

Guide to Primary Production and Processing of Bivalve Molluscs in Tasmania

**A guide to assist compliance with the Seafood
Food Safety Scheme of the Primary Produce
Safety (Seafood) Regulations 2014 and
Standard 4.2.1 of the Food Standards Code**



Primary Produce Safety Program
Biosecurity Tasmania

Department of Natural Resources and Environment Tasmania

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Introduction

This document is designed to assist primary producers and processors of bivalve molluscs in Tasmania to achieve compliance with the requirements of the Seafood Food Safety Scheme established under the *Primary Produce Safety (Seafood) Regulations 2014* and Standard 4.2.1 of the Food Standards Code of Australia and New Zealand (FSANZ).

The purpose of this document is to provide guidance on structural and general requirements for bivalve mollusc primary producers and processors in Tasmania to assist and support them to achieve the food safety outcomes of our contemporary risk based regulatory framework established under the *Primary Produce Safety Act 2011*.

Prescriptive elements have been included in the Guide, where appropriate, to assist producers to achieve compliance and aid in the development of systems that meet the minimum requirements of a contemporary risk based regulatory framework for the safe production of bivalve molluscs in Tasmania.

Achieving these outcomes provides for a robust primary production and processing food safety system that supports the application of the National Food Standards Code, reduces risks to consumers from unsafe or unsuitable primary produce, promotes consumer confidence in the safety and integrity of Tasmanian primary produce and facilitates market access and the trade of Tasmanian primary produce domestically and internationally.

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Scope

This Guide applies to accredited producers of bivalve molluscs and includes the range of activities, structures and equipment utilised from cultivation and harvesting (pre-harvest) through to the land based activities of packing, grading, processing, storage, supply and transport of bivalve molluscs (post-harvest).

This includes growing and harvest areas, vessels, sheds, process/packing rooms, wet storage and depuration tank rooms, transport vehicles and refrigeration.

This Guide does not apply to retailers of bivalve molluscs or the food service sector that serves bivalve molluscs in the retail, café, restaurant or catering settings.

In Tasmania, food safety controls and requirements in these settings are administered by Local Government through the *Food Act 2003*.

Definitions

Accreditation	Authority to undertake primary production and processing in accordance with the requirements of the <i>Primary Produce Safety Act 2011</i>
ASQAP	Australian Shellfish Quality Assurance Program
Bivalve molluscs	Cockles, clams, mussels, oysters, pipis and scallops
Depuration	The process that uses a controlled aquatic environment to reduce the level of certain pathogenic organisms that may be present in live shellfish
HACCP	A management system in which food safety is addressed through the analysis and control of biological, chemical and physical hazards - Hazard Analysis Critical Control Point
PPSP	Primary Produce Safety Program
Regulated fish	Abalone, bivalve molluscs and smoked or preserved fish as gazetted by the Chief Inspector of Primary Produce
Relay	the transfer of regulated fish from one area to another for the purpose of growing on or eliminating or controlling pathogenic organisms, toxins or contaminants by using the change of ambient environment as a treatment process
Shellfish	All edible species of bivalve molluscs such as oysters, clams, scallops, pipis and mussels harvested for human consumption Does not include spat, scallops or pearl oysters where only the adductor muscle is the consumable part of the product for human consumption
ShellMAP	ShellMAP Regulatory Services
Wet storage	The storage of live seafood in a land based tank that contains water

Part I - Seafood Food Safety Scheme

Legislative Framework

The Tasmanian *Primary Produce Safety Act 2011* (the 'Act') establishes a risk based regulatory framework for the application of the Chapter 4 Primary Production and Processing Standards of the Food Standards Code (the 'PPP standards') across a range of primary production commodities that are supported by industry specific regulations.

The Chief Inspector of Primary Produce Safety is a statutory role established under this Act and is held by a person who is suitably qualified in the area of primary production and processing food safety.

The PPP Standards require business to identify potential food safety hazards and implement controls that are commensurate with the risk to achieve the food safety outcomes of the PPP Standards, to their business.

Standard 4.2.1 *Primary Production and Processing Standard for Seafood* places additional requirements on producers and processors of bivalve molluscs to implement a documented food safety management system.

For primary producers and processors of bivalve molluscs, a documented food safety management system includes controls across the whole process from cultivation through to harvest and supply into the human supply chain that effectively controls the identified hazards.

The Act lists 'bivalve molluscs' as including cockles, clams, mussels, oysters, pipis and scallops.

The Australian Shellfish Quality Assurance Program (ASQAP) is referenced in Standard 4.2.1 as the National guideline for managing risks in the harvesting, relaying, depuration and wet storage of shellfish and needs to be considered in the development of a food safety management system.

The Tasmanian *Primary Produce Safety (Seafood) Regulations 2014* establish the requirement for a Seafood Food Safety Scheme for seafood businesses in Tasmania.

The Regulations, through the adoption of Standard 4.2.1 *Primary Production and Processing Standard for Seafood*, also adopt ASQAP as the relevant operational standard applicable to Tasmanian shellfish producers.

The Seafood Food Safety Scheme requires accreditation of seafood businesses and may include the preparation and implementation of a food safety program and audit by a food safety auditor in some cases.

Part 2 – Accreditation Requirements

Who needs accreditation?

If you are engaged in the activity of the primary production of seafood and any regulated fish in Tasmania, you are required to hold an Accreditation issued by the **Chief Inspector of Primary Produce Safety**.

Regulated fish includes:

- (a) abalone; and
- (b) bivalve molluscs; and
- (c) smoked or preserved fish; and
- (d) any other species, or class of fish determined under regulation 4 to be regulated.

Primary production of seafood includes the following activities:

- (a) the growing, cultivating, picking, harvesting, collecting or catching of seafood;
- (b) the growing on of seafood;
- (c) the transportation or delivery of seafood;
- (d) the holding of live seafood;
- (e) seafood processing;

This includes growers, harvesters, collectors, processors/packers, tank operators and wholesalers.

Processing of seafood includes the following activities:

- (a) the killing, cutting or gutting of seafood; and
- (b) the depuration of seafood; and
- (c) the shucking or peeling of seafood; and
- (d) the cooking, including steaming or boiling, of seafood; and
- (e) the brining of seafood; and
- (f) the smoking of or crumbing of, or addition of other food to, seafood; and
- (g) the packing, treating, washing, freezing, refrigerating, canning or storing of seafood;

Processing does not include the cooking or handling of seafood to prepare a meal for a person or the sale or service of seafood by way of retail.

Shellfish means all edible species of bivalve molluscs such as oysters, clams, scallops, pipis and mussels, either shucked or in the shell, fresh or frozen, whole or in part or process, and harvested for human consumption. The definition does not include spat, or scallops and pearl oysters where the consumed product is only the adductor muscle. (ASQAP)

Before you apply for accreditation, it is recommended that you review this Guide prior to contacting the Primary Produce Safety team to discuss your proposal.

How do I apply?

Before applying for accreditation, you will need to establish with the ShellMAP team, the process around participating in the ShellMAP harvest area management system as it applies to the farming of shellfish in Tasmania.

Once you have identified and confirmed an available lease(s) in a shellfish growing area with ShellMAP, it is recommended that you then contact the Primary Produce Safety Program to discuss your proposed primary production activity.

To apply for accreditation the following information is required to be submitted for review by the Primary Produce Safety Program:

- Form I2 - Application for Accreditation and Applicant Checklist, accompanied by:
 - A documented food safety management system
 - Documentary evidence of statutory approvals from other Government agencies
 - Supporting documentation, as outlined in the Applicant Checklist; and
- Payment of the prescribed application fee

Review will involve a desk audit of the documentation and a site inspection.

An Applicant Checklist has been included in Appendix I to assist you with collating the required supporting documentation

Approval

Once your application for accreditation as a primary producer has been assessed as satisfactory and approved by the **Chief Inspector of Primary Produce Safety**, you will be sent a Certificate of Accreditation.

The Certificate of Accreditation will include details such as:

- Your business details and trading name
- Site locations
- Species and processes covered under the scope of the Accreditation
- Authorisations granted
- Conditions of accreditation under which you must operate; and
- A Certificate expiry date

Mandatory conditions of accreditation include:

- Compliance with the legislation and your approved Food Safety Management System
- At least annual auditing of all operations by an approved Food Safety Auditor

Those producers accredited for nursery operations or growing on are exempt from the requirement to implement a Food Safety Management System and annual food safety auditing.

The Certificate of Accreditation is to be displayed in a prominent position and be available for examination at all times by an Authorised Officer of Biosecurity Tasmania or a Food Safety auditor, approved by the **Chief Inspector of Primary Produce Safety**.

As an accredited producer, you will be required to complete an Annual Return form to confirm your business and operation details, as they relate to your primary production and processing activities.

If your business details or activities change, you are required to notify the Primary Produce Safety Program to ensure that your accreditation can be varied to capture the change in your structure or operations.

Changes such as business structure/ownership, location, product or process may require you to apply for a variation to your accreditation.

Food Safety Audits

Audits may be conducted by a regulatory food safety auditor or a Third Party Food Safety Auditor, approved by the Chief Inspector of Primary Produce.

Audits are conducted to verify that controls in your Food Safety Management System are in place, and you are complying with the relevant legislation.

Where non-compliance is found, the operator and auditor will discuss outcomes and agree on a satisfactory timeframe to rectify the noncompliance and verify corrective actions so that it does not reoccur.

All audit reports are forwarded to the **Primary Produce Safety Program (PPSP)** for review and filing.

The **Primary Produce Safety Program (PPSP)** may check the work of approved Third Party Food Safety auditors to verify independence and accuracy of audits by another 'check' audit.

Third Party Food Safety Auditors are approved by the Chief Inspector of Primary Produce Safety and adhere to an Auditor Code of Conduct as a mandatory condition of their approval as a Third Party Auditor under the Act.

Audits are conducted at the producer's expense.

Variation to Accreditation

As your business grows and evolves, you may need to make changes to the activities covered by the scope of your accreditation.

This may include processes such as relay, wet storage and depuration operations or the addition of product lines and processes to an existing FSMS.

These changes are all considered a **variation** to your existing accreditation.

Each of these operations is different and will require different authorisations or approval under the Act.

Before you apply, contact the relevant team to discuss your proposal.

Current contact points are:

Relay Authorisation	ShellMAP
Wet Storage Authorisation	PPSP
Depuration Authorisation	PPSP
FSMS and process changes	PPSP

The process of application and assessment is similar to the initial accreditation application and includes the review of:

- Form 17B - Application for Variation to Accreditation
- Applicant Checklist accompanied by:
 - Amended food safety management system to include proposed new operations
 - Documentary evidence of statutory approvals from other Government agencies
 - Supporting documentation, as outlined in the Applicant Checklist; and
- Payment of the prescribed application fee

Review will involve a desk audit of the documentation and a site inspection.

The additional documentation will become part of your existing Food Safety Management System (FSMS).

Part 3 – Application Process

Review of your Food Safety Management System (FSMS)

The objective of a **Food Safety Management System** is to ensure that food produced is suitable for human consumption.

Standard 4.2.1 Primary production and processing standard for seafood of the **Food Standards Code** specifies that it must be documented for bivalves (shellfish).

Standard 4.2.1 also specifies that the Food Safety Management System includes compliance with the **Australian Shellfish Quality Assurance Program (ASQAP)**.

The **scope** of a shellfish **Food Safety Management System** includes pre and post-harvest operations.

The Food Standards Code is the Australian standard and has been modelled on an international standard described by the WHO/FAO Codex Alimentarius Commission.

This model relies on controls throughout food preparation rather than relying on end product standards alone.

According to the Food Standards Code, 3.2.1 a **Food Safety Management System** must:

- a. systematically identify the potential hazards that may be reasonably expected to occur in all food handling operations of the food business;
- b. identify where, in a food handling operation, each hazard identified under paragraph (a) can be controlled and the means of control;
- c. provide for the systematic monitoring of those controls;
- d. provide for appropriate corrective action when that hazard, or each of those hazards, is found not to be under control;
- e. provide for the regular review of the program by the food business to ensure its adequacy; and
- f. provide for appropriate records to be made and kept by the food business demonstrating action taken in relation to, or in compliance with, the food safety program.

What is a FSMS?

A **FSMS** describes and analyses your operations such that you can manage and control all possible hazards.

Documentation of the system and monitoring activities means that your operations can be verified independently through an audit process.

What does a FSMS look like?

The **Primary Produce Safety Program (PPSP), ShellMAP**, Tasmanian oyster industry and various independent consultants have developed a template specifically for bivalves (shellfish) to assist in development of your specific Food Safety Management System.

The industry template may not reflect your actual practices so it will need amendment before you forward it to the PPSP for review.

What does the industry FSMS template include?

The scope of the industry template includes receiving, growing, collecting, harvesting, relaying, handling, packaging, labelling, despatch and transport of shellfish and all other inputs e.g. packaging.

It includes procedures and monitoring records for these operations according to the **Food Standards Code**.

The template also includes other controls which you may require including for relay, wet storage operations and *Vibrio parahaemolyticus*.

It does not currently include all controls necessary for wet storage and depuration.

Review of Premises Plans and Statutory Approvals

Site and Premises Plans

To understand how your business will operate and assist in the review of the Food Safety Management System (FSMS), plans of your premises will be reviewed.

Plans of your premises should include:

A locality map and premises plan to show:

- a. Site plan including boundaries, buildings and structures
- b. Floor plan of the processing and storage areas
- c. Water supply and storage
- d. Wastewater treatment (if applicable)
- e. Plumbing and drainage
- f. Handwash station/s
- g. Amenities
- h. Packaging and hazardous substances storage
- i. Refrigeration
- j. Fixtures and fittings

These may be hand drawn, however must be legible and show adequate detail to enable a desktop review to be undertaken.

For new premises or those premises undergoing refurbishment and fit out, you will need to consult a Building Surveyor to discuss the referral and assessment process for buildings used for primary production activities (Special Use Buildings) under the *Building Act 2016*.

Statutory Approvals

According to the *Primary Produce Safety Act 2011* s 11(2):

The (food safety) accreditation does not authorise the accredited producer to do anything prohibited under another Act.

Therefore, the application must acknowledge that requirements of other applicable legislation (through other Government agencies) have been approved and provided.

Documentary evidence from other Government agencies that approvals are not required can also be provided in support of your application.

Other approvals may include:

1. Council - building, planning and plumbing design and construction
2. Council – environmental approvals for solid and liquid waste off site discharges
3. Building Surveyor – Form 10 referral to the Chief Inspector of Primary Produce Safety for the construction and/or fit out of Special Use buildings
4. Tas Water – trade waste disposal
5. NRE Tasmania Marine Resources Division – Marine farming licence and lease
6. Authority to take water

7. Environment Protection Authority – process water discharge approval
8. Animal Biosecurity – movement permits

Note – Building Act 2016

Premises used for primary production activities under the *Primary Produce Safety Act 2011* are considered 'Special Use buildings' under Schedule 3 of the *Building Regulations 2016*.

The construction and/or fit out of 'Special Use buildings' will require a Form 10 referral from your Building Surveyor to the Chief Inspector of Primary Produce Safety to assess compliance of your plans against the National Construction Code and suitability for the production, processing and handling of food.

The installation of plumbing fixtures and fittings including water treatment and storage systems (ie wet storage and depuration systems) are considered plumbing installations under the *Building Act 2016* and will require you to seek advice from your Council in relation to any approvals that may be required.

Site Inspection

On application, the **Primary Produce Safety Program (PPSP)** will contact you to arrange a site inspection of your premises.

A physical site inspection is preferable in most cases however, may be done with photos and video if necessary.

The inspection will include observations of any buildings, structures, infrastructure, fixtures, fittings and equipment that you intend to use and their suitability for use in primary production and processing.

Site inspection is included in the application fee.

The PPSP has developed a guide to assist you in determining if your premise will be compliant. Below is a summary of requirements:

More detailed information is provided in Part 4 – Premises and Equipment of this Guide, however, examples of items that will be assessed during a site inspection are:

What will be inspected?	Requirement
Premises plans and the site layout	Accurate and as shown on plans
Product and staff flows through the premises	Prevention of cross contamination
Waste and wastewater	Prevention of cross contamination Not a pest attractant
Packaging and PPE storage	Dust and pest proof
Water (fresh) and ice (if applicable)	Potability considerations
Walls, floors, ceiling and equipment	Well maintained and easy to clean and dust and pest proof (to extent necessary)
Refrigeration (if applicable)	Capacity to store at required temperature
Chemicals and storage	Prevention of cross contamination
Processing handwash facilities (or alternative)	Accessibility and equipped
Cleaning chemicals and equipment	Appropriate and stored appropriately
Amenities	Toilet and handwash available and equipped
Vehicle food carrying compartment	Well maintained and easy to clean
Surrounds	Entries treated with concrete or gravel Do not attract or provide pest harbourage
Pest control program	Accurate and appropriate
Other eg harvest vessels and vehicles	Prevention of cross contamination

If deficiencies are found at the inspection, PPSP staff will discuss with you and may request further information or structural changes to demonstrate compliance with the legislative requirements.

Part 4 – Premises and Equipment

Premises

The purpose of this information is to provide guidance on structural and general requirements for live bivalve premises in Tasmania in order to comply with the *Primary Produce Safety Act 2011* (the Act)

A seafood business must ensure that the seafood premises, including live seafood premises and equipment used in the primary production of seafood are:

- a) so far as reasonably necessary, kept clean and*
- b) designed, constructed, maintained and operated such that the safety or suitability of the seafood will not be adversely affected.*

The design and construction of premises used for food production outlined in the national Construction code states they must –

- (a) be appropriate for the activities for which the premises are used; and
- (b) provide adequate space for the activities to be conducted; and
- (c) permit the premises to be effectively cleaned and if necessary sanitised;
- (d) to the extent that is practicable –
 - a. exclude dirt, dust, odours, fumes, smoke and other contaminants; and
 - b. not permit entry of pets; and
 - c. not provide harbourage for pests; and
 - d. provide that the food premises is able to be used in a manner that minimises opportunities for food contamination

Utilising construction materials and finishes and equipment, fixtures and fittings that comply with the minimum standards outlined in Chapter 3 of the Food Standards Code and the National Construction Code will assist you with a premises that is designed to enable safe production and processing of primary produce.

General

Shed and equipment must be designed and maintained to:

- Allow effective cleaning of floors and bivalve equipment. Unsealed timber is not permitted unless adequately protected from product;
- Ensure that all water and ice (town, rain, bore, river) collection, delivery and storage is hygienic and discourages pest entry and harborage and prevent contamination
- Protect product from the environment, pests, microbiological, chemical and physical contaminants
- Pets and other animals must be excluded

Storage areas must be designed and maintained to:

- Allow effective cleaning of floors, walls, ceiling and other equipment and is dust and pest proof
- Protect product and packaging from contamination and stored off the floor
- Be adequate in size to allow for maximum capacity and

- Ensure cool rooms must have a readily accessible temperature gauge and maintain air temperature at 10°C or less taking into account maximum cool room capacity and environmental conditions

Surrounds

- Reveal and despatch entries must be treated to minimise dirt and dust transferring into the shed eg concrete or gravel and
- Be clear of possible pest harbourage eg shell waste, vegetation and disused equipment

Amenities (toilets, kitchens, office, cleaning facilities)

- Amenities must be readily accessible for staff
- Amenities (including walls, floors, ceilings and equipment) must be easily cleanable and maintained in good condition
- Toilets and hand wash stations must be readily accessible and provided with effective hand washing, sanitising and clean hand drying facilities
- If water for handwashing is not potable, non-rinse sanitiser must be available
- Sewage water must be directed into an approved onsite wastewater disposal system or Taswater's reticulated sewer network

Water

- Water that comes into direct or indirect contact with bivalves eg washing bivalves or containers and hand washing, is potable or equivalent to *Approved area* ('open status') and in adequate supply
- Ice must be made from potable water. Evidence of water and ice quality verification must be available for audit
- Installation of UV and filtration is recommended for non-reticulated water supply

Lighting

- Natural and/or artificial lighting is sufficient to carry out activities and
- Must not be a contamination risk eg shatter proof globes

Waste

- Solid waste is contained and disposed of regularly through an approved disposal system
- Waste containers are easily cleaned and pest proof
- Shell and farming material waste does not create a pest risk
- Diseased waste is contained, treated and disposed of according to biosecurity arrangements
- Liquid waste or process water is directed into drainage and an approved onsite wastewater disposal system or Taswater's reticulated sewer network

Chemicals

- Chemicals must be clearly labelled and stored in a segregated and designated area

Tractors and Forklifts

- Must be constructed to allow effective cleaning and maintained in good condition
- Ventilation (natural or artificial) must be provided to remove fumes when used near product

Personal Protective Equipment (PPE)

- PPE must be clean, well maintained and adequately stored to protect from contamination

Transport of Final Product

- Parts of vehicles used to transport final product must be constructed to allow effective cleaning and maintained in good condition
- Refrigerated compartments must have a readily accessible temperature gauge and be designed to maintain air temperature requirements, taking into account maximum capacity and environmental conditions
- Other items must not be transported adjacent to product unless effectively segregated

Vessels, vehicles and equipment used for harvest and transport

- Must be constructed to prevent contamination and deterioration of bivalves and maintained in good condition
- Unsealed timber is not permitted where frequently in contact with moisture or product
- Bilge and other polluted water including discharge must be prevented from contacting bivalves
- Containers, bags and coverings to protect bivalves from the environment and contamination must be clean and made from food safe materials
- Other items/substances (which may contaminate) must not be stored adjacent to product unless effectively segregated
- Human sewage must not be discharged overboard
- Effective hand sanitising facilities must be available onboard vessels
- Pets and other animals must be excluded

Wet storage and depuration shed and equipment

- Storage tanks, containers and related plumbing are self-draining, easily cleanable and fabricated from non-toxic, corrosion resistant materials that comply with the Plumbing Code of Australia
- Be designed to allow adequate water flow and aeration to all tank positions as far as practicable
- Have adequate security to prevent unauthorised entry while in operation

Part 5 – Food Safety Practices and General Requirements

A seafood business must take all necessary steps to prevent the likelihood of seafood being or becoming contaminated through the cultivation, harvest, packing, processing, storage and transport of seafood.

Steps to achieve this food safety outcome may include:

- Only harvesting from areas in the 'Open' status
- Exercising best practice harvest techniques that avoid:
 - Sediment disturbance
 - Harvesting during extreme water and air temperatures
 - Protecting oysters from sun and animal contamination
 - Ensuring product enters the cold chain at 10°C or less within 24 hours of harvest
 - Being aware of changes to land and water based activities in proximity to your growing and harvest areas
- Adherence to harvest area management plan requirements in relation to environmental monitoring and sampling programs
- Training of staff to handle seafood safely to avoid contamination
- Maintaining an effective cleaning, sanitation and maintenance program for the premises and equipment
- Only using water to wash shellfish that is equivalent to or better than the water quality of the harvest area
- Regular review and update of your FSMS and associated support programs
- Promote and encourage a robust food safety culture in your organisation
- Maintaining a system of effective traceability that will enable trace back to the point of cultivation
- Complying with conditions of Accreditation or Authorisation
- Adhering to your food safety audit schedule

Part 6 – Cultivation of Shellfish

Requirements

The cultivation of shellfish in Tasmania is administered by the ShellMAP Regulatory Services program located within the Marine Resources Division of NRE Tasmania.

The ShellMAP Program develop and implement Harvest Area Management plans for bivalve mollusc growing areas throughout Tasmania that outline environmental parameters for harvest and sampling programs to ensure that seafood is harvested within the parameters outlined in ASQAP, the Food Standards Code and meets the requirements of the *Primary Produce Safety Act 2011* and the *Primary Produce Safety (Seafood) Regulations 2014*.

The ShellMAP monitoring program provides for comprehensive sampling of marine environments for microbiological contaminants in shellfish waters and meats and biotoxin surveillance through the Biotoxin monitoring program.

Accredited bivalve producers that have questions around their marine farming licences and/or leases or Harvest Area Management criteria are advised to contact the ShellMAP Program via Marine Resources of NRE Tasmania, mfops@nre.tas.gov.au.

Part 7 – Harvest of Shellfish

Direct Harvest

Accredited bivalve producers harvesting for human consumption are required to ensure they comply with the requirements of Standard 4.2.1 of the Food Standards Code.

This means that harvest may only occur under the following conditions:

- The harvest area has been classified in accordance with the requirements outlined in ASQAP
- The harvest area is subject to a marine Biotoxin Management Plan
- The harvest areas is in 'Open' status at the time of harvest
- The Accredited producer is operating under a documented and approved FSMS
- The producer holds a valid accreditation under the Act

Accredited producers engaged in the cultivation of spat for the purposes of growing on are not permitted to direct harvest bivalves for supply into the human consumption market.

Some accredited producers engage in the cultivation of spat and the direct harvest of bivalves for supply into the human consumption market.

Conditions of accreditation reflect the variety of activities and sometimes multiple site locations that form part of an accredited producer's business.

Harvest for Wet Storage and Depuration

Mechanisms to 'purify' shellfish date back over a hundred years in areas where shellfish have been contaminated by increased human activity. At the basic level contaminated shellfish are relayed to clean growing areas before harvest.

Depuration mimics this process on land where shellfish are placed into tanks of clean seawater and left for a period. If clean seawater is provided throughout this period, contaminants will eventually be purged by the normal filter-feeding habit of shellfish.

It is widely recognised that although depuration systems have greatly improved, depuration has limitations and harvest from clean growing areas is preferable. The Australian Shellfish Quality Assurance Manual was developed as a standard to classify shellfish growing areas (according to environmental conditions) in response to continued food borne illness outbreaks due to contaminated oysters in NSW in the 1980s and 1990s where depuration was mandated.

Depuration will remove light to moderate levels of faecal contamination however it will not remove heavy contamination, viruses, vibrios, pesticides, heavy metals and biotoxins unless specifically designed to do so.

Little research has been done on the removal of these contaminants and may be impractical due to long retention times. The design of depuration systems and procedures must be validated against the specific required outcome.

Wet storage is a process where live shellfish, intended for human consumption are stored temporarily in land based tanks containing clean seawater (natural or synthetic), before being packaged for sale. Temporary storage in clean seawater can assist primary producers to match market demands, remove sand and may also assist by improving the condition of seafood before sale.

Wet storage is not designed to purify (depurate) contaminated shellfish but the outcome is the same in that shellfish must be safe and fit for human consumption after the process.

Food Safety Management System - Documentation

Outcome: A documented food safety management system accurately describes and analyses the primary producers operations such that all possible hazards can be analysed and managed. Documentation of the system and monitoring activities means that these operations can be reviewed and assessed:

- by the **PPSP**
- by the Primary Producer through internal audit
- and verified independently through regular Third Party audit

Requirements:

- Procedures for wet storage and depuration must form part of the existing authorised Food Safety Management System
- All documentation must be available onsite at all times
- All wet storage and depuration documentation must be handled according to existing Food Safety Management System document control procedures including:
 - Operating procedures
 - Records and laboratory reports
 - Specifications and diagrams
 - Validation study (where applicable)

Design and Construction of Wet Storage and Depuration Systems

Outcome: Wet storage and/or depuration system must be designed and constructed to ensure an adequate quality and quantity of water throughout the treatment to ensure food safety and suitability of shellfish for human consumption.

For **depuration** to be effective in removing microbiological contamination, the design of the system and the operation of the entire process must allow shellfish to:

- rapidly resume normal filter-feeding activity and to maintain this for the duration of the process. This requires optimisation of physiological conditions;
- facilitate removal and separation of thermotolerant contaminants excreted by shellfish. This requires appropriate design and operation of systems; and

- avoid any contamination or re-contamination of the shellfish during the process. This requires an appropriate quality of seawater used in the process and hygienic operation of the system.

Wet storage systems differ in that they are not intended to remove microbiological contamination, however the design of the system and operation of the process must also allow shellfish to:

- rapidly resume normal filter-feeding activity and to maintain this for the duration of their time in the wet storage process.;
- facilitate the removal of sand and improve condition of shellfish;
- avoid any contamination or re-contamination of the shellfish during the process either through mishandling the product, not adhering to approved operating procedures or poor hygienic operation of the wet storage system.

General requirements – wet storage and depuration:

The system must be approved by the **PPSP** prior to use including:

- i) Wet storage and Depuration System Specifications (see Appendix I- Applicant Checklist);
- ii) Wet storage and Depuration diagrams;
- iii) Site plans and location of seawater source/s;
- iv) Documented operating procedures; and
- v) Validation studies to ensure that water and shellfish are purified by the system under normal operating conditions as described by the above requirements

Significant changes in equipment and design must be communicated to the **PPSP** for review and approval before use and may include revalidation.

Storage tanks, containers and related plumbing are self-draining, easily cleanable and fabricated from non-toxic, corrosion-resistant materials and be protected from contamination.

Shellfish tanks are designed and constructed so that they allow the free flow of water to all shellfish in the tank. For example:

- Adequate clearance between shellfish and the tank bottom should be maintained and designed not to impact on water flow
- The waterflow should be uniform across the width of tank/s

There must be effective barriers to prevent entry of birds, animals and pests.

Indoor and outdoor systems must be secure to prevent unauthorised access through the wet storage or depuration period.

Indoor and outdoor systems must be able to operate within the critical temperature range to ensure:

- UV systems operate at optimal levels
- Shellfish continuously filter-feed and remove contaminants at an effective level
- Shellfish do not spawn or become stressed

Water Source and Quality

Outcome: Water for wet storage and depuration must be of an adequate quality that it will not adversely affect the food safety and suitability of shellfish for human consumption.

Requirements:

Water for wet storage or depuration must be sourced from an area that

- a) has been classified by the **ShellMAP Program** as –
 - (i) Approved; or
 - (ii) Conditionally approved; or
 - (iii) Approved as remote; or
 - (iv) Offshore; and
- b) is subject to a marine biotoxin management plan; and
- c) has an open status;

OR

- d) is of a quality that will not adversely affect the safety and suitability of shellfish; and
- e) is effectively disinfected or maintained during the course of wet storage (or depuration) to satisfy the conditions specified in a)

All water sources must comply with:

- i) authorisation conditions; and
- ii) Microbiological and biotoxin critical limits are as described in Appendix 2; and
- iii) Water quality critical limits are as described in Appendix 2.

Recirculating systems must be validated to demonstrate the system will consistently produce water that tests negative for thermotolerant coliforms in 100ml under normal operating conditions.

Water quality parameters such as dissolved oxygen, salinity, water temperature will affect the physiology of shellfish and consequently will affect safety and suitability of shellfish while in wet storage and depuration. Water quality parameters must be monitored and recorded.

Reused and carted water must:

- i) Comply with all water requirements
- ii) Be stored appropriately to maintain water quality

Carted water must be sourced from an area classified by the ShellMAP program and approved for use by the PPSP as part of your accreditation.

The above requirements refer to natural seawater.

Further requirements for artificial seawater (with the addition of any chemicals) or other water source eg bore water, potable supply, *Public Health Act 1997* approved commercial water supplier must be sought from the **PPSP**.

Operation of Wet Storage and Depuration Systems

Outcome: The operation of wet storage and depuration must result in safe and suitable shellfish that is fit for human consumption

Requirements:

Standard Operating procedures must be documented and reflect normal operating procedures including the following:

Pre operational requirements

Harvest for wet storage

Shellfish must be sourced from:

- i. Harvest areas in the open status that are classified as;
 - a. approved,
 - b. approved remote,
 - c. conditionally approved; or
 - d. off-shore; or
- ii. Harvest areas in the open status that are classified as restricted or conditionally restricted areas after shellfish has been subject to effective depuration
- iii. Shellfish are harvested in accordance with authorisation conditions and requirements of the harvest area management plan
- iv. Harvest areas are subject to a Biotxin Management Plan
- v. Shellfish from different harvest areas must not be co-mingled
- vi. Shellfish from different lots (ie day of harvest) are identified and traceable
- vii. Shellfish are not mixed with different species (unless authorised)

Wash and cull – wet storage

- i. Shellfish are washed to remove mud, bottom sediments, detritus and seaweed with water meeting the approved area classification or potable water standard prior to placement in wet storage tanks
- ii. Dead and damaged shellfish and other species must be removed as soon as practicable after harvesting

Note: Due to the adverse effects of culling on mussel physiology, culling of mussels may be done after wet storage

Harvest for depuration

Shellfish must be sourced from:

- i. Harvest areas in the open status and classified as;
 - a. restricted; or
 - b. conditionally restricted; or
- ii. Harvest areas in the closed status and classified as;
 - a. approved,
 - b. approved remote; or
 - c. conditionally approved
- iii. Shellfish to be depurated must not exceed a microbiological limit of 46cfu/g meat
- iv. Shellfish are harvested in accordance with authorisation conditions and requirements of the harvest area management plan
- v. Harvest areas are subject to a Biotoxin Management Plan
- vi. Shellfish from different harvest areas must not be co-mingled
- vii. Shellfish from different lots (ie day of harvest) are identified and traceable
- viii. Shellfish are not mixed with different species (unless authorised)

Wash and cull - depuration

- i. Shellfish must be thoroughly washed to remove mud, bottom sediments, detritus and seaweed with pressurised water of a standard which is at least equal to the water quality of the harvest area before placement in depuration tanks
- ii. Dead and damaged shellfish and other species must be removed as soon as practicable after harvesting

Note: Due to the adverse effects of culling on mussel physiology, culling of mussels may be done after depuration

Transport and Storage – wet storage and depuration

- i) Transport conditions from harvest to the wet storage or depuration facility including vessel and vehicle and subsequent storage must protect shellfish from adverse environmental conditions and contamination to prevent unacceptable increase in temperature and/or bacterial levels
- ii) Time between harvest and wet storage or depuration must be recorded taking into account environmental conditions

Handling – wet storage and depuration

- i) General handling must not compromise shellfish health prior to wet storage or depuration

Operational requirements

Water quality – wet storage

Water used in wet storage tanks is sourced from an area classified as **approved** and in the **open** status or from a water source that meets the following requirements:

- a. Meets the bacteriological criteria for restricted classification;
- b. Is continuously disinfected or treated so it is safe and does not adversely impact the shellfish survival and viability; and
- c. Either
 - i. is sampled daily for the total coliform group post disinfection; and
 - ii. has no detectable (ND) levels of total coliforms/100ml after treatment
or
 - iii. is proved to be of a quality following disinfection that tests negative for total coliforms, under normal operating conditions, by a validation (disinfection) study

Water quality – depuration

Water used in a depuration system is sourced from an area that is classified and in open status and meets the restricted or conditionally restricted classification. Water may be sourced from outside a classified harvest area (with the approval of PPSP) or from a closed approved, approved remote or conditionally approved harvest area provided the source water quality does not exceed total coliforms of 70 cfu/100ml.

Water treatment or disinfection processes need to achieve a total coliforms level of not detected in 100 ml for use as part of the depuration process.

Common methods of source water treatment and disinfection may include UV, chlorine or ozone processes. The system design and operational procedures for your depuration facility will be specific to the chosen water treatment process and site specific design considerations.

System loading – wet storage and depuration

Wet storage and depuration systems vary in purpose, design and type, however there are general principles that apply to both types of systems around hygienic operation, ensuring adequate water flow, achieving and maintaining an acceptable water quality and preventing the contamination or re-contamination of shellfish undergoing the process.

Tray and basket systems are commonly used methods to load tanks, however, your system may utilise another method which will need to be considered when designing your process and preparing your operational procedures for consideration by PPSP.

Tray/basket loading

- i) Trays/baskets must be cleaned according to cleaning procedures prior to loading
- ii) Shellfish must be added to trays/baskets according to the System Specification Form with regard to maximum stock capacity and number of layers/capacity of shellfish in trays/baskets
- iii) Dead and damaged shellfish must be removed before loading
- iv) Trays/baskets should not sit directly on the base of the tank and typically are placed on battens that run parallel to the direction of flow so as not to impede or restrict water flow through the system
- v) There should be free flow of water through the trays/baskets and the shellfish to ensure they are able to open freely and excreted faeces can fall through to the base of the system

Tank loading

- i) Tanks and tray frames must be cleaned according to cleaning procedures prior to loading
- ii) Water quality parameters must be measured before loading to ensure minimal shock to shellfish when filling
- iii) Trays must be added according to the System Specification Form with regard to maximum stock capacity and number of layers of trays prior to filling with water

Tank filling

- i) Filling tanks after treatment of source water is the optimal practice
- ii) In the case of tanks that are filled with water requiring a water treatment process, tanks would only be loaded with shellfish once an effective level of disinfection had been achieved and verified
- iii) Shellfish must be fully immersed once the tank is filled

Period of wet storage

- i) Wet storage is intended for the temporary post-harvest storage of shellfish
- ii) Time of commencement and cessation of wet storage must be recorded eg means the time when the shellfish are fully immersed and when the shellfish are removed from the tank
- iii) Extended wet storage (if applicable) must be validated to ensure the safety and suitability of shellfish for human consumption
- iv) Controls for the use of biofilters, filters, ozone and UV or other methods of disinfection must be documented as applicable
- v) Adjustments to filters or other equipment during wet storage must be done according to documented procedures

- vi) Traceability of shellfish must be maintained

Period of depuration

- i) The documented period of depuration is a minimum of 36 hours with the method of disinfection capable of achieving a 3 log reduction of Escherichia coli
- ii) Alternate timeframes may be considered if supported by a validation study to demonstrate the time and method of disinfection are capable of achieving a 3 log reduction of Escherichia coli
- iii) Time of commencement of treatment must be recorded eg means the time when the stock are fully immersed and water is pumping through the system
- iv) The treatment process must continue uninterrupted for a minimum of 36 hours or for the period validated and with equipment specified in the System Specification Form
- v) Controls for the use of biofilters, filters, ozone and UV or other methods of disinfection must be documented as applicable
- vi) Adjustments to filters or other equipment during treatment period must be done according to documented procedures
- vii) Traceability of shellfish must be maintained

Drain down – wet storage and depuration

- i) Any foam or scum on the water surface must be removed prior to drain down
- ii) Shellfish must not be disturbed while draining and only removed after water is drained to below the level of shellfish
- iii) Water remaining after draining must be discarded or treated according to documented procedures

Handling of shellfish after wet storage or depuration

- i) Shellfish must be stored, transported and packed for market according to the Food Safety Management System

Removal (harvest) from the wet storage or depuration system

Shellfish harvested after treatment or wet storage must be protected from contamination and temperature abuse according to the Food Safety Management System.

Shellfish must be packed, labelled and despatched according to the Food Safety Management System.

Malfunction

If there is a breakdown of services, during depuration, due to equipment failure or interruption of electrical supply of less than 6 hours duration, the period of depuration must be made up to the required **36 hour** period following resumption of normal services.

If a breakdown of services of more than six hours occurs, depuration of the shellfish must recommence from the beginning for the full 36 hours, or the shellfish must be returned to the harvest area.

If there is a breakdown of water disinfection processes, during wet storage in systems that utilise continuous disinfection and recirculation, there is potential for the quality of the water used in the wet storage tank to degrade and compromise the microbiological quality of the shellstock in the wet storage tank.

On becoming aware of a breakdown impacting the efficacy of water disinfection processes, the operator will need to verify that the quality of the tank water has not been compromised, and confirm the breakdown has not introduced contamination to the shellstock in the wet storage system.

Shellfish must be closely inspected for signs of gaping, weakness or tightly closed, corrective action taken.

If water quality parameters are not within critical limits corrective action must be taken.

The Tank operator must notify the **PPSP** in writing, of malfunction of the system where food safety may be compromised.

Monitoring and recording

Harvest records must be completed for each day of harvest;

OR

Transfer records (if applicable) must be completed for every movement of shellfish harvested for wet storage or depuration;

Wet storage / Depuration cycle records must be completed throughout every cycle of the system including any corrective actions taken;

Malfunction nature and duration must be recorded according to corrective action procedures in the Food Safety Management System including actions to ensure the event does not reoccur.

Validation Study of the Recirculation System

Outcome: The operation of recirculating wet storage or depuration systems must be validated to ensure safe and suitable shellfish under normal operating conditions, taking into account the uniqueness of the system.

The recirculating system must ensure that contamination is reduced (or maintained) after wet storage or depuration to achieve the required finished product limits outlined in the Food Standards Code of *Escherichia coli* - Not exceeding 2.3 cfu/ g (meat).

Requirements:

Validation is required for wet storage and depuration recirculation systems to ensure that they are capable of maintaining or reducing bacterial levels to specified levels from a specified initial bacterial loading and under normal operating conditions.

Source water and source shellfish contamination levels must be:

Parameters	Critical limits
Wet Storage	
Source water No treatment	Total coliforms not exceeding 14 cfu/100ml
Source water To be treated/disinfected	Total coliforms - Not exceeding 70 cfu/100ml
Treated water (sample taken from spray bar)	Total coliforms not detected (ND) in 100ml
Source stock	<i>Escherichia coli</i> - Not exceeding 2.3 cfu/ g (meat)
Finished Product	<i>Escherichia coli</i> - Not exceeding 2.3 cfu/ g (meat)
Depuration	
Source water Pre-treatment	Total coliforms not exceeding 70 cfu/100ml
Treated water (sample taken from spray bar)	Total coliforms not detected (ND) in 100ml
Source stock	<i>Escherichia coli</i> - Not exceeding 46 cfu/g (meat)
Finished product	<i>Escherichia coli</i> - Not exceeding 2.3 cfu/ g (meat)

A validation study must be done:

- i) prior to authorisation (per tank)
- ii) when any validation study has failed to comply with critical limits
- iii) when there is a significant change to system equipment or operational procedures
- iv) at a frequency specified by the **PPSP** eg to take into account seasonal water conditions or different water sources

A validation study does not negate the need for further verification testing.

- Authorisation conditions include ongoing verification testing at a specified frequency

The validation study must follow the validation study protocol in Appendix 3 or an approved alternative.

Good Manufacturing Practices (GMP)

Outcome: The operation of wet storage and depuration must result in safe and suitable shellfish for human consumption.

Requirements:

Standard Operating procedures designed to ensure the hygienic operation of the system and must be documented to reflect normal operating procedures including the following:

- **Personal Hygiene**
 - i) Staff must comply with personal hygiene procedures documented in the Food Safety Management System
- **Water**
 - i) Water used for cleaning must be potable or from an Approved water source
 - ii) The cleanliness of water must be verifiable by test results if not from Taswater
- **Cleaning**
 - i) Staff must comply with cleaning procedures documented in the Food Safety Management System and the cleaning schedule
 - ii) Cleaning chemicals must be sourced from Approved Suppliers and suitable for use in the food industry
 - iii) Cleaning must be recorded on the wet storage and depuration monitoring record

Example cleaning schedule:

NOTE: this is an example of how a cleaning schedule may be presented and is not an example of the minimum standards required. Please customise to your business activity.

Equipment to be cleaned	Frequency	Procedure for cleaning	Chemical*	Responsible
Tanks, baffles and trays	After and before every cycle	Rinse	Potable water only	Tank Operator
Tank system including baffles and trays (cleaning in place)	After discarding used water and as per manufacturers instructions	Circulation for at least 2 hours followed by rinsing or as per manufacturers instructions	Chlorine based or as per manufacturers instructions Note UV will deactivate chlorine	Tank Operator
Water cartage containers				Approved supplier assessment
Filters	Daily/As per manufacturers instructions	High pressure rinse/ As per manufacturers instructions	Potable water only/ As per manufacturers instructions	Tank Operator
UV sleeve	As per manufacturer instructions			

*Dilute chemicals at manufacturers instructions or specify

- **Maintenance**

- i) Staff must comply with maintenance procedures documented in the Food Safety Management System and the Preventative Maintenance schedule
- ii) All maintenance must be recorded on the Wet storage and depuration cycle record

Example maintenance schedule:

NOTE: this is an example of how a maintenance schedule may be presented and is not an example of the minimum standards required. Please customise to your business activity.

Equipment	Requirement	Frequency	Responsible
Pump/s check	Fully operational	Before every cycle	Tank Operator
			Contractor

UV bulb replacement	Replacement	As per manufacturers instructions	Tank Operator
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- **Pest Control**

- i) Staff must comply with pest control procedures documented in the Food Safety Management System

- **Calibration**

- i) Staff must comply with calibration procedures documented in the Food Safety Management System and the Calibration schedule
 - ii) Calibration must be recorded
 - iii) Equipment out of tolerance must be recalibrated or replaced
 - iv) Calibration schedule example:

Example calibration schedule:

NOTE: this is an example of how a calibration schedule may be presented and is not an example of the minimum standards required. Please customise to your business activity.

Equipment	Calibration Check Method	Frequency	Responsible	Recorded
Salinity meter	As per Manufacturer instructions	Before every cycle	Tank Operator	Calibration record
Thermometer probes	Ice slurry method	Monthly	Tank Operator	Calibration record
Water flow pressure gauge				
Temperature control gauges				

Responsibilities and Training

Outcome: Tank operators must have the skills and knowledge to carryout operations according to documented procedures and responsibilities.

Requirements:

Responsibilities of the designated tank operator/s must be documented for example;

- Operating the system according to documented procedures and authorisation conditions

- Verifying that procedures are current (through internal audit) and maintaining document control
- Validation of the system as required
- Verification testing of input water and shellfish and output water and shellfish as required
- Completion of all applicable records
- Ensuring staff are trained in Good Manufacturing Practices and other relevant procedures
- Arranging and verifying maintenance to the system
- Notifying the **PPSP** of significant changes to equipment or procedures
- Verifying traceability of product throughout the process of wet storage or depuration
- Collating all information in the event of recall
- Notifying the **PPSP** of serious malfunction of the system where food safety may be compromised
- Malfunctions and corrective action are recorded including actions to ensure the event does not reoccur
- Validation of the system as required (repeat from above)
- Verification testing of input water and shellfish and output water and shellfish as required (repeat)

The designated tank operator/s must be trained to a level of expertise considered adequate by the **PPSP** which may include some or all of the following areas:

- Depuration training recognised by PPSP
- Principles and Application of HACCP
- Mentoring/peer support from plant operators recognised by PPSP as being suitably qualified and experienced
- Sampling and despatch of samples
- System operating procedures
- Use and calibration of equipment
- Analysing laboratory reports (unless undertaken by a trained expert)

Evidence of tank operator/s training must be documented including experience.

Identification, Traceability and Recall

Outcome: To ensure that all shellfish can be accurately identified and traced from harvest, throughout wet storage or depuration and to point of sale if investigation, withdrawal, and/or recall is required.

Requirements:

Staff must comply with traceability and labelling procedures documented in the Food Safety Management System.

Staff must comply with recall procedures documented in the Food Safety Management System.

Traceability is maintained through the following identification and example records:

Process step	Product markings	What is recorded	Records
Receival and storage	Bag tags	<ul style="list-style-type: none"> – Harvest details – Confirmation of source shellfish harvest area status 	Harvest record or Receival and transfer records
Tanking	Tank No	<ul style="list-style-type: none"> – Tank No – Grades – Batch No 	Whiteboard Wet Storage or Depuration cycle form
Packing and storage	Trade description	<ul style="list-style-type: none"> – Batch no – Dates of treatment 	Wet Storage or Depuration cycle form
Despatch	Trade description	<ul style="list-style-type: none"> – Batch no – Date Packed – Grade 	Despatch record and or Invoice

Testing

Outcome: Shellfish and water treated for wet storage or depuration are verified on regular basis using correct techniques.

Requirements:

A primary producer implementing wet storage or depuration treatments must comply with the biological sampling and provisions of Appendix 2 (Analysis of water for wet storage and depuration).

A primary producer collecting or harvesting shellfish (for treatment or market) must comply with the biological sampling and provisions of Appendix 4 (Analysis of shellfish).

Samples must be taken and handled by staff trained in documented sampling procedures, taking into account:

- Sterile (aseptic) techniques
- Number of shellfish required per sample
- Recording of accurate sampling and traceability details
- Transport conditions including temperature and time to transport
- Filing sample submissions and results

Analysis must be carried out in a laboratory approved by the National Association of Testing Authorities (NATA) for the specific type of biological indicator

Laboratory reports must be analysed by trained staff.

Part 8 – Resources

The following resources are provided for informative purposes only.

Standards

Food Standards Code

<https://www.foodstandards.gov.au/code/Pages/default.aspx>

Chapter 3

Chapter 4 – Standard 4.2.1 primary Production and Processing Standard for Seafood

Australian Shellfish Quality Assurance Manual (ASQAP)

<https://www.safefish.com.au/reports/manuals-and-guidelines/the-australian-shellfish-quality-assurance-program-manual>

Legislation

<https://www.legislation.tas.gov.au/>

Primary Produce Safety Act 2011

Primary Produce Safety (Seafood) Regulations 2014

Building Act 2016

Building Regulations 2016

Technical Documents

FAO Fisheries Technical Paper 511 Bivalve depuration: fundamental and practical aspects

<https://www.fao.org/3/i0201e/i0201e00.pdf>

Appendices

Appendix I – Application Checklist

This checklist has been developed to assist bivalve producers to consider all relevant factors and collate the required supporting documentation for an application for accreditation under the *Primary Produce Safety Act 2011*.

I am applying for			
<input type="checkbox"/> Accreditation including (check all that apply):			
<input type="checkbox"/> Relay Authorisation (PPSP refers to ShellMAP) <input type="checkbox"/> Wet Storage Authorisation <input type="checkbox"/> Depuration Authorisation <input type="checkbox"/> Other (please specify):			
<input type="checkbox"/> Variation to Accreditation including (check all that apply):			
<input type="checkbox"/> Relay Authorisation (PPSP refers to ShellMAP) <input type="checkbox"/> Wet Storage Authorisation <input type="checkbox"/> Depuration Authorisation <input type="checkbox"/> Other (please specify):			
Species			
<input type="checkbox"/> Pacific Oyster <input type="checkbox"/> Mussel <input type="checkbox"/> Other (please specify):			
Supporting Documentation to be Included			
<input type="checkbox"/> Application form			
<input type="checkbox"/> Statutory Approvals (attach documentary evidence)			
Yes	No	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Planning
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Building
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Plumbing
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Taswater Trade Waste Agreement (If in Taswater's reticulated sewer network)

<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Export Registration <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Other (please specify):
<input type="checkbox"/> Site services Water Supply <ul style="list-style-type: none"> <input type="checkbox"/> Reticulated water (Taswater) <input type="checkbox"/> Rainwater tank <input type="checkbox"/> Bore <input type="checkbox"/> Other (please specify): <ul style="list-style-type: none"> <input type="checkbox"/> Treated <input type="checkbox"/> Untreated <input type="checkbox"/> Chlorine <input type="checkbox"/> UV <input type="checkbox"/> Other (please specify): Wastewater Disposal <ul style="list-style-type: none"> <input type="checkbox"/> Onsite wastewater treatment and disposal <input type="checkbox"/> Reticulated sewer network (Taswater) <input type="checkbox"/> Other (please specify):
<input type="checkbox"/> Plans & diagrams – may be hand drawn, but must be legible and show adequate detail <ul style="list-style-type: none"> <input type="checkbox"/> Site plan including boundaries, buildings and structures <input type="checkbox"/> Floor plan of the processing and storage areas <input type="checkbox"/> Water supply and storage (if applicable) <input type="checkbox"/> Onsite wastewater treatment (if applicable) <input type="checkbox"/> Plumbing and drainage <input type="checkbox"/> Handwash station(s) <input type="checkbox"/> Staff amenities <input type="checkbox"/> Packaging and chemical storage <input type="checkbox"/> Refrigeration <input type="checkbox"/> Internal fixtures, fittings and equipment

Food Safety Management System (FSMS) Documentation

This may include a HACCP based program or your industry template which is customised to reflect the operations of your business

FSMS document

Items to consider in your FSMS document:

Yes No N/A

- | | | | |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Process flow diagram (HACCP flow chart), depicting all steps in your process |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Product specifications for all products |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Hazard analysis table includes all process steps and hazards |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | HACCP table includes all identified CCP's |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Validation table includes all identified CCP's |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Training identified as a result of changes to FSMS |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Support programs and work instructions amended/developed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Procedures amended/developed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Verification schedule includes all activities |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Site and floor plans updated |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Forms register updated |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Amendment register updated |

Wet Storage and Depuration Process Description

Process

Wet storage Depuration Both

Type of facility

Indoor Outdoor Other (please specify):

Schematic flow diagram with the main individual components labelled (please provide for review)

Sole occupancy

Shared occupancy (please specify name of business and activity undertaken):

Species

Pacific Oyster Mussel Other (please specify):

Type of system

Recirculation Continuous flow Both

Pool type High Density Tray

Schematic flow diagram with the main individual components labelled provided

Name of system designer (if applicable):

Source water

Classified harvest area (please specify):

Unclassified waters

Both

Artificial sea water

Source water pre-treatment

Filtration Settlement UV Chlorine Ozone Other (please specify):

Water re-use Yes No

If 'yes' describe how water will be stored and treated between use:

Describe where and how water is sourced and transported to the processing facility for the system. Please include the location and depth of intake:

Describe how and where water from the tanks will be disposed of at the end of the cycle and after cleaning:

Operating procedures

- Incorporated into FSMS
- Stand alone manual (please provide a copy for review)

Training

Please indicate any training already undertaken or proposed to be undertaken in relation to the operation of a wet storage process

- HACCP
- Self-taught through the use of online technical resources and professional networks
- Course provided through a Registered Training Organisation (RTO)
- Course provided by an Australian shellfish regulator
- Mentoring and technical support from a producer who currently holds a wet storage authorisation
- Training provided by your industry organisation
- Other (please specify):

Wet Storage and Depuration Tank Specifications

Note - If multiple tanks will be used, please provide a separate specification listing for each tank utilised in the system

Total number of tanks (please specify):

Tank No.

Construction material (please specify):

Type of tank Pool High Density Tray Other (please specify):

Water area dimensions

Length (m)

Width (m)

Depth (m)

Sump volume (L x W x D)

Gross tank capacity (L)

Volume within pipe work (L)	
Gross tank capacity + volume of pipe work (L)	
Net Tank Volume (L) (gross tank capacity + pipe work (~100L) – displacement volume of stock)	
Minimum flow rate L/hr (net volume x 2)	
Maximum flow rate L/hr (net volume x 5)	
Tank flow rate	
Stock displacement volume (L) (~25% gross tank capacity)	
Method of aeration	
Re-use storage tank capacity (L)	
Drainage residual (L)	
Self-draining tank?	
Tray/Basket and Tank Loading	
Maximum stock capacity (grade and numbers/m ² , kg or count)	
Maximum number of layers of shellfish/tray	
Type of tray/basket used	
Partitioning between layers and material used for partition (if applicable)	
Pump Specifications	
Pump make and model	
Flow rate (L/hr @ 0m head)	
Recirculation systems only: Rate of water circulation (Net tank volume/hr)	
Filtration Specifications	
Filter type	

<input type="checkbox"/> Cyclonic <input type="checkbox"/> Sand <input type="checkbox"/> Bag <input type="checkbox"/> Cartridge <input type="checkbox"/> Other (please specify):	
Filter sizes (micron)	
Fractionator utilised (ie skimmer)	
Disinfection System Specifications	
The disinfection system must be capable of achieving a minimum 99.9% kill rate (3 log reduction) of Escherichia coli	
Disinfection unit make and model	
Manufacturer's operating temperature range (°C)	
Number of disinfection units	
UV dose (mJ/cm ²)	
Total disinfection capacity (L/hr)	
Lamp type and wattage	
Lamp life according to manufacturer (hrs)	
Is turbidity <20 NTU prior to entering disinfection unit	
Other Equipment	
Please provide details of the equipment that will be used in the operation of the system. Including thermometers, sensors, hand held meters etc.	
Heating present	
Cooling present	
Temperature monitoring method	
Supplementary aeration	
Dissolved oxygen monitoring method (Maintain >5mg/l)	
Salinity monitoring method (Maintain >20.5 ppt)	
Turbidity monitoring method	

Other parameters monitored	
Checklist completed by: Name: _____ Signature: _____ Date: _____	

Appendix 2 – Water Quality Parameters

Table 2a Analysis of water used for wet storage and depuration - biological

Water used for WET STORAGE – biological requirements						
System	Collection site	Sample site	When	Indicator	Critical limits	Frequency
Flow through	Open Approved harvest area	Approved harvest area water sample site	While wet storage	Thermotolerant coliforms	Not exceeding 14 cfu/100ml	As required by the harvest area management plan
Recirculating	Open Approved harvest area	Storage tank outlet	<i>Before</i> entering wet storage	Thermotolerant coliforms	Not exceeding 14 cfu/100ml	<ul style="list-style-type: none"> – Monthly – Validation – As required by the Authority eg wet storage failure or start up after a prolonged period
Recirculating	Open Approved harvest area	Spray bar outlet	<i>After water treatment</i>	Thermotolerant coliforms	Not detected in 100ml	<ul style="list-style-type: none"> – Monthly – Validation – As required by the Authority eg wet storage failure or start up after a prolonged period
Flow through and Recirculating	Open Approved harvest area	Approved harvest area water sample site	<i>Before</i> entering wet storage	Total PST	<0.8 STX eq. mg/kg	As required by the biotoxin management plan
Recirculating	Approved water collection site	Approved sample site	<i>Before</i> entering wet storage	Total PST	<0.8 STX eq. mg/kg	As required by the biotoxin management plan

Water used for DEPURATION – biological requirements						
System	Collection site	Sample site	When	Indicator	Critical limits	Frequency
Recirculating	Approved water collection site	Storage tank outlet	<i>Before</i> entering depuration	Thermotolerant coliforms	Not exceeding 70cfu/100ml	<ul style="list-style-type: none"> – Monthly – Validation – As required by the Authority eg wet storage failure or start up after a prolonged period

Recirculating	Approved water collection site	Spray bar outlet	After water treatment and during depuration	Thermotolerant coliforms	Not detected in 100ml	<ul style="list-style-type: none"> - Monthly - Validation - As required by the Authority eg wet storage failure or start up after a prolonged period
Recirculating	Open Approved harvest area	Approved harvest area water sample site	Before entering depuration	Total PST	<0.8 STX eq. mg/kg	As required by the biotoxin management plan
Recirculating	Approved water collection site	Approved sample site	Before entering depuration	Total PST	<0.8 STX eq. mg/kg	As required by the biotoxin management plan

Table 2b - Analysis of water used for wet storage and depuration – water quality

Recirculating water systems – water quality requirements						
System	Collection site	Sample site	When	Indicator	Critical limits	Frequency
Recirculating	Wet storage - Open Approved harvest area OR Approved water collection site Depuration – water not exceeding 70 cfu/100ml	Storage tank outlet and Spray bar outlet	Before and during wet storage or depuration	Salinity	Greater than 20.5 parts per thousand	Every cycle
				Temperature	8 - 18°C	Prior to and throughout each cycle
				Turbidity	Not exceeding 20 (NTUs) ¹	Prior to and throughout each cycle
				Dissolved oxygen,	Maintain >5mg/l	Prior to and throughout each cycle
				Nitrates/nitrites, pH	As required by Wet storage Depuration standard operating procedures	As required by Wet storage Depuration standard operating procedures

¹ Measured in accordance with the Standard Methods for the Examination of Water and Wastewater, 17 ed., APHA et al., 1989.

Appendix 3 – Validation (Disinfection) Study Protocol

Title	Validation study for wet storage and depuration recirculation tanks
Objectives	<ol style="list-style-type: none"> 1. To ensure that disinfected water used for wet storage and/or depuration in a recirculating system meets ASQAP criteria: “to test negative for the total coliform group, under normal operating conditions” and 2. To ensure that shellfish meet the ASQAP criteria for harvest after wet storage or depuration under normal operating conditions
Scope:	This study is used to validate wet storage and depuration recirculation tanks where normal operating conditions are described by the System Specification Form and documented procedures
a) Water source/s	<p>Wet storage – sourced in accordance with the options outlined in section 8.3 of ASQAP</p> <ol style="list-style-type: none"> 1. Depuration – sourced in accordance with the options outlined in section 8.2 of ASQAP <p>Note Water collection point/s must be approved by the PPSP prior to undertaking a disinfection study</p>
b) Species	Pacific oyster
c) Target pathogen	<p>Water - Thermotolerant coliforms</p> <p>Meat - <i>Escherichia coli</i></p>
Validation method	<p>The parameters used to validate the disinfection of water are based on the ASQAP manual. In summary this requires testing:</p> <ul style="list-style-type: none"> – source water and disinfected water for a specified period and – reused water and disinfected water for the same period – source and disinfected meats for the same period
Re validation frequency	<p>A validation study must be done:</p> <ul style="list-style-type: none"> – prior to authorisation (per tank) – when any validation study has failed to comply with critical limits – when there is a significant change to system equipment or operational procedures – at a frequency specified by the Authority eg to take into account seasonal water conditions or different water sources <p>Note Authorisation conditions include ongoing verification testing at specified frequency</p>
Wet storage period	<p>Short term wet storage</p> <p>Commencement of treatment means - the time when the stock are fully immersed and water is pumping through the system</p>

	End of treatment means – the time when tank is empty and stock are no longer immersed
Depuration period	At least 36 hrs where: Commencement of treatment means - the time when the stock are fully immersed and water is pumping through the system End of treatment means – the time when tank is empty and stock are no longer immersed
Parameters	Critical limits
Source water/s	Wet storage – Total coliforms - Not exceeding 14 cfu/100ml Depuration - Total coliforms - Not exceeding 70 cfu/100ml
Disinfected water	Total coliforms - Not detected in 100ml
Source stock	Wet storage – <i>Escherichia coli</i> - Not exceeding 2.3 cfu/ g (meat) Depuration - <i>Escherichia coli</i> - Not exceeding 46 cfu/g (meat)
Finished Product	<i>Escherichia coli</i> - Not exceeding 2.3 cfu/ g (meat)
Sampling	Method
Source water	One 100ml sample daily for five consecutive days prior to the source water entering the disinfection system Sampled at pre-disinfection point – position must be identified eg on a diagram
Treated water (per tank)	Collect three 100ml samples per day (4hrs apart) for five consecutive days Sampled at inlet or outlet of each disinfection unit – positions must be identified eg on a diagram
Source stock	At least five samples (12 shellfish) pre-treatment Note stock should come from one lease only
Treated stock (per tank)	At least five samples (12 shellfish) post-treatment to represent all parts of each tank on a horizontal plane – positions must be identified eg on a diagram At least five samples (12 shellfish) post depuration to represent all tray layers in the water column – positions must be identified eg on a diagram Note samples should not be composited
Reused water	Where water is reused, the validation study must be repeated ie the second cycle
Laboratory	NATA accredited for Thermotolerant coliforms and <i>Escherichia coli</i>
Monitoring	All monitoring of the recirculation system is carried out during the period of the disinfection study to demonstrate normal operating conditions

Training	<p>Staff operating the system must be trained in:</p> <ul style="list-style-type: none"> – sampling and despatch procedures – recirculation system operations and maintenance/cleaning – use and calibration of monitoring equipment – analysing laboratory reports
Results and Corrective action	<p>Where any water or meat sample exceeds critical limits, the study must be repeated</p>
Validation records	<p>Validation records must be available for review including:</p> <ul style="list-style-type: none"> – Wet storage and/or depuration specification form – Diagram of recirculation system and source water collection including sample locations – Laboratory submission records – Laboratory results – Harvest record – Wet Storage or Depuration cycle record – Equipment calibration record – Observations by the recirculation system operator where appropriate – Water quality checks – Graphs eg coliforms in water over wet storage/depuration period

Appendix 4 – Analysis of Shellfish – biological requirements

Product	Sample site	When to test	Indicator	Critical limits	Frequency
Wet storage shellfish (meat) – Biological requirements					
Shellfish (including wild stock) harvested	Shellfish received	Before wet storage	<i>E coli</i>	Not exceeding 2.3 cfu/g (meat)	As required by the harvest area management plan

for wet storage						
Wet storage shellfish	Flow through or Recirculating tank	After wet storage	<i>E coli</i>	Not exceeding 2.3 cfu/g (meat)	Validation, monthly verification and as required by the Authority eg system failure or start up after a prolonged period	
Shellfish	Shellfish for sale	Before harvest for sale	Marine biotoxins	AST	< 20 mg/kg	As required by the harvest area management plan
				DST	< 0.2mg/kg	
				PST	< 0.8mg/kg	
				NST	< 0.8mg/kg	
Depuration shellfish (meat) – Biological requirements						
Shellfish (including wild stock) harvested for depuration	Shellfish received	Before depuration	<i>E coli</i>	Not exceeding 46 cfu/g (meat)	Validation only	
Depurated shellfish	Recirculating tank	After depuration	<i>E coli</i>	Not exceeding 2.3 cfu/g (meat)	Validation, monthly verification and as required by the Authority eg disinfection failure or start up after a prolonged period	
Shellfish	Shellfish for sale	Before harvest for sale	Marine biotoxins	AST	< 20 mg/kg	As required by biotoxin management plan
				DST	< 0.2mg/kg	
				PST	< 0.8mg/kg	
				NST	< 0.8mg/kg	

Wild stock	Shellfish received from collector	<i>Before harvest for sale</i>	Marine biotoxins	AST	< 20 mg/kg	As notified by the Authority
				DST	< 0.2mg/kg	
				PST	< 0.8mg/kg	

Contact

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