

Western Australia's Shellfish Quality Assurance Program - Monitoring the Environment

Intended as a guide only, this document sets out key requirements in respect of ongoing environmental and shellfish monitoring that need to be met prior to the harvest of shellfish for human consumption. These requirements apply to the commercial harvesting (wild capture, marine and land based aquaculture) of all bivalve mollusc shellfish, including, but not limited to edible oysters, cockles, clams, uneviscerated scallops and mussels.¹

Food businesses considering area classification should liaise with the Department of Health (DoH) as the Shellfish Control Authority (SCA) in Western Australia and should allow 9 -18 months to achieve area classification in accordance with the Western Australia Shellfish Quality Assurance Program Operations Manual 2017 (WASQAP). The DoH can be contacted on (08) 9388 4999 or alternatively by emailing foodsafety@health.wa.gov.au

Summary

To harvest shellfish from an area for human consumption, the food business (or consultant engaged by the food business) must first achieve approval of the area under one of the following different classifications:

- Approved Remote;
- Approved;
- Conditionally Approved;
- Restricted;
- Conditionally Restricted;
- Nursery/Source); or
- Prohibited

This classification process involves compiling a **Sanitary Survey Report** and **Marine Biotoxin Management Plan** for the DoH's consideration and approval.

Once approved, the food business must maintain this approval through regular testing, monitoring and reporting, the frequency of which will vary depending on the results of the sanitary survey (which includes the shoreline survey) and marine biotoxin risk analysis.

Overview of the steps involved in Classification of a Growing Area

¹ Scallops and pearl oysters where the only part made available for human consumption is the adductor muscle, and a hazard analysis approved by the West Australian Department of Health shows that heavy metals and, or, marine biotoxins are not an identified hazard are exempt from the requirements of the WASQAP and the ASQAP but would still be required to meet the requirements of the Food Standards Code (the Code). This does not however preclude these from the requirement for control measures to be in place, to ensure they are safe for human consumption, if the hazard analysis indicates that heavy metals or marine biotoxins occur at levels of concern. The spat of bivalve molluscs are exempt from the requirements of the WASQAP and the ASQAP.

An overview of the steps involved in obtaining area classification to be able to harvest shellfish for human consumption is set out below:

1. Assess the area where the operator is growing or intends to grow shellfish for human consumption. As part of this assessment, identify and evaluate contamination sources which could adversely affect the water quality of the shellfish harvest area.
2. If, in undertaking the assessment described at 1 above (and in more detail on page 4 a) Shoreline Survey below) no actual or potential pollution sources are identified, the operator will need to undertake a minimum of 15 water samples and, or, 15 shellfish samples from each of the sites determined in the **number and location of sampling stations** provided on page 6 below. These samples need to be collected under a range of environmental conditions.
3. If, in undertaking the assessment described at 1 above (and in more detail on page 4 a) Shoreline Survey below), actual or potential pollution sources are identified, the operator will need to undertake a minimum of 30 water and, or, 30 shellfish samples from each of the sites determined in the **number and location of sampling stations** on page 6 below. These samples need to be collected under a range of environmental conditions.
4. Bacteriological, chemical and biotoxin water and, or, flesh testing of the samples conducted as part of 2 or 3 above will need to be undertaken by the operator to inform area classification and analysed by a laboratory accredited by the National Association of Testing Authorities Australia (NATA).
5. Following undertaking the investigative work involved in the sanitary survey and the associated sampling (pages 4-7 below) the operator/food business must compile a **Sanitary Survey Report** and **Marine Biotoxin Management Plan** for the DoH to consider and to classify the growing area.

Background

Oysters and other bivalve molluscs are filter feeders, so have the ability to bioaccumulate bacteria, viruses, toxins, heavy metals, chemicals and other harmful substances derived from the waters in which they grow. Because of this their consumption can lead to an increased risk of foodborne illness. For these reasons, a food business (or a consultant engaged by the food business) must obtain a classification for the shellfish harvest area in accordance with the WASQAP and the *Australian Shellfish Quality Assurance Program Operations Manual 2016* (ASQAP) and prior to the commercial harvesting of bivalve molluscs for human consumption.

Classification of the Growing Area

As the SCA in Western Australia, the DoH is responsible for the classification of harvest areas to ensure food safety requirements are met. The DoH classifies harvest areas as:

- Approved Remote;

- Approved;
- Conditionally Approved;
- Restricted;
- Conditionally Restricted;
- Nursery/Source); or
- Prohibited.²

For the DoH to classify a harvest area as set out above, the food business (or a consultant engaged by the food business) must compile a **Sanitary Survey Report** for the DoH's consideration and approval.

Sanitary Survey Report

The Sanitary Survey Report needs to include the following:

- a) an Executive Summary;
- b) a description of the growing and harvest areas;
- c) a location map or chart showing the harvest area(s), with boundaries clearly defined using landmarks or GPS coordinates;
- d) if applicable, a history of harvest area classification, such as the date of last survey and previous classification maps;
- e) a pollution source survey, including:
 - identification and evaluation of pollution sources such as domestic wastes, stormwater, agricultural waste (farms, feedlots and slaughterhouse operations), wildlife areas and industrial wastes;
 - a map or chart showing the location of major sources of actual or potential pollution;
 - a table of sources of pollution cross-referenced to the map;
- f) relevant hydrographic and meteorological characteristics, including tides (type and amplitude), rainfall (amount, pattern and frequency of significant rainfalls), winds and river discharges (volumes and seasonality);
- g) evidence that the classification status, arrived at by the food business or consultant, was determined by shellfish or water samples (shellfish or water samples need to be tested at NATA accredited laboratory);
- h) a map of sampling stations and the sampling plan and its justification;
- i) tables containing analytical statistics, including the number of samples, median or geometric mean and the respective variability factors (as discussed in Section 3 of the ASQAP);

² A comprehensive sanitary survey is not required in order to classify an area as Prohibited (refer to page 16 ASQAP)

- j) a discussion regarding variability in the data and its cause(s);
- k) overall compliance with the relevant classification criteria (as per Section 3 of the ASQAP which will aid the food business in ensuring the classification they have arrived at is correct);
- l) the harvesting/growing area's proposed classification (use the checklist in Section 3 of the ASQAP to determine the classification);
- m) a management plan, if classified as Conditionally Approved or Conditionally Restricted (Section 3.4 and 3.6 of the ASQAP will assist the food business or consultant to write a management plan. Note that the majority of the information required for a management plan will have been gathered as part of this Sanitary Survey Report. This management plan is different from the Marine Biotoxin Management Plan); and
- n) a description of future monitoring arrangements.

Note: the monitoring components and work involved in determining the classification of a harvest area(s) may require consideration of factors such as seasonality as part of a sampling regime (discussed below) and could take 9 -18 months.

Sanitary Survey

The work involved in compiling a Sanitary Survey Report and gathering the information required to address a) – n) above is obtained by undertaking a sanitary survey for the area. Undertaking a sanitary survey consists of a number of components detailed below (taken from Section 2 of the ASQAP):

- a) a shoreline survey;
- b) a survey of the bacteriological quality of the water and, or, shellfish;
- c) an evaluation of the potential for chemicals to contaminate shellfish in the growing area;
- d) an evaluation of the effect of any meteorologic, hydrographic and geographic characteristics of the growing area; and
- e) determination of the risk of biotoxin occurrence in shellfish in the growing area (this is part of the requirement below for the operator to develop a Marine Biotoxin Management Plan).

The first three components of the sanitary survey (a-c above) and what each entails are detailed below.

a) Shoreline Survey

The purpose of undertaking a shoreline survey is to identify and evaluate contamination sources that could adversely affect the water quality of a shellfish harvest area.

The following points need to be considered (where applicable) as part of undertaking a shoreline survey.

- **Location:** the boundaries of the shoreline adjacent to the harvest area must be identified by in-field investigation and mapped accordingly. All information relevant to the shoreline should be identified and labelled on the map.
- **Pollution:** all actual and potential, point and non-point, sources of pollution in the catchment to a growing area which may adversely affect the sanitary quality of the harvest area need to be identified, evaluated and reported by qualified personnel.
- **Waste Water Treatment:** an assessment of the reliability and effectiveness of sewage treatment plants or other waste treatment systems with respect to:
 - the concentrations to be achieved;
 - monitoring information that demonstrates what concentrations are achieved consistently;
 - presence and operating history of overflow devices and infiltration in collection systems, flow equalisation, equipment redundancy, increased disinfection contact times, sand filtration and, or, alternative power sources in terms of their reliability;
 - the safeguards within the treatment system to assure its reliability; and
 - the measures available to provide early warning in the event of system failure.
- **Properties and nearby land-use:** the identification, evaluation and mapping of all properties with the potential to discharge contaminants that may impact on the harvest area, including those with raw sewage, kitchen, laundry, agricultural, food processing plant and animal wastes and industrial discharge.
- **Discharge from properties and nearby land-use:** an attempt to quantify the volume of any discharge in relation to the above properties and land-use.
- **Consideration of watersheds:** the evaluation of agricultural run-off from feed lots and farmed fields, urban stormwater discharges, freshwater intrusion into estuaries, nitrate contamination in water bodies, atmospheric deposition of contaminants, failing septic systems, recreational boats and marinas.
- **Poisonous or deleterious substances:** a determination of poisonous or deleterious substances that may adversely affect the harvest area, including those that bioaccumulate.
- **Birds:** consideration of the presence of domestic, wild animal or resident and migrating bird populations in the growing area and possible adverse effects.

- **Impacts of pollution sources:** a determination that each pollution source has a direct, indirect, or no impact on the shellfish harvest area.
- **Hydrodynamics:** how drainage patterns and hydrodynamic factors in the growing area could affect the dispersal of potential pollution inputs.

b) Survey of the bacteriological quality of the water and, or, shellfish

The purpose of undertaking a survey of the bacteriological quality of the water and, or, shellfish is to supplement the findings of the shoreline survey and to support what contamination sources the operator identified in the shoreline survey.

The classification of the harvest area that the food business believes is achievable (following undertaking the shoreline survey) will determine the number of samples discussed below.

The following points need to be considered (where applicable) as part of undertaking a survey of the bacteriological quality of the water or shellfish.

- **Number and location of sampling stations:** sampling stations in the harvest area are sufficient in number and appropriately located so as to effectively evaluate all pollution sources.
- **Ensuring the integrity of samples:** sampling is conducted to assure the integrity of the samples.
- **Water samples:** testing of water samples and specifically counts of the thermotolerant coliform bacteria indicator group (refer to Section 4.2.1 of the WASQAP); and/or
- **Shellfish samples:** testing of shellfish samples and specifically counts of *Escherichia coli* bacteria (refer to Section 4.2.2 of the WASQAP).
- **Actual or potential pollution sources where a shoreline survey:**
 - has not identified actual or potential pollution sources that may impact on water quality, a minimum of 15 water samples and, or, 15 shellfish samples (from each of the sites determined above in the **number and location of sampling stations**) are collected under a range of environmental conditions; or
- **Actual or potential pollution sources where a shoreline survey:**
 - has identified actual or potential pollution sources that may have an impact on the water and shellfish quality, a minimum of 30 water and, or, 30 shellfish samples (from each of the sites determined above in the **number and location of sampling stations**) need to be collected under a range of environmental conditions which are expected to include the worst pollution conditions.
- **If sewage treatment plant outfall or other pollution point source:** if the shoreline survey identifies a sewage treatment plant outfall(s) or other point sources of public health significance within or adjacent to the growing area, a closed safety zone adjacent to the outfall(s) (where shellfish harvesting is

prohibited) should be established by the operator. Shellfish and/or water samples, taken from around the perimeter of a closed safety zone will need to be analysed to verify the size and adequacy of the zone.

Note: a harvest area may be classified using bacteriological data from water and, or, shellfish samples. Where both shellfish and water data are available, the more conservative classification must be used.

c) An evaluation of the potential for chemicals to contaminate the shellfish

An evaluation of the potential for toxic substances to contaminate shellfish in the growing area needs to be undertaken. The following points need to be considered (where applicable) as part of undertaking this evaluation.

- **Chemicals:** information gathered in the shoreline survey is used to select the chemicals to be included in the initial chemical monitoring program (refer to the note below).
- **Chemical contaminant loading:** the location of sampling sites needs to reflect the chemical contaminant loading associated with point and non-point source discharges, the dispersion of any discharge plume and/or key drainage areas.
- **Pesticides:** if applicable, the monitoring program includes the most heavily used pesticides in the watershed, particularly if these pesticides have a tendency to be bioaccumulated.
- **Chemical concentrations:** sites with chemical concentrations in excess of acceptable levels listed in the *Food Standards Code* (the Code) are immediately resampled in an intensive pattern to determine the extent of the contamination.

Note: This component of the sanitary survey will involve monitoring of chemicals in the harvest area and can be undertaken concurrently with b) above (Survey of the bacteriological quality of the water and, or shellfish). To select the chemicals to be included the food business should, as a minimum, refer to those listed in Schedule 19 of the Code (Maximum levels of contaminants and natural toxicants) i.e. cadmium, mercury, lead and inorganic arsenic. Inorganic arsenic testing is expensive and therefore total arsenic may be tested and the inorganic component can then be calculated from this result. If applicable, the monitoring program must also include the most heavily used pesticides in the watershed.

Marine Biotoxin Management Plan

In addition to compiling a Sanitary Survey Report and the work involved in the components of a sanitary survey (shoreline survey and water and/or flesh testing), the food business is also required to undertake a marine biotoxin risk analysis for the harvest area and develop an appropriate Marine Biotoxin Management Plan for the DoH's approval prior to classification. For further information, refer to Section 4 of the ASQAP.

An operator's Marine Biotoxin Management Plan should include:

- a) **Responsible Parties:** identification of all parties involved in the marine biotoxin management plan and their respective responsibilities;
- b) **Hydrographic details:** describe predominant currents and circulatory patterns in the growing area (note this information should have been gathered as part of the Sanitary Survey Report);
- c) **Species:** of shellfish to be cultured or harvested;
- d) **Sample sites:** that are representative of the harvest area, taking account of both benthic and suspended culture, where relevant;
- e) **Sampling frequencies:** consider factors such as seasonality (toxicity and, or, harvesting), accessibility, historical baseline information (including toxin and phytoplankton data) and the effects of environmental factors such as wind, tide and currents to determine sampling frequency.

Note: *WA's Marine Biotoxin Monitoring and Management Plan 2016* currently specifies biotoxin flesh testing be undertaken once a month while phytoplankton testing is to be undertaken twice a month; however, this is where there are established phytoplankton data for the growing area. Where limited data exist to inform a comprehensive risk analysis, a minimum of weekly biotoxin testing may be required initially following classification);

- f) **Sampling methods:** refer to section 4.3.1 and 4.3.2 of the WASQAP for further details);
- g) **Methods of analysis and Laboratories used:** for water and shellfish samples;
- h) **Alert level/s and/or closure levels:** for toxic/potentially toxic algal species (refer to Table 1 of *WA's Marine Biotoxin Monitoring and Management Plan 2016*);
- i) **Potentially toxic algal species list:** refer to Table 1 of *WA's Marine Biotoxin Monitoring and Management Plan 2016*);
- j) **Closure levels:** for toxins in shellfish flesh (refer to Table 1 and 2 of *WA's Marine Biotoxin Monitoring and Management Plan 2016*);

The DoH can only approve the classification of a shellfish harvest area when the operator has undertaken the work associated with a compiling a Sanitary Survey Report (i.e. the components of the sanitary survey – shoreline survey and water and/or shellfish testing) and developed a Marine Biotoxin Management Plan.

Components of the sanitary survey (specifically the sampling involved in b and c above, pages 6-7 above) provide the operator a cost effective opportunity to concurrently gather baseline and/or general environmental monitoring data for the site

required by the Department of Primary Industries and Regional Development for shellfish related aquaculture applications. In the case of an Aquaculture operation, the operator should consider collecting information on water and sediment quality parameters relevant to the species and scale of their proposed operation as part of baseline information required to inform their Management and Environmental Monitoring Plan (MEMP) required to accompany an application for an Aquaculture licence under section 92A of the *Fish Resources Management Act 1994*. In addition an operator must register with the DOH as a food business under the *Food Act 2008*.

Maintaining Harvest Area Classification Status

In addition to the requirements to achieve classification of a harvest area set out above, there is a number of ongoing post-classification requirements.

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.

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.

A review of the harvest area classification is to be undertaken by 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.

The harvest area classification re-evaluation also includes:

- a) review of the previous twelve months' 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 Marine Biotoxin Management Plan is inadequate, further investigation will need to be undertaken by the food business to determine the nature of the change.