Ministry for Primary Industries
Manatū Ahu Matua

Operational Code

Processing of Seafood Products

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Issued by the Ministry for Primary Industries

New Zealand Government

TITLE

Operational Code: DRAFT Processing of Seafood Products

COMMENCEMENT

This Operational Code is effective from [Effective Date]

ISSUING BODY

This Operational Code is issued by the Ministry for Primary Industries.

Dated at Wellington this ... day of .....

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(acting under delegated authority of the Director-General)

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Contents

Introduction

This introduction is not part of the Operational Code, but is intended to indicate its general effect.

Purpose

This Operational Code was developed by the New Zealand Seafood Standards Council and the Ministry for Primary Industries (MPI) to assist seafood operators to meet the requirements of the Animal Products Act 1999 (APA).

Background

This Code applies to seafood processors under the Animal Products Act 1999 and replaces the Seafood Code of Practice (COP) that was introduced in 2011. The Code has been updated to:

a) align with changes to the legislation;
b) combine existing parts into one document;
c) align its format with MPI's standardised template.

The Code is being updated in stages. Work will commence to update Part 3 and the RMP models once these Parts have been finalised.

Processors who operate under the Food Act 2014 may use this Code as guidance.

Who should read this Operational Code?

This Operational Code applies to businesses involved in the primary and secondary processing of seafood products for human consumption and should be read by:

a) RMP operators;
b) recognised evaluators;
c) recognised verifiers;
d) regulators; and
e) transporters.

Examples of primary processing include:

a) heading, gutting, and filleting of fish;
b) shucking, heat shocking, land-based wet storage and depuration of bivalve molluscan shellfish;
c) tubing of squid; and
d) tailing of crustaceans.

Examples of secondary processing include:

a) acidification, salting, brining, smoking, thermal processing, refrigeration, storage;
b) extraction, drying, blending of powders from fish or shellfish; and
c) addition of non-animal product ingredients to seafood products e.g. breading, coating, saucing, assembling.

Manufacturers of seafood products under the Food Act 2014 operate under a custom Food Control Plan. This Operational Code is a good source of guidance for those manufacturers.

Exclusions

This Operational Code does not apply to:

(1) Activities covered by the Regulated Control Scheme (RCS) and notice for the growing, harvesting, sorting and transporting bivalve molluscan shellfish for commercial purposes up until the time when the shellfish are received by a wholesaler or retailer or sold direct to the consumer, or undergo primary processing. Refer to the following links for the requirements:

a) Animal Products (Regulated Control Scheme – Bivalve Molluscan Shellfish) Regulations 2006; and
b) Animal Products Notice: Regulated Control Scheme – Bivalve Molluscan Shellfish for Human Consumption.

This means that relaying, temporary storage, and wet storage occurring in a coastal marine area or a land-based aquaculture facility are not covered by the Operational Code. However, it does cover wet storage in a land-based facility or any other forms of primary processing that operate under a RMP.

(2) Activities carried out on Limited Processing Fishing Vessels that are covered under the RCS, regulations, notice and operators' guidelines. Refer to the following links for details:

a) Animal Products (Regulated Control Scheme-Limited Processing Fishing Vessels) Regulations 2001;
b) Animal Products (Specifications for Limited Processing Fishing Vessels) Notice 2005; and
c) Regulated Control Scheme for Limited Processing Fishing Vessels: Operator Guidelines.

(3) Activities carried out under the Regulated Control Scheme -Transportation and Handling of Products for Export with an Official Assurance.

(4) The Operational Code has been developed based on New Zealand requirements only and does not cover overseas market access requirements. It is important to note however, that the procedures and some guidance in this Code forms the basis of the minimum standard for those who wish to export.

Why is this important?

The APA allows for an RMP to be based on a COP, a template, or a model if in the view of the Director-General it is valid and appropriate for businesses of that kind. A COP that is considered to be valid and appropriate after an assessment by MPI is formally recognised as an "approved code of practice". This Seafood Operational Code is an approved COP.

Seafood operators are expected to develop and implement their RMPs in accordance with this Code. This will:

a) ensure compliance with acceptable industry practices and procedures;
b) ensure that relevant regulatory requirements are met;
c) simplify and reduce the cost of developing the RMP.

When developing an RMP, parts of the Operational Code maybe incorporated by reference, provided the parts referenced reflect the actual activities / processes that take place within the business. If an RMP operator incorporates the whole or part(s) of this Operational Code into their RMP, those part(s) become mandatory and legally enforceable.

Document History

This revised Operational Code reflects the changes made to the Animal Products Notice: Specifications for Products Intended for Human Consumption issued 1 March 2016.

No.	Version Date	Section Changed	Change(s) Description
0	July 2011		
1		All	Update content. New format and branding.

Part 1: Structure of Code

1.1 General

(1) This Code is separated into Parts. Each Part gives requirements and procedures relating to different aspects of seafood production and processing.

(2) Parts 1 and 2 gives an overview of the requirements of the APA and the Operational Code.

(3) Parts 3-27 covers Good Operating Practices (GOP or supporting systems) and process control. It sets out the regulatory requirements, and acceptable or agreed procedures for meeting the requirements, particularly the Animal Products Notice: Specifications for Products Intended for Human Consumption (HC Spec) and the Animal Products (Risk Management Programme Specifications) Notice 2008 (RMP Spec).

GOP is essential to be able to consistently produce seafood products that are fit for their intended purpose. It is the foundation for HACCP and of RMPs. The expectation is that GOP is effectively implemented prior to the application of HACCP principles. GOP includes several interacting components such as hygienic practices, process control and quality assurance systems. Operators will usually document GOP in their supporting systems.

(4) The RMP Spec requires an RMP to contain sufficient procedures to ensure that GOP is applied [RMP spec 11]. These procedures must cover:

a) the control measures to be used to control hazards and other risk factors;
b) any parameters to be met;
c) any monitoring procedures that are to be carried out; and
d) any corrective action procedures that are to be applied in the event of loss of control, including restoration of control; identification and disposition of affected animal material or animal product; and any measures to be taken to prevent reoccurrence.

When documenting GOP, the procedures should cover:

a) Purpose and scope;
b) Authorities and responsibilities;
c) Materials and equipment, as applicable;
d) Procedures (e.g. control measures, monitoring, corrective action and operator verification);
e) Records;
f) References to any other relevant documents.

(5) Part X (to be decided when these parts are reviewed) shows how the principles of HACCP can be applied to seafood products processing. It also covers the identification of risk factors and controls related to the wholesomeness and labelling of seafood products.

1.2 Layout of Parts

Parts 3-27 are generally laid out with the following subheadings:

1.2.1 Purpose and Scope

This describes the contents of the particular GOP and its application.

1.2.2 Sources of Hazards

This section identifies the sources of hazards that are controlled under the particular GOP measure, and gives examples of hazards associated with each source. This has not been provided for those GOP measures that do not directly address a particular source of hazard (e.g. inventory control, calibration).

1.2.3 Mandatory Requirements

These requirements are mandated by legislation, and the operator must comply with them. Where the meaning of the legislation is clear, it is quoted directly. In other cases, the legislation is paraphrased so it is easier to understand and to highlight its relevance to seafood products. The originating legislation is cited for those who wish to read the piece of legislation referred to. Legislation will always take precedence, and it is the operator's responsibility to check for amendments to legislation. The key pieces of legislation referenced in this Operational Code are:

- Animal Products Regulations 2000 [AP Reg];
- Animal Products Notice: Specifications for Products Intended for Human Consumption [HC Spec];
- Animal Products (Risk Management Programme Specifications) Notice 2008 [RMP Spec].

It should be noted that some mandatory requirements (e.g. those that are specific and clear in their intent) are not repeated or expanded upon in the Procedures.

1.2.4 Procedures

The procedures given are the accepted or industry agreed means of achieving or complying with the mandated requirements. These procedures cover control, monitoring, corrective action and verification. Operators are expected to comply with the procedures that are applicable to their product and process. To differentiate procedures from regulatory requirements, the word "should" is used rather than "must".

Alternative approaches to those given in the procedures may be used. Where this is done, the operator will need to demonstrate that the alternative approach will consistently meet all relevant regulatory requirements. Validation of any alternative process, procedure or parameter may involve the collection and analysis of evidence (e.g. data from testing or trials, published scientific information, report from an expert), and if significant, will require evaluation. Those who wish to use an alternative approach should refer to the RMP Manual for guidance.

If exporting, there is an expectation that the procedures will be read as "must", as many markets would require this

1.2.5 Guidance

Guidance is presented in a box. It provides explanatory information and options or examples for achieving a particular outcome or requirement.

Guidance

Operators may use alternative approaches to those set out in the guidance provided they do not compromise GOP and still achieve the regulatory requirements. Operators do not need to provide justification when deviating from guidance.

1.2.6 Records

This section gives the list of records that the operator should keep.

1.3 Definitions

Act or **APA** means the Animal Products Act 1999

amenities includes toilets, wash rooms, locker rooms, change rooms, lunch/smoke rooms, and cafeterias

animal material depot is a facility in which fish (other than bivalve molluscan shellfish) can be temporarily held prior to processing. Permitted activities in an animal material depot are holding, chilling, refrigeration, application of temporary covers and sedation using veterinary medicines registered for that purpose under the ACVM Act

approved maintenance compound means any maintenance compound that is approved by MPI or listed in specifications made under the Animal Products Act 1999

batch means a quantity of fish or fish product of the same type processed under essentially the same conditions during a particular time interval, generally not exceeding 24 hours, i.e. considered to be all products processed between major clean-downs

BMS means all species of bivalve molluscan shellfish, including oysters, clams, mussels, and scallops

BMS depot means a depot, refrigerated container unit, or other building or structure used for holding BMS in a temperature-controlled environment prior to delivery to a processor, wholesaler, or retailer

BMS sorting shed means a building or structure where BMS are handled directly after harvesting to enable separation of BMS for farm management, wet storage, relaying, or culling, prior to transport to a processor, wholesaler, or retailer

calibration means the procedure used for the comparison of a measuring instrument with a standard, under specific conditions, and adjustment of the instrument, if necessary

clean, when used as a verb, means to remove visible contaminants from any surface

clean-in-place (CIP) means cleaning the interior surfaces of pipes, vessels, process equipment, filters and associated fittings, generally without disassembly

clean seawater means seawater that —

a) is free of excessive turbidity, colour, offensive odours, and any contaminants; and
b) for land based premises complies with the requirements of Schedule 2 of the Animal Products Notice: Specifications for Products Intended for Human Consumption

control measure means any action and activity that can be used to prevent or eliminate a product safety hazard or reduce it to an acceptable level

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

depuration means to reduce the level of contaminants in live bivalve molluscan shellfish by the use of a managed aquatic environment as the treatment process

equipment includes —

a) the whole or any part of any utensil, machine, fitting, device, instrument, stamp, apparatus, table, or article, that is used or available for use in or for the preparing, marking, processing, packing, storing, carrying, or handling of any animal material, animal product, ingredient, additive, or processing aid; and
b) any utensil or machine used or capable of being used in the cleaning of any equipment or facilities

essential services includes the provision of process gases, lighting, ventilation, and water and waste management

event means the detection of *L. monocytogenes* in the zone 4 environment or in ready-to-eat seafood product

exposed, ready-to-eat animal product means a ready-to-eat animal product that has the potential to be contaminated by any *Listeria* present in a high-care area before it is packaged

facilities includes amenities, storage areas, and processing areas

fish means finfish and shellfish

Guidance

Fish is often referred to as seafood. Fish also includes freshwater species and terrestrial snails.

finfish has the same meaning as in the Fisheries Act 1996. **Finfish** is defined in the Fisheries Act to include all species of the classes Agnatha, Chondrichthyes, and Osteichthyes, at any stage of their life history, whether living or dead

growing area means any coastal marine area, and any land-based aquaculture facility used for the cultivation of BMS for commercial purposes, that —

a) contains natural deposits of BMS harvested for commercial purposes; or
b) is used for cultivation of BMS for commercial purposes

harvest means the act of removing BMS, for wet storage, relay, retail sale, wholesale, or processing, from a growing area and its placement on or in a harvest vessel, vehicle or container

harvest declaration means the written declaration of the harvest details of BMS, as required by clause 11.8 of the Animal Products Notice: Regulated Control Scheme – Bivalve Molluscan Shellfish for Human Consumption

hazard means a biological, chemical or physical agent, or condition of, food with the potential to cause an adverse health effect

high-care area means any area used for processing exposed, ready-to-eat animal product after a listericidal process, whether after a critical control point for *Listeria monocytogenes* or after the final microbiological hurdle has been applied

hygiene environment means the zones where RTE seafood product is processed.

a) High-care area (zones 3 and 4) means those zones (rooms) of a seafood operation after the final *L. monocytogenes* control step, or where there is no *L. monocytogenes* control step, where RTE seafood can be exposed to potential contamination from equipment, the environment, handling or ingredients incorporated into the product
b) Standard hygiene environment (zone 2) means all internal zones (rooms) of a seafood operation that are not part of the high-care area, e.g. where initial preparation occurs, process zones for protected product such as dry stores, raw product chillers/storage zones, amenities, etc.
c) Non-processing environment (zone 1) means those zones outside of a seafood premises

ingredient means any substance, including a food additive, used in the processing of food

independent supply (water) means water supplied to a seafood facility by any person or agency (e.g. city, town, local council) that is independent of the operator

intermittent processing means processing that occurs from time to time or is periodic and not more than four days processing in any working week. For example, two days during the 1st week, one day the 2nd week and three days the following week, etc.

ISO 17025 standard means the current edition of ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories"

label includes any wording, tag, brand, symbol, picture, or other descriptive matter written, printed, stencilled, marked, embossed, impressed on, appearing on, attached to, or enclosed within any animal material or animal product

listericidal process means a process (for example heat treatment or high-pressure processing) that reduces counts of *Listeria monocytogenes* to a safe level

lot means a quantity of seafood material or seafood product that has been produced and handled under uniform conditions and within a limited period of time

lot identification means an identifier that is sufficient to enable the source of a lot to be traced

maintenance compound means any substance:

a) used for maintaining, repairing, servicing, cleaning, or sanitising equipment or surfaces that may be the source of, or result in, contamination of animal material, animal product or associated things;
b) used for treating water; or
c) used for pest control

monitoring means the act of conducting a planned sequence of observations or measurements of control parameters to assess whether an operation or activity is carried out effectively and/or assess whether a CCP is under control

MPI means the Ministry for Primary Industries

non-complying product means any product that:

a) does not meet a regulatory requirement (e.g. animal material eligibility, process or product criteria);
b) does not meet a limit or criteria defined by the operator in the RMP; or
c) has not been processed in accordance with procedures written in the RMP

on hold means that the product is retained within control of the operator, has not yet entered the retail distribution chain or been dispatched from New Zealand. It does not necessarily mean it is being held at the site of processing

operator means a risk management programme (RMP) operator

operator supply (water) means water that is supplied by an operator solely for the use of that operator at a seafood processing facility

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

a) compliance of the risk management programme to the legislative requirements; and
b) compliance of the operation to the risk management programme as written; and
c) applicability of the risk management programme to the operation; and forms part of confirmation as described in section 17(3) (f) of the Act

packaging:

a) means any material that is intended to protect and that comes into immediate contact with the animal material or animal product; and
b) includes rigid materials such as cartons and containers where animal material or animal product is filled directly into the carton or container; and
c) includes any other material contained with, in, or attached to, the animal material or animal product (such as labels, satay sticks, and heat sensors)

pathogen means an organism such as bacteria (e.g. *Salmonella* spp.), viruses (e.g. norovirus, hepatitis A virus), or parasites (e.g. Giardia, Cryptosporidium) that may cause illness

potable water means water that:

a) in relation to water supplied by an independent supplier (including a public or private supplier), is of a standard administered by the independent supplier under the Health Act 1956 and any regulations made under that Act; or

b) in relation to water supplied by the operator solely for the use of the operator (such as bore water, rainwater, surface water, or ground water):

i) is of a standard equivalent to that referred to in paragraph a), as determined by the operator based on an analysis of hazards and other risk factors; or
ii) complies with the requirements in Schedule 1 (of the Animal Products Notice: Specifications for Products Intended for Human Consumption); or

c) meets the requirements of the current "Meat Division Circulars 86/3/2 Surveillance of Potable Water in Meat and Game Export Premises" and "86/3/5 Amendment to MDC 86/3/2 86/14/5 on Surveillance of Potable Water in Meat and Game Export premises" issued by MPI

processing area is an area where unprotected (exposed) product is processed or packed or temporarily held

product contact surface means a surface in a high-care area with which exposed, ready-to-eat animal product comes in contact prior to being packaged

protective clothing means special garments intended to preclude the contamination of animal material or animal product that are used as outer wear by persons; and includes head coverings and footwear

product support areas are areas where ingredients, packaging, chemicals (including approved maintenance compounds), protective clothing, or processing equipment may be stored, cleaned, transferred through and/or prepared

relay means to transfer BMS from a growing area to another growing area for the purpose of reducing pathogens or other contaminants by using the ambient coastal marine area environment or a land-based aquaculture facility as the treatment process

repacking means, in relation to bivalve molluscan shellfish, the process of removing shucked bivalve molluscan shellfish from the package and placing them in another package

reticulation management plan means a documented programme that contains procedures for the management of the water reticulation system, (including pipe work and fittings e.g. backflow prevention devices etc.), within the premises or place to ensure that the water quality is not adversely affected prior to the point of use

risk management programme operator means an operator of a premises or place who operates an animal product business that is subject to a risk management programme

sanitary design —

a) in relation to any premises or place, facility, internal structure, equipment, or conveyance, means designed, constructed, and located so that it —

i) meets the requirements appropriate to the type of animal material or animal product and process, and which includes consideration of the movement of people, access, and process flow; and
ii) can be readily maintained, cleaned, sanitised, and sterilised where required, to ensure that risk factors from contaminants and pests are minimised; and

b) in relation to any equipment or accessway in any processing area, means that the equipment or accessway is designed, constructed and located so that it —

i) is easily accessible for maintenance, cleaning, operation, checking, and inspection; and
ii) minimises the contact of contaminants with any animal material (other than live mammals or live birds), or animal product or other equipment; and
iii) precludes the harbouring or accumulation of any contaminants or pests

sanitise means the application of an approved maintenance compound or physical agent with the intention of reducing microbial contamination to a level that will avoid the creation of a hazard

seafood product includes whole and processed fish and fish product

shellfish has the same meaning as in the Fisheries Act 1996. Shellfish is defined in the Fisheries Act to include 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

shellstock means live bivalve molluscan shellfish in the shell

stated shelf life means the period of time in which a product remains safe and suitable under the intended conditions of distribution, storage and use, as indicated by the date mark

suitably skilled person means a person who in the opinion of the operator is skilled in a particular activity or task through training, experience, or qualifications

supplier guarantee programme means a programme documented in a risk management programme, that identifies specified suppliers, and establishes the animal treatment and exposure status of animal material presented for primary processing, and in the case of farmed fish provides information that would be equivalent to the supplier statement for that animal material

supplier statement means a statement set out in Schedule 5 of the HC Spec, which is signed by a supplier to confirm that certain requirements of those specifications have been met, and includes electronic supplier statements for farmed animals

task group means a group appointed by the MPI and endorsed by NZSSC to review the *L. monocytogenes* control procedures in a seafood operation and to specify remedial action in relation to *L. monocytogenes* control for that operation during a *L. monocytogenes* event

transport includes transport by road, rail, sea or air

transport operator means any person or business that engages in the transport of animal material or product between places or premises within New Zealand and includes courier operations and subcontractors who are used intermittently

transportation unit includes vehicles, aircraft, railway wagons, ships, shipping containers, bulk tanks, trailers and any other form of transport used in the transport of animal material or product

vulnerable population means children under 5 years of age, people over 65 years of age, pregnant women and people with compromised immune systems

waste includes, without limitation, all solids, liquids, and gases that the operator intends to dispose of as being unwanted and that may become a source of contamination or attract pests

water management plan means a documented programme that specifies the water quality standard and criteria, and procedures for the management of the water quality within the premises or place to ensure that the appropriate quality of water is delivered at the point of use

withholding period (for veterinary medicines) means the minimum period that must elapse between the last treatment of an animal with a veterinary medicine and the presentation of the animal for primary processing in order for residues of the veterinary medicine in the animal material to meet the relevant residue threshold

wet storage means the temporary holding of shellstock in onshore units or tanks for the purposes of desanding, conditioning, or storage, prior to retail sale, wholesale or processing

whole fish means fish that have not been subjected to gutting, scaling, shelling, deheading, tailing, or any other form of processing (other than chilling, washing or packing)

working day means a normal processing day by the operator producing seafood products

zone means the specific area of a seafood operation that is determined based on the potential risk of contaminating the food product to human health hazards and the opportunity to eliminate or inactivate hazard.

a) **zone 1** means the non-processing environment of a seafood operation
b) **zone 2** means the standard hygiene environment of a seafood operation
c) **zone 3** means the non-product contact surfaces in the high-care area of a seafood operation
d) **zone 4** means product contact surfaces (only) within the high-care area of a seafood operation

1.4 Abbreviations

AMD means animal material depot

AP Reg means the Animal Products Regulations 2000

APA means Animal Products Act 1999

APC means aerobic plate count

AS/NZS means Joint Australian and New Zealand Standards

ATP means adenosine triphosphate

BMS means bivalve molluscan shellfish

CATR means continuous automatic temperature recording device

COP means Code of Practice

DWSNZ means Drinking Water Standards New Zealand

EEZ means exclusive economic zone

EN means European standards

ETP means environmental testing programme

EU means European Union

FCP means food control plan

FSC means the Australia New Zealand Food Standards Code

GOP means Good Operating Practice

GREX means General Requirements for Export

HACCP means Hazard Analysis and Critical Control Point

HC Spec means the Animal Products Notice: Specifications for Products Intended for Human Consumption 2016

MAV means maximum acceptable value

MPI means the Ministry for Primary Industries

MPL means maximum permissible level

MRL means maximum residue limit

NP means national programme

NZQA mean New Zealand Qualifications Authority

NZSSC means the New Zealand Seafood Standards Council

OAS means the Animal Products Notice: Official Assurances Specifications for Animal Material and Animal Products

OC means Operational Code

OMAR means Overseas Market Access Requirements

PSP means paralytic shellfish poison

PST means paralytic shellfish toxins

PT means product testing

PTP means product testing programme

RCS means regulated control scheme

RMP means risk management programme

RMP Spec means the Animal Products (Risk Management Programme Specifications) Notice 2008

RTE means ready-to-eat

SL means shelf life

US means the United States of America

Part 2: Overview of the APA and the Food Act 2014

(1) The APA provides New Zealand's legal framework for the processing of animal products for human and animal consumption. It establishes a risk management system that requires all animal products traded and used to be "fit for its intended purpose". The APA sets out the duties of the operator and the requirements related to RMPs, RCSs, and exporter controls.

(2) The Food Act 2014 provides the equivalent regulatory framework for those processing food for human consumption. Generally, if processing animal products that are not intended for export, the Food Act can be applied after the completion of primary processing. The risk management measure under the Food Act are:

- Food Control Plans (FCPs), which are equivalent to RMPs; and
- National Programmes (NPs), which are a set of food safety rules for medium and low risk businesses.

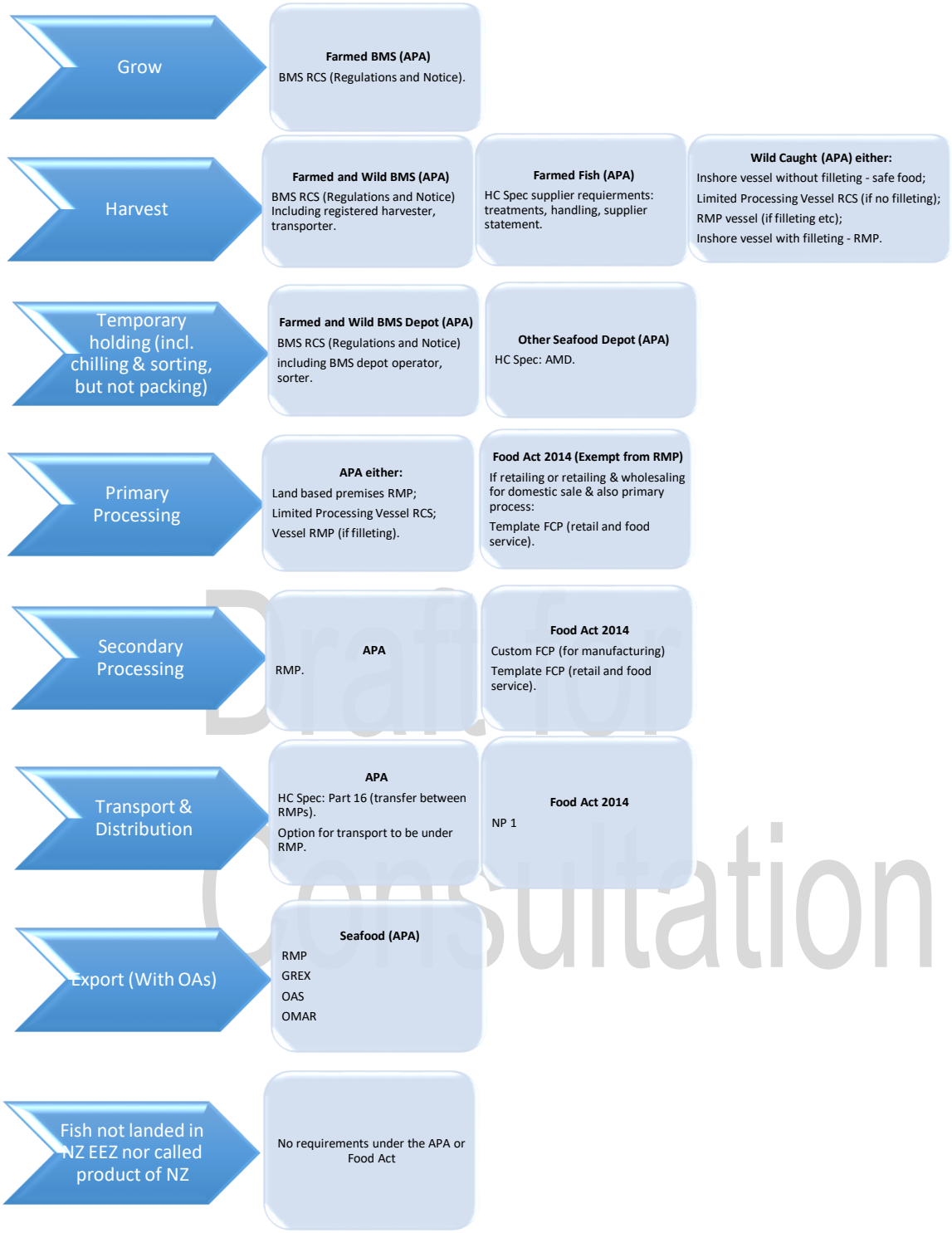
2.1 Which Risk Management Measure Applies

(1) A variety of risk management measures could apply to seafood operators under the APA and/or the Food Act, depending on the activities carried out. These include:

- listing requirements under the APA for certain persons, activities or operations;
- RCSs under the APA (which may require some documentation for compliance);
- template RMPs or FCPs;
- fully customised RMPs or FCPs; or
- National programmes under the Food Act.

(2) Figure 1 summarises the various risk management measures, depending on the activities or part of the supply chain a business operates in.

Figure 1: Which risk management measure applies?



2.1.1 Fish Primary Processing

(1) When deciding which measure applies, the definition of primary processor under the APA[1] should be considered. Primary processing on land occurs at a place where:

a) the first methodical assessment of the fish for processing is made; and
b) the fish are processed.

(2) If processing in a **land-based premises**, the following operations are considered primary processing:

a) de-sliming, beheading, gutting, or filleting of finfish;
b) tubing of squid;
c) wet-storage, depuration, or shucking of shellfish;
d) removing of roe from kina;
e) holding of live crustaceans (otherwise than in a marine farming operation), or tailing crustaceans;
f) for fish to be sold whole or after processing at sea, any steps (including washing, chilling, freezing, or packing) taken to ensure delivery of the fish to a buyer in good condition.

(3) If processing **at sea**, following operations are considered primary processing:

a) the filleting of finfish (but not just their deheading, gutting, or scaling);
b) for fish processed at sea intended for export that are not to be delivered to an on-shore primary processor, any other process normally applied to fish, including —

i) washing, chilling, freezing, and preserving;
ii) deheading, gutting, scaling, and tubing;
iii) packing, transport, and storage.

This means that if an operator is primary processing, they will most likely need to operate under a RMP, unless the operator:

a) is exempt, enabling them to operate under the Food Act (also see section 2.1.2); or
a) grows and harvests bivalve molluscan shellfish (BMS), in which case this must occur under the BMS RCS; or
b) harvests or processes at sea (the vessel may operate under the Limited Processing Vessel RCS, a RMP or neither if operating an inshore vessel and no filleting is carried out on that vessel).

Although secondary processors of seafood products intended for export are not required to have a RMP, a RMP is usually necessary to comply with overseas market access (OMARs) and obtain official assurances (OAs).

2.1.2 Exemptions from a RMP

(1) Provided no fish are exported, a business can operate under a risk-based measure (a FCP) under the Food Act 2014, instead of a RMP if they:

a) are a fish retailer and primary process the fish that are sold from that outlet; or
b) sell fish by both wholesale and retail, and primary process the fish at the same premises; but
c) if a business sells fish by wholesale only, even if no fish is exported (including export to Australia), a RMP is required.

(2) A RMP is also not required for those who[2]:

a) temporarily hold, store, or transport fish before it is transported to a primary processor;
b) process fish bait, fish berley, chum or ground bait;

[1] Animal Products Definition of Primary Processor Notice 2000, clauses 7 and 8.
[2] Animal Products (Exemptions and Inclusions) Order 2000, clauses 10 and 11.

c) operate fishing boats where the fish is not landed[3] in New Zealand or claimed to be a product of New Zealand; or
d) catch, carry out limited processing or sell whitebait for consumption or processing.

(3) Table 1 can be used to help a business decide whether it should operate under a RMP or an FCP. The key considerations are whether the premises is used for retail sale and whether product is to be exported.

Table 1: Should you operate under a RMP or FCP?

Process type	Exporting		Not Exporting	
	With official assurances	Without official assurances	Wholesale only	Retail & wholesale or Retail only
Primary processing only	RMP/RCS	RMP/RCS	RMP	RMP or FCP
Primary and secondary processing	RMP	RMP[a]	RMP[a]	RMP or FCP
Secondary processing only	RMP	RMP or FCP	RMP or FCP	RMP or FCP

[a] If secondary processing, this may be carried out under a FCP.

2.2 Risk Management Programmes

(1) A RMP is a documented programme designed to identify and manage hazards and other risk factors in relation to the production and processing of animal material and animal products, to ensure that the animal product is fit for its intended purpose.

(2) The risk factors that must be considered are:

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

(3) An operator's registered RMP is "legally binding" so it must be developed and implemented in accordance with relevant New Zealand legislation.

(4) If commercial quality issues are included in the RMP, food safety and other regulatory requirements must be clearly differentiated from this content. This may be done by highlighting relevant sections that address the regulatory requirements or by identifying them in the document list or contents page.

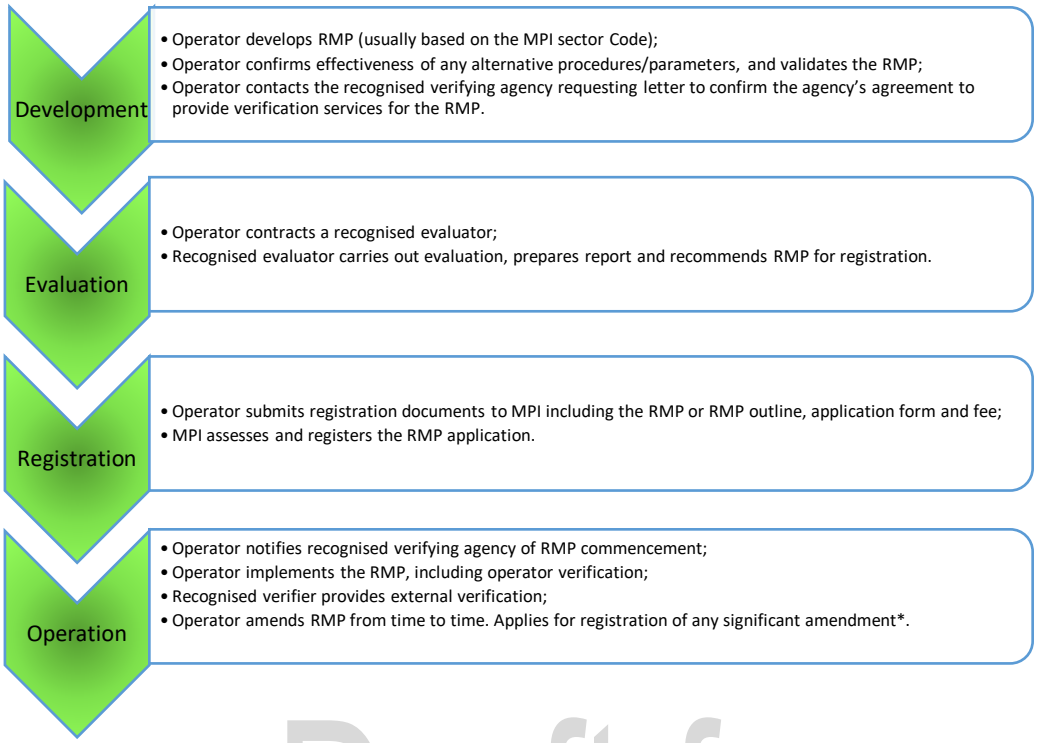
(5) MPI does not require overseas market access requirements to be part of a seafood RMP.

2.2.1 Registration and Operation of a RMP

(1) The steps involved in having a RMP registered are summarised in Figure 2. For more detail about each step, refer to the Risk Management Programme Manual.

[3] The Animal Products (Exemptions and Inclusions) Order 2000, clause 4(2) defines fish landing.

Figure 2: Steps for the development, registration and operation of a RMP



* Significant amendments require evaluation prior to registration – for information about significant amendments refer to Appendix G of the Risk Management Programme Manual.

2.2.2 Exporter Controls

(1) Exporters of seafood products must register with MPI. They are responsible for exporting in accordance with the APA and, where appropriate, to meet specified market access requirements of foreign governments that are additional to the New Zealand standard.

(2) Operators need to be aware of the export requirements and ensure that their documented systems include procedures and records necessary to demonstrate compliance with all relevant requirements notified in the Official Assurance Specification, and the Overseas Market Access Requirements (OMARS) for the intended markets.

(3) For more information about exporting, refer to the "exporting" tab on the MPI website.

2.2.3 Authorisations, Duties and Responsibilities

(1) Under the APA, agencies and persons are recognised to evaluate and externally verify RMPs.

(2) MPI maintains a public register of all recognised agencies and recognised persons, which is available on the MPI website by searching on registers and lists.

(3) The APA imposes duties on these key persons. It is a legal requirement to comply with the duties:

a) operators of RMPs (section 16 of the APA);
b) exporters (section 51 of the APA);
c) recognised agencies (section 106 of the APA); and
d) recognised persons (section 107 of the APA).

(4) The APA also provides for penalties to be applied when an offence occurs (Part 10 of the APA).

2.3 Other Legislation

(1) Operators must ensure that they comply with all other relevant legislation. This is may include:

a) Agricultural Compounds and Veterinary Medicines Act 1997;
b) Biosecurity Act 1993;
c) Fair Trading Act 1986;
d) Food Act 2014;
e) Resource Management Act 1991;
f) Fisheries Act 1996;
g) Australia New Zealand Food Standards Code;
h) Animal Welfare Act 1999;
i) Weights and Measures Act 1987.

2.4 Other Information

(1) Further information is available on the seafood part of the MPI website.

(2) Other general information about the APA and RMPs can be found at the following links:

a) Animal Products – General;
b) Risk Management Programmes (RMPs);
c) Exporting;
d) Food safety (including science reports);
e) Hazard database;
f) Food Act.

(3) The Seafood Standards Council website has a number of publications that are useful when developing and operating a RMP, including:

a) Operator Verification: A Guideline for the Seafood Industry;
b) Histamine. A Guideline for the Seafood Industry;
c) Damaged packaging: Prevention and Management: A Guideline for the Seafood Industry;
d) Traceability: A Guideline for the Seafood Industry.

(4) Information about fisheries management and the rules for commercial fishers and aquaculture operations is available at Fisheries New Zealand (MPI website).

Part 3: Design, Construction and Maintenance of Buildings, Facilities and Equipment

3.1 Purpose and Scope

To ensure that all buildings, facilities and equipment are designed, constructed, installed and operated in a manner that prevents or minimises contamination of seafood products, packaging, equipment, and the processing environment.

3.2 Sources of Hazards

Source	Examples of hazards
Facilities, equipment	Microbiological pathogens (e.g. *Listeria monocytogenes*, *Salmonella* spp., *E.coli* spp., viruses) Chemical residues (e.g. cleaning chemicals, hydraulic fluids, heating or cooling fluids) Physical hazards (e.g. metal, glass, hard plastics)
Maintenance compounds (e.g. lubricating fluids)	Chemical residues
Environmental contaminants (e.g. dust, fumes, pollutants, sewage)	Microbiological pathogens (e.g. *Listeria monocytogenes, Salmonella* spp., *E. coli* spp., *Clostridium* spp., viruses) Chemical residues (e.g. agricultural chemicals)

3.3 Mandatory Requirements

AP Reg 10 Requirements for premises, places, facilities, equipment, and essential services

All specified persons must ensure that the premises, places, facilities, equipment, and essential services for which they are responsible in relation to the processing of animal material or animal product are —

a) designed, constructed, and located to enable suitability of the animal material to be maintained, and the fitness for intended purpose of the animal product to be achieved and maintained, having regard to—

i) the animal material or animal product to be processed; and
ii) the nature of the processes involved; and
iii) the range of the animal products to be produced; and

b) operated to minimise and manage the exposure of animal material or animal product or associated things to risk factors, having regard to—

i) the animal material or animal product to be processed; and
ii) the operational capability and capacity of the premises or place, facilities, equipment, and essential services; and
iii) the range of animal products to be produced.

HC Spec 2.2 Design and construction

(1) Any material or exposed internal surface finish used in the building, manufacture, or maintenance of facilities, equipment or internal structures that may affect the suitability for processing of animal

material (other than live mammals or live birds) or the fitness for intended purpose of animal product, must:

a) be impervious, non-absorbent, and free from depressions, pits, cracks, and crevices that may harbour contaminants; and
b) be easily cleaned and sanitised; and
c) be unaffected by any corrosive substance with which it is likely to come into contact, to the extent necessary to ensure that it will not harbour contaminants and is not a source of contamination; and
d) be durable, resistant to fracture, and capable of withstanding repeated exposure to normal cleaning and sanitising; and
e) in the case of surfaces (other than those used for walking or standing on during operations), be smooth and minimise the accumulation of condensation; and
f) in the case of materials lining the walls, floors, and ceilings, be of a colour that does not disguise contaminants having regard to the lighting arrangements.

(2) The facilities, equipment, and internal structures, that may affect the suitability for processing of animal material or the fitness for intended purpose of animal product, must be of sanitary design.

HC Spec 2.3 Facilities and equipment etc.

(1) Temperature-controlled rooms and equipment must be operated within their design capabilities and capacity. These rooms must consistently deliver any temperatures as required by this Notice or as specified in the risk management programme (as the case may require).

(2) Cleaning and sanitation facilities, and equipment, must be provided to ensure that the hygiene of personnel, equipment and the premises or place can be maintained so that the suitability for processing of animal material and the fitness for intended purpose of animal product are not adversely affected.

(3) Premises or places subject to full-time supervision must provide adequate amenities and lockable office facilities for official assessors and animal product officers. All other premises and places must provide access to facilities that are sufficient for official assessors and animal product officers to perform their roles.

HC Spec 2.4 Lighting

(1) Lighting must be of a sufficient intensity and quality to enable the satisfactory performance of all operations that might affect the suitability for processing of animal material, or the fitness for intended purpose of animal product.

HC Spec 2.12 Process gases

(1) Process gases that come in to direct contact with animal material or animal product must meet the current Australia New Zealand Food Standards Code, Section 1.1.1—15 “Identity and purity”.

HC Spec 2.13 Compressed air

(1) When compressed air is generated on site for the purpose of processing and comes in to direct contact with animal material or product, the air must be filtered and the source must be clean and external to the building.

(2) The filters for filtering air that is in contact with animal material or animal product, or is in contact with product contact surfaces, must comply with:

a) the air purity classes for solid particulate, water and total oil as defined in the current International Organization for Standardization standard “Compressed air — Part 1: Contaminants and purity classes”, Ref. No. ISO 8573-1; or

b) any other international standard recognised by the Director-General as being equivalent to the international standard specified in clause 2.13(2)a).

HC Spec 3.2 Management of animal material and animal product not for human consumption

(1) Equipment and storage areas used to store or contain animal material that is not suitable for processing or animal product that is not fit for human consumption but is suitable or fit for some other purpose must:

a) be clearly identified; and
b) not be sources of contamination to other animal material and animal product that is intended for human consumption.

(2) Animal material or animal product that is not suitable for processing or not fit for human consumption but is suitable or fit for some other purpose, must be kept under controlled conditions until it is adequately identified in a manner that will ensure that it will not be mistakenly or fraudulently released as suitable for processing or fit for human consumption.

HC Spec 3.3 Waste Management

(1) Not applicable

(2) Equipment and storage areas used to store or contain waste must:

a) be clearly identified, and if equipment is permanently installed and in an identified storage area then either the equipment or the storage area may be identified; and
b) not be sources of contamination to other animal material or animal product.

(3) Waste must be kept under controlled conditions until adequately identified in a manner that will ensure that it will not be mistakenly or fraudulently released as suitable for processing or fit for human consumption.

(4) Waste must be disposed of by a method that ensures that it will not become a source of contamination to other animal material or animal product.

3.4 Procedures

3.4.1 Site

(1) The operator must consider potential sources of contamination when deciding where to locate the premises, and assess the effectiveness of any reasonable measures that might be taken to protect the product. [AP Reg 10]

Guidance

Ideally, premises should be located away from areas that are on-going sources of contamination. Operators should avoid areas that are:

- environmentally polluted;
- sites for industrial activities that pose a serious threat of contamination;
- subject to flooding, unless sufficient safeguards are provided;
- prone to infestation of pests; and
- situated so that wastes, either solid or liquid, cannot be effectively removed.

(2) Transport access ways, and areas between and around buildings, should be constructed and maintained so that they drain surface water, and minimise dust and other environmental contamination.

Guidance

These areas should be concreted or suitably sealed to minimise contamination and allow for easy cleaning. Operators should also consider how they will protect product from adverse environmental conditions when moving it between buildings, for example by installing canopies overhead.

3.4.2 Buildings and Facilities [AP Reg 10, HC Spec 2.2, 2.3, definition of sanitary design]

(1) Adequate facilities must be available for:

a) the hygienic performance of all operations;
b) storage of products, packaging, ingredients, cleaning materials, maintenance compounds, and other materials;
c) storage and distribution of water;
d) cleaning and where appropriate, sanitation of facilities and equipment;
e) personnel hygiene (e.g. toilets, hand washing units, changing facilities); and
f) effective drainage and disposal of wastes.

(2) Adequate working space must be provided to allow for:

a) the hygienic performance of all operations;
b) access of personnel;
c) installation of equipment;
d) effective cleaning; and
e) storage of, and access to, materials.

(3) Internal structures of buildings, including floors, ceilings and walls, must be designed and constructed in a manner that:

a) minimises contamination of the product;
b) facilitates cleaning and maintenance;
c) minimises the entrance and harbourage of pests; and
d) minimises the entry of environmental contaminants.

Guidance

Personnel making decisions on design and construction should be suitably qualified. Operators may seek guidance from local authorities or organisations (e.g. the Master Builders Association) regarding qualifications of contractors.

The *Listeria* guide, Part 2: Good Operating Practices provides further guidance about layout and design, particularly for operators processing ready-to-eat seafood products. This information may also be useful for operators of any other products who are interested in implementing an enhanced level of GOP.

The European Hygienic Engineering and Design Group (EHEDG) have developed a number of guidelines about best practice of building design and alterations. These include:

- Doc. 44 – Hygienic design principles for food factories, First edition, September 2014
- Doc. 47 – Guidelines on Air Handling Systems in the Food Industry - Air Quality Control for Building Ventilation, First edition, September 2016 (55 pages)
- Doc. 49 – Hygienic Design Requirements for Processing of Fresh Fish, First edition, October 2017 (44 pages).

Rodents can:

- climb up wires and the outside of vertical pipes less than 76mm in diameter;
- climb up the inside of vertical pipes less than 102mm in diameter;
- jump 660 to 915 mm both vertically and horizontally from a flat surface;
- drop 15 to 25 metres without being killed;

- gain entrance through holes 12.7mm in diameter (for rats) or 6.4mm (for mice).

Premises should also be constructed to minimise areas where birds can perch or roost.

Exporters should note there are restrictions on the use of wood in EU listed premises and US listed bivalve molluscan shellfish premises. These are specific market access requirements and exporters should consult the relevant OMARs for further information. In other premises the operator should, wherever possible, exclude unprotected wood from all processing areas.

(4) Buildings and facilities should be designed to provide separation, by partition, location, or other effective means, between operations (including waste disposal) that may cause contamination of seafood products.

3.4.3 Design and Layout [AP Reg 10]

(1) The design and layout of the processing facilities and equipment in the premises must:

a) facilitate the control of movement of personnel, raw materials and products, and equipment;
b) facilitate effective cleaning and sanitation between handling seafood products for human consumption and seafood products for animal consumption, and between handling of raw and RTE products; and
c) minimise cross contamination between seafood products for human consumption and seafood products for animal consumption, and between raw and RTE products and processes.

Guidance

The processing areas of premises, including fishing vessels, should be separated by a physical partition from living quarters, retail shops and auction places.

In case of vessels separation should be by:
- doors or hatches made of permanent material; or
- adequate space so that contamination is minimised.

3.4.4 Floors [HC Spec 2.2]

(1) The floor in a processing area must be:

a) impervious to the effects of cleaning chemicals, seafood products and water;
b) sufficiently strong to withstand its normal use (e.g. by foot traffic, forklifts); and
c) easy to clean and sanitise.

Guidance

Materials considered suitable for floors include sealed concrete, floor tiles, concrete or mortar with a monolithic surface coating (e.g. a proprietary epoxy coating) and other synthetic material; and in the case of fishing vessels, painted steel is also an option.

Concrete or mortar floors which incorporate an approved latex or synthetic resin finish tend to have better resistance.

(2) The floor in a processing area should be adequately graded to prevent the pooling of water.

Guidance

A gradient of 1 in 50 sloped towards drainage outlets will meet the requirement. Consideration should also be given to the direction of flow so that staff do not walk through waste water.

(3) Floor and wall angles and joints should be constructed in a manner that allows effective cleaning.

Guidance

To allow effective cleaning, the floor/wall joint should be coved in areas where wet operations or wet cleaning occur. A 75 mm radius coving will usually achieve this outcome. Several options are available including:

- standard coving using concrete or other floor materials;
- covings recessed behind the wall surface; and
- covings made from aluminium (or other suitable material) attached over existing floor and wall surfaces.

Hollow coving should be avoided to prevent dirt from accumulating and pest harbourage.

All joints should be effectively sealed to prevent the entry of water, pests and contaminants. Joints should be finished flush with the surface.

3.4.5 Walls

(1) The internal walls of processing areas must be:

a) smooth;
b) impervious to moisture and cleaning chemicals;
c) of a colour that does not disguise dirt and contaminants; and
d) easily cleanable. [HC Spec 2.2]

(2) Where sheeting is used, all joints should be welded, or effectively sealed with a sealing compound. The same applies to rivet holes and any holes created when fixtures have been moved.

(3) Porous surfaces such as cement or plaster should be sealed to render them impervious to moisture.

(4) Exposed pipes and/or ducting for cables should be designed and installed so they do not become dirt traps (e.g. use of a bracket to hold ducting away from the wall).

3.4.6 Ceilings

(1) The ceilings of processing areas must be:

a) smooth;
b) impervious to moisture and cleaning chemicals;
c) of a colour that does not disguise dirt and contaminants; and
d) easily cleanable. [HC Spec 2.2]

(2) Overhead fixtures attached to ceilings (e.g. pipe work, overhead cranes and hoses) should be located so that they can be easily cleaned and are not a source of contamination.

(3) The joints between the ceiling and the wall should be constructed and sealed so that they are easily cleanable.

Guidance

Rounded joints will usually achieve this outcome.

3.4.7 Doors

(1) Door jambs and hatchway frames should be sealed to adjoining walls and floor junctions.

(2) Doors in areas that open directly to the outside should be kept closed except when used for the movement of product, containers, personnel etc.

(3) Doors in areas where processing and/or packing is carried out, and which open directly to the outside should be self-closing.

(4) Doors in processing areas should be wide enough to ensure that unprotected seafood products does not come into contact with them during passage.

Guidance

Sections 3.4.7(2) to 3.4.7(4) do not apply to emergency exit doors or to hatches on fishing vessels.

3.4.8 Access Ways and Traffic Flows

(1) Stairs in processing areas and walkways, which pass over conveyors or tables, should be constructed so as to prevent contaminants falling on to seafood products, ingredients, additives, containers or seafood products contact surfaces.

3.4.9 Windows

(1) Windows in processing and packing areas (other than in fishing vessels) that may be kept open during operations should be covered by screens or similar material to prevent entry of pests.

(2) Internal windows should be constructed so as to be easily cleanable and prevent accumulation of dirt.

Guidance

Any opening windows in amenities and product support areas should also be kept closed or covered by screens.

Internal window sills should be sloped e.g. at an angle of 45°.

3.4.10 Drainage [AP Reg 10]

(1) The drainage system must have sufficient capacity to handle the wastewater and any particulate matter entering the system. Screens should be installed to prevent large fragments of solid material from entering the drains.

(2) The design and construction of the drainage system should prevent:

a) odours, pests, other objectionable material and storm water from entering the premises; and
b) contamination of products, packaging and equipment from aerosols and splashes from drains.

Guidance

Drains should be covered by a grating that is slightly lower than floor level and has perforations of sufficient size and number to allow rapid drainage, but does not allow rats to enter e.g. less than 12.7 mm wide.

Consideration should also be given to the siting of machinery and drainage should be provided so that any discharge or overspill from processing goes directly into a drain rather than on the floor.

Operators should check with their territorial authority for any specific drainage requirements that apply.

3.4.11 Lighting [HC Spec 2.2 and 2.4]

(1) Lights and light fixtures over seafood products or exposed packaging material must be of a safety type or otherwise protected to prevent contamination of products in the event of breakage.

(2) Lights must be of sufficient intensity to allow the required operations, checks, and inspections to be carried out effectively.

Guidance

If questions are asked about the intensity or quality of lighting in any area, the following are some recommendations:

- In areas where quality control inspection is carried out, illumination of at least 540 lux at the point of inspection is recommended.
- In other areas (e.g. areas used for cleaning appliances or for hand washing), illumination of at least 220 lux is usually adequate.

For further information about lighting levels refer to AS/NZS 1680.1.2006 - Interior and workplace lighting.

3.4.12 Ventilation [AP Reg 10]

(1) Adequate ventilation must be provided in processing areas to minimise steam and condensation, and to prevent airborne contamination of seafood products.

Guidance

Options for ventilation in processing areas include natural ventilation using suitably screened air intakes or ventilating-type windows; or mechanical ventilation that is adequate for the size of the premises, the number of persons working there, and environmental conditions (e.g. heat gain from equipment, condensation).

The direction of air flow should minimise cross contamination from earlier to later stages of seafood processing (e.g. air should flow from cooked processing areas to uncooked processing areas and not the reverse).

For further information about ventilation refer to ISO 16890-1:2016 Air filters for general ventilation and the Ambient Air Quality Guidelines (2002) prepared by the Ministry for the Environment and the Ministry of Health.

(2) Fresh air intakes for processing areas, stores and amenities must be located so that incoming air is not contaminated with odours, dust, smoke and other environmental contaminants. [HC Spec definition of sanitary design]

Guidance

Effective filters should be installed, maintained, monitored and cleaned in accordance with the manufacturer's recommendations.

3.4.13 Process Gases and Compressed Air

(1) Compressed air generated on-site for processing and that comes in direct contact with any seafood material or product, must be clean and filtered. The appropriate air purity classes for the intended use should be specified in the RMP. [HC Spec 2.13]

Guidance

Product contact air includes:

- air used for cleaning, cooling, drying, conveying, mixing and stirring; and
- compressed air that comes in contact with inputs, product or product contact surfaces.

Equipment using pressurised air in direct product contact should be fitted with a filter located as near to the outlet as is feasible. The choice of filter will depend on the product and process, and the size, type and

concentration of the particulate matter to be removed. Filters should be readily removable for replacement or cleaning.

Process gases may be used as food additives, to modify atmospheres in packaging, cooling or freezing, or as a propellant to dispense food. Gases include carbon dioxide, nitrogen, oxygen and argon.

3.4.14 Equipment

(1) Equipment that comes into contact with any edible seafood products should be designed, constructed, installed and operated in a manner that:

a) ensures the effective performance of the intended task;
b) ensures effective cleaning and sanitation;
c) facilitates good hygienic practices, and effective process control, including monitoring; and
d) does not cause contamination of the product.

(2) Equipment should be:

a) durable;
b) resistant to chipping, flaking, delamination, abrasion;
c) able to withstand exposure to heat, water and all seafood products under normal operating conditions;
d) corrosion resistant;
e) inert to seafood products, cleaning materials and other substances under normal conditions of use; and
f) able to be cleaned without damage to the material's surface.

(3) The following materials should not be used in any equipment that may come into contact with exposed/unprotected seafood products:

a) toxic metals such as cadmium, lead and their alloys;
b) metals whose contact with liquid or other material may create harmful chemical or electrolytic action;
c) porous materials such as sponge rubber, stone slabs, linoleum, leather and fabrics (excluding strainers/filters); and
d) wood (except on fishing vessels as long as it is easy to clean and does not contaminate the product).

Guidance

Austenitic stainless steel (300 series or better) is the preferred material for equipment that comes into contact with seafood products. The most common austenitic stainless steel is Type 304, also known as 18/8 or A2. It is used in cookware, cutlery and equipment. Type 316 contains some molybdenum to improve acid resistance (e.g. pitting and crevice corrosion). Commonly used grades of stainless steel are AISI 304 and AISI 304L, or for improved performance AISI 316 and AISI 316L.

Other suitable materials include:

- plastic materials and coatings that are abrasion- and heat-resistant, shatterproof, are food grade if in direct or indirect contact with food, and do not contain components that will adhere to seafood products when coming into contact with those materials or coatings;
- good quality galvanised iron, when used in bulk containers for transporting or holding whole headed or gutted fish; in fish scaler drums; and in thawing tanks and freezer trays used for whole and/or headed and gutted fish.

Aluminium should be used only for equipment that has short contact periods with seafood products. Aluminium sheet has a tendency to warp and is susceptible to the effects of both oxidation and certain types of corrosion, especially from alkaline cleaning chemicals. The soft nature of the metal also leaves it susceptible to pitting and scratching.

When purchasing new equipment for direct contact use with seafood products, the operator should obtain a letter of guarantee from the supplier certifying its suitability for food use (where appropriate), or alternatively they may make their own assessment.

For further information refer to EN 1672-2 Food Processing Machinery, the European standard that establishes a general code of practice for hygienic design or ISO 14159:2002 Safety of machinery -- Hygiene requirements for the design of machinery.

(4) Equipment, such as weighing scales, thermometers (whether stand alone or forming part of a piece of equipment) must have the accuracy, precision, and conditions of use appropriate to the task performed. [HC Spec 6.2]. Also see Part 5 Calibration of Measuring Devices.

a) product, process, facility and/or equipment it is fitted to; and
b) measurement being taken.

(5) Monitoring equipment should be installed where it:

a) can be easily read;
b) is able to take accurate readings (e.g. warmest temperature within refrigeration equipment, the coldest temperature within a cooker); and
c) is adequately protected from physical and chemical damage.

(6) Product contact surfaces:

a) the product contact surfaces of conveyor belts must be constructed of smooth material, have undamaged edges, and be a colour that does not disguise contaminants;
b) cutting boards must be smooth, shatterproof, and of a colour that does not disguise contaminants; and
c) welds in equipment must be smooth, complete, and without gaps, and angled so as to facilitate cleaning. [HC Spec 2.2]

(7) Non-product contact equipment and surfaces must be constructed so they are easily cleanable. [HC spec 2.2]

Guidance

In premises processing ready-to-eat seafood product, non-product contact surfaces that are in critical hygiene areas and that have the potential to impact on the product should be constructed to meet full sanitary design requirements.

(8) Storage equipment [AP Reg 10, HC Spec 3.3]

a) Containers used within the premises for holding seafood products, cleaning materials, wastes or other materials must be identifiable to differentiate between uses (e.g. by labels or colour coding);
b) Storage racks or shelving should be a sufficient height off the floor to allow cleaning underneath.

(9) Cleaning equipment [HC Spec 2.3]

a) Suitable equipment must be made available for cleaning and sanitising equipment and facilities, and must be maintained in a hygienic and good working condition.

3.4.15 Product Support Areas [AP Reg 10, HC Spec 2.2]

(1) Product support areas must be designed and constructed to:

a) facilitate maintenance and cleaning; and
b) avoid pest access and harbourage.

3.4.16 Amenities for Staff

(1) The operator should provide sufficient space and facilities for staff to consume food, change clothes, store personal belongings and to attend to personal hygiene.

Guidance

For land-based premises, the territorial authority can advise on the numbers of toilets required for staff employed on the premises, and on other amenities such as showers and hand wash basins.

For fishing vessels, the amenities may be located within the accommodation section of the vessel. See section 3.4.3 Design and Layout for more detail.

(2) The amenities must be designed, constructed and maintained in a manner that facilitates cleanliness and tidiness. [HC Spec 2.2]

(3) The amenities should not open directly onto food areas.

(4) Lockers for storing staff clothing and personal belongings (if provided) must be constructed in such a manner that they and the surrounding area can be easily cleaned. [HC Spec 2.2]

Guidance

Lockers should be off the floor (e.g. 300 mm higher) to allow for easy cleaning underneath. Alternatively lockers could be placed directly on the floor without any gaps. The tops of lockers should be flush with ceiling or tapered to reduce the ability for dirt to build up.

Storage facilities should be adequate to allow for the separation of personal clothing and other personal items from clean protective clothing.

3.4.17 Hand Washing and Sanitising Facilities

(1) Hand washing units should not be operated by hand. The design should allow for non-hand operation (e.g. operated by knee or foot) or automatic sensor.

(2) Hand washing facilities should be located in every toilet and/or amenities area, and in places that are accessible to all persons working in rooms where seafood products are processed. This requirement does not apply to rooms used exclusively for smoking, cooking, drying, chilling, freezing or thawing seafood products.

(3) Hand washing facilities should be provided with warm potable water, liquid soap dispensers and single use towels, or other hand drying facilities that do not contaminate washed hands or the surrounding area (e.g. roller towels fitted with a timed automatic retraction device that removes the soiled piece of towel immediately after use).

Guidance

Potable water at about 30˚C should be provided for hand washing. Note that there are specific hand washing temperature requirements for US listed shellfish premises in the Model Ordinance: XI Shucking and Packing, Requirements for Dealers, .02 Sanitation, Section D. Maintenance of Hand Washing, Hand Sanitising & Toilet Facilities (external website).

(4) Hand sanitising units (where these are used) must be provided with MPI approved hand sanitiser (see the List of Approved Maintenance Compounds and the Approved Maintenance Compounds Manual). [HC Spec 3.4]

(5) Facilities for washing and, where necessary, sanitising waterproof protective clothing (e.g. boots, aprons, gloves), should be provided in or adjacent to the processing area.

3.4.18 Refrigeration Facilities [HC spec 2.2 and 2.3]

(1) Refrigeration facilities must be designed and constructed to:

a) be capable of reducing all part of the seafood products to required preservation temperatures (refer to Part 23 Refrigeration and storage of seafood products) within the required time, and/or holding and storing the seafood products constantly at or below those temperatures;
b) minimise the possibility of contamination of seafood products; and
c) minimise fluctuations in temperature caused by movement of products, people and equipment.

Guidance

Temperature fluctuations can be minimised by using self-closing doors, air curtains, plastic strip curtains and, in the case of doors that open to the outside, truck dock seals or full environmental facilities. Build-up of snow and ice in a freezer indicates that a significant entry of warm air has been occurring over a period of time.

(2) All chillers and cold stores should be fitted with temperature indicating devices and where possible these should be continuous automatic temperature recorders.

Guidance

Temperature sensors (probes) should be located so that they accurately monitor the temperature within the room. If only one temperature sensor is used it should be located in the return air flow to the evaporator unit as this usually has the highest temperature.

If temperatures are not recorded automatically, they should be checked and recorded periodically and at a frequency based on performance.

3.4.19 Repairs and Maintenance

(1) The operator must document and implement a repairs and maintenance programme for the premises, facilities and equipment, to ensure they are maintained in good working condition and are not a source of contamination to seafood products. [RMP Spec 11].

Guidance

For small operations with simple processes, a checklist for repairs and maintenance, rather than a full programme, may be sufficient.

(2) The repairs and maintenance programme should include the following information:

a) roles and responsibilities;
b) procedures for routine or programmed maintenance (i.e. preventative maintenance), including a monitoring schedule for the plant, facilities and equipment;
c) procedures for facilities and equipment breakdown;
d) procedures for how corrective actions will ~~to~~ be taken when defects are identified;
e) target date or time for completion of repairs or maintenance;
f) records to be kept; and
g) signature or other unique identifier (in the case of electronic records) of the responsible person(s) once work is completed.

Guidance

An effective repairs and maintenance programme should be designed to proactively identify and record areas requiring work and to ensure that an appropriate timeframe for resolution is applied. The action taken and the target date for completion should be based on the seriousness of the problem identified and the

extent to which it may affect the seafood products fitness for purpose. Serious non-compliances should be corrected immediately.

See Appendix G of the RMP Manual for information about the types of maintenance activities that may require a significant amendment to the RMP.

(3) All alterations, repairs and maintenance work on buildings, facilities and equipment should be carried out in a manner that minimises exposure of seafood products to any hazards introduced by this work.

(4) Prior to any alteration, repair or maintenance work on buildings, facilities or equipment, a suitably skilled person should:

a) assess its potential for contaminating inputs, products, packaging, equipment and the processing environment; and
b) put in place appropriate controls to minimise exposure to contamination.

(5) Maintenance personnel must comply with the requirements for personnel hygiene appropriate to the area they are operating in, including access restrictions, hygienic practices and protective clothing requirements. [AP Reg 12]

(6) Chemicals used during repairs and maintenance must be used in accordance with MPI's Approved Maintenance Compounds Manual. [HC Spec 3.4]

Guidance

Not all chemicals used for repairs and maintenance need to be approved maintenance compounds. The Approved Maintenance Compound Manual outlines the requirements for the use of chemicals when carrying out maintenance work and identifies the situations when approval is not required. Once the maintenance has been completed the affected parts of the room and equipment should be wet cleaned to remove chemical residues and a pre-operation hygiene check carried out before processing re-commences.

3.5 Monitoring [APA section 17]

(1) The operator must carry out regular checks for compliance with documented procedures.

Guidance

The frequency and type of monitoring will depend on the nature of the operation, and on the degree of risk if hazards are uncontrolled. Monitoring options to identify repairs and maintenance problems include:

- daily checks on processing areas;
- weekly checks on product support areas (e.g. chemical stores, packaging stores, dry stores);
- monthly check on the entire premises and surrounding areas;
- specific checks on equipment at defined intervals.

Monitoring activities should identify and record all issues that need to be addressed and specific checks should be carried out to ensure that the issues are dealt with as stated.

3.6 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) Records must include monitoring carried out, problems identified and corrective action taken.

Guidance

Examples of other records that may be used to demonstrate compliance are:

- Site plans;
- Equipment registers;
- Alteration / maintenance plans.

Refer to Part 19 for record keeping requirements.

Part 4: Construction and Operational Requirements for the Swimming of Live Fish

4.1 Purpose and Scope

To ensure that premises and equipment used for the swimming and / or holding of live fish (including crustaceans and abalone) are suitable for their intended purpose and to minimise contamination of the live animals.

This programme does not cover marine farming operations nor the storage and/or depuration of molluscan bivalve shellfish. It does not cover areas of the premises where fish processing occurs.

4.2 Sources of Hazards

Source	Examples of hazards
Swimming water	Chemical residues
Water	Chemical residues
Holding tank	Chemical residues

4.3 Mandatory Requirements

AP Reg 10 Requirements for premises, places, facilities, equipment, and essential services (paraphrased)

(1) The premises, facilities, equipment and essential services must be designed, constructed, located and operated in a manner that:

a) enables the suitability of any seafood products to be maintained;
b) enables the fitness for intended purpose of any product to be achieved and maintained; and
c) minimises and manages the exposure of any product, packaging, equipment, and the processing environment to hazards and other risk factors.

AP Reg 11 Hygiene of processing environment (paraphrased)

(1) All operators must establish and carry out effective procedures to:

a) ensure appropriate and adequate maintenance, cleaning and sanitation of processing premises, facilities, essential services, and equipment (including conveyances); and
b) manage waste; and
c) control pests.

HC Spec 3.3 Waste Management

(1) Clause not applicable

(2) Equipment and storage areas used to store or contain waste must:

a) be clearly identified, and if equipment is permanently installed and in an identified storage area then either the equipment or the storage area may be identified; and
b) not be sources of contamination to other animal material or animal product.

(3) Waste must be kept under controlled conditions until adequately identified in a manner that will ensure that it will not be mistakenly or fraudulently released as suitable for processing or fit for human consumption.

(4) Waste must be disposed of by a method that ensures that it will not become a source of contamination to other animal material or animal product.

4.4 Procedures

4.4.1 Construction [AP Reg 10]

(1) Live fish swimming areas must be designed, constructed and maintained in such a manner so as to:

a) minimise contamination of the live fish; and
b) facilitate cleaning and maintenance.

Guidance

Live fish swimming areas do not have to comply with construction requirements for seafood products processing premises – for example smooth impervious walls are not mandatory.

Construction materials in such areas may include exposed wood and roofing iron provided they are not detrimental to the health of the live fish and do not contaminate the swimming water. In some instances materials such as wood or porous concrete may form part of the biofilter system used for maintaining water quality.

(2) The area for the swimming and holding of live fish should be separated from any place used for living quarters by:

a) doors made of permanent material; or
b) other forms of physical separation that minimise contamination of live fish.

Guidance

If processing and packing live fish in the same area that is used for swimming and holding, the processing and packing areas should meet the full hygienic standards that apply to seafood processing premises. Packing is considered a process step in the RMP.

(3) Toilet areas should not open directly on to any live swimming area.

(4) Service lines such as cables and pipes should be located and installed in such a manner that they do not contaminate the live swimming area.

4.4.2 Water Supply

(1) The quality of water used for the purpose of swimming live fish should be sufficient to maintain the fish in their live state.

Guidance

Water containing treatment chemicals (e.g. chlorine) is unsuitable for swimming live fish as the chemicals will have an adverse effect on their health and welfare. Live crustaceans are sensitive to water quality and, hence, are good indicators of water quality. The water does not need to meet the criteria in the HC Spec for potable water or clean seawater.

Compounds (e.g. bacterial cultures, pH modifiers and salt) may be used to modify the water conditions to ensure survival of the fish.

4.4.3 Lighting

(1) Refer to Part 3 for relevant requirements.

4.4.4 Cleaning and Sanitising Facilities

(1) Facilities for hand washing and for the cleaning of waterproof clothing must be available in or near the live swimming area. Refer to Part 8 for further information.

(2) Cleaning materials and cleaning equipment must be stored in a way that prevents contamination of live seafood products, ice, water and containers.

4.4.5 Equipment [HC Spec 2.2]

(1) All equipment used in contact with live fish must be made of material that will not contaminate the live fish or the water.

4.4.6 Maintenance Compounds

(1) Maintenance compounds that are used in a live swimming or holding area must meet the requirements of Approved Maintenance Compounds Manual and Part 10.

4.4.7 Compressed Air

(1) Where compressed air is used it should be used in accordance with the requirements of Part 3.

4.4.8 Containers

(1) Containers used in a live fish swimming and holding plant should meet the requirements of Part 15.

(2) Containers should be stored in such a way as to minimise contamination of the live fish and live swimming area.

4.4.9 Cleaning and Sanitation Programme [APA section 17, AP Reg 11, RMP Spec 11]

(1) The operator must document and implement a cleaning programme for all live swimming and holding areas to ensure that these areas are kept in a clean and tidy condition.

Guidance

Maintenance compounds for cleaning and sanitising should not be used in live swimming or holding areas because they may contaminate the swimming/holding water. Chemical exposure may have detrimental effects on the fish and could result in death, and could also lead to chemical residues.

4.4.10 Disposition of Unsuitable Material [HC Spec 3.2 and 3.3]

(1) Material that is unsuitable for further processing for human consumption (e.g. diseased or dead fish) must be transferred to a temporary holding area and physically separated from healthy live fish, until it is sent for further processing to products for animal consumption, or for disposal.

(2) All live fish found to be unfit for human consumption must be handled and disposed of in a manner to minimise contamination and to prevent such fish entering the human food chain.

4.5 Monitoring [APA section 17]

(1) The operator must carry out regular checks on compliance with documented procedures.

Guidance

The frequency and type of monitoring will depend on the nature of the operation and the degree of risk if hazards are uncontrolled. Monitoring options include:

- daily checks on swimming/holding areas
- weekly or monthly checks to confirm that the cleaning requirements have been met.
- monthly checks on repairs and maintenance.

4.6 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) These records must include monitoring carried out, problems identified and corrective action taken.

Guidance

Examples of other records that could be used to demonstrate compliance are:

- Cleaning & maintenance records;
- Inventory records.

Refer to Part 19 for record keeping requirements.

Part 5: Calibration of Measuring Devices

5.1 Purpose and Scope

To ensure that measurements taken to demonstrate conformity with mandatory and other requirements are accurate and valid.

5.2 Mandatory Requirements

AP Reg 14 Required measuring equipment to be calibrated and function as intended

(1) All specified persons must ensure that measuring equipment that is used to carry out a critical measurement is properly calibrated and functions as intended.

(2) In this regulation, critical measurement means a parameter identified as critical in any—

a) specifications or regulated control scheme; or
b) risk management programme, being a parameter of the nature of the parameters referred to in section 17(3)(c) of the Act in relation to points at which hazards of significance occur.

HC Spec 6.2 Calibration and measuring equipment suitability

(1) Measuring equipment, such as scales, thermometers, pH meters and flow meters (whether standalone or forming part of a piece of equipment), that is used to provide measurements identified as critical in the operator's risk management programme must:

a) have the accuracy, precision and conditions of use appropriate to the task performed; and
b) be calibrated against a reference standard showing the traceability of calibration to a national or international standard of measurement (where available) or (if no such reference standard exists) be calibrated on a basis that is documented in, or incorporated by reference into, the risk management programme; and
c) be uniquely identified to enable the traceability of the calibrations and to identify calibration status.

(2) Minimum frequencies of calibration must be specified in the risk management programme for each piece of measuring equipment used to provide critical measurements, or used as reference standards, taking into consideration the following (as appropriate):

a) the stability of the piece of equipment;
b) the nature of the measurement;
c) the manufacturer's instructions.

(3) Safeguards must be in place to prevent unauthorised adjustments to the calibration of the measuring equipment, including movement of the equipment where this may invalidate the calibration.

Guidance

Critical measurements are measurements taken to confirm (directly or indirectly) the fitness for intended purpose of the product (e.g. equipment used for taking measurements at a Critical Control Point (CCP)). Operators are responsible for determining the critical measurements for their operations. Critical measurements may be identified in a RMP or mandated as critical in the legislation, e.g. the critical preservation (load-out) temperatures in clause 13.37 of the HC spec.

The calibration requirements in HC Spec clause 6.2 apply only to equipment used to provide critical measurements. When developing a RMP, seafood operators should determine which of their processes require critical measurements to be taken, and document the result of this determination in their RMP.

5.3 Procedures [HC Spec 6.2]

(1) Measuring equipment (whether stand-alone or forming part of a piece of equipment) must have the accuracy, precision, and conditions of use appropriate to the task performed.

(2) The operator must document and implement a calibration programme, which in relation to critical measurements, must include the elements listed below as appropriate: [APA section 17, RMP Spec 11]

a) a description or list of the equipment used to take critical measurements (e.g. its name, make, model and/or other identification characteristics, location);

Guidance

Such equipment may include process temperature measuring/recording devices, timing devices, flow meters, thermometers used for taking temperatures of cooked product or temperatures of product at load-out; moisture or water activity meters for measuring the moisture level in dried products; pH meters used for checking the pH of marinated product; scales used for measuring critical ingredient weights; and metal detectors.

It is important to consider the level of use of the instrument, its stability and the degree of accuracy required. Some pieces of equipment (e.g. scales), which become inaccurate if moved, may require calibration after any such movements.

Calibration of continuous automatic temperature recording devices (CATRs) that are used for non-critical measurements is recommended but not mandatory. Verification against a calibrated thermometer would be acceptable.

b) a means of identifying the equipment (e.g. serial numbers, indelible tags) or other permanent means of identification. The identifying feature must be recorded on the calibration record sheet;
c) the frequency of calibration required for each piece of equipment;
d) procedure for calibrating the instrument;
e) controls to minimise or prevent movement of the equipment if this could affect the calibration;
f) the maximum error allowed before corrective action is taken (e.g. ± 1 g, ± 1°C); and
g) how any correction factor will be dealt with and/or affixed to the measuring device.

Guidance

This can be achieved by using suitable testing facilities capable of providing certification to show the required traceability, or by using reference materials (e.g. certified test weights or standard solutions).

(3) Reference standards (e.g. reference thermometer or reference weights) should have a current calibration certificate before they can be used.

(4) Any in-house routine check of measuring equipment should be carried out at regular and established frequencies by suitably skilled personnel.

Guidance

Table 2 provides guidance on calibration of equipment used for critical measurements. It may also useful for equipment used for non-critical measurements.

Table 2: Guidance on calibration methods and frequencies for measuring equipment

Measuring equipment	Method	Minimum recommended frequency	Person / agency responsible
Standardised thermometer (reference thermometer)	Standardised against a national or international standard	Annually	Accredited / approved laboratory
Working thermometers	Calibrated against a reference thermometer	Annually	Accredited person or agency
	Ice point and / or boiling point method, as appropriate (Refer to methods in following this table)	Those used daily for monitoring of critical limits – weekly or fortnightly. Other working thermometers - monthly	Suitably skilled person
Continuous automatic temperature reading devices (CATR)	Calibrated against a reference thermometer	Annually	Accredited person or agency / suitably skilled person
Temperature probe and/or recorder (e.g. data logger, cooker probe)	Calibrated against a reference thermometer	Annually	Accredited person or agency
	Calibrated against a reference thermometer (in-house check)	Probe - monthly, e.g. if used to measure final cooked product temperatures	Suitably skilled person
Water activity meter	Calibration against standard solutions; manufacturer's instructions	Before each day's use, or as recommended by manufacturer	Suitably skilled person
	Servicing and calibration	Annually or as recommended	Instrument specialist
pH meter	Check against standard solutions; manufacturer's instructions	At least daily, or as recommended by manufacturer	Suitably skilled person
	Servicing and calibration	Annually	Instrument specialist
Metal detector	Test against metal test pieces	At least daily	Suitably skilled person
	Servicing and calibration	Annually	Instrument specialist
Weighing scales (ingredient and product scales)	Check against test weights	Daily	Suitably skilled person

Weighing scales	Certify for accuracy as per the Weights and Measurement Act 1987	Annually	Accredited person or agency
Test weights	Standardised against a national standard	Annually	Accredited / approved laboratory
Light meter	Servicing and calibration	Annually	Instrument specialist

Calibration methods

Boiling point calibration is used when monitoring temperatures higher than room temperature (e.g. cooking temperatures). When probes are used to monitor freezer or cold storage temperatures it is recommended that calibration is also carried out at freezer temperatures. At least two temperatures (e.g. a combination of the ice point and boiling point methods) is recommended for a more accurate calibration of thermometers used to monitor a wide range of temperatures.

Ice point method:

- use enough crushed ice in a container to allow immersion of most of the probe stem. Add just enough water to remove the air around the ice particles and to form a slush. Wait for the ice to appear clear;
- stir the mixture (do not use the probe for mixing), tip off excess water, insert the probe and leave it for about 2 minutes. Ensure that the tip of the probe is in good contact with the slush ice at the centre of the container;
- stir the mixture again and check the reading on the thermometer. Accept if the deviation from 0°C is within the declared limits of accuracy; and
- if the deviation from 0°C is greater than the limit of accuracy, or greater than ± 1.0°C, adjust the thermometer accordingly or discard and replace the thermometer.

Boiling point method:

- place the probe in a container with boiling water for about 2-3 minutes until the thermometer reading stabilises. The probe should be at the centre of the container;
- accept if the deviation from 100°C, or appropriate temperature according to elevation, is within the declared limits of accuracy; and
- if the deviation from 100°C is greater than the limit of accuracy, or greater than ± 1.0°C, adjust the thermometer accordingly or discard and replace the thermometer.

Freezer method

- place the reference thermometer and probe to be checked side by side in the freezer or cold store;
- once the temperatures have stabilised record the temperatures, wait another minute and repeat (up to3 times);
- accept if the deviation is within the declared limits of accuracy; and

if the deviation is greater than the limit of accuracy, or greater than ± 1.0°C, adjust the thermometer accordingly or discard and replace the thermometer.

5.4 Monitoring [APA section 17]

(1) The operator must carry out checks for compliance with documented procedures and to demonstrate that equipment used remains within an acceptable range.

Guidance

Monitoring should also include regular checks to ensure calibration is up-to-date. The level of monitoring will depend on how frequently the device is calibrated; for example if annual calibration is required operators

should schedule six-monthly checks.

5.5 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) The records must include:

a) calibration records;
b) certificates showing traceability to appropriate standard measurement;
c) identification, location and calibration status of equipment;
d) calibration schedules;
e) training records for persons involved in key tasks; [RMP Spec 15(3)]
f) monitoring and verification records.

(3) Refer to Part 19 for record keeping requirements.

Part 6: Water

6.1 Purpose and Scope

To ensure that an adequate supply of potable water or clean seawater is available for hygienic operations so as to minimise contamination and maintain the fitness for intended purpose of seafood products. Water includes ice and steam.

6.2 Sources of Hazards

Potable water

Source	Examples of hazards
Faecal material (e.g. animal droppings, sewage), dead animals, offal pits, vegetation	Pathogenic microorganisms – *E.coli* spp., *Campylobacter* spp., *Cryptosporidium, Giardia*, viruses
Agricultural chemicals (e.g. fertiliser, pesticides), industrial waste	Nitrate, cadmium
Soil	Pathogenic microorganisms – *E.coli* spp., *Campylobacter* spp., *Cryptosporidium, Giardia*, viruses Toxic chemicals, e.g. arsenic, boron
Pipes and tanks	Copper
Roof materials and paint for roof collected water	Lead, asbestos

Seawater

Source	Examples of hazards
Faecal material (e.g. animal droppings, sewage)	Pathogenic microorganisms – *E.coli* spp., *Campylobacter* spp., *Cryptosporidium, Giardia*, viruses
Agricultural chemicals (e.g. fertiliser, pesticides)	Nitrate
Pollution from vessels in area	Fuel, diesel, hydraulic fluid

6.3 Mandatory Requirements

AP Reg 10 Requirements for premises, places, facilities, equipment, and essential services (paraphrased)

(4) The premises, facilities, equipment and essential services must be designed, constructed, located and operated in a manner that:

a) enables the suitability of any seafood products to be maintained;
b) enables the fitness for intended purpose of any product to be achieved and maintained; and
c) minimises and manages the exposure of any product, packaging, equipment, and the processing environment to hazards and other risk factors.

HC Spec 2.5 Water coming into contact with animal material or animal product

(1) Water (including ice and steam) that comes into direct contact or indirect contact with animal material or animal product must be potable water, or clean seawater, at the point of use.

(2) Despite clause 2.5(1), the operator may use an alternative water quality standard as determined by the operator provided:

a) the water quality standard is determined by an analysis of hazards and other risk factors; and
b) the suitability for processing of animal material or fitness for intended purpose of animal product is not adversely affected.

(3) Clauses 2.5(1) and (2) do not apply to water used for live animals, or to water used for washing bivalve molluscan shellfish prior to depuration, or for depuration, or for wet storage.

(4) The water used for activities relating to bivalve molluscan shellfish referred to in clause 2.5(3) must comply with the requirements of the Animal Products (Regulated Control Scheme—Bivalve Molluscan Shellfish) Regulations 2006.

HC Spec 2.6 Water not coming into contact with animal material or animal product

(1) Water that does not come into direct contact or indirect contact with animal material or animal product must meet the requirements of clause 2.5, or may meet an alternative non-contact water quality standard.

(2) If an alternative non-contact water quality standard is used, the appropriate standard must be determined by the operator —

a) by an analysis of hazards and other risk factors; and
b) taking into consideration the intended use of the water.

HC Spec 2.7 Water on fishing vessels

(1) If clean seawater described in clause 2.5 is used on fishing vessels it must only be taken from places that are of a distance offshore sufficient to ensure that the water quality is not at risk from pollution sources.

(2) All water treatment equipment, including desalination plants must be installed, maintained and operated in accordance with the manufacturer's instructions.

HC Spec 2.8 Requirement for reticulation management plan

(1) The operator must implement a reticulation management plan for potable water used within a premises or place, (including its use on fishing vessels), where the water is supplied by an independent supplier, or is supplied on fishing vessels by the operator.

(2) The reticulation management plan must include:

a) systems to ensure that the water that is reticulated throughout the premises or place is not adversely affected by the reticulation system so that the intended water quality is delivered at point of use; and
b) systems to ensure that there is no unintentional mixing of water of different standards; and
c) an action plan with appropriate sanitation procedures to be implemented in the event of non-compliance with the reticulation management plan.

HC Spec 2.9 Requirement for water management plan

(1) The operator must implement a water management plan for water described in clause 8, other than water used on a fishing vessel, if:

a) water is supplied by an independent supplier and is subjected to any treatment by the operator; or
b) water is supplied by the operator solely for the operator's use; or
c) an alternative water quality standard as described in clause 2.5(2) is used; or
d) clean seawater is used in a land based premises or place.

(2) The water management plan must include:

a) any additional treatments:

i) as required by the operator supplying potable water or using clean seawater in a land based premises or place; or
ii) in the case of an alternative water quality standard, as determined through the analysis of hazards and other risk factors; and

b) the water quality standard (including criteria) as determined through an analysis of hazards and other risk factors; and
c) a water sampling and testing programme; and
d) an action plan in the event of non-compliance with the water management plan; and the requirements of the reticulation management plan described in clause 2.8(2).

HC Spec 2.10 Water analyses

(1) Water analyses used to demonstrate compliance with clause 2.9 and conducted on water supplied by an independent supplier or by the operator solely for the operator's use, must be performed by a recognised laboratory with the required tests in the laboratory's scope of accreditation.

(2) The operator must ensure that the training of water samplers is undertaken by a laboratory referred to in clause 2.10(1).

(3) Clause 2.10(1) does not apply to chlorine, pH or turbidity measurements, which are performed by a suitably skilled person using documented test methodologies (including calibration procedures) and/or calibrated equipment.

HC Spec 2.11 Non-complying water

(1) This clause applies only to water to which clause 2.5 applies.

(2) If potable water supplied by an independent supplier is used, and the independent supplier advises the operator that the water is not fit for drinking without additional treatment, or the operator has reason to believe that the water is not fit for use, and the operator has no other means described in a water management plan that meets the requirements of clause 2.9(2) a)-c) to ensure that the water is potable at the point of use, all operations involving that water must cease.

(3) If water used is supplied by the operator, or is of an alternative water quality standard that has been determined under clause 2.5(2), or is clean seawater used in a land based premises or place, and the operator fails to comply with any of the requirements of the water management plan (including corrective actions), and has no other means described in the risk management programme to ensure the water meets the original standard at the point of use, all operations involving that water must cease.

HC Spec – Schedule 1 and Schedule 2

(1) HC Spec Schedule 1 (Specification for potable water supplied by operator) & Schedule 2 Clean seawater specification.

6.4 Procedures

6.4.1 Water Supply [AP Reg 10]

(1) An adequate supply, volume, temperature (if applicable) and pressure of potable water[4] and/or clean seawater must be available and used for:

[4] Throughout this section reference is made to potable water. An alternative water standard may apply where the requirements of HC Spec 2.5 or 2.6 have been met.

a) processing product;
b) cleaning and sanitation;
c) personnel hygiene; and
d) any other activity where water comes into direct or indirect contact with any edible product.

Guidance

Water used in seafood premises may be sourced from the local authority or council (town supply, or other independent supply), or it may be the operator's own supply. Seafood premises can use potable water and/or clean seawater.

Table 3: Water sources and summary of requirements

Source	Requirements and section reference
Potable water: Town supply or other independent supply with no additional treatment by the operator. Applies to potable water used in land-based premises and on fishing vessels.	Assessment of water supply- section 6.4.2-6.4.3 Reticulation management plan - section 6.4.6 Water sampling - section 6.4.8 Non-complying water - section 6.4.9 Handling and disposition of contaminated materials - section 6.4.10
Potable water: Town supply or other independent supply with additional treatment[5] by the operator. Applies to potable water used in land-based premises and on fishing vessels.	Assessment of water supply - section 6.4.2-6.4.3 Reticulation management plan - section 6.4.6 Water management plan - section 6.4.7 Water sampling and testing - section 6.4.8 Non-complying water - section 6.4.9 Handling and disposition of contaminated materials - section 6.4.10
Potable water: Operator's own supply with or without treatment. Includes water sourced from, wells, bores, or artesian supply, rivers and lakes, reservoirs, or rainwater.	Assessment of water supply - section 6.4.2, 6.4.4 Reticulation management plan - section 6.4.6 Water management plan - section 6.4.7 Water sampling and testing - section 6.4.8 Non-complying water - section 6.4.9 Handling and disposition of contaminated materials - section 6.4.10
Clean seawater: Used in land-based premises.	Assessment of water supply - section 6.4.2, 6.4.5 Reticulation management - section 6.4.6 Water management plan – section 6.4.7 Water sampling and testing – section 6.4.8 Non-complying water - section 6.4.9 Handling and disposition of contaminated materials - section 6.4.10
Clean seawater: Used on fishing vessels.	Assessment of water supply - section 6.4.2 Non-complying water - section 6.4.9 Handling and disposition of contaminated materials - section 6.4.10
Water of an alternative standard. Based on an analysis of hazards and other risk factors.	Assessment of water supply - section 6.4.2 Reticulation management plan - section 6.4.6

[5] Examples of additional treatments are the use of chlorine or chlorine dioxide, ozone, filtration, boiling, ultraviolet radiation and reverse osmosis.

	Water management plan - section 6.4.7 Water sampling and testing - section 6.4.8 Non-complying water - section 6.4.9 Handling and disposition of contaminated materials - section 6.4.10

6.4.2 Assessment of Water Supply

(1) Before processing at a seafood premises can begin, the operator must carry out an assessment of the water supply (other than town supply or other independent supply with no additional treatment) by the operator to determine its suitability for use. [HC Spec 2.5]

(2) The water should be sourced, inspected, and where necessary, tested and treated so as to provide potable water or clean sea water supply and minimise contamination.

Guidance

The scope of the assessment will depend on the type of water and supply being used.

Operators receiving ice from another premises for use on vessels or in land-based premises, which comes in direct or indirect contact with seafood should have evidence to demonstrate that the ice is made from potable water or clean seawater. On delivery, ice should be inspected and rejected if delivered in a manner that may have permitted contamination or if contamination is evident (e.g. from dust, chemicals, foreign matter).

Ice should be stored and handled to prevent contamination and to retain its potable water or clean sea water status.

6.4.3 Potable Water: Town Supply or Other Independent Supply

(1) Potable water supplied by an independent supplier (whether or not it is further treated by the operator) should be assessed to determine whether it meets the criteria in Table 4: Criteria for potable water at point-of-use.

Table 4: Criteria for potable water at point of use

Measurement	Criteria
E.coli or Faecal coliforms	Must not be detectable in any 100 ml sample
Chlorine (when chlorinated)	Not less than 0.2 mg/l (ppm) free available chlorine with a minimum of 20[6] minutes contact time. The Drinking-water Standards for New Zealand 2005 (revised 2008) requires that the concentration in the water does not exceed the MAV of 5 mg/L as chlorine.
pH (when chlorinated)	6.5 – 8.0[7]
Turbidity	Should not routinely exceed 1 NTU, must not exceed 5 NTU

(2) If water is found to be not potable, it must be treated to ensure at the point-of-use, the water is potable, or processing stopped until the water is potable.

[6] The DWSNZ specifies a contact time of 30 minutes.
[7] The DWSNZ refers to a pH of 7-8.5.

Guidance

If water is supplied to a premises by an independent supplier and is not treated by the operator, no further evidence is required.

It is recommended however, that all water supplies, and all alterations to existing water reticulation or treatment systems that may affect the potability of the water, are inspected and tested in accordance with the above criteria, to verify that they have not affected the quality of water within the premises.

6.4.4 Potable Water: Operator's Own Supply [HC Spec 2.5 and schedule1 of HC Spec]

(1) Potable water supplied by an operator for their own use (with or without further treatment) must be assessed to determine potability by:

a) completing the Water Supply Assessment Checklist from Schedule 1 of the HC Spec; or
b) carrying out an analysis of hazards and other risk factors to confirm that it meets the DWSNZ; and
c) an assessment to determine whether the supply meets the criteria in Table 4: Criteria for potable water at point-of-use.

(2) Operators who supply their own water must assess the water supply at least once every 3 years (e.g. by completing the Water Supply Assessment Checklist).

(3) If changes to the water source or its environment occur, the operator must re-assess the water supply according to the following:

a) if a new source of water is being used (that is, the source changes or a new source is added), the assessment in section 6.4.4 (1) must be completed prior to use of the water; and
b) if there are any changes to the environment on or around the water source that may affect the water quality, the assessment in section 6.4.4 (1) must be completed within 1 month.

(4) If water is found to be not potable, it must be treated to ensure that, at the point-of-use, the water is potable.

Guidance

The Water Supply Assessment Checklist is used to determine whether the water source is secure or satisfactory, and what, if any, additional treatment and/or other corrective action the operator should apply. It also provides a simple way of documenting the water management plan.

For guidance on:

- ways to keep roof water safe - see Water Collection Tanks and Safe Household Water, Ministry of Health, revised September 2014 (code HE10148).
- protecting bore and well water - see Secure Groundwater (Bores and Wells) For Safe Household Water, Ministry of Health, March 2000 (code HE1129).
- water safety and tank installation - see Household Water Supplies, Ministry of Health, revised August 2013 (code HE4602)

These documents are available on the HealthEd website (external website).

If you are concerned about your water supply, contact a Health Protection Officer at the local public health service or an Environmental Health Officer at the local council. They will be able to recommend a local water testing laboratory.

6.4.5 Clean Seawater: Land-based Premises or on a Fishing Vessel

(1) Clean seawater used in a land based premises must be assessed to determine whether it meets the criteria Table 5: Criteria for clean seawater in a land-based premises, at point-of-use. [HC Spec schedule 2]

Table 5: Criteria for clean seawater in land-based premises

Measurement	Criteria
Escherichia coli	Must not be detectable in any 100 ml sample
Total coliforms (in treated water)	Must not be detectable in any 100 ml sample
Chlorine (when chlorinated)	Not less than 0.2 mg/l (ppm) free available chlorine with a minimum of 20 minutes contact time. The concentration in the water should not exceed the MAV of 5 mg/L as chlorine.
pH (when chlorinated)	6.5 – 8.0
Turbidity (when water is treated)	Should not routinely exceed 1 NTU except as allowed for in the current DWSNZ, must not exceed 5 NTU.

(2) If seawater supplied to land-based premises is found to be microbiologically contaminated, the water must be treated to ensure that, at the point-of-use, meets the criteria in Table 5.

Guidance

Evidence that can be used to determine whether the supply meets the standard for clean seawater in land based premises could include:

- a declaration that the clean seawater will be taken from a place that is remote from estuaries, fiords, inlets, harbours and river mouths and is a sufficient distance offshore so that it is not affected by any actual or potential pollution sources; or
- results of testing showing that the clean seawater meets the criteria in Table 5.

The operator should ensure that all new water supplies, including seawater intakes, and all alterations to existing water reticulation or treatment systems that may affect the clean seawater, are inspected and tested in accordance with the above recommendations, to verify that they have not affected the quality of water within the premises.

(3) The clean seawater intake on a fishing vessel should be situated so as to minimise contamination of the clean seawater by waste water discharges, and waste and engine coolant outlets.

6.4.6 Reticulation Management Plan

(1) Operators using any water source, other than seawater on a vessel must document and implement a reticulation management plan, which includes the elements set out in HC Spec clause 2.8. [HC Spec 2.8 and 2.9]

Guidance

The documented reticulation management plan should also include:

- an up-to-date plan of the reticulation system; and
- procedures for systematic checks:
  - on all water reticulation pipe work and equipment, and storage facilities; and
  - on integrity of all backflow prevention devices and valves connecting potable and non-potable water reticulations; and
  - for evidence of leaks.

(2) The water reticulation system should be designed, installed and operated in a manner that prevents:

a) cross connections between potable water, clean seawater (if being used) and non-potable water;
b) stagnant water (i.e. no dead ends or unused pipes in the system);
c) back flow that may cause contamination of the water supply; and
d) water pipes, storage tanks and facilities, and other parts of the reticulation system should be maintained in good condition.

(3) The reticulation system should be flushed (i.e. taps are opened at point-of-use to allow a significant flow of water to occur) when water is not used for an extended period, and after any repairs to the system, to ensure that stagnant water, rust, scale and other material is flushed out of the system.

Guidance

The water reticulation system should also meet the requirements of relevant New Zealand legislation such as the Building Act and any local council regulations. These include:

- The Water Supplies Protection Regulations 1961;
- The Building Act 2004;
- The Building Regulations;
- The Building Code.

Building Industry Authority (BIA) Approved Document G12 Water Supplies, referenced to Australian Standard AS 3500.1:1992 National Plumbing Drainage Code, Part 1, Water Supply as a design method in the Verification Method G12/VM1.

It is the operator's responsibility to ensure that this is the case, and does not need to be addressed as part of the evaluation.

(4) All water lines should be identified so that potable water, clean seawater and non-potable water lines are distinguishable. Water lines conveying non-potable water must be clearly identified at:

a) all outlets;
b) junctions and valves;
c) both sides of all wall penetrations; and
d) at any other place where identification is necessary to distinguish water type.

Guidance

The code used for identification of water lines may be ~~that~~ as described in NZS 5807:1980 Industrial Identification by Colour, Wording or Other Coding. Operators can determine their own identification system which should be documented as part of the RMP.

6.4.7 Water Management Plan

(1) In addition to section 6.4.7, the operator must document and implement a water management plan for:

a) water from an independent supplier that is further treated by the operator of a land-based premises;
b) water supplied by operators of land-based premises for their own use (whether treated or not – this may be addressed in the Water Supply Assessment Checklist); and
c) clean seawater used in land-based premises.

(2) The documented water management plan must include:

a) the elements set out in clauses 2.9(2) and 2.10 of the HC Spec; and
b) if the water is treated, the type of water treatment; parameters; procedures for control, monitoring/testing; acceptable limits;
c) a water sampling and testing programme;

d) corrective action procedures when the water source is found to be unsatisfactory based on the results of any tests done; and
e) the procedures to ensure that the ongoing checks and actions required under the Water Supply Assessment Checklist are completed.

Guidance

The procedures for ongoing checks, for example in relation to the Water Supply Assessment Checklist section B3: Roof water, could include procedures to ensure the gutters are cleaned out monthly, and in relation to C1: Holding tanks, the procedures to ensure that the tanks are inspected and maintained each year and cleaned when necessary.

Examples of water treatment that may be applied by the operator to an independent supply, their own supply or to clean seawater are: chlorination, ultraviolet treatment, ozone treatment, heating and filtration. The operator should discuss with the supplier of the particular treatment, the types and frequency of the water testing necessary to confirm the effectiveness of the treatment and to ensure that it does not adversely affect the quality of the water.

6.4.7.1 Chlorine Disinfection

(1) When a water supply is treated with chlorine, a residual free available chlorine level of at least 0.2 mg/L (ppm) must be maintained throughout the reticulation system. The system must be designed so that the chlorine has a minimum contact time of 20 minutes prior to use of the water, and must be monitored on a regular basis to demonstrate that there has been adequate disinfection. [HC Spec schedule 1]

Guidance

Options for monitoring include:
- fitting automatic water chlorination systems with alarm devices that indicate when the systems have ceased to function correctly; or
- manual checking of the system.

The DWSNZ has a minimum chlorine contact time of 30 minutes prior to use of the water and would add a safety margin to the current contact time in the HC spec.

6.4.7.2 Ultra-violet (UV) Light Disinfection

(1) If UV treatment is used, the disinfection unit should be adequate to disinfect the maximum flow for the system it is to serve. UV light water disinfection systems should be fitted with monitoring and alarm systems to automatically shut down the water supply to the UV water treatment unit, in the event of:

a) power failure to the treatment unit;
b) lamp failure of the treatment unit; and
c) excessive water turbidity.

Guidance

If UV treatment is being used for enhanced water quality and not to ensure potability, an alarm is not necessary.

As UV disinfection has no residual sanitising ability UV-treated water can be re-contaminated immediately after treatment. To control this hazard, there should be no holding tanks or reservoirs between the disinfection unit and the point of use.

Refer to the Drinking Water Standards for New Zealand 2005 (Revised 2008) for guidance about other types of water treatments such as ozone and chlorine dioxide. The OMARs should also be checked for any restrictions on water treatment.

6.4.8 Water Sampling and Testing: Potable Water and Clean Seawater in Land-based Premises [HC Spec 2.10]

(1) The minimum testing frequency required for potable water and clean seawater used in land-based premises is set out in Table 6 Frequency of testing for potable water and clean seawater used in land-based premises.

(2) Testing carried out to demonstrate compliance with the HC Spec (other than chlorine, pH or turbidity) must be performed by a recognised laboratory with the required tests within the laboratory's scope of accreditation.

(3) Water samplers must be trained by the laboratory carrying out the water testing.

(4) If chemical hazards are identified, the operator must arrange for relevant chemical analyses of the water and test for compliance with the relevant Maximum Acceptable Values (MAV) in the DWSNZ.

(5) Chlorine, pH or turbidity measurements must be carried out by suitably skilled people using documented tests and/or calibrated equipment.

Guidance

Operators who use an independent water supply that is not further treated on site do not have to carry out water testing. However, they should consider using simple, low cost techniques such as monitoring free available chlorine levels, taste and odour to pick up any changes in water quality. This is particularly important to ensure that the water at point-of-use has not been degraded by the premises reticulation system.

The operator should:

- take samples from a number of points in the reticulation system to ensure that the sampling is representative of the system as a whole;
- record the location of each sampling point so the source can be identified (this could be done by identifying the water sampling points on the reticulation plan);
- ensure that samples handled and transported so there is no significant change in the quantitative value of the determinands;
- ensure that samples for microbiological analysis are analysed promptly.

If the laboratory cannot analyse samples within 1 hour of collection the operator should:

- immediately chill the samples to 10°C or cooler (but do not freeze) and deliver them to the laboratory within 6 hours of collection; or
- immediately chill the samples to 2 - 5°C and deliver them to the laboratory within 24 hours of collection.

It is recommended that total coliforms be included in the water monitoring programme. This tests for a wider range of bacteria that can then give an early warning sign that there may be problems with the water supply. Total coliforms should not be detected in any 100 ml sample.

Table 6: Frequency of testing for potable water and clean seawater used in land-based premises

Average daily water use while processing	Microbiological testing	Turbidity testing[1]	pH testing (for chlorinated water)[2]	Chlorine testing (for chlorinated water)[2]
Using < 100m^3/day and product packaged at all times	1 per 6 months	1 per 6 months	1 per 6 months	Daily
Using 100 -1000 m^3/day and product packaged at all times	1 per 3 months	1 per 3 months	1 per 3 months	Daily
< 2000 m^3/day	1 every month	1 every month	1 every month	Daily
2000 – 10,000 m^3/day	1 every 2 weeks	1 every 2 weeks	1 every 2 weeks	Daily
> 10,000 m^3/day	1 every week	1 every week	1 every week	Daily

[1] The frequency of turbidity testing will depend on the degree of protection of the water source and whether the operator elects to filter the water. Alternative frequencies maybe validated in the RMP.

[2] Chlorine and pH testing applies if the water is chlorinated.

(6) Operators who cease processing for a period of time (e.g. several months of "off season") may suspend routine monitoring provided:

a) there is no holding, processing, packing or storage of seafood during the period when monitoring is suspended; and
b) the operator develops a documented programme outlining the procedures to be followed before holding, processing, packing or storage of seafood recommences, to ensure that the water in the premises is potable or clean seawater.

Guidance

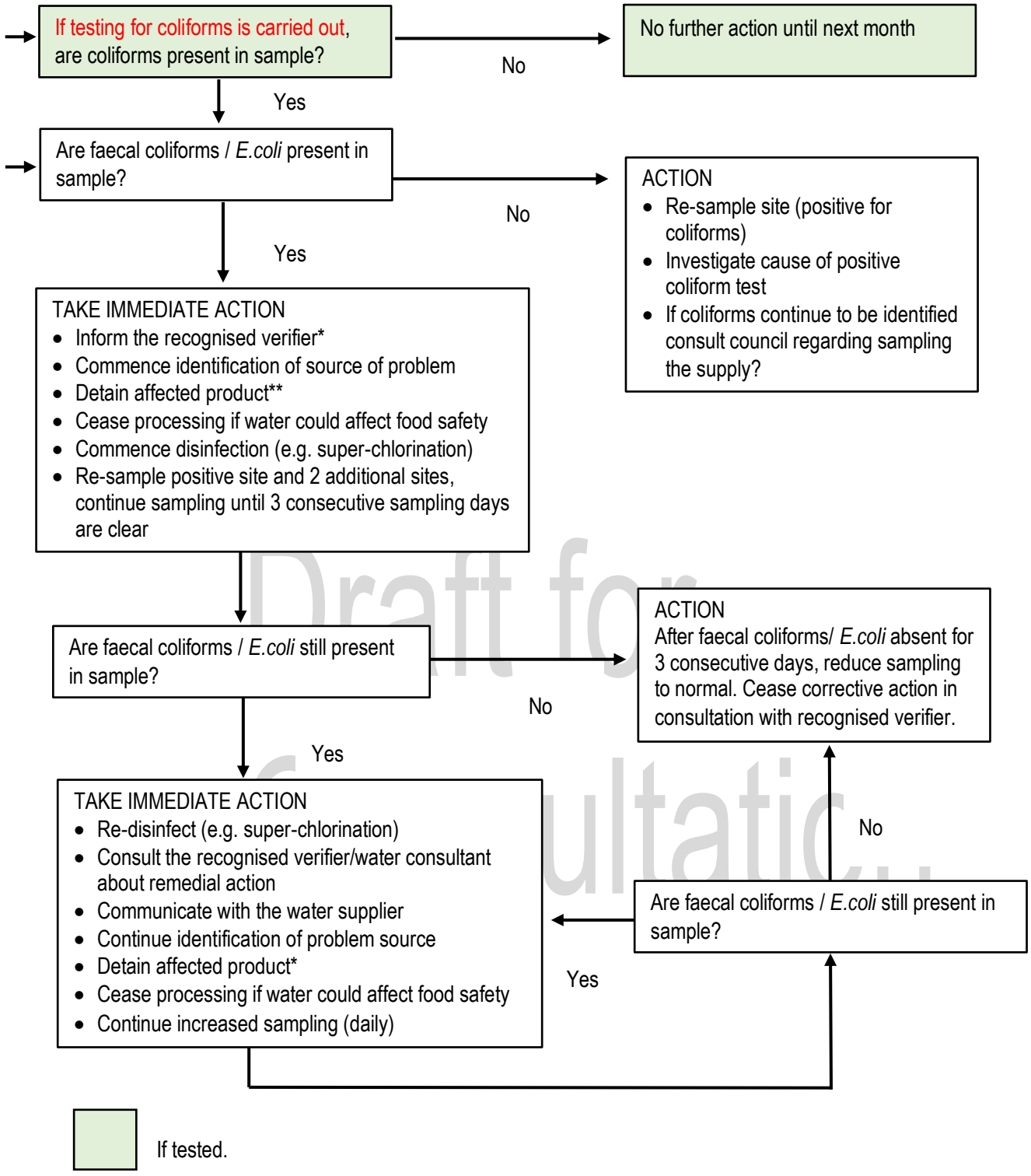
Export premises must carry out microbiological sampling of potable water (whether or not treated) to confirm the safety of point-of-use water at the frequency given in Table 6 Frequency of testing for potable water and clean seawater used in land-based premises.

6.4.9 Non-complying Water [HC Spec 2.11]

(1) If the operator is advised or becomes aware that faecal coliforms or *E. coli* have been identified in the independent water supply, the operator must start daily point-of-use sampling. No further actions are necessary unless the sampling identifies faecal coliforms or *E. coli* at the point of use.

(2) If faecal coliforms or *E. coli* are identified at the point of use, the operator should follow the corrective action flow path outlined in Figure 3, or in the DWSNZ for responses to contamination of a drinking-water supply distribution zone.

Figure 3: Corrective actions for microbiological non-compliance in water



*Your recognised verifier will treat the detection of faecal coliforms or *E. coli* as a non-compliance and will require you to complete a form to capture the issue, cause, corrective actions and decisions made.

** Disposition will depend on the product and the nature of the non-compliance. Product sampling may be required. Market restrictions may apply.

(3) All operations requiring the use of potable water in land-based premises must cease if the water is supplied by an independent supplier (e.g. local council) and:

a) the independent supplier advises the operator that the water is not fit for drinking without additional treatment; or
b) the independent supplier issues a 'boil water' notice; and
c) the operator is not able to comply with the advice in respect of all potable water, or has no other means described in the risk management programme to ensure the water is potable at the point of use; or
d) the operator has reason to believe that the water is not fit for use and has no other means described in the risk management programme to ensure the water is potable at the point of use; or
e) the operator is not able to use an alternative supply which meets the standards.

(4) All operations requiring the use of potable water must cease if the water is supplied by the operator, and the operator fails to comply with any of the requirements of the water management plan (including corrective actions), and has no other means described in the risk management programme to ensure the water meets the original standard at the point of use.

Guidance

The operator should notify their recognised verifier if they receive a non-complying water result or notification.

(5) All operations requiring the use of clean sea water in land-based premises must cease if the operator fails to comply with any of the requirements of the water management plan (including corrective actions), and has no other means described in the risk management programme to ensure the water meets the original standard at the point of use.

Guidance

If total coliforms are identified at the point-of-use, the operator should re-sample the water supply, investigate the cause of the problem and take corrective action.

To minimise downtime if a problem were to arise it is recommended that operators have a procedure to super-chlorinate the premises reticulation system after microbiological contamination. Some examples of how this could be done are:

- Flush the entire water system including, storage tanks and distribution pipes with super-chlorinated water (>40 ppm) for at least 30 minutes, followed by an overnight soaking (12 hours) of the entire system with super-chlorinated water. After the overnight soaking, test the water for free residual chlorine at the point of use from 5 randomly selected sampling points, and then drain the water out. If no residual chlorine is detected, repeat the super-chlorination procedure. Otherwise refill the system with potable water or clean seawater.
- Flush the entire water system with super-chlorinated water at 200 ppm and leave for 30 minutes. After the 30 minutes soaking, test the water for free residual chlorine at the point of use from 5 randomly selected sampling points and drain the water out. If no residual chlorine is detected, repeat the super-chlorination procedure. Otherwise rinse the system and refill it with potable water or clean seawater.

(6) If any chemical Maximum Acceptable Values (MAVs) are exceeded, the operator should:

a) follow the requirements of the DWSNZ in relation to non-compliance with a chemical MAV; or
b) resample the water supply, investigate the cause of the non-compliance and take appropriate action; and
c) continue weekly sampling until the levels of chemicals detected are less than the relevant MAVs.

(7) If radiological limits are exceeded, the operator must follow the requirements of the DWSNZ for non-compliance with the relevant radiological MAV.

6.4.10 Handling and Disposition of Contaminated Materials [AP Reg 10]

(1) If contamination with non-potable water occurs:

a) affected animal product should be appropriately dealt with so that it becomes fit for its intended purpose, or it must not be used for human consumption;
b) affected product contact surfaces should be cleaned and sanitised prior to reuse; and
c) affected packaging materials and containers that cannot be effectively cleaned and sanitised must not be used for packing of any animal product.

(2) The operator should also comply with the requirements and procedures for non-complying products given in Part 26.

Guidance

Non-potable water may sometimes be used in seafood premises (e.g. for flushing toilets and urinals, washing down areas outside the fish premises like roadways and external drains, washing down truck exteriors, wash down of inedible areas), as long as the risk management programme identifies any associated hazards, together with their controls.

6.5 Records [APA section 17, RMP Spec 20]

(1) The operator must keep records demonstrating compliance with documented procedures. These must include:

a) water assessment records (if required for the water source and/or treatment);
b) a plan of the reticulation system and records of checks;
c) monitoring carried out (including water testing results), problems identified and corrective action taken;
d) results of any analysis undertaken;
e) training records for persons involved in key tasks. [RMP Spec 15(3)]

Guidance

Examples of other records that may be used to demonstrate compliance are:

- Pre-operational or daily checks;
- Evidence from water supplier.

Part 7: Cleaning and Sanitation

7.1 Purpose and Scope

To ensure the effective cleaning and sanitation of the premises, facilities and equipment so as to prevent or minimise the contamination of seafood products.

7.2 Sources of Hazards

Source	Examples of hazards
Facilities and equipment	Bacterial pathogens (e.g. *Listeria monocytogenes*, *E. coli* spp.) Chemical residues (allergens)[8]
Waste	Bacterial pathogens (e.g. *E. coli* spp., *Salmonella* spp.)
Cleaning chemicals	Chemical residues
Cleaning implements (e.g. mops, cloths)	Bacterial pathogens (e.g. *Listeria monocytogenes*, *E. coli* spp.) Physical hazards (e.g. metal fibres, bristles)

7.3 Mandatory Requirements

AP Reg 11 Hygiene of processing environment

(1) All specified persons must establish and carry out effective procedures to:

a) ensure appropriate and adequate maintenance, cleaning and sanitation of processing premises, facilities, essential services, and equipment (including conveyances); and
b) manage waste; and
c) control pests.

HC Spec 3.4 Approved maintenance compounds

(1) Only approved maintenance compounds may be used during processing operations and in the maintenance of processing areas, facilities and equipment.

7.4 Procedures

7.4.1 Cleaning Programme

(1) The operator must document and implement a cleaning and sanitation programme for processing areas, equipment, storage areas, support areas and amenities. [APA section 17, AP Reg 11, RMP Spec 11]

(2) The programme should include the following information:

a) areas/equipment to be cleaned;
b) procedures and work instructions for all cleaning and sanitising operations, including the cleaning method, frequency of cleaning and sequence of cleaning;
c) any specific competencies required;

[8] If intending to separate certain allergens.

d) detergents/sanitisers to be used, their concentration, application method, and contact time required;
e) cleaning equipment to be used and how it is cleaned/sanitised;
f) monitoring procedures, record forms or check sheets;
g) personnel responsible; and
h) methods of verifying the effectiveness of the cleaning and sanitation programme.

Guidance

It may be possible to obtain information from your chemical supplier about the bactericidal properties of sanitising chemicals in particular. Providing that the chemical is being used in the way recommended by the supplier, this information could be used to support other verification evidence such as visual or other sensory assessments and testing.

Many microbiological techniques are available to validate and/or verify the effectiveness of cleaning and sanitation programmes. These include swabs, contact slides and hygiene swab tests. Product contact surfaces such as conveyor belts, tables, bins, knives, etc. should be selected for sampling and also non-contact surfaces such as floors, drains, underneath tables and equipment. Swabs should be taken after the last step in the cleaning process. Sites should be sampled under essentially the same conditions each time (same day, time, etc.), so that comparisons can be made over time.

Microbiological criteria for surfaces

Microbiological guidelines for surfaces after cleaning and sanitising vary widely. The criteria to apply depends on the product, process and 'risk area'. Various aerobic plate count (APC) levels have been suggested including <2.5 cfu/cm^2 (Winfield and Campbell, 1990; Griffith, 2005), <10 cfu/cm^2 (Brown and Baird Parker, 1982; EC Decision 2001/471/EC), and <100 cfu/cm^2 (Holah, 2003).

As an example of a criteria for a product surface, an APC_{30} for clean product contact surfaces in NZ raw poultry processing operations is typically <100 cfu/cm^2. Setting a lower limits for surfaces that come into direct contact with cooked or RTE products is recommended.

7.4.2 General Cleaning

(1) Cleaning and sanitising operations must be carried out in a way that does not contaminate seafood products, ingredients, additives or containers. [AP Reg 11]

(2) All product surfaces, including equipment, should be cleaned:

a) at least at the end of each working day;
b) whenever surfaces become contaminated or come into contact with waste;
c) when changing from processing raw seafood products to processed seafood products, and when changing from seafood product types such as from shellfish or freshwater fish (e.g. mussels, eel) to other types of fish; and
d) in the case of fishing vessels, at each break in processing.

(3) Cleaning and sanitising of equipment used for ready-to-eat seafood products should be carried out:

a) every half shift or every 4 hours; or
b) at the end of each shift; or
c) at the start of each new process operation (unless it has already been cleaned and sanitised); or
d) at a frequency that has been demonstrated to achieve the same outcome.

(4) Only cleaners and sanitisers that are approved maintenance compounds can be used, and must be used in accordance with any conditions. See the List of Approved Maintenance Compounds and the Approved Maintenance Compounds Manual. [HC Spec 3.4]

Guidance

A basic cleaning and sanitising procedure usually involves:

- removal of gross contamination (e.g. removing scraps);
- rinsing the area with cold or warm water (60°C or cooler to prevent coagulation of protein);
- applying a detergent solution or foam and leaving it on all surfaces for the time specified by the manufacturer;
- scrubbing surfaces to loosen and remove dirt;
- rinsing with water and draining;
- if scale has to be removed, an acid detergent is used at this stage, followed by rinsing and draining;
- applying a chemical sanitiser and leaving it on all surfaces for the time specified by the manufacturer;
- rinsing off the chemical sanitiser with water and draining; and
- allowing surfaces and equipment to dry.

The use of no rinse sanitisers (without rinsing) are under review. It is likely that they will no longer be permitted for use on product contact surfaces, as they can lead to elevated chemical residue levels in products.

For more guidance about cleaning and sanitation in areas used for ready-to-eat product processing, see: Guidance for the Control of *Listeria monocytogenes* in Ready-to-eat Foods Part 2: Good Operating Practices.

7.4.3 Cleaning of Processing Areas

(1) Products, packaging material and other materials that may be contaminated during wash down should be removed from the area and stored in appropriate locations, or they must be protected by covers.

(2) Floors should be cleaned by hosing or other effective means. Water must be drained or removed completely.

Guidance

Only low to medium pressure hosing should be used to remove seafood products soil. High pressure hosing is not recommended as it is likely to cause contamination by splashing, and create aerosols capable of carrying contaminants and micro-organisms for considerable distances.

Other effective means of cleaning floors include sweeping, flushing and use of squeegees.

(3) Drains in the processing area (other than on fishing vessels) should be sanitised daily to reduce contamination levels and prevent the formation of foul odours.

Guidance

Drains should be sanitised during the process of rinsing sanitiser from equipment and surrounding floor areas. Pouring large amounts of sanitiser concentrate directly into drains is not recommended.

(4) Before sanitising, seafood products contact surfaces and equipment should be washed in cold potable water or cold clean seawater, to remove solid residues.

Guidance

Sanitising should be carried out using chemical sanitisers or hot water (82°C).

(5) Equipment (e.g. tubs) that is used for conveying material not for human consumption, should be cleaned and sanitised:

a) at the end of each working day in the case of premises other than fishing vessels; and

b) at each break in processing in the case of fishing vessels.

(6) Cleaned and sanitised portable appliances (e.g. knives, trolleys) should be:

a) stored so that they are protected from contamination (e.g. dust, splashes); or
b) cleaned and sanitised immediately before they are taken into a processing area.

(7) Staff performing cleaning duties should inspect their own work and report to their supervisor if the methods or chemicals used do not produce the expected results.

7.4.4 Clean-in-place Systems

(1) Clean-in-place (CIP) systems should be as effective as those used for cleaning and sanitising disassembled equipment.

(2) When cleaning (direct or indirect product contact surfaces) in place:

a) the cleaning and sanitising solutions, and rinse water should come in contact with all interior surfaces of the equipment; and
b) all internal surfaces should be either designed for self-draining or be physically disassembled for draining after rinsing; and
c) pipe interiors should be constructed of highly polished stainless steel or some other appropriate smooth-surfaced material; and
d) sections of the system should be designed to be completely disassembled for periodic inspection of the internal surfaces.

(3) Operators using CIP should validate the procedure to ensure that the cleaned equipment does not have unacceptable levels of chemical residues, microbial contaminants or product residues.

(4) The validated CIP parameters should be documented in the RMP and implemented.

Guidance

Validation of a CIP procedure should be carried under worst case conditions. It is recommended that the following information be collected:

- flush efficiency (e.g. gross soiling is removed before CIP chemicals are introduced);
- chemical concentration (start and end of the system to be cleaned);
- temperature (start and end of the system);
- flow rates;
- final flush prior to production (conductivity or other measure to ensure chemicals are removed);
- results from inspecting internal surfaces;
- final product microbiology.

7.4.5 Cleaning of Storage Areas

(1) Packed products, raw material, packaging and other materials should be stacked and stored in a tidy manner. Adequate space must be available to allow effective cleaning in the storage area.

(2) Spills should be cleaned up immediately or at the next opportunity when it is safe to do so.

(3) Damaged packaged products and other materials should be removed and disposed of as soon as possible.

(4) Dry stores should be kept dry and should be cleaned regularly by sweeping or vacuuming.

7.4.6 Cleaning of Amenities [AP Reg 11]

(1) Amenities must be cleaned regularly and maintained in a hygienic condition.

Guidance

Specific attention should be given to areas where clean protective clothing (including gumboots) is stored.

7.4.7 Maintenance and Storage of Cleaning Equipment

(1) Cleaning implements and equipment must be maintained in a hygienic condition and must not introduce any hazard or foreign object to any product, packaging or product contact surface. [AP Reg 11]

(2) Cleaning equipment that will be reused (e.g. brushes) should be sanitised after each use.

Guidance

Reusable cleaning equipment should be cleaned and sanitised, then stored so that it is allowed to dry.

(3) Equipment (e.g. brushes, brooms, etc.) used for cleaning and sanitising in seafood products premises, including fishing vessels, should be stored in a designated area in such a manner as to prevent contamination of seafood products, ingredients, additives or containers.

7.5 Monitoring [APA section 17]

(1) The frequency of monitoring must be sufficient to give confidence that the cleaning and sanitation programme is operating effectively.

Guidance

Routine monitoring can include:

- Pre-operational checks: visual checks of all processing areas to ensure they are clean and ready for processing.
- Pre-operational checks should assess whether:
  - surfaces look clean. There should not be any debris (product, scales, slime, dirt, protein, oil, etc.);
  - work areas smell clean;
  - surfaces feel clean, without the presence of grease or solid particles;
  - there is no pooling of water.
- During processing: visual checks of all processing areas to ensure the cleaning programme is effective for example between shifts and periodically during the day.

Visual inspection of cleaned surfaces is the simplest and quickest way of assessing cleanliness. Other methods may include an ATP method.

(2) Pre-operational checks of facilities and equipment should be conducted by a suitably skilled person to ensure that operations only begin after sanitation requirements have been met.

Guidance

The person responsible for doing pre-operational checks should have good knowledge of the cleaning methods and the criteria for assessing cleanliness. He/she should be able to assess the potential effect of particular defects on food safety and determine appropriate corrective actions for any non-compliance.

(3) If immediate corrective action is required (e.g. for a defect that will result in direct contamination of a product), the corrected item should be rechecked before processing begins.

(4) Repetitive failures of the cleaning and sanitation programme should be investigated and corrected.

Guidance

Also see Table 9: Examples of cleaning and sanitation operator verification activities.

7.6 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) These records must include:

a) the monitoring carried out, problems identified and corrective action taken;
b) list of approved maintenance compounds;
c) training records for persons involved in key tasks. [RMP Spec 15(3)]

Guidance

Examples of records that could be used to demonstrate compliance are:

- pre-operational, daily, weekly checks;
- cleaning records;
- validation records;
- verification of cleaning records (e.g. reality checks, chemical strength tests, microbiological tests).

Refer to Part 19 for record keeping requirements.

Part 8: Personal Health and Hygiene

8.1 Purpose and Scope

To ensure that all personnel are medically fit to perform their duties, and that they comply with good hygienic practices. Personnel include all staff, contractors providing services, and visitors.

8.2 Sources of Hazards

Source	Examples of hazards
Personnel	Bacterial pathogens (e.g. *Salmonella* spp., *E. coli* spp., *Staphylococcus aureus*) Hepatitis A virus, Norovirus
Clothing, protective equipment (e.g. earmuffs), footwear	Bacterial pathogens (e.g. *Salmonella* spp., *E. coli* spp., Clostridium spp.) Chemical residues (e.g. sanitisers, allergens[9]) Physical objects (e.g. parts of rubber gloves, pieces of plastic)
Personal items	Metal objects (e.g. jewellery, pens, hair clips)

8.3 Mandatory Requirements

AP Reg 12 Hygiene of persons whose presence or actions may result in contamination of animal material or animal product (paraphrased)

(1) The operator must ensure that all personnel whose presence or action within the premises may result in contamination of product:

a) wear appropriate protective clothing, where necessary;
b) follow an appropriate personal hygiene routine; and
c) behave in such a manner as necessary to minimise contamination of product, other inputs, packaging and the processing environment.

AP Reg 13 Persons infected by or carriers of disease or illness to be excluded from working areas or from handling animal material or product

All specified persons must ensure that persons, including visitors, who are known to be, or suspected of being, infected by or a carrier of a disease or illness of public health concern (including a notifiable infectious disease listed in section A of Part 1 of Schedule 1 of the Health Act 1956) that is likely to be transmitted through animal material, animal product, or associated things are precluded from —

a) working in areas where animal material or animal product is processed, if that may result in contamination of animal product; or
b) handling animal material, animal product, or associated things that may result in contamination of animal product.

[9] If intending to exclude certain allergens.

HC Spec 4.2 Health

(1) The operator must take reasonable measures to ensure that a person (including any visitor or contractor) who is:

a) confirmed as or suspected of suffering from or being a carrier of a disease as described in section A, Part 1 of Schedule 1 of the Health Act 1956 that is likely to be transmitted through animal material, product or associated things; or
b) confirmed as or suspected of suffering from or being a carrier of another disease or condition of public health concern, including verocytotoxin-producing or shiga-toxin-producing *Escherichia coli*, that is likely to be transmitted through animal material, animal product or associated things; or
c) suffering from boils, sores, infected wounds, or any other condition that cannot be adequately protected from becoming a source of contamination;

does not work as a product handler or enter an area where he or she may adversely affect the suitability for processing of animal material or the fitness for intended purpose of animal product.

(2) A person who handles animal material or product, or any other person who may affect the suitability for processing of animal material or the fitness for intended purpose of animal product, after suffering from a disease or condition described in:

a) clause 4.2(1)a) or b) must follow the exclusion and clearance criteria in Table 2.4, Appendix 2 of the Ministry of Health Communicable Disease Control Manual 2012, or any update to that Manual where specified for a particular disease or condition; and
b) clause 4.2(1)a), if no exclusion and clearance criteria are specified for hepatitis A or cholera, must not resume work in that role until, in the view of a medical practitioner, the person is no longer likely to contaminate the animal material or animal product; and
c) clause 4.2(1)a), if no exclusion and clearance criteria are specified for listeriosis or acute gastroenteritis, must be excluded from resuming their food-handling duties until 48 hours of being symptom free have passed; and
d) clause 4.2(1)b) must not return to food-handling duties until, in the view of a medical practitioner, the person is no longer able to contaminate the animal material or animal product, unless exclusion and clearance criteria specified in clause 4.2(2)a) apply and are complied with.

(3) A person who handles animal material or product, or any other person who may affect the suitability for processing of animal material or the fitness for intended purpose of animal product, who suffers from a condition described in clause 4.2(1)c) must, before resuming work, be assessed by a suitably skilled person, nominated by the operator, to confirm that the condition is no longer likely to contaminate the animal material or animal product, or that the handler or other person is adequately protected from being a source of contamination.

8.4 Procedures

8.4.1 Health of Personnel

(1) The operator must document and implement procedures to ensure that any person including staff, visitors and contractors do not contaminate food or associated things as consequence of a health condition. [APA section 17, RMP Spec 11]

(2) The operator should ensure that all staff understand relevant health and hygiene requirements and that visitors and contractors are made aware of these requirements.

Guidance

A documented health policy may be useful, covering matters such as working with wounds, communicable diseases, and notification procedures for staff suffering from any illness or injury.

The conditions under HC Spec 4.2, together with their exclusions criteria are summarised in the following table. The exclusion criteria have been taken from Table 2.4, Appendix 2 of the Ministry of Health Communicable Disease Control Manual 2012 and the HC Spec and were current at the time of writing.

Table 7: Health conditions and exclusion criteria

Illness/condition	Exclusion criteria.
Acute gastroenteritis (including salmonellosis, campylobacteriosis, cryptosporidiosis giardiasis, listeriosis, yersiniosis, norovirus and rotavirus)	Exclude until symptom free for 48 hours.
Cholera, Hepatitis A	Exclude until a medical practitioner confirms that the person is no longer likely to contaminate food.
Shigellosis, VTEC/STEC	Exclude until symptom free for 48 hours and 2 consecutive negative stools have been provided at least 48 hours apart.
Typhoid and paratyphoid fever	Exclude until symptom free for 48 hours and 2 consecutive negative stools have been provided at least 48 hours apart after completing treatment with antibiotics. If not treated with antibiotics, no earlier than 1 month after on-set of symptoms.
Skin conditions e.g. boils, sores, infected wounds, or any other condition that cannot be adequately protected	Exclude until a suitably skilled person* confirms that the condition is not likely to contaminate the food, or where possible, cover the wound so that it is not source of contamination. Depending on the condition, the suitably skilled person will need to be a medical practitioner.
Other	Exclude until a medical practitioner confirms that the person is no longer likely to contaminate food.

*The suitably skilled person should have sufficient knowledge and experience to make this determination (e.g. someone with first aid or nursing qualifications).

(3) Personnel should inform the person responsible for operations if they are (or suspect that they are) suffering from gastroenteritis, diarrhoea, acute respiratory infection, skin conditions~~;~~ or any other illness listed in Table 8.

(4) Product handlers suffering from any of the conditions identified in section 8.4.1(3) must not work in food contact areas until the exclusion criteria in Table 8 has been met.

(5) Any injury, wound, or cut sustained during processing should be treated immediately and dressed with a secure waterproof dressing to prevent contamination of seafood products, packaging or equipment, with blood or other fluid discharge. The dressing should be kept clean and properly secured to prevent it from becoming loose or falling off.

Guidance

For skin conditions, one way to ensure that the handler is unlikely to contaminate the product is to apply a waterproof dressing which can be:

- properly secured to prevent it from falling off; and
- kept clean.

Brightly coloured dressings are recommended.
To protect the dressing from moisture, staff should wear gloves (for wounds on the hands), and protective sleeves or clothing over wounds on the forearm.

8.4.2 Hygienic Practices

(1) The operator must document and implement procedures for personnel hygiene that apply to all staff in food handling, preparation and related areas, and to all contractors and visitors. [APA section 17, RMP Spec 11]

(2) Personnel in processing areas should not wear insecure jewellery and must remove from their hands any jewellery that cannot be adequately sanitised.

Guidance

Plain wedding bands (i.e. no stone) are acceptable, as long as the wedding bands cannot be easily dislodged and can be effectively cleaned in the same manner as hands. Medical devices such as a medical alert necklace or cultural gifts such as a taonga necklace are also acceptable if they are securely worn under clothing.

(3) Personal items such as sweets, cigarettes, and false finger nails or eyelashes should not be taken into or worn in processing or packing areas.

(4) The following activities are not permitted inside processing or packing areas:

a) eating of any food;
b) smoking or vaping;
c) spitting; or
d) any other activity that may cause contamination of any seafood products or seafood products contact surfaces [AP Reg 12 (c)].

8.4.3 Protective Clothing

(1) All personnel who enter any processing or packing area must wear suitable, clean protective clothing and foot wear. Protective clothing (e.g. coats, overalls, aprons, plastic sleeves (waterproof armbands), hair restraints, and gloves) should be visibly clean at the start of each day's operation and be of a colour that does not disguise contamination.

Guidance

Hair restraints include paper, cloth or plastic hats or hair nets. Several types of beard masks and all-over hat styles are available for personnel with full beards. Each operator should set their own policy on acceptable facial hair length.

Protective clothing in colours other than white can be used. The key is that contaminants should be visible so that appropriate actions can be taken. If assigning colours to different areas or activities, the type of the work should be considered.

(2) Personnel who handle exposed product should wear protective clothing that suitably covers all street clothing, along with a water-proof front or a waterproof apron. If clothing sleeves are below the elbow, personnel should wear waterproof arm covers or waterproof sleeves.

(3) Any protective gloves used should be non-absorbent, and may be either single use or reusable. Reusable gloves should be washed and sanitised at meal breaks, at the end of each working day, or whenever contaminated.

Guidance

Disposable gloves and plastic sleeves should meet the composition and conditions of use requirements for indirect food additives (polymers) in the US Code of Federal Regulations, Title 21, Part 177, or relevant EU standard.

(4) All protective clothing and personal equipment should be:

a) kept in good condition, changed (or in the case of waterproof clothing, cleaned) at least daily, or more often if it becomes excessively contaminated; and
b) stored so that it protected from contamination when not in use.

(5) Staff should use boot wash facilities or foot baths to clean footwear before, or on, entering processing areas and must change other protective clothing (e.g. overalls, hats) if it becomes contaminated from the external environment.

(6) Staff handling exposed product should not wear waterproof protective clothing (e.g. aprons, plastic sleeves, gloves) or equipment (e.g. knives and steels) outside the processing area, except in the case of emergencies.

8.4.4 Hand Washing and Sanitising

(1) All personnel should thoroughly wash (with hand detergent and water), and dry hands and sanitise (where appropriate):

a) when entering any processing or packing areas;
b) before handling any seafood products or exposed packaging;
c) after using the toilet;
d) after handling or coming into contact with waste and contaminated surfaces or material;
e) if working in a raw product area, before entering a cooked or ready-to-eat product area; and
f) if swapping between products of different allergen status (if allergens are to be controlled);
g) any other time when hands may become contaminated (e.g. after coughing, sneezing or blowing the nose).

(2) Hand sanitisers should be used in areas where cooked or ready-to-eat seafood products is processed or packed. Any chemical used must be MPI approved and used in accordance with the manufacturers' instructions. For further information see: List of Approved Maintenance Compounds and the Approved Maintenance Compounds Manual

(3) Hands should be thoroughly dried using disposable paper towels, or other hand drying facilities that do not contaminate washed hands or the surrounding area (e.g. roller towels fitted with a timed automatic retraction device that removes the soiled piece of towel immediately after use).

8.4.5 Hygiene when moving between areas of different hygiene status

(1) Product handlers and other persons who move from areas of a lower hygienic status to a higher hygienic status should take adequate measures to minimise contamination to product.

Guidance

Hygiene routines for staff and other persons moving between areas of different hygiene status will depend on the degree of risk of contamination. Operators should consider the need for:

- hand washing;
- changing or cleaning/sanitising of outer protective clothing (aprons); and
- cleaning/sanitising of footwear.

"Other persons" include non-product handlers, other staff, visitors, contractors etc. These persons should be aware of the hygiene routines required for movement between different areas of the premises.

(2) Personnel who work in raw seafood products areas should change their protective clothing before entering areas where ready-to-eat seafood product is produced.

(3) Personnel (e.g. fish meal operators) assigned to work in dedicated areas where materials for animal consumption are handled should wear some form of identification to distinguish them from other seafood products processors; and before entering areas processing seafood products for human consumption, such personnel should:

a) remove any contaminated outer clothing, footwear or protective coverings;
b) thoroughly wash any exposed contaminated skin surfaces; and
c) dress in clean protective clothing as described in sections 8.4.3(1) and (2).

Guidance

This applies to staff working in dedicated areas for processing animal consumption products. Its purpose is to prevent contamination of human consumption products, should the staff be required to enter areas processing products for human consumption.

If handling material derived from normal processing (e.g. fish offal) which is intended for bait, ~~to be sold for~~ further processing for animal consumption or for disposal, it may be held and/or packed in a processing area and dedicated protective clothing is not required. The operator should consider any potential risks of contamination and implement measures to mitigate these.

8.4.6 Designated Areas

Guidance

The purpose of designated areas is to allow staff to go outside the premises during breaks without having to change out of all protective clothing, as long as precautions are in place to minimise contamination. Protective clothing should only be worn outside in dedicated access ways or areas, and not worn off-site. This practice is not recommended for businesses producing high risk products (e.g. ready-to-eat seafood products)

(1) The operator should document procedures for the use of designated areas that include the following:

a) the name of the person responsible for the procedures;
b) a description (or diagram) of the areas where protective clothing may be worn;
c) the cleaning programme for the designated areas;
d) instructions for staff on the use of designated areas and conduct in those areas so that contamination of protective clothing is minimised;
e) the checks to be carried out to ensure that personnel comply with the procedures; and
f) the records to be kept to demonstrate compliance with these requirements.

8.4.7 Visitors and Contractors

(1) Visitors and contractors who wish to enter a seafood products processing or packing area must comply with the operator's documented health requirements and follow all hygienic practices and procedures required for food handlers. [AP Reg 12]

(2) Visitors and contractors should be supervised by an assigned staff member while within the premises unless they have been inducted and are familiar with the required hygienic practices.

Guidance

Visitors and contractors who wish to enter a processing or packing area should sign a visitors' logbook on arrival.

8.5 Monitoring [APA section 17]

(1) The operator must regularly check compliance with documented procedures.

Guidance

The frequency and type of monitoring will depend on the nature of the operation. Monitoring options could

include the following daily checks:

- Before processing: checks to confirm all staff are following correct procedures for wearing protective clothing, and for entering the processing areas.
- During processing: checks to confirm that all staff are complying with requirements for personal hygiene and hygienic work practices.

8.6 **Records** [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) These records must include:

a) the monitoring carried out, problems identified and corrective action taken;
b) medical certificates or assessments of staff;
c) training records for persons involved in key tasks; [RMP Spec 15(3)]
d) supplier guarantees (e.g. or gloves);
e) list of approved maintenance compounds (e.g. hand sanitisers).

Guidance

Examples of other records that could be used to demonstrate compliance are:

- pre-operational or daily checks;
- designated area checks; or
- visitor log book.

Refer to Part 19 for record keeping requirements.

Part 9: Control of Contamination and Waste Management

9.1 Purpose and Scope

To ensure that contamination of seafood products is minimised and that seafood product is fit for its intended purpose.

9.2 Mandatory Requirements

AP Reg 3 Interpretation

Waste includes, without limitation, all solids, liquids, and gases that the operator intends to dispose of as being unwanted and that may become a source of contamination or attract pests.

AP Reg 9 Animal material and product to be processed in manner that minimises contamination and deterioration

(1) All specified persons must ensure that animal material and animal product in their charge is processed in a manner that minimises the contamination or deterioration of the animal material or animal product.

AP Reg 11 Hygiene of processing environment

(1) All specified persons must establish and carry out effective procedures to:

a) ensure appropriate and adequate maintenance, cleaning and sanitation of processing premises, facilities, essential services, and equipment (including conveyances); and
b) manage waste; and
c) control pests.

HC Spec 3.2 Management of animal material and animal product not for human consumption

(1) Equipment and storage areas used to store or contain animal material that is not suitable for processing or animal product that is not fit for human consumption but is suitable or fit for some other purpose must:

a) be clearly identified; and
b) not be sources of contamination to other animal material and animal product that is intended for human consumption.

(2) Animal material or animal product that is not suitable for processing or not fit for human consumption but is suitable or fit for some other purpose, must be kept under controlled conditions until it is adequately identified in a manner that will ensure that it will not be mistakenly or fraudulently released as suitable for processing or fit for human consumption.

HC Spec 3.3 Waste management

(1) Not applicable

(2) Equipment and storage areas used to store or contain waste must be clearly identified, and if equipment is permanently installed and in an identified storage area then either the equipment or the storage area may be identified; and

a) be clearly identified, and if equipment is permanently installed and in an identified storage area then either the equipment or the storage area may be identified; and
b) not be sources of contamination to other animal material or animal product

(3) Waste must be kept under controlled conditions until adequately identified in a manner that will ensure that it will not be mistakenly or fraudulently released as suitable for processing or fit for human consumption.

(4) Waste must be disposed of by a method that ensures that it will not become a source of contamination to other animal material or animal product.

9.3 Procedures

9.3.1 Contamination from Waste Water

(1) The operator should document and implement procedures for controlling contamination from waste water, including product wash water, thawing tank water, defrost water and condensate from refrigeration units.

(2) During operation, processing should must be maintained and operated so that water from unclean sources is controlled and contained so that it does not drip or splash onto seafood products, seafood products contact surfaces or onto any other areas where seafood products could become contaminated; or does not flow across areas people walk. This includes:

a) water from condensation;
b) water used to clean floors, walls, or appliances;
c) excess water used during processing (e.g. product wash water, thawing-tank water, defrost water); and
d) non-potable water.

(3) All seafood products processing areas should, as far as practicable, be kept free from steam and surplus water.

9.3.2 Contamination from Equipment

(1) The operator should document and implement procedures for controlling the movement of equipment from areas processing seafood products for human consumption to areas processing seafood products for animal consumption within the premises. The procedures should cover the following:

a) construction, maintenance and cleanliness of the equipment;
b) designation of specific areas within the premises in which particular categories of equipment can be used; and
c) conditions for use of equipment in the premises so as to minimise contamination of equipment and products.

(2) Equipment (e.g. slicers, conveyors, packing machines, containers and trolleys), maintenance tools and utensils that are used:

a) in areas for processing seafood products for animal consumption should not be used for processing seafood products for human consumption; and
b) for processing raw products should not be used for processing RTE products; and
c) for processing products of a particular allergen status should not be used for another, if allergens are to be controlled.

(3) Despite section 9.3.2 (2), equipment, tools, and utensils may be thoroughly cleaned and sanitised and then used for the purposes listed.

Guidance

Colour coding may be used to identify portable equipment and utensils (e.g. containers, knives, cutting boards, slicers) for exclusive human/animal consumption seafood products or raw/RTE seafood products.

Particular consideration should be given to the type of processing operation in an area when appliances are moved from areas processing seafood products for human consumption to areas processing seafood products for animal consumption. Use of floor markings to define areas for particular types of equipment movement may be helpful.

(4) All hand-held equipment designated for use in processing areas, should be stored in a manner that protects it from contamination, when not in use.

(5) Seafood products containers that can be stacked and/or have drain holes should be placed above the floor (e.g. on metal gratings, or on metal or plastic surfaces raised off the floor) so as to minimise contamination.

Guidance

Operators should identify "bottom bins" i.e. bins that are placed at the bottom of a stack on the floor, but that are not used to contain seafood products.

9.3.3 Contamination from Material

(1) The operator must document and implement procedures for:

a) controlling the movement of material from areas processing seafood products for human consumption to areas processing seafood products for animal consumption; and
b) for dealing with seafood products that are unfit for human consumption.

(2) Any unpackaged seafood products for human consumption that are moved into or through any non-processing area should at all times be contained and covered, to minimise contamination.

(3) Waste or seafood products for animal consumption that are moved through any processing area must be handled in a manner that minimises contamination of seafood products for human consumption. [HC Spec 3.3]

(4) Material derived from normal processing (e.g. fish offal) and intended for bait, for further processing for animal consumption or for disposal as waste, can be:

a) held in a processing area until removal for such purposes; or
b) packed in a processing area, providing the operator has considered any potential contamination hazards and implemented measures to mitigate these.

Guidance

See Part 24 for information on processing products for animal consumption.

(5) Seafood products intended for use as bait or for the manufacture of pet food may be stored in the same room as packaged seafood products intended for human consumption ONLY if they are enclosed in containers and if the risk of contamination is minimised.

(6) All other non-product waste (e.g. damaged packaging, disposable gloves, hats, etc.) should be regularly removed from the processing area or placed in appropriate rubbish receptacles so that it does not create a risk of contamination.

9.3.4 Waste Management

(1) The operator must document and implement procedures for the management of waste. [APA section 17, RMP Spec 11]

(2) Waste containers and associated equipment such as trolleys must not be a source of contamination. [HC Spec 3.3]

(3) Waste containers, in processing or support areas, should be cleaned at a frequency specified in the cleaning and sanitation programme.

Guidance

The outside and underneath of waste containers should be sanitised before re-entering a processing area or area of higher hygienic status if they have been taken outside or moved through an area of lower hygienic status.

(4) Waste material (including waste food additives and ingredients) should be:

a) managed so that it is not a source of contamination to product (including as a result of its allergen status);
b) conveyed to a waste area in a timely manner;
c) kept in covered pest-proof containers (if receptacles are kept outside or are not in continuous use inside); and
d) regularly collected and disposed of.

Guidance

Trucks used for the storage of waste should be kept covered as much as practicable, (e.g. by netting or other appropriate material), particularly if they are located in a semi-permanent position on the premises.

9.4 Monitoring [APA section 17]

(1) The operator must regularly check compliance to documented procedures.

Guidance

The frequency and type of monitoring will depend on the nature of the operation and the degree of risk if hazards are uncontrolled. Monitoring options include daily checks to confirm that procedures such as water containment, waste management, and movement of appliances, materials, equipment and personnel are carried out correctly.

9.5 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) The records must include monitoring carried out, problems identified and corrective action taken.

Guidance

Examples of other records that could be used to demonstrate compliance are daily/weekly checks, site diagrams where designated equipment can be used.

Refer to Part 19 for record keeping requirements.

Part 10: Control of Maintenance Compounds

10.1 Purpose and Scope

To ensure the proper use and storage of maintenance compounds (chemicals) so as to prevent or minimise the contamination of seafood products, packaging, equipment, and the processing and storage environment. Most maintenance compounds used within the boundaries of the RMP must be approved. Maintenance compounds include chemicals used for cleaning, sanitation, personnel hygiene, fumigation, pest control and for repairs and maintenance of equipment.

Guidance

The following is the link to the list of Approved Maintenance Compounds.

The Approved Maintenance Compounds Manual outlines the requirements for the use of approved maintenance compounds. In some situations when carrying out maintenance work, chemical approval is not required. This is explained in the Manual.

10.2 Sources of Hazards

Source	Examples of hazards
Maintenance compounds (e.g. cleaning or sanitising agents, pesticides, lubricants)	Chemical residues
Chemical containers	Chemical residues

10.3 Mandatory Requirements

AP Reg 11(3) Hygiene of processing environment (paraphrased)

(3) Maintenance compounds must be stored, handled, and used in a manner that minimises contamination of seafood products, other inputs, packaging, equipment, and the processing environment.**HC Spec 3.4 Approved maintenance compounds**

(1) Only approved maintenance compounds may be used during processing operations and in the maintenance of processing areas, facilities and equipment.

(2) All containers of maintenance compounds must be labelled with the name(s) of the maintenance compound as so approved, or as they appear in the list of approved maintenance compounds in specifications.

10.4 Procedures

(1) The operator must document and implement procedures for the use of maintenance compounds within the boundaries of the RMP. [APA section 17, RMP Spec 11]

(2) The procedures for maintenance compounds should address:

a) handling;
b) storage;
c) use; and

d) actions to be taken in the event that inputs, products or product contact surfaces are potentially contaminated or contaminated with a maintenance compound.

(3) The operator should maintain an up-to-date list of all maintenance compounds used and held in the premises.

(4) When not in use, maintenance compounds must be stored in a designated area (e.g. shelf, cupboard, room) and kept separate from seafood products, ingredients, and packaging. [AP Reg 11(3)]

(5) All maintenance compounds must be used according to the manufacturer's directions and the conditions of MPI approval.

(6) Directions for use should be readily available to the user (e.g. given in the label, posted on the wall or in product information data sheets).

(7) Maintenance compounds must be handled and used, by or under the supervision of, suitably trained personnel.

(8) When specified in the conditions of use set out in Approved Maintenance Compounds Manual:

a) products and exposed packaging must be removed from the area or kept protected (e.g. covered) prior to use of the maintenance compound; and
b) equipment and other product contact surfaces must be cleaned by thorough washing after exposure to a maintenance compound (e.g. after spraying with insecticide).

(9) All containers or utensils used for measuring, mixing or transferring maintenance compounds should be:

a) clearly identified (e.g. labelled as 'For Chemicals Only'); and
b) only used for the identified purpose.

(10) Disposal of empty chemical containers should be in accordance with manufacturer's instructions. Re-use of empty chemical containers may be permitted provided that these containers are not be used in a way that could contaminate food.

(11) If contamination from a maintenance compound occurs:

a) affected product should be retained for assessment by a suitably skilled person, to determine its suitability for human consumption, animal consumption or for some other purpose;
b) affected product must be appropriately disposed of if it is no longer fit for any purpose; and [HC Spec 3.3]
c) affected product contact surfaces must be cleaned and where appropriate sanitised prior to re-use; [AP Reg 11] and
d) affected packaging materials that cannot be effectively cleaned and sanitised must not be used for packing of any seafood products and should be appropriately disposed of. [AP Reg 16]

10.5 Monitoring [APA section 17]

(1) The operator must regularly check compliance to documented procedures.

Guidance

Monitoring options include:

- daily and weekly checks to confirm maintenance compounds are being handled and used correctly.
- annual (or when new chemicals are purchased) checks to confirm that maintenance compounds are approved and identified on the company list.

10.6 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) These records must include:

a) monitoring carried out, problems identified and corrective action taken;
b) list of maintenance compounds used and held in the premises; and
c) training records for persons involved in key tasks. [RMP Spec 15(3)]

Guidance

Refer to Part 19 for record keeping requirements.

Part 11: Pest Control

11.1 Purpose and Scope

To ensure the effective control of pests so as to prevent or minimise the contamination of seafood products, packaging, ingredients, equipment, and the processing and storage environment. Pests include rodents, birds, insects, dogs and cats.

11.2 Sources of Hazards

Source	Examples of hazards
Insects, rodents, birds, cats and dogs	Bacterial pathogen, e.g. *Salmonella*, *Campylobacter* spp., *E.coli* spp., *Listeria monocytogenes*
Pesticides	Chemical residues

11.3 Mandatory Requirements

AP Reg 10 Requirements for premises, places, facilities, equipment, and essential services (paraphrased)

Premises, facilities, equipment and essential services must be designed, constructed, located and operated to minimise the exposure of animal product to hazards and other risk factors from pests.

AP Reg 11 (1) - (3) Hygiene of processing environment (paraphrased)

Effective procedures must be established and carried out to minimise the exposure of seafood products, packaging, other inputs, equipment, and the processing environment to hazards associated with pests.

Maintenance compounds must be stored, handled, and used in a manner that minimises contamination of animal product, other inputs, packaging, equipment, and the processing environment.

HC Spec 3.4 Approved maintenance compounds

(1) Only approved maintenance compounds may be used during processing operations and in the maintenance of processing areas, facilities and equipment.

(2) All containers of maintenance compounds must be labelled with the name(s) of the maintenance compound as so approved, or as they appear in the list of approved maintenance compounds in specifications.

11.4 Procedures

11.4.1 Pest Control Programme

(1) The operator must document and implement a pest control programme. [APA section 17, RMP Spec 11]

(2) The pest control programme ~~which~~ should include the following information:

a) the person or agency responsible for undertaking pest control activities;
b) pest control procedures;

c) approved maintenance compounds used;
d) site plan indicating location of baits and other pest control devices;
e) monitoring procedures and frequency; and
f) corrective action procedures (including escalation of response in the event of ongoing problems).

Guidance

The operator may employ a pest control person or agency to develop and implement a pest control system (e.g. set up traps, spraying programme) and monitor the premises. The operator is responsible for ensuring that the person or agency employed is competent to perform the task and that they comply with their contractual obligations.

Operators using a contracted pest control agency should also document procedures for addressing pest control problems that arise between scheduled agency visits.

11.4.2 Prevention of Infestation and Access of Pests

(1) Premises and facilities (including storage facilities, and water storage tanks) must be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. [AP Reg 10]

(2) Holes, drains and other places where pests are likely to gain access should be sealed, or covered with screens or similar materials that prevent the entry of pests.

Guidance

To prevent the entry of insects, birds and other pests, mesh screens should be used on windows, doors, ventilators and any other external openings into processing areas, amenities and product support areas that may be kept open during operations.

(3) External doors and windows that open directly to processing areas and that are not screened ~~must~~ should be kept closed at all times when not in use.

(4) Internal and external areas of the premises should be kept clean and tidy. The external environment should be checked regularly and kept free of any food sources and breeding sites (e.g. bird's nests, long grass).

Guidance

Areas that are likely to attract flies and other insects should be sprayed, as necessary.

(5) Skip bins or other waste receptacles should be kept covered when not being filled or emptied.

11.4.3 Use of Pesticides

(1) Pest control maintenance compounds should be used in accordance with any approval conditions.

(2) Pest control maintenance compounds (rodenticides and insecticides) should be handled, used and stored according to the control procedures in Part 10.

Guidance

Insecticides that have any residual activity or are dispensed as continuous aerosols should not be used in any processing or storage area in a manner that could cause the contamination of inputs, products or product contact surfaces.

Seafood products and exposed packaging should be removed from the area or kept protected (e.g. covered) prior to the use of maintenance compounds that may contaminate them. Equipment and other

product contact surfaces should be cleaned by thorough washing after exposure to any maintenance compound (i.e. after spraying with insecticide is completed).

11.4.4 Use of Pest Traps

(1) Pest traps (including rodent boxes, bait stations and electric insect traps) should be positioned so as to minimise contamination of seafood products, additives, ingredients or containers.

Guidance

Bait stations should not be located inside any processing or product storage area. The location of pest traps should be identified on a site or building plan, or other suitable record.

(2) Rodenticides should be used only in enclosed bait boxes.

(3) Insect traps, which include ultra-violet lamps, pheromone traps and any form of attractant device, should:

a) be constructed so they catch and secure insects in a suitable drawer, tray or adhesive mat that facilitates the capture and removal of insects;
b) not cause any air-borne contamination; and
c) be sited so there is no contamination from insects falling on to exposed seafood products, packaging, or product contact surfaces.

Guidance

Due to animal welfare restrictions, adhesive traps may only be used for insect traps, and may be suitable for processing areas. Operators should take care when using electric insect traps to ensure that they do not cause contamination of seafood products or product contact surfaces.

11.4.5 Handling and Disposition of Contaminated Materials

(1) When there is evidence of contamination from pests:

a) affected product should be considered unfit for human consumption and an assessment must be made to determine its suitability for animal consumption or for some other purpose;
b) affected product must be appropriately disposed of if it is no longer fit for any purpose; [HC Spec 3.3] and
c) affected product contact surfaces must be cleaned and sanitised prior to re-use; [AP Reg 11] and
d) affected packaging materials that cannot be effectively cleaned and sanitised must not be used for packing any seafood products and should be appropriately disposed of. [AP Reg 16]

11.5 Monitoring [APA section 17]

(1) The operator must regularly check ongoing compliance to documented procedures and the effectiveness of the pest control programme.

(2) Pest traps should be checked regularly:

a) to ensure they are correctly located as indicated in the plan or record, and presence of bait;
b) for evidence of pest activity (e.g. nibbled bait, bait missing, droppings); and
c) to check that the traps are in good working condition and legibly identified.

Guidance

Monitoring options include:

- daily visual checks of processing and product areas for any signs of pest activity, and for evidence that rubbish and food waste is properly managed.
- monthly checks on integrity of pest proofing (e.g. screens, seals).
- monthly checks of pest traps or bait station.

When determining monitoring frequency for bait stations and pest traps, operators should consider the type of traps used and the level of pest activity. Adhesive boards can often give a good indication of insect levels and should be changed often. If pest activity increases, monitoring frequency should increase and appropriate corrective actions taken.

11.6 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures [RMP Spec 20(2)].

(2) These records must include:

a) monitoring carried out, problems identified and corrective action taken;
b) details of the contracted pest control person or agency, if applicable;
c) training records for persons involved in key tasks; [RMP Spec 15(3)]
d) list of approved maintenance compounds.

Guidance

Refer to Part 19 for record keeping requirements.

Part 12: Training and Competency of Personnel

12.1 Purpose and Scope

To ensure that all staff involved in the handling of seafood products are competent to perform their duties, and are aware of and comply with good hygiene practices and with operating procedures.

12.2 Mandatory Requirements

RMP Spec 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.

HC Spec 5.2 Competency

(1) An operator's risk management programme must make provision, where appropriate, for the following:

a) Not applicable
b) persons responsible for the supervision of thermal processing operations for the thermal processing of low-acid canned products (including aseptic processing and packaging options) must meet the competency specification set out in Schedule 3 for supervisors of thermal processing of low-acid canned products;
c) premises processing fish must have on-site, during processing, at least 1 person(s) who individually or jointly meets the competency specifications set out in Schedule 3 for persons involved with fish handling, and hygiene activities.

(2) Thermal processes for low-acid canned products (including aseptic processing and packaging operations) must be developed by or under the supervision of a person who meets the competency specifications set out in Schedule 3 for a qualified person (thermal processing). The final process schedule must also be checked and signed off by a qualified person who is independent of the development process.

(3) Processes involving the depuration of bivalve molluscan shellfish must be under the direct supervision of a person why has been assessed as competent in shellfish depuration as part of the attendance at a training course set out in Schedule 3.

HC Spec 5.3 Skills maintenance and supervision

(1) The operator must ensure that the skills of those persons involved in key tasks that could have a significant impact on the suitability for processing of animal material or the fitness for intended purpose of animal product, or who are required to carry out the activities listed in clause 5.2, are maintained on an ongoing basis.

(2) The operator must keep records demonstrating that skills identification, achievement and maintenance is being carried out effectively.

HC Spec 15.5 Competencies (*Listeria monocytogenes* in certain RTE products only)

(1) The operator must ensure that:

a) the person responsible for designing and implementing the requirements for *Listeria monocytogenes* management within the premises, has knowledge of:

i) *Listeria monocytogenes*: the illness it causes, sources of contamination, harbourage sites and transmission routes; and
ii) the specific control measures that eliminate, prevent or reduce the likelihood of *Listeria monocytogenes* contamination during processing, distribution, storage and use; and
iii) how to develop and implement an environmental and product testing programme if required; and
iv) how to analyse and review test results, if any testing is undertaken; and
v) he actions to be taken following a detection of *Listeria* or *Listeria monocytogenes*; and

b) personnel involved in processing ready-to-eat animal product or entering areas used to process ready-to-eat animal product, including shift managers, process staff, cleaners, engineers and maintenance staff, have an understanding that is appropriate to their roles of:

i) the risks to the operation and consumers of *Listeria monocytogenes*; and
ii) *Listeria monocytogenes*: the illness it causes, sources of contamination, harbourage sites and transmission routes; and
iii) the specific procedures for the roles, tasks or control measures for which they are responsible; and

c) sampling, if required, is undertaken by a person who has received appropriate training, including in the identification of sampling sites, and how and when samples may be composited.

(2) Training records must be kept.

HC Spec Schedule 3

Fish handling and hygiene

(1) The NZQA qualifications for persons involved with fish handling or hygiene activities are:

a) either:

i) 5331: Handle seafood products; or
ii) 15344: Handle bivalve shellfish products; and

b) 5332: Maintain personal hygiene and use hygienic work practices working with seafood products; and
c) 6212: Clean and sanitise a seafood products processing plant.

(2) A person may also meet the requirements of Schedule 3 clause 2(1) if the risk management programme provides for equivalent competency to the qualifications specified in that clause.

Supervisors of thermal processing of low-acid canned products

(3) The competency specifications referred to in clause 5.2(1)b) include any of the following qualifications:

a) Principles of Thermal Process Control, Acidification and Container Closure Evaluation, Massey University, New Zealand:
b) Retort supervisors certification course, DWC Food TechPty Ltd, Australia:
c) New Zealand Retort Supervisors and Process Control School, Food Processing Specialists Pty, Australia.

(4) The Director-General may recognise alternative qualifications that he or she considers equivalent to any of the qualifications listed in Schedule 3 clauses 3(1)a) to c).

Qualified person (thermal processing)

(5) The competency specifications referred to in clause 5.2(2) include any of the following qualifications, as appropriate to the nature of the operation:

a) Qualified Cannery Persons (Thermal Processing) Course, Western Sydney University (Hawkesbury), Australia;
b) Approved Persons Course for thermally processed low-acid foods, DWC FoodTech Pty Ltd and CSIRO, Australia;
c) Approved Persons Course for UHT Processing and Aseptic and Packaging, DWC FoodTech Pty Ltd, Australia;
d) Introduction to the Fundamentals of Thermal Process Evaluation, Massey University, Palmerston North, New Zealand.

(6) The Director-General may recognise alternative qualifications that he or she considers equivalent to any of the qualifications listed in Schedule 3 clause 4(1)a) to d).

Depuration of bivalve molluscan shellfish

(7) The training courses referred to in clause 5.2(3) include either of the following courses:

a) SIS Training and Consulting Ltd Depuration course, Solutions in Seafood Ltd, New Zealand;
b) Aquabio Consultants Depuration Training Course, Aquabio Consultants Ltd, New Zealand.

(8) The Director-General may recognise alternative qualifications that he or she considers equivalent to the qualifications arising from the training courses listed in Schedule 3 clause 5(1)a) to b).

12.3 Procedures

12.3.1 Competencies

(1) The day-to-day manager or person authorising all or part of the RMP should be familiar with the documented RMP and have the following competencies:

a) knowledge of those food safety matters relevant to seafood products included in the RMP, and of hygienic procedures and practices documented in this Code;
b) knowledge of regulatory requirements, including responsibilities, related to the RMP;
c) ability to liaise and communicate effectively with personnel and the regulator.

(2) Personnel performing key tasks including monitoring, corrective action and operator verification should have:

a) the knowledge and skill to carry out the relevant tasks; and
b) knowledge of hygienic practices and procedures and the ability to consistently comply with these requirements.

(3) The knowledge and skills needed by personnel or positions performing key tasks must be documented in the RMP and must be maintained. [RMP Spec 15]

Guidance

Ideally, personnel performing key tasks should be employed in a supervisory or higher operational role within a premises for 6 months or longer.

Equivalent competencies to the fish handling and hygiene qualifications listed in HC Spec Schedule 3 in clause 2(1), include on the job or in-house training in:

- handling methods to maintain food safety, wholesomeness, control of food safety risks factors;
- personal hygiene and hygienic work practices to prevent foodborne diseases in seafood products; and
- contamination in a seafood processing premises, and cleaning and sanitising of facilities and equipment.

Alternatively, other handling and hygiene unit standards may be used to demonstrate competence, these include:

- 28630 "Apply hygiene and food safety requirements to own work area in a primary products food processing operation"; and
- 29089 "Apply product safety practices to own work area in a primary products food processing operation".

Hazard Identification and Analysis

Persons responsible for the development or review of a hazard identification and analysis should hold the following competency:

- unit standard 17996 'Develop and review a hazard identification and analysis for a seafood products product'; or
- a higher level HACCP unit standard (such as one of those described below for development or review of a HACCP plan); or
- other training or competency equivalent.

HACCP Plans

Persons responsible for the development or review of a HACCP Plan should hold at least one of the following competencies:

- unit standard 12316 'Coordinate development, and discuss implementation and verification of a HACCP plan for a seafood processing operation'; or
- unit standard 19514 'Explain the application of HACCP principles'; or
- unit standard 12626 'Coordinate the development and/or verification of a HACCP plan or application for a meat processing operation'; or
- 28265 'Develop, implement and review a HACCP application for a food processing operation'; or
- 28264 'Implement a HACCP system in a food processing operation'; or
- other training or competency equivalent.

Persons responsible for the review of HACCP plan records (the HACCP supervisor) should hold the following competency:

- unit standard 12315 'Supervise a seafood processing operation under a HACCP system; or
- a higher level HACCP unit standard (such as one of those described above); or
- other training or competency equivalent.

Exporter should check the OMARs for the destination country, to determine if there are any specific HACCP competency requirements. For example, if exporting to the US, HACCP competencies are mandatory.

For further information on training available for the seafood industry see: Primary ITO and the New Zealand Qualifications Authority. (external websites)

12.3.2 Training Programmes

(1) The operator should document a training programme for seafood products handlers and associated staff that includes skills required for key tasks, skills maintenance, monitoring, corrective action and records.

(2) The operator should provide regular training for all seafood product handlers in safe food handling, personal hygiene and sanitary practices to ensure they maintain the competencies required for their tasks.

(3) Training programmes should be reviewed at least annually to ensure that staff training remains up-to-date and effective, and to identify any need for new or refresher training.

Guidance

Induction programmes should be provided for all staff (including temporary staff and contactors), involved in or associated with the handling of seafood product, informing them of health requirements, personal hygiene and hygienic work practices and other requirements associated with the tasks they are to perform. Staff should be trained against written instructions or procedures for their specific tasks, including machine operation and monitoring of product and process parameters. Staff should be supervised until they are adequately trained to perform their assigned tasks on their own.

On-going training may take the form of regular staff meetings, in-house on-job training or external training courses. Staff should be involved in some form of on-going training every 3-4 months.

Where appropriate, clear instructions on hygienic practices (e.g. hand washing, use of protective clothing) and on operational tasks should be posted in the premises to re-enforce the procedures.

12.3.3 Competencies if producing certain ready-to-eat seafood products

(1) Operators processing certain ready-to-eat seafood products must ensure that the people described HC Spec clause 15.5(1)a), b) and c) have the required skills and knowledge for the role.

Guidance

Also see Part 27 Management of *Listeria monocytogenes* in RTE Seafood Products

12.4 Monitoring [APA section 17]

(1) The operator must regularly check compliance with documented procedures.

Guidance

Monitoring options include:

- using personal hygiene checks to confirm that personal hygiene training is effective.
- checks to confirm that staff who carry out key tasks (e.g. those responsible for monitoring and corrective action under the RMP) are appropriately skilled and are performing those tasks correctly.

12.5 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) These records must include:

a) monitoring carried out, problems identified and corrective action taken;
b) training records for persons involved in key tasks. [RMP Spec 15(3), HC Spec 15.5(2)]

Guidance

Examples of other records that could be used to demonstrate compliance are:

- training records including the training undertaken and dates when training occurred;
- records of group training, staff meetings;
- assessments and evidence of personnel competencies;
- training materials;

- list of any external training providers;
- copies of certificates.

Refer to Part 19 for record keeping requirements.

Part 13: Ingredients, Additives and Other Inputs

13.1 Purpose and Scope

To ensure that additives, ingredients and other process inputs meet relevant regulatory requirements, and are received, handled and stored in a manner that minimises contamination and deterioration. This Part does not apply to raw seafood used as an ingredient.

13.2 Mandatory Requirements

HC Spec 2.14 Additives, processing aids, vitamins, minerals and other nutrients

(1) The identity and purity of additives, processing aids, vitamins, minerals, and other added nutrients must comply with the current Australia New Zealand Food Standards Code, Section 1.1.1—15 "Identity and purity"

HC Spec 14.8 Process inputs

(1) All process inputs, including ingredients, additives, processing aids, and packaging must be stored, handled, and transported so as to minimise any potential contamination or deterioration.

Australia New Zealand Food Standards Code, Part 1.3, Substances added to or present in food

(1) This Standard regulates the use of food additives, vitamins and minerals and processing aids in the production and processing of food. A food additive may only be added to food where expressly permitted in this standard. Additives can only be added to food in order to achieve an identified technological function according to Good Operating Practice.

13.3 Procedures

13.3.1 Purchase and Receiving

(1) The operator must document and implement procedures for the sourcing of incoming goods to confirm that regulatory requirements are met. [APA section 17, RMP Spec 11]

(2) The procedures should include the inspection of incoming goods to confirm that:

a) they are fit for their intended purpose and comply with any regulatory requirements; and
b) sufficient information is provided on labels and accompanying documentation for their proper identification, storage and use.

Guidance

The procedures should also cover:

- sourcing of inputs (e.g. ingredients, additives and processing aids) from reputable suppliers with reliable traceability procedures;
- written specifications for inputs, including any relevant regulatory requirements and acceptance criteria, that have been agreed between the operator and the supplier;
- consideration of allergens;
- the provision of certificates of analysis or supplier guarantees, when required;
- actions to be taken when inputs do not meet agreed specifications.

(3) All inputs should be:

a) checked for the presence of visible contaminants, damage; and for other relevant characteristics (e.g. temperature);
b) moved in a way that minimises any contamination or damage (e.g. forklift damage).

(4) Inputs with damaged packaging should be handled in a manner that will minimise:

a) the exposure or spillage of the inputs (e.g. they can be wrapped and sealed); and
b) contamination or deterioration of the inputs.

13.3.2 Storage

(1) Inputs should be:

a) stored separately in an appropriate area in a manner that minimises potential contamination or deterioration (e.g. shelf, cupboard, chiller, freezer or room); or
b) adequately protected from chemicals or other products that may cause taint; and
c) stored on racks, shelves or pallets to ensure no contact with the floor.

(2) The method of storage should comply with instructions indicated on the label or provided by the supplier (e.g. some items may require clean, dry storage, others may require refrigeration).

(3) Inputs should be kept in closed containers when not in use.

(4) All containers of inputs should be clearly identified and labelled so that inventory control and traceability can be maintained.

(5) Storage areas should be kept clean and tidy.

13.3.3 Use

(1) Inputs should be checked before use to ensure they are within their recommended shelf life requirements (where relevant).

(2) Ideally, outer pallet wrapping should be removed before these products enter the processing area. However, if this is not practical wrapping can be removed in the processing area provided effective controls are in place to minimise any risk of contamination to surrounding seafood products or product contact materials.

(3) Inputs:

a) must be permitted for use in the product and at levels to comply with any limits; and [FSC]
b) should be used in accordance with manufacturers' instructions.

Guidance

Exporters should check the OMARs for the destination country, to determine any specific country regulations for inputs.

13.4 Monitoring [APA section 17]

(1) The operator must regularly check compliance with documented procedures.

Guidance

Monitoring options include:

- Checks of all inputs on arrival;
- Checks during processing to ensure that inputs are used correctly.
- Weekly checks to confirm that inputs are clearly identified and stored correctly.

13.5 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) These records must include monitoring carried out, problems identified and corrective action taken.

Guidance

Examples of other records that could be used to demonstrate compliance are:

- register of inputs (including additives and other ingredients) and their specifications;
- register of suppliers;
- incoming goods delivery documentation e.g. supplier statements/guarantees;
- any supplier audit reports;
- daily & weekly check sheets.

Refer to Part 19 for record keeping requirements.

Part 14: Allergen Management

14.1 Purpose and Scope

To ensure that foods that contain allergens are appropriately managed and labelled so that they don't cause harm to consumers.

This Part applies to operators that process or handle products that contain inputs that require a declaration for allergens under the FSC. Operators such as those who process finfish or crustaceans only and use no other additives or ingredients, are not expected to have procedures for managing cross contamination. However, management is expected if an operator is processing allergenic and none allergenic products. The allergenic substances under Standard 1.2.3 of the FSC include:

- added sulphites in concentrations of 10 mg/kg or more;
- cereals containing gluten and their products, i.e. wheat, rye, barley, oats, spelt and their hybridised strains (with some exceptions, see the FSC);
- crustacea and their products;
- egg and egg products;
- fish and fish products (with an exception for beer and wine);
- milk and milk products (other than alcohol distilled from whey);
- peanuts and peanut products;
- soybeans and soybean products (with exceptions);
- sesame seeds and sesame seed products;
- tree nuts and tree nut products;
- lupin and lupin products.

Guidance
More detailed information on allergen management and labelling is available from the Allergen Bureau website and The Food Industry Guide to Allergen Management and Labelling.

Exporters should also consider if there are any additional allergens that need to be addressed for countries they export to.

14.2 Mandatory Requirements

Australia New Zealand Food Standards Code — Standard 1.2.3 — Information requirements — warning statements, advisory statements and declarations.

14.3 Procedures

14.3.1 General

(1) Procedures must be documented and implemented where necessary based on the products and operations within the premises, to manage and label allergenic products that are regulated under the FSC. [APA section 17, RMP Spec 11]

(2) The potential sources or causes of unintended exposure or contact of product, or surfaces, with allergens should be identified and controls established.

(3) Key personnel should be trained in allergen management and the consequences of unintentional consumption of allergens by allergic consumers, as appropriate to their role.

Guidance

A HACCP approach is recommended for the systematic identification of food allergens for products and processes, and to implement appropriate control measures. The product and process should be assessed starting with sourcing of raw materials and at every step of the process through to labelling and packaging.

Unintended exposure or contamination may result from:

- using the wrong formulation;
- inadequate separation of materials (e.g. fish and shellfish if appropriate), equipment and processes;
- changes to product scheduling;
- rework;
- insufficient or ineffective cleaning and sanitation of equipment, containers and other product contact surfaces;
- contamination from air-borne allergens; or
- personnel practices that could lead to incidental contamination.

14.3.2 Inputs

(1) Accurate allergen information should be obtained from suppliers for all inputs.

Guidance

Suppliers should provide allergen information about each raw material, identifying any allergens, products that are derived from allergenic foods, or those that have a high likelihood of cross contact with allergenic substances. For example, premixes of fillers or binders may contain milk or egg powder.

(2) All inputs should be handled and stored to prevent cross-contamination between inputs of different allergen status.

14.3.3 Formulation

(1) Formulations should identify all inputs, including compound ingredients, substitute ingredients, additives and processing aids, and any rework.

(2) The person responsible for formulation development should assess any change in an input on the allergen status of the product, and ensure that any changes in management and labelling is made before a new formulation is used.

14.3.4 Processing

(1) Products and processes of different allergen status should be physically separated, separated by time or separated by distance, as appropriate to the type and size of the operation, based on an assessment of the potential for product contamination and risk to human health.

(2) If rework is to occur, this must be done with full knowledge of the allergen status of both the rework and the product in which it is to be reused to prevent cross-contamination. [AP Reg 6].

Guidance

Ideally, processors should use dedicated equipment or have separate processing lines for products of different allergen status. If separation is achieved by time, non-allergenic products should be processed first, when the equipment is clean. Products of different allergenic status can also be done on different days.

14.3.5 Cleaning

(1) In addition to the procedures in Part 7, the cleaning programme should cover:

a) cleaning of all surfaces, equipment, utensils, clothing and hands of product handlers that may have come in contact with products that contain allergens;
b) cleaning of spills; and
c) cleaning of hidden or static areas and dismantling of equipment to remove residues.

(2) Facilities, equipment and utensils should be cleaned and sanitised, and protective clothing changed:

a) before processing a non-allergenic product, if the previous product contained an allergen; and
b) between processing products containing different allergens.

(3) A pre-operational check should be performed after cleaning, when swapping between allergenic and non-allergenic products.

(4) Operators should validate the cleaning procedure to ensure that it is effective.

Guidance

Testing for allergens can provide confirmation of the effectiveness of allergen management. The most commonly used analytical method for detecting the presence of food allergens is the Enzyme Linked Immuno Sorbent Assay (ELISA) technique. A number of allergen ELISA test kits are currently available for the routine detection of allergens in foods.

14.3.6 Labelling

(1) Labelling must comply with Standard 1.2.3 of the FSC, which requires the mandatory declaration of certain substances and their products.

Guidance

The FSC is not entirely clear in relation to the labelling of fish allergens. It requires declaration if crustaceans or fish are in the product. Fish includes molluscs. A separate allergen warning is not required if the name of the food is the allergen. At the time of writing, allergens in the FSC are under review.

A number of tools are available to assist with decision making about allergen declarations on labels. An example is VITAL which provides processors a systematic way of assessing the impact of allergen cross contact and assists in determining appropriate precautionary allergen labelling.

Also see the FSANZ Warning and Advisory Statements and Declarations User Guide for labelling guidance.

14.4 Monitoring [APA section 17]

(1) The operator must carry out regular checks on the effectiveness of, and compliance with, the documented procedures.

14.5 Records [APA section 17, RMP Spec 20]

(1) The operator must keep records demonstrating compliance with documented procedures.

(2) These records must include:

a) monitoring carried out, problems identified and corrective action taken;
b) training records for persons involved in key tasks. [RMP Spec 15(3)]

Guidance

Examples of other records that could be used to demonstrate compliance are:

- cleaning records;

- formulations;
- product information sheets;
- supplier agreements;
- records of labelling decisions (e.g. VITAL).

Refer to Part 19 for record keeping requirements.

Part 15: Packaging and Containers

15.1 Purpose and Scope

To ensure that product contact materials, such as fish bins and containers, and plastic bags / liners, etc., used for edible seafood products, are fit for their intended purpose.

This programme does not apply to packaging applied to bivalve molluscan shellfish while subject to the shellfish regulated control scheme.

15.2 Sources of Hazards

Source	Examples of hazards
Product contact packaging (plastic bags, wraps, liners, and may include cardboard cartons)	Chemical residues (e.g. inks) Physical hazards such as foreign material (e.g. cardboard slivers, pieces of plastic, etc.)
Reusable product containers (e.g. plastic bins, tubs)	Bacterial pathogens Chemical residues (e.g. cleaning chemicals) Physical hazards such as foreign material (e.g. pieces of plastic from damaged containers, etc.)

15.3 Mandatory Requirements

AP Reg 16 Packaging requirements for animal material and product

(3) All risk management programme operators, operators of animal material depots, and other categories of person specified in specifications for the purposes of this regulation must ensure that any packaging materials (including reusable packaging and inner and outer packaging of any kind) used for animal material, animal product, and associated things are designed, made, stored, and used in a manner that—

a) maintains the status of the animal material as suitable for use in processing; and
b) maintains the status of the animal product as fit for its intended purpose; and
c) minimises contamination of the animal material or animal product.

HC Spec 7.2 Packaging

(1) The composition and, where appropriate, the conditions of use of packaging must:

a) comply with the requirements specified in the current US Code of Federal Regulations, Title 21, Parts 170-199, which applies equally to coatings and linings and cartons where these are the direct product contact surface; or
b) comply with the requirements specified in the current "Australian Standard: Plastics materials for food contact use", AS2070-1999; or
c) be determined by the operator to be suitable for use, based on an analysis of hazards and other risk factors from the packaging.

(2) The type and composition of the packaging must be appropriate for its intended use.

(3) If compliance with this specification is achieved through meeting the requirements of clause 7.2(1)a) or b), the risk management programme must state the full reference to the regulation, part, section or standard with which the packaging complies.

(4) If the packaging is damaged such that the suitability for processing of animal material or the fitness for intended purpose of animal product may be affected, the animal material or product must be:

a) handled in a manner that minimises contamination and the damage to the packaging rectified; or
b) appropriately disposed of.

(5) Reused and recycled packaging must not be a source of contamination to the animal material or product

Guidance

For further guidance on dealing with damaged packaging refer to the Damaged Packaging: Prevention and Management, A Guideline for the Seafood Industry. This is available on the Seafood Standards Council website.

15.4 Procedures

15.4.1 Receiving and Storage

(1) Operators should obtain a written guarantee from the supplier stating that packaging meets mandatory requirements for composition and conditions of use or complete their own packaging assessment.

Guidance

The operator is responsible for ensuring that packaging is safe and complies with the legislation. This can be achieved either by getting information from their packaging suppliers, or carrying out their own assessment.

Compliance with recognised international food standards such as those of the European Union (EU) or the United States Food and Drug Administration (FDA) would be reasonable evidence that materials are suitable for food use.

If complying with clause 7.2(3) of the HC Spec the full regulation, part, section or standard with which the packaging complies must be documented in the RMP. This may be in a letter or form from the supplier.

(2) All packaging and product contact containers should be checked on receipt to ensure they are received in a condition that is fit for purpose.

(3) Once accepted into the premises, all packaging and product contact containers must be handled in a manner that minimises contamination and deterioration. [AP Reg 16]

(4) Containers and packaging held in a warehouse-type store should be securely wrapped and stored off the floor (e.g. on pallets) to minimise contamination.

15.4.2 Use

(1) Containers and packaging should be unwrapped only in a support area or processing area. After unwrapping, containers and packaging may be stored, handled or transported only in a support area or processing area. Refer to Part 2 for information on the design of such areas.

Guidance

Ideally, outer pallet wrapping should be removed before entering the processing area. However, if this is not practical, wrapping can be removed in the processing area provided effective controls are in place to minimise any risk of contamination to surrounding products or product contact materials.

Unused containers and packaging may be returned to a warehouse-type store providing the packaging is re-wrapped to minimise contamination.

(2) Operators should ensure that opened cartons are re-closed and covered during storage to prevent dust contamination. Any wet plastic packaging must be disposed of rather than stored.

(3) Only containers or packaging required for immediate use (e.g. for that shift or batch) may be held in any area where seafood products is processed or packaged.

(4) Packaging and containers must be clean and undamaged at the time of use. [AP Reg 16]

(5) All packaging materials should be removed from the processing area or adequately protected before any cleaning and sanitising operations are carried out.

Guidance

Made-up cartons may be:
- left in the processing room during sanitation and cleaning as long as they are adequately protected; or
- brought into the processing room once cleaning and sanitation is complete, ready for the next processing shift.

Made up cartons may be protected from dust by covering the top layer of cartons or inverting the topmost carton.

(6) Re-usable containers (for example those used for transporting or storing product) must be:

a) clean before use; and
b) cleaned and sanitised at a frequency specified in the cleaning and sanitation programme;
c) undamaged and replaced if they are not fit for use. [AP Reg 16]

(7) The frequency of cleaning and sanitation should take into account the areas in which the containers are used and whether or not product comes into direct contact with the container.

(8) Re-usable containers that have been cleaned should be protected from contamination.

15.5 Monitoring [APA section 17]

(1) The operator must regularly check compliance with documented procedures.

Guidance

Monitoring options could include:
- checks on arrival to confirm they have not been damaged in transit, and show no visual signs of contamination;
- checks before use to confirm they are clean and suitable for use;
- checks that the documentation confirms that the packaging meets the compositional requirements;
- weekly checks to confirm proper storage.

15.6 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) These records must include monitoring carried out, problems identified and corrective action taken.

Guidance

Examples of other records that could be used to demonstrate compliance are:

- register of packaging and/or suppliers;
- supplier statements/guarantees for product contact packaging and containers;
- daily & weekly check sheets.

Refer to Part 19 for record keeping requirements.

Part 16: Traceability and Inventory Control

16.1 Purpose and Scope

To ensure that procedures are in place to manage traceability and inventory control of seafood products.

16.2 Mandatory Requirements

AP Reg 18 Identification system requirements

(1) All operators of risk management programmes, all exporters, and all other categories of person required by specifications to do so, must have a tracking system that –

a) allows for the identification of animal material and animal product; and
b) enables the movement of the animal material or animal product to be traced –

i) where required by specifications, from the origin, through the supplier and the operator's business premises to the next recipient of the animal material or product; or
ii) where specifications do not require tracing from origin, from the supplier and the operator's business premises to the next recipient of the animal material or product.

HC Spec 9.2 Documented programmes and record keeping

(3) An inventory control programme must be documented for animal material and product and records maintained.

16.3 Procedures

(1) Inventories must be maintained for all inputs, including ingredients and additives, and finished products (including imported fish and fish products) and for any non-complying materials and products. [HC spec 9.2(3)]

(2) Procedures must be documented and implemented for the identification and tracking of all inputs (including rework) and products, including imported seafood products that will allow inputs to be traced to the finished product. [APA section 17, RMP Spec 11]

(3) The tracking system must allow for products to be traced:

a) back to the supplier of the seafood product and other inputs; and
b) to the next person or company that the seafood product is transferred to for further processing, packing, storage; distribution or sale. [AP Reg 18(1)]

(4) All outgoing products must be clearly identified and accompanied by appropriate documentation. [AP Reg 18(1)]

Guidance

The following table provides an example of an inventory and traceability system.

Table 8: Steps in the processing chain and examples of inventory and traceability records to be kept

	Process step	Inventory records	Description
Reception records	Product received from catching vessel	Reception check sheets Unloading documentation	Record date, supplier details e.g. vessel name, fish species, and quantity
	Product received from other premises in NZ – fresh or frozen	Purchasing records	Details of product received
Processing records	Reception, weighing & grading	Reception check sheets, delivery documents	Date received, weight, species
		Unloading dockets Weigh sheets	
	Processing	Formulations, batch record sheets (including rework), production records	Production lot ID, pack date, amount of product
Cold store inventory	Frozen storage	Store records	Product ID, amount of product
Dispatch records	Dispatch	Sales records	Date, customer, product ID, pack date, amount of product

For further guidance about traceability, refer to "Traceability: A Guideline for the Seafood Industry", on the Seafood Standards Council website.

For further detail about exported seafood products, refer to:

- the Official Assurance Specification and more particularly the export requirements for inventory records and transport conditions etc.; and
- the OMARS for the intended markets. Some OMARs require the separation of products on the basis of country eligibility.

16.4 Monitoring [APA section 17]

(1) The operator must regularly check ongoing compliance with documented procedures.

Guidance

The operator should check, at least annually, that the documented procedures are appropriate.

16.5 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) These records must include:

a) monitoring carried out, problems identified and corrective action taken;
b) inventory records (either electronic or hard copy); [HC Spec 9.2(3)]

c) supplier contact details; and
d) details of the person or company to whom the products are supplied.

Guidance

Examples of other records that could be used to demonstrate compliance are: ~~inventory records.~~

- batch number, input, quantity and delivery date;
- records indicating the type, formulation and quantity of finished products, production or manufacturing dates and batch numbers, the use of any reworked products, and any repacking done;
- load in and load out checks.

Refer to Part 19 for record keeping requirements.

Part 17: Labelling

17.1 Purpose and Scope

To ensure that labelling on seafood products meets the relevant labelling requirements under the APA and the FSC.

17.2 Mandatory Requirements

17.2.1 Seafood and Seafood Products

HC Spec 8.2 Labelling of transportation outers

(1) This clause applies to transportation outers, but does not apply to the labelling of bulk transportation units.

(2) This clause applies to animal material or product that has been received by a primary processor but does not apply to animal material and product that is transferred within New Zealand between sites of a single company or subsidiaries of a parent company, or between subsidiaries of a parent company and the parent company, prior to the completion of processing, provided the operator has documented systems to ensure that traceability is maintained.

(3) Labelling must be provided on transportation outers and must state:

a) the animal material or animal product name or description; and
b) storage directions where necessary to maintain the animal material as suitable for processing or the animal product as fit for intended purpose; and
c) lot identification (except that this requirement is optional if the application of lot identification to the retail packaging is a mandatory requirement under other legislation and that legislation is complied with); and
d) in the case of fish product, the scientific name of the fish as specified by the Director-General; or
e) in the case of minced fish, surimi, reformed fish, shark livers or multi-ingredient fish products that have undergone further processing, the scientific name, either on the label of the transportation outer or on the accompanying documentation; or
f) in the case of shucked pāua that is intended for canning and is held at temperatures not exceeding 6°C, that the pāua is for canning only in New Zealand.

(4) The label of the transportation outer, or the accompanying documentation, of animal material or animal product that is not intended for human consumption but has the appearance of, or could be mistaken for, animal material or animal product that is intended for human consumption, must clearly indicate that the animal material or animal product it contains is not intended for human consumption.

Guidance

The New Zealand List of scientific names of fish as required by HC Spec 8.2 (3)d) and e) and the Approved fish names can be seen on the MPI website.

HC Spec 8.3 Identification of animal material or product in bulk transportation units

(1) Transport units use for the transportation of unpackaged bulk animal material or product that cannot practicably be labelled, must have the information specified in clause 8.2(3) provided with the animal material or product or on the accompanying documentation.

HC Spec 8.4 Labelling and accompanying documentation changes

(1) If the status of an animal material's suitability for processing or an animal product's fitness for intended purpose changes, and the animal material or product has been identified, all affected labelling or the accompanying documentation (where there is no label) must be amended to reflect its new status prior to its release for trade, or the packaging (including labelling) must be replaced.

(2) If animal material or product is downgraded and is no longer intended to be traded for human consumption, any labelling on the transportation outer, accompanying documentation, inspection legends and any other identification of the product as being suitable for processing for human consumption or as being fit for human consumption must be removed or defaced at the consigning premises.

(3) Any false or misleading labelling on reused or recycled packaging resulting from previous uses must be removed or defaced at the consigning premises.

17.2.2 Food Standards Code Part 1.2 Labelling and other information requirements

Standard 1.2.1 Requirements to have labels or otherwise provide information

Standard 1.2.2 Information requirements – Food identification

Standard 1.2.3 Information requirements – Warning statements, advisory statements and declarations

Standard 1.2.4 Information requirements – Statement of ingredients

Standard 1.2.5 Information requirements – Date marking of food for sale

Standard 1.2.6 Information requirements – Directions for storage and use

Standard 1.2.7 Nutrition, health and related claims

Standard 1.2.8 Nutrition information requirements

Standard 1.2.10 Information requirements – characterising ingredients and components of food

Standard 1.2.11 Information requirements – country of origin labelling requirements

Guidance

FSANZ has a number of guidance documents to assist with compliance with the labelling requirements in the FSC.

17.2.3 Bivalve Molluscan Shellfish

HC Spec 14.34 Bivalve molluscan shellfish labelling

(4) Containers of shellfish leaving the processing premises must be labelled with:

a) the growing area lease, licence, resource consent, or permit number; and
b) the date of harvest; and
c) the type and quantity (number or weight) of shellfish.

(5) However, a lot number labelling system may be used to replace the requirements of clause 14.34(1)a) and b) of the HC Spec if adequate traceback to the specific harvest dates and harvest areas is provided in the risk management programme.

(6) If reshipping (the purchase and resale of shellfish without repacking) occurs:

a) the original labels on shucked shellfish and shellstock must be maintained on the product containers; and
b) the labelling information must not be altered or removed, nor the product mixed with other shellfish, resorted, or repackaged; and
c) the name of the operator responsible for reshipping must be added to the container.

17.3 Procedures

(1) The operator should develop and implement labelling procedures to ensure that all information printed on a label or on packaging is accurate, and that the correct label is applied to the product.

(2) Labelling procedures should cover the identification, storage, inventory and use of labels, and the disposition of obsolete labels or labels with wrong information.

Guidance

For exported seafood products, every container must be labelled with any information required by the country to which they are to be exported. This may include a requirement for the label to be in the language commonly used in the destination country.

The requirements for foreign language translations are contained in the country specific OMARs (such as the EU OMAR) and the Animal Products (Fish Export Processing Requirements) Notice 2011 (FEP Notice).

When obtaining translations of foreign languages used on labels, only persons resident in New Zealand (or New Zealand registered translation service companies) can provide translations. This is because only New Zealand residents can be held accountable if the translation is incorrect. The person confirming the translation needs to be independent of:

- the commercial client, to meet the FEP Notice; and
- both the operator and the commercial client, to meet the EU OMAR.

The Seafood Standards Council created a data sheet of confirmed EU language seafood translations. The data sheet is maintained by the SSC and is available on the MPI website under 'Seafood Industry Certified Translations'.

Processors also need to be aware of the country of origin labelling requirements if exporting to Australia.

For further information on labelling requirements for overseas countries see the MPI website: Exporting.

(3) Labelling on containers of seafood products must not contain any false or misleading statements, words, pictures or marks. [AP Reg 8]

(4) Labelling is not required for:

a) shipping containers; or
b) an interior wrapper that is intended to facilitate packing and is not intended to serve as the sole container of the contents of a package; or
c) any transparent wrapping material that has no label and encloses another container.

17.4 Monitoring [APA section 17]

(1) The operator must regularly check ongoing compliance to documented procedures.

Guidance

Monitoring options include:

- daily labelling checks on specified products;
- checks on new labels at the design phase to ensure they are accurate, comply with legislation and are not misleading.

17.5 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) These records must include monitoring carried out, problems identified and corrective action taken.

Guidance

Examples of other records that could be used to demonstrate compliance are:

- copies of labels that have been checked and comply with requirements;
- label checklists;
- daily/weekly checks.

Refer to Part 19 for record keeping requirements.

Part 18: Operator Verification and Notifications

18.1 Purpose and Scope

(1) To verify compliance to documented procedures and to confirm that they are appropriate and effective by ensuring that operator verification, including internal audits, are undertaken at the required frequencies.

(2) To ensure that notification requirements are met by the operator.

18.2 Mandatory Requirements

RMP Spec 11 Control of hazards and other risk factors

(3) (c)(iv) The operator must document sufficient procedures to cover any corrective action procedures to be applied when loss of control is due to unforeseen circumstances for which no specific corrective action is documented. These procedures must include 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 delay.

RMP Spec 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.

RMP Spec 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.

HC Spec 14.13 Testing (which applies to BMS)

(1) A laboratory performing analyses to confirm compliance with clauses 14.14 to 14.34 must have accreditation to ISO/IEC 17025 or be a recognised laboratory.

HC Spec 15.4 Testing (which applies to *Listeria* management)

(1) An operator must use a laboratory with an accreditation to ISO/IEC 17025 with the required tests in the laboratory's scope of accreditation.

18.3 Procedures

18.3.1 Scope and Frequency of Operator Verification Activities

(1) The operator must document and implement operator verification procedures. [APA section 17, RMP Spec 11]

(2) The documented operator verification procedures must include:

a) the responsible person(s) or position(s) and any required competencies to complete the activities;
b) what and how the activities will be carried out;
c) the frequencies that are sufficient to ensure compliance with the RMP, including GOP and process control procedures, and to enable prompt identification and correction of any problems;
d) actions to be taken if deficiencies are identified, including the timeframes, considering the nature of the deficiency;
e) the need to consider and where appropriate implement preventative actions; and
f) the records to be kept. [RMP Spec 16]

(3) A review of the RMP should be undertaken at least annually.

Guidance

Operator verification is not routine monitoring, validation or external verification. Operator verification is the dedicated activities carried out to gather evidence to show that the:

- RMP continues to meet the requirements in the legislation (particularly if amendments have been made to the RMP or the legislation);
- procedures address all activities carried out under the RMP;
- RMP is being implemented as documented; and
- procedures are resulting in animal material that is suitable for processing or animal product that is fit for its intended purpose.

Operator verification activities include reviewing procedures and records, reality checks, interviews, testing product, and looking at customer complaints. Table 9 provides examples of operator verification activities for cleaning and sanitation.

Table 9: Examples of cleaning and sanitation operator verification activities

Activity	Frequency of checks
Checks when programme is first implemented or if a substantial change is made to assess effectiveness.	Initially, every time the cleaning procedure is carried out. (e.g. over 1-2 weeks).
Carrying out microbiological tests to confirm that the programme is effective.	Sample every day for at least a week to allow for normal variation.

	Resample if changes made or new equipment introduced; otherwise resample at least 6 monthly or annually. If using new maintenance compounds, facilities, or if trouble-shooting, daily for 7-14 days. Otherwise consult expert to determine frequency or need.
Assessing the cleaning and sanitation process as it is being carried out.	Periodically e.g. weekly. Review records weekly or 2 weekly. Frequency increased if ongoing problems, until resolved.
Checking that maintenance compounds are: • approved, with the correct approval conditions; • appropriate for the job; • applied correctly and at the right strength prior to and, in some cases during use (e.g. foot-baths or knife sanitisers); • left for the required time (if important); • at the correct temperature (if important); • doing its job, i.e. removes the grease and soil etc., adequately; and • properly rinsed (where appropriate).	Weekly or monthly as part of programme review.
Checks of product support areas (e.g. maintenance compound stores, packaging stores, dry stores, cold stores).	Weekly.

For detailed guidance about operator verification refer to "Operator Verification. A Guideline for the Seafood Industry" on the Seafood Standards Council website.

(4) The RMP must also be reviewed and where necessary amended when:

a) significant changes are made to the product, process or premises; or
b) the RMP or parts of it are not working effectively. [APA section 17, RMP Spec 22].

Guidance

Indications that the RMP or parts of it are not working effectively include:

- a series or trend of non-compliance or out of specification product test results;
- customer complaints;
- product recall;
- failed external verification audit.

18.3.2 Non-compliances with the RMP

(1) If ongoing or recurring non-compliances occur, the operator must:

a) investigate to determine possible causes of non-compliance;
b) take appropriate corrective actions to regain control and prevent recurrence of the problem within appropriate timeframes;
c) increase surveillance of the system; and
d) review the RMP or the relevant GOP programme and make necessary changes.

18.3.3 Notification

(1) The day-to-day manager of the RMP must contact MPI without delay when it is necessary to notify MPI about the issues identified in RMP Spec clause 13(1) and (2).

(2) The day-to-day manager of the RMP must notify their recognised verifying agency in writing (e.g. by email or letter), as required by, about the issues identified in RMP Spec clause 11(2)(c)(iv) and 13(3).

18.4 Monitoring [APA section 17]

(1) The operator must regularly check ongoing compliance with documented procedures.

18.5 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) These records must include monitoring carried out (e.g. observations made during the operator verification activities), problems identified and corrective action taken.

Guidance

Examples of other records that could be used to demonstrate compliance are:

- operator verification records;
- internal audit records;
- RMP review records;
- copies of communication sent to MPI, the recognised verifying agency or recognised evaluator.

Refer to Part 19 for record keeping requirements.

Part 19: Document Control and Record Keeping

19.1 Purpose and Scope

To ensure that all RMP documents, including records, are managed under a document control system that meets the requirements of the APA.

19.2 Mandatory Requirements

RMP Spec 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 working days of any request to:

a) recognised persons; and
b) animal product officers; and
c) the Director-General; and
d) persons authorised by the Director-General.

RMP Spec 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.

HC Spec 9.2 Documented programmes and record keeping

(1) Operators and other persons as required in this Notice must implement the procedures contained in the relevant risk management programme and retain records to demonstrate that the requirements of relevant animal product regulations and this Notice have been met.

(2) Records must be:

a) accessible to the recognised verifier, the recognised verifying agency, animal product officers and the Director-General and any other person authorised by the Director-General; and
b) retained for a period of at least 4 years or other period where provided for in this Notice; and
c) retrievable within 2 working days.

(3) An inventory control programme must be documented for animal material and product and records maintained.

19.3 Procedures

19.3.1 Document Control

(1) The operator must keep a register or list of all current RMP documents showing the current version and/or date of issue. For multi-business RMPs the document list must also specify, where necessary, which documents relate to which business. [RMP Spec 12]

(2) The register or list should include the site plan and all record forms (e.g. blank check sheets used for monitoring and operator verification activities) if these are separate from the procedures.

Guidance

The register or list should identify previous authorised versions of the RMP documents and when they were replaced, as well as the date or version of the RMP documents when registered.

It is common practice to include both the version number and date of issue of each RMP document. If more than one controlled copy of the RMP is issued, each set of documents should have additional identification showing the copy number.

The operator should maintain a register of controlled copies showing who is responsible for each copy.

Authorisation of version control may be shown in several ways, including:
- signature & date on the cover page of each RMP document;
- initials & date in the header or footer of every page;

- signature & date on the document register;
- other reliable means within an electronic system.

(3) Details of all amendments must be recorded. [RMP Spec 19]

Guidance

An amendment register is a good way of keeping a record of all amendments and may be presented in a table with the headings: document name or reference, details of amendment, reason for amendment, date of change.

19.3.2 Amendments to the RMP

(1) Significant amendments to the RMP must be evaluated and registered. [APA section 25]

(2) Certain minor amendments must be notified to MPI. [APA section 26]

(3) When the operator determines that an amendment is not significant, changes may be made at any time to update the RMP document(s).

Guidance

Guidelines for determining whether an amendment is significant or minor, and if a minor amendment needs to be notified to MPI is in Appendix G of the RMP Manual. The Manual also provides examples of significant and minor amendments. If there is still doubt as to whether proposed changes are significant or not, operators should contact their recognised verifier or evaluator.

To notify MPI of certain minor amendments to the RMP, use Notification Form AP50: Minor Update to Risk Management Programme Details.

(4) Amendments to RMP documents must be clearly identifiable. [RMP Spec 19]

Guidance

Options for identifying amendments to the documented procedures include use of italics, highlighting the amended text, or other electronic means, or by identifying the amended documents and/or section(s) in the amendment register.

The document control procedure may also allow for small changes to be made by hand. In such cases, the nominated person should sign and date the changes to indicate they are legitimate. This may occur at the time of annual review or more often as required.

(5) Electronic versions of RMP documents must be protected with an effective backup system. [RMP Spec 19]

Guidance

Operators may wish to keep electronic copies of the RMP off-site in case of major loss (such as an earthquake which prevents building re-entry).

19.3.3 Record Keeping

(1) All GOP and processing records must be kept in accordance with RMP Spec 20.

(2) Electronic records must be backed up and protected from corruption, damage or loss. [RMP Spec 20]

(3) The person entering the data ~~must~~ should be identified according to systems developed for the protection of electronic records.

(4) Records must:

a) accurately reflect the observations made;
b) facilitate verification;
c) if kept in hard copy, documented on permanent materials; and
d) be readily retrievable. [RMP Spec 20]

Guidance

Consideration should be given to the durability of paper on which records are kept (pen does not write well on wet paper), and its suitability for storage (thermal papers can fade over time). Pencil is not suitable for recording information because it is easy to erase or alter.

(5) Any alterations made to hard copy records should be made alongside the original entry and initialled by the person amending the record.

Guidance

The use of white out products (such as Twink™) is not acceptable to auditors as it is not possible to see what the original entry was.

(6) The manner in which the date and time are documented in the record should be appropriate to the activity being monitored.

Guidance

For some observations (e.g. process temperatures) the exact date and time should be recorded. However, for other observations (e.g. checking compliance with protective clothing requirements) a more general record over a specified time period may be acceptable.

19.4 Monitoring [APA section 17]

(1) The operator must regularly check ongoing compliance with documented procedures.

Guidance

The operator should check, at least annually, that all documented procedures are appropriate.

19.5 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) These records must include:

a) the monitoring carried out, problems identified and corrective action taken;
b) the list of documents comprising the RMP;
c) a record of RMP amendments.

Part 20: Supply and Reception of Fish and Shellfish

20.1 Purpose and Scope

To ensure that all edible seafood products received for processing is fit for its intended purpose and meets the regulatory requirements.

20.2 Mandatory Requirements

AP Reg 5 Animal material to be suitable for processing into animal product

(1) Animal material used for processing into animal product must be suitable for that purpose.

HC Spec 11.31 Supply of Fish

(1) Suppliers of fish, other than live fish, must ensure that they are:

a) subject to chilling or freezing from the time of catching or harvesting to the time of arrival at the processing premises; and
b) handled in a manner such that contamination and deterioration is minimised.

(2) Fish, other than bivalve molluscan shellfish, that is temporarily held prior to transfer to the primary processor, must be held on the vessel by the producer or the harvester of that fish or in an animal material depot that is listed for that purpose by MPI.

Guidance

Some markets may require specific country listings for animal material depots. For example, a depot must be EU listed if fish that is held in the depot is intended for export to the EU.

HC Spec 13.35 Reception of fish

(1) The operator must carry out an assessment to confirm that, from the time of catching to the time of arrival at the premises:

a) the fish has been subjected to chilling or freezing (unless they are live fish); and
b) the fish has been handled, held and transported so as to minimise deterioration and have been protected from contamination.

(2) If the fish has passed through an animal material depot, the operator must confirm that the depot is listed for that purpose with MPI.

(3) In the case of farmed fish (other than bivalve molluscan shellfish), the operator must not accept the fish for processing (except for initial storage) if:

a) the required supplier statement is absent or incomplete, unless:

i) the operator has a supplier guarantee programme and the supplier is a specified supplier within that programme; and
ii) the supplier has provided to the operator information in accordance with the supplier guarantee programme at least on a six monthly basis; and
iii) the animal material is of the type that is described in the supplier guarantee programme; or

b) the operator is aware of, or has received, information that would give reasonable grounds to suspect that the information in the supplier statement cannot be relied on.

(4) For farmed fish (other than bivalve molluscan shellfish) the operator:

a) must inform the recognised verifier within one working day if a situation described in clause 13.35(3)b) occurs; and
b) may, despite clauses 13.35(3)a) and b), hold the fish and give the supplier an opportunity to produce a completed or a replacement supplier statement that clarifies the status of the fish as suitable for processing to the satisfaction of the operator; and
c) must keep a copy of every supplier statement for a minimum of four years.

(5) Despite clauses 11.31 and 13.35(1), an operator may process fish that have been seized by a fisheries officer as defined in section 2 of the Fisheries Act 1996, subject to the operator:

a) obtaining written approval from the Director-General prior to the processing of the fish; and
b) complying with any conditions specified by the Director-General in the approval for the processing or labelling of the fish.

See Supplier statement for the supply of farmed fish for human consumption (other than bivalve molluscan shellfish)

HC Spec 14.14 Reception (BMS)

(1) The operator must only accept shellstock if the operator has confirmed that the shellstock complies with the specifications or requirements of the shellfish regulated control scheme and, in particular, must ensure that:

a) the shellfish harvesting statement details are correct and complete (subject to clause 14.14(2)); and
b) the containers are labelled correctly in accordance with the shellfish regulated control scheme; and
c) the containers are of appropriate hygienic status; and
d) the shellstock is alive and not damaged and the shells are reasonably free of mud, marine flora, bottom sediments and detritus, and not contaminated by material potentially hazardous to human health; and
e) the time-temperature control requirements in Schedule 4 of the Animal Products Notice: Regulated Control Scheme – Bivalve Molluscan Shellfish for Human Consumption have been complied with.

(2) If the statement (referred to in clause 14.14(1)a)) or labelling (referred to in clause 14.14(1)b)) is incomplete or missing, the shellstock may only be accepted into the premises if:

a) the shellstock is kept separate from other shellstock; and
b) an animal product officer is notified of the non-compliance within 24 hours of the arrival of the shellstock; and
c) the shellstock is detained under refrigerated storage until the animal product officer has determined the disposition of the shellstock.

(3) If shellstock has not been grown, harvested, handled and transported according to the requirements of the shellfish regulated control scheme, and the operator prohibits the shellstock from entering the premises, the operator must advise the animal product officer of that within 24 hours of imposing the prohibition.

Guidance

For detailed information on requirements for harvest declarations, refer to Part 11.8 of the Animal Products Notice: Regulated Control Scheme – Bivalve Molluscan Shellfish for Human Consumption.

Also see Part 13 Ingredients, Additives and Other Inputs for reception of other raw materials.

20.3 Procedures

20.3.1 Supply and Reception of Wild Fish

(1) The operator must document procedures for the reception of wild fish into the premises. The procedures must include checks to determine if the fish is fit for its intended purpose, and specify corrective actions to be taken when requirements are not met. [APA section 17, RMP Spec 11]

Guidance

Signs of spoilage in finfish may include:

- Skin/slime: dull gritty colours with yellow-brown dotting slime;
- Eyes: concave, opaque, sunken, discoloured;
- Gills: grey-brown or bleached, slime opaque yellow, thick of clotting;
- Odour: flesh odour amines, ammonia, milky lactic, sulphide, faecal, putrid, rancid. [CAC/RCP 52-2003 Code of Practice for Fish and Fishery Products]

If the assessment indicates spoilage or potential temperature abuse has occurred, such that the fish are not suitable for processing, the cause of the problem should be investigated and where appropriate, procedures implemented to prevent reoccurrence.

Rock Lobster

Rock lobster are known to accumulate Paralytic Shellfish Toxins (PSTs) in their gut during PST biotoxin events. The rock lobster industry has implemented a National Programme to manage this risk at the point of fishing. However, if lobsters are received from an area under warning due to PSTs and there remains a potential risk of PSTs, they need to be processed in accordance with section 21.3.3 Fish Processing (Other than Primary Processing of Bivalve Molluscan Shellfish).

(2) Fish processed on fishing vessels should be checked on landing on the fishing vessel or at the start of processing, for:

a) contamination with foreign matter that cannot be completely removed during processing;
b) contamination with chemicals (e.g. fuel oil, cleaning compounds, filth);
c) the presence of strong odours or other indications of microbiological spoilage; and
d) in the case of fish that must be alive before processing (e.g. rock lobsters), for signs that the fish is alive on arrival at the fishing vessel.

(3) Fish received at all other premises should comply with (2) and, in addition, be checked:

a) for evidence that the fish has been handled and transported in an appropriate manner (e.g. the presence of ice, temperature of the fish); and
b) that it has been appropriately labelled or identified to provide for adequate traceability, for example labelled to meet the guidance in Part 16, Table 8 Steps in the processing chain and examples of inventory and traceability records to be kept.

(4) Processors receiving fish species that are susceptible to histamine formation should have appropriate reception procedures in place for the reception and processing of those fish to ensure that histamine levels are minimised and must ensure that the regulatory limits are met.

Guidance

Marine species most susceptible to histamine formation are Scombridae, Clupeidae, Engraulidae, Coryphaenidae, Pomatomidae, and Scomberesocidae. Examples include tuna, kahawai, mackerel and kingfish.

The limit of 200mg/kg histamine is specified in the FSC for fish and fish products. Numerous documents are available to advise operators about GOP to ensure that this limit is not exceeded. These include:

- Histamine. A Guideline for the Seafood Industry. SSC, October 2013. Fish species that are susceptible to histamine formation are listed in section 5.0 of this guide.
- Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products, July 2012, Rome.
- Harvesting, Processing, Storage and Distribution of Fish and Fishery Products at Risk for Scombrotoxin (Histamine Formation). [CAC/RCP 52-2003 Code of Practice for Fish and Fishery Products]

The key control measure to minimise the potential for histamine formation is ensuring that the fish are harvested and held under chilled temperatures at all stages in the supply chain until (and if) a preservation step is applied that will inhibit or inactivate the histamine forming bacteria.

(5) Corrective actions to be taken if fish don't meet the reception requirements must be documented in the RMP. [APA section 17, RMP Spec 11]

20.3.2 Supply and Reception of Farmed Fish

(1) The operator must document procedures for the reception of farmed fish into the premises. [APA section 17, RMP Spec 11]

(2) The procedures should:

a) include the checks to be carried out to confirm that the requirements of the supplier statement (or supplier guarantee programme) have been met;
b) describe how the recognised verifier will be notified within one working day if there is any reason to suspect that the information in the supplier statement cannot be relied upon; and
c) include the checks to be carried out to determine if the fish is suitable for processing or fit for its intended purpose; and
d) specify the corrective actions to be taken when requirements are not met.

Guidance

The supplier statement or supplier guarantee programme addresses any treatments that the fish may have been subject to, maximum residue limits and/or maximum permissible limits, and fish handling.

Potential feed contaminants such as chemicals (including heavy metals, pesticides, herbicides, mycotoxins) and microbial contamination should also be considered. It is recommended that:

- guarantees are obtained from feed supplier(s) to confirm that the feeds are formulated as expected and meet agreed specifications;
- feeds are periodically checked to ensure compliance to agreed specifications;
- feeds are stored to prevent spoilage, mould growth and contamination, and used within any expiry dates; and
- systems are implemented to allow traceability of feed lots to seafood stock. [CAC/RCP 52-2003 Code of Practice for Fish and Fishery Products]

20.3.3 Reception of Bivalve Molluscan Shellfish

(1) The operator must document procedures for the reception of bivalve molluscan shellfish to determine that the bivalve molluscan shellfish/shellstock meets regulatory requirements. The procedures must include checks to determine if the bivalve molluscan shellfish is fit for its intended purpose, and specify corrective actions to be taken when requirements are not met. [APA section 17, RMP Spec 11]

Guidance

Once placed under temperature control, BMS should continue to be cooled on a downward trend towards

10°C.

20.3.4 Reception of Imported Fish

(1) Food importers must be registered under the Food Act 2014.

(2) Before receiving any imported fish, the operator should obtain sufficient information from their supplier to ensure the fish is suitable for processing or is fit for its intended purpose.

Guidance

Biosecurity and food safety risks associated with the importation of food into New Zealand are managed under the Biosecurity Act 1993 and the Food Act 2014. Food importers must meet relevant requirements of both Acts. This includes ensuring that imported food meets the relevant requirements of New Zealand food legislation, including the FSC. The following are key documents that food importers must comply with.

Import Health Standards. These standards are issued under the Biosecurity Act 1993. All imported food must meet biosecurity requirements specified in applicable Import Health Standards (IHS) to gain biosecurity clearance for entry into New Zealand.

Food Notice: Importing Food. This Notice is issued under the Food Act 2014 to manage risks to consumers. This Notice specifies which foods are of high regulatory interest (HRI) and those that are of increased regulatory interest (IRI). Consignments of imported food categorised as HRI or IRI require food safety clearance in addition to biosecurity clearance to be allowed entry into New Zealand. At the time of writing, the following fish were identified as HRI food:

- Fish species susceptible to production of histamine;
- Puffer fish;
- Chilled ready-to-eat smoked and smoked-flavoured fish;
- BMS and products containing BMS;
- Ready-to-eat crustacea.

The MPI website provides detailed information for importers, e.g. Guidance Document: Meeting requirements as a registered food importer.

Imported fish and other inputs are may have foods safety hazards that differ from those that are reasonably likely to occur in New Zealand. It is important that these hazards are not overlooked when applying the principles of HACCP.

If imported product is to be re-exported, additional export requirements may apply. For example, see OMAR 01-172.

(3) The operator must document procedures for the reception of imported fish. [APA section 17, RMP Spec 11]

(4) The procedures should specify:

a) the checks to be carried out to determine if the fish is suitable for processing or fit for its intended purpose;
b) the checks to be carried out to ensure that the requirements for imported products are met; and
c) the corrective actions to be taken when requirements are not met.

20.4 Monitoring [APA section 17]

(1) The operator must regularly check compliance with documented procedures.

Guidance

Every consignment should be checked on reception. The nature and extent of the monitoring will depend on the type(s) of product received.

20.5 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) These records must include monitoring carried out, problems identified and corrective action taken.

Guidance

Examples of other records that could be used to demonstrate compliance are:

- landing dockets;
- harvest declarations & tags;
- supplier statements;
- the certificates of analysis or supplier guarantees;
- growing area opening and closure notifications;
- reception / load-in check sheets;
- list of bivalve molluscan shellfish depots or animal material depots;
- list of bivalve molluscan shellfish sorting sheds;
- list of approved bivalve molluscan shellfish transporters;
- transport checks for incoming goods.

Refer to Part 19 for record keeping requirements.

Part 21: Fish Processing (Other than Primary Processing of Bivalve Molluscan Shellfish)

21.1 Purpose and Scope

To ensure that fish and fish product is processed in a manner that minimises its contamination and deterioration, and maintains its fitness for intended purpose.

This section applies to operators of land-based premises processing fish (including farmed fish) and to fishing vessels that process fish at sea and require risk management programmes.

In this section, **fish** means all finfish, crustaceans, echinoderms, and molluscs (squid, pāua) but not bivalve molluscan shellfish.

For further information about secondary processing e.g. heat treatment, smoking, drying, high pressure processing, refer to the Further Processing Guidance Document.

21.2 Mandatory Requirements

AP Reg 9 Animal material and product to be processed in manner that minimises contamination and deterioration

(1) All specified persons must ensure that animal material and animal product in their charge is processed in a manner that minimises the contamination or deterioration of the animal material or product.

HC Spec 5.3 Skills maintenance and supervision

(1) The operator must ensure that the skills of those persons involved in key tasks that could have significant impacts on the suitability for processing of animal material or the fitness for intended purpose of animal product, or who are required to carry out the activities listed in clause 5.2, are maintained on an ongoing basis.

(2) The operator must keep records demonstrating that skills identification, achievement and maintenance are being carried out effectively.

HC Spec 13.36 Handling and processing

(1) Handling and processing procedures must be carried out without unnecessary delay and in a manner that minimises the contamination and deterioration of the fish.

(2) Pāua, kina, crabs, rock lobsters and other species as notified by the Director-General, harvested from water likely to be contaminated with biotoxin, must be managed or processed in such a way as to minimise relevant risk factors.

HC Spec 13.37 Chilling and freezing

(1) Any chilling or freezing must be conducted without unnecessary delay and in a manner that minimises any potential microbial proliferation and contamination of the fish.

HC Spec 14.9 Process control

(1) If pre-programmed process control parameters are used to operate and control a process that is critical to product safety, unauthorised access to the programmed parameters must be prevented.

Guidance

There are requirements that must be met under the Animal Welfare Act. These can be viewed on the MPI website by searching on "animal welfare". For example, the Commercial Slaughter Code of Welfare (December 2016) Part 6, specifies requirements for farmed and wild captured finfish (including eels); and crabs, rock lobsters and fresh water crayfish.

21.3 Procedures

21.3.1 Live Fish

(1) Fish (e.g. lobsters, eels) should be alive at the time of packing and in a condition such, that under normal circumstances, they will remain alive during transport to their final destination.

(2) The outer surfaces of live fish, in particular pāua and whelks, should be reasonably free from dirt, weed and marine organisms.

(3) Live fish should be packed at a temperature sufficient to maintain the species in a live state during transport.

Guidance

If appropriate, cooling media should be added to the container to maintain the required conditions during transit.

(4) To avoid doubt, ice used in direct or indirect contact with fish:

a) must be produced from potable water or clean sea water; and [HC Spec 2.5]
b) must be produced, stored, handled and transported so as to prevent contamination and to retain potable water or clean sea water quality at point of use; and [HC Spec 2.5]
c) when delivered from another premises, should be inspected on arrival at the processing premises, and rejected if delivered in a manner that may have permitted contamination (e.g. from dust, chemicals, foreign matter) or if contamination is evident.

(5) Cooling media such as chilling or freezer packs must comply with HC Spec clause 7.2.

21.3.2 Heading, Gutting and Filleting

(1) Wet fish should be stored chilled or frozen unless they are to be processed immediately.

(2) Where relevant, the operator should establish temperature and/or time parameters to ensure that fish and fish product are processed without unnecessary delay.

Guidance

To ensure product is processed quickly, operators should implement maximum processing times for filleting or other processing steps, to minimise the time that fish are out of temperature controlled conditions. A good guide is for product to be out of temperature control for no longer than 2 hours and/or product not to exceed 7°C. When setting times and temperatures operators should consider the process flow, processing steps and species. Corrective actions should be documented to address situations where the times or temperatures are exceeded and the operator should monitor this at an appropriate frequency. If regular checks demonstrate good control, frequency may be reduced (e.g. to monthly).

(3) Processing operations such as gutting, skinning, tailing and filleting must be carried out in a manner that minimises contamination of the fish or fish product. When fish are washed after gutting, potable water or clean seawater must be used. [HC Spec 13.36]

(4) Eels or other fresh water species that are harvested from waterways that have public health warnings in place for biological or chemical hazards can be processed, but must be gutted or the hazard(s) managed in some other way. [HC Spec 13.36(2)].

21.3.3 Shucking and Gutting of Shellfish (other than BMS)

(1) Shellfish to be shucked must be:

a) alive and undamaged;
b) held in cool conditions; and
c) protected from the sun and wind prior to shucking. [HC spec 14.14]

(2) The shucking process should be separated from other processes (e.g. packing) by time, adequate space, or physical barriers.

(3) Shucked shellfish should be stored, chilled or frozen unless they are to be further processed immediately.

(4) Pāua or crab that are received from areas that are closed to the harvesting of BMS must be separated and identified for gutting and washing, or the hazard must be managed in some other way [HC Spec 13.36(2)].

(5) In addition to complying with the requirements in sections 21.3.3(1) to (4), gutted pāua should be washed in potable water or clean seawater immediately after gutting, and then drained. The exception to this is it is being sent as unwashed pāua for canning in New Zealand only.

Guidance

Separated pāua gut does not need to be washed.

If pāua is to be canned in a fish processing premises, washing may be carried out in that processing premises.

Current advice is that kina received from areas that are closed to the harvesting of shellfish should not be used for human consumption. To process kina for human consumption, the operator would need to have evidence that the biotoxins are controlled.

(6) Rock lobster received from areas that are closed to the harvesting of BMS due to a PST event, and where the risk of PST accumulation has not been assessed or is unknown, must be processed to manage any risk factors. [HC Spec 13.36]

Guidance

The Rock Lobster Industry has implemented a National Programme to manage the risk of PSTs in lobsters, which includes communication of event information to the RMP operators. Normally this will mean that if rock lobster is sourced from an area under warning or closure, it has been assessed and is low risk (or has been tested and is under the regulatory limit for paralytic shellfish poison (PSP) in shellfish). However, if there are situations where lobster is fished from areas under closure and it is identified that the PST risk is unknown, it can be either:

- identified to maintain traceability, held in tanks and tested for PSTs prior to exporting as a live product; or
- processed to remove the gut, i.e. tailed and only the tail sold for human consumption.

21.3.4 Thawing

(1) To minimise deterioration and contamination of the fish or fish product, the operator should establish and comply with process criteria for thawing fish (including air and water thawing).

Guidance

Thawing criteria should include product loading, air or water temperatures, water flow rate (if water thawing), time of thawing and temperature of the fish at the completion of thawing. Practical factors such as number of staff, the speed at which a species can be processed, and equipment failure should also be considered when establishing thawing process criteria.

Generally fish are thawed in water at a water temperature of 18°C, with a final product temperature of -1°C to 1°C. [Fish for Food, SITO 1998].

(2) Fish that have been thawed must be processed without unnecessary delay or must be held under chilled conditions. [HC Spec 13.36]

21.3.5 Tempering

Guidance

The principles of thawing also apply to tempering, with the restriction that the end point temperature remains colder than the freezing point of the product.

21.3.6 Dropped Product

(1) The operator should document and implement procedures for managing dropped product.

Guidance

Dropping of product should be considered unacceptable and every effort should be made to prevent it.

Dropped product procedures should be developed taking in account the nature of the situation, e.g. what has been dropped and where. In general, dropped product should be immediately picked up and its suitability for processing assessed. The product may be washed and/or trimmed, or disposed of. If it is to be processed it must be hygienically returned to the processing line. The staff member who carried out those tasks should complete an appropriate hygiene routine before recommencing processing.

Any product that is dropped in more highly contaminated areas (such as drains, high traffic areas or outside of processing areas) should be downgraded as not fit for human consumption. Decisions about whether product should be disposed of is to be based on food safety considerations rather than economics.

21.3.7 Specific hazards and control measures

21.3.7.1 Psychrotrophic Non-proteolytic *C. botulinum*

(1) When processing at risk fish (e.g. imported fish), the operator should carry out an assessment to determine whether *C. botulinum* is a hazard that is reasonably likely to occur and if so, implement measures to ensure that the product will be fit for its intended purpose.

Guidance

Psychrotrophic non-proteolytic *C. botulinum* is able to grow and produce toxins at temperatures as low as 3°C in the absence of oxygen. It is considered a hazard reasonably likely to occur in the MPI Hazard database and should be assessed as a potential hazard in chilled, vacuum packed or modified atmosphere packed products with a shelf life of 10 days or more that are stored above 3°C. If non-proteolytic *C. botulinum* is identified as a hazard, growth and toxin formation can be prevented using a range of control measures including packaging and atmosphere, storage temperature, pH, salt or water activity. See Table 10 for details of those control measures and a comparison with controls for *L. monocytogenes*).

Table 10: Controls measure for non-proteolytic *C. botulinum* and *L. monocytogenes*.

Parameter	Non-proteolytic (psychrotrophic) *C. botulinum*	*L. monocytogenes*
An equilibrated pH throughout the food	pH 5 or less (In addition to chilled storage)	pH 4.4 or less
Minimum salt content throughout all parts of the product	3.5% in the aqueous phase (In addition to chilled storage)	More than 6% in the aqueous phase[10]
Water activity (a_w) in all components of the product	0.97 or less	0.92 or less
Minimum temperature for growth	3°C	-1.5°C
Heat treatment at the slowest heating point in the food	90°C for 10 minutes or equivalent lethality (which will provide a 6 log reduction on the spore concentration). (In addition to chilled storage)	72°C for 66 seconds[11, 12]. (In addition to chilled storage)

Further guidance on the processing of Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish can be seen in CODEX STAN 311-2013.

21.3.7.2 Parasites

(1) Processors of fish species that are susceptible to the presence of parasites should have procedures in place for their management.

Guidance

Species such as barracouta, jack mackerel, red cod and ling are more susceptible to parasites, especially worms. Anisakis is identified as a biological hazard in the hazard database.

The procedures should include quick and hygienic gut removal, visual examination, and training for staff undertaking filleting to minimise the presence of parasites. Adequate lighting should be available to assist in the visual inspection. (Also see section 3.4.11). As parasites die during freezing, parasites are considered a wholesomeness issue in frozen product rather than a food safety concern. Most people also cook the fillets mitigating the risk further. The freezing process encourages some parasites to come to the surface which means a fillet may look clean during filleting but have parasites visible on the surface once frozen.

If freezing is used as a control measure, its effectiveness depends on a number of variables e.g. the freezing temperature, freezing time, the time the fish is held frozen, the species and source of fish, and the type of parasite. Flukes are more resistant to freezing than tapeworms and roundworms. The following times and temperatures are sufficient to kill **all** parasites (unless the fish are particularly large e.g. thicker than 15 cm):

- -20°C or below for 7 days (total time); or
- -35°C or below until frozen solid and storing at -35°C or below for 15 hours; or

[10] FDA (2001) Processing Parameters Needed to Control Pathogens in Cold-Smoked fish.
[11] These are the default cooking parameters for seafood product. Refer to the Further Processing Guidance Document, Chapter 2, Section 1 for further heat treatment parameters for specific seafood products.
12 New Zealand Institute for Crop and Food Research Limited (1998). Guidelines for the Safe Preparation of Hot-smoked Seafood in New Zealand.

- -35°C or below until solid and storing at -20°C or below for 24 hours.

Refer to the FDA Fish and Fishery Products Hazards and Controls Guidance (Chapter 5) for more information.

Freezing at -18°C for 24 hours is an effective control measure for Anisakis. [Generic Models for the Processing of Seafood Product, MPI July 2011].

21.3.7.3 Carbon Monoxide

(1) The FSC prohibits the use of carbon monoxide in the processing of fish (other than carbon monoxide that is naturally present or occurring in smoke) if its use results in a change or fixes the colour of the flesh of the fish. This applies to both its use as a:

a) processing aid, under standard 1.3.3, where its use is prohibited; and
b) food additive, under standard 1.3.1, where there is no permission for use.

Guidance

Use of carbon monoxide for colour preservation occurs typically in species where red colour is important. It is of particular concern in relation to histamine poisoning, as it can make inferior quality fish look fresher or mask the decomposition, which would otherwise warn against consumption.

21.3.7.4 Histamine

(1) Processors of fish species that are susceptible to histamine formation should have procedures in place to ensure that increases in histamine levels are minimised.

Guidance

In most cases GOP should be sufficient to manage histamine formation. However operators processing histamine fish species should review their procedures to confirm that the controls are effective. Also see section 20.3.1 for supply and reception requirements.

21.3.7.5 Polycyclic Aromatic Hydrocarbons (PAH)

(1) Smoking of fish should be carried out in a manner that minimises the formation of polycyclic aromatic hydrocarbons (PAH).

Guidance

This can be achieved by following the Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH from smoking and Direct Drying Processes (CAC/RCP 68-2009). Also see the Smoking Part of the Further Processing Guidance Document on the MPI website.

21.4 Monitoring [APA section 17]

(1) The operator must regularly check ongoing compliance to documented procedures.

Guidance

The frequency and type of monitoring will depend on the nature of the operation and the degree of risk if hazards are uncontrolled. Monitoring options include daily checks during processing to confirm that operations are carried out according to documented procedures.

21.5 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) These records must include monitoring carried out, problems identified and corrective action taken.

Guidance

Examples of other records that could be used to demonstrate compliance are:

- processing records, including thawing records;
- daily checks;
- CCP records.

Refer to Part 19 for record keeping requirements.

Part 22: Bivalve Molluscan Shellfish Processing

22.1 Purpose and Scope

To ensure that bivalve molluscan shellfish are processed in a manner that minimises contamination and deterioration, and maintains their fitness for intended purpose. This section covers only primary processing of bivalve molluscan shellfish. Heat shocking is considered primary processing. Refer to Part 21 for secondary processing.

22.2 Mandatory Requirements

The mandatory requirements for primary processing of bivalve molluscan are extensive and detailed and so are referenced in this section rather than quoted in full as occurs in other Parts. In addition, since the detailed mandatory requirements cover most aspects of primary processing of bivalve molluscan shellfish, few documented procedures are needed in this Part.

Operators must ensure that they study all relevant clauses of the HC Spec (listed below) and comply with their requirements.

22.2.1 Wet Storage

HC Spec 14.17 General requirements

HC Spec 17.18 Wet storage process water supply

HC Spec 17.19 Treatment of water for wet storage

HC Spec 14.20 Continuous flow through wet storage system

HC Spec 14.21 Recirculating water wet storage system

HC Spec 14.29 Minimum requirements of depuration/wet storage operation

HC Spec 14.34 Alternative means

22.2.2 Depuration

HC Spec 5.2(3) – Competency of depuration supervisor

HC Spec 14.22 Depuration

HC Spec 14.23 Depuration process water: seawater supply

HC Spec 14.24– Depuration process water: water standards

HC Spec 14.25 Shellfish storage

HC Spec 14.26 Depuration unit: Loading and unloading

HC Spec 14.27 Cleaning and sanitising plan and equipment

HC Spec 14.28 Depuration process operator verification

HC Spec 14.29 Minimum requirements of depuration/wet storage operation

HC Spec 14.30 Alternative means

22.2.3 Shucking, Processing and Packing

HC Spec 14.9 Process control

HC Spec 14.15 Raw harvested bivalve molluscan shellfish

HC Spec 14.16 Processing bivalve molluscan shellfish

HC Spec 14.31 Shucking, processing and packing

22.2.4 Heat Shocking

HC Spec 14.32 Heat shocking

22.2.5 Repacking and Labelling

HC Spec 14.33 Repacking

HC Spec 14.34 Bivalve molluscan shellfish labelling

22.3 Procedures

(1) During packing, processing and shucking, shellfish must be handled so that they are not subject to contamination, or unacceptable increases in temperature and/or bacterial levels. [HC Spec 14.31]

(2) When shellfish are processed in a room or area where other fish processing operations are performed, the operator should take adequate measures to minimise contamination of the shellfish by the other operations (e.g. by splash, personnel, dual use of appliances) or from any other source.

(3) Shellfish should be stored off the floor and protected from contamination from floor water, splash water or foot traffic.

(4) Shucking and packing operations should be carried out in separate rooms or in areas that are physically separated to ensure effective control of any potential contamination from either operation to the other.

(5) Surfaces that come in contact with shucked shellfish (including containers) should be protected from contamination e.g. from product handlers or their clothing, or splash liquid.

(6) Shucked shellfish containers should be completely emptied in the packing area and must be cleaned before they are returned to the shucking area.

(7) Shucked shellfish must be packed in clean containers made from safe materials. [AP Reg 9]

(8) Returnable containers may only be used for interplant shipment of shucked shellfish and should be sealed during such transport. On receipt of shellfish in returnable containers the operator should repack the shellfish into single-use containers.

(9) Containers of shucked shellfish should be closed promptly after filling.

(10) Skimmer tables and other packing equipment should be located so that they are not contaminated by drainage from the delivery window or from shucking room equipment and utensils.

(11) Shucked shellfish must only be packed into containers labelled in accordance with Part 17.

(12) Ice used in direct or indirect contact with shellstock or shucked shellfish:

a) should be manufactured in a premises operating under a RMP, or a business registered under the Food Act 2014;
b) must be of potable water quality; [HC Spec 2.5]
c) must be manufactured, stored, handled and transported so as to prevent contamination; and [AP Reg 9]
d) when delivered from another premises, inspected on arrival at the processing premises, and rejected if delivered in a manner that may have permitted contamination (e.g. from dust, chemicals, foreign matter) or if contamination is evident.

(13) Staff and other persons who move from areas of a lower hygienic status to a higher hygienic status must take adequate measures to minimise contamination of product. [AP Reg 9]

Guidance

Hygiene routines for staff and other persons moving between areas of different hygiene status will depend on the degree of risk of contamination. Operators should consider the need for:

- hand washing;
- changing or cleaning/sanitising of outer protective clothing (aprons); and
- cleaning/sanitising of footwear.

For more detailed guidance about how to manage separation between areas of different hygiene status see the *Listeria* Guide Part 2: Good Operating Practice.

(14) Operators who heat shock shellfish must develop a heat shock process that meets HC Spec 14.32.

(15) The heat shock process should not result in an increase in microbiological levels in the shellfish.

Guidance

For information on shellfish labelling see Part 17 Labelling.

22.4 Monitoring [APA section 17]

(1) The operator must regularly check ongoing compliance to documented procedures.

Guidance

The frequency and type of monitoring will depend on the nature of the operation and the degree of risk if hazards are uncontrolled. Monitoring options include daily checks during processing to confirm that operations are carried out according to documented procedures.

22.5 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) These records must include monitoring carried out, problems identified and corrective action taken.

Guidance

Examples of other records that could be used to demonstrate compliance are:

- information necessary to trace shellfish back to their growing area source;
- harvest, landing and processing records;
- daily checks;
- processing records.

Refer to Part 19 for record keeping requirements.

Part 23: Refrigeration and Storage

23.1 Purpose and Scope

To ensure that all seafood product is refrigerated and stored under appropriate conditions so that it remains fit for its intended purpose.

23.2 Mandatory Requirements

HC Spec 13.37 Chilling and freezing

(1) Any chilling or freezing must be conducted without unnecessary delay and in a manner that minimises any potential microbial proliferation and contamination of the fish.

(2) Fish (other than live fish) that are preserved primarily by refrigeration must be reduced to the maximum chilled or frozen temperature, validated at the thermal centre of the animal material or product, as specified in HC Spec Table 7, prior to release from any primary processing premises.

HC Spec Table 7: Maximum Critical Preservation (Loadout) Temperatures

Product type	Chilling / Freezing temperature
Shucked pāua intended for canning in New Zealand	6°C
Chilled whole fish	-1°C to 1°C
Chilled fish product	-1°C to 4°C
Frozen fish or fish product (including shellfish)	-18°C
Brine frozen fish	9°C

(3) HC Spec Clause 13.37(2) does not apply if the further processing or transportation of the animal material or animal product is documented in a registered risk management programme or approved food safety programme under the Food Act 1981 or a food control plan under the Food Act 2014, so that the relevant risk factors are managed.

(4) If the documentation as described as HC Spec clause 13.37(3) forms part of another risk management programme or a food safety programme or a food control plan, the consigning operator must ensure that:

a) the operator of the receiving programme is identified in the consigning operator's risk management programme; and
b) there is no gap in the process documentation as the animal material or animal product is transferred between programmes or plans; and
c) all relevant programmes or plans are registered or approved as appropriate prior to the commencement of the operation.

(5) A brief temperature fluctuation up to a maximum temperature of -15°C during transportation is permitted for frozen fish or fish product (including shellfish). The temperature must be reduced to a temperature of -18°C or colder without unnecessary delay

(6) Shucked pāua must not be held at greater than 1°C for more than three days.

HC Spec 14.31 Shucking, processing, and packing clauses (7)-(10)

(7) The temperature of chilled shucked shellfish must be reduced to 4°C or less prior to leaving the premises and the temperature must be maintained during transport and storage.

(8) The temperature of chilled live shellfish must be reduced to 10°C or less prior to leaving the premises and the temperature must be maintained during transport and storage.

(9) Despite HC Spec clause 14.31(8), chilled live shellfish may leave the premises when the temperature is greater than 10°C if they are stored at the originating premises for less than 12 hours and are maintained under temperature control at all times while in that premises.

(10) Shellfish that are to be frozen must be arranged to ensure rapid freezing and must be frozen at a temperature of -18°C or colder, with shellfish frozen solid within 12 hours from the start of the freezing process.

Guidance

Frozen solid is generally taken to mean that the product temperature is -10°C or colder.

Good practice would be to ensure that product is at least - 4°C or colder on exiting the blast freezer, and reaches -10°C or colder within 12 hours from the start of freezing.

23.3 Procedures

(1) The operator should have refrigeration facilities that are capable of achieving the outcomes listed below (as appropriate to the processing carried out at the premises):

a) rapid chilling of whole fish received at the premises to a temperature between -1°C and 1°C and holding the chilled fish within this temperature range;
b) rapid chilling of processed fish and fish products produced on the premises to a temperature between -1°C and 4°C and holding the fish and fish products within this temperature range;
c) rapid freezing of fish and fish products produced on the premises to -18°C or colder; and
d) rapid freezing of brine frozen fish produced on the premises to -9°C or colder; and
e) maintaining frozen fish and fish products produced or stored on the premises at -18°C or colder.

Guidance

Chillers may also be used for tempering product and for short term storage during processing. In such cases, there is no requirement to hold the product at 1°C.

Only brine frozen fish that is intended for canning can be exported to the EU.

Also see Part 20 for guidance on histamine controls.

(2) Equipment used to control temperatures and other parameters (e.g. airflow) within the refrigeration facilities should be operating at all times while refrigeration facilities are in use.

Guidance

Continuous monitoring of refrigeration temperatures and other relevant parameters is recommended. If this is not possible, temperatures should be monitored periodically and at a frequency based on performance. (Also see Part 3).

If exporting, operators must use CATRs to continuously monitor temperatures in refrigeration facilities.

(3) Condensation drip on to seafood products or equipment should be minimised.

(4) Products that may taint or contaminate other seafood products should be kept separately, or be prevented, by other effective means, from contaminating seafood products.

Guidance

Seafood products may be stored with other foods, provided the other foods are adequately enclosed in containers and handled in such a way that the seafood products is not contaminated.

(5) Seafood products that are intended for use as bait or for animal consumption should be stored separately from seafood products intended for human consumption, unless measures are put in place to minimise contamination.

(6) Packed products, raw materials, packaging and other materials should be stored off the floor (e.g. on clean pallets).

23.4 Monitoring [APA section 17]

(1) The operator must regularly check ongoing compliance to documented procedures.

Guidance

The frequency and type of monitoring will depend on the nature of the operation and the degree of risk if hazards are uncontrolled. Monitoring options include:

- daily checks of refrigerated products and storage areas to confirm that storage temperatures are met;
- checks of all storage areas to confirm that products are stored to minimise contamination.

23.5 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) These records must include monitoring carried out, problems identified and corrective action taken.

Guidance

Records could include:

- temperature monitoring and corrective action records;
- inventories.

Refer to Part 19 for record keeping requirements.

Part 24: Products for Animal Consumption

24.1 Purpose and Scope

To ensure that products for animal consumption derived from seafood products processing are managed to minimise contamination of products for human consumption and to ensure that the products are fit for their intended purpose.

This Part does not include requirements under the Animal Products Notice: Specifications for Products intended for Animal Consumption.

Guidance

Some material resulting from the processing of seafood products product for human consumption may be sold as bait. Under the APA, bait is not considered to be material for animal consumption. Bait is often treated as product for human consumption up until the point of labelling. For example an operator may process fish heads under their RMP with 10% of these labelled and sold for human consumption, while the remainder, which have gone through identical processing, are deemed bait and labelled as inedible.

Despite being destined for inedible use, bait should be handled and processed in a hygienic manner with as little delay as possible to prevent spoilage.

24.2 Mandatory Requirements

HC Spec 3.2 Management of animal material or animal product not for human consumption

(1) Equipment and storage areas used to store or contain animal material that is not suitable for processing or animal product that is not fit for human consumption but is suitable or fit for some other purpose must:

a) be clearly identified; and
b) not be a source of contamination to other animal material or animal product that is intended for human consumption.

(2) Animal material or animal product that is not suitable for processing or not fit for human consumption but is suitable or fit for some other purpose, must be kept under controlled conditions until it is adequately identified in a manner that will ensure that it will not be mistakenly or fraudulently released as suitable for processing or fit for human consumption.

24.3 Procedures

(1) The operator:

a) should establish criteria for deciding which materials are to be classified as products for animal consumption; and
b) must document procedures to control the handling, storage and disposal of such materials. [APA section 17, RMP Spec 11]

(2) All seafood products destined for animal consumption must be handled and maintained so that it is suitable for further processing or fit for its intended purpose. [AP Reg 9]

Guidance

Material that is to be transferred to a fishmeal plant should not be spoilt to such an extent that it becomes

unfit for animal consumption.

(3) Equipment used to handle, contain or store seafood products for animal consumption must be clearly identified (e.g. by labelling, colour coding), except as allowed under section 9.3.2(2) and (3). [HC Spec 3.2]

(4) Bins with drainage holes should not be used for storing seafood products for animal consumption unless the bins are located close to a drain, to minimise any contamination of seafood products for human consumption or product contact surfaces.

Guidance

Contamination can be caused by the splash from bins onto seafood products for human consumption or product contact surfaces.

24.4 Monitoring [APA section 17]

(1) The operator must regularly check compliance to documented procedures.

Guidance

The frequency and type of monitoring will depend on the nature of the operation and the degree of risk if hazards are uncontrolled. Monitoring options include daily checks to ensure that procedures for identifying and managing products intended for animal consumption are carried out correctly.

24.5 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) The records must include monitoring carried out, problems identified and corrective action taken.

Guidance

Inventory records could be used to demonstrate compliance.

Refer to Part 19 for record keeping requirements.

Part 25: Load out and Transport

25.1 Purpose and Scope

To ensure all seafood product is transported in a manner that minimises contamination and ensures that it is fit for its intended purpose.

25.2 Sources of Hazards

Source	Examples of hazards
Transportation units & loading equipment	Bacterial pathogens (e.g. *E. coli* spp., *Salmonella* spp., *Listeria* spp.) Chemical pollutants (e.g. oil, grease, dust) Physical objects (e.g. metal, plastic)
Personnel	Bacterial pathogens (e.g. *E. coli* spp., *Salmonella* spp., *Staphylococcus aureus*)
Other materials transported in the same vehicle	Bacterial pathogens (e.g. *E. coli* spp., *Salmonella* spp., *Listeria* spp.)

25.3 Mandatory Requirements

AP Reg 17 Carriage and delivery requirements for animal material and product

All persons engaged in the carriage and delivery of animal material or animal product must as far as practicable ensure that the means of carriage and delivery are designed, made, maintained, and operated to minimise contamination or deterioration of animal material or animal product.

HC Spec 16.1 Application of this Part

(1) This Part applies to transport operators who are transporting animal material during primary processing, or animal product between premises or places operating under risk management programmes, but does not apply to transport operators transporting live animals to primary processors.

HC Spec 16.2 Design and construction

(1) Transportation units and loading equipment must be designed, constructed, equipped and operated to maintain the status of animal material as suitable for processing and animal product as fit for intended purpose and to minimise hazards and other risk factors.

(2) Transportation units must be constructed from materials that will maintain animal material as suitable for processing and animal product as fit for intended purpose.

(3) If a transportation unit provides the means by which animal material or product is refrigerated, the unit must be designed, constructed and equipped to ensure that the specified temperatures are achieved and maintained throughout transportation.

(4) Temperature-measuring devices used to measure critical temperatures must be calibrated and located to measure the internal temperature of a transportation unit at the warmest point.

HC Spec 16.3 Hygiene and maintenance

(1) The hygiene and maintenance of transportation units and loading equipment must be such that the contamination and deterioration of animal material and product are minimised.

(2) The hygiene and behaviour of persons involved in the transportation of animal material and product must be such that the contamination and deterioration of animal material and product from this source are minimised.

(3) The transport operator must take reasonable measures to ensure that exposed animal material and product are not handled by any person who is:

a) confirmed as or suspected of suffering from or being a carrier of a disease as described in section A, Part 1 of Schedule 1 of the Health Act 1956 that is likely to be transmitted through animal material, animal product or associated things; or
b) confirmed as or suspected of suffering from or being a carrier of another disease or condition of public health concern, including verocytotoxin-producing or shiga-toxin-producing *Escherichia coli*, that is likely to be transmitted through animal material, animal product or associated things; or
c) suffering from boils, sores, infected wounds, or any other condition that cannot be adequately prevented from becoming a source of contamination.

HC Spec 16.4 Operation

(1) Animal material or product that is conveyed together with any other animal material or product or any other thing that may be a source of contamination must be adequately separated from the source of contamination unless adequately protected in a manner that prevents cross-contamination.

(2) Evidence of the maintenance of the preservation temperature (if required) during transportation must be available for verification to ensure that the suitability for processing of the animal material or the fitness for intended purpose of the animal product is maintained.

(3) The determination of animal material or product temperature and the taking of any samples must be carried out in such a manner that contamination of that animal material or product is minimised.

(4) Refrigerated animal material or product must not be accepted from the primary processor for transportation until the preservation temperature has been met as specified in either:

a) the Act, the Food Act 1981 or the Food Act 2014; or
b) the registered risk management programme.

(5) The transport operator must have a documented contingency plan to deal with any failure to maintain preservation temperatures during transportation that may affect the suitability for processing of the animal material or the fitness for intended purpose of the animal product, including:

a) immediate notification to the person who has responsibility for the animal material or product; and
b) actions to prevent recurrence.

(6) The transport operator must ensure that persons transporting animal material or product are aware of the relevant specifications and are adequately trained.

HC Spec 16.5 Records

(1) The transport operator must comply with the records requirements of HC Spec clause 9.2(2)

HC Spec 14.31 Shucking, processing, and packing (clause 7-9)

(7) The temperature of chilled shucked shellfish must be reduced to 4°C or less prior to leaving the premises and the temperature must be maintained during transport and storage.

(8) The temperature of chilled live shellfish must be reduced to 10°C or less prior to leaving the premises and the temperature must be maintained during transport and storage.

(9) Despite HC Spec clause 14.31(8), chilled live shellfish may leave the premises when the temperature is greater than 10°C if they are stored at the originating premises for less than 12 hours and are maintained under temperature control at all times while in that premises

HC Spec 13.37 Chilling and freezing (clause 5)

(5) A brief temperature fluctuation up to a maximum temperature of -15°C during transportation is permitted for frozen fish or fish product (including shellfish). The temperature must be reduced to a temperature of -18°C or colder without unnecessary delay.

Guidance

This specification allows for minor temperature changes during loading and unloading, short distance trips (e.g. processing premises to a neighbouring cold store) or unforeseen situations (e.g. mechanical breakdown), when a brief temperature increase in the seafood products may occur.

Operators need to ensure that the loadout checks required by clauses 2.1 and 2.2 of the Official Assurances Specs are undertaken for export product.

25.4 Procedures

25.4.1 Transport Included in Operator's RMP

(1) RMP operators who use their own vehicles for the transport of seafood products within the scope of their RMP are responsible for complying with the relevant requirements of the HC Spec.

(2) Procedures for cleaning vehicles and containers used by the operator to transport seafood products must be documented in the RMP. See Part 7 Cleaning and Sanitation. [APA section 17, RMP Spec 11]

(3) The operator must ensure that, before loading, the vehicle or shipping container used to transport seafood products is clean and free from odours, chemicals or other residues. [HC Spec 16.3(1)]

25.4.2 Transport NOT Included in Operator's RMP

(1) Transport operators who provide vehicles for the transport of seafood products under contract to RMP operators are responsible for complying with the relevant requirements of HC Spec.

(2) RMP operators should ensure that contracted vehicles used for the transport of seafood products are in a suitable condition to minimise product contamination.

(3) Where vehicle and container cleaning is the responsibility of the contracted transporter, the RMP operator should verify the state of cleanliness of each vehicle and of all containers prior to their use. The RMP should have documented procedures describing how the assessment is carried out and the actions to be taken if the unit is not up to the required standard.

Guidance

Operators should provide advice to staff on how to manage situations where they are confronted with a dirty vehicle or container. This should include advice on how to ensure that the vehicle or container is cleaned or sanitised as necessary, at an appropriate site.

25.4.3 Transport of Fish to Primary Processor

(1) Live fish (other than molluscan bivalve shellfish), and pāua that are intended for canning in New Zealand, should be transported in cool conditions and protected from sun and wind, so that they are alive and undamaged on arrival at the processing premises.

(2) All other fish must be:

a) subjected to chilling or freezing from the time of catching to the time of arrival at the fish premises; and
b) transported in clean containers and in a manner that minimises contamination. [HC Spec 13.35]

25.4.4 Transport of Bivalve Molluscan Shellfish to Primary Processor

(1) For requirements for transport of bivalve molluscan shellfish from harvest to receipt at the primary processor, refer to Part 13 of the Animal Products Notice: Regulated Control Scheme – Bivalve Molluscan Shellfish for Human Consumption.

Guidance

Operators who transport seafood products destined for export must also meet relevant export criteria. For further information see the Export Clearance information on the MPI website.

25.5 Monitoring [APA section 17]

(1) The operator must regularly check ongoing compliance to documented procedures.

Guidance

The frequency and type of monitoring will depend on the nature of the operation and the degree of risk if hazards are uncontrolled. Monitoring options include:

- checks of transport vehicles to confirm they are in a condition that minimises contamination of the seafood products;
- temperature checks on refrigerated vehicles.

25.6 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures. [HC Spec 16.5]

(2) The records must include monitoring carried out, problems identified and corrective action taken.

(3) Operators need records to demonstrate compliance with the loadout temperature requirements of HC spec 13.37(2).

Guidance

Examples of other records that could be used to demonstrate compliance are:

- load-in and load-out checks;
- container / vehicle checks;
- daily/weekly checks;
- cleaning checks;
- CATR checks;
- calibration records.

Refer to Part 19 for record keeping requirements.

Part 26: Handling, Disposition and Recall of Non-complying Products

26.1 Purpose and Scope

To ensure a system is in place for the handling, disposition and recall from distribution or sale, of seafood products that is not fit for intended purpose.

26.2 Mandatory Requirements

RMP Spec 13 Notifications

(1) 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.

(2) 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 risk management programme is no longer considered to be effective:

RMP Spec 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.

HC Spec 3.2 Management of animal material and animal product not for human consumption

(3) Animal material or animal product that is not suitable for processing or not fit for human consumption but is suitable or fit for some other purpose, must be kept under controlled conditions until it is adequately identified in a manner that will ensure that it will not be mistakenly or fraudulently released as suitable for processing or fit for human consumption.

HC Spec 3.3 Waste Management (clause 4)

(4) Waste must be disposed of by a method that ensures that it will not become a source of contamination to other animal material or animal product.

26.3 Procedures

(1) Non-complying (e.g. damaged, spoiled, deteriorated or contaminated) products must be handled and stored in a manner that prevents contamination and deterioration of other products, and contamination of the storage environment. They must be:

a) clearly identified and segregated from other products;
b) assessed by a suitably skilled person for appropriate method of disposition; and
c) included in the inventory (not available for load out).

(2) Operators must designate a person to take overall responsibility for any recall of seafood products and allocate recall tasks to appropriately skilled people.

Guidance

The person with overall responsibility for a recall may be the Day-to-day Manager of the RMP or a person at a senior level of responsibility within the operation.

It is important the operator is well prepared to deal with a recall event. It is often the case that key people are not available just when they are needed. The procedures and contacts need to be up-to-date and robust, and sufficient staff should be trained.

For more detailed information on establishing and implementing recall procedures, and carrying out mock recalls, refer to the following:

- Recalls section of the RMP Manual;
- MPI's Recall Guidance Material.

If exporting, you are required to notify the D-G as soon as possible, and no later than 24 hours after certain export non-conformance events (or first knowledge of the event). For more information see Export non-conformance on the MPI website.

(3) The recall procedure should be periodically tested by carrying out a traceability and recall exercise, sometimes referred to as a "mock recall".

Guidance

The procedure for carrying out a mock recall should be included in the recall procedure. It is recommended that a mock recall be carried out annually or more frequently if appropriate and the effectiveness of the procedure reviewed based on findings from the exercise.

(4) After a recall, the recall procedure should be reviewed and, if necessary, updated.

26.4 Monitoring [APA section 17]

(1) The operator must regularly check ongoing compliance with documented procedures.

26.5 Records [APA section 17, RMP Spec 20]

(1) The operator must keep relevant records demonstrating compliance with documented procedures.

(2) The records must include monitoring carried out, problems identified and corrective action taken.

Guidance

Examples of other records that could be used to demonstrate compliance are:

- inventory records;
- records of assessment and disposition of non-complying product;
- incident reports;
- recall records, including mock recall records.

Refer to Part 19 for record keeping requirements.

Part 27: Management of *Listeria monocytogenes* in Ready-To-Eat (RTE) Seafood Products

27.1 Purpose and Scope

(1) This Part describes how to meet the requirements for managing *Listeria monocytogenes* (*L. monocytogenes*) in RTE seafood as required by:

a) Standard 1.6.1 of the FSC; and
b) Part 15 of the HC spec.

(2) Frozen product is not subject to the requirements for *Listeria* management in the HC Spec. However, if frozen RTE product, or frozen heat shocked BMS is to be exported, it must meet the requirements in this Part.

(3) Alternative approaches maybe used provided the mandatory requirements are met. Where this occurs the alternative approach will need to consistently result in products that are fit for their intended purpose.

27.2 Mandatory Requirements

FSC Standard 1.6.1

Ready-to-eat food in which growth of *Listeria monocytogenes* can occur
Listeria monocytogenes n =5 c = 0 m = not detected in 25g

Ready-to-eat food in which growth of *Listeria monocytogenes* will not occur
Listeria monocytogenes n = 5 c = 0 m = 10^2cfu/g

1.6.1—4 Food in which growth of *Listeria* monocytogenes will not occur

(1) For the purposes of the table to section S27—4, growth of *Listeria monocytogenes* will not occur in a ready-to-eat food if:

a) the food has a pH less than 4.4 regardless of water activity; or
b) the food has a water activity less than 0.92 regardless of pH; or
c) the food has a pH less than 5.0 in combination with a water activity of less than 0.94; or
d) the food has a refrigerated shelf life no greater than 5 days; or
e) the food is frozen (including foods consumed frozen and those intended to be thawed immediately before consumption); or
f) it can be validated that the level of *Listeria monocytogenes* will not increase by greater than 0.5 log cfu/g over the food's stated shelf life.

(2) For the purposes of the table to section S27—4, a ready-to-eat food that does not receive a listericidal process during manufacture is taken to be a food in which growth of *Listeria monocytogenes* will not occur if the level of *Listeria monocytogenes* will not exceed 100 cfu/g within the food's expected shelf life.

(3) For the purposes of subclause (2), a ready-to-eat food that does not receive a listericidal process during manufacture is taken to include:

a) ready-to-eat processed finfish; and
b) fresh cut and packaged horticultural produce.

HC Spec Part 15: *Listeria* requirements for processors of certain ready-to-eat animal products

ready-to-eat animal product means, for the purpose of Part 15, a chilled animal product that is ordinarily consumed in the same state as that in which it is sold or distributed and will not be subject to a listericidal process before consumption.

HC Spec 15.2 Application of this Part

(1) This Part applies to risk management programme operators who are processing ready-to-eat animal product for human consumption.

(2) This Part does not apply to risk management programme operators who are processing ready-to-eat animal product, where that product:

a) is raw animal product; or
b) is live bivalve molluscan shellfish; or
c) receives a listericidal process after being sealed in the final packaging where that packaging ensures the prevention of recontamination until opened by the consumer or until the packaging is otherwise compromised; or
d) is subject to aseptic processing and packaging; or
e) contains a listericidal component that ensures the rapid inactivation of *Listeria monocytogenes* if re-contaminated.

(3) HC Spec Clause 15.3(2)f) (product testing programme) does not apply to risk management programme operators processing ready-to-eat animal product that has:

a) a shelf life of five days or fewer; or
b) a pH of less than 4.4; or
c) a water activity (aw) of less than 0.92; or
d) a combination of pH less than 5 and water activity (aw) less than 0.94; or
e) been validated that the level of *Listeria monocytogenes* will not increase by more than 0.5 log cfu/g over the products stated shelf life.

(4) The Director-General may exempt certain ready-to-eat animal product from all or part of this Part if an analysis of the product and process demonstrates to the Director-General that the management of *Listeria* as required by this Part is not appropriate.

(5) Any exemptions given by the Director-General under HC Spec clause 15.3(5) must be given in writing.

HC Spec 15.3 Procedures for *Listeria* management

(1) An operator processing animal product to which this Part applies must review, document and implement procedures in the risk management programme for the management and control of *Listeria monocytogenes* in the premises.

(2) The documented procedures must include:

a) the name(s) and position(s) of the person(s) responsible for developing and implementing the procedures for *Listeria monocytogenes* management; and
b) a description of the product covered by the *Listeria monocytogenes* management procedures; and
c) a description of the transmission routes for *Listeria monocytogenes* into and within the processing areas; and
d) a description of or reference to the specific control measures within the product, the process itself and the good operating practices that control *Listeria monocytogenes*; and
e) an environmental testing programme that

i) proactively looks for *Listeria monocytogenes* to minimise the likelihood of *Listeria monocytogenes* contaminating product; and
ii) confirms that any controls for *Listeria monocytogenes* are effective; and

f) a product testing programme to confirm that any controls for *Listeria monocytogenes* set out in the risk management programme are effective.

(3) The environmental testing programme referred to in HC Spec clause 15.3(2)e) must include a site plan or other means of identifying each high-care area where ready-to-eat animal product is processed and identifying the sampling sites in the high-care area (including product contact surface sampling sites and non-product contact surface sampling sites) that specifically target areas that are most likely to be contaminated.

(4) The environmental testing programme referred to in HC Spec clause 15.3(2)e) and the product testing programme referred to in HC Spec clause 15.3(2)f) must set out:

a) the number of samples to be taken during each sampling period and when each sampling period will occur; and
b) the name(s) or designation(s) of personnel responsible for carrying out sampling; and
c) procedures for sampling, sample handling and sample delivery to the laboratory; and
d) procedures for communicating with the laboratory, including:

i) the key contact at the laboratory; and
ii) whom the laboratory will immediately notify of a detection of *Listeria* species *or Listeria monocytogenes;* and

e) a system for recording and reporting laboratory results in a way that allows for easy review of the results; and
f) an action plan that will be implemented immediately in the event of a detection of *Listeria monocytogenes* in the environmental samples or product samples, and which includes:

i) the name or designation of the person who will be responsible for managing the actions to be taken; and
ii) procedures for the immediate notification to the recognised verifier if *Listeria monocytogenes* is detected in product or on product contact surfaces; and
iii) procedures for actions to be taken to help identify the source of the detection and any affected product; and
iv) procedures for the management of any affected product, including product disposition; and
v) procedures for taking corrective actions and confirmation that the actions were effective; and
vi) procedures for review and reporting on the actions taken; and
vii) procedures for the consideration of actions to prevent recurrence.

(5) The operator must regularly review the documented procedures:

a) at least annually; and
b) in response to any matter or event that could affect the effectiveness of the controls for *Listeria monocytogenes*, including but not limited to:

i) a product; or
ii) a process; or
iii) the premises, facilities or equipment; or
iv) the risk management programme; or
v) the person with responsibility for *Listeria monocytogenes* management; or
vi) after the detection of *Listeria monocytogenes* on product contact surface samples or in product.

HC Spec 15.4 Testing

An operator must use a laboratory with an accreditation to ISO/IEC 17025 with the required tests in the laboratory's scope of accreditation.

Guidance

The products covered by the *Listeria* requirements in the HC spec and the microbiological limits in standard 1.6.1 FSC don't entirely align. More product types must meet the requirements in the FSC. For example,

frozen RTE products must comply with the FSC but are not covered by the HC spec (which applies to chilled product only).

27.3 Procedures

27.3.1 Application

Guidance

Table 11 identifies the categories of seafood products that are subject to the *Listeria* requirements in the FSC and the HC Spec. The broad product categories are:

- chilled RTE seafood product with a shelf life (SL) of 5 days or less;
- chilled RTE seafood products with a SL of 6 days or more; and
- frozen seafood products.

The table indicates whether a product needs to meet the requirements in the FSC and/or the HC Spec and whether the following testing is needed:

- product testing (PT) to demonstrate compliance with standard 1.6.1 of the FSC;
- an environmental testing programme (ETP) to meet the requirements of the HC Spec; and/or
- a product testing programme (PTP) to meet the requirements of the HC Spec.

There are two different limits in the FSC for *L. monocytogenes*, which apply depending on whether the product will support growth:

- RTE products in which growth will not occur, have a limit of up to 100 cfu/g in the product at the end of shelf life (SL).
- RTE products in which growth may occur, have a limit of absent in 25 g (0cfu/25g).

In this Part, the term "specified limits" for *L. monocytogenes* in the product refers to the limits (as listed above) that have been documented by the operator in their RMP for a particular product. If a limit of 100 cfu/g has been specified, the operator must have evidence to show that this limit will not be exceeded at the end of the product shelf life.

To be clear, the following products don't need to meet the requirements in this Part:

- raw fish or live shellfish (including finfish, crustaceans, echinoderms, cephalopods and bivalve molluscan shellfish) unless the product is retail ready RTE product;
- canned or aseptically packaged and processed products;
- products that receive a validated *L. monocytogenes* control step in the final pack e.g. heating, high pressure processing;
- product that contains a listericidal component that has been validated to ensure the rapid inactivation of *L. monocytogenes* if recontaminated.

Table 11: Product description and regulatory requirements

PT: FSC product testing, ETP: HC Spec Environmental testing programme, PTP: HC Spec Product testing programme

Product category	Need to comply with FSC 1.6.1?	Need to comply with the HC Spec Part 15?	Product support growth? Yes/No	Procedures needed	Reference in this Part
Live BMS	No	No	NA	NA	-
Chilled raw fish	No	No	NA	NA	-
Chilled raw RTE seafood e.g. pottled oysters, kina, retail ready fish, ½ shell oysters	Yes	No	Yes if shelf life > 5 days	PT	27.5
			No if shelf life ≤ 5 days	PT	27.5
Chilled processed RTE seafood e.g. hot or cold smoked fin-fish, shellfish, eels, crabs or rock lobster Without validated in-pack listericidal step	Yes	Yes	Yes if: Shelf life > 5 days; and pH ≥ 4.4; or Water activity (a_w) ≥ 0.92; or pH ≥ 5 and a_w ≥ 0.94; or More than 0.5 log cfu/g increase in *L. monocytogenes* over shelf life.	PT ETP PTP	27.5 27.6.1 27.6.2
			No if shelf life ≤ 5 days	PT ETP	27.5 27.6.1
Chilled marinated RTE seafood e.g. BMS, squid Shelf life more than 5 days	Yes	Yes	Yes if pH ≥ 4.4	PT ETP PTP	27.5 27.6.1 27.6.2
			No if pH < 4.4	PT ETP	27.5 27.6.1
RTE seafood with a_w less than 0.92 Shelf life more than 5 days	Yes	Yes	No	PT ETP	27.5 27.6.1
Chilled or frozen processed RTE seafood With validated in-pack listericidal step	No	No	NA	NA	-
Frozen raw seafood	No	No	NA	NA	-
Frozen RTE seafood Including seafood thawed immediately before consumption	Yes	No	No	PT	27.5

Product category	Need to comply with FSC 1.6.1?	Need to comply with the HC Spec Part 15?	Product support growth? Yes/No	Procedures needed	Reference in this Part
Frozen RTE seafood for export[13] e.g. frozen hot or cold smoked salmon	Yes	No	No	PT ETP PTP	27.5 27.6.3 27.6.3
Frozen heat shocked BMS for export[9]	No	No	No	ETP PTP	27.6.3 27.6.3

Guidance

Operators that have a product testing programme (PTP) to meet the requirements of the HC Spec will meet the product testing (PT) requirements of the FSC using this testing programme.

If processing raw oysters (chilled raw RTE seafood), or frozen RTE product that is thawed and stored for a period of time prior to consumption, the operator should also consider implementing the *Listeria* management procedures as required by the HC Spec.

It may also be appropriate to manage seafood products that are to be fully cooked prior to consumption as RTE, if they appear to be or could be mistaken as RTE.

Marinated products such as mussels, squid and octopus will need to be assessed on a case by case basis to determine whether they meet the criteria for exclusion from Part 15 of the HC Spec. To be excluded an operator would need to validate that the product receives a listericidal process after being sealed in the final packaging. See Appendix 6 Validation of listercidal process after being sealed in final packaging (marinated products) for more detail.

27.4 *Listeria* Management Procedures

(1) Operators identified in Table 11 as required to meet Part 15 of the HC Spec, and processors of frozen RTE seafood must have written procedures for the management of *Listeria*. The procedures must address the elements required by HC Spec Part 15.3, and include:

a) the procedures for environmental testing;
b) procedures for product testing (including testing for compliance with standard 1.6.1 of the FSC), where required; and
c) procedures that will be followed if *Listeria* spp. or *L. monocytogenes* is detected in product or the environment, including the:
   i) name(s) or designation(s) of the personnel responsible for managing the actions to be taken; and
   ii) action plan that will be immediately implemented.

(2) The person(s) who designs and implements the *Listeria* management procedures must have good knowledge of the matters listed on HC Spec clause 15.5(1)a).

[13] In this Part, frozen RTE seafood for export and frozen heat shocked BMS will be referred to as frozen RTE seafood. If the BMS is to be traded as RTE, the heat shock step would need to be validated as a listercidal process, and the BMS would then be considered frozen RTE seafood (domestic or export, as appropriate).

(3) Staff who enter areas used to process RTE products (including engineers, maintenance staff and cleaners) must have an understanding of *Listeria* management that is appropriate to their role. [HC Spec clause 15.5(1)b)]

Guidance

Staff who manage *Listeria* within the premises should have a senior role within the business or report directly to senior management. The MPI *Listeria* guides provide detailed information about the management of *Listeria*. Responsible staff should be familiar with "Guidance for the control of *L. monocytogenes* in ready-to-eat foods":

- Part 1: *Listeria* Management and Glossary
- Part 2: Good Operating Practices
- Part 3: Monitoring activities
- Part 4: Corrective Actions

MPI has also developed a series of fact sheets to help operators train their staff. The factsheets provide information about *Listeria* and key GOP for its management and control:

- *Listeria monocytogenes* and ready-to-eat foods
- *Listeria* control measures
- Cleaning and sanitising
- Environmental testing for *Listeria*
- Testing product for *Listeria monocytogenes*

A number of NZQA unit standards are also available that address *Listeria* management.

(4) Samplers should have received training from a person competent in the following areas:

a) identifying and selecting suitable environmental sample sites and sources of possible contamination;
b) the correct techniques for taking samples;
c) the correct method for completing the sample submission form;
d) the correct method for the storage and dispatch of samples to the laboratory;
e) the significance of following correct procedures;
f) understanding how and when to composite samples.

(5) A sufficient number of staff should be trained in taking samples to cover for all times the premises is operating (e.g. shifts and annual leave).

Guidance

The MPI "Swabbing for *Listeria*" video can assist operators with their environmental testing programme. The video instructs on how to collect environmental samples from processing areas for *Listeria* testing. Video: Swabbing for *Listeria* – YouTube

(6) Training records must be kept. [HC Spec 5.3(2)].

(7) The recognised laboratory must be accredited to ISO/IEC 17025, with the required tests within the scope of their accreditation.

(8) The procedures must include the key contact at the laboratory, and the person at the premises whom the laboratory will notify if *Listeria* spp. or *L. monocytogenes* is detected. [HC Spec 15.3]

(9) The operator should have a written agreement with the laboratory to receive email or telephone notification of the detection of any presumptive (i.e. unconfirmed) and confirmed *L. monocytogenes* as soon as the results are known and for receipt of the laboratory report of the results.

(10) The procedures must include how the recognised verifier will be immediately notified if *L. monocytogenes* is detected in product or on product contact surfaces. This should be followed up in writing as soon as practicable. [HC Spec 15.3]

(11) The requirement to report *L. monocytogenes* results as outlined in section 27.4 (10) applies not only to the testing required by this Part, but also to any results from additional environmental monitoring of zone 4 environment or product testing covered by the scope of this Part that the operator has undertaken on their own behalf.

(12) The procedures must be regularly reviewed and updated as necessary. [HC Spec clause 15.3(5)]

27.5 Product Testing (PT) of Chilled or Frozen Product [FSC]

Guidance

The following sections describe the recommended sampling plans and minimum sampling frequencies. They apply to the product categories identified in Table 11 that require product testing (PT), an environmental testing programme (ETP), and/or a product testing programme (PTP).

(1) The operator must document the limit for *L. monocytogenes* for each product or product category, in their RMP. [RMP Spec 7]

(2) If growth of *L. monocytogenes* will not occur in the product and a limit of 100cfu/g is selected, the operator must have evidence to demonstrate that the limit will not be exceeded at the end of the product shelf life. [FSC]

Guidance

MPI has developed a fact sheet about Microbiological Limits for *L. monocytogenes* in RTE foods to help explain when validation of no growth may be needed and what it may involve.

If a limit of 100cfu/g at the end of shelf life is selected, a lower limit is usually set at the end of processing (for example 10cfu/g). Using this as a starting point, the operator would then validate that the limit of 100 cfu/g would not be exceeded at the end of shelf life. See Appendix 5 Validation that 100cfu/g met at end of shelf life, for more information.

(3) PT of product with a shelf life of 5 days or less is only required to verify compliance with the limits in the FSC.

(4) The PT sampling plan is specified in Table 12. Product should be tested at the end of the shelf life.

Table 12: Product testing (PT) sampling plan for chilled or frozen product

Sample type	Minimum Frequency	Test
Each product in its final form (FSC standard 1.6.1)	Minimum of five samples annually or seasonally	Composite or individual depending on whether enumeration is required.

27.6 Environmental and Product Testing Programme [HC Spec 15.3]

(1) The competent person must design and implement an appropriate ETP, and where required a PTP. [HC Spec 15.5]

(2) The ETP must include a site plan or other means to identify the sampling sites. Sampling sites should be selected in various zones with the aim of finding *L. monocytogenes*.

(3) The ETP sampling plan must include:

a) when each sampling period will occur and the sampling dates;
b) the number of environmental samples to be taken at each sampling period and the location where each sample will be taken; and
c) the number of product samples and description of each product sample to be taken for each sampling period.

Guidance

Zone 1 testing is carried out at the discretion of the operator. Zone 1 testing is usually only performed for investigative purposes during an incident when seeking to identify the source of contamination.

(4) All product should be subject to the sampling plan specified in the relevant table, unless an alternative is documented in the RMP.

27.6.1 ETP Sampling Plans for Chilled RTE Product

(1) The ETP sampling plan for the environment (zones 2, 3, and 4) is specified in Table 14 if processing chilled product.

Guidance

Table 13 describes the zones within a processing area. The zones are based on the likelihood that a RTE product may be contaminated with *L. monocytogenes*. The terms "zones" or "hygiene areas" maybe used interchangeably.

Table 13: Description of Zones

Zone	Description
1	Sample sites in the non-processing environment (outside).
2	Sample sites in the **standard hygiene environment** accessed by processing staff in personal protective clothing and equipment.
3	Sample sites on non-product contact surfaces in the high-care area. The high-care area is any area used for processing exposed RTE product after a listercidal process, whether after a CCP for *L. monocytogenes* or after the final microbiological hurdle has been applied.
4	Sample sites on **product contact surfaces and surfaces from which product can be contaminated** (including ingredients) in the high-care area.

Table 14: ETP sampling plan if processing chilled RTE products

Zone	Minimum Frequency[14]	Test[15]
2, 3 or 4	Five sites from each zone per fortnight	Composite or individual

[14] All samples taken from the zone 2, 3, 4 environment and product from the same batch being processed when the samples were taken.

[15] A number of swabs may be taken from the same site or zone and can be analysed as a single or composite from one site.

27.6.2 PTP Sampling Plans for Chilled RTE Product

(1) The PTP sampling plan for chilled RTE seafood product with a shelf life of 6 days or more is specified in Table 15.

Table 15: PTP sampling plan for chilled RTE products with a shelf life of 6 days or more

Sample Type	Minimum Frequency[16]	Test
Each product in its final form	Five samples per fortnight	Composite or individual

(2) All chilled RTE product processed at the same time as the zone 4 environment sampling and product sampling should be held under control of the operator until the results of the microbiological analysis is received (see definition of on hold).

27.6.3 ETP and PTP Sampling Plans for Frozen RTE Product

(1) Operators processing frozen RTE product, with the exception of intermittent operators, should comply with the sampling plan in Table 16.

(2) Operators may document alternative sampling plans within their RMP. Alternative sampling plans should be set within the context of the risk based procedures based on HACCP, the nature of the product and processing environment. Approval for this would be given through registration of the RMP or through a significant amendment to a RMP.

Table 16: ETP and PTP sampling plan for frozen RTE products

Sample type	Minimum Frequency	Test[17]
Zone 2	Five sites per fortnight	Composite or individual
Zone 3	Five sites per fortnight	Composite or individual
Zone 4	Five sites per week	Composite or Individual
Each product in its final form	Five samples per fortnight[18]	Composite or individual

(3) All frozen RTE product processed between the scheduled sampling of the zone 4 environment sampling and product sampling should be held under control of the operator until the results of the sampling is received (see definition of on hold).

27.6.4 Intermittent Processors of Chilled or Frozen RTE Product

(1) Operators intermittently processing chilled or frozen RTE product may document an alternative sampling plan within their RMP. Alternative sampling plans should be set within the context of the risk based procedures based on HACCP, the nature of the product and processing environment. Approval for this would be given through registration of the RMP or through a significant amendment to a RMP.

27.6.5 General Sampling Requirements

(1) Sampling should be planned and conducted in a manner that potential contamination is not transferred by the person performing the sampling or by the introduction of another contaminant.

[16] All samples taken from the zone 2, 3, 4 environment and product from the same batch being processed when the samples were taken.

[17] A number of swabs may be taken from the same site or zone and can be analysed as a single or composite from one site.

[18] Fortnightly testing of product should be carried out on the same batch being processed while the zone 4 environment samples are taken to ensure that reliable information is obtained.

(2) All samples should be taken aseptically.

(3) If a number of RTE products are processed on the same process line, these can be considered to be part of the same batch, if they are processed between major clean downs and subject to the same conditions, i.e. hot smoked eel and hot smoked salmon, and heat shocked half-shell mussels and mussel meat where they are processed on the same line. However, hot smoked salmon is different to cold smoked salmon due to the different times and temperatures during smoking and an individual sampling programme should run for each.

(4) The requirement for five environmental swabs from zone 4 cannot be divided between different product lines where these are distinct and separate. The requirements for five product samples cannot be split between different product types if these are processed on different and distinct process lines.

Guidance

Where there are multiple process lines operating in the same zone, then each process line should be subject to environmental monitoring on the designated sample day if in operation. However, all products processed in the zone on the day of sampling will be subject to corrective action where *L. monocytogenes* is detected on any particular line unless it can be demonstrated that each line is separate and distinct.

Where there are multiple seafood products processed on any one process line, only one product type needs to be sampled, however all products processed on this line on the day of sampling will be subject to corrective action if *L. monocytogenes* is detected in the product.

(5) Where the operator processes on a shift basis, the operator or personnel responsible should ensure that all shifts are covered by the *Listeria* management programme, at the frequencies described above, i.e. should have the opportunity to take samples from each shift.

Guidance

If the operator processes seafood on a shift basis and performs a major clean down between each, then each shift is considered to be distinct and the product processed is a different batch. Therefore each shift, e.g. day and evening, should each be subject to the requirements for sampling. Considering each shift on an individual basis may have advantages for the operator in terms of reduced commercial risk in the case of the detection of *L. monocytogenes*.

Whereas if there is a single major clean down per working day, then all product processed over the shifts on the same working day are considered to be part of the same batch and corrective actions in the event of the detection of *L. monocytogenes* will apply to product from both shifts.

27.6.6 Environmental Sampling

(1) Samples should be taken at random times during the normal processing of products to cover different times within the processing day and different shifts. Surfaces should not be cleaned or sanitised immediately prior to sampling.

(2) Environmental samples should be taken after 2-3 hours of operation and should not occur during a work break.

(3) Where there are designated sample sites, all of the sample sites selected should be sampled on a regular rotational basis with the flexibility to sample additional sites depending on the circumstances, e.g. past results, maintenance, construction, or when new or modified equipment is installed.

(4) The selection of sampling sites should be reviewed regularly based on the trend analysis of past results, process conditions, or as part of investigative sampling.

Guidance

Any sampling to check the effectiveness of the cleaning and sanitation programme i.e. as part of the pre-operational checks, is in addition to this *L. monocytogenes* management programme.

A suitable aseptic sampling technique for taking environmental swabs is the use of large gauze swabs and metal forceps. This ensures that sufficient pressure can be applied to remove contaminants that may adhere very tightly to surfaces in the processing environment. This technique is particularly useful for accessing cracks and crevices that may harbour *L. monocytogenes*. An alternative aseptic sampling method is to use a large gauze swab and a gloved hand to provide consistent and sufficient pressure to remove contaminants.

27.6.7 Product Sampling

(1) Five 25 g samples of each type of product should be randomly selected from a batch just prior to packing or in its final packaging depending on the process and product.

(2) Product which is processed on the same line in essentially the same process in the same shift would be considered the same type (unless a major clean down had occurred between shifts) e.g. mussel meat and half shell mussel would be considered the same type; hot smoked salmon is a different type to cold smoked salmon.

27.6.8 Composite Samples

Guidance

The compositing of samples for analysis may be a more cost effective option compared with the analysis of individual swabs and product samples (check with your recognised laboratory). This is because when demonstrating compliance with the microbiological limit (e.g. absence of *L. monocytogenes* / 25g where n=5, c=0) instead of the laboratory testing five product samples of 25g, one combined sample of 125g is required.

If *Listeria* is to be enumerated (for example in product that will not support the growth of *L. monocytogenes* and has a limit of 100cfu/g) product samples cannot be composited.

The microbiological limit for *L. monocytogenes* is specified for a particular weight of product sample, usually 25g. However this does not always correlate to the size of the sample analysed. Therefore it is important to check with your recognised laboratory to determine the amount of product required for analysis to avoid sending insufficient product samples.

Environmental swabs taken from the same zone at the same time can be composited during routine monitoring. However, if *L. monocytogenes* is detected in a composite environmental sample it generally takes longer to identify the source of contamination, as individual swabs will need to be tested to identify the root cause.

The compositing of environmental samples from different sites in the same zone is not appropriate during investigative or exploratory sampling when *L. monocytogenes* has been detected. Although in those cases it is possible to composite from a single piece of equipment e.g. water bath or trolley.

Compositing of product samples

- Individual samples may form a composite sample for the purposes of laboratory analysis. For example:
  - Five individual samples of 25g may form one composite sample of 125g (laboratory analytical results should report presence or absence of *L. monocytogenes* in a 125g sample); or
  - Ten individual samples of 25g may form two composite samples, e.g. 2 x 125g (laboratory analytical results should report presence or absence of *L. monocytogenes* in a 125g sample); or
  - Twenty individual samples of 25g may form four composite samples, e.g. 4 x 125g (laboratory analytical results should report presence or absence of *L. monocytogenes* in a 125g sample); or

  - Thirty individual samples of 25g may form six composite samples, e.g. 6 x 125g (laboratory analytical results should report presence or absence of *L. monocytogenes* in a 125g sample), or
  - Sixty individual samples of 25g may form 12 composite samples, e.g. 12 x 125g (laboratory analytical results should report presence or absence of *L. monocytogenes* in a 125g sample).
- There are two options when the composite sampling of product is required when large sample numbers are being analysed. For example, sample size n=60.
  - The unopened packages of product may be submitted to the laboratory where they will be aseptically opened and a 25g sample taken from each. These will form the composite sample which will be tested; the composite sample should not be more than five 25g samples (125g).
  - The unopened packages (including large cartons) of seafood product are aseptically opened by the operator and a 25g sample taken from each. Precautions should be taken to prevent the contamination of the sample. These individual samples will form a composite sample which will be tested; the composite should not be more than five 25g samples (125g).

If analysis of composite samples is required, the operator should check with the laboratory to confirm that the analytical method used is appropriate and that the sensitivity is not compromised.

27.6.9 Transportation

(1) Samples should be transported under refrigeration or in transport medium that maintains the preservation state and integrity of product, that is, properly packed in a cool box with ice packs. Frozen product should remain frozen whilst chilled product should remain chilled. Environmental swabs should be transported to the laboratory using a method that ensures that the samples remain chilled.

(2) All samples (product samples and environmental swabs) should be sent to the laboratory as soon as practical.

Guidance

For example, samples of RTE product may be sent to the laboratory:
- in an intact food grade plastic bag, such as those used for routine packaging; or
- in another suitable container; or
- as individual consumer packs.

Because environmental swabs provide a snapshot of what was happening at a particular time it is preferable that they are tested promptly upon receipt by the laboratory. It is important that any bacteria that may be present, including *L. monocytogenes*, are not altered due to transportation.

Where possible, samples should arrive at the laboratory within 48 hours following collection. This is important as it may allow time for samples to be taken randomly throughout the day, rather than soon after the first 2-3 hours of processing.

27.7 Results

(1) All results (including results of any samples taken in addition to the requirements of the HC Spec) must be reviewed on receipt and appropriate actions taken. [HC Spec 15.3]

(2) The operator should also review and analyse laboratory results and routine monitoring data at least on a six weekly basis to identify trends and any corrective actions.

Guidance

One way to facilitate trend analysis is to set up a table that records sampling sites, date of sampling and laboratory results for *Listeria spp*. and *L. monocytogenes*. Another way to identify trends, problems and

sources of contamination is to record *Listeria spp*. and *L. monocytogenes* results on a schematic diagram (flowchart) of the seafood operation, as this builds up a picture of where problems exist.

27.8 Actions in the Event of Detection

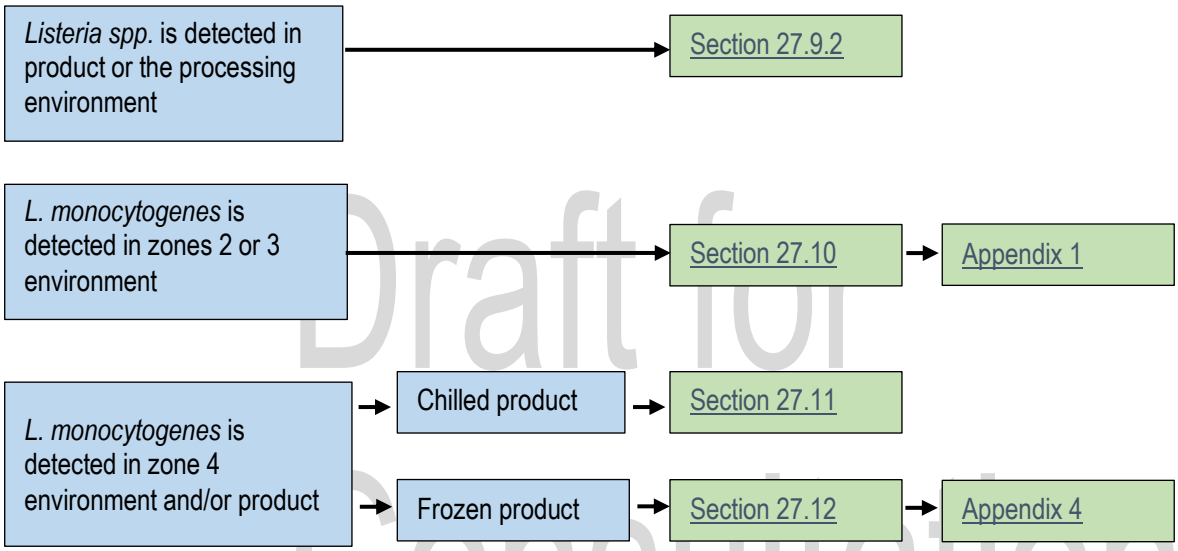
Figure 4 shows the sections of this Part to refer to for actions when *Listeria spp*. and/or *L. monocytogenes* is detected in the product or processing environment.

Guidance

When managing an incident, the operator needs to be able to justify any decisions made and records kept of all decisions and actions taken should be kept.

Refer to Part 4 Corrective Actions of the *Listeria* guides for more information.

Figure 4: Section references for actions when *Listeria* spp. or *L. monocytogenes* is detected



27.9 *Listeria* spp. Detection in Chilled or Frozen RTE Product or Environment

27.9.1 Summary

(1) The following actions should be taken when *Listeria spp*. is detected in chilled or frozen RTE product (including heat shocked mussels) and/or in the processing environment. That is, *Listeria spp*. has been identified but it may take another 24-48 hours before a confirmed result of the detection or non-detection of *L. monocytogenes* is available.

Guidance

The laboratory culture analysis for *L. monocytogenes* usually identifies *Listeria* spp. first, and then confirms whether the species is *L. monocytogenes*. The identification of *Listeria* spp. will occur one or two days before any confirmation of *L. monocytogenes* and early notification will allow you to take immediate action whilst waiting for identification of the *Listeria* species.

The detection of *Listeria* spp. may provide an early indication of a breakdown of controls. The presence of *Listeria* spp. (and *L. monocytogenes*) in the environment may place product at risk from *L. monocytogenes* contamination. Finding *Listeria* spp. indicates that environmental conditions may be suitable for the harbourage, survival and/or growth of other *Listeria* spp. including *L. monocytogenes*.

If the PCR method is to test for the presence or absence of *L. monocytogenes*, operators should talk to their laboratory about interpretation of the results, particularly if detections are being made. The operator needs to be clear about whether the results are indicating the presence of viable cells. Appropriate actions are to be taken based on these results.

Requirements in relation to product do not apply to product with a shelf life of 5 days or less.

27.9.2 *Listeria spp.* Detected but Identification of Species Not Confirmed

(1) Within one working day of receiving the laboratory notification of the detection of *Listeria spp.* (i.e. a presumptive positive) in the standard hygiene environment, the high-care area, and/or the product, the operator should carry out the actions in Table 17.

Table 17: Actions when *Listeria spp.* is detected but species is not confirmed

Sampling	Review of results and trend analysis	*Listeria* controls review and corrective actions
Conduct an initial investigation to determine the source of *Listeria spp.* include samples from the same sample sites and from the surrounding area, i.e. spatial sampling to determine the source of contamination. Consider increasing the monitoring frequency of the environment (e.g. all zones) and product for *L. monocytogenes*;	Review the trend analysis to determine patterns or contamination and potential sources.	Review: • process records to identify whether anything has changed and ensure that process controls for *L. monocytogenes* are operating correctly; • the potential for the contamination of product and the high-care area, e.g. personnel movement and access from the standard hygiene environment. • cleaning and sanitation records. Take relevant corrective actions to prevent potential future contamination from *L. monocytogenes* where necessary e.g. staff training. Other than product with a shelf life of 5 days or less, if the detection of *Listeria spp.* is in zone 4 or the product then the operator should determine the range of seafood product batches that were processed on the day of sampling, and their current location.

Guidance

Some careful compositing of swabs from the areas within a site, e.g. specific items of equipment or from specific areas may be useful in the first instance to isolate potential sites for further investigation

27.10 *L. monocytogenes* Detection in Zone 2 and 3 Environment

(1) This section covers the actions that operators processing chilled or frozen RTE seafood product (including product with a shelf life of 5 days or less and those who are intermittently processing) should take if *L. monocytogenes* is detected during the monitoring of the environment in zones 2 and/or 3.

Guidance

Also see Appendix 1 What zones should be considered when investigating the possible source of L. monocytogenes contamination?

The following points should be noted in relation to environmental testing:

- Compositing environmental swabs from different sites during investigative sampling to determine the source of contamination is not permitted, although it is possible to composite from a single piece of equipment e.g. water bath or trolley.
- Taking additional samples will help identify the source of contamination, whether *L. monocytogenes* contamination has spread and if the product may be at risk from *L. monocytogenes*.
- Taking environmental samples after cleaning and sanitising will help to pinpoint the source of contamination.
- If the operation separates the processing of raw and RTE products using separation by time, unless there are control measures such as a full clean down between handling raw or RTE products, the entire processing area should be considered as high-care, i.e. Zone 3.

27.10.1 *L. monocytogenes* Detection in Zone 2 Environment

(1) Figure 5 describes the actions to be taken if *L. monocytogenes* is detected in the zone 2 environment.

27.10.2 *L. monocytogenes* Detection in Zone 3 Environment

(1) Figure 6 describes the actions to be taken if *L. monocytogenes* is detected in the zone 3 environment.

Guidance

Continued sampling of the environment in zone 3 as well as zones 2 and 4 will provide an early warning of whether the product is at risk from *L. monocytogenes* contamination.

Figure 5: Actions following the detection of *L. monocytogenes* in zone 2 environment

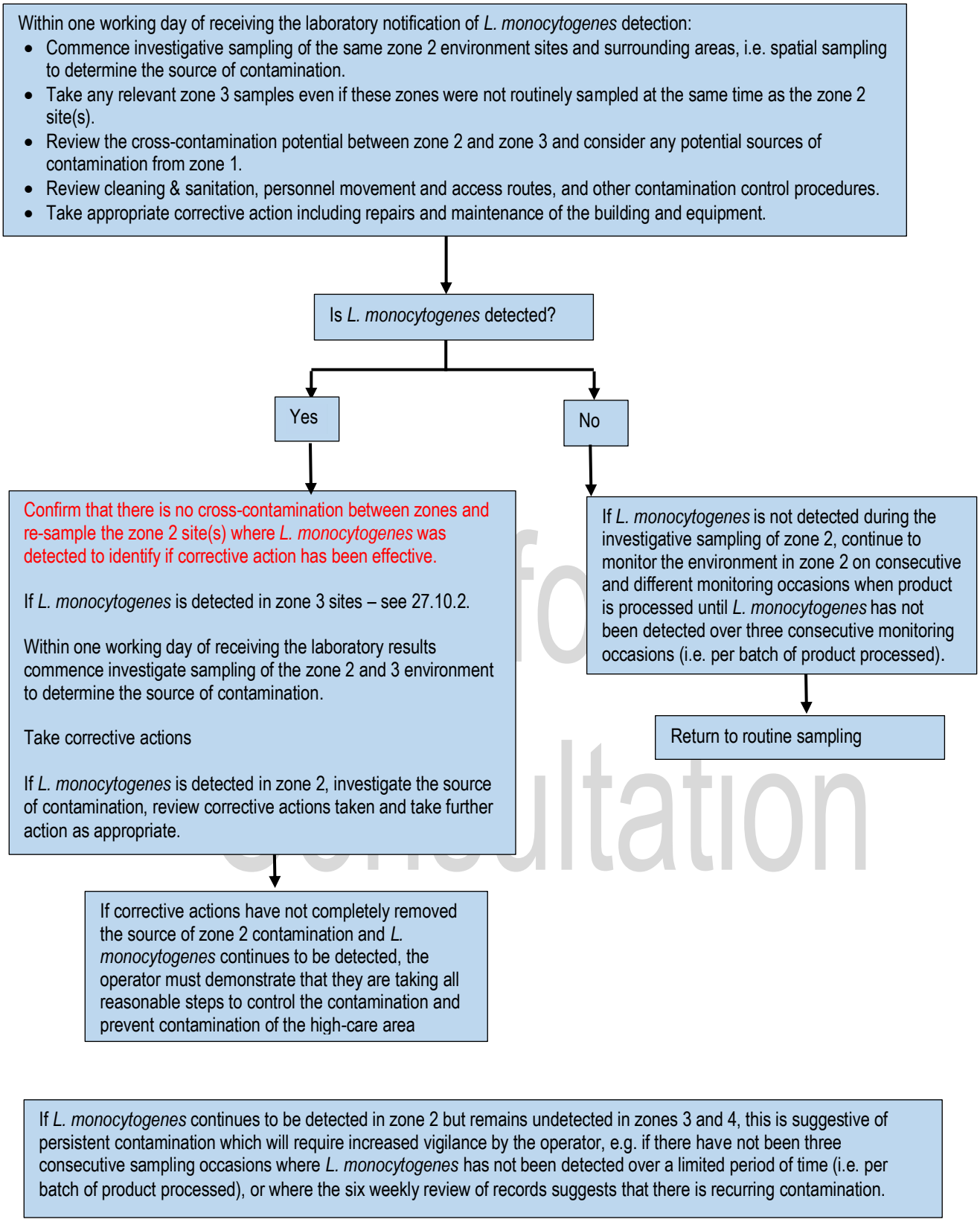
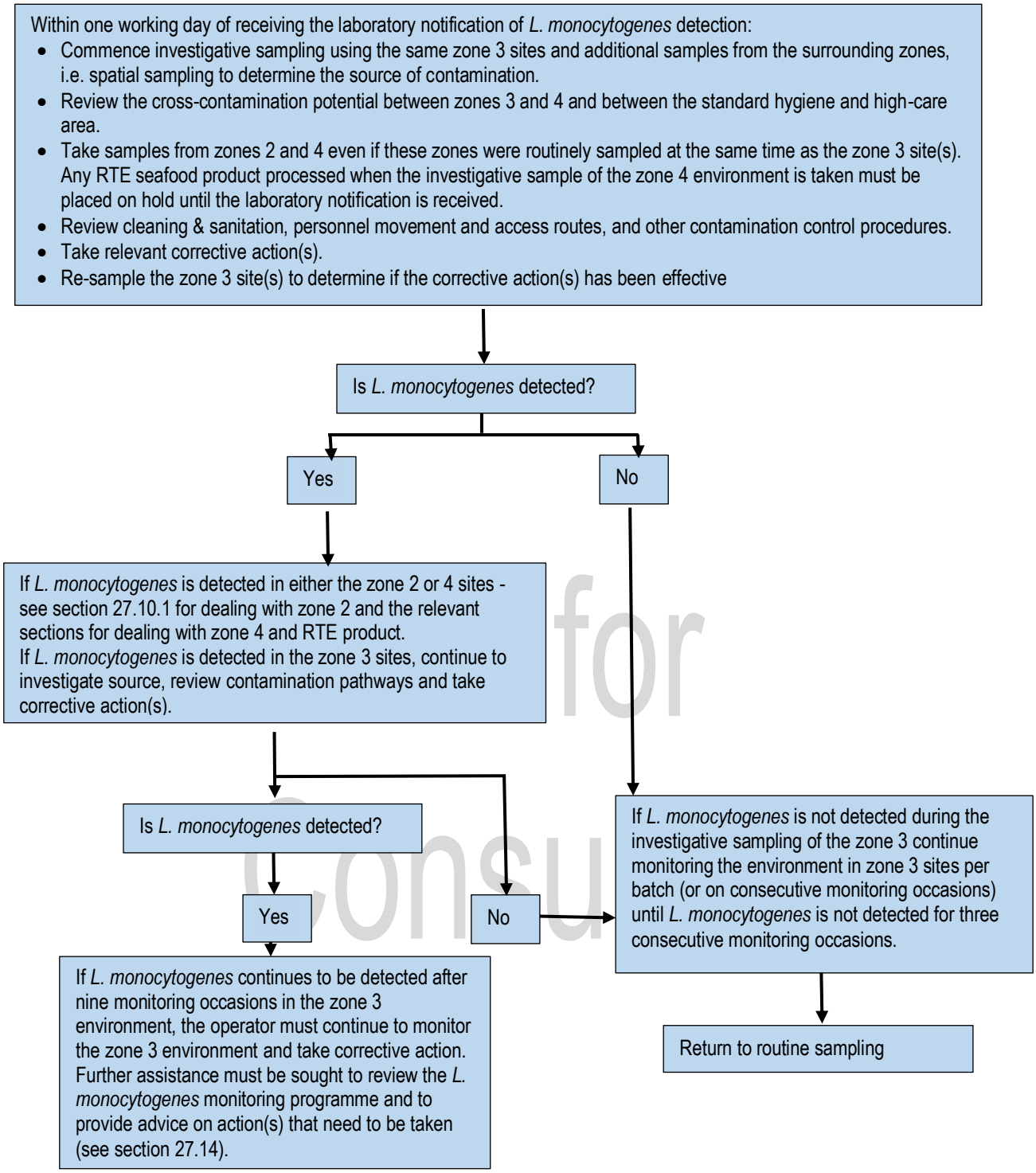


Figure 6: Actions following the detection of *L. monocytogenes* in zone 3 environment



27.11 *L. monocytogenes* Detection in Zone 4 Environment and Chilled RTE Product

Guidance

L. monocytogenes contamination of the zone 4 environment (the product contact surfaces in the high-care area) may result in the cross-contamination of any exposed product processed between major clean downs.

Investigative sampling should sample the original sample sites and those from surrounding zones, i.e. spatial sampling, to determine the source of contamination. Taking environmental samples after cleaning and sanitising will help to pinpoint the source of contamination.

The compositing of samples from different items of equipment during investigative sampling is not permitted, although it is possible to composite from a single piece of equipment.

Refer to Appendix 2 for guidance on systematic sampling and testing, and the compositing of samples.

27.11.1 First *L. monocytogenes* Detection in Zone 4 Environment and/or Chilled RTE Product

Guidance

The corrective actions in this section apply when *L. monocytogenes* is detected in the zone 4 environment or chilled RTE product at the start of an event, rather than as part of a recurring problem identified through the trend analysis of the microbiological results.

(1) If *L. monocytogenes* is detected during the routine monitoring of the zone 4 environment and/or chilled RTE product, actions should commence within one working day to deal with:

a) the environmental contamination; and
b) the product processed at the same time as the zone 4 environment was monitored; and
c) the zone 4 environment and the product processed after laboratory notification of *L. monocytogenes.*

(2) Figure 7 describes the actions to be taken if *L. monocytogenes* is detected in the zone 4 environment and/or in chilled RTE product.

27.11.2 Second Detection of *L. monocytogenes* in Zone 4 Environment and/or Chilled RTE Product During Continued Monitoring

(1) If during the continued increased monitoring of the zone 4 environment and the product or within the six week review period of laboratory results and routine monitoring results there is a second detection of *L. monocytogenes*, Figure 8 describes the actions to be taken.

(2) Actions should be taken for the environment and the product within one working day of receiving the laboratory notification of *L. monocytogenes* detection.

Guidance

An event is the single detection of *L. monocytogenes* in either the zone 4 environment or the product. A trend, is at least 2 detections of *L. monocytogenes* in the zone 4 environment and/or the product within the 6-weekly review of the laboratory results (see section 27.7). Multiple detections of *L. monocytogenes* may indicate that there may have been a breakdown of *Listeria* controls.

Figure 7: Actions following first detection of *L. monocytogenes* in zone 4 environment and/or chilled RTE product

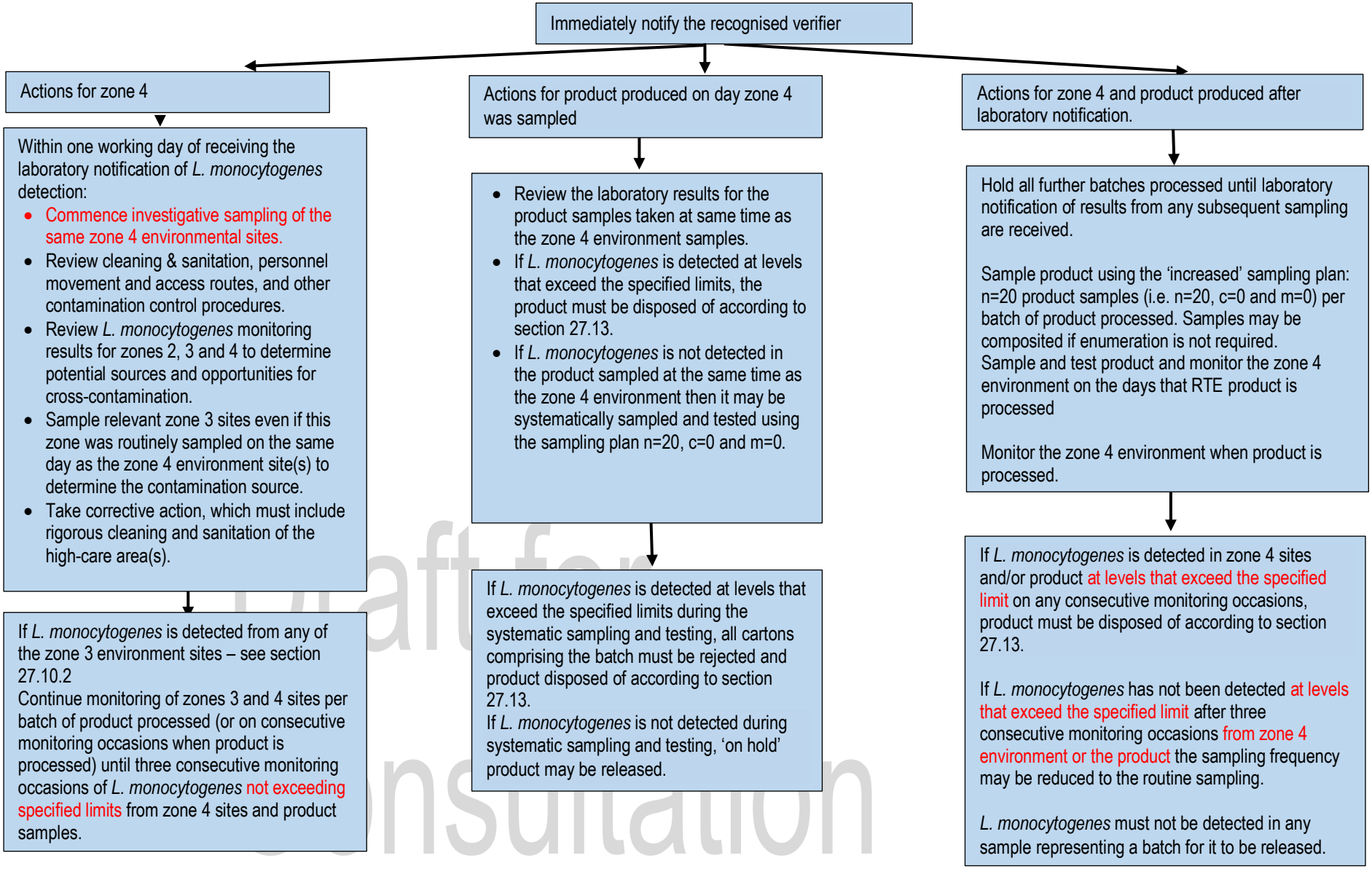
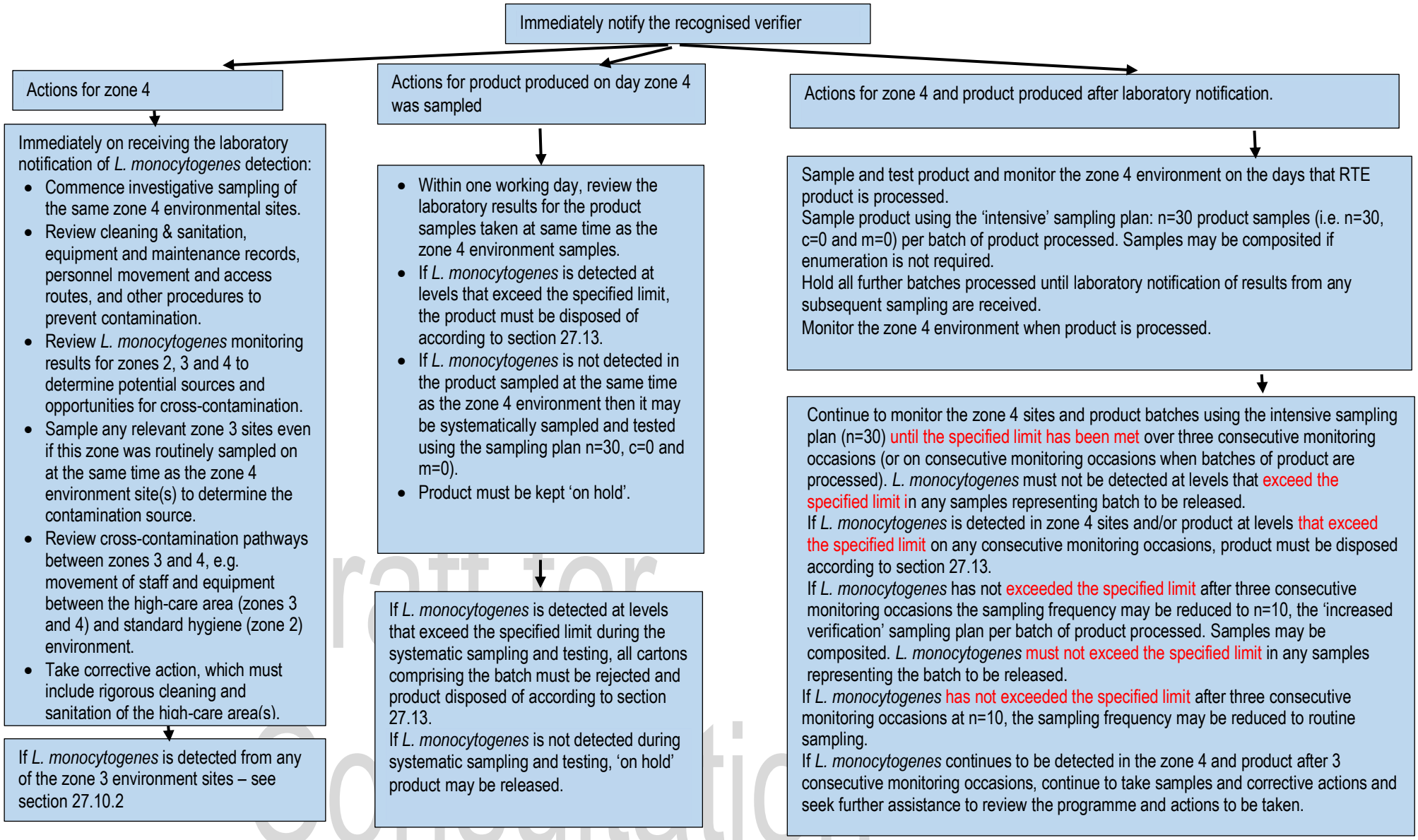


Figure 8: Actions following second detection of *L. monocytogenes* in zone 4 environment and/or chilled RTE product



27.11.3 Third Detection of *L. monocytogenes* in Zone 4 Environment and/or Chilled Product During Continued Monitoring

(1) Figure 9 describes the actions to be taken if *L. monocytogenes* is detected in the zone 4 environment and/or in chilled product for a third time.

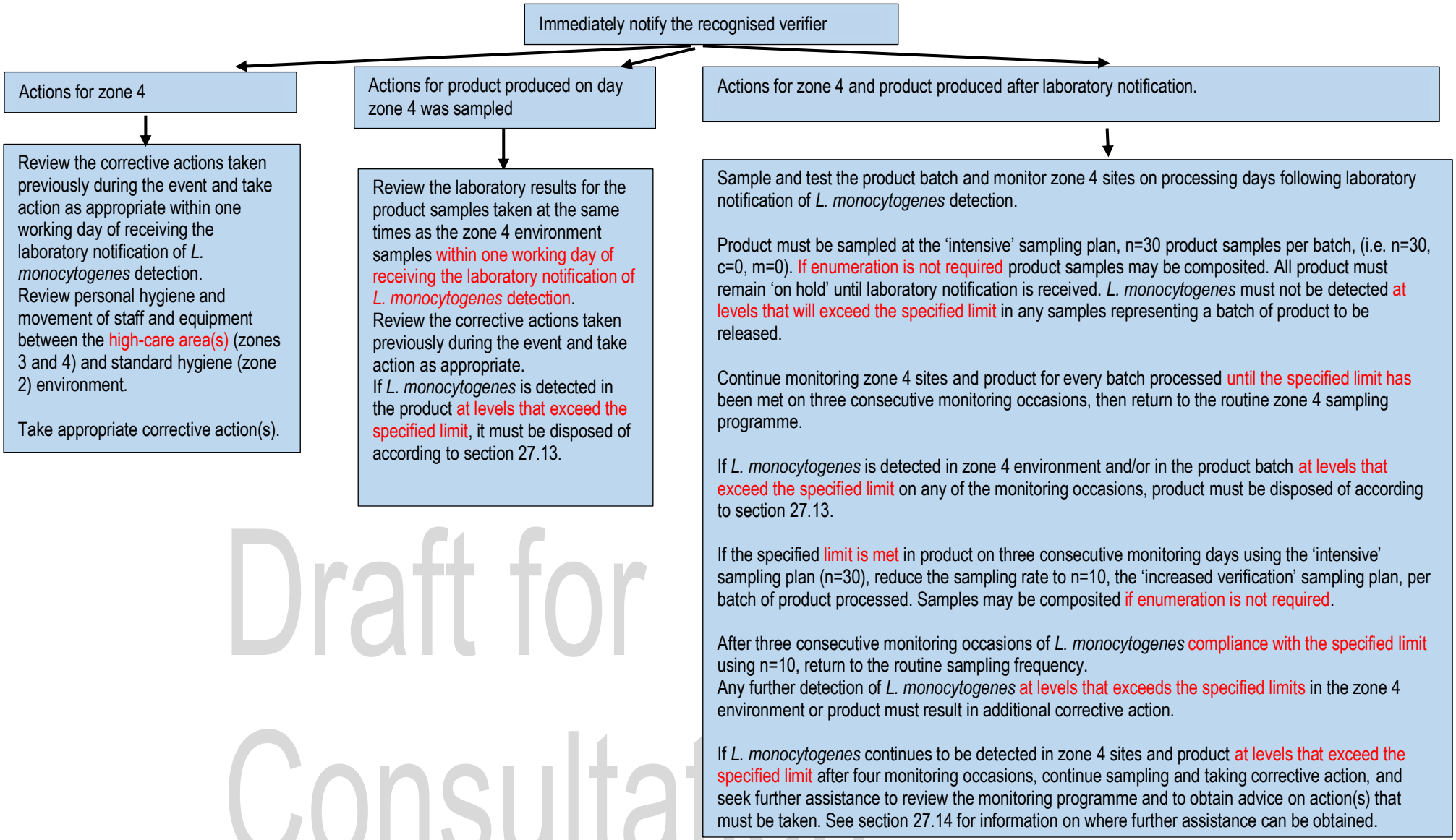
(2) The operator should seek further assistance. See section 27.14 for information on where further assistance can be obtained.

(3) Consider temporarily ceasing the processing of seafood product whilst a thorough and intensive cleaning and sanitising programme is conducted.

Guidance

The continued detection of *L. monocytogenes* in the zone 4 environment and/or product indicates that there has been a serious breach of the hygienic controls in the high-care area.

Figure 9: Actions following third detection of *L. monocytogenes* in zone 4 environment and/or chilled RTE product



27.11.4 *L. monocytogenes* Sampling Frequencies for Chilled RTE Product

Table 18 summarises the number of product samples that should be taken based on whether the sampling is for the purpose of routine or increased testing due to *L. monocytogenes* detections. These are the sampling frequencies referred to in section 27.11.

Table 18: Product sampling frequency

Sampling plan	Definition	Minimum frequency	Sample size~~15~~
Routine	Sample of product processed at the same time as the zone 4 environment is sampled	Fortnightly[19]	5 samples[20]
Increased	After the 1st detection of *L. monocytogenes*	Per batch of product processed after notification	20 samples[20]
Intensive	After the 2nd detection of *L. monocytogenes* After the 3rd detection of *L. monocytogenes*	Per batch of product processed after notification	30 samples[20]
Increased Verification	After three consecutive monitoring occasions of the non-detection of *L. monocytogenes* at the intensive sampling plan	Per batch of product processed after notification	10 samples[20]

Guidance

The operator has an option to analyse product using an n=60 sampling plan. They may decide to use an n=60 sampling plan when (not an exclusive list):

- trend analysis shows that there has been *L. monocytogenes* detected on a number of occasions in the high-care area.
- analysing a larger sample of seafood product, n=60 may provide the operator and MPI with a greater level of certainty whether *L. monocytogenes* is present, e.g. the use of an n=60 sampling plan will provide 95% confidence of detecting at least one case where the incidence level in the batch is 5%;
- depending on the market that the seafood product is intended for and any specific assurances required following the detection of *L. monocytogenes*.

27.12 Detection of *L. monocytogenes* in Zone 4 Environment and Frozen RTE Product

(1) Figure 10 describes the actions to be taken if *L. monocytogenes* is detected in frozen RTE product or the zone 4 environment. Further detail is provided after figure 10.

(2) If *L. monocytogenes* is detected during the routine monitoring of zone 4 environment or product, action must be taken within one working day to deal with:

a) the environmental contamination; and
b) the product that was processed when the zone 4 environment was monitored (also see section 27.12.1); and
c) the product that was processed since the last non-detection in the zone 4 environment (also see section 27.12.2); and

[19] All sampling (zones 2, 3, 4 and product) should be taken on the same day, within essentially the same time frame.

[20] The samples may be individual or composited. Typically 5 x 25g samples are tested, which may form a single 125g composite sample to meet the microbiological requirement of absence of *L. monocytogenes* in 125g.

d) the product that has been processed since the zone 4 environment samples were taken (see section 27.12.3).

Guidance

Frozen RTE products (including products consumed frozen and those intended to be thawed immediately before consumption) are considered to be foods in which growth of *L. monocytogenes* will not occur under the FSC. These products have a limit of up to 100 cfu/g of *L. monocytogenes* in the product at the end of shelf life.

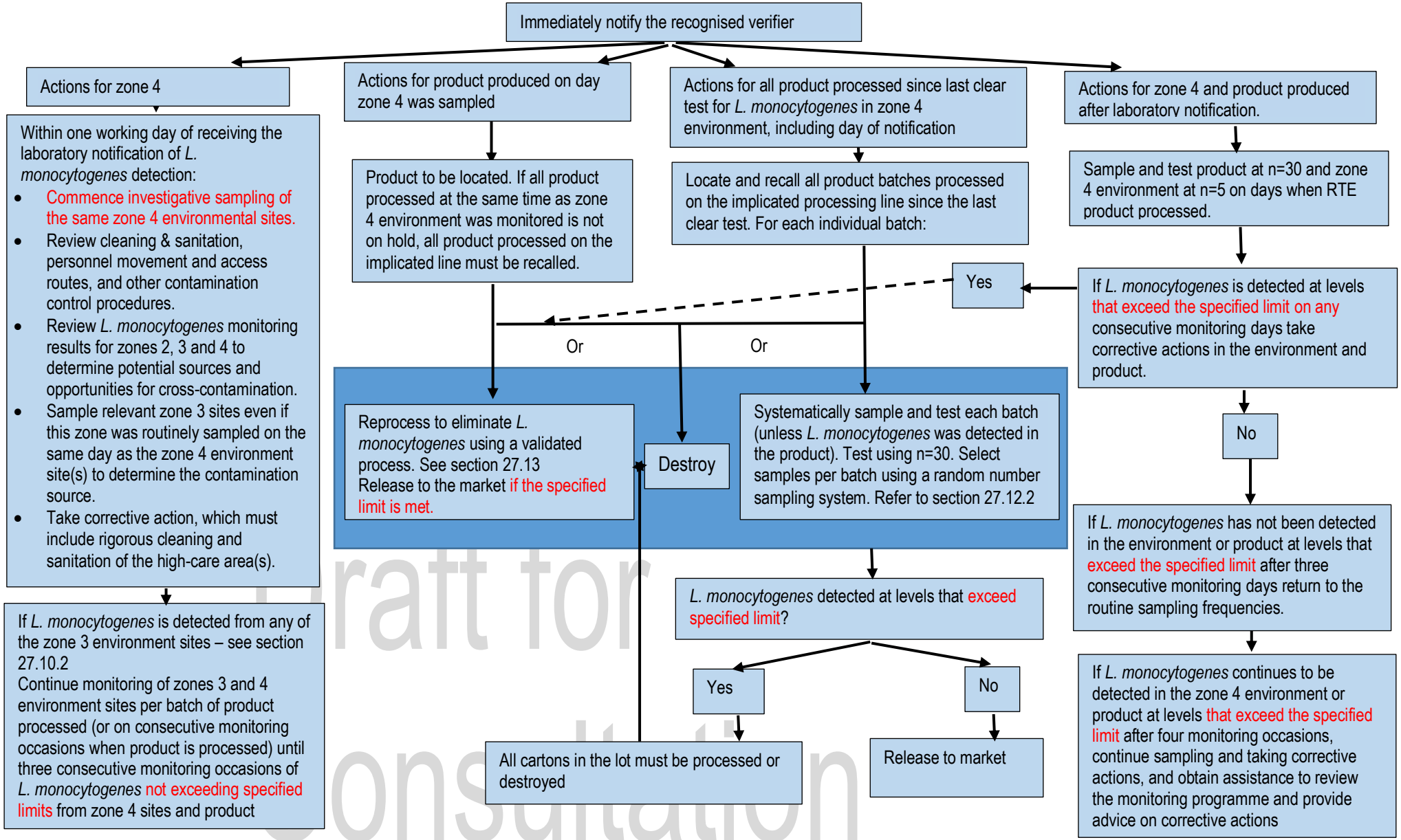
Frozen products for export may have a limit of absent (0cfu/25g) or 100 cfu/g depending on the intended market.

Operators also need to consider whether the product will be thawed and held for a length of time before retail or consumption when setting limits for *L. monocytogenes.* This should be addressed as part of validation.

L. monocytogenes contamination of the zone 4 environment, the product contact surfaces in the high-care area may result in the cross-contamination of any exposed product processed.

Refer to Part 4 Corrective Actions of the *Listeria* guides for more information.

Figure 10: Actions following detection of *L. monocytogenes* in zone 4 environment and/or frozen RTE product



27.12.1 Actions for Frozen RTE Product Processed when Zone 4 Environment or Product was Monitored

(1) If the operator does not have all the seafood product processed at the same time as the zone 4 environment was monitored on hold, the operator should recall all product processed (covered by the scope of this Part) on the implicated processing line where *L. monocytogenes* was detected.

(2) The product that was processed on the day that *L. monocytogenes* was detected in the zone 4 environment sites should be disposed of according to the procedures documented in the operator's RMP.

(3) Requirements for disposition of frozen RTE product include:

a) reprocessing;
b) destruction; or
c) the systematic sampling and testing. The systematic sampling and testing is not permitted if *L. monocytogenes* is detected at levels that exceed the specified limits in the product sampled at the same time as the zone 4 environment sample. The retesting of the batch (i.e. testing into compliance) is not permitted. For further information on the reprocessing and destruction of product refer to section 27.13 Disposition of product, and for systematic sampling and testing refer to section 27.12.2(3) and Appendix 3.

27.12.2 Actions for Product Processed since the last *L. monocytogenes* Non-detection in Zone 4 Environment until Laboratory Notification

(1) The operator should recall all affected seafood product which is not on hold under the control of the operator. Affected seafood product is batches of product processed from the implicated processing line since the last non-detection of *L. monocytogenes* in the zone 4 environment until laboratory notification of the result.

(2) The operator should take action for each individual batch processed (see section 27.13 for requirements for product disposition) to reprocess, destroy, or systematically sample and test each product line batch.

(3) Systematic sampling and testing – Backdating.

Guidance

The purpose of systematically testing each batch processed, also called 'backdating', is to determine if and when the product was contaminated with *L. monocytogenes*. Due to the sporadic nature of *L. monocytogenes* contamination events it is feasible that the high-care area, especially zone 4, may have been a source of *L. monocytogenes* contamination before it was detected.

See Appendix 3 for information on how to select samples using a random sampling system.

a) The product must not be released if *L. monocytogenes* is detected at levels that exceed the specified limit during systematic sampling. There are two options for the systematic sampling and testing:

i) Work systematically backwards from the day before the notification of *L. monocytogenes* detection in the zone 4 environment. Randomly sample product from each batch (e.g. a working day) until there has been three consecutive monitoring occasions of compliance with the specified limit for *L. monocytogenes*.
ii) Work systematically forward from the last compliance with the specified limit for *L. monocytogenes* in the zone 4 environment, up until the day that the laboratory notification that *L. monocytogenes* was detected to sample product from each batch processed on the processing line. Product should be randomly sampled from each batch.

b) In the option outlined in section 3a)(i) if *L. monocytogenes* is detected in one batch processed at levels that exceed the specified limit then all product from that point until the day that zone 4 environmental samples were taken is deemed to be contaminated with *L. monocytogenes* and should be either reprocessed according to a validated method in the RMP, or destroyed.

c) Product should be sampled at:

i) n=30 product samples per batch (i.e. n=30, c=0, m=0).

ii) *L. monocytogenes* must not be detected at levels that exceed the specified limit in the product in order for it to be released.

Guidance

Operators may decide to use a n=60 sampling plan when (not an exclusive list):

- trend analysis shows that there has been *L. monocytogenes* detected on a number of occasions in the high-care area;
- analysing a larger sample of seafood product, n=60 may provide the operator with a greater level of certainty whether *L. monocytogenes* is present. This will provide 95% confidence of detecting at least one case where the incidence level in the batch is 5%;
- depending on the market that the seafood product is intended for and any specific assurances.

iii) If *L. monocytogenes* is detected in any sample at levels that exceed the specified limit, all cartons comprising the batch must be rejected. Retesting of the batch is not permitted. When *L. monocytogenes* is not detected the operator may release the product.

iv) If reprocessed, product should be retested to confirm it has been effective, using n=5 product samples per batch (i.e. n=5, c=0, m=0) to determine of compliance with the specified limit for *L. monocytogenes*.

(4) Examples of how to respond to analytical results during the investigative sampling of different batches of RTE seafood product are provided Appendix 4.

Guidance

If there are multiple occurrences of the detection of *L. monocytogenes* from different product batches processed during the systematic sampling this indicates that the process and any *L. monocytogenes* control steps are not under control. Further investigative sampling and reviews may be undertaken.

Information on where to obtain further assistance is provided in section 27.14.

Refer to Part 4 Corrective Actions of the *Listeria* guides for more information.

27.12.3 Actions for Zone 4 Environment and Frozen Product Processed after Laboratory Notification of *L. monocytogenes* in Zone 4 Environment

Guidance

Refer to Appendix 2 and 3 for guidance on the compositing of samples.

(1) *L. monocytogenes* must not be detected at levels that exceed the specified limit in any samples representing a batch of seafood product in order for it to be released.

Guidance

Operators may decide to use an n=60 sampling plan when (not an exclusive list):

- trend analysis shows that there has been *L. monocytogenes* detected on a number of occasions in the critical hygiene environment;

- analysing a larger sample of seafood product, n=60 may provide the operator and MPI with a greater level of certainty whether *L. monocytogenes* is present. This will provide 95% confidence of detecting at least one case where the incidence level in the batch is 5%;
- depending on the market that the seafood product is intended for and any specific assurances.

(2) If *L. monocytogenes* is detected in the zone 4 environment and/or product on any of the consecutive monitoring occasions, then the product must be disposed of in accordance with section 27.13.

27.13 Disposition of Product

(1) If *L. monocytogenes* is detected in the product at levels that exceed the limit specified in the RMP, the method of product disposition must be specified in the RMP. Product should be disposed of using the methods in Table 19.

Table 19: Product disposition

Method of Disposal	Details of Disposal Method	Conditions	Sampling
Destroyed	Managed in a way that product cannot be mistakenly or fraudulently released for consumption.	NA	NA
Reprocessed and released for trade	Reprocessed to reduce *L. monocytogenes* to acceptable levels using a validated process as described in the RMP, with documented evidence; or Released to another business for reprocessing to reduce *L. monocytogenes* to acceptable levels using a validated process.	Where product is to be reprocessed under another operator's RMP, the transfer document accompanying the product should be endorsed with the following statement: "This product must be reprocessed in New Zealand in accordance with a *L. monocytogenes* control step". If the product is to be transferred to a business operating under the Food Act, this same information needs to be passed to the business operator.	If reprocessing is to take place on the same processing line where *L. monocytogenes* was detected, where possible this should not occur until the relevant number of non-detections of *L. monocytogenes* from the zone 4 environment and product batches has occurred on subsequent monitoring occasions. Reprocessed product should be sampled to confirm that the reprocessing has been effective at n=5 product samples (n=5, c=0 and m=0) Samples may be composited if enumeration is not required at *L. monocytogenes*/125g, (5 x 25g sub-samples = 125g tested). Where reprocessing is to take place on the same processing line where *L. monocytogenes* was detected but the relevant

Method of Disposal	Details of Disposal Method	Conditions	Sampling
			number of non-detections from the zone 4 environment and product batches has not occurred on subsequent monitoring occasions, reprocessed product should be sampled to confirm that the reprocessing has been effective at n=60 product samples (n=60, c=0 and m=0). Samples may be composited if enumeration is not required at *L. monocytogenes*/125g, where (12 x 125g sub-samples).
Released for trade if the limit for *L. monocytogenes* is 100cfu/g and this limit is not exceeded.		If: • growth of *L. monocytogenes* will not occur in the product; and • the operator has evidence to that effect; and • the limit for *L. monocytogenes* specified in the RMP at the end of processing is not exceeded (e.g. 10 cfu/g).	Enumerate the number of *L. monocytogenes*/g where n=5, c=1, m=0 and M=10^2 cfu/g. If the level of *L. monocytogenes* is less than 100 cfu/g then in consultation with MPI, product may either be sold to the final consumer: - chilled, provided the operator has evidence that the level will not exceed 100cfu/g at the end of the product shelf life; or - frozen and labelled as "For immediate consumption following thawing". If the enumerated level exceeds the limit specified in the RMP, the product should be reprocessed or destroyed.
Frozen product: released for trade if specified limit for *L. monocytogenes* is not exceeded.		If: • growth of *L. monocytogenes* will not occur in the product; and • the operator has evidence to that effect (e.g. if product is to be	Enumerate the number of *L. monocytogenes*. If the level of *L. monocytogenes* is less than 100 cfu/g, in consultation with MPI product may be sold to the final consumer

Method of Disposal	Details of Disposal Method	Conditions	Sampling
		thawed and held prior to sale and/or consumption); and • the if level of *L. monocytogenes* is less than 100cfu/g and product is frozen. If product is to be exported, it must comply with the limits set by the relevant market. Discuss with the recognised verifier	provided it is frozen and labelled as "For immediate consumption following thawing". If the enumerated level exceeds the limit specified in the RMP, the product should be reprocessed or destroyed.
Alternative disposition	Plan must be documented in the operator's RMP. [HC Spec 15.3]		

27.14 Further Assistance

(1) If environmental monitoring indicates that there is a persistent contamination problem with *L. monocytogenes* in zones 3 or 4, the operator should seek further assistance to review the monitoring programme and to get advice on what action(s) to take.

(2) MPI reserves the right to call in the Task Group when the operator is managing corrective actions following the detection of *L. monocytogenes* to provide further technical expertise and to advise on remedial action.

(3) Where further assistance is required to review the *L. monocytogenes* management procedures, the operator should implement the remedial actions and procedures within the timeframe specified by the expert.

Guidance

A persistent contamination problem may be considered to be one where three consecutive *L. monocytogenes* non-detection has not been achieved after nine separate monitoring occasions from product batches and/or environmental samples from the critical hygiene environment following an event.

Further assistance can be obtained from:
- the Task Group;
- laboratory personnel;
- industry;
- other technical experts;
- the MPI *Listeria* guides.

For information about further assistance contact Seafood New Zealand: cathy.webb@seafood.org.nz

27.15 Records

(1) Sufficient records must be kept to demonstrate compliance with this Part. [RMP Spec 20]

(2) Records:

a) should include details of the sample (e.g. date and time of sampling, sample type and means of identification, identity of the sampler);

Guidance

One way to record the individual environmental sampling sites is to place these on a schematic diagram (flowchart) of the seafood operation. The plan may show each sample site, the frequency of sampling, etc.

b) should include the analytical results (including copies of reports from the laboratory);
c) must include details of actions in the event of a detection of *L. monocytogenes* in environment or product samples (date, action taken, etc.). [RMP Spec 20]

(3) Records must be:

a) retained for at least four years;
b) retrievable within two working days;
c) readily available to the verifier or Director-General. [RMP Spec 20]

Appendix 1: What zones should be considered when investigating the possible source of *L. monocytogenes* contamination?

(1) Zones and issues to consider when investigating the source of *L. monocytogenes* contamination include:

a) dismantling and stripping down of equipment. Take swabs from internal surfaces and analyse after cleaning to confirm any sources of contamination have been removed. Taking environmental samples after cleaning and sanitising will help pinpoint the source of contamination;
b) check for cracks, chips or other possible sources of *L. monocytogenes* in surrounding zones such as the floors, walls and/or equipment;
c) review cleaning and sanitation procedures, including the use of mid-shift hose-downs. Check correct detergent, correct sanitizer, chemical strength, contact time, use of manual scrubbing, hard to clean zones, impossible to clean zones (metal-to-metal sandwiches, nylon-to-nylon sandwiches or nylon-to-metal sandwiches), care of cleaning equipment, etc.
d) ensuring separation between the standard hygiene environment and high-care area, e.g. dedicated personnel, clothing and equipment, separate changing rooms with boot exchanges or boot washes;
e) ensure that access routes between the standard hygiene environment and high-care area are controlled;
f) the use of positive air pressure in the high-care area;
g) review procedures for incoming materials to minimise the risk of introducing *L. monocytogenes*;
h) pipe water on floors away to drains to prevent the creation of wet conditions in which *L. monocytogenes* can grow. Ensure that there are no opportunities for condensation to drip onto product contact surfaces from overhead structures, such as overhead wiring, metal work, pipes, air conditioning units or vents.

Guidance

Also see the *Listeria* Guides for further information about investigating contamination sources.

Appendix 2: Compositing of products and environmental samples for testing Q & As

What is a sample?

A "sample" is a small part or quantity that when tested is deemed to represent the lot as a whole. A sample may be from a seafood product or from an environmental swab(s).

What is the compositing of samples?

Compositing is the amalgamation of a number of samples from the same batch to produce a single 'final sample' or 'test portion' for microbiological or chemical testing.

A number of environmental swabs from the same zone, e.g. zone 2, zone 3, etc. may also be amalgamated to form a composite sample for *Listeria* spp. or *L monocytogenes* testing.

When is compositing appropriate?

Compositing is appropriate if the number of samples required to assess the microbiological or chemical quality of a batch is prohibitively large in terms of laboratory resource or cost, and the power of the decision is not lessened by compositing.

Compositing of samples is appropriate only for qualitative analyses, i.e. presence/absence tests often described as 2-class sampling plans and represented by parameters of n=5 and c=0. Compositing is not appropriate for quantitative tests. If producing seafood products for export, operators should check the OMARs to determine whether the compositing of samples is permitted.

Compositing of samples is appropriate only if the whole composite is tested. The analytical sample cannot be a sub-sample of the composite.

Are there a maximum number of samples that can be composited?

The maximum number of samples composited may be specified in the regulatory or private standards or guidelines against which the test result will be judged. Typically a single composite sample is formed from 5 samples of 25g to produce a final sample of 125g.

If not stated, the maximum number of samples that may be composited is 15, as stated by the American Public Health Association (APHA). A lesser number may be specified by the laboratory depending on suspension volume and equipment capacity.

Are there any products or situations where compositing is not appropriate?

Compositing of samples is not appropriate for Norovirus testing of shellfish from growing areas or if quantitative tests are to be carried out.

Compositing of samples may not be appropriate for investigative or exploratory sampling when routine environmental monitoring has detected *L. monocytogenes* on a zone 4 site, i.e. when trying to identify a contamination source.

Where should the compositing of samples take place?

Compositing of swab samples may occur as collected.

Compositing of product samples should occur in the laboratory to enable verification of equal proportion. Product or samples should be submitted to the laboratory either in the original unopened container or

packaging, or as separate samples. Samples should be collected aseptically by appropriately trained samplers and transported in sterile, labelled, containers to ensure maintenance of integrity of the sample.

Where compositing occurs at the premises, the operator should send the entire final composite sample to the laboratory, irrespective of final analytical sample size/weight, unless otherwise informed by the laboratory.

What are the limitations to the use of composite samples?

The testing of composite samples may reduce the sensitivity of the analytical method at very low levels of contamination such that a potentially positive result is missed.

Appendix 3: Systematic sampling of product and composite samples

Systematic sampling

The purpose of systematically testing the day's production is to determine if and when the product was contaminated with *L. monocytogenes*. Due to the sporadic nature of *L. monocytogenes* contamination events it is feasible that the high-care area, especially zone 4, may have been a source of *L. monocytogenes* contamination before it is detected.

(1) All samples should be selected using a random sampling system, e.g. the total number of cartons in the batch should be known prior to computing the sampling plan. Each carton in the batch should be issued with a sequential number and the required numbered cartons selected using random number tables.

(2) Any carton which fits the parameters of the batch but which was not included in the batch at the time of sampling should not, under any circumstances, be considered to be part of that batch (i.e. as a late entry) for the purposes of release/certification.

(3) No carton should be removed from the batch between the allocation of sequential numbers and the taking of samples. Cartons should only be removed after the samples have been taken from the batch.

(4) All cartons comprising the batch should be disposed of according the requirements in section 27.13. Disposition if *L. monocytogenes* is detected in any sample above the regulatory limit, i.e.:

a) *L. monocytogenes* is detected in a sample of product that has a regulatory limit of 0cfu/25g; or
b) *L. monocytogenes* is enumerated at levels above the limit set by the operator that has been validated to confirm that the product will not exceed the regulatory limit of 100cfu/g at the end of shelf life.

(5) If the specified limit for *L. monocytogenes* is met the operator may release the product.

Example:
The batch is:
- all chilled RTE processed and packaged between major clean downs;
- determine where this product is held and document the total number of cartons of seafood product and their location;
- assign each carton in the batch a sequential number;
- using random number tables, generate X random numbers (e.g. 30) from cartons;
- a sample should be taken from each of the X cartons (e.g. 30) corresponding to the random numbers. These samples should be stored separately to the batch.

Compositing of samples (not possible for enumeration)

(1) How to composite samples – following the detection of *L. monocytogenes* in the zone 4 environment or the product:

a) when the composite sampling of recalled product is required, the unopened packages of frozen product may be submitted to the laboratory. The laboratory will aseptically open the packages and take 25 g samples from each. These will form the composite sample which will be tested; the composite sample should not be more than five 25g samples (125g);
b) alternatively where there are large cartons of product the samples should be taken aseptically by the operator at the premises. Care should be taken to ensure that the equipment and packaging material used will not contaminate the RTE product.
c) when using an n=30 sampling plan:

i) the 30 samples may form 6 composite samples comprising five individual samples for the purposes of laboratory analysis;
ii) *L. monocytogenes*/125g, n=5, c=0, m=0 (30 x 25g sub-samples per batch = 750g tested as 6 x 125g composites, laboratory analytical results should report presence or absence of *L. monocytogenes* in a 125g sample.
iii) *L. monocytogenes* must not be detected in the product in order for it to be released;

d) when using an n=60 sampling plan:

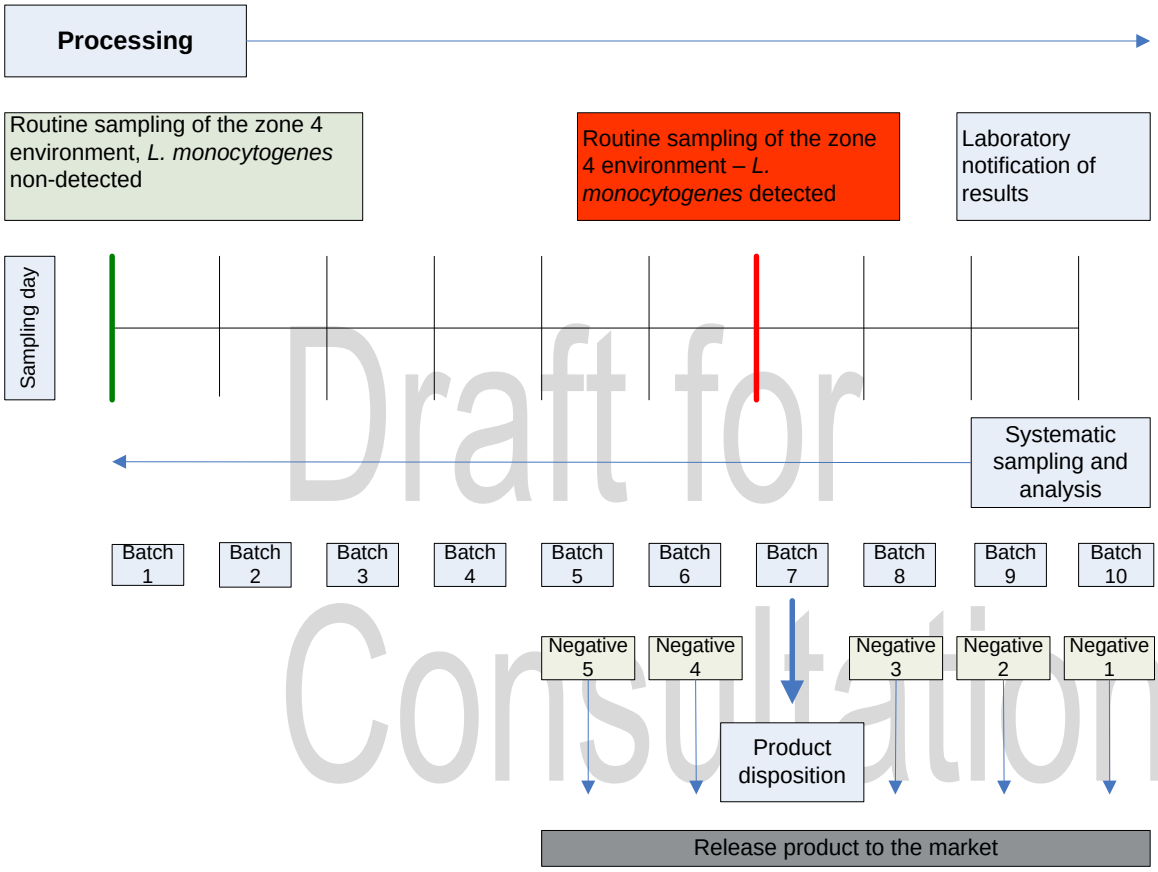
i) the 60 samples may form 12 composite samples comprising five individual samples for the purposes of laboratory analysis;
ii) *L. monocytogenes*/125g, n=5, c=0, m=0 (60 x 25g sub-samples per batch = 1500g tested as 12 x 125g composites, laboratory analytical results should report presence or absence of *L. monocytogenes* in a 125g sample.
iii) *L monocytogenes* must not be detected in the product in order for it to be released.

Appendix 4: Frozen seafood products - Examples of how to respond to analytical results during the investigative sampling of different batches of RTE seafood product

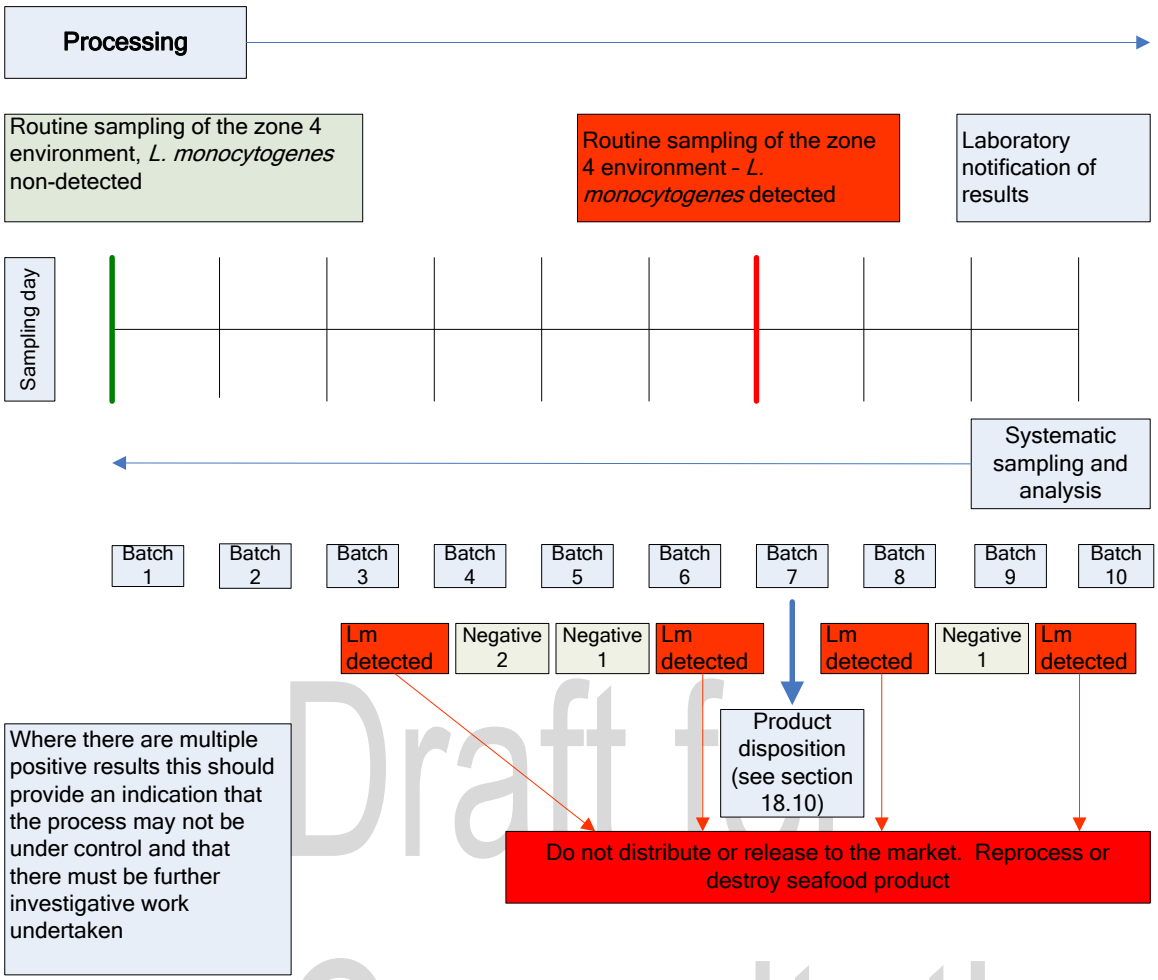
Backdating means the systematic sampling and testing of each batch of seafood product following the detection of *L. monocytogenes* in the zone 4 environment and/or product.

Example 1: Three consecutive monitoring days of compliance with specified limits for *L. monocytogenes*

A negative result means the specified limits have been met.



Example 2: Multiple detections of *L. monocytogenes* in product above specified limits during systematic sampling and testing



Appendix 5: Validation that 100cfu/g met at end of shelf life

(1) When deciding which limits to apply, if your product meets the definition of RTE and does not fall into one of the following categories, then it should be considered a product that supports growth and the 'no detect' in 25 g limit applies:

a) The food has a pH less than 4.4 (regardless of water activity); or
b) The food has a water activity less than 0.92 (regardless of pH); or
c) The food has a pH of less than 5.0 in combination with a water activity of less than 0.94; or
d) The food has a refrigerated shelf life of no greater than 5 days; or
e) The food is frozen (including foods consumed frozen and those intended to be thawed immediately before consumption)

(2) If you can validate that the level of *L. monocytogenes* will not increase by more than 0.5 log cfu/g for at least the expected shelf life, and that the level is 100 cfu/g or less throughout the stated shelf life, then it can be considered as 'not supporting growth' and the 100 cfu/g limit can be applied.

(3) There are a number of options that can be used either alone or in combination for validation:

a) consideration of process parameters, historical data and information from literature;
b) challenge testing; and
c) predictive models.

(4) Validation evidence should include how the evidence was generated e.g. the conditions under which the process or product parameters were validated.

Consideration of Process Parameters

(1) While Standard 1.6.1 of the FSC identifies some product characteristics that if applied are sufficient to inhibit the growth of *L. monocytogenes*, there are other parameters or processing methods that in combination may also work, for example pH, water activity, salt content, preservatives, use of processing aids or antibacterial agents, washing, smoking, packaging, modified atmosphere packaging.

(2) You may also have a history of testing that confirms compliance to the standard, which can be used as supporting evidence.

Challenge Testing

Challenge testing involves inoculating product with the bacteria of concern and then testing to determine the rate of growth (or not) of these bacteria during the product's shelf-life. This will usually involve sending product to a laboratory that can:

- inoculate the product with a cocktail of *L. monocytogenes* strains;
- store the product under comparable storage conditions (i.e. storage conditions that would replicate those encountered through-out the product's shelf-life); and
- test the product at regular intervals, including at the beginning and end of shelf-life.

Product submitted for shelf life testing should have characteristics that represent the worst case parameters likely to be encountered during commercial processing, and processed under the worst case conditions in relation to the inhibition of *L. monocytogenes* e.g. highest a_w, least salt, lowest additive levels etc.

This information would then be used to determine whether the level of *L. monocytogenes* will not increase by more than 0.5 log cfu/g during the shelf life.

Predictive Models

(1) Predictive models can be used to determine how bacteria will behave during the shelf life of certain products. Various details about the characteristics of the product are entered into a computer model, which will then predict the rate of growth or inactivation that will occur during the shelf-life. Many models require some knowledge of microbiology.

(2) To gather the data to enter into the model will require the identification of the pertinent product and process parameters and measuring the worst case levels for the characteristics that are likely to be encountered during processing and storage. Depending on the model used, the characteristics may include temperature, atmosphere, pH, a_w, salt content, phenol content (smoke), nitrite, organic acids e.g. acetic, diacetic, citric, lactic). For example, if salt is used as a control, salt content is measured in a number of products/batches until the lowest level of salt likely to be encountered when producing the product is determined. This then becomes an input into the model.

(3) There are a number of predictive models available. Some examples that may be suitable for use for seafood products are:

a) Food Spoilage and Safety Predictor Software, National Food Institute (DTU Food) within the Technical University of Denmark (DTU)
b) Pathogen Modeling Program - The latest version includes more than 40 models for different bacterial pathogenic bacteria and allows growth or inactivation of pathogenic bacteria to be predicted for different combinations of constant temperature, pH, NaCl/a_w and, in some cases, other conditions such as organic acid type and concentration, atmosphere, or nitrate.
c) ComBase - includes Combase Predictor (previously Growth Predictor and Food MicroModel) with growth or inactivation models for 12 foodborne pathogenic bacteria.
d) Corbion *Listeria* Control Model - predicts the growth of *Listeria monocytogenes* in food products, with the use of eight food characteristics.
e) Shelf Stability Predictor - Developed by the Center for Meat Process Validation at the University of Wisconsin - Madison to predict the growth of *Listeria monocytogenes* and *Staphylococcus aureus* on ready-to-eat meat products as a function of pH and water activity.

Other resources:

The following documents also provide useful information when validating shelf life.

a) FSANZ Guidance on the Application of Microbiological Criteria for Listeria in RTE Food.
b) MPI Guide: How to Determine the Shelf Life of Food.
c) MPI Guide: What is Validation.

Appendix 6: Validation of listericidal process after being sealed in final packaging (marinated products)

Pottled, marinated products such as mussels, squid and octopus will need to be assessed on a case by case basis to determine whether they meet the criteria for exclusion from Part 15 of the HC Spec.

To be excluded it needs to be demonstrated that the product "receives a listericidal process after being sealed in the final packaging, where that packaging ensures the prevention of recontamination until opened by the consumer or until the packaging is otherwise compromised".

One way to validate this would be to gather information about the pH, a_w, aqueous phase salt, storage temperature and time of the product and then use a modelling programme such as ComBase to determine the time to achieve a minimum of 2 $\log_{10}$ reduction in the concentration of *L. monocytogenes*. The product should not be available for sale until the time for inactivation has elapsed.

Another option would be to carry out a challenge trial where a cocktail of at least 3 strains of *L. monocytogenes* is inoculated in the product and inactivation determined.