Implementation of the Protocol

When there is insufficient evidence to demonstrate the effectiveness of the RMP at the time of application for registration (e.g. for a new businesses or a new process), you may need to document a protocol for collection of evidence.

A protocol is not required for most GOP procedures.

4.4.1 Developing the Protocol

The protocol must contain:

• details of the evidence required and how it is to be collected
• a proposal for the disposition of animal material or product produced during implementation of the protocol; and
• a timeframe for completion of the protocol.

You may use an external competent person to design and document the protocol or parts of it, e.g. to design sampling plans or to confirm the capability of complex machinery such as retorts and rendering dryers.

The protocol will need to be submitted to the recognised evaluator as part of the evaluation, and NZFSA when applying for registration.

4.4.1.1 Contents of a protocol

The protocol should include the following information, as appropriate:

1. Scope/purpose
   • person responsible for protocol
   • description of the specific aspects of the process(es) or operation(s) to be validated
   • product to be produced.

2. Competencies
• mandatory qualifications, when appropriate (e.g. thermal processing)
• intended use of any technical expert and details about the expert’s competence.

3. Commissioning of equipment
• details of the equipment that will be commissioned and how this will be done.

4. Criteria against which the effectiveness will be determined:
• regulatory limits (if any)
• operator-defined limits (if any)
• critical limits (if any)
• GOP requirements (for procedures requiring validation as listed in Appendix F).

5. Trial design
You should consider the following trial design parameters and incorporate variations where necessary to cover likely trial outcomes (valid, not yet fully valid, not valid) when developing the protocol:
• specific process step(s) that will be studied
• specific trial conditions to be used including processing variables (e.g. throughput, size and configuration of product, equipment settings, ingredients) and other variables that impact on the operation, e.g. season, work-shift, processing days
• the data to be collected (e.g. time, temperature, humidity, moisture content, specific microorganisms)
• sampling plan:
  The sampling plan should indicate where, when and how the samples are to be taken. Ideally, statistical-based sampling plans should be used. However, it is recognised that for practical reasons such as cost, time, etc this may not be feasible. You must at least develop a sampling plan that specifies a sufficient number of samples and/or process runs/batches to provide assurance of the effectiveness of the RMP
• test methods (details as appropriate), laboratory that will do the testing
the proposed trial start and completion dates. It is generally expected that validation is completed within four working weeks unless the processing schedule makes this impractical. Where processing is discontinuous or production volume is low, the validation may be completed over the equivalent of ten processing days, and without unnecessary delay; and

- method for analysing results.

6. Product disposition

- how the product resulting from the trials is to be disposed of. Disposition options include release as is, restricted release, rework, dump or burn, and will depend on the results of the trial.

4.4.2 Implementation of the Protocol

Once the RMP is registered, operations producing product for trade can commence. You must follow the protocol and any conditions imposed by NZFSA at registration, and collect data over the stated period. If the protocol needs to be changed, e.g. because the design is not practical or the proposed process is not producing acceptable results, you should discuss this with the evaluator and, if required, provide them with further documentation to support the agreed changes.

The external RMP verifier will check that the protocol is being followed and is completed during any verification visit.

4.4.3 Reporting Protocol Results

Immediately after completion of the protocol, you should prepare a report and submit this to the evaluator for assessment. The report should include the following:

- results from process records, test results, certificates of analysis, and other records collated in an appropriate way for easy review (e.g. tabulated, graphed)

- analysis or interpretation of the results

- conclusion regarding the effectiveness of the RMP to achieve the criteria

- confirmation that product disposition occurred as agreed; and

- any significant amendments to the RMP (see section 7.5.1).
Refer to section 5.5 for the procedures to be followed to complete the registration process.

4.5 Validation Examples

The following provides examples of how a regulatory limit or operator-defined limit may be validated26.

4.5.1 Evidence to Show Achievement of Regulatory Limits

4.5.1.1 Where the regulatory limit is a product requirement:

Example 1: Limit for a biological hazard (e.g. absence of Listeria monocytogenes in 25 g of packaged heat treated meat paste)

a. Conduct a hazard identification and analysis. Identify the regulatory limit appropriate to the hazard and the product. Identify any other regulatory limits, that assist in achievement of this product regulatory limit, e.g. such as performance criteria (log reduction) or process parameters (time/temperatures).

Also consider other microbiological hazards associated with your product and process at this stage, and whether they have a regulatory limit and or/similar control measures that may be able to be validated together.

b. Reference New Zealand or international literature that confirms that the chosen measures are capable of and appropriate for achieving the regulatory limit. Codes of Practice may be useful in obtaining information for validation.

c. Determine own performance criteria by the following steps, as appropriate:

- establish incoming microbiological load of the pathogen, unless already well established within food sector
- establish reduction of microbiological pathogens required to meet regulatory limit for product
- develop process to meet product requirements (including establishment of key process parameters for intervention(s))

26 Also see more detailed validation guidance in product specific NZFSA COPs, e.g. the Further Processing COP.
• prove achievement of regulatory limit.

Example 2: Limit for a chemical hazard e.g. 10mg/kg sulphite in dried apricots, 125µg/200ml Vitamin A in vitamin fortified milk powders, the level of histamine in fish or fish products must not exceed 200 mg/kg.

a. Identify the regulatory limit appropriate to the hazard and the product.

b. 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 NZFSA or international information, e.g. temperature controls to limit toxin development, chemical degradation curves, processing losses.

c. 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.

d. Prove achievement of the regulatory limit. Samples (taken from commercial production runs) must be tested or achievement demonstrated by other acceptable means to NZFSA, e.g. for histamine.

   Where sampling occurs, it is recommended that 3-5 production batches are tested taking:

   • at least 3 samples per batch of homogenous material;
   • at least 8 samples per batch of non-homogenous material.

4.5.1.2 Where the regulatory limit is a performance criterion:

Example: Limit for a biological hazard (e.g. 6 log reduction for Listeria)

a. Conduct a hazard identification and analysis. Identify the regulatory limit appropriate to the hazard and the product.

   Reference any other regulatory limits if applicable, that assist in achievement of this performance regulatory limit, such as process parameters to be applied at a process step
to achieve this log reduction.

Also consider other microbiological hazards associated with your product and process at this stage, and whether they have a regulatory limit and or/similar control measures that may be able to be validated together.

b. Reference New Zealand or international literature that confirms that the chosen measures are capable of and appropriate for achieving the regulatory limit.

Establish incoming microbiological load of the pathogen unless already well established within food sector.

Develop process to meet performance criterion (including establishment of key process parameters for intervention(s)).

Prove achievement of the regulatory limit e.g. by establishing the pathogen microbiological load in the food post-intervention to determine the effectiveness of the intervention, or using a predictive modelling programme to demonstrate that the required reduction is achieved (e.g. Tom Ross Model for UCFM).

4.5.1.3 Where the regulatory limit is a process parameter

Example: Limits for a biological hazard to eliminate *Listeria monocytogenes*: by application of time and temperature requirements for cooking raw poultry meat.

a. Conduct a hazard identification and analysis. Identify the regulatory limit(s) appropriate to the product.

b. Develop process and include the regulatory limits (or equivalent alternatives where permitted).

c. Prove achievement of the regulatory limit e.g., achievement of those parameters using calibrated equipment.

4.5.2 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. For example setting a limit for water activity in dried product, or a microbiological limit for RTE product where there is no limit in the legislation.

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

- where the limit came from (e.g. industry or NZFSA COP, literature, an overseas regulatory agency, own trials)
- what hazard and food the limit applies to
- why the limit is set at the particular level.

4.5.3 Evidence to Show Achievement of Operator-defined Limits

The evidence will be the same as described for regulatory limits.

4.6 Amendments to the RMP

When amending an RMP you must consider whether validation is needed and where it is necessary, ensure that it is undertaken in accordance with the requirements of this section. For further information on the requirements when amending an RMP refer to section 7.
5 Evaluation

5.1 Introduction

(Section 20 of the Animal Products Act)

This section describes the evaluation process. Evaluation leads to the recognition of validity of your RMP so that it can be recommended for registration. Evaluation is necessary for most RMPs, however the Director-General may waive or modify the requirement for evaluation if:

- your RMP is fully based on a template, model, or code of practice approved under section 12(3A) of the APA

For a list of RMP templates for which evaluation has been waived see:


- your RMP is a multi-business RMP approved by the Director-General in accordance with section 17A; or

- the risks to human or animal health are negligible, and the Director-General is satisfied that the nature of your business does not require an independent evaluation report to ensure validity in terms of sections 12 and 17 of the APA.

You must contract an independent evaluator recognised under the APA to evaluate your RMP.

Figure 5A shows the sequence of events and linkages between evaluation and registration (also see section 6).

NZFSA have issued documents relating to evaluation which are available on the NZFSA web site at:
5.2 Selection of Recognised Evaluator

You must contract a recognised evaluator with competencies appropriate to your operation. Specific competencies may be shown in the register of recognised evaluators by an activity endorsement applied to their recognition. In some cases it is mandatory to use an evaluator with the appropriate activity endorsement e.g. low acid canned foods, or dairy heat treatment. In any case it is your responsibility to check that the evaluator has the required competencies. A list of all recognised evaluators and their activity endorsements is available on the website at the following address: http://www.nzfsa.govt.nz/registers-lists/.

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

The evaluator may obtain technical assistance from other recognised evaluators or technical experts as necessary.

You are responsible for costs associated with evaluation.
5.3 Evaluation Prior to RMP Registration

5.3.1 Desk-top Review

The evaluator carries out a desk-top review of all documentation to ensure that it is complete, meets all the relevant regulatory requirements and that the proposed controls will deliver animal product that is fit for its intended purpose. This would typically occur prior to the on-site assessment. Dairy evaluators review the reports from the heat treatment and premises evaluators as part of the evaluation.

5.3.2 On-site Assessment

<table>
<thead>
<tr>
<th>Statement of Policy: Operator Responsibilities during Registration of an RMP (V1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. On site assessment</td>
</tr>
<tr>
<td><em>The operator must ensure that an on-site assessment, in relation to the evaluation report required under section 20(2)(b) of the Act, is performed when the premises and equipment are ready to operate in accordance with the risk management programme and legislative requirements.</em></td>
</tr>
</tbody>
</table>

During the on-site assessment the evaluator will:

- conduct a reality check of your operation against the documented RMP including discussions with staff
- confirm that the scope of your RMP is appropriate (including 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 get this information from heat treatment and premises evaluation reports)
- talk to key staff to ensure an acceptable level of understanding of the RMP
- check relevant documents and records, including any validation evidence.

An on-site assessment may require more than one visit.

In the case of mobile premises, fishing vessels or dairy transporters, the on-site assessment may be done at the home base or home port.
If your RMP covers a number of businesses or sites, depending on the nature of operations, the evaluator may only need to visit selected sites. The evaluator must consult NZFSA regarding this prior to the on-site assessments to determine whether this is acceptable.

If your premises is not operational at the time of evaluation e.g. in the case of a new premises or new process, you must make reasonable attempts to demonstrate or explain normal operations.

5.3.3 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, the document list, version numbers etc.

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

5.4 Reporting and Registration Documentation

When your RMP is satisfactory, the evaluator must prepare an evaluation report which recommends the RMP for registration. The evaluator must endorse the RMP or the outline.

You must submit the evaluation report, the endorsed RMP or outline (see section 6.2.1) and any other required documents (see section 6.2) to NZFSA with your application for registration.

The evaluation report is only valid for 6 months. The evaluation must be repeated if this timeframe is exceeded. For this reason you should apply for registration as soon as possible after evaluation.

5.5 Validation after Registration

If your RMP is not valid at the time of registration, you must complete the validation in accordance with your validation protocol (see section 4.4). You must provide a report and any significant amendments to the evaluator.

The report and any RMP amendments are evaluated and this may require an on-site assessment. Deficiencies should be resolved in accordance with section 5.3.3.
Once the evaluator is satisfied that validation is complete, the final evaluation report is prepared. You must forward this report, together with any endorsed RMP amendments to the NZFSA to satisfy the registration conditions.

5.6 Evaluation of Significant Amendments

Significant amendment of a registered RMP follows the evaluation process as described in this section. An on-site assessment may not be necessary depending on the nature of the amendment and this must be justified in the evaluation report. See section 7.5.1 for further information on significant amendments.
5.7 Linkage between Evaluation and Registration

Figure 5A: Evaluation and Registration Process

1. Develop RMP and, where possible, validate

2. RMP (and protocol if applicable)

3. Evaluation necessary?
   - NO
   - YES

3A. Evaluation successful?
   - NO
   - YES

4. Apply for registration

5. NZFSA assesses RMP as OK
   - NO
   - YES

6. Validation complete?
   - NO
   - YES

7. Registration +/- conditions

7a. Registration + conditions

8. Registration letter etc to:
   - Operator
   - Recognised Verifying Agency
   - NZFSA
   - TLA (where necessary)

8a. Registration letter etc to:
   - Operator
   - Recognised Verifying Agency
   - NZFSA
   - TLA (where necessary)

9. Complete validation as per protocol and conditions
   - NO
   - YES

10. Evaluation successful?

11. Submit RMP and final evaluation documents for assessment
   - YES
   - NO
6 Registration

6.1 Introduction

This section describes how you should apply for registration of your RMP and how NZFSA processes your application.

6.2 Application for Registration

(Section 20 of the Animal Products Act)

You must apply to NZFSA for registration of the RMP, using the correct application form for your situation. Your RMP must be registered before you commence operations for trade. The application forms are:

AP3 – Dual Operator Butcher RMP Registration

AP4 – Risk Management Programme Registration

AP5 – Risk Management Programme under New Operator Registration

AP6 – Risk Management Programme Amendment Registration

These forms are available on the NZFSA web site at:

http://www.nzfsa.govt.nz/animalproducts/publications/forms/index.htm


The AP3, AP4 and AP6 application forms prompt you to include all other information that will be required for registration of the RMP including:

- the document list (see section 3.3)
- the endorsed RMP or RMP outline
- the independent evaluation report (no more than 6 months old) if required (see section 5.4). For dairy processors the evaluation report will include heat treatment and/or premises evaluation reports.
• confirmation that the recognised RMP verifying agency has agreed to verify the RMP (see section 3.18)

• the application fee; and

• AP49 Principle Categories of Processing tables as applicable.

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

6.2.1 RMP Documents to be Submitted for Registration

The entire endorsed RMP may be submitted, or an outline as defined below.

<table>
<thead>
<tr>
<th>AP (Requirements for RMP Outlines) Notice 2008 clause:</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Documentation to be submitted as an outline of the contents of a risk management programme</td>
</tr>
<tr>
<td>(1) For all outlines:</td>
</tr>
<tr>
<td>If an operator chooses to submit an outline under section 20(2)(a)(ii) of the Act for a risk management programme, the documentation to be submitted must include all of the following—</td>
</tr>
<tr>
<td>(a) the name and address (including the electronic address, if available) of the operator of the risk management programme;</td>
</tr>
<tr>
<td>(b) the business identifier;</td>
</tr>
<tr>
<td>(c) A unique location identifier or identifiers required by clause 5(3) of the Animal Products (Risk Management Programme Specifications) Notice 2008;</td>
</tr>
<tr>
<td>(d) the name, position or designation of the person responsible for the day-to-day management of the risk management programme, as nominated by the operator;</td>
</tr>
<tr>
<td>(e) one of —</td>
</tr>
<tr>
<td>(i) the physical address of the premises; or</td>
</tr>
<tr>
<td>(ii) for a mobile premises - any vehicle registration numbers, and the location at which the mobile premises is principally based; or</td>
</tr>
<tr>
<td>(iii) for a fishing vessel - the physical address of the operator, the name of the fishing vessel, and the fisheries registration number;</td>
</tr>
<tr>
<td>(f) the physical boundaries of the risk management programme and a description of any shared facilities as required by clauses 5(5) and 5(6) of the Animal Products (Risk Management Programme Specifications) Notice 2008;</td>
</tr>
<tr>
<td>(g) the information required under clauses 6 and 7 of the Animal Products (Risk</td>
</tr>
</tbody>
</table>
Management Programme Specifications) Notice 2008;
(h) a step-by-step description of each process covered by the risk management programme, including all inputs and outputs in accordance with clause 9 of the Animal Products (Risk Management Programme Specifications) Notice 2008;
(i) where appropriate, the protocol in accordance with clause 18(1)(b) of the Animal Products (Risk Management Programme Specifications) Notice 2008;
(j) the document list required under clause 12 of the Animal Products (Risk Management Programme Specifications) Notice 2008;
(k) a statement in writing from the recognised risk management programme verifying agency, (or if appropriate in the case of a food safety programme to be registered as a risk management programme under section 34 of the Act, the approved auditor under the Food Act 1981) indicating that the agency has accepted the responsibility for the verification of the risk management programme.
(l) the operator must ensure that any outline of the risk management programme submitted to the Director-General accurately represents the programme at the time of application for registration.
(2) Additional requirements for outlines involving multi-business risk management programmes:
If an operator chooses to submit an outline under section 20(2)(a)(ii) of the Act for a multi-business risk management programme, the documentation to be submitted must include all of the following —
(a) the documents required under clause 4(1) with business-specific details where appropriate; and
(b) either —
   (i) the name, position or designation of the person(s) responsible for the day-to-day management of the multi-business risk management programme at each premises or place; or
   (ii) where the multi-business risk management programme will apply to a general type of business, premises or place, alternative details as approved by the Director-General;
(c) evidence in writing that the operator of the multi-business risk management programme will have sufficient control, authority, and accountability for all matters covered by that programme in relation to the businesses subject to its coverage;
(d) evidence in writing that the operator of the multi-business risk management programme has obtained the consent or otherwise taken into account the views of any person whose business is to be covered by the risk management programme.
6.2.2 Electronic Applications

If you submit documents electronically they must be in Microsoft Word, PDF or a format agreed with NZFSA prior to submission.

NZFSA recommends that hard copies are submitted as electronic applications may take longer to process and be more costly as a result.

6.3 Assessment and Registration

(Sections 19 and 22 of the Animal Products Act)

The standard timeframe for processing RMP applications is 10 working days from receipt.

An RMP cannot be registered until the documentation is complete, the premises and equipment are ready to operate and this has been signed off by the evaluator (where required). As a result, you should plan for the time taken to finalise the evaluation (including reporting) and NZFSA assessment time when determining when operations may be able to commence. You may elect to use an NZFSA policy that allows for pre-assessment of RMP documentation before the premises is complete. This could minimise the NZFSA assessment time after the premises construction has been complete for a new operation. See section 6.3.1.

NZFSA may request further information from you before determining whether to register an RMP. The application for registration will lapse if the information has not been supplied within 6 months from the date of request, or within an extended date as agreed with NZFSA.

NZFSA will register an RMP if satisfied that it meets all the requirements under the Act. If not, the registration may be refused (see section 6.5).

NZFSA will notify you when the RMP is ready for registration and will request payment of an assessment fee. This relates to the time involved in assessing your application and is calculated on an hourly basis. You must pay this fee prior to RMP registration.

After registering your RMP, NZFSA, will supply you with:

- a letter confirming registration
- a notice of registration
- a notice of conditions if applicable (legal requirements that you must comply with); and
- an authorised copy of the registered RMP or outline.
Your RMP verifying agency will be provided with copies of these documents. The original authorised documents will be held by NZFSA.

Once a programme is registered NZFSA enters details about the RMP onto the public register. The current RMP registers are located at:

http://www.nzfsa.govt.nz/animalproducts/registers-lists/risk-management-programmes/index.htm; (non dairy)


6.3.1 Pre-registration Assessment

NZFSA has developed an option for pre-assessment of the RMP documentation before premises construction is complete. This is intended to assist in the registration process and may reduce the time taken.

The use of this policy is limited to situations where:

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

In pre-assessment, the evaluator prepares an interim report. You must submit this report together with the application documentation to NZFSA for assessment. Any changes that are required prior to registration of the RMP can then be made and the application put on hold until the on-site assessment of the completed premises has occurred. NZFSA cannot register the RMP until evaluation has been completed, including on-site assessment, and any critical non-compliances have been closed out.

NZFSA will complete the registration process once construction is complete, the on-site assessment has occurred and the evaluation report is updated and submitted. Provided there are no changes, or only a few minor changes to the pre-assessed programme, registration should proceed without delay.

6.4 Compliance with RMP Registration Conditions

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

6.5 Refusal to Register

(Section 23 of the Animal Products Act)

If NZFSA declines to register your RMP, you will be notified in writing, clearly stipulating the reasons. You will be given a reasonable opportunity to make written submissions or be heard in respect of the notification to decline registration (i.e. within 30 days or as agreed).

Under Section 162 of the Animal Products Act, you may apply for a review of the decision if a person other than the Director-General makes the original decision to decline registration of your RMP. However, if the Director-General makes the original decision, there is no right of review.

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

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

The Director-General’s decision is final and subject to judicial review.

6.6 Completion of Validation

Where you have not been able to complete validation before the RMP is registered you must implement the protocol once the process is operating (see section 4.4). Once you have received an evaluation report confirming that validation has been completed, you must forward this report to NZFSA along with any other required documents (see section 6.2.1).

NZFSA will carry out an assessment of the documents and will notify you in writing of the outcome of the assessment and any changes to the RMP conditions.
6.7 Registration of Significant Amendments

Where a significant amendment to your RMP is made under section 25 of the Act, you must submit an application to NZFSA for registration of the amendment using form AP6. This must be accompanied by an evaluation report and the documentation listed below.

<table>
<thead>
<tr>
<th>AP (RMP Specifications) Notice 2008 clause:</th>
</tr>
</thead>
<tbody>
<tr>
<td>21. Documentation to be submitted for registration of a significant amendment of a risk management programme.</td>
</tr>
<tr>
<td>An application for registration of a significant amendment of a risk management programme must be accompanied by the following—</td>
</tr>
<tr>
<td>(a) the risk management programme pages affected by the amendment with the changes clearly identified; and</td>
</tr>
<tr>
<td>(b) where appropriate, the protocol in accordance with clause 18 (1)(b)</td>
</tr>
</tbody>
</table>

The process for registration of a significant amendment is the same as for initial registration of the RMP. You must develop your amendment and where appropriate validate it prior to having the amendment evaluated and then registered (see section 7.5).

6.8 Change of Registration Details

(Section 24 and 25 of the Animal Products Act)

You must notify NZFSA of any of the following changes to your RMP:

6.8.1 Change in Operator Only

Where a change in "operator" or "operator name" is the only change to your entire registered RMP, you must complete application form AP5.

The following circumstances involve a change in operator of a registered RMP, and so require completion of AP5:

- a change of company name
- a change to the (number of) members of a partnership
- a change in the names of the directors
- the operator’s death, bankruptcy, receivership, or liquidation.
6.8.2   Change in Day-to-day Manager of a Risk Management Programme

**AP (RMP Specifications) Notice 2008 clause:**

13. Notifications

(1) A risk management programme must contain a procedure for notification of the Director-General in writing, without unnecessary delay, of any change to the name or position or designation of the person(s) responsible for the day-to-day management of the risk management programme.

You must notify NZFSA of this change using an AP50 form. This is not a significant amendment to your RMP.

6.8.3   Change in Recognised Agency

(Section 16(2) of the Animal Products Act)

You must notify NZFSA as soon as possible of a change in the recognised verifying agency using form AP60.

This is not a significant amendment of your RMP.

6.9   Multi-Business RMP Registration

(Section 17A of the Animal Products Act)

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 where required. The documents submitted differ slightly (see section 6.2.1). NZFSA must be satisfied that the requirements in Section 17A of the Act have been met before the RMP is registered.
7 Operating the Registered RMP

Amendment 3

October 2009

7.1 Introduction

This section summarises your key responsibilities once your RMP has been registered.

You may only commence processing for trade from the date of notification of registration of your RMP. Prior to this, you can only process on a trial basis and no animal material or animal product can be traded. This means that the resulting animal material or animal product must be disposed of. (e.g. burnt or buried and in accordance with any other applicable legislation).

You must comply with any conditions specified by NZFSA on your RMP. You are required to operate in accordance with your RMP. It is illegal to operate outside the scope of your RMP.

When implementing the registered RMP, you must achieve ongoing effective control of hazards and other risk factors associated with the product and the process.

You must have your RMP verified by a recognised verifying agency.

7.2 Operator’s Duties

(Section 16 of the Animal Products Act)

You have the following duties:

• to ensure that the operations of your business do not contravene the relevant requirements of and under the Act, including the requirements set out in your RMP

• to ensure that your RMP, is consistent with the requirements of regulations and specifications under the Act

• to adequately implement and resource all operations under the programme, including provision for the instruction, competency, and supervision of staff to ensure the delivery of product that is fit for intended purpose
• to ensure that the capability and capacity of your premises, facilities, equipment and staff are adequate to deliver product that is fit for intended purpose

• to give the recognised verifying agency such freedom and access to carry out their functions and activities under the Act.

The resources required to ensure that your registered RMP continues to be effective should include, as appropriate:

• trained and competent personnel (see section 3.12)

• calibrated measuring equipment; and

• competent laboratory services (this work may be contracted out).

(Section 16(2) of the Animal Products Act)

Where you fail to undertake your duties you will be in breach of APA requirements. 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

• prosecution where appropriate.

7.3 Conflict between RMP and Regulations or Specifications

(Section 30 of the Animal Products Act)

Where there is any conflict between documented requirements of a registered RMP and requirements of regulations or specifications made under the APA, the requirements of the regulations or specifications will prevail.
7.4 External Verification

(Sections 101 and 107 of the Animal Products Act)

The verification requirements carried out by the recognised verifier for non-dairy RMPs that do not require official assurances for export is prescribed by the Verification Statement of Policy. This is available at the following website address:


For dairy RMPs that do not require official assurances for export, the verification system is described in the Approved Criteria for the Manufacturing of Dairy Material and Product (DPC3), available at the following website address:


For all export animal products (including dairy) that require an official assurance the verification requirements are prescribed by the Animal Products (Export Verification Requirements) Notice 2009 and the Animal Products Export Verification Programme, available at the following website address:

Notice:


The verification frequency will depend on your level of compliance with the registered RMP and any applicable export requirements (i.e. is performance based). If the operation complies with the documented programme and can consistently demonstrate its effectiveness, the verifier may be able to apply a lower frequency. A higher frequency will be applied if the programme is not implemented correctly. More frequent verification may be required if the business is exporting.

7.5 Amendments to the RMP

If you amend your RMP for any reason the amendment will either be classified as significant or minor. Information on significant amendments and the requirements of clause 22 of the
Animal Products (RMP Specifications) Notice 2008 is given in Appendix G. The tables provide examples of significant and minor amendments.

**AP (RMP Specifications) Notice 2008 clause:**

22. Significant amendments to the risk management programme

22(1) The following activities that result in changes to the risk management programme require registration as an amendment in accordance with section 25 of the Act (except where they are done on a trial basis and the affected animal material or animal product is not traded)—

(a) making major alterations to the processing facilities or equipment which may impact on fitness for intended purpose of the animal material or animal product.
(b) relocating processing operations to a new physical address (except where this is already permitted for mobile premises and vessels):
(c) processing animal material or animal product that is not covered by the risk management programme, except —
   (i) where the product and process are similar, and
   (ii) a documented risk factor identification and hazard analysis has shown that all risk factors associated with that animal material or animal product are already adequately addressed by the risk management programme:
(d) setting up a new process or process modification that is not covered by the risk management programme, except —
   (i) where the process or process modification is similar to existing processes, and
   (ii) a documented risk factor identification and hazard analysis has shown that all risk factors associated with that process are already adequately addressed by the risk management programme:
(e) making any other changes that introduce new risk factors, or adversely impact on existing risk factors:
(f) merging two or more registered risk management programmes:
(g) splitting a registered risk management programme into two or more risk management programmes:
(h) adding a business to a multi-business risk management programme except where the Director-General’s approval under section 17A of the Act applies to a type of business, premises or place rather than to specific businesses.

Significant amendments require evaluation by a recognised evaluator and registration with NZFSA. Minor amendments can be made without evaluator or NZFSA involvement. The key consideration when deciding this is whether or not the amendment meets criteria set in Section 25 of the Act and Part 4 of the Animal Products (RMP Specifications) Notice 2008.
You may consult a recognised evaluator or a technical expert to assist in making this decision. In addition, if your product is intended for export NZFSA strongly recommends that you discuss proposed amendments with your verifier to identify any potential market access implications.

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

### 7.5.1 Significant Amendments to the RMP

Significant amendments to the RMP must be registered in accordance with the APA and validated as described in section 4.

*(Section 25 of the Animal Products Act)*

You must apply for registration of the amendment, where any change, event or other matter means that the programme:

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

You must apply for registration of the amendment in advance of any known change, event, or other matter. In all other cases you must apply for registration of the amendment as soon as practicable. Refer to sections 5 and 6 for the evaluation and registration requirements.

If you do not comply with registration requirements for a significant amendment to your RMP, you will be in breach of the APA. Depending on the circumstances, this could result in suspension or de-registration of the RMP, or prosecution.

### 7.5.2 Minor Amendments to RMPs

*(Section 26 of the APA)*

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

- a full description of the amendment (including details of any planned construction or alterations); and
• evidence that clause 22 of the Animal Products (RMP Specifications) Notice 2008 has been considered.

If the changes are editorial, no evidence is required.

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

7.5.2.1 Notifications to NZFSA

To ensure the registration details shown on the public register of RMPs are current and accurate, some changes require notification to NZFSA. The AP50 form (available on NZFSA website) specifically details which changes are to be notified to NZFSA, for instance changes in trading name, or the addition of products where this is not considered a significant amendment.

This change to the RMP will undergo an assessment process at NZFSA. In situations where NZFSA then deems the change to in fact be significant, the operator will be notified and will be required to complete a significant amendment application.
8 Ceasing Registration of an RMP

Amendment 3

October 2009

8.1 Introduction

The section provides guidance for when your RMP ceases operating or your business is removed from the coverage of a multi-business RMP. You will need to give consideration to the control and disposition of any remaining animal material and animal product. If only part of your RMP ceases operation, you should consider any impact on the part of your RMP that is still operating.

8.2 Surrender of Registration

(Section 29 of the Animal Products Act)

Where you choose to surrender your registered RMP (permanently as opposed to seasonal closure), you (or, where appropriate, the liquidator, receiver, executor, or other successor to title of the operator) must, within 30 days of cessation:

- notify NZFSA in writing (the AP50 form may be used for this), and include how any remaining animal material or product covered by the registered RMP will be dealt with
- surrender the notice of registration to NZFSA; and
- notify the appropriate recognised (verifying) agency.

NZFSA must confirm agreement with your proposal for dealing with the remaining animal material or product. Alternatively, NZFSA may direct you to take appropriate action to deal with any affected animal material or product, or may use animal product officers or other NZFSA employees to act on their behalf. All associated costs will then be recovered from you (section 82 of the APA).

Where you are surrendering an RMP registration for manufacture of export eligible product that will require official assurances, it will no longer possible to raise an eligibility document for animal product from your premises. To overcome this, you need to ensure that prior to surrender of the RMP, eligibility documents are raised for all animal product that you intend to be exported.
Should you choose to leave the coverage of a multi-business RMP you must notify NZFSA of your business details and provide evidence in writing that you have the consent of the person whose business it affects. However, if NZFSA has approved an alternative means by which businesses that make up the multi business RMP had been approved, no notification is necessary, so long as the conditions of registration are met.

NZFSA will notify the relevant territorial authority (section 32 of the APA) when a surrender involves a secondary processor who has elected to operate under an RMP rather than under the Food Act regime.

8.3 Suspension of Registration

(Section 27 of the Animal Products Act)

NZFSA may suspend part of, or the whole operation (including one or more businesses under a multi-business RMP) from 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; and/or
- animal product produced under the RMP does not meet the requirements of the APA.

NZFSA must notify the recognised verifying agency of any suspension of an RMP. The suspension may be notified in the Gazette. You will be given a written notice of the suspension, specifying the following:

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

Where a person acting under the delegated authority of the Director-General suspends any operations, you may seek a review of the suspension by applying in writing to NZFSA within 30 days of notification (section 162 of the APA).
NZFSA may direct you to take appropriate action to deal with any affected animal material or product, or may use animal product officers or other NZFSA employees to act on their behalf. All costs associated with this will be recovered from you (section 82 of the APA).

If there are reasonable grounds, the period of suspension may be extended for an additional 3 months. NZFSA must notify you in writing of an extension to the period of suspension, before the expiry of the original suspension. However, this extension can only take place after you have been notified of the proposed extension and the reasons for it, and have had a reasonable opportunity to respond.

8.4 Deregistration of the RMP

(Section 28 of the Animal Products Act)

NZFSA 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.

Where NZFSA intends to deregister your RMP or remove your business from the coverage of a multi-business RMP, oral or written notice of the intention will be given to you, giving reasons. You must be given the opportunity to respond.

When NZFSA decides to deregister your RMP or remove your business from the coverage of a multi-business RMP, written notice will be given to you, with reasons and specifying the date that deregistration or removal takes effect. The deregistration date must not be earlier than the date of notification. Notification of deregistration or removal will also be given to your recognised RMP verifying agency. NZFSA may notify any deregistration in the Gazette.

If a person acting under the delegated authority of the Director-General 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 NZFSA within 30 days of notification (section 162 of the APA).
NZFSA may direct you to take appropriate action to deal with any affected animal material or product, or may use animal product officers or other NZFSA employees to act on their behalf. All costs associated with this will be recovered from you (section 82 of the APA).
9 Appendix A: Glossary of Terms

Amendment 3

October 2009

Act means the Animal Products Act 1999 unless otherwise stated.

Amendment means any change or event or other matter that:

- means that the programme is no longer appropriate, or will no longer be appropriate to the animal material or product, processes or premises or place covered by the programme; or

- otherwise impacts, or will impact, on the fitness for intended purpose of the animal product concerned or the content of the RMP.

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

- any mammal, bird, finfish, shellfish, reptile, amphibian, insect or invertebrate;

- any other creature or entity that is declared by the Minister by notice in the Gazette to be an animal for the purposes of this Act; but does not include a human being.

Animal consumption (See human or animal consumption).

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

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

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

- produces or processes animal material or product; or

- exports animal material or product

Animal product officer, or officer means a person appointed as an animal product officer under section 78 of the APA and includes the Chief Executive.
**Animal product standard, or standard** means a standard prescribed by regulations and specifications that specifies the criteria that must be met to determine fitness for intended purpose of any class or description of animal product.

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

**Business** (See animal product business).

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

**Consumption** (See human or animal consumption).

**Contaminant** means any substance or thing which:

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

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

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

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

**Corrective action** means any action to be taken when the results of monitoring indicate a loss of control.

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

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

**Director-General** means the Chief Executive of the New Zealand Food Safety Authority or such other Ministry as has, with the authority of the Prime Minister, for the time being assumed responsibility for the administration of the APA 1999.
Day-to-day manager means the person identified in a risk management programme either by name, position or designation as being responsible for the day-to-day management of that programme.

Document (verb) means to include in writing in the RMP.

Dual operator butcher or dual operator means a retail butcher who:

• is listed by the Director-General as a homekill or recreational catch service provider; and

• processes homekill or recreational catch at the same premises or place as the retail butcher processes or trades in regulated animal product.

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

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

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

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

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

1. subject to paragraph (2), includes:

   a. any stockyard, milking yard, feed yard, silo pad, or other construction associated with or involved in the activity of extracting milk from milking animals; and

   b. any place where milk from the milking animals is first collected, filtered, deposited, cooled, stored, or treated for transport or for further processing; but

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

Farm dairy operator means the person in charge of operations at a farm dairy, including the extraction of milk from milking animals.
**Finfish** includes all species of finfish of the Classes Agnatha, Chondrichthyes, and Osteichthyes, at any stage of their life history, whether living or dead (Fisheries Act, 1996).

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

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

**Food** -

1. means anything that is used or represented for use as food or drink for humans; and

2. includes—
   a. any ingredient or nutrient or other constituent of any food or drink, whether that ingredient or nutrient 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
   b. anything that is or is intended to be mixed with or added to any food or drink; and
   c. 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
   d. anything that is declared by the Governor-General, by Order in Council, to be food for the purposes of this Act; but

3. does not include—
   a. any tobacco; or
   b. any cosmetics; or
   c. any substances used only as medicines (within the meaning of the Medicines Act 1981) or any controlled drugs (within the meaning of the Misuse of Drugs Act 1975); or
   d. any cookware and related products; or
e. any packaging (except edible packaging).

**Food Act regime** means the alternative regimes under the Food Act 1981 that consist of, or relate to:

- Part IA of that Act and food safety programmes;
- the Food Hygiene Regulations 1974.

**Food safety programme** means a documented programme designed to identify and control food safety risk factors in order to establish and maintain food safety. A food safety programme within the meaning of the Food Act 1981 is a programme whose adoption gives rise to an exemption from the Food Hygiene Regulations 1974 under Part 1A of that Act.

**Good operating practice** (including good agricultural practice, good hygienic practice and good manufacturing practice) means documented procedures relating to practices that –

1. are required to ensure animal material and animal product are fit for intended purpose; and
2. are appropriate to the operating circumstances.

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

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

**Hazard** means a biological, chemical, or physical agent that:

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

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

**Homekill** means an animal that is killed or processed by its owner for the use or consumption of the owner, or by a person who is listed as a homekill or recreational catch service provider under section 76 of the Act.
**Homekill product** is product for the use or consumption of the animal owner including his or her family or household and must not be traded (includes barter, supply as part of a service, public prize or reward etc).

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

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

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

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

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

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

**New Zealand Food Safety Authority** is a public service department administering food and under other specified conditions safety.

**Officer** (see Animal product officer).

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

- specified processes have been completed under the Act; or

- the animal product meets the relevant standards set under the Act; or

- the processing system used meets any market access requirements of the importing country, which New Zealand has agreed to meet; or
• the situation in New Zealand, in relation to any matter concerning animal material or animal product is as stated in the assurance.

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

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

Operator verification means the application of methods, procedures, tests and other checks by a risk management programme operator to confirm the ongoing:

• compliance of the RMP with the legislative requirements; and

• compliance of the operations within the RMP as written; and

• applicability of the RMP to the operation;

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

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

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

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

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

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

Protocol means a document that describes the work to be undertaken when there is insufficient evidence to complete validation immediately and includes details of the experimental design and analysis of the results.

Readily accessible means that no matter where documents are stored, they can be mailed, couriered, faxed, emailed or transferred by other means within the time period stated.
Recognised agency in relation to any function or activity means a person or body recognised by the Director-General under section 103 of the Act for the purpose of performing that function or activity. This will include the management and supply of recognised persons to perform specialist functions and activities for the purposes of the Animal Products Act, including evaluation and verification functions and activities.

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

Recreational catch is a hunted or harvested wild animal for the hunter’s own consumption or use.

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

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

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

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

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

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

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

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

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

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

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

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

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

**Single-business risk management programme** means an RMP covering a single business.

**Standard** (see Animal product standard).

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

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

**Topically** means applying a substance externally to a part of the body of a human or animal.

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

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

• barter; and

• 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

• supplying an article where there is a statutory responsibility to supply; and

• 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

• every other method of disposition for valuable consideration.

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

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

**Validate** means the process by which evidence is obtained to demonstrate that animal material or animal product will be fit for intended purpose, through the achievement of any regulatory limit or operator-defined limit.
**Verification** includes the ongoing checks carried out by recognised verifiers to determine whether:

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

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

**Wild animal** means an animal that:

- is a kind that occurs in the wild or in the sea; and
- is not, immediately before its taking or capture, owned by any person.
10 Appendix B: Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACVM:</td>
<td>Agricultural Compounds and Veterinary Medicines Act 1997</td>
</tr>
<tr>
<td>APA:</td>
<td>Animal Products Act 1999</td>
</tr>
<tr>
<td>CCP:</td>
<td>Critical Control Point</td>
</tr>
<tr>
<td>COP:</td>
<td>Code of Practice</td>
</tr>
<tr>
<td>DOB:</td>
<td>Dual Operator Butcher</td>
</tr>
<tr>
<td>FSP:</td>
<td>Food Safety Programme</td>
</tr>
<tr>
<td>GOP:</td>
<td>Good Operating Practice</td>
</tr>
<tr>
<td>HACCP:</td>
<td>Hazard Analysis and Critical Control Point</td>
</tr>
<tr>
<td>ISO:</td>
<td>International Organisation for Standardisation</td>
</tr>
<tr>
<td>NZFSA:</td>
<td>New Zealand Food Safety Authority</td>
</tr>
<tr>
<td>NZFSA VA:</td>
<td>New Zealand Food Safety Authority Verification Agency</td>
</tr>
<tr>
<td>NZQA:</td>
<td>New Zealand Qualifications Authority</td>
</tr>
<tr>
<td>OMAR:</td>
<td>Overseas Market Access Requirement</td>
</tr>
<tr>
<td>RCS:</td>
<td>Regulated Control Scheme</td>
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<tr>
<td>RMP:</td>
<td>Risk Management Programme</td>
</tr>
<tr>
<td>TLA:</td>
<td>Territorial Local Authority</td>
</tr>
</tbody>
</table>
11 Appendix C: Businesses Requiring RMPs

You must operate under a registered RMP if you are producing or processing animal material or animal product (subject to the exclusions described in Appendix D) if one of the following applies to you:

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

11.1 Primary Processors (Including Dairy Processors)

Because the term ‘primary processor’ determines who must have an RMP, the term is specifically defined in the APA as:

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

1. slaughters and dresses mammals or birds; or
2. dresses mammals or birds that are killed wild animals or are killed as if they were wild animals; or
3. removes or extracts or harvests any animal material from live animals for the purpose of processing for human or animal consumption; or
4. is a dairy processor; or
5. in the case of:
a. finfish or shellfish, or animal material derived from finfish or shellfish; or

b. a mammal or bird, or animal material derived from a mammal or bird, if in the opinion of the Minister it is appropriate that the primary processing of that mammal or bird or animal material should extend beyond the matters referred to in paragraphs (1) and (2); or

c. 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 in the Gazette after appropriate consultation in accordance with section 163 and after having regard to the following matters;

• industry practice in relation to the animal material concerned

• the degree of processing and number of processing operations required in relation to the animal material

• the risk factors involved in processing the animal material

• whether or not the processing of the animal material is or may be appropriately addressed by any legislative regime other than this Act

• such other matters as the Minister considers relevant in the particular circumstances;

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

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

“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—

• a farm dairy operator

• a transporter of dairy material from a farm dairy to a place of processing or manufacture

• a transporter of dairy material from one place of processing or manufacture to another
• an operator of any premises where dairy material is processed or manufactured or stored

• a transporter of dairy material to the place of export or sale for consumption or end use for purposes other than consumption

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

(Animal Products (Definition of Primary Processor) Notice 2000)

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

• a person who harvests and candles\(^{27}\) 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

• a person who removes or extracts or harvests or undertakes drying, slicing, grinding or preserving of deer velvet

• 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):

  a. the deheading, gutting, or filleting of finfish
  
  b. the tubing of squid
  
  c. the wet-storage, depuration, or shucking of shellfish

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\(^{27}\) 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.
d. the removing of roe from kina

e. the holding of crustaceans live (otherwise than in a marine farming operation), or their tailing

f. 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

- a person who, in fish processing at sea, carries out any of the following operations:
  
  a. 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

  b. 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

  • washing, chilling, freezing, and preserving
  • deheading, gutting, scaling, and tubing
  • packing, transport, and storage.

11.2 Secondary Processors of Animal Products28

*(Sections 13 and 33 of the Animal Products Act)*

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

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

28 Secondary processing is not a term that is applied to dairy processing. Section 11.2 does not apply to dairy operators.
11.3 Dual Operator Butchers

(Section 71 of the Animal Products Act)

Dual operator butchers are those butchers dealing in both homekill and retail meat at the same premises or place. They must have an RMP covering processing of their regulated product. There are also additional requirements for them to meet (see section 3.21).

11.4 Inclusions by Order in Council

(Clause 20 of the Animal Products (Exemptions and Inclusions) Order 2000)

You must develop and operate an RMP for the following operations if carried out for trade purposes in relation to any dairy, mammal or bird material or product, whether or not the product concerned is intended for human or animal consumption:

- rendering\(^{29}\) operations
- blood-drying operations
- technical grade dairy product\(^{30}\) 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.

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\(^{29}\) In this regulation, “rendering” means the breaking down of animal tissues into constituent fat and protein elements, whether by the application of heat and pressure or otherwise.

\(^{30}\) Technical grade dairy product means dairy product for sale or export that is not intended for human or animal consumption.
12 Appendix D: Businesses Not Requiring RMPs

Amendment 3

October 2009

(Section 13 of the Animal Products Act)

The following persons are not required to have RMPs:

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

12.1 Exemptions by Order in Council


The following persons are not required to have an RMP:

a. those operating fishing boats where the fish is not landed in New Zealand nor claimed to be a product of New Zealand
b. those whose products are covered by the Medicines Act 1981 (except where required for Official Assurances)
c. those whose products are covered by the Agricultural Compounds and Veterinary Medicines Act 1997 (except for rendering and blood-drying operations, or where required for Official Assurances)
d. those who process certain dairy products that are consumed on the premises

e. those who process certain dairy products that are food (e.g. multi-ingredients foods such as cakes, biscuits, soups and pastries, caffeinated or alcoholic drinks) except those who process multi-ingredient foods that consist principally of dairy products (see Appendix H), ice cream, or where required for Official Assurances

f. those who process dairy material for the NZ or Australian market only, under a food safety programme, but are not a farm dairy operator

g. those who process dairy material for animal consumption for the domestic market, if no other operations at the same premises require an RMP

h. those who are primary processing animal material for purposes other than human or animal consumption e.g. skinning and shearing

i. those processing animal food in accordance with the Food Act regime, e.g. raw meat suitable for human consumption is sold by a supermarket delicatessen as petfood

j. those who have fish on a retail premises and fish is sold by a combination of retail and wholesale where the trader has a food safety programme under the Food Act regime

k. those who operate temporary holding and storage places for fish

l. those who operate limited processing on registered limited processing fishing vessels

m. those who harvest, collect, grade, store or transport raw deer velvet

n. apiarists who harvest, store and transport bee material or product

o. taxidermists (so long as no part of the animal is traded for human or animal consumption – except to rendering, and homekill and recreational catch services are not carried out on the same premises)

p. processors of fish bait, fish berley, chum, or ground bait

q. certain tourist or charter fishing vessel operators and fishing guides

r. whitebait catching and limited processing operations

s. muttonbird primary processors

t. certain primary processors of eggs (those with 100 or less female birds and who sell directly to the consumer – not through a third party); and
u. airline holding facilities operators.

12.2 Exemptions by the Director-General

NZFSA may grant exemptions under exceptional circumstances, under section 14 of the Act, from the requirement to have all or part of an RMP.
### 13 Appendix E: Examples of Limits

#### Table 1: Examples of Limits for Products for Human Consumption

<table>
<thead>
<tr>
<th>Product</th>
<th>Regulatory Limits</th>
<th>Operator-Defined Limits</th>
<th>Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Specifications</strong></td>
<td><strong>Food Standards Code</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RAW, NOT FURTHER PROCESSED</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raw red meat and offal</td>
<td>----</td>
<td>----</td>
<td>Operator may define microbiological and defect levels</td>
</tr>
<tr>
<td>Poultry</td>
<td>3.78 log_{10} CFU / carcass (Schedule 1, NMD Programme)</td>
<td>----</td>
<td>Operator may define microbiological and defect levels</td>
</tr>
<tr>
<td>MSM - red meat and poultry</td>
<td>----</td>
<td>----</td>
<td>Operator should define microbiological limits</td>
</tr>
<tr>
<td>Wetfish</td>
<td>Histamine level ≤ 200mg/kg</td>
<td>Histamine level ≤ 200mg/kg</td>
<td>----</td>
</tr>
</tbody>
</table>
## Appendix E: Examples of Limits

<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>RAW, NOT FURTHER PROCESSED</strong></td>
<td></td>
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<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td><strong>GOP</strong></td>
</tr>
<tr>
<td>RAW, NOT FURTHER PROCESSED</td>
<td>Operator should establish requirement for viable parasites to be absent, if known that fish is to be eaten raw</td>
<td></td>
<td><strong>GOP</strong></td>
</tr>
<tr>
<td>Bivalve molluscan shellfish other than scallops</td>
<td></td>
<td></td>
<td><strong>GOP</strong></td>
</tr>
<tr>
<td>E. coli/g: n = 5 c = 1 m = 2.3 M = 7</td>
<td>E. coli/g: n = 5 c = 1 m = 2.3 M = 7</td>
<td></td>
<td><strong>GOP</strong></td>
</tr>
<tr>
<td>Salmonella/25g: n = 5 c = 0 m = 0</td>
<td></td>
<td></td>
<td><strong>GOP</strong></td>
</tr>
<tr>
<td>Raw crustacean (not live)</td>
<td>Coagulase - positive staphylococci/g: n = 5 c = 2 m = 10^2 M = 10^3</td>
<td></td>
<td><strong>GOP</strong></td>
</tr>
<tr>
<td>Salmonella/25g: n = 5 c = 0 m = 0</td>
<td></td>
<td></td>
<td><strong>GOP</strong></td>
</tr>
<tr>
<td>SPC/g: n = 5 c = 2 m = 5 x 10^5 M = 5 x 10^6</td>
<td>Specified additive level (e.g. sulphur dioxide, sodium and potassium sulphites ≤ 100 mg/kg)</td>
<td></td>
<td><strong>GOP</strong></td>
</tr>
</tbody>
</table>
## Appendix E: Examples of Limits

<table>
<thead>
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<tr>
<td></td>
<td>Specifications</td>
<td>Food Standards Code</td>
<td></td>
</tr>
<tr>
<td><strong>FURTHER PROCESSED</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Casings.</td>
<td>Water activity ≤ 0.83</td>
<td>SO₂ ≤ 500 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>GOP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raw meat &amp; poultry products (e.g. patties, sausage)</td>
<td>----</td>
<td>Specified additive level (e.g. nitrate ≤ 125 mg/kg)</td>
<td>----</td>
</tr>
<tr>
<td></td>
<td>GOP or CCP - metal detection</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Operator may define hazard levels (e.g. microbiological or metal level)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cooked cured/salted meat</td>
<td>----</td>
<td>Coagulase - positive staphylococci/g: n = 5 c = 1 m = 10² M = 10³ Listeria monocytogenes/25g: n = 5 c = 0 m = 0 Salmonella/25g: n = 5 c = 0 m = 0</td>
<td>Operator must define lethality (e.g. 6D destruction of Listeria monocytogenes), or cooking time and temperature that will achieve required lethality</td>
</tr>
<tr>
<td></td>
<td>GOP</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>GOP or CCP - metal detection</td>
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</tbody>
</table>
## Appendix E: Examples of Limits

### FURTHER PROCESSED

<table>
<thead>
<tr>
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<th>Controls</th>
</tr>
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<tbody>
<tr>
<td></td>
<td><strong>Specifications</strong></td>
<td><strong>Food Standards Code</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Specified additive level (e.g. nitrite ≤ 125 mg/kg)</td>
<td></td>
<td>GOP if curing mix used. May be a CCP when nitrite added on its own</td>
</tr>
<tr>
<td>Heat treated meat paste and paté</td>
<td><strong>Listeria monocytogenes/25g:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>[ \text{n} = 5 \quad \text{c} = 0 \quad \text{m} = 0 ]</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Salmonella/25g:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>[ \text{n} = 5 \quad \text{c} = 0 \quad \text{m} = 0 ]</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Specified additive level (e.g. nitrite ≤ 125 mg/kg)</td>
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<tr>
<td></td>
<td><strong>GOP if curing mix used. May be a CCP when nitrite added on its own</strong></td>
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</tr>
<tr>
<td></td>
<td><strong>CCP – Cooking</strong></td>
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</tr>
</tbody>
</table>
### Appendix E: Examples of Limits

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<td><strong>Food Standards Code</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FURTHER PROCESSED</strong></td>
<td><strong>Coagulase - positive staphylococci/g:</strong></td>
<td>Operator must define pH and water activity</td>
<td>CCP - fermentation, maturation</td>
</tr>
<tr>
<td>Uncooked comminuted fermented meats</td>
<td>$n = 5$ $c = 1$ $m = 10^3$ $M = 10^4$</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>$E. coli/g$:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>$n = 5$ $c = 1$ $m = 3.6$ $M = 9.2$</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>$Salmonella/25 g$:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>$n = 5$ $c = 0$ $m = 0$</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Nitrite ≤ 500 mg/kg</strong></td>
<td></td>
<td>GOP if curing mix used. May be a CCP when nitrite added on its own</td>
</tr>
<tr>
<td>Cooked uncured meats (e.g. roast beef, chicken)</td>
<td><strong>----</strong></td>
<td>Operator must define microbiological levels (e.g. same as that for cooked cured meats)</td>
<td>CCP - cooking GOP post - cook handling</td>
</tr>
</tbody>
</table>
### Product Regulatory Limits Operator-Defined Limits Controls

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Food Standards Code</th>
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<tr>
<td><strong>FURTHER PROCESSED</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Operator must define lethality (e.g. 6D destruction of <em>Listeria monocytogenes</em>), or cooking time and temperature that will achieve required lethality</td>
<td>CCP-cooking</td>
</tr>
<tr>
<td>----</td>
<td>Specified additive level</td>
<td>----</td>
<td>GOP.</td>
</tr>
<tr>
<td>Dried meat &amp; poultry (e.g. jerky; freeze dried meat)</td>
<td>----</td>
<td>----</td>
<td>Operator <strong>should</strong> define microbiological levels, water activity and/or moisture content</td>
</tr>
<tr>
<td>----</td>
<td>Specified additive level (e.g. nitrite ≤ 125 mg/kg)</td>
<td>----</td>
<td>GOP if curing mix used. May be a CCP when nitrite added on its own</td>
</tr>
</tbody>
</table>

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Note: The text and table are based on the content extracted from the image, with proper formatting and alignment adjusted for clarity and readability.
<table>
<thead>
<tr>
<th>Product</th>
<th>Regulatory Limits</th>
<th>Operator-Defined Limits</th>
<th>Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FURTHER PROCESSED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Cooked crustacean                                                      | Coagulase - positive staphylococci/g:  
  n = 5  c = 2  m = 10^2  M = 10^3  
  *Salmonella* 25g:  
  n = 5  c = 0  m = 0  
  SPC/g:  
  n = 5  c = 2  m = 10^5  M = 10^6 | Operator must define lethality                                                      | CCP – cooking           |
| RTE processed finfish other than retorted (e.g. smoked fish, vacuum packaged cooked fish, manufactured fish products) | *Listeria monocytogenes*/g:  
  n = 5  c = 1  m = 0  M = 10^2 | Operator must define lethality (e.g. 6D destruction of *Listeria monocytogenes*), or cooking time and temperature that will achieve required lethality | CCP – hot smoking or cooking |

Histamine level ≤ 200mg/kg  
Histamine level ≤ 200mg/kg  
----  
GOP
### Appendix E: Examples of Limits

<table>
<thead>
<tr>
<th>Product</th>
<th>Regulatory Limits</th>
<th>Operator-Defined Limits</th>
<th>Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FURTHER PROCESSED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bivalve molluscan shellfish that have undergone processing other than depuration (e.g. heat shocked, cooked)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Listeria monocytogenses/25g:</strong> n = 5, c = 0, m = 0</td>
<td>Operator must define lethality (e.g. 6D destruction of <em>Listeria monocytogenes</em>), or cooking time and temperature that will achieve required lethality</td>
<td>CCP - thermal step</td>
</tr>
<tr>
<td>Dried shelf stable fish</td>
<td><strong>Histamine level ≤ 200mg/kg</strong></td>
<td></td>
<td>GOP</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fish or fish products with pH &lt; 4.6 (e.g. marinated mussels)</td>
<td><strong>Histamine level ≤ 200mg/kg</strong></td>
<td>Operator should define water activity and/or moisture content</td>
<td>GOP</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pasteurised egg</td>
<td><strong>Salmonella:</strong> n = 5, c = 0, m = 0</td>
<td></td>
<td>CCP – pasteurisation</td>
</tr>
<tr>
<td>Product</td>
<td>Regulatory Limits</td>
<td>Operator-Defined Limits</td>
<td>Controls</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-------------------</td>
<td>------------------------</td>
<td>----------</td>
</tr>
<tr>
<td></td>
<td>Specifications</td>
<td>Food Standards Code</td>
<td></td>
</tr>
<tr>
<td><strong>FURTHER PROCESSED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low acid canned foods</td>
<td>----</td>
<td>----</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Commercially sterile by application of a 12D thermal process for <em>C. botulinum</em></td>
<td>CCP – retorting</td>
</tr>
<tr>
<td></td>
<td>----</td>
<td>Specified additive level</td>
<td>----</td>
</tr>
<tr>
<td>Edible fat/oils</td>
<td>----</td>
<td>Specified additive level</td>
<td>----</td>
</tr>
<tr>
<td>Dried deer velvet</td>
<td>----</td>
<td>----</td>
<td>Operator <em>should</em> define water activity and/or moisture content</td>
</tr>
<tr>
<td>Honey</td>
<td>Moisture content ≤ 21%</td>
<td>----</td>
<td></td>
</tr>
<tr>
<td>Product</td>
<td>Regulatory Limits</td>
<td>Operator-Defined Limits</td>
<td>Control</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Raw meat and offal</td>
<td>----</td>
<td>Operator may define microbiological and defect levels</td>
<td>GOP</td>
</tr>
<tr>
<td>Dry rendered meals (e.g. meat and bone, blood)</td>
<td>Medium risk material: No vegetative pathogens, viruses and protozoa, and inactivate chemical substances that are harmful if consumed by animals. AC spec 72(1)</td>
<td>----</td>
<td>CCP - rendering or drying GOP post CCP</td>
</tr>
<tr>
<td></td>
<td>----</td>
<td>Operator <strong>should</strong> define moisture content (e.g. ≤ 10%)</td>
<td>GOP</td>
</tr>
<tr>
<td>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)</td>
<td>No viable hydatids (Biosecurity Notice No. 1204)</td>
<td>Operator may define microbiological levels</td>
<td>CCP – cooking</td>
</tr>
<tr>
<td>Dried meat products (e.g. jerky)</td>
<td>----</td>
<td>Operator <strong>should</strong> define water activity and/or moisture content</td>
<td>CCP - drying/cooking</td>
</tr>
<tr>
<td>Low acid canned foods</td>
<td>----</td>
<td>Commerically sterile by application of a 12D thermal process for C. botulinum</td>
<td>CCP – retorting</td>
</tr>
</tbody>
</table>
### Table 3: Examples of Limits for Dairy Material and Dairy Products for Human Consumption

<table>
<thead>
<tr>
<th>Product</th>
<th>Regulatory Limits</th>
<th>Operator-Defined Limits</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>All dairy products for human consumption</td>
<td>All dairy products must be wholesome and not contain any foreign matter that constitutes a food safety hazard</td>
<td>Operator must define what constitutes a food safety hazard</td>
<td>GOP</td>
</tr>
<tr>
<td></td>
<td>Dairy product must not exceed the following Product Safety Limits at any time during the product’s shelf life (assuming the product is stored and handled according to manufacturer guidelines):</td>
<td>----</td>
<td>GOP</td>
</tr>
<tr>
<td></td>
<td>General Specific</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Salmonella</em> spp.</td>
<td>ND/25g ND/250g</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>L. mono.</em></td>
<td>ND/25g(4) ND/25g</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coag. Pos. <em>Staph</em></td>
<td>1000/g 100/g</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>B. cereus</em></td>
<td>1000/g 100/g(5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>E. coli</em></td>
<td>100/g 10/g</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Further detail is contained in DPC1: Approved Criteria for General Dairy Processing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product</td>
<td>Regulatory Limits</td>
<td>Operator-Defined Limits</td>
<td>Control</td>
</tr>
<tr>
<td>---------</td>
<td>------------------</td>
<td>-------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>All dairy products manufactured in NZ or for sale in NZ or Australia</td>
<td>Dairy products must comply with the microbiological limits in the Australia New Zealand Food Standards Code (refer to <a href="http://www.foodstandards.govt.nz">www.foodstandards.govt.nz</a> for details)</td>
<td>Operator may define additional microbiological levels for in-process or final product</td>
<td></td>
</tr>
<tr>
<td>Dairy products manufactured in NZ or for sale in NZ</td>
<td>Dairy products must not contain any residues exceeding the limits specified in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2005</td>
<td>Operator may define additional residue limits</td>
<td></td>
</tr>
<tr>
<td>Dairy products manufactured for export</td>
<td>Dairy products must not contain any residues exceeding the limits specified by Codex</td>
<td>****</td>
<td></td>
</tr>
<tr>
<td>Dairy products for sale in NZ</td>
<td>Levels of toxic trace metal should not exceed the limits specified in the Food Standards Code (refer to Volume Two Standard 1.4.1 Contaminants and Natural Toxicants) Further detail is contained in DPC1:Approved Criteria for General Dairy Processing</td>
<td>****</td>
<td></td>
</tr>
<tr>
<td>All dairy products for human consumption</td>
<td>Dairy product must comply with the food safety limits specified in fortification standards issued by Codex – refer to Codex Standard 72, 1981 “Infant Formula” and Codex Standard 156, 1987</td>
<td>****</td>
<td></td>
</tr>
</tbody>
</table>
### Appendix E: Examples of Limits

<table>
<thead>
<tr>
<th>Product</th>
<th>Regulatory Limits</th>
<th>Operator-Defined Limits</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&quot;Follow-up Formula&quot; (available on the Codex website) and the Food Standards Code</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
14 Appendix F: Procedures or Steps that Require Data as Evidence for Demonstrating Effectiveness

As part of the validation of the RMP, you must provide data to demonstrate the effectiveness of certain procedures or steps that:

- are essential to the achievement of any regulatory limits or operator-defined limits (these steps are likely to be considered as CCPs); or measurable GMP requirements
- historically have not been well controlled (i.e. reported occurrence of industry failures); and/or
- are not well established in the industry (e.g. new procedures/methods, procedures not covered in a COP).

If the required evidence is not available prior to application for registration of the RMP, you must document a protocol for collection of evidence.

Examples of procedures or steps that require a protocol are shown in the table below.

Where no protocol is required, this has been based on the assumption that procedures comply with a COP that is acceptable to NZFSA. Procedures that deviate from a COP may require a protocol.
## 14.1 General Requirements

<table>
<thead>
<tr>
<th>Procedures/operation</th>
<th>No protocol</th>
<th>Protocol required</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design and construction of premises, facilities, equipment</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WATER (SUPPLY, QUALITY, RETICULATION)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Council water</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Other sources</td>
<td>√</td>
<td></td>
<td>Water requirements must already be met before implementation of the RMP.</td>
</tr>
<tr>
<td>• Fishing vessel</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supply of process gases, compressed air</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Receipt, handling, storage of additives, processing aids, etc.</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cleaning of facilities and equipment (normal circumstances)</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cleaning of facilities and equipment (prior to switching to processing materials or products with stricter requirements)</td>
<td>√</td>
<td></td>
<td>E.g. alternating between manufacture of animal and human consumption products.</td>
</tr>
<tr>
<td>Cleaning (post-CCP areas for RTE products)</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waste management</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control of chemicals</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health of personnel</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pest control</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repairs and maintenance of facilities and equipment</td>
<td>√</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 14.2 Supply of Animal Material

<table>
<thead>
<tr>
<th>Procedures/operation</th>
<th>No protocol</th>
<th>Protocol required</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply of animals (eligibility, locations, supplier statements, etc)</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hygienic handling and dressing of killed mammals</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cooling and transportation of killed mammals</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supply of deer velvet</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supply of fish</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Holding in animal material depots</td>
<td>√</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 14.3 Primary Processing

<table>
<thead>
<tr>
<th>Procedures/operation</th>
<th>No protocol</th>
<th>Protocol required</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRIMARY PROCESSING - FARMED MAMMALS, KILLED MAMMALS, FARMED BIRDS, LIVE POSSUMS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reception (animal health status, supplier statements)</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identification and control of suspect animal material</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ante-mortem and post-mortem examination</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hygienic slaughter and dressing</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Washing of carcasses of mammals</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cooling of poultry to 7°C</td>
<td></td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Procedures/operation</td>
<td>No protocol</td>
<td>Protocol required</td>
<td>Comments</td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
<td>-------------</td>
<td>-------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Chilling or freezing below 7°C</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chilled and frozen storage (maintenance)</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capability of freezers/chillers when reducing temperature to preservation temperature</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRIMARY PROCESSING - DEER VELVET</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reception</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRIMARY PROCESSING - FISH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reception</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Handling and processing</td>
<td>√</td>
<td></td>
<td>Histamine level is a required specification but it is not expected to be measured by the processor. Effectiveness can be demonstrated by compliance to established procedures.</td>
</tr>
<tr>
<td>Chilling and freezing to preservation temperature</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capability of freezers and chillers</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRIMARY PROCESSING – BIVALVE MOLLUSCAN SHELLFISH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reception</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wet storage and depuration</td>
<td>√</td>
<td></td>
<td>Refer to HC Specification</td>
</tr>
<tr>
<td>Shucking</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heat Shocking (Listeriocidal)</td>
<td>√</td>
<td></td>
<td>Refer to HC Specification</td>
</tr>
<tr>
<td>Chilling and freezing to preservation temperature</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capability of freezers and chillers</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRIMARY PROCESSING – EGGS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole flock health scheme</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reception of birds</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bird management</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harvesting and handling of eggs</td>
<td>√</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Appendix F: Procedures or Steps that Require Data as Evidence for Demonstrating Effectiveness

<table>
<thead>
<tr>
<th>Procedures/operation</th>
<th>No protocol</th>
<th>Protocol required</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Washing of eggs</td>
<td>√</td>
<td></td>
<td>Protocol needed if criteria in NZFSA approved egg RMP template is not followed.</td>
</tr>
<tr>
<td>Candling and packing</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Storage</td>
<td>√</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### PRIMARY PROCESSING – HONEY/BEE PRODUCTS

<table>
<thead>
<tr>
<th>Procedures/operation</th>
<th>No protocol</th>
<th>Protocol required</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reception</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Handling, processing, packing</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Storage</td>
<td>√</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 14.4 Secondary Processing

<table>
<thead>
<tr>
<th>Procedures/Operation</th>
<th>No protocol</th>
<th>Protocol required</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>SECONDARY PROCESSING - GENERAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cleaning, sorting, grading of materials</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cutting, boning, size reduction</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thawing/tempering of meat and poultry</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mixing, emulsification</td>
<td>√</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

THERMAL PROCESSING - including Dairy

<table>
<thead>
<tr>
<th>Procedures/Operation</th>
<th>No protocol</th>
<th>Protocol required</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial sterilisation (aseptic, in container retorting)</td>
<td>√</td>
<td></td>
<td>Cooling is not critical for small products (e.g. cooked frankfurters). Protocol may not be necessary for such products.</td>
</tr>
<tr>
<td>Pasteurisation</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cooling of thermally processed product</td>
<td>√</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heat processing other than sterilisation and pasteurisation (i.e. non-lethal heating) | √ | Heating for other technical reasons (e.g. grill marking of patties, heating of honey to reduce viscosity) does not require a protocol. |

Drying                                      | √           |                  |                                                                         |
<table>
<thead>
<tr>
<th>Procedures/Operation</th>
<th>No protocol</th>
<th>Protocol required</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SMOKING</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hot smoking</td>
<td></td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Cold smoking of RTE products</td>
<td></td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Cold smoking of products that require further cooking by the consumer</td>
<td>√</td>
<td>Smoking for flavour only does not require a protocol.</td>
<td></td>
</tr>
<tr>
<td><strong>COOLING</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chilling/freezing of mechanically separated meat</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cooling of hot boned products to 7°C</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SALTING, CURING, BRINING</strong></td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ACIDIFICATION</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Addition of acid for preservation (pH control) e.g. marinated mussels/fish</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Addition of acid for flavour only</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FERMENTATION</strong></td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>HIGH PRESSURE PROCESSING</strong></td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>EXTRACTION, EXPRESSION</strong></td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>EVAPORATION, CONCENTRATION FOR PRESERVATION</strong></td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>RENDERING</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rendering</td>
<td>√</td>
<td></td>
<td>Achievement of 90°C for 10 minutes must be confirmed for medium risk material. Requirement presently being reviewed.</td>
</tr>
<tr>
<td>Drying</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>REFINING OF FATS AND OILS</strong></td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PACKING</strong></td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CAPABILITY OF FREEZERS/CHILLERS WHEN USED FOR REDUCING TEMPERATURE TO PRESERVATION TEMPERATURE</strong></td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>STORAGE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refrigerated storage (cold store)</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dry storage</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TRANSPORT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meat and meat products above 7°C</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedures/Operation</td>
<td>No protocol</td>
<td>Protocol required</td>
<td>Comments</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>-------------</td>
<td>-------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Dairy, meat and meat products at or below 7°C</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other products (non-refrigerated)</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>OTHER PRODUCT SPECIFIC PROCESSES</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cleaning and processing of green offal and runners</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salting of casings</td>
<td>√</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
15 Appendix G: Guidance on Difference between Significant and Minor Amendments

Amendment 4
November 2010
This topic is introduced in section 7.5 of this manual. This appendix provides guidance and examples. Mostly for non-dairy operators, of each of the Animal Products (Risk Management Programme Specifications) Notice 2008 clauses relevant to significant amendments. For further guidance on significant and minor amendments for dairy operations see:


This appendix is intended as a guide only, so will not cover every possible scenario and may not be representative of every situation. Each amendment is considered on a case by case basis. It may be necessary to consult with a recognised agency or NZFSA for further clarification.

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

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

(for registration scope see http://www.nzfsa.govt.nz/animalproductsregisters-lists/risk-management-programmes/index.htm (non-dairy) and/or; http://www.nzfsa.govt.nz/dairy/registers-lists/index.htm (dairy)).

You should document the basis for the decision, including any advice received from recognised evaluators, verifiers, experts, writers or NZFSA, and make this available to recognised evaluators, recognised verifiers or NZFSA.

15.1 Major Alterations to Processing Facilities or Equipment

AP (RMP Specifications) Notice 2008 clause:
22. Significant amendments to the risk management programme

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

(a) making major alterations to the processing facilities or equipment which may impact on fitness for intended purpose of the animal material or animal product:

Your justification should consider and include:

- what is the potential for your change to adversely affect the fitness for purpose of your product? Consider the nature of your process (e.g. enclosed vs. exposed product)?

<table>
<thead>
<tr>
<th>Examples of Significant Amendments</th>
<th>Examples of Minor Amendments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changes that can alter the processing environment temperature and humidity and the introduction of new hazards.</td>
<td>Altering floor layouts in standard hygiene areas.</td>
</tr>
</tbody>
</table>

15.1.1 Altering the Physical Boundaries of the RMP

In general, increasing the physical boundaries is a significant amendment. However, where the increase in boundary does not introduce new hazards and/or affect processes, the amendment may be considered minor. You need to provide a written justification to the recognised agency detailing why the increase in boundary is not considered a significant amendment. Where the physical boundaries of the RMP are reduced, this would be minor, unless the change adversely impacts on the RMP. Regardless of whether the change in physical boundary is significant or minor, you should notify the recognised agency and provide an updated site plan.

15.1.2 Removal of Buildings/Facilities

Your justification should include consideration of:

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

<table>
<thead>
<tr>
<th>Examples of Significant Amendments</th>
<th>Examples of Minor Amendments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Removal of facilities/equipment that prevents essential processes from being carried out, e.g. removal of a blast freezer.</td>
<td>Removal of redundant or disused facilities/buildings.</td>
</tr>
</tbody>
</table>

15.1.3 Construction of New Buildings and Facilities

To decide whether building construction is a significant or minor amendment you should consider:

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

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

15.1.4 Building and Facility Alterations

Your justification should consider:

• the extent of alterations needed;
• the impact of the alterations on the process and operations, e.g. changes to process flow; new process steps.
• whether the alterations will change the use of the existing facilities, room or area.
• whether the change impacts on the effectiveness of a critical control point (CCP).
### Examples of Significant Amendments

| **Reconfiguration or reconstruction of a processing area where there has been a substantial change to the process or a new hazard or risk is identified.** |
| **An accumulation of minor changes which together would be the equivalent of a significant amendment.** |

### Examples of Minor Amendments

| **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.** |
| **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 or to allow halal slaughter;** |
| **Alterations to stable ingredient (e.g. salt) storage, or alterations to animal holding facilities;** |
| **Changes to essential services where this does not introduce new hazards.** |

| **Changing the use of a room from a lower standard to a higher standard, e.g. support facility to a process room, pet food to human consumption, raw to cooked, or becoming part of a critical hygiene area, except where the RMP already contains buildings or facilities of a similar higher standard.** |
| **Construction in non-processing areas such as amenities, support facilities and engineering facilities, but not to change them to a higher standard of use.** |

| **A new heat treatment facility where the RMP does not contain similar facilities.** |
| **A new heat treatment facility where the RMP already contains similar facilities.** |

### 15.1.5 New Processing Equipment

Your justification should include consideration of:

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

<table>
<thead>
<tr>
<th>New processing equipment that is essential for food safety, e.g.:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• new technology, e.g. high pressure processing, filtration as a microbiocidal step;</td>
</tr>
<tr>
<td>• new equipment used for heat shocking mussels for listeriocidal effect.</td>
</tr>
<tr>
<td>• alterations to pasteuriser flow rates.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>New processing equipment that can be detrimental to food safety if not set up and operated correctly, e.g.:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• new type of machine for mechanically separating meat;</td>
</tr>
<tr>
<td>• new type of egg washing system.</td>
</tr>
</tbody>
</table>

| A new retort that is a different make and model to any existing retorts covered by the existing RMP. |

| Major changes to rendering equipment e.g.; changing from batch Iwell cookers to continuous low temperature cookers. |

### Examples of Minor Amendments

<table>
<thead>
<tr>
<th>New processing equipment that is not essential for food safety e.g.:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• new conveyor belts;</td>
</tr>
<tr>
<td>• new mixers, blenders;</td>
</tr>
<tr>
<td>• new cutting equipment.</td>
</tr>
</tbody>
</table>

| A new retort that is the same make and model as an existing retort covered by the existing RMP. |

### 15.2 Relocating Processing Operations

**AP (RMP Specifications) Notice 2008 clause:**

22. **Significant amendments to the risk management programme**

(1)(b) relocating processing operations to a new physical address (except where this is already permitted for mobile premises and vessels)

This is always a significant amendment.

### 15.3 New Animal Material or Animal Product

**AP (RMP Specifications) Notice 2008 clause:**

22. **Significant amendments to the risk management programme**

(1)(c) processing animal material or animal product that is not covered by the risk
management programme, except —
(i) where the product and process are similar, and
(ii) a documented risk factor identification and hazard analysis has shown that all
risk factors associated with that animal material or animal product are already
adequately addressed by the risk management programme:

15.3.1 Primary Processing of a New Animal Material

Primary processing of a new animal material not currently covered by the RMP is always
considered a significant amendment except as agreed by NZFSA. Such agreement may
require you to notify NZFSA of changes so that accurate registration information can be
maintained.

<table>
<thead>
<tr>
<th>Animal Material</th>
<th>Significant Amendment</th>
<th>Minor Amendment and Notification to NZFSA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammals including:</td>
<td></td>
<td>Changing between non-farmed types (i.e. from wild to game estate or to farmed gone feral or vice versa).</td>
</tr>
<tr>
<td>Alpacas / llamas;</td>
<td>Changing from farmed to non-farmed (e.g. wild / game estate/ farmed gone feral) and vice versa.</td>
<td></td>
</tr>
<tr>
<td>Bobby calves;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buffaloes / bison /</td>
<td></td>
<td></td>
</tr>
<tr>
<td>cattle hybrids;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cattle;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chamois;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deer;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Horses / other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>equines;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pigs;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Possums;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rabbits / hares;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sheep / goats.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Risk Management Programme Manual for Animal Product Processing

**Amendment 4**

**Appendix G: Guidance on Difference between Significant and Minor Amendments**

<table>
<thead>
<tr>
<th>Animal Material</th>
<th>Significant Amendment</th>
<th>Minor Amendment and Notification to NZFSA</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Thar;</td>
<td></td>
<td>Changing within a bullet in column 1.</td>
</tr>
<tr>
<td>• Wallabies.</td>
<td></td>
<td>Adding live fish when the RMP already covers live rock lobster.</td>
</tr>
<tr>
<td>• Finfish / squid &amp; other cephalopods / eels / paua / kina, crabs / non bivalve molluscan shellfish;</td>
<td>Changing between animal materials bulleted in column 1 except as listed in column 3.</td>
<td>Changing from farmed to non-farmed species and vice versa.</td>
</tr>
<tr>
<td>• Crustaceans;</td>
<td>Adding live rock lobsters when the RMP already covers live fish (no processing) if tailing needs to be considered.</td>
<td>Adding paua or kina when the RMP already covers crustaceans or bivalve molluscan shellfish.</td>
</tr>
<tr>
<td>• Bivalve molluscan shellfish (BMS).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Chickens / pouisson / fowl / ducks / geese / pheasants / quail / guinea fowl;</td>
<td>Changing between animal materials bulleted in column 1.</td>
<td>Changing within a bullet in column 1.</td>
</tr>
<tr>
<td>• Turkey;</td>
<td>Changing from farm to non-farm and vice versa.</td>
<td>Adding live fish when the RMP already covers live rock lobster.</td>
</tr>
<tr>
<td>• Layer hens.</td>
<td>Changing within a bullet in column 1.</td>
<td>Changing from farmed to non-farmed species and vice versa.</td>
</tr>
<tr>
<td>• Whole shell eggs.</td>
<td>Changing between farm methods (e.g. caged, barn, free range) for harvesting.</td>
<td>Changing between farm methods (e.g. caged, barn, free range) for other operations.</td>
</tr>
<tr>
<td>• Honey;</td>
<td>Changing between animal materials bulleted in column 1.</td>
<td>Changing between bee products (other than honey).</td>
</tr>
<tr>
<td>• Other bee products.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Deer velvet.</td>
<td>N/a.</td>
<td>N/a.</td>
</tr>
</tbody>
</table>
15.3.2 New Dairy Material or Dairy Product

Primary processing of a new dairy material

Primary processing of a new dairy material not currently covered by the RMP should always be considered a significant amendment except as agreed by NZFSA. Such agreement may nevertheless require you to notify NZFSA of changes so that accurate registration information can be maintained.

Processing of a new dairy product

Processing of a new dairy product not currently covered by the RMP should always be considered a significant amendment except as agreed by NZFSA.

15.3.3 Secondary Processing of a New Animal Product

New animal products can be added to your RMP without the need for a significant amendment. These can be notified to NZFSA and a minor amendment made to your RMP. To decide if a significant amendment is required, refer to NZFSA categories table: Principal Categories of Processing, Animal Material/Animal Product Produced or Processed, http://www.nzfsa.govt.nz/animalproducts/publications/forms/ap-49-processing-tables/index.htm.

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

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

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

Where the amendment would be considered significant under any process category being undertaken a significant amendment must be registered.
Note: This section applies to the addition of new animal products within process categories already covered by the RMP. Refer to section 15.4.2 below for addition of new process categories.

For example:

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

<table>
<thead>
<tr>
<th>Process Category</th>
<th>Animal material or product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acidification</td>
<td>Red meat</td>
</tr>
<tr>
<td>Aseptic processing</td>
<td>Red meat</td>
</tr>
<tr>
<td>Blending / Mixing</td>
<td>Red meat</td>
</tr>
<tr>
<td>Boning / Cutting</td>
<td>Red meat</td>
</tr>
<tr>
<td>Collection</td>
<td>Red meat</td>
</tr>
</tbody>
</table>

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 NZFSA. 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.

#### 15.3.4 Processing of Animal Material or Animal Product for a Different Consumer

Includes, for example:

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

<table>
<thead>
<tr>
<th>Examples of Significant Amendments</th>
<th>Examples of Minor Amendments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where the RMP only covers processing for animal consumption and the operator wants to start processing for human consumption.</td>
<td>If all product is produced to human consumption standards according to the RMP, but the operator now wants to down grade to pet food. Note that risks involved in production of animal feed will need to be managed in the RMP. Management of loss stream product needs to be considered as a product output.</td>
</tr>
<tr>
<td>Where the RMP only covers processing for general consumption and the operator wants to start processing for susceptible population consumption.</td>
<td></td>
</tr>
</tbody>
</table>

15.4 New Process or Process Modifications

*AP (RMP Specifications) Notice 2008* clause:

22. Significant amendments to the risk management programme

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

(i) where the process or process modification is similar to existing processes, and

(ii) a documented risk factor identification and hazard analysis has shown that all risk factors associated with that process are already adequately addressed by the risk management programme:

15.4.1 Where an Existing Process Flow does not Adequately Describe the New/Amended Process

Your justification should include consideration of:

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

<table>
<thead>
<tr>
<th>Examples of Significant Amendments</th>
<th>Examples of Minor Amendments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where a less severe preservation step is proposed, e.g. reduction in cooking temperatures, higher water activity for a dried product.</td>
<td>Altering a drying process but still achieving the critical product parameter for water activity.</td>
</tr>
<tr>
<td>Making the process less effective, e.g. extending holding times at temperatures that allow growth of pathogens or slower cooling rate for a cooked product, except where the operator can demonstrate that they still meet the relevant criteria in an approved COP.</td>
<td>Different thermal process where operator can demonstrate that they still meet the relevant criteria in an approved COP.</td>
</tr>
<tr>
<td>Changing from cold boning to hot boning except where the operator can demonstrate that they still meet the relevant criteria in an approved COP.</td>
<td>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.</td>
</tr>
<tr>
<td>Where processing of ready-to-eat product is to occur and the RMP does not cover this.</td>
<td>A new thawing/tempering process that complies with a recognised code of practice, e.g. IS6.</td>
</tr>
<tr>
<td>Addition of a CCP, e.g. using a new type of preservation such as drying, not currently covered under the RMP.</td>
<td></td>
</tr>
<tr>
<td>Removal of a CCP, e.g. removing a pathogen kill step, e.g. changing from hot smoked mussels process, where hot smoking is a listericidal step, to cold smoking which is not a listericidal step.</td>
<td>Removal of a control point that had been incorrectly designated a CCP.</td>
</tr>
<tr>
<td>Changing from in-container sterilisation to aseptic processing in a cannery.</td>
<td></td>
</tr>
<tr>
<td>Amendment to process flow e.g. additional filters fitted that affect flow rates to heat treatment equipment.</td>
<td>Removal of an external storage silo.</td>
</tr>
<tr>
<td>Processes for loading out product above the maximum critical preservation (loadout) temperatures specified in clauses 76, 83, 90, 98, 104 of the Human Consumption Specifications this may be significant for either the consigning or the receiving RMP or both.</td>
<td></td>
</tr>
</tbody>
</table>
15.4.2 Changes to Categories of Processing in the Registration Details

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


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

<table>
<thead>
<tr>
<th>Examples of Significant Amendments</th>
<th>Examples of Minor Amendments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where a new dairy material or product is being added to an RMP that does not cover that class of dairy product or material.</td>
<td>Where a new dairy material or product is being added to an RMP that does cover that class of dairy product or material.</td>
</tr>
</tbody>
</table>

15.5 New Risk Factors or Adverse Impact on Existing Risk Factors

**AP (RMP Specifications) Notice 2008 clause:**

22. Significant amendments to the risk management programme (1)(e) making any other changes that introduce new risk factors, or adversely impact on existing risk factors:

This is always a significant amendment.
15.6 Merging RMPs

**AP (RMP Specifications) Notice 2008 clause:**

22. Significant amendments to the risk management programme
(1)(f) merging two or more registered risk management programmes.

This is always a significant amendment.

15.7 Splitting RMP

**AP (RMP Specifications) Notice 2008 clause:**

22. Significant amendments to the risk management programme
(1)(g) splitting a registered risk management programme into two or more risk management programmes.

This is always a significant amendment.

15.8 Adding a Business to a Multi-Business RMP

**AP (RMP Specifications) Notice 2008 clause:**

22. Significant amendments to the risk management programme
(1)(h) adding a business to a multi-business risk management programme except where the Director-General's approval under section 17A of the Act applies to a type of business, premises or place rather than to specific businesses.

<table>
<thead>
<tr>
<th>Examples of Significant Amendments</th>
<th>Examples of Minor Amendments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where the new business is being added to a multi-business RMP that is approved for specific businesses.</td>
<td>Where the new business is being added to a multi-business RMP that that is approved for a type of business, premises or place.</td>
</tr>
</tbody>
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16 Appendix H: Determination of Principally Dairy

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

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

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

3. However other factors are also taken into consideration such as:
   
   i. the characterising ingredient of the food and nature of the food, for example lactose as an inert carrier in tabletted products;
   
   ii. dilution and concentration through processing;
   
   iii. any other relevant factor.

4. Please note this determination does not take into account any applicable export requirements.

See section 12.1 (e). 12 Appendix D: Businesses Not Requiring RMPs

Notes:

“Dairy product” means – (a) animal material that, having originally been dairy material, - (i) has been delivered to the place of sale for consumption or for end use for purposes other than consumption;

“Dairy processing” means - All processing activities in relation to dairy material; and includes …

(e) the manufacture of products, including milk, butter, cream, milk-fat products, cheese, processed cheese, whey cheese, dried milks, milk-based infant formula, evaporated milks, condensed milks, whey, whey powder, whey products, casein, milk protein products, ice-
cream, low dairy fat ice-cream-like products, yoghurt, other fermented milks, dairy desserts, lactose, and colostrum products:

(h) further processing of dairy material that was previously dairy product with or without the addition of other material (including food, ingredients, additives, or processing aids as defined in the Food Standards Code), including reprocessing, repacking, reconstitution with water, and recombination of dairy products with or without water to make any dairy products.