Generic RMP Models for the Processing of Seafood Product

July 2011

Ministry of Agriculture and Forestry
Te Manatū Ahuwhenua, Ngāherehere

BIOSECURITY NEW ZEALAND

NEW ZEALAND FOOD SAFETY AUTHORITY

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Prelims

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Review of Code of Practice

This code of practice will be reviewed, as necessary, by the Ministry of Agriculture and Forestry. Suggestions for alterations, deletions or additions to this code of practice, should be sent, together with reasons for the change, any relevant data and contact details of the person making the suggestion, to:

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Wellington

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1 Introduction

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1.1 PURPOSE OF THIS DOCUMENT

These generic Risk Management Programme (RMP) models have been produced by the New Zealand Seafood Industry Council and the Ministry of Agriculture and Forestry (MAF), in consultation with an industry working group, to assist seafood product processors in the development of their RMPs. These models provide guidance on the application of Hazard Analysis and Critical Control Points (HACCP) and the development of certain RMP components for seafood product processing operations. Operators may develop their RMPs based on these models but they are expected to customise their RMP to their specific products, processes and premises.

Since many shellfish processors export their products to the United States, US market access requirements related to HACCP have been incorporated in the generic RMPs for shellfish. These market access requirements are shown in a box and/or are colour shaded to clearly identify them and differentiate them from New Zealand requirements.

These generic RMPs replace the Generic HACCP Models published in June 1997 as part of A *Guide to HACCP Systems in the Seafood Industry*. Their contents and format have been updated to comply with the requirements of the Animal Products Act 1999 and associated legislation, particularly the current version of the Animal Products (Risk Management Programme Specifications) Notice. RMP components that are not covered in a HACCP plan (e.g. management authorities and responsibilities, identification of hazards to animal health and risk factors associated with wholesomeness and false or misleading labelling) are included in these generic RMP models.

1.2 CONTENTS OF THE GENERIC RMPS

Table 1 summarises the components of an RMP. **For practical reasons, not all requirements regarding the documentation of the RMP are covered in this generic RMP**. Table 1 indicates whether the component is covered or not in the generic RMP models.

A brief instruction or explanation about the RMP component is given for each section in the model, followed by a worked example presented as a form or table. **Instructions and explanations are not part of the RMP and should be removed by the operator when preparing their own RMPs based on the generic models**. Operators do not need to follow the format used in the generic models but it is important that all required information is documented clearly in their RMP.

Supporting systems must be documented and form part of the RMP. A list of recommended supporting systems is given for each generic model, however, examples of documented supporting systems are not provided. Guidance on the documentation of supporting systems is given in Part 2 of the Code of Practice.

A comprehensive discussion of the RMP requirements and components is given in the Risk Management Programme Manual which is available on the MAF (Food Safety) website.

Table 1: RMP components

Components	Section of the generic RMP models
Operator, business and RMP identification	Form 1
List of RMP documents	A list of the documents comprising the RMP, with their date and version, must be included in the RMP. An example is not shown in this generic RMP
Management authorities and responsibilities	Form 2
Scope of the RMP	Form 3
Product description	Form 4
Process description	Form 5
Good Operating Practice (supporting systems)	A list of recommended supporting systems is given for each model. The supporting systems must be documented in the RMP
Application of HACCP (identification, analysis and control of hazards to human or animal health)	Forms 6A, 6B and 7
Identification and control of other risk factors (wholesomeness, false or misleading labelling)	Forms 8 and 9
Identification and competency of responsible persons	This must be documented in relevant sections of the RMP. Records of competencies are expected to be documented in a supporting system An example is not shown in this generic RMP. Refer to Part 2 section 9 of the COP
Recall procedures	This must be documented in a supporting system An example is not shown in this generic RMP. Refer to Part 2 section 35 of the COP
Corrective action procedures for unforeseen circumstances	This must be documented in a supporting system An example is not shown in this generic RMP. Refer to Part 2 section 37 of the COP
Notification requirements	This must be documented in a supporting system An example is not shown in this generic RMP. Refer to Part 2 section 37 of the COP
Operator verification	Form 10
Provision for external verification	RMP Specification, Clause 17 should be copied or referenced in the RMP
Document control and requirements for records	This must be documented in a supporting system. An example is not shown in this generic RMP Refer to Part 2 section 38 of the COP
Validation of the RMP	Refer to the RMP Manual

2 Generic RMP for half-shell mussels

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2.1 OPERATOR, BUSINESS AND RMP IDENTIFICATION

The name and address of the business operator must be documented in the RMP. The unique business identifier and the RMP identifier should also be included in this section of the RMP to assist in the traceability of documents.

Form 1: Operator, business and RMP identification

Information required	Details
Business identifier	*e.g. FP81, PET123*
RMP no.	*e.g. 01, 02*
Name of the operator	*Legal name of the business operator (i.e. the owner of the business)*
Address of the operator	*Business address of the operator (e.g. postal address of office)*
Electronic address of the operator	*Email address and/or web site address*
Name of the business	*The registered company name, if different from the operator's name*
Physical address of the premises	*Location of the premises*

2.2 MANAGEMENT AUTHORITIES AND RESPONSIBILITIES

The operator must identify the person who is responsible for the day-to-day management of the RMP. It is recommended that a deputy be designated who can take over from the day-to-day manager when necessary.

Form 2: Management authorities and responsibilities

Authority/responsibility	Details
Day-to-day manager	*Give name or, preferably, give position or designation*
Deputy for day-to-day manager	*Give name or, preferably, give position or designation*

2.3 SCOPE OF THE RMP

The operator must clearly define the coverage and application of the RMP.

Form 3: Scope of the RMP

Elements	Description/Details
Physical boundaries	Physical boundaries are indicated in the site plan given in Appendix xx. *Attach an accurate site plan. Ensure that amenities and external areas that may be a source of hazards and other risk factors are considered when establishing the physical boundaries. The site plan should also show any areas within the boundaries that are excluded from the RMP*
Risk factors covered by the RMP	Risk factors associated with: • Human health (for products intended for human consumption) • Animal health (for products intended for animal consumption) • Wholesomeness • False or misleading labelling
Animal material entering the RMP	Live greenshell mussels (*Perna canaliculus*)
Products leaving the RMP [1, 2]	• Half-shell mussels • Mussel meat • Blue mussels, damaged mussels
Process [1]	From receipt of live mussels to dispatch of packed frozen half-shell mussels Principal processing categories: • Chilling • Heat shocking • Shucking • Refrigeration
Exclusions	*Identify those materials, products or activities excluded from the RMP, and the alternative regulatory regime they are under* [3]

1. The products and processes covered by this generic RMP are examples only, based on a typical New Zealand mussel processing operation. The operator must ensure that their RMP accurately reflects their own products and processes.
2. Products should be listed either individually or as product groups with similar characteristics, processes and intended purpose. The list should be as specific as necessary for proper identification of hazards and their controls, but at the same time should allow flexibility in terms of other products of the same group that can be processed without the need for a significant amendment.
3. If any animal material or product processed within the physical boundaries of the RMP is excluded from the scope of the RMP, the operator must identify the material or product, the alternative regulatory regime that they are under (e.g. Food Act), and explain how the interfaces between regimes are managed. The operator must also document authorities and responsibilities, and the management of interfaces in relation to any activity undertaken by another person within the physical boundaries of the RMP.

2.4 PRODUCT DESCRIPTION

The operator must describe the animal products covered by the RMP, either individually; or as product groups with similar characteristics, processes and intended purpose. The product description must include the intended use and consumer, and any regulatory requirements or operator-defined limits relevant to the product. Other information such as company specifications for packaging, labelling, and shelf life may be included.

Form 4: Product description and intended purpose

	Products for human consumption	Products for animal consumption
Product name	• Half-shell mussels (*Perna canaliculus*) • Mussel meat	Blue mussels [1]; damaged/defective mussels
Intended consumer	Humans (general public)	Animals
Intended use of product	• Half-shell mussels – for direct consumption (ready-to-eat[2]) • Mussel meat - for further processing (e.g. hot smoking of mussel meat) or cooking	For further processing to animal feed
Regulatory requirements	Marine biotoxins limits specified in the AP Human Consumption Specifications clause 121 (3) Microbiological limits for mussels set in the Food Standards Code: Standard 1.6.1 and AP Human Consumption Specifications clause 121 (1): n c n M *E. coli*/g 5 1 2.3 7 *Salmonella*/25g 5 0 0 L. monoctygenes/25g 5 0 0	----- Microbiological limits – None
Operator-defined limits	Microbiological limits for mussels that are for cooking or further processing	
Packaging	As per regulatory and company specifications Refer to Supporting System[3]	As per regulatory and company specifications Refer to Supporting System[3]
Labelling	As per regulatory and company specifications. Refer to Supporting System[3]	As per regulatory and company specifications. Must be labelled "Not for Human Consumption" Refer to Supporting System[3]
Shelf-life and storage requirements	As per regulatory and company specifications Refer to Supporting System[3]	As per regulatory and company specifications Refer to Supporting System[3]

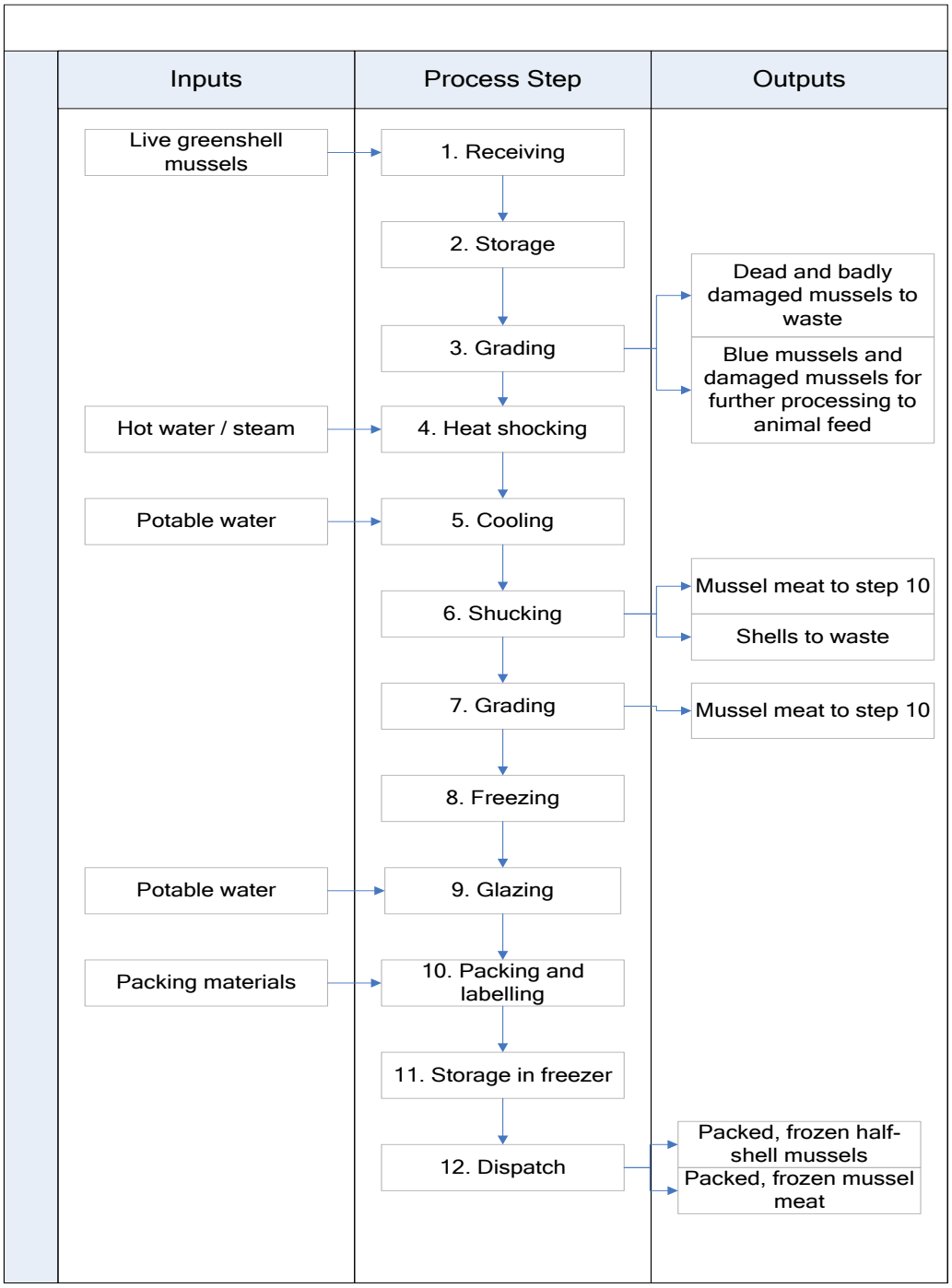
1. It has been assumed in this generic RMP that blue mussels are intended for animal consumption. If an operator uses blue mussels for further processed products for human consumption, the operator must ensure that this product/process is included and considered in their hazard analysis.
2. See Clause 140 of AP Human Consumption specifications for information on ready-to-eat (RTE) fish products.
3. Packaging, labelling and storage specifications must be documented in the operator's supporting systems. The operator should reference the relevant supporting system in the product description.

2.5 PROCESS DESCRIPTION

The processes covered in the RMP must be described accurately using process flow diagrams. There is no prescribed format for the diagram but the process flow should set out all steps in the process sequentially, and show relevant inputs and outputs. The process flow(s) must show the full extent of the process for all products covered by the RMP (i.e. up to dispatch of each product or product group, including any rework or recycling steps).

It should be noted that the examples given in this generic RMP are simplified presentations of the key steps based on a generic process.

Form 5: Process flow diagram for processing of half-shell mussels



2.6 GOOD OPERATING PRACTICE

The operator must document all relevant supporting systems (also known as prerequisite programmes, good hygienic practices) before applying HACCP principles to the process. These supporting systems must comply with all relevant regulatory requirements, particularly the Animal Product Regulations 2000 and the current Animal Products (Specifications for Products Intended for Human Consumption) Notice. Information in the documented supporting systems should include: authorities and responsibilities, procedures (including control, monitoring, corrective action and operator verification), and recording requirements.

Part 2 of the Seafood Code of Practice provides guidance on supporting systems relevant to the processing of shellfish. Supporting systems must address the activities and procedures listed below:

- Design, construction and maintenance of buildings, facilities and equipment;
- Calibration of measuring devices;
- Water;
- Cleaning & sanitation;
- Personnel health and hygiene;
- Control of chemicals;
- Pest control;
- Training and competency of personnel;
- Reception of shellfish;
- Other incoming materials (specifications, handling & storage of ingredients and additives);
- Packaging;
- Bivalve molluscan shellfish processing;
- Control of contamination of seafood product;
- Products for animal consumption;
- Labelling;
- Refrigeration & storage of product;
- Transport;
- Handling, disposition and recall of non-complying products;
- Traceability and inventory control;
- Operator verification and other operational requirements;
- Document control & record keeping.

2.7 HAZARD ANALYSIS AND CCP DETERMINATION

2.7.1 Identification of hazards from inputs

The operator must identify any hazards associated with each input considering any supplier agreements and raw material specifications.

Form 6A: Identification of hazards from inputs

Inputs	Description/specification [1]	Biological hazard (B)	Chemical hazard (C)	Physical hazard (P)
Live mussels	• Sourced from suppliers that comply with the Regulated Control Scheme for BMS [2] • Each consignment to be accompanied by a Shellfish Harvesting Declaration	• Pathogens from the marine environment (e.g. Vibrio spp., *Salmonella* spp., Norovirus) [3] • Pathogens due to contamination of mussels during harvest or transport (e.g. *Salmonella* spp., *Campylobacter jejuni*, *Listeria monocytogenes*) [4] • Marine biotoxins associated with the marine environment	• Chemical pollutants from harvest areas (e.g. heavy metals) • Chemical contaminants due to contamination during harvest or transport (e.g. fuel oil)	None
Water	Potable water as per the AP Human Consumption specifications clauses 8 to 14	None	None	None
Packaging materials	Suitable for use as food contact material as per AP Human Consumption specifications Part 6	None	None	None

1. Agreed specifications for inputs must be documented in a supporting system.
2. The Regulated Control Scheme (RCS) for Bivalve Molluscan Shellfish is administered by MAF and applies to all commercial shellfish growers and harvesters. The RCS covers the control and classification of shellfish growing areas, marine biotoxin control, and the requirements for harvesting and storage of shellfish. It also includes a surveillance programme for monitoring marine biotoxins, the bacteriological quality of the water, and compliance to the RCS requirements. The RCS minimises the risk from shellfish contaminated by microbiological (e.g. *Salmonella*, Norovirus, marine biotoxins) and chemical hazards (e.g. agricultural chemicals) due to pollution of the aquatic environment. Unless shellfish are harvested from a restricted area for post harvest treatment such as depuration, the shellfish are considered fit for human consumption as is.
3. Vibrio species are part of the normal microflora of estuarine and coastal waters worldwide. V. parahaemolyticus has been identified in New Zealand coastal waters, and in pacific oysters at low levels (Fletcher, 1985). Analysis of shellfish samples taken during the mid-1990s as part of the Ministry of Health's Domestic Food Monitoring programme and analysis by ESR Public Health Laboratories did not isolate V. parahaemolyticus from 12 mussel samples from Northland, Auckland, Waikato or Tairawhiti (Lake et al., 2003).

   The shallow waters and poor flushing of estuaries in certain areas present the greatest risk of viral contamination in shellfish. Mussels are commercially grown on ropes in deep water, so present less risk from viruses such as the Norovirus (Greening et al., 2003).
4. Shellfish may be contaminated after harvesting through the use of unclean equipment and containers, and through exposure to environmental contaminants such as dust, dirt, and bird droppings. However, this is not reasonably likely to occur.

   Cross-contamination during processing is considered to be the major source of *Listeria* in processed seafood product rather than the natural marine environment (Bremmer and Osborne, 1996). *Listeria* monocytogenes was not detected in samples of mussels collected from approved growing areas (Fletcher et al, 1994).

2.7.2 Hazard analysis and Critical Control Point (CCP) determination

Form 6B: Hazard analysis and CCP determination for half-shell mussels

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? [1] If yes, identify the control measure and then answer Q2 If no, consider hazard at next step	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit or an IPC related to food safety? If yes, this step is a CCP If no, this step is not a CCP	CCP no. [2]
1. Receiving	Live mussels	B – Bacterial pathogens	Refer to Form 6A	Yes. GOP: Reception procedures, including checking of Shellfish Harvesting Declarations to confirm compliance with the RCS. Refer to Supporting System xx	No	CCP1 – market access
		B - Marine biotoxins	Refer to Form 6A	Same as above	Yes	
		C – Chemical residues	Refer to Form 6A	Same as above	Yes	
2. Storage	Live mussels	B - Bacterial pathogens	Micro carried from previous step	Yes – GOP: correct storage temperature will minimise micro growth; hygienic practices will minimise contamination Refer to Supporting System xx	No	CCP2 – market access
3. Grading	Live mussels	B - Bacterial pathogens	Micro carried from previous step	No		
4. Heat shocking[3]	Live mussels	B - Bacterial pathogens	Micro carried from previous step	No		
5. Cooling	Heat shocked mussels Water	None				CCP3 – market access

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? [1] If yes, identify the control measure and then answer Q2 If no, consider hazard at next step	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit or an IPC related to food safety? If yes, this step is a CCP If no, this step is not a CCP	CCP no. [2]
6. Shucking	Heat shocked mussels	B- *Listeria monocytogenes*	Contamination of mussels by *Listeria* can occur after heat shocking	Yes – GOP: cleaning and sanitation and hygienic procedures will minimise *Listeria* contamination[4]. *Listeria* monitoring programme will confirm effectiveness of control measures Refer to Supporting System xx	No	
		P – Shell pieces [5]	Broken shell pieces can occur in mussels	Yes – GOP: correct shucking procedures will minimise the occurrence of broken shell pieces Refer to Supporting System xx	No	
7. Grading	Half-shell mussels	B- *Listeria monocytogenes*	Contamination of mussels by *Listeria* can occur during processing	Yes – GOP: cleaning and sanitation and hygienic procedures will minimise *Listeria* contamination. *Listeria* monitoring programme will confirm effectiveness of control measures Refer to Supporting System xx	No	
		P – Shell pieces	Hazard carried from previous step	Yes – GOP: removal of shell pieces during grading will minimise, but not completely eliminate its occurrence	No	
8. Freezing	Half-shell mussels	B- *Listeria monocytogenes*	Micro carried from previous step	No		

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? [1] If yes, identify the control measure and then answer Q2 If no, consider hazard at next step	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit or an IPC related to food safety? If yes, this step is a CCP If no, this step is not a CCP	CCP no. [2]
9. Glazing	Half-shell mussels	B- *Listeria monocytogenes*	Micro carried from previous step	No		
	Potable water	None				
10. Packing and labelling	Glazed half-shell mussels	B- *Listeria monocytogenes*	Micro carried from previous step	No		
	Packaging materials	None				
11. Storage in freezer	Packed half-shell mussels	B- *Listeria monocytogenes*	Micro carried from previous step	No		
12. Dispatch	Packed frozen half-shell mussels	B- *Listeria monocytogenes* [6]	Micro carried from previous step	No		

1. The supporting system where the particular control measure is documented should be cited in this column.
2. CCPs that have been mandated as a requirement for entry to the US market are shaded and indicated as market access CCPs. The requirements for these market access CCPs are explained in the US FDA Guide for the Control of Molluscan Shellfish 2003, Model Ordinance, XI. Shucking and Packing. Operators must clearly identify any client or market access CCP in their RMP.
3. Heat shocking is done primarily to facilitate opening the mussels and to inhibit enzymes that can reduce the shelf-life of mussel products. The regulatory requirements for heat shocking are specified in AP Human Consumption Specifications clause 137.
4. The regulatory requirements for the shucking, processing and packing of bivalve molluscan shellfish are specified in AP Human Consumption Specifications clause 136.
5. The operator should set a limit for shell pieces that is appropriate to their product and its intended use. As a guide, industry information on customer complaints indicates that the presence of shell pieces greater than 5 mm is unacceptable. The US FDA considers products unacceptable when they contain any hard or sharp foreign object that measures 7 mm to 25 mm in length (FDA/ORA Compliance Policy Guide 555.425).
6. Sporadic cases of *Listeria* monocytogenes in uncooked mussels have been reported to occur. They have been attributed to cross-contamination and contamination from the processing environment.

2.7.3 CCP summary

Form 7: Summary table for CCPs

Three market access CCPs have been identified in this generic RMP. These CCPs apply only to RMPs that cover the processing of shellfish for export to the US. Under the New Zealand standard, the hazards that are controlled by these CCPs are expected to be adequately addressed by GOP. The requirements for these market access requirements are given in the US FDA Guide for the Control of Molluscan Shellfish 2003. Model Ordinance. XI. Shucking and Packing.

The number of CCPs within the RMP, their location within the process, the monitoring and other CCP procedures may differ for each premises. The procedures for each CCP must be fully documented (consider who, what, when and how) in the RMP. The regulator will verify the effectiveness of any market access CCP against the relevant OMAR.

Process step	Hazard	CCP no.	Critical limits	Monitoring procedures	Corrective actions	Verification procedures	Records
1. Receiving	B- Bacterial pathogens, viruses, marine biotoxin from the marine environment	1 – market access	All consignments must be sourced from approved growing areas and accompanied by a Shellfish Harvest Declaration Shellstock must have a tag on each container, or transaction record on each bulk shipment	Visual check of harvest declaration and identification tag	Reject non-compliant consignment of shellstock	Reality checks of CCP monitoring and corrective action taking Review of records Internal audit External audit	Daily CCP monitoring worksheet Receival records Corrective action report Internal audit report External audit report
2. Storage	B – Bacterial pathogens	2 – market access	Storage at ≤ 7°C Periods without ice or refrigeration not to exceed 2 hours at points of transfer such as loading docks	Visually check level of icing, or Check temperature of refrigerated storage facility	Add more ice, or adjust setting of refrigerated room Reject shellstock for further processing if temperature requirement is not met	Reality checks of CCP monitoring and corrective action taking Review of records Calibration of temperature measuring device Internal audit External audit	Daily CCP monitoring worksheet Corrective action report Calibration record Internal audit report External audit report

Process step	Hazard	CCP no.	Critical limits	Monitoring procedures	Corrective actions	Verification procedures	Records
5. Cooling of heat shocked mussels	B – Bacterial pathogens	3 – market access	Cooling regime that will achieve cooling of mussels to ≤ 7°C within two hours of being heat shocked, and ≤ 4°C within 4 hours of being heat shocked	Monitor cooling parameters, or temperature of mussels	Adjust cooling parameters	Reality checks of CCP monitoring and corrective action taking Review of records Internal audit External audit	Daily CCP monitoring worksheet Corrective action report Internal audit report External audit report

2.8 IDENTIFICATION AND CONTROL OF RISKS TO WHOLESOMENESS

The RMP must identify the risk factors related to wholesomeness that are reasonably likely to occur for each product covered by the RMP. It must also identify the control measures for addressing the risk factors. The control measures must be documented, including procedures for monitoring, corrective action and verification, and records.

Form 8: Summary of identified risk factors and controls related to wholesomeness

Risk factor	Source or cause of risk factor	Control measure
Spoilage	Micro growth due to improper time/temperature control	GOP – time/temperature control, proper refrigeration Refer to Supporting Sys. xx
Foreign objects that are not hazards, e.g. hair, personal items	Contaminants from personnel	GOP – personnel hygienic practices Refer to Supporting Sys. xx
Other wholesomeness defects (e.g. pea crabs, small shell pieces < 5 mm)	Broken shell pieces due to improper handling and shucking	GOP- washing, inspection, proper handling
	Pea crabs naturally present when mussels are harvested	Refer to Supporting Sys. xx

2.9 IDENTIFICATION AND CONTROL OF RISKS FROM FALSE OR MISLEADING LABELLING

Any information applied to the packaging must be correct and accurate. The RMP must identify the risk factors related to false or misleading labelling that is reasonably likely to occur for each product. It must also identify the control measures for addressing the risk factors. The control measures must be documented, including procedures for monitoring, corrective action and verification, and records. An example is shown in Form 9.

Form 9: Summary of identified risk factors and controls related to false or misleading labelling

Risk factor	Source or cause of risk factor	Control measure(s)
Incorrect details on label or transportation outers, e.g. • type of product • product description • lot id • storage directions	Incorrect label design	Procedures for ensuring correct label design Refer to Supporting Sys. xx
	Product put in wrong carton or pack	Procedures for ensuring correct packaging of products Refer to Supporting Sys. xx

2.10 OPERATOR VERIFICATION

The operator must verify the effectiveness of their RMP against their documented procedures and any criteria defining the product's fitness for intended purpose (e.g. regulatory requirements and operator-defined limits, GOP requirements, and critical limits). The verification procedures must be documented, including responsibilities, corrective action, frequencies, and records. The various verification activities may be summarised as shown in Form 10.

Form 10: Summary of operator verification activities

Activity	Description	Supporting system
Review of monitoring and corrective action records (CCPs and GOP controls)	All daily monitoring sheets checked to ensure that documented procedures are complied with, limits are adhered to, and appropriate corrective actions are taken	xxx
Listeria monitoring (environment and product testing)	As per documented *Listeria* monitoring programme	xxx
Internal audits	Internal audit involving: • review of records • review of test results • reality checks	xxx
Review of RMP including supporting systems	Review of effectiveness of RMP. Reassessment of RMP (e.g. new hazards; changes in inputs, process steps, critical limits)	xxx
Other activities related to the verification of CCPs, any operator-defined limits, and supporting systems		

3 Generic RMP for hot smoked mussel meat

Amendment 0

July 2011

3.1 OPERATOR, BUSINESS AND RMP IDENTIFICATION

The name and address of the business operator must be documented in the RMP. The unique business identifier and the RMP identifier should also be included in this section of the RMP to assist in the traceability of documents.

Form 1: Operator, business and RMP identification

Information required	Details
Business identifier	*e.g. FP81, PET123*
RMP no.	*e.g. 01, 02*
Name of the operator	*Legal name of the business operator (i.e. the owner of the business)*
Address of the operator	*Business address of the operator (e.g. postal address of office)*
Electronic address of the operator	*Email address and/or web site address*
Name of the business	*The registered company name, if different from the operator's name*
Physical address of the premises	*Location of the premises*

3.2 MANAGEMENT AUTHORITIES AND RESPONSIBILITIES

The operator must identify the person who is responsible for the day-to-day management of the RMP. It is recommended that a deputy be designated who can take over from the day-to-day manager when necessary.

Form 2: Management authorities and responsibilities

Authority/responsibility	Details
Day-to-day manager	*Give name or, preferably, give position or designation*
Deputy for day-to-day manager	*Give name or, preferably, give position or designation*

3.3 SCOPE OF THE RMP

The operator must clearly define the coverage and application of the RMP.

Form 3: Scope of the RMP

Elements	Description/details
Physical boundaries	Physical boundaries are indicated on the site plan given in Appendix xx *Attach an accurate site plan. Ensure that amenities and external areas that may be a source of hazards and other risk factors are considered when establishing the physical boundaries. The site plan should also show any areas within the boundaries that are excluded from the RMP*
Risk factors covered by the RMP	Risk factors associated with: • Human health • Wholesomeness • False or misleading labelling
Animal material entering the RMP	Shucked mussel meat
Products leaving the RMP [1, 2]	Hot smoked mussel meat
Process[1]	From receipt of shucked mussel meat to dispatch of packed smoked mussel meat Principal processing categories: • Thawing • Smoking • Refrigeration
Exclusions	*Identify those materials, products or activities excluded from the RMP, and the alternative regulatory regime they are under* [3]

1. The products and processes covered by this generic RMP are examples only based on a typical New Zealand hot smoked mussel processing operation. The operator must ensure that their RMP accurately reflects their own products and processes.
2. Products should be listed either individually or as product groups with similar characteristics, processes and intended purpose. The list should be as specific as possible, but at the same time should allow flexibility in terms of other products of the same group that can be processed without the need for a significant amendment.
3. If there is any animal material or product processed within the physical boundaries of the RMP but are excluded from the scope of the RMP, the operator must identify the material or product, the alternative regulatory regime that they are under (e.g. Food Act), and explain how the interfaces between regimes are managed. The operator must also document authorities and responsibilities, and the management of interfaces in relation to any activity undertaken by another person within the physical boundaries of the RMP.

3.4 PRODUCT DESCRIPTION

The operator must describe the animal products covered by the RMP, either individually; or as product groups with similar characteristics, processes and intended purpose. The product description must include the intended use and consumer and any regulatory requirements or operator-defined limits relevant to the product. Other information such as company specifications for packaging, labelling, and shelf life may be included under the product description.

Form 4: Product description and intended purpose

Product name	Hot smoked mussel meat (*Perna canaliculus*)
Intended consumer	Humans (general public)
Intended use of product	Ready-to-eat [1]
Regulatory requirement	Microbiological limit set in the Food Standards Code: Standard 1.6.1: *Listeria monoctygenes* = 0 in 25g
Operator-defined requirement	No shell pieces greater than specified size [2]
Packaging	As per regulatory and company specifications (refer to Supporting System xx) [3]
Labelling	As per regulatory and company specifications (refer to Supporting System xx)
Shelf-life and storage requirements	As per regulatory and company specifications (refer to Supporting System xx)

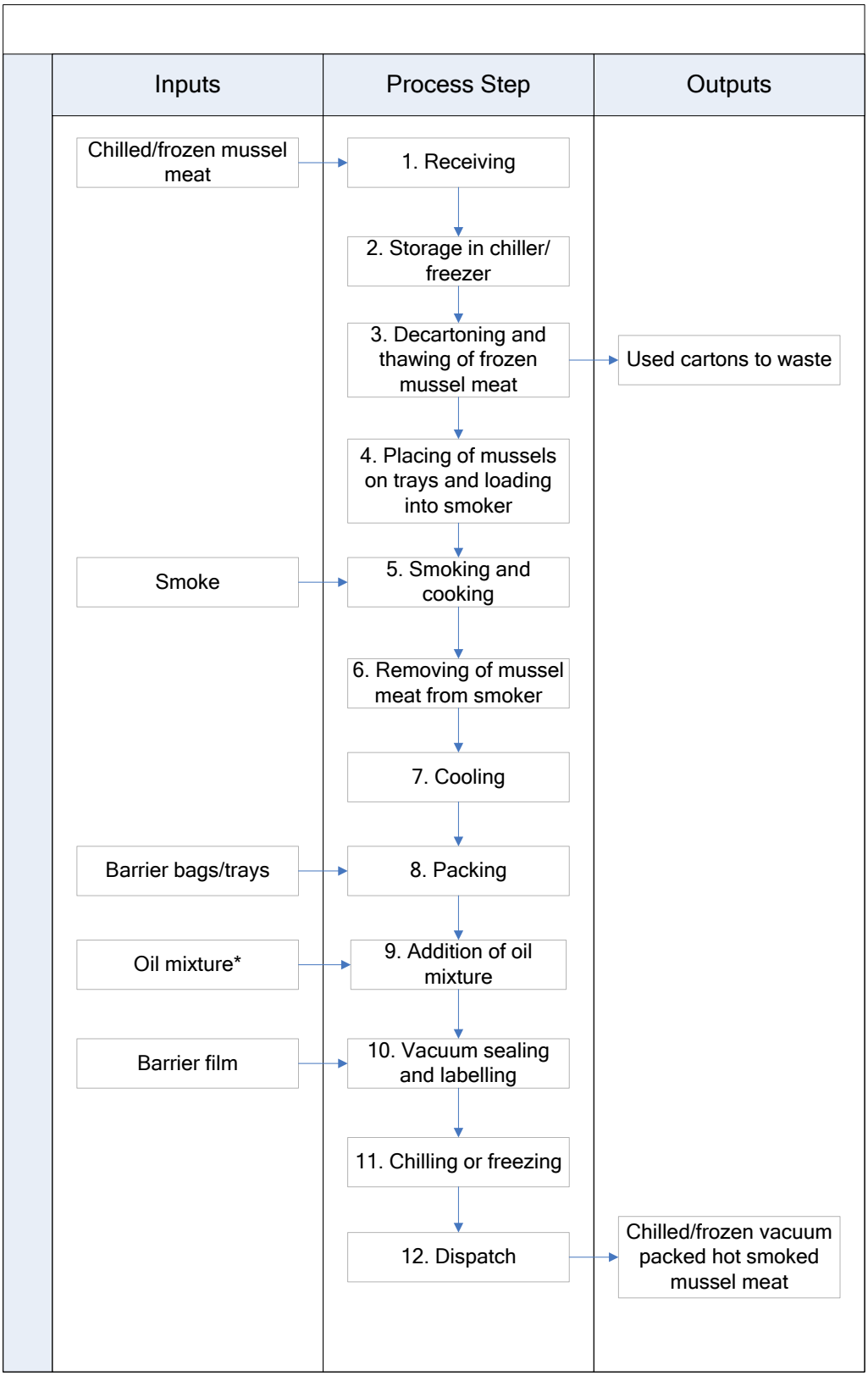
1. See Clause 140 of AP Human Consumption specifications for information on ready-to-eat (RTE) fish products.
2. The operator should set their own limit for shell pieces that is appropriate to their product and its intended use. As a guide, industry information on customer complaints indicates that the presence of shell pieces greater than 5 mm is unacceptable. The US FDA considers products unacceptable when they contain any hard or sharp foreign object that measures 7 mm to 25 mm in length (FDA/ORA Compliance Policy Guide 555.425).
3. Packaging, labelling and storage specifications are expected to be documented in supporting systems.

3.5 PROCESS DESCRIPTION

The processes covered in the RMP must be described accurately using process flow diagrams. There is no prescribed format for the diagram but the process flow should set out all steps in the process sequentially, together with relevant inputs and outputs. The process flow(s) must show the full extent of the process for all products covered by the RMP (i.e. up to dispatch of each product or product groups, including any rework or recycling steps).

It should be noted that the examples given in this generic RMP are simplified presentations of the key steps based on a generic process.

Form 5: Process flow diagram for processing of hot smoked mussels



*It is assumed in this generic RMP that a commercially produced oil mixture is used. If the operator makes their own mixture, the ingredients used and the preparation procedures must be covered in the hazard identification and analysis.

3.6 GOOD OPERATING PRACTICE

The operator must document all relevant supporting systems (also known as prerequisite programmes, good hygienic practices) before applying HACCP principles to the process. These supporting systems must comply with all relevant regulatory requirements, particularly the Animal Product Regulations 2000 and the current Animal Products (Specifications for Products Intended for Human Consumption) Notice. Information in the documented supporting systems should include: authorities and responsibilities, procedures (including control, monitoring, corrective action and operator verification), and recording requirements.

Part 2 of the Seafood Code of Practice provides guidance on supporting systems relevant to the scope of this RMP. Supporting systems must address the activities and procedures listed below:

- Design, construction and maintenance of buildings, facilities and equipment;
- Calibration of measuring devices;
- Potable water;
- Cleaning & sanitation;
- Personnel health and hygiene;
- Control of chemicals;
- Pest control;
- Training and competency of personnel;
- Reception of mussel meat;
- Other incoming materials (specifications, handling & storage of ingredients and additives);
- Packaging;
- Processing of shellfish;
- Contamination control;
- Products for animal consumption;
- Labelling;
- Refrigeration and storage of product;
- Transport;
- Handling, disposition and recall of non-complying products;
- Traceability and inventory control;
- Operator verification and other operational requirements;
- Document Control and record keeping.

3.7 HAZARD ANALYSIS AND CCP DETERMINATION

3.7.1 Identification of hazards from inputs

The operator must identify any hazards associated with each input considering any supplier agreements and raw material specifications.

Form 6A: Identification of hazards from inputs

Inputs	Description/specification [1]	Biological hazard (B)	Chemical hazard (C)	Physical hazard (P)
Mussel meat	• Sourced from a supplier with a registered RMP for the processing of shucked mussel meat • Chilled or frozen as per agreed specification	*Listeria monocytogenes* [2]	None	Shell pieces > xx *(specify size)* [3]
Smoke	From non-tanalised wood	None	None	None
Oil mixture	Sourced from a supplier with an approved FSP or registered RMP	None	None	None
Packaging materials	Suitable for use as food contact material as per AP Human Consumption Specification clause 30	None	None	None

1. Agreed specifications for inputs must be documented in a supporting system.
2. Sporadic cases of *Listeria* monocytogenes in mussel meat has been reported to occur.
3. The operator should set a limit for shell pieces that is appropriate to their product and its intended use. As a guide, industry information based on customer complaints indicates that the presence of shell pieces greater than 5 mm is unacceptable. The US FDA considers products with hard or sharp foreign objects that measure 7 mm to 25 mm in length to be unacceptable (FDA/ORA Compliance Policy Guide 555.425).

3.7.2 Hazard analysis and Critical Control Point (CCP) determination

Form 6B: Hazard analysis and CCP determination for hot smoked mussel meat

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? If yes, identify the control measure and then answer Q2 If no, consider hazard at next step	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit or an IPC related to food safety? If yes, this step is a CCP If no, this step is not a CCP	CCP no.
1. Receiving	Mussel meat	B – *Listeria monocytogenes*	Refer to Form 6A	No		
		P – Shell pieces	Refer to Form 6A	No		
2. Storage in chiller or freezer	Mussel meat	B – *Listeria monocytogenes*	Micro carried over from previous step	Yes – GOP: proper temperature control will minimise micro growth	No	
		P – Shell pieces	Hazard carried from previous step	No		
3. Decartoning /thawing	Mussel meat	B – *Listeria monocytogenes*	Micro carried over from previous step	Yes – GOP: proper temperature control will minimise micro growth	No	
		P – Shell pieces	Hazard carried from previous step.	No		
4. Loading mussels into smoker	Mussel meat	B – *Listeria monocytogenes*	Micro carried over from previous step	No		
		P – Shell pieces	Hazard carried from previous step	No		
5. Smoking and cooking	Mussel meat	B – *Listeria monocytogenes*	Micro carried over from previous step	Yes, heat treatment during smoking will kill *L. monocytogenes*	Yes	CCP1
		P – Shell pieces	Hazard carried from previous step	No		
6. Removing trays from smoker	Hot smoked mussel meat	P – Shell pieces	Hazard carried from previous step	No		

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? If yes, identify the control measure and then answer Q2 If no, consider hazard at next step	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit or an IPC related to food safety? If yes, this step is a CCP If no, this step is not a CCP	CCP no.
7. Cooling	Hot smoked mussel meat	P – Shell pieces	Hazard carried from previous step	No		
		B – *Listeria* monocytogenes	Smoked mussels may be recontaminated after smoking	Yes – GOP: hygienic practices will prevent contamination	No	
8. Packing	Hot smoked mussel meat	P – Shell pieces	Hazard carried from previous step	Yes – GOP: any shell pieces found on the product during packing is removed	No	
		B – *Listeria* monocytogenes	Smoked mussels may be recontaminated after smoking	Yes – GOP: hygienic practices will prevent contamination	No	
	Barrier bags/trays	None				
9. Addition of oil mixture	Hot smoked mussel meat	None				
	Oil mixture	None				
10. Vacuum sealing and labelling	Hot smoked meat with oil mixture	None				
	Labels	None				
11. Chilling or freezing	Packed hot smoked meat	None				
12. Dispatch	Packed hot smoked meat	None				

3.7.3 CCP summary

Form 7: Summary table for CCPs

The number of CCPs within the RMP, their location within the process, the monitoring and other CCP procedures may differ for each premises. The procedures for each CCP must be fully documented (consider who, what, when and how) in the RMP.

Process step	Hazard	CCP no.	Critical limits	Monitoring procedures	Corrective actions	Verification procedures	Records
5. Smoking and cooking	B – *Listeria* monocytogenes	1	Product time-temperatures that will achieve 6D reduction of *Listeria* monocytogenes[1] Or Validated smoker parameters that will achieve the established final product temperature/ time	Monitor time and temperature of product, or validated smoker parameters	Reprocess non compliant product Adjust smoker settings	Reality checks of CCP monitoring and corrective action taking Review of cooking records Finished product micro testing Calibration of measuring devices Internal audit External audit	Daily CCP monitoring worksheet Receival records Corrective action report Micro test results Calibration record Internal audit report External audit report

[1] The US FDA recommends a 6D reduction of *Listeria* monocytogenes for cooked seafood product to destroy organisms of public health concern (US FDA, 2001). D-values for *Listeria* monocytogenes in smoked mussels can be found in the Guidelines for the Safe Preparation of Hot-smoked Seafood in New Zealand (Fletcher et al., 2003).

3.8 IDENTIFICATION AND CONTROL OF RISKS TO WHOLESOMENESS

The RMP must identify the risk factors related to wholesomeness that are reasonably likely to occur for each product covered by the RMP. It must also identify the control measures for addressing the risk factors. The control measures must be documented, including procedures for monitoring, corrective action and verification, and records.

Form 8: Summary of identified risk factors and controls related to wholesomeness

Risk factor	Source or cause of risk factor	Control measure
Spoilage	Micro growth due to improper time/temperature control	GOP – time/temperature control, proper refrigeration Refer to Supporting Sys. xx
	Shelf-life exceeded	GOP – procedures for monitoring shelf-life; inventory control Refer to Supporting Sys. xx.
Small shell pieces (e.g. < 5 mm)	Poor shucking techniques and inspection by supplier	GOP – inspection and removal of shell pieces during placing of mussel meat on trays and during packing Refer to Supporting Sys. xx
Other foreign objects (e.g. hair, plaster)	Contaminants from personnel	GOP – personnel hygienic practices Refer to Supporting Sys. xx

3.9 IDENTIFICATION AND CONTROL OF RISKS FROM FALSE OR MISLEADING LABELLING

Any information applied to the packaging must be correct and accurate. The RMP must identify the risk factors related to false or misleading labelling, which are reasonably likely to occur for each product. It must also identify the control measures for addressing the risk factors. The control measures must be documented, including procedures for monitoring, corrective action and verification, and records. An example is shown in Form 9.

Form 9: Summary of identified risk factors and controls related to false or misleading labelling

Risk factor	Source or cause of risk factor	Control measure(s)
Incorrect details on label or transportation outers, e.g. • type of product • product description • lot id • storage directions	Incorrect label design	Procedures for ensuring correct label design Refer to Supporting Sys. xx
	Product put in wrong carton or pack	Procedures for ensuring correct packaging of products Refer to Supporting Sys. xx

3.10 OPERATOR VERIFICATION

The operator must verify the effectiveness of their RMP against their documented procedures and any criteria defining the product's fitness for intended purpose (e.g. regulatory requirements and operator-defined limits, GOP requirements, and critical limits). The verification procedures must be documented, including responsibilities, corrective action,

frequencies, and records. The various verification activities may be summarised as shown in Form 10.

Form 10: Summary of operator verification activities

Activity	Description	Supporting system
Review of monitoring and corrective action records (CCPs and GOP controls)	All daily monitoring sheets checked to ensure that documented procedures are complied with, limits are adhered to, and appropriate corrective actions are taken	xxx
Listeria monitoring (environment and product testing)	As per documented *Listeria* monitoring programme	xxx
Internal audits	Internal audit involving: • review of records • review of test results • reality checks	xxx
Review of RMP including supporting systems	Review of effectiveness of RMP. Reassessment of RMP (e.g. new hazards; changes in inputs, process steps, critical limits)	xxx
Other activities related to the verification of CCPs, any operator-defined limits, and supporting systems		

4 Generic RMP for oysters

Amendment 0

July 2011

4.1 OPERATOR, BUSINESS AND RMP IDENTIFICATION

The name and address of the business operator must be documented in the RMP. The unique business identifier and the RMP identifier should also be included in this section of the RMP to assist in the traceability of documents.

Form 1: Operator, business and RMP identification

Information required	Details
Business identifier	*e.g. FP81, PET123*
RMP no.	*e.g. 01, 02*
Name of the operator	*Legal name of the business operator (i.e. the owner of the business)*
Address of the operator	*Business address of the operator (e.g. postal address of office)*
Electronic address of the operator	*Email address and/or web site address*
Name of the business	*The registered company name, if different from the operator's name*
Physical address of the premises	*Location of the premises*

4.2 MANAGEMENT AUTHORITIES AND RESPONSIBILITIES

The operator must identify the person who is responsible for the day-to-day management of the RMP. It is recommended that a deputy be designated who can take over from the day-to-day manager when necessary.

Form 2: Management authorities and responsibilities

Authority/responsibility	Details
Day-to-day manager	*Give name or, preferably, give position or designation*
Deputy for day-to-day manager	*Give name or, preferably, give position or designation*

4.3 SCOPE OF THE RMP

The operator must clearly define the coverage and application of the RMP.

Form 3: Scope of the RMP

Elements	Description/Details
Physical boundaries	Physical boundaries are indicated in the site plan given in Appendix xx. *Attach an accurate site plan. Ensure that amenities and external areas that may be a source of hazards and other risk factors are considered when establishing the physical boundaries. The site plan should also show any areas within the boundaries that are excluded from the RMP*
Risk factors covered by the RMP	Risk factors associated with: • Human health (for products intended for human consumption) • Animal health (for products intended for animal consumption) • Wholesomeness • False or misleading labelling
Animal material entering the RMP	Live oysters
Products leaving the RMP [1, 2]	Pottled oysters
Process [1]	From receipt of live shellstock to dispatch of pottled oysters. Principal processing categories: • Chilling • Shucking • Refrigeration
Exclusions	*Identify those materials, products or activities excluded from the RMP, and the alternative regulatory regime they are under* [3]

1. The products and processes covered by this generic RMP are examples only based on a typical New Zealand oyster processing operation. The operator must ensure that their RMP accurately reflects their own products and processes.
2. Products should be listed either individually or as product groups with similar characteristics, processes and intended purpose. The list should be as specific as necessary for proper identification of hazards and their controls, but at the same time should allow flexibility in terms of other products of the same group that can be processed without the need for a significant amendment.
3. If there is any animal material or product processed within the physical boundaries of the RMP but are excluded from the scope of the RMP, the operator must identify the material or product, the alternative regulatory regime that they are under (e.g. Food Act), and explain how the interfaces between regimes are managed. The operator must also document authorities and responsibilities, and the management of interfaces in relation to any activity undertaken by another person within the physical boundaries of the RMP.

4.4 PRODUCT DESCRIPTION

The operator must describe the animal products covered by the RMP, either individually; or as product groups with similar characteristics, processes and intended purpose. The product description must include the intended use and consumer and any regulatory requirements or operator-defined limits relevant to the product. Other information such as company specifications for packaging, labelling, and shelf life may be included.

Form 4: Product description and intended purpose

Product name	Pottled pacific oysters (*Crassostrea gigas*)
Intended consumer	Humans (general public)
Intended use of product	• Ready-to-eat in raw form [1] • Cooked before consumption
Regulatory requirement	Marine biotoxins limits specified in the AP Human Consumption Specifications clause 121 (3) Microbiological limits for ready-to-eat oysters must meet the limits set in the Food Standards Code: Standard 1.1.6 and AP Human Consumption Specifications clause 121 (1) *E. coli*/g n=5 c=1 m=2.3 M=7 *Salmonella*/25g n=5 c=0 m=0
Operator-defined requirement	Microbiological limits for oysters that are cooking or further processing
Packaging	As per regulatory and company specifications (refer to Supporting System xx) [2]
Labelling	As per regulatory and company specifications (refer to Supporting System xx)[2]
Shelf-life and storage requirements	As per regulatory and company specifications (refer to Supporting System xx)[2]

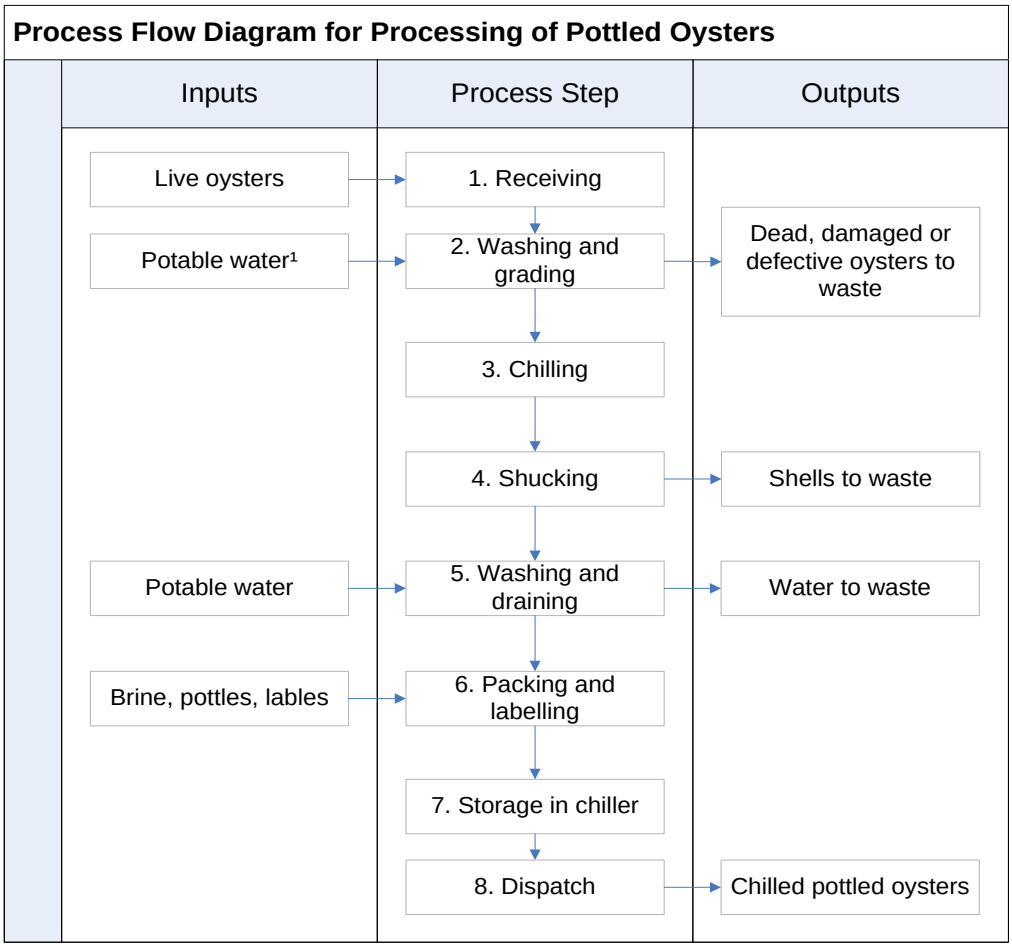
1. See Clause 140 of AP Human Consumption specifications for information on ready-to-eat (RTE) fish products.
2. Packaging and labelling specifications are expected to be documented in supporting systems.

4.5 PROCESS DESCRIPTION

The processes covered in the RMP must be accurately described using process flow diagrams. There is no prescribed format for the diagram but the process flow should sequentially set out all steps in the process, and show relevant inputs and outputs. The process flow(s) must show the full extent of the process for all products covered by the RMP (i.e. up to dispatch of each product or product groups, including any rework or recycling steps).

It should be noted that the examples given in this generic RMP are simplified presentations of the key steps based on a generic process.

Form 5: Process flow Diagram for processing of pottled oysters



[1]water obtained from an approved growing area or a conditionally approved growing area, that is open for harvesting

4.6 GOOD OPERATING PRACTICE

The operator must document all relevant supporting systems (also known as prerequisite programmes, good hygienic practices) before applying HACCP principles to the process. These supporting systems must comply with all relevant regulatory requirements, particularly the Animal Product Regulations 2000 and the current Animal Products (Specifications for Products Intended for Human Consumption) Notice. Information in the documented supporting systems should include: authorities and responsibilities, procedures (including control, monitoring, corrective action and operator verification), and recording requirements.

Part 2 of the Seafood Code of Practice provides guidance on supporting systems relevant to the scope of this RMP. Supporting systems must address the activities and procedures listed below:

- Design, construction and maintenance of buildings, facilities and equipment;
- Calibration of measuring devices;
- Water;
- Cleaning & sanitation;
- Personnel health and hygiene;
- Control of chemicals;
- Pest control;

- Training and competency of personnel;
- Reception of shellfish;
- Other incoming materials (specifications, handling & storage of ingredients and additives);
- Packaging;
- Processing of shellfish;
- Contamination control;
- Products for animal consumption;
- Labelling;
- Refrigeration and storage of product;
- Transport;
- Handling, disposition and recall of non-complying products;
- Traceability and inventory control;
- Operator verification and other operational requirements;
- Document control and record keeping.

4.7 HAZARD ANALYSIS AND CCP DETERMINATION

4.7.1 Identification of hazards from inputs

The operator must identify any hazards associated with each input considering any supplier agreements and raw material specifications.

Form 6A: Identification of hazards from inputs

Inputs	Description/specification [1]	Biological hazard (B)	Chemical hazard (C)	Physical hazard (P)
Live oysters	Sourced from suppliers who comply with the Shellfish Regulated Control Scheme [2] Each consignment to be accompanied by a Shellfish Harvesting Declaration	Pathogens associated with the marine environment (e.g. *Vibrio* spp., *Salmonella* spp., Norovirus) [3] Pathogens associated with contamination during harvest or transport (e.g. *Salmonella* spp., *Campylobacter jejuni*, *Listeria monocytogenes*) [4] Marine biotoxins associated with the marine environment	Chemical pollutants from harvest areas (e.g. heavy metals) Chemical contaminants associated with contamination during harvest or transport (e.g. fuel oil)	None
Water	For shellstock - potable water or water that complies with AP Human Consumption specifications, clause 122(2)	None	None	None
	For live oysters – potable water as per AP Human Consumption specifications clauses 8 to 14	None	None	None
Salt	Food grade	None	None	None
Packaging materials	Suitable for use as food contact material as per the AP Human Consumption specifications Part 6	None	None	None

1. Agreed specifications for inputs must be documented in a supporting system.
2. The Regulated Control Scheme (RCS) for Bivalve Molluscan Shellfish is administered by MAF and applies to all commercial shellfish growers and harvesters. The RCS covers the control and classification of shellfish growing areas, marine biotoxin control, and the requirements for harvesting and storage of shellfish. It also includes a surveillance programme for monitoring marine biotoxins, the bacteriological quality of the water, and compliance to the RCS requirements. The RCS minimises the risk from shellfish contaminated by microbiological (e.g. *Salmonella*, Norovirus, marine biotoxins) and chemical hazards (e.g. agricultural chemicals) due to pollution of the aquatic environment. Unless shellfish are harvested from a restricted area for post harvest treatment such as depuration, the shellfish are considered fit for human consumption as is.
3. Vibrio species are part of the normal microflora of estuarine and coastal waters worldwide. V. parahaemolyticus has been identified in New Zealand coastal waters, and in Pacific oysters at low levels (Fletcher, 1985). Results of monitoring of V. parahaemolyticus levels in Pacific oysters at fours sites over a two to three year period showed that numbers peaked in the summer but only relatively low levels were present. Correct processing and maintaining the cold chain are expected to provide sufficient control of this bacterium as it does not normally grow at refrigeration temperatures. The risk of food poisoning from V. parehaemolyticus in New Zealand-grown Pacific oysters appears to be minimal (Fletcher, 1985). Noroviruses have been identified in commercially farmed New Zealand oysters associated with outbreaks of viral gastroenteritis (Greening et al., 2003).
4. Shellfish may be contaminated after harvesting through the use of unclean equipment and containers, and through exposure to environmental contaminants such as dust, dirt, and bird droppings, but this is highly unlikely.

4.7.2 Hazard analysis and critical control point (CCP) determination

Form 6B: Hazard analysis and CCP determination for pottled oysters

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? [1] If yes, identify the control measure and then answer Q2 If no, consider hazard at next step	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit or an IPC related to food safety? If yes, this step is a CCP If no, this step is not a CCP	CCP no. [2]
1. Receiving	Live oysters	B – Bacterial pathogens, Norovirus	Refer to Form 6A	Yes. Shellfish Harvesting Declarations are checked at receiving to confirm compliance with the Shellfish Regulated Control Scheme. Refer to Supporting System xx.	No	CCP1 – market access
		B - Marine biotoxins from marine environment.	Refer to Form 6A	Same as above	Yes	
		C – Chemical residues	Refer to Form 6A	Same as above	Yes	
2. Washing & grading	Live oysters Water	B – Bacterial pathogens,	Micro carried from previous step. Sporadic cases of low levels of contamination may still occur despite compliance to the RCS.	No		
3. Chilling	Live oysters	B – Bacterial pathogens,	Micro carried from previous step.	Yes – GOP: temperature control during processing will minimise the growth of any existing microorganisms	No	
4. Shucking	Live oysters	B – Bacterial pathogens,	Micro carried from previous step.	No		
5. Washing & draining	Shucked oyster Water	B – Bacterial pathogens	Micro carried from previous step	No		

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? [1] If yes, identify the control measure and then answer Q2 If no, consider hazard at next step	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit or an IPC related to food safety? If yes, this step is a CCP If no, this step is not a CCP	CCP no. [2]
6. Packing & labelling	Shucked oyster	B – Bacterial pathogens	Micro carried from previous step	No		
	Salt	None				
	Pottles and labels	None				
7. Storage in chiller	Pottled oysters	B – Bacterial pathogens	Micro carried from previous step	Yes – GOP: temperature control during storage will minimise the growth of any existing microorganisms	No	
8. Dispatch	Chilled pottled oysters	B – Bacterial pathogens	Micro carried from previous step[3]	Same as above	No	

1. The supporting system where the particular control measure is documented should be cited in this column.
2. CCPs that have been mandated as a requirement for entry to the US market are shaded and indicated as market access CCPs. The requirements for these market access CCPs are explained in the US FDA Guide for the Control of Molluscan Shellfish 2003, Model Ordinance, XI. Shucking and Packing. Operators must clearly identify any client or market access CCP in the RMP.
3. Compliance to the RCS, the requirements of the Human Consumption specifications and hygienic processing minimises the risk from microbiological and chemical hazards in raw oysters for the general public. However, pregnant women and the immunocompromised are advised to avoid the consumption of raw shellfish.

4.7.3 CCP summary

Form 7: Summary table for CCPs

A market access CCP has been identified in this generic RMP. This CCP only applies to RMPs that cover the processing of shellfish for export to the US. Under the New Zealand standard, the hazards that are controlled by these CCPs are expected to be adequately addressed by GOP. The requirements for these market access requirements are given in the US FDA Guide for the Control of Molluscan Shellfish 2003. Model Ordinance. XI. Shucking and Packing.
The number of CCPs within the RMP, their location within the process, the monitoring and other CCP procedures may differ for each premises. The procedures for each CCP must be fully documented (consider who, what, when and how) in the RMP. The regulator will verify the effectiveness of any market access CCP against the relevant OMAR.

Process step	Hazard	CCP no.	Critical limits	Monitoring procedures	Corrective actions	Verification procedures	Records
1. Receiving	B- Bacterial pathogens, viruses, marine biotoxin from the marine environment	1 – market access	All consignments are sourced from approved growing areas and accompanied by a Shellfish Harvest Declaration Shellstock with a tag on each container, or transaction record on each bulk shipment	Visual check of harvest declaration and identification tag	Reject non-compliant consignment of shellstock	Reality checks of CCP monitoring and corrective action taking Review of records Internal audit External audit	Daily CCP monitoring worksheet Receival records Corrective action report Internal audit report External audit report

4.8 IDENTIFICATION AND CONTROL OF RISKS TO WHOLESOMENESS

The RMP must identify the risk factors related to wholesomeness that are reasonably likely to occur for each product covered by the RMP. It must also identify the control measures for addressing the risk factors. The control measures must be documented, including procedures for monitoring, corrective action and verification, and records.

Form 8: Summary of identified risk factors and controls related to wholesomeness

Risk factor	Source or cause of risk factor	Control measure
Spoilage	Micro growth due to improper time/temperature control	GOP – time/temperature control, proper refrigeration Refer to Supporting Sys. xx
	Shelf-life exceeded	GOP – procedures for monitoring shelf-life; inventory control Refer to Supporting Sys. xx.
Small shell pieces (e.g. < 5 mm)	Poor shucking techniques and inspection by supplier	GOP – inspection and removal of shell pieces during packing Refer to Supporting Sys. xx
Other foreign objects (e.g. hair, plaster)	Contaminants from personnel	GOP – personnel hygienic practices Refer to Supporting Sys. xx

4.9 IDENTIFICATION AND CONTROL OF RISKS FROM FALSE OR MISLEADING LABELLING

Any information applied to the packaging must be correct and accurate. The RMP must identify the risk factors related to false or misleading labelling that is reasonably likely to occur for each product. It must also identify the control measures for addressing the risk factors. The control measures must be documented, including procedures for monitoring, corrective action and verification, and records. An example is shown in Form 9.

Form 9: Summary of identified risk factors and controls related to false or misleading labelling

Risk factor	Source or cause of risk factor	Control measure(s)
Incorrect details on label or transportation outers, e.g. • type of product • product description • lot id • storage directions	Incorrect label design	Procedures for ensuring correct label design Refer to Supporting Sys. xx
	Product put in wrong carton or pack	Procedures for ensuring correct packaging of products Refer to Supporting Sys. xx

4.10 OPERATOR VERIFICATION

The operator must verify the effectiveness of their RMP against their documented procedures and any criteria defining the product's fitness for intended purpose (e.g. regulatory requirements and operator-defined limits, GOP requirements, critical limits). The verification procedures must be documented, including responsibilities, corrective action, frequencies, and records. The various verification activities may be summarised as shown in Form 10.

Form 10: Summary of operator verification activities

Activity	Description	Supporting system
Review of monitoring and corrective action records (CCPs and GOP controls)	All daily monitoring sheets checked to ensure that documented procedures are complied with, limits are adhered to, and appropriate corrective actions are taken	xxx
Internal audits	Internal audit involving: • review of records • review of test results • reality checks	xxx
Review of RMP including supporting systems	Review of effectiveness of RMP. Reassessment of RMP (e.g. new hazards; changes in inputs, process steps, critical limits)	xxx
Other activities related to the verification of CCPs, any operator-defined limits, and supporting systems		

5 Generic RMP for the processing of finfish

Amendment 0

July 2011

5.1 OPERATOR, BUSINESS AND RMP IDENTIFICATION

The name and address of the business operator must be documented in the RMP. The unique business identifier and the RMP identifier should also be included in this section of the RMP to assist in the traceability of documents.

Form 1: Operator, business and RMP identification

Information required	Details
Business identifier	*e.g. FP81, PET123*
RMP no.	*e.g. 01, 02*
Name of the operator	*Legal name of the business operator (i.e. the owner of the business)*
Address of the operator	*Business address of the operator (e.g. postal address of office)*
Electronic address of the operator	*Email address and/or web site address*
Name of the business	*The registered company name, if different from the operator's name*
Physical address of the premises	*Location of the premises*

5.2 MANAGEMENT AUTHORITIES AND RESPONSIBILITIES

The operator must identify the person who is responsible for the day-to-day management of the RMP. It is recommended that a deputy be designated who can take over from the day-to-day manager when necessary.

Form 2: Management authorities and responsibilities

Authority/responsibility	Details
Day-to-day manager	*Give name or, preferably, give position or designation*
Deputy for day-to-day manager	*Give name or, preferably, give position or designation*

5.3 SCOPE OF THE RMP

The operator must clearly define the coverage and application of the RMP.

Form 3: Scope of the RMP

Elements	Description/Details
Physical boundaries	Physical boundaries are indicated in the site plan given in Appendix xx. *Attach an accurate site plan. Ensure that amenities and external areas that may be a source of hazards and other risk factors are considered when establishing the physical boundaries. The site plan should also show any areas within the boundaries that are excluded from the RMP*
Risk factors covered by the RMP	Risk factors associated with: • Human health (for products intended for human consumption) • Animal health (for products intended for animal consumption) • Wholesomeness • False or misleading labelling
Animal material entering the RMP	Chilled whole fish (various species)
Products leaving the RMP [1, 2]	• Chilled or frozen fish (whole, fillets) • Other fish products for human consumption (e.g. roe, bladder) • Fish offal, heads, frames for further processing to products for animal consumption
Process [1]	From receipt of fresh fish to dispatch of packed chilled or frozen fish. Principal processing categories: • Heading, gutting, filleting, washing • Chilling/freezing • Refrigeration
Exclusions	*Identify those materials, products or activities excluded from the RMP, and the alternative regulatory regime they are under* [3]

1. The products and processes covered by this generic RMP are examples only based on a typical New Zealand fish processing operation. The operator must ensure that their RMP accurately reflects their own products and processes.
2. Products should be listed either individually or as product groups with similar characteristics, processes and intended purpose. The list should be as specific as necessary for proper identification of hazards and their controls, but at the same time should allow flexibility in terms of other products of the same group that can be processed without the need for a significant amendment.
3. If there is any animal material or product processed within the physical boundaries of the RMP but are excluded from the scope of the RMP, the operator must identify the material or product, the alternative regulatory regime that they are under (e.g. Food Act), and explain how the interfaces between regimes are managed. The operator must also document authorities and responsibilities, and the management of interfaces in relation to any activity undertaken by another person within the physical boundaries of the RMP.

5.4 PRODUCT DESCRIPTION

The operator must describe the animal products covered by the RMP, either individually; or as product groups with similar characteristics, processes and intended purpose. The product description must include the intended use and consumer, any regulatory requirements relevant to the product, and any operator-defined limits. Other information such as company specifications for packaging, labelling, and shelf life may be included.

Form 4: Product description and intended purpose

	Products for human consumption	Products for animal consumption
Product name	• Chilled or frozen whole fish (various species) • Chilled or frozen fish fillets • Other fish products (e.g. roe, bladder)	Fish offal, head, frames
Intended consumer	Humans (general public)	Animals
Intended use of product	• For further cooking or further processing • Ready-to-eat in raw form [1]	For further processing to animal feed
Regulatory requirements	Human Consumption Specification clause (2) Histamine limit [2] (scombroid species) = 200mg/kg	None
Operator-defined limits	No viable pathogenic parasites (Anisakis spp) in susceptible species	
Packaging [3]	As per regulatory and company specifications Refer to Supporting System xx	As per regulatory and company specifications Refer to Supporting System xx
Labelling [3]	As per regulatory and company specifications Refer to Supporting System xx	As per regulatory and company specifications. Must be labelled "Not for Human Consumption"
Shelf-life and storage requirements	As per regulatory and company specifications Refer to Supporting System xx	As per regulatory and company specifications Refer to Supporting System xx

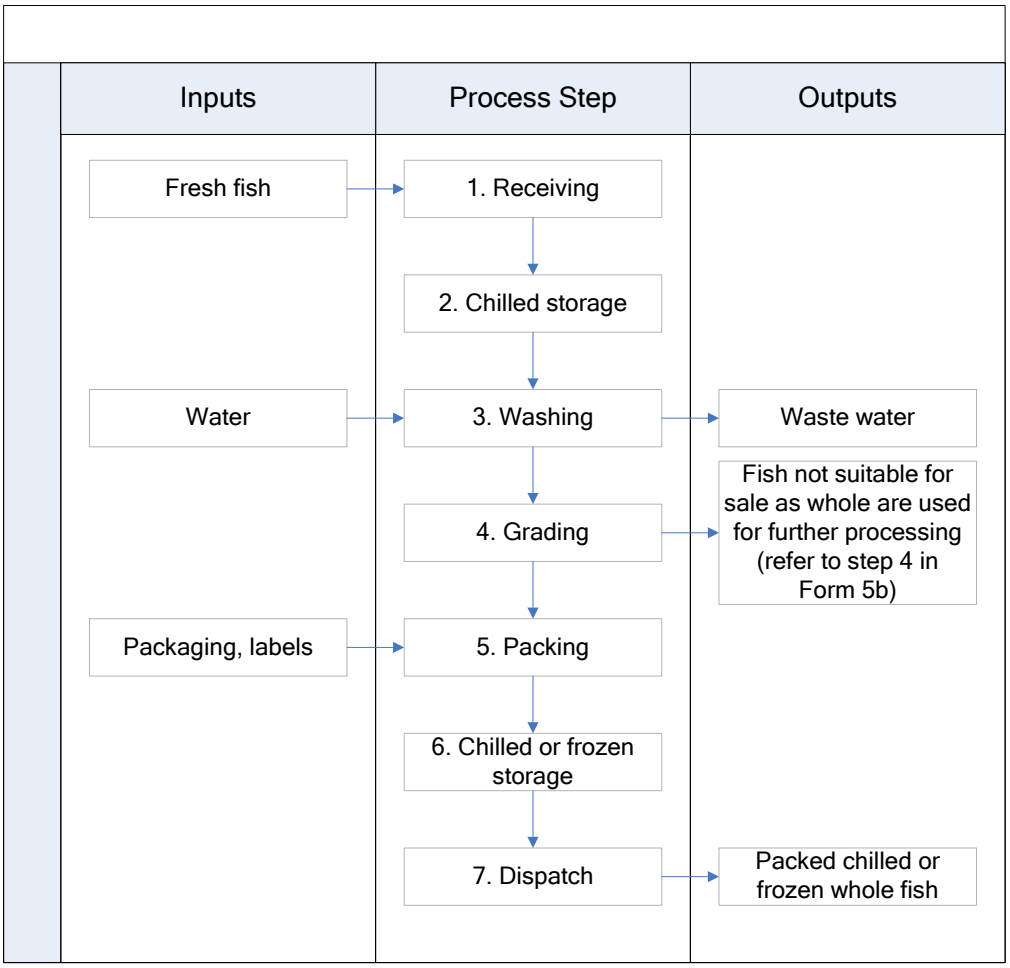
1. Some types of fish may be eaten raw, e.g. sushi and marinated fish.
2. The histamine limit is 50 mg/kg for the US market.
3. Packaging, labelling, and storage specifications are expected to be documented in the operator's supporting systems. The operator should reference the relevant supporting system in the product description.

5.5 PROCESS DESCRIPTION

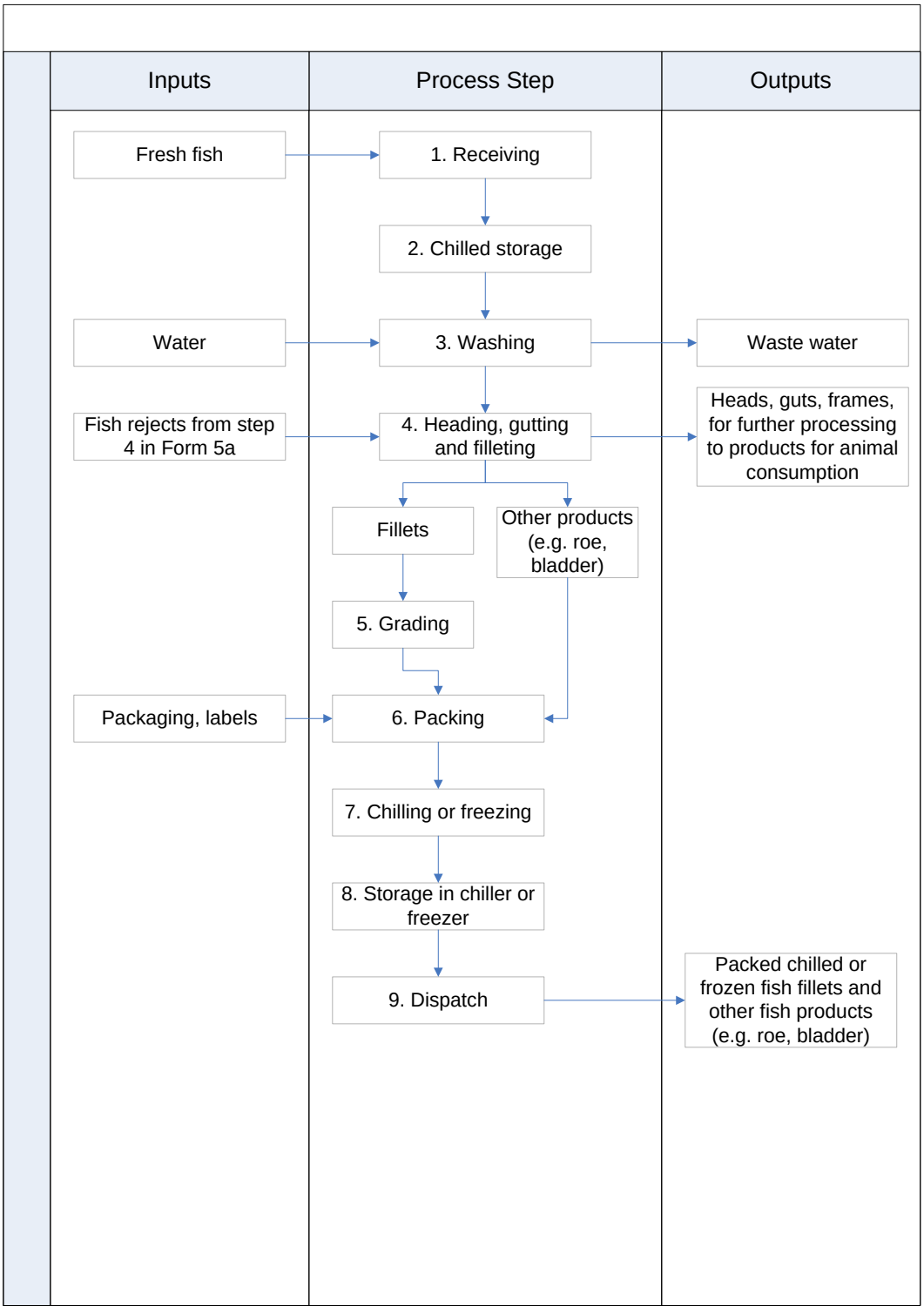
The processes covered in the RMP must be accurately described using process flow diagrams. There is no prescribed format for the diagram but the process flow should set out all steps in the process sequentially, and show relevant inputs and outputs. The process flow(s) must show the full extent of the process for all products covered by the RMP (i.e. up to dispatch of each product or product groups, including any rework or recycling steps).

It should be noted that the examples given in this generic RMP are simplified presentations of the key steps based on a generic process.

Form 5A: Process flow diagram for processing of chilled or frozen whole fish



Form 5B: Process flow diagram for processing of chilled or frozen fish fillet



5.6 GOOD OPERATING PRACTICE

The operator must document all relevant supporting systems (also known as prerequisite programmes, good hygienic practices) before applying HACCP principles to the process. These supporting systems must comply with all relevant regulatory requirements, particularly the Animal Product Regulations 2000 and the current Animal Products (Specifications for Products Intended for Human Consumption) Notice. Information in the documented

supporting systems should include: authorities and responsibilities, procedures (including control, monitoring, corrective action and operator verification), and recording requirements.

Part 2 of the Seafood Code of Practice provides guidance on supporting systems relevant to the scope of this RMP. Supporting systems must address the activities and procedures listed below:

- Design, construction and maintenance of buildings, facilities and equipment;
- Calibration of measuring devices;
- Water;
- Cleaning & sanitation;
- Personnel health and hygiene;
- Control of chemicals;
- Pest control;
- Training and competency of personnel;
- Reception of fish;
- Other incoming materials (specifications, handling & storage of ingredients and additives);
- Packaging;
- Processing of fish;
- Contamination control;
- Products for animal consumption;
- Labelling;
- Refrigeration and storage of product;
- Transport;
- Handling, disposition and recall of non-complying products;
- Traceability and inventory control;
- Operator verification and other operational requirements;
- Document Control and record keeping.

5.7 HAZARD ANALYSIS AND CCP DETERMINATION

5.7.1 Identification of hazards from inputs

The operator must identify any hazards associated with each input considering any supplier agreements and raw material specifications.

Form 6A: Identification of hazards from inputs

Inputs	Description/specification [1]	Biological hazard (B)	Chemical hazard (C)	Physical hazard (P)
Fresh fish (various species)	Properly iced or chilled No signs of deterioration For farmed fish, consignment to be accompanied by a Supplier Statement; or the supplier must be a specified supplier in the operator's Supplier Guarantee Programme (Human Consumption specification 102 (3))	Bacterial pathogens associated with contamination after catching (e.g. *Salmonella* spp., *Listeria* monocytogenes) [2] Pathogenic parasites (e.g. Anisakis) in susceptible species[3]	Histamine in scombroid species (e.g. jack mackerel, kahawai, tuna species) [4]	None
Water	Potable water as per the AP Human Consumption specifications clauses 8 to 14	None	None	None
Packaging materials	Suitable for use as food contact material as per AP Human Consumption specifications Part 6	None	None	None

1. Agreed specifications for inputs must be documented in a supporting system.
2. Fish may be contaminated after catching through the use of unclean equipment and containers, and through exposure to environmental contaminants such as dust, dirt, and bird droppings.
3. Anisakid nematodes are known to occur in New Zealand fish such as barracouta and jack mackerel, and there has been at least one reported case of illness in New Zealand due to this parasite (Fletcher, 1996).
4. Scombroid poisoning is internationally considered to be the most common intoxication arising from eating fish. Histamine is the toxin responsible for this type of poisoning which results from the ingestion of spoiled fish. When fish are improperly handled and temperature abused certain types of bacteria breakdown histidine in fish tissue to histamine. Elevated levels of histamine only occur in fish which contains naturally high levels of free histidine, such as members of the Scombroid family, e.g. tuna and mackerel.
   Most New Zealand incidents of scombroid poisoning are due to the consumption of smoked fish. Although there have been several reported cases of scombroid fish poisoning in New Zealand, it does not appear to be a major problem for New Zealand seafood (Fletcher, 1996).

5.7.2 Hazard Analysis and Critical Control Point (CCP) Determination

Form 6B: Hazard analysis and CCP determination for the processing of fish

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? [1] If yes, identify the control measure and then answer Q2 If no, consider hazard at next step	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit or an IPC related to food safety? If yes, this step is a CCP If no, this step is not a CCP	CCP no.
1. Receiving	Fresh fish	B – Bacterial pathogens	Refer to Form 6A	Yes. GOP – Checking of product temperatures and for visible contamination, and rejection of non-complying fish will minimise contamination Refer to Supporting System xx	No	
		B – Pathogenic parasites in certain species	Refer to Form 6A	No	No	
		C – Histamine in scombroid fish	Refer to Form 6A	Yes. GOP – Checking of product temperatures and for deterioration, and rejection of non-complying fish will minimise the occurrence of fish with high levels of histamine from being processed Refer to Supporting System xx	No	
2. Chilled storage	Fresh fish	B - Bacterial pathogens	Micro carried from previous step	Yes. GOP – correct storage will minimise microbial growth; hygienic techniques will minimise contamination Refer to Supporting System xx	No	

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? [1] If yes, identify the control measure and then answer Q2 If no, consider hazard at next step	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit or an IPC related to food safety? If yes, this step is a CCP If no, this step is not a CCP	CCP no.
		B – Pathogenic parasites in certain species	Hazard carried from previous step	No		
3. Washing	Chilled fish	B - Bacterial pathogens	Micro carried from previous step	Yes. GOP – Proper temperature control will minimise the growth of microorganisms, and hygienic processing techniques will minimise contamination	No	
		B – Pathogenic parasites in certain species	Hazard carried from previous step	No		
4. Gutting and filleting	Chilled fish	B - Bacterial pathogens	Micro carried from previous step	Yes. GOP – Proper temperature control will minimise the growth of microorganisms, and hygienic processing techniques will minimise contamination	No	
		B – Pathogenic parasites in certain species	Hazard carried from previous step	Yes. GOP – Quick and hygienic removal of the gut will remove most of the Anisakis that may present in the fish Refer to Supporting System xx	No	
5. Grading	Fish fillets and edible by-products	B - Bacterial pathogens	Micro carried from previous step	Yes. GOP – Proper temperature control will minimise the growth of microorganisms, and hygienic processing techniques will minimise contamination Refer to Supporting System xx	No	

Process step	Inputs	Hazard reasonably likely to occur on or in the	Justification	Q1. Is there a control measure(s) for the hazard at this step? [1]	Q2. Is the control measure at this step essential to food safety	CCP no.

		product at this step		If yes, identify the control measure and then answer Q2 If no, consider hazard at next step	**as defined by a regulatory limit or an IPC related to food safety?** If yes, this step is a CCP If no, this step is not a CCP
		B – Pathogenic parasites in fish fillet	Hazard carried from previous step. Some Anisakis can be found in the flesh of certain fish species	No	No
6. Packing	Fish fillets and edible by-products	B - Bacterial pathogens	Micro carried from previous step	Yes. GOP – Proper temperature control will minimise the growth of microorganisms, and hygienic processing techniques will minimise contamination Refer to Supporting System xx	No
		B – Pathogenic parasites in fish fillet	Hazard carried from previous step	No	No
	Packaging	None			
7. Chilling/freezing	Fish fillets and edible by-products	B - Bacterial pathogens	Micro carried from previous step	Yes. GOP – Proper temperature control will prevent or minimise the growth of microorganisms Refer to Supporting System xx	No
		B – Pathogenic parasites in fish fillet	Hazard carried from previous step	No for chilled fish Yes for frozen fish. Freezing at -18°C for 24 h will inactivate the parasite Refer to Supporting System xx	No

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? [1] If yes, identify the control measure and then answer Q2 If no, consider hazard at next step	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit or an IPC related to food safety? If yes, this step is a CCP If no, this step is not a CCP	CCP no.
8. Storage in chiller or freezer	Packed chilled/ frozen fish fillets and edible by-products	B - Bacterial pathogens	Micro carried from previous step	Yes. GOP – Proper temperature control will prevent or minimise the growth of microorganisms Refer to Supporting System xx	No	
		B – Pathogenic parasites in certain species of **chilled** fish	Hazard carried from previous step	No for chilled fish Yes for frozen fish. Freezing at -18°C for 24 h will inactivate the parasite Refer to Supporting System xx	No	
9. Dispatch	Packed chilled/ frozen fish fillets and edible by-products	B - Bacterial pathogens	Micro carried from previous step	Yes. GOP – Proper temperature control will prevent or minimise the growth of microorganisms Refer to Supporting System xx	No	
		B – Pathogenic parasites in certain species of **chilled** fish	Hazard carried from previous step	No	No	

1. The procedures for the identified control measures at the different process steps must be documented in a supporting system. The supporting system should be referenced in this table.

5.8 CCP SUMMARY

The hazard analysis and CCP determination did not identify a CCP for the processing of fish. The bacterial hazards identified are adequately controlled by GOP procedures (e.g. temperature control and hygienic practices).

5.9 IDENTIFICATION AND CONTROL OF RISKS TO WHOLESOMENESS

The RMP must identify the risk factors related to wholesomeness that are reasonably likely to occur for each product covered by the RMP. It must also identify the control measures for addressing the risk factors. The control measures must be documented in supporting systems, including procedures for monitoring, corrective action and verification, and records.

Form 8: Summary of identified risk factors and controls related to wholesomeness

Risk factor	Source or cause of risk factor	Control measure
Spoilage	Micro growth due to improper time/temperature control	GOP – time/temperature control, proper refrigeration Refer to Supporting Sys. xx
Non-pathogenic parasites	Can be found in certain fish	GPO – proper gutting, on-line checks
Bone in fillets, scales in scaled fish	Poor filleting and scaling techniques	GOP – training of staff on proper techniques, on-line checks Refer to Supporting Sys. xx
Other foreign objects that are not hazards (e.g. hair, plasters)	Contaminants from personnel	GOP – personnel hygienic practices Refer to Supporting Sys. xx

5.10 IDENTIFICATION AND CONTROL OF RISKS FROM FALSE OR MISLEADING LABELLING

Any information applied to the packaging must be correct and accurate. The RMP must identify the risk factors related to false or misleading labelling that is reasonably likely to occur for each product. It must also identify the control measures for addressing the risk factors. The control measures must be documented, including procedures for monitoring, corrective action and verification, and records. An example is shown in Form 9.

Form 9: Summary of identified risk factors and controls related to false or misleading labelling

Risk factor	Source or cause of risk factor	Control measure(s)
Incorrect details on label or transportation outers, e.g. • type of product • product description • lot id • storage directions	Incorrect label design	Procedures for ensuring correct label design Refer to Supporting Sys. xx
	Product put in wrong carton or pack	Procedures for ensuring correct packaging of products Refer to Supporting Sys. xx

5.11 OPERATOR VERIFICATION

The operator must verify the effectiveness of their RMP against their documented procedures and any criteria defining the product's fitness for intended purpose (e.g. regulatory requirements and operator-defined limits, GOP requirements, critical limits). The verification procedures must be documented, including responsibilities, corrective action, frequencies, and records. The various verification activities may be summarised as shown in Form 10.

Form 10: Summary of operator verification activities

Activity	Description	Supporting system
Review of monitoring and corrective action records	All daily monitoring sheets checked to ensure that documented procedures are complied with, limits are adhered to, and appropriate corrective actions are taken	xxx
Internal audits	Internal audit involving: • review of records • review of test results • reality checks	xxx
Review of RMP including supporting systems	Review of effectiveness of RMP. Reassessment of RMP (e.g. new hazards; changes in inputs, process steps, critical limits)	xxx
Other activities related to the verification of CCPs, any operator-defined limits, and supporting systems		

6 References

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Greening, G., Lake, R., Hudson, A., Cressey, P. and Nortje, G. (2003) *Risk Profile: Norwalk-like Virus in Mollusca (Raw).* Report prepared for the New Zealand Food Safety Authority. Institute of Environmental Science and Research Ltd, Christchurch, New Zealand.

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