



Government of **Western Australia**  
Department of **Health**

# **WESTERN AUSTRALIA SHELLFISH QUALITY ASSURANCE PROGRAM (WASQAP)**

## **INDUSTRY MANUAL/USER GUIDE**

**Version 7**  
**2020**

REQUIREMENTS TO COMPLY WITH THE FOOD ACT 2008 (WA) AND STANDARD 4.2.1  
PRIMARY PRODUCTION AND PROCESSING STANDARD FOR SEAFOOD OF THE FOOD  
STANDARDS CODE

# WESTERN AUSTRALIA SHELLFISH QUALITY ASSURANCE PROGRAM (WASQAP) Industry Manual/ User Guide

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## Acronyms

ASP	Amnesic shellfish poisoning (domoic acid)
ASQAAC	Australian Shellfish Quality Assurance Advisory Committee
ASQAP	Australian Shellfish Quality Assurance Program (Operations Manual)
DAWE	Australian Government Department of Agriculture, Water and the Environment
DPIRD	Department of Primary Industries and Regional Development (Fisheries WA)
DOH	Department of Health Western Australia
DSP	Diarrhetic shellfish poisoning (okadaic acid)
Food Act	Food Act 2008 (Western Australia)
FSANZ	Food Standards Australia and New Zealand
FSMS	Food Safety Management System
FSP	Food Safety Program
HACCP	Hazard Analysis Critical Control Point
HCSMP	Harvest Controls and Surveillance Management Plan
KGT	Kwinana Grain Terminal
MBMMP	Marine Biotoxin Monitoring and Management Plan
MF	Membrane Filtration
MPN	Most Probable Number
NATA	National Association of Testing Authorities, Australia
NSP	Neurotoxic shellfish poisoning (brevetoxins or polycyclic polyethers)
OC	Organochlorine (pesticides)
OH	Oyster Harbour – Albany
OP	Organophosphate (pesticides)
PCB	Polychlorinated biphenyls
PSP	Paralytic shellfish poisoning (saxitoxin)
SF	Southern Flats
the Code	Australia New Zealand Food Standards Code
TSP	Toxic Shellfish Poisoning
WASQAP	Western Australian Shellfish Quality Assurance Program
YTX	Yessotoxins

## DEFINITIONS

**Adverse pollution conditions** means a state or situation caused by meteorological, hydrological or seasonal events or point source discharges that has historically resulted in elevated thermotolerant coliform or total coliform levels in a particular harvest area. Examples may include unusual climatic conditions, rain after long dry periods, unusually hot temperatures, consecutive days of light rainfall, heavy rainfall, tidal effects, salinity and wind effects.

**Adverse pollution conditions sampling strategy** means a water quality sampling program designed to assess the impacts of adverse pollution conditions.

**Approved harvest area** means a shellfish harvest area classified (as *Approved*) for harvesting or collecting shellfish for direct marketing.

**Closed status** means a condition that may apply to a harvest area where the commercial harvesting of shellfish is temporarily prohibited. A closed status may be placed on any of six classified harvest area categories: *Approved*, *Approved Remote*, *Conditionally Approved*, *Restricted*, *Conditionally Restricted* or *Off-shore*.

**Closed Safety Zone (CSZ)** means that part of a shellfish growing area which lies adjacent to a sewage outfall or other area of contamination and where shellfish harvesting is prohibited.

**Conditionally Approved** means the classification of a shellfish harvest area which meets Approved harvest area criteria for a predictable period. The period depends upon established performance standards specified in a management plan. A *Conditionally Approved* area is closed when it does not meet the *Approved* harvest area criteria.

**Conditionally Restricted** means the classification of a shellfish harvest area that meets *Restricted* area criteria for a predictable period. The period depends upon acceptable performance standards specified in a management plan. A *Conditionally Restricted* harvest area is closed when it does not meet the *Restricted* harvest area criteria.

**Depuration** means the process that uses a controlled aquatic environment to reduce the level of certain pathogenic organisms that may be present in live shellfish.

**Food Standards Code** means the Food Standards Australia New Zealand Food Standards Code

**Growing area** means a marine or enclosed body of water (i.e. bay, harbour, gulf, cove, lagoon, inlet, estuary or river) in which commercial species of bivalve molluscs grow naturally or are grown by means of aquaculture. A growing area may consist of one or more harvest areas.

**Harvest area** means an area that has been designated by a competent authority for the purpose of growing and/or harvesting commercial quantities of shellstock and may include wildstock or aquacultured shellstock.

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

**Marine biotoxins** means toxic compounds produced by some species of phytoplankton.

**Membrane Filtration (MF)** means the direct method of enumerating the number of bacteria per volume of water by counting bacterial colonies grown on a thin membrane which is placed on artificial solid media and reported as colony forming units per volume of water.

**Most Probable Number (MPN)** means the statistical estimate of the number of bacteria per unit volume and is determined from the number of positive results in a series of fermentation tubes.

**Nursery/Source growing area** means an area classified for the stocking of shellfish from where the product is to be relayed to a classified area for a minimum period of 60 days prior to harvest for human consumption.

**Open status** with respect to an *Approved, Approved Remote, Conditionally Approved* or *Off-Shore* harvest area, means that shellfish may be harvested for direct marketing when shellfish harvest waters or shellfish meet harvesting criteria as determined by the SCA and in the case of a conditional classification, as defined in the harvesting criteria detailed in the management plan for the shellfish growing area.

**Phytoplankton** are planktonic minute plants and other photosynthetic organisms, including cyanobacteria, diatoms, and dinoflagellates.

**Prohibited area** means an area from which shellfish cannot be harvested for human consumption under any circumstances.

**Relaying** means the transfer of shellfish for the reduction of pathogens or poisonous or deleterious substances that may be present, by using the ambient environment in a classified harvest area as a treatment process, for a time determined by the SCA.

**Remote shellfish area** means a harvest area that has no human habitation in the catchment and is not affected by any actual or potential pollution sources.

**Restricted area** means a classified harvest area from which shellfish may be harvested with the approval of the competent authority and then subjected to an effective purification process such as relaying or depuration.

**Risk Analysis** means a systematic, disciplined approach for making food safety decisions which includes three major components: risk management, risk assessment and risk communication. The risk analysis process normally begins with a risk management step, to define the problem, articulate the goals of the risk analysis and identify questions to be answered by the risk assessment, if and when one is required.

**Sanitary survey** means the (written) evaluation of all actual and potential pollution sources and environmental factors which may affect shellfish harvest area water quality and hence the shellfish.

**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.

**Shellstock** means live shellfish in the shell.

**Spat** means non-marketable juvenile shellfish which are taken for the purposes of on-growing.

**Shellfish Control Authority (SCA)** means the government agency or agencies having the legislative authority to classify shellfish harvest areas, control the relaying, harvesting, wet storage, depuration and handling of shellstock and to seize shellstock that is contaminated or has been harvested from prohibited or closed shellfish harvesting areas.

**Systematic Random Sampling (SRS) Strategy** means a water sampling program, designed to be undertaken on a systematic randomised basis, to assess the effects of pollution events that

may occur in growing areas that are affected only randomly or by intermittent pollution events and are not impacted by discharges from sewage treatment plants or combined sewer overflows.

**Thermotolerant (faecal) coliforms** are those members of the coliform group that ferment lactose with gas production within 48 hours at 44.0 to 44.5°C.

**Toxic substance** means a toxic compound occurring naturally or added to the environment that may be found in shellfish which may impact the food safety status of the shellfish. Examples include but are not limited to: marine biotoxins; trace elements such as mercury, zinc and copper; agricultural pesticides; polynuclear aromatics from oil spills; and polychlorinated biphenyls.

**Wet storage** means the temporary post-harvest storage of shellfish in containers or floats in tanks containing natural or synthetic seawater. Wet storage may be used to remove sand from, or to add salt to the shellfish or to prolong quality attributes of the shellfish.

# 1.Introduction

## 1.1 Scope

***This industry manual/user guide applies to all bivalve molluscan shellfish species commercially harvested or handled for the purpose of human consumption regardless if they are harvested from the wild or from marine or land-based aquaculture facilities. Includes bivalve molluscan shellfish harvested for domestic and export markets.***

***Bivalve molluscan shellfish species include, but are not limited to: cockles, clams, mussels, oysters, pipis and uneviscerated scallops, but do not include:***

- ***Scallops and pearl oysters where the only part made available for human consumption is the adductor muscle and a hazard analysis approved by the DOH shows that heavy metals and/or marine biotoxins are not an identified hazard. If the hazard analysis indicates that heavy metals or marine biotoxins may occur at levels of concern control measures must be in place to confirm that scallop and pearl oyster products are safe for human consumption***
- ***Bivalve molluscs harvested for use only as bait***
- ***the spat of bivalves for on growing***
- ***Recreational take of wild shellfish***

This manual should be read in conjunction with the current versions of;

- Australian Shellfish Quality Assurance Program (ASQAP)
- Marine Biotoxin Monitoring and Management Plan (MBMMP)
- Sampler Manual/Online Training
- WASQAP Classification Framework Template (for new harvesting areas)

Legislation and Standards applicable to the WASQAP;

[Food Act 2008 \(WA\)](#)

[Food Regulations 2009 \(WA\)](#)

[Australia New Zealand Food Standards Code](#)

[Australian Shellfish Quality Assurance Program: Export Standards 2004 edition](#)

[Export Control \(Fish and Fish Products\) Orders 2005 as amended](#)

The last revision of WASQAP Operations Manual (edition 6) was written in 2017 and this document supersedes it.

**Note: Unless defined in this document, terms used throughout are consistent with those described in ASQAP and relevant Standards of the *Australia New Zealand Food Standards Code (the Code)*.**

## 1.2 Seafood Business Requirements

Comply with the *Food Act 2008 (WA)* including the following;

### 1.2.1 Registration

A seafood business that engages in the primary production of seafood or the manufacturing of seafood, if the seafood involved in that primary production or manufacturing consists of or includes bivalve molluscs must be registered with Department of Health of Western Australia (DOH).

### 1.2.2 Comply with *the Code* - Standard 4.2.1 – Primary Production and Processing Standard for Seafood;

#### Food Safety Management System

a) A seafood business that engages in the primary production or processing of, or manufacturing activities concerning, bivalve molluscs must implement a documented food safety management system that effectively controls the hazards.

### 1.2.3 All records associated with the implementation of the food safety management system must be kept for a minimum of two years.

### 1.2.4 In addition to the above a seafood business must comply with:

### 1.2.5 The conditions of the ASQAP Operations Manual specified in the Schedule to Standard 4.2.1 of the *Code*, and

### 1.2.6 conditions recognised by the DOH, which are the requirements specified in this Industry Manual/User Guide.

## 1.3 Export

1.3.1 The Industry Manual/User Guide addresses the requirements of the Australian Government Department of Agriculture, Water and the Environment (DAWE) for export. However, it should be noted that individual importing countries may have further requirements that will need to be addressed by

the food business for further information refer to DAWE website

<https://www.awe.gov.au/>

- 1.3.2 The WASQAP also addresses requirements of pre-harvest controls of Standard 4.2.1 of *the Code*
- 1.3.3 If you are interested in gaining export listing for a particular harvesting area you should firstly contact the DOH with regards to the classification, sampling requirements, harvest management plans and biotoxin management plans for the specific harvesting area. The DoH can guide you through the initial process of obtaining export listing however the DAWE provides export controls and assistance regarding exporting goods from Australia.
- 1.3.4 Shellfish businesses that wish to export product can find further information to meet their responsibilities from DAWE.

## 1.4 Program Overview and Structure

- 1.4.1 Bivalve molluscs are filter feeders and have the ability to bioaccumulate pathogens and toxins derived from contaminated growing waters. Bivalve molluscs are often eaten raw or are only lightly cooked and are consumed with the gastrointestinal tract intact, leading to an increased risk of foodborne illness.
- 1.4.2 The main purpose of this Manual is to minimise the level of risk and protect the health of consumers through the administration and application of procedures that:
  - a) Assess the risk of shellfish contamination by pathogenic bacteria and viruses, biotoxins and chemicals derived from the growing area;
  - b) Control the harvesting of shellfish in accordance with the assessed risk and controls described in ASQAP;
  - c) Protect shellfish from contamination after harvesting.
- 1.4.3 WASQAP recognises that the impact of contamination events on shellfish growing areas can vary significantly; therefore shellfish harvesting areas are classified in accordance with the assessed food safety risk - classification standards are specified in Section 3 of ASQAP.

## 1.5 Table1 WASQAP Roles and Responsibilities of DOH, DPIRD and Industry

DoH	DPIRD	Industry
<p><b>Administer</b> food safety standards, including but not limited to:</p> <ul style="list-style-type: none"> <li>• <i>Food Act</i></li> <li>• <i>Food Regulations</i></li> <li>• <i>the Code</i></li> <li>• ASQAP/WASQAP</li> </ul>	<p>Administer aquaculture licences and leases under the Fish Resources Management Act 1994</p>	<p>To register as a food business under the Food Act.</p>
<p><b>Registration</b> of food businesses and maintain a register of shellfish businesses.</p>	<p>Provide information to DoH on commercial shellfish licences issued</p>	<p>To manage risks in accordance with the assigned classification. Notify any variation to identified hazards and methods of control i.e. FSMS</p>
<p><b>Determine</b> classification of new harvesting areas based on submitted applications from Industry. <b>Review</b> sanitary survey information and data for existing classified harvesting areas.</p>	<p>Assist industry with preparation of sanitary surveys and make classification recommendation to DoH</p>	<p>To provide assistance in the collation of historical sampling data and advise on changes to catchment land use patterns for the Triennial Reports and annual reviews.</p>
<p><b>Consult stakeholders</b> and produce Triennial and annual reports</p>	<p>Assist with information and communication across government agencies, industry, consultants and other stakeholders</p>	<p>To provide assistance in information gathering.</p>
<p><b>Verify</b></p> <ul style="list-style-type: none"> <li>• Food safety management systems (FSMS)</li> <li>• sampling program and samplers</li> <li>• compliance with relevant food safety legislation through assessments</li> </ul>	<p>Assist with training and content for sampler manuals</p>	<ul style="list-style-type: none"> <li>• Implement and maintain a FSMS</li> <li>• Develop a sampling program</li> <li>• Undertake bacteriological sampling (systematic and adverse) in accordance with the Sampling Plan.</li> <li>• Carry out Phytoplankton and biotoxin sampling in accordance with the Biotoxin Monitoring and Management Plan.</li> <li>• Undertake annual Chemical Analysis of shellfish.</li> <li>• Ensure DOH receives a copy of the sampling data</li> </ul> <p>Provide annual reports (production quantities) to DoH</p>

<p><b>Develop, Review and maintain;</b></p> <ul style="list-style-type: none"> <li>• Marine Biotoxin Monitoring and Management Plan (MBMMP)</li> <li>• WA Shellfish Quality Assurance Program Manual (WASQAP)</li> <li>• Harvest Controls and Surveillance Management Plan (HCSMP)</li> </ul>	<p>Coordinate risk assessments, data review and development of centralised WASQAP data management systems</p>	<p>Determine sampling program dates for Growing areas and keep sampling records in accordance with the program. Ensure WASQAP Samplers are adequately trained.</p> <p>Provide feedback on the Industry Manual/User Guide and other associated documents</p>
<p><b>Assist and Provide</b> legislative and technical advice to stakeholders</p>	<p>Identify relevant R&amp;D and assist industry to prepare funding applications</p> <p>Keep industry informed of latest technology/research via industry peak body</p>	
<p>As state regulator <b>maintain</b> membership on ASQAAC</p>	<p>Provide observer status at the national ASQACC</p>	<p>To appoint an industry representative</p>
<p><b>Confirm</b> harvest area closures and re-openings; Notifying relevant stakeholders</p>		<p>Initiating closures</p> <ol style="list-style-type: none"> <li>1. Initiate re-opening</li> <li>2. Maintain records of closure and re-opening notices</li> </ol> <ul style="list-style-type: none"> <li>• Notify DOH immediately of any unusual events observed within the harvest area that could impact on safety of shellfish.</li> <li>• Notify DOH and DOF of any fish kills that occur within the area</li> </ul>
<p><b>Function</b> as SCA</p>		

DAWE perform annual audits of the WASQAP for export listed harvesting areas

1.4.5 ASQAP is endorsed nationally by the Implementation Subcommittee for Food Regulation and the Australian Shellfish Quality Assurance Committee (ASQAAC). The committee is comprised of state representatives (regulatory) and industry state representatives

- 1.4.6 DAWE has the statutory authority to administer the export inspection system and to provide certification for shellfish exports. This authority is vested under the *Export Control Act 1982* and related Orders. Export certification of bivalve molluscan shellfish is issued on the basis of compliance with the requirements of the ASQAP, *Export Control (Fish and Fish Products) Orders 2005* and relevant State legislation.
- 1.4.7 **The Shellfish industry is responsible for the management and operation of WASQAP and providing a safe food product.** Assessments will be carried out by the DOH and where applicable are regularly reviewed by DAWE. Shellfish food businesses will be transitioning to regulatory food safety audits carried out in accordance with Part 8 of the Food Act and the Regulatory Food Safety Auditor Framework (implementation date to be determined by DOH).

## 2. Classification of Harvesting Areas

### 2.1 Background

**A shellfish harvesting area must be classified in accordance with the requirements of WASQAP prior to the harvesting of shellfish for human consumption.**

A comprehensive sanitary survey is completed for each growing area and reviewed by DOH prior to the classification of a harvesting area (a sanitary survey is not required to classify an area as prohibited). Any upward revision of a classification must be supported by an adequate re-evaluation of the sanitary survey.

For more details regarding the classification process for shellfish growing areas and for sanitary surveys that effectively and comprehensively determine the sanitary quality of shellfish harvesting areas refer to ASQAP manual (section 2) and the WASQAP Classification Framework Template for new harvesting areas.

## 2.2 Table 2 Summary of Classification Criteria

Approved remote	The area has no human habitation in the catchment and is not affected by any actual or potential pollution sources. The area meets Approved classification criteria for water and/or shellfish.
Approved	The sanitary survey has found that the harvest area is not subject to contamination from: a) human or animal faecal matter at levels that present an actual or potential public health hazard; or b) pathogenic organisms, poisonous or deleterious substances and/or biotoxins exceeding the levels required by the Code
Conditionally approved	A comprehensive sanitary survey finds that the shellfish harvesting area will be open for the purposes of harvesting shellfish for a reasonable period of time and the factors determining this period are known, predictable and are not so complex as to preclude a reasonable management approach. Bacteriological water and shellfish quality correlates with environmental conditions or other factors affecting the distribution of pollutants onto the harvest area. Each potential source of pollution that may adversely affect the harvesting area must be evaluated. In addition the water quality of the harvesting area must meet the requirements of an 'Approved Area' classification when open for the purposes of harvesting shellfish for direct human consumption. The area will meet Approved classification criteria when open to harvesting for direct human consumption for a minimum of fifteen of the full complement of samples collected as specified in ASQAP section 2.3. A written management plan has been completed for the harvest area (specific details refer to ASQAP section 3.4.4).
Restricted	The sanitary survey has found the area is: a) subject to a limited degree of pollution; and b) the level of faecal pollution, human pathogens and toxic or deleterious substances are at such an amount that shellfish can be made fit for human consumption by either relaying or depuration. Refer to ASQAP section 3.5.2 - 3.5.4 for SRSS and APCSS for bacteriological water quality criteria.
Conditionally restricted	A comprehensive sanitary survey finds that the shellfish harvesting area will be open for the purposes of harvesting shellfish for relaying or depuration for a reasonable period of time and the factors determining this period are known, predictable and are not so complex as to preclude a reasonable management approach. Bacteriological water and shellfish quality correlates with environmental conditions or other factors affecting the distribution of pollutants into the harvest area. The area will meet Restricted classification criteria when open to harvesting for relaying or depuration for fifteen of the full complement of samples collected as specified in ASQAP section 2.3. A written management plan has been completed for the harvest area (for specific details refer to ASQAP section 3.6.4)
Nursery/ Source	A chemical assessment is undertaken of the catchment area with follow-up sampling where potential risks are identified. Heavy metal tests show compliance with the Code.(Further details refer to ASQAP section 3.7)
Prohibited	Shellfish are so highly or frequently contaminated that harvesting controls cannot be implemented to adequately ensure the protection of public health. Prohibited area is an area from which shellfish cannot be harvested for human consumption under any circumstances.

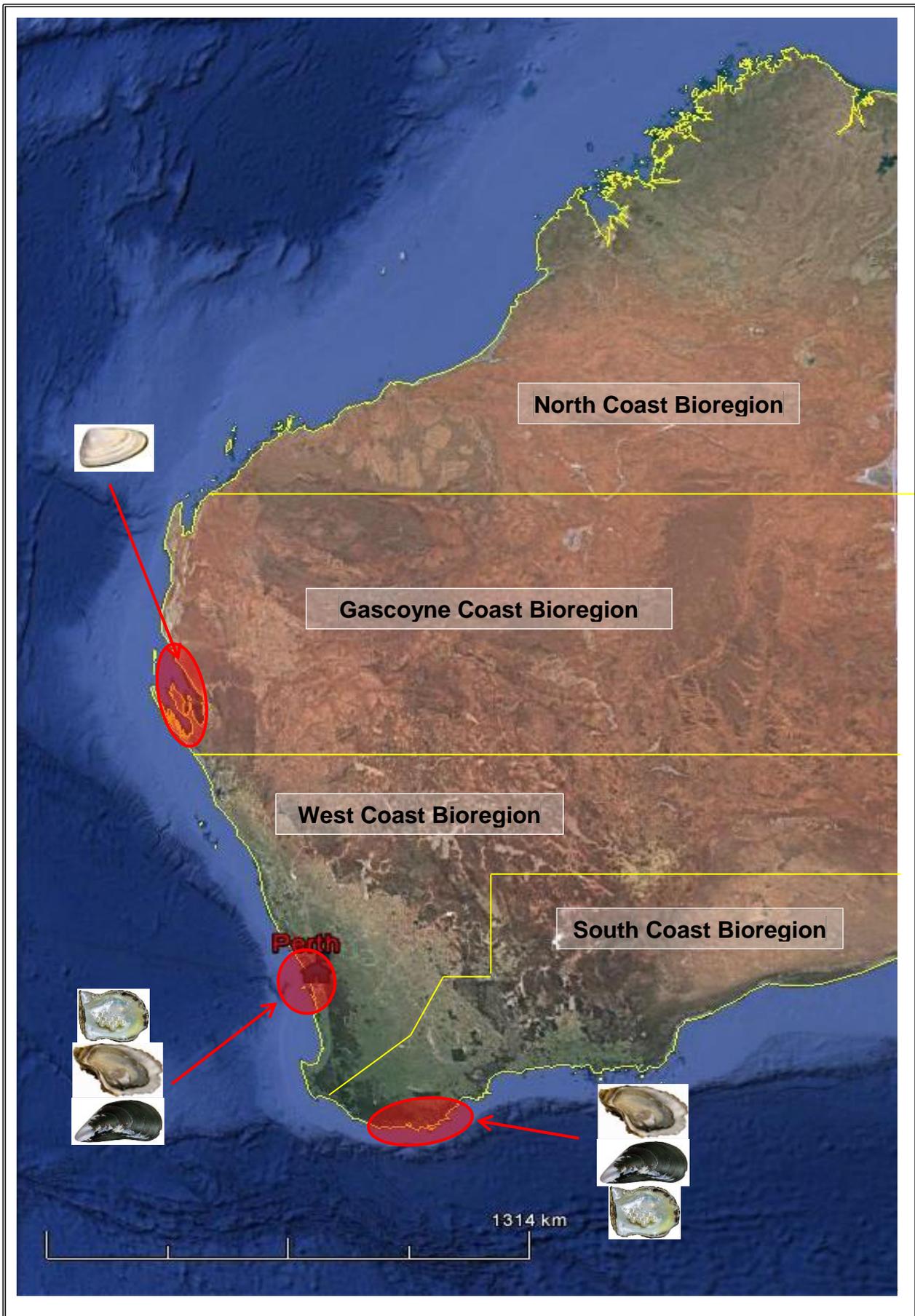
### 3. Shellfish Harvesting Areas in WA

#### 3.1 Table 3 Summary of Classified Harvesting Areas in WA

Region	Harvest Area	Classification
West Coast	Kwinana Grain Terminal (Cockburn Sound)	Conditionally Approved
	Southern Flats (Cockburn Sound)	Approved
Great Southern	Oyster Harbour	Conditionally Approved
	Mistaken Island	Approved
Gascoyne	Shark Bay	Approved Remote

WA does not currently have any areas with Restricted Area/Conditionally Restricted/Nursery Source and Prohibited Classifications further details can be found in the ASQAP manual.

### 3.2 WA Growing areas



### 3.3 Maintaining the Classification Status

- 3.3.1 Further details on maintaining the classification status can be found in Section 5 of the ASQAP Operations Manual.
- 3.3.2 A harvest area's classification must be reviewed at least annually or more frequently. In the case that a review identifies an issue; for example, marketed shellfish do not comply with relevant standards or are implicated in a disease outbreak, the classification will be reviewed.
- 3.3.3 A review of the harvest area classification aims to identify, record and assess changes in conditions in the harvest area and determine if the current sanitary survey data is consistent with the current classification category for the harvest area. DoH conducts annual and triennial reviews as required under section 5 of ASQAP.
- 3.3.4 A review of the harvest area classification is to be undertaken by DoH in consultation with the food business and comprises:
- Field observation of actual and potential pollution sources**, which may include:
- a) a drive-through survey;
  - b) observations made during sample collection; and
  - c) information from other sources, where relevant.
- 3.3.5 The harvest area classification re-evaluation also includes:
- a) review of the previous twelve months' or longer sampling data;
  - b) review, if applicable, of inspection reports and effluent samples collected from pollution sources;
  - c) review, if applicable, of performance standards for various types of discharges that impact the harvest area;
  - d) review, if applicable, of the biotoxin risk analysis and the associated Marine Biotoxin Management Plan;
  - e) review, if applicable, of closure and opening dates and supporting information; and
  - f) a report documenting all of the findings of a) - e) above.
- If a review indicates conditions have changed, or samples have indicated that the current Biotoxin Management Plan or HCSMP is inadequate, further investigation will need to be undertaken by the food business with DoH to determine the nature of the change.
- 3.3.6 Further details on maintaining the classification status can be found in section 5 of the ASQAP operations manual.

## 4. Sampling Overview and general requirements

### 4.1 Overview of Sampling

- 4.1.1 Any person undertaking sampling must be appropriately trained. Refer to “Sampler Manual”.
- 4.1.2 All sampling is performed by nominated personnel for each harvest area, in accordance with the method outlined in “*Standard Microbiological Water Sampling Techniques*” produced by the Water Unit of the DOH. This guideline incorporates the *Australian Standard ASNZF 5667.9-1998 Part 9 “Guidance on Sampling from Marine Waters”* as well as other relevant information and guides (e.g. on-line sampler training module)
- 4.1.3 Depending on the analytical laboratory used, you must ensure you are familiar with all necessary requirements specific to the sampling, transportation and storage of samples. Consult the relevant laboratory for more details.
- 4.1.4 Areas classified as being approved (and conditionally approved), water and shellfish flesh samples are collected routinely for bacteriological analysis under a **Systematic Random Sampling (SRS)** strategy. Refer to ASQAP manual.
- 4.1.5 Phytoplankton water samples and flesh samples for chemical and biotoxin analysis are also taken routinely from sampling location points within each harvest area.
- 4.1.6 Sampling dates for the year ahead are scheduled by food businesses and verified by DOH. However, if for example, weather conditions or equipment mechanical failure prevents the safe collection of samples on the scheduled day, then the collection shall be deferred to the next available day.
- 4.1.7 Sampling dates may be altered but only with prior agreement with DOH to ensure samples remain random and meet the desired number required for classification purposes.
- 4.1.8 The sampling program information form 008 (refer to Appendix 1) must be completed every time samples are collected detailing water temperature,

previous rainfall, wind speed and direction, tide etc. A copy should be sent to Department of Health WA, by email [tracey.stamp@health.wa.gov.au](mailto:tracey.stamp@health.wa.gov.au) and [Foodsafety@health.wa.gov.au](mailto:Foodsafety@health.wa.gov.au).

## 4.2 Bacteriological water sampling

- 4.2.1 Sampling of water from growing areas is carried out to manage the potential food safety risks so that shellfish harvested from registered growing areas is safe to eat.
- 4.2.2 For export listed harvest areas samples are collected 12 times each year from conditionally approved areas and 6 times per year from approved areas (Export Standards 2004).
- 4.2.3 When taking bacteriological water samples aseptic technique is essential to avoid contaminating the samples. Methods are outlined in the Sampler Manual.
- 4.2.4 (Pathwest Laboratories use methods documented on the reports as MWM001 and MWM002 for water testing methods that are equivalent to AS 4276.5 (2007) and AS 4276.7(2007) respectively).

## 4.3 Bacteriological Shellfish sampling

The following is based on [PathWest Food Sample Collection and Submission Instructions](#)

- 4.3.1 Sampling of Shellfish flesh from growing areas is carried out to manage the potential food safety risks so that shellfish harvested from growing areas are safe to eat.
- 4.3.2 A representative shellfish sample for bacteriological testing is submitted unshucked and should provide between 100g - 200g of flesh.  
  
Analysis for E.coli in shellfish flesh must meet ISO16649-3 or an AS method

## 4.4 Phytoplankton Monitoring

**4.4.1 N.B. Further details of phytoplankton and biotoxin sampling and testing are contained within the Marine Biotoxin Monitoring and Management Plan (MBMMP).**

### 4.4.2 Water Sampling - Phytoplankton

Water samples are also analysed for phytoplankton species known to potentially produce toxins which may be concentrated in shellfish.

Consumption of shellfish containing such toxins may result in food poisoning. Different phytoplankton produce different toxins and the type of food poisoning are dependent on which phytoplankton toxin has been concentrated.

The types of food poisoning associated with consumption of shellfish containing phytoplankton toxins are PSP (paralytic shellfish poisoning), ASP (amnesic shellfish poisoning), NSP (neurologic shellfish poisoning) and DSP (diarrhoetic shellfish poisoning).

4.4.3 Under the Systematic Random Sampling (SRS) strategy, samples for phytoplankton identification and enumeration are collected twice monthly on the dates predetermined on the sampling program for the year.

4.4.4 Identification of potentially toxic species as a result of enumeration of phytoplankton may be an indication of a public health risk.

4.4.5 Representative phytoplankton samples should be collected at the same location as those for flesh testing. Water samples should ideally be taken at high tide and sampling at low tide should be avoided. Variation in the depth of water sampled means that different methods may be employed generally <2m a bucket is used and >2m a tube sampler is used.

Refer to sampler manual for further details

4.4.6 Alert level counts for each type of potentially toxic phytoplankton have been established at levels where further appropriate action should be taken. Refer to the MBMMP for further details.

## 4.5 Shellfish Monitoring - Testing for Algal Toxins

- 4.5.1 A composite sample (12-15 approx. to provide 100g flesh) of shucked shellfish for each species harvested is collected for biotoxin testing.
- 4.5.2 The flesh sample must be collected at the same time as the phytoplankton water sample. The sample of shellfish is either frozen pending the phytoplankton results or submitted as one of the monthly routine samples required under the MBMMP.
- 4.5.3 If phytoplankton counts do not exceed alert levels the shellfish samples are kept frozen and are held on rotation for a minimum of six weeks. This establishes a library of samples to do retrospective testing in the event that the phytoplankton analysis does not detect a problem at the time.
- 4.5.4 If the potentially toxic phytoplankton counts exceed the alert level, a sample is submitted for biotoxin analyses.

## 4.6 Chemical Monitoring - Testing for Chemical Contaminants

- 4.6.1 Shellfish are generally to be tested on an annual basis to determine levels of chemical contamination within the harvesting area. This frequency may be varied provided sufficient evidence exists to support any variation. Additional testing may be required should results show elevated levels or it has been determined that there is an elevated risk of pollutants affecting the area.
- A representative sample from the harvesting area of shellfish flesh (200g shucked and sent frozen) is tested for the presence of relevant chemical contaminants (i.e. cadmium, lead, mercury and inorganic arsenic\*).
- 4.6.2 Listed in Schedule 19 Maximum levels of contaminants and natural toxicants Standard 1.4.1 Contaminants and Natural Toxicants.
- 4.6.3 Other chemicals that may also be tested for depending on the risk are:
- organochlorine (OC) and organophosphate (OP) pesticides
  - and polychlorinated biphenyls (PCB's).
  - or any other additional chemicals as directed by DOH that may impact on the harvest area e.g. PFOS.

*\*The DOH accepts that using total arsenic as a screening tool (10% of total arsenic is assumed to be present as the inorganic form), combined with further inorganic arsenic analysis for samples in which total arsenic levels are  $\geq 10$  mg/kg in molluscs ensures cost effective analytical laboratory services.*

#### 4.7 Table 4 Minimum Tests required and threshold limits

Analysis	Frequency	Threshold	Source
<b>BACTERIOLOGICAL</b>			
<b>Water</b> <i>Thermotolerant coliforms</i>	as per sampling schedule	14 cfu/100mL <sup>a</sup>	ASQAP <sup>g</sup>
<b>Flesh</b> - <i>E.coli</i>	as per sampling schedule	2.3. cfu/g <sup>b</sup>	FSANZ Std 1.6.1 <sup>d</sup>
<b>BIOTOXINS (refer to MBMMP for full details)</b>			
<b>PSP</b> toxins ( <i>saxitoxins equivalent</i> )	monthly	0.8 mg/kg	FSANZ Std 1.4.1 <sup>c</sup>
<b>ASP</b> toxins ( <i>domoic acid equivalent</i> )	monthly	20 mg/kg	FSANZ Std 1.4.1 <sup>c</sup>
<b>DSP</b> toxins ( <i>okadaic acid equivalent</i> )	monthly	0.2 mg/kg	FSANZ Std 1.4.1 <sup>c</sup>
<b>NSP</b> toxins	monthly	200 MU/kg	FSANZ Std 1.4.1 <sup>c</sup>
<b>PHYTOPLANKTON</b>			
<b>Phytoplankton</b>	Twice monthly	Refer MBMMP <sup>f</sup>	MBMMP <sup>f</sup>
<b>CHEMICAL – Heavy Metals</b>			
Arsenic (inorganic)	annual	1mg/kg	FSANZ Std 1.4.1 <sup>c</sup>
Cadmium	annual	2mg/kg	FSANZ Std 1.4.1 <sup>c</sup>
Lead	annual	2mg/kg	FSANZ Std 1.4.1 <sup>c</sup>
Mercury	annual	mean level 0.5g/kg	FSANZ Std 1.4.1 <sup>c</sup>
<b>PESTICIDES</b>			
<b>OP and OC</b> Polychlorinated biphenyls (PCB's)	annual	As per FSC std 1.4.2 MRL's	FSC std 1.4.2 MRL's <sup>e</sup>

<sup>a</sup> (by membrane filtration from any single sampling point)

<sup>b</sup> wet weight

<sup>c</sup> FSANZ – Contaminants and Natural Toxicants Standard 1.4.1 (Schedule 19)

<sup>d</sup> FSANZ Standard 1.6.1 Microbiological limits in food

<sup>e</sup> FSANZ Standard 1.4.2 MRL's

<sup>f</sup> Marine Biotxin Monitoring and Management Plan

<sup>g</sup> Australian Shellfish Quality Assurance Program Operations Manual

## 5. Harvesting Management Plans

### 5.1 Background

Harvesting area management plans aim to ensure that only those shellfish that are safe and suitable for consumption are released onto the market.

Management plans have been developed for each applicable harvesting area with further detail specified within individual Food Safety Management System.

The DOH as the Shellfish Controlling Authority maintains a supplementary document to the Manual titled 'Harvesting Controls and Surveillance Management Plans (HCSMP)' which is not publicly available. These documents detail operational aspects of the harvest areas and site-specific management triggers.

### 5.2 Table 5 Closure criteria

Harvest areas may be closed due to any of the following criteria, but is not limited to;

Criteria	Example
1. Unsatisfactory results	Biotoxin, Phytoplankton, Microbiological, Chemical <ul style="list-style-type: none"> <li>Non-compliant with the Code, WASQAP, MBMMP, HCSMP, FSMS or any other document used in the risk assessment</li> </ul>
2. Results not received in a timely manner	<ul style="list-style-type: none"> <li>Delays in laboratory analysis/reporting</li> <li>Samples not received by laboratory</li> </ul>
3. No sample collected/provided	As required by the DoH <ul style="list-style-type: none"> <li>The DoH may ask you to collect samples in response to an 'event' to inform of risk status</li> </ul>
4. Pollution events	Sewage/chemical spills which have the potential to impact on harvest areas
5. Required by the FSMS	The means of control for an identified hazard.
6. Public health risk	Any other risk determined by the DoH to be potentially harmful E.g. Viral contamination /foodborne illness
7. Absence of data	No relevant data to inform of risk. E.g. new algal species

DoH may determine additional criteria is necessary which has the potential to close a harvest area.

- 5.2.1 If any triggers apply, it is the responsibility of the relevant food business to determine the most appropriate course of action and advise the DoH accordingly.
- 5.2.2 The efficacy of any risk mitigation strategy is largely dependent on the suitability of controls and how timely these controls have been implemented. Therefore, it is critical the food business/s initiate appropriate corrective action and advises the DoH in a timely manner.
- 5.2.3 There may be situations where the DOH may order a cessation of harvesting and/or follow-up sampling before imposing a formal closure or re-opening the harvesting area. When a public health risk has been identified, the DOH may implement a formal closure without awaiting the results of follow-up sampling.
- 5.2.4 Decisions regarding this process are performed in accordance with the [DOH Compliance and Enforcement Policy](#).
- 5.2.5 Results over the threshold limits (documented in table 4) may result in cessation of harvesting, re-sampling and possibly mandatory closure of the harvesting area.
- 5.2.6 Viral Contamination: Should viral pathogens (e.g. Hepatitis A or Norovirus) be identified or suspected from epidemiological evidence then the harvest area shall remain closed for 21 days before re-testing may be undertaken.
- 5.2.7 Coliforms and *E.coli* are indicative of faecal pollution and may not correlate with the presence of enteric viruses.

### 5.3 Procedure for the Closure of a harvest area

- 5.3.1 Food businesses to complete the Harvest area status form 002 (refer to appendix 2) to advise the DOH of the current status of the harvest area and confirmation is provided by the DOH.
- 5.3.2 Submit form to the DoH (see form for submission details)
- 5.3.3 Upon receipt of the notification the DoH will either respond confirming the status or request further information.

- 5.3.4 The DOH will communicate the notification to relevant stakeholders.
- 5.3.5 The food business should also consider whether a recall is applicable. Industry shall be responsible for conducting any food recall in accordance with FSANZ Food Industry Recall Protocol [refer to FSANZ website for further information.](#)
- 5.3.6 Harvested product that is deemed to be unfit for human consumption is to be disposed.

#### Closures of Harvest Areas with Product Destined for Export

- 5.3.7 If the closure affects any export listed business the DOH has an obligation to notify the DAWE for the purposes of issuing export permits and export certificates via the Electronic Export Documentation System EXDOC. Therefore, any food business which is export listed must notify the DoH immediately.

#### 5.4 Procedure for Re-opening of Harvest Areas:

- 5.4.1 After the relevant laboratory analysis the DOH must confirm that the environmental conditions and the quality of shellfish in the affected area have returned to normal.
- 5.4.2 The confirmation that the quality of shellfish in the affected area have returned to normal varies according to the type of contamination. For example faecal bacterial contamination: Leases may be re-opened after results of **water and flesh testing** for that **shellfish species** meet WASQAP threshold limits.
- 5.4.3 A closed harvesting area must be formally reopened before harvesters are able to recommence operation.
- 5.4.4 Harvesting area is re-opened once it is no longer considered to be a potential public health risk and the shellfish are safe for human consumption.
- 5.4.5 All those notified of the closure will be notified of the re-opening by the appropriate means.

- 5.4.6 Depending on the reason for the closure, further testing will be taken to determine compliance with Table 4.
- 5.4.7 Following an adverse event compliant water and flesh samples are required prior to re-opening.
- 5.4.8 Successful management of shellfish harvesting areas is reliant on a good understanding of risk factors and the actions of the food business if situations which threaten the food safety of the product are identified. Generally, the identification of any potential risk factors must be considered in the FSMS which may result in the cessation of harvesting.

## 5.5 Relaying of product

- 5.5.1 The practice of 'relay' is internationally recognised as the transfer of shellfish from a growing area to another growing area for farm management purposes or alternatively to reduce pathogens or other contaminants by using the ambient marine environment as the treatment process.

For WASQAP purposes the Australian Shellfish Quality Assurance Program (ASQAP) Manual, defines relay as – 'the transfer of shellfish for the reduction of pathogens or poisonous or deleterious substances that may be present, by using the ambient environment in a classified harvest area as a treatment process, for a time determined by the state shellfish control authority'. Section 8 of the ASQAP Operations Manual details relaying controls to ensure shellfish safety including minimum holding times, authorisations, reporting and record keeping obligations.

Relayed shellfish must be left in the receiving area for the minimum time (holding) periods specified in Table 6, before they are harvested. This gives the relayed shellfish time to naturally depurate (cleanse) themselves of any contaminants.

- 5.5.2 When holding periods apply, harvesting shellfish for relaying requires authorisation from DOH which is non-transferable; and only issued for a specific relaying operation.

The relaying of shellfish is carefully monitored and recorded due to the risks involved. These include:

- Cross-contamination of shellfish in the receiving waters
- Mistaken harvest of recently relayed shellfish
- Inability of relayed shellfish to effectively pump clean water and flush out contaminants caused by overcrowding of relayed shellfish
- Inappropriate time periods for cleansing.

5.5.3 A seafood business harvesting shellfish for relaying must comply with Standard 4.2.1 of the Food Standards Code and not relay from a prohibited area. The area will be subject to a marine biotoxin management plan; and (a) be in the open status for the purposes of relaying; or (b) undergoing classification (and approved by the DOH - subject to conditions specified by the DOH in the harvest area management plan).

5.5.4 DOH may establish critical values for water temperature, salinity and any other environmental variables which may affect the natural treatment process in the area to which shellfish will be relayed. The harvest area to be used for the treatment process must be monitored with sufficient frequency to identify when limiting critical values might be approached.

## 5.6 Table 6 Relay holding periods

<b>Relaying From</b>	<b>Permit Required From DOH</b>	<b>Minimum Holding Period Post Relay</b>
Unclassified Areas (under certain conditions)	Yes	60 days*
Restricted Areas (open)	Yes	14 days
Conditionally Approved or Approved Areas in closed status	Yes	14 days
Any permitted harvest area	Yes	21 days

closed due to sewage contamination		
Any permitted harvest area closed due to biotoxins	Yes	60 days (14 days with testing**)
Conditionally Approved or Approved Areas in open status.	No	0 Days***

*\*Additional testing may be required \*\*14-day minimum holding period for relays from areas closed due to biotoxins requires two biotoxin results seven days apart to be within limits set out in the Biotoxin Management Plan. \*\*\*Must comply with any minimum holding requirements detailed in receiver's Food Safety Program. When shell stock is sourced from harvest areas that are closed due to rainfall or salinity, is classified as approved or restricted, are meeting current biotoxin management plan requirements and not impacted by sewage and relayed into an approved or restricted harvest area. The shell stock must be relayed for at least **14 days** unless testing approved by the DOH shows they have been adequately cleansed of all contaminants.*

## 5.7 Traceability of relayed stock

- 5.7.1 All relayed product must be clearly marked to distinguish it as relay product during transport and on the farm during the relay period. Relayed shellfish should be placed in lots (easily identified from market ready shellfish), in a separate area of the farm so they do not contaminate stock already on the farm.
- 5.7.2 A seafood business undertaking relay of shellfish must keep adequate records of relay operations. This includes the completion of a stock movement log which maintains the following information:
- The name of the harvest area from which the shellfish were relayed;
  - The date and time at which the shellfish were relayed from the harvest area;
  - The name of the harvest area to which the shellfish were relayed;
  - The date and time at which the shellfish were relayed to the harvest area;
  - The species of shellfish relayed, and the quantity of each species relayed.
  - Where required by the DOH, the results of analyses on each lot of relayed shellfish before and after the relaying period.

## 5.8 Relaying from Nursery/Source growing area

5.8.1 Nursery/Source growing area is an area classified for the stocking of shellfish from where the product is to be relayed to a classified area for a minimum period of 60 days prior to harvest for human consumption.

The DOH may implement additional requirements on the relaying of *Nursery/Source* stock movements from specific harvest areas that are affected by:

- a) gross human faecal contamination or
- b) algal biotoxin contamination or
- c) heavy metal contamination or
- d) chemical contamination or
- e) any other prevailing condition that may cause the shellfish to remain unsuitable for human consumption following 60 days in the destination harvest area.

## 6. Harvesting, Transport and Identification of Shellfish

### 6.1 General Requirements

Commercially harvested bivalve shellfish must comply with WASQAP and may only be harvested from areas classified by the DOH. DPIRD provide details of the aquaculture licences which includes GPS co-ordinates.

### 6.2 Shellfish Identification

6.2.1 All harvested shell stock is to be clearly identified as follows:

A durable legible waterproof label is affixed to the exterior of the container or bag, at the time of filling, once the shellstock has been graded and cleaned.

6.2.2 If shellfish are harvested at more than one licensed site, each container/bag is labelled at its harvesting area.

6.2.3 The tag or label remains affixed to each bag or container of shellstock until the bag or container is emptied.

6.2.4 At a minimum the tag or label must contain the following information:

- The name and address of the seafood business;
- A unique identifier of the batch of shellfish (to ensure traceability)
- The name of the harvesting area (i.e. Cockburn Sound, Albany or Shark Bay) or relevant site code: SF (Southern Flats), KGT (Kwinana Grain Terminal) OH (Oyster Harbour) or MI (Mistaken Island).
- The date the shellfish is harvested; and
- The type and quantity of shellfish (e.g. mussels (10kg)).
- A statement indicating the conditions under which the shellfish should be stored (e.g. keep refrigerated for mussels)
- Use-by date or best before date (if frozen)
- Any other requirement in accordance with the Food Standards Code

These details are inscribed on all documentation and packaging to the final point of consumption and accompany individual consignments.

## 6.3 Product Traceability

- 6.3.1 Traceability is the ability to track a food through all stages of production, processing and distribution and should mean that movements can be traced one step backwards and one step forward at any point in the supply chain.
- 6.3.2 Co-mingling of harvested batches is prohibited.
- 6.3.3 All sales to restaurants and retail outlets (domestic and export) must be traceable to the farm. All packaging carries an identification label or tag in accordance with the above.
- 6.3.4 All food businesses must maintain sufficient record keeping, to demonstrate compliance with the food safety legislation. For example, information on date of sale, quantity and where the product is distributed. Records of all customer complaints must also be maintained.

## 7. Surveillance

- 7.1 The DOH will implement an annual Surveillance Plan which applies to all commercial harvesting areas in WA. This surveillance plan will be updated and reported annually by DOH to DAWE.
- 7.2 The *Surveillance plan* includes:
- inspection frequency
  - record keeping
  - verification activities through audit
  - reporting requirements
- 7.3 The surveillance plan sets out inspection (assessments/audits) frequencies according to risk, procedures and processes for record keeping and reporting requirements.

## 8. Product Recall

8.1 The *Code* requires manufacturers, wholesalers and importers of food to have a system in place to manage the recall of unsafe food.

8.2 The requirement is specified in Clause 12 of Standard 3.2.2 – Food Safety Practices and General Requirements. It states that:

*A food business engaged in the wholesale supply, manufacture or importation of food must-*

- a) have in place a system to ensure the recall of unsafe food;*
- b) set out this system in a written document and make this document available to an authorised officer upon request; and*
- c) Comply with this system when recalling unsafe food*

8.3 The food recall plan enables the food business to recall unsafe food from the marketplace and consumers, effectively and efficiently in order to protect public health and safety.

8.4 Further guidance on writing a food recall plan and a checklist summarising the actions a food business needs to take, if a food safety issue is identified with a food product, is contained in the Food Industry Recall Protocol Food Standards Australia and New Zealand (FSANZ 2014).

8.5 Due to the short-shelf life of shellfish products it is not practicable to apply a test and hold approach for each batch. Therefore, it is essential that the above recall process is incorporated into the staff training program. For example all staff are familiar with the latest Food Industry Recall Protocol.

8.6 The food business with primary responsibility for the supply of a food product (sponsor) normally initiates food recall action. Food businesses need to contact FSANZ and DOH, as soon as they consider a food recall is, or may be, needed. There are several different types of recall and different parties involved in the food recall process therefore for further information refer to DOH Fact Sheet 14 – Food Recall that is available on the DOH website [http://ww2.health.wa.gov.au/Articles/F\\_I/Food-recalls](http://ww2.health.wa.gov.au/Articles/F_I/Food-recalls)

## **9. Review**

This manual will be reviewed annually in consultation with relevant stakeholders to reflect changes in scientific knowledge, shellfish culture techniques, processing technology and changes in legislation.

Appendix 1

WESTERN AUSTRALIAN SHELLFISH QUALITY ASSURANCE PROGRAM SAMPLING PROGRAM INFORMATION FORM	
Rainfall (24hr)..... wind direction.....  Rainfall (48hr)..... wind speed.....  Water Temp. .... Salinity .....  Date.....	<b>Adverse Conditions</b>  True <input type="checkbox"/> False <input type="checkbox"/>  Other comments on conditions e.g. water clarity, fish kills, pollution spills, discolouration, blooms etc.
Tide: Incoming <input type="checkbox"/> Tide: Outgoing <input type="checkbox"/>	

**NAME OF HARVESTING AREA:**

Sample Site ID Number	Microbial Testing		Phytoplankton Testing	Biotoxin Testing	Chemical Testing
	Water Time Taken	Flesh Time Taken	Water Time Taken	Flesh Time Taken	Flesh time taken

LABORATORY:  
.....

Samples Taken by:

**Please send this to [tracey.stamp@health.wa.gov.au](mailto:tracey.stamp@health.wa.gov.au) and [Foodsafety@health.wa.gov.au](mailto:Foodsafety@health.wa.gov.au).**



Government of Western Australia  
Department of Health

**WA Shellfish Program**  
 P: 9222 2000  
 E: [tracey.stamp@health.wa.gov.au](mailto:tracey.stamp@health.wa.gov.au)  
[foodsafety@health.wa.gov.au](mailto:foodsafety@health.wa.gov.au)

## Notification of Harvest Area Status

<b>Harvest area</b>	[ ] [ ]		
<b>Lease</b>	[ ] [ ]		
<b>Status</b> (circle/delete)	[ OPEN ]	[ CLOSED ]	
<b>Effective date</b>	[ ] [ ]		

**Reason:**

**Biotoxin**   
  **Phytoplankton**   
  **Microbiological**   
  **Commercial**

**Chemical**   
  **Other**

[ ] [ ]

**Note:** Food businesses must notify of any closures immediately using this form.  
 A harvest area will remain **CLOSED\*** until advised otherwise by the WA Department of Health Shellfish program.

*\*except for commercial decision to close where the form only needs to be submitted.  
 (See WASQAP section 5.2)*

<b>Name:</b>	[ ] [ ]
<b>Date of notification:</b>	[ ] [ ]
<b>Contact No:</b>	[ ] [ ]

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## REFERENCES

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