

# **AUSTRALIAN SHELLFISH QUALITY ASSURANCE PROGRAM**

**Operations Manual**

**Version 8**

**December 2024**

***Australian Shellfish Quality Assurance Advisory Committee***

## FOREWORD

The Australian Shellfish Quality Assurance Program (ASQAP) is a government-industry co-operative program that provides for the food safety of shellfish managed in accordance with its operational guidelines. The *Australian Shellfish Quality Assurance Program Manual* (the Manual) comprises the procedures and administrative practices that, if adhered to, enable food safety programs to comply with the Food Standards Australia New Zealand *Food Standards Code* and *Export Orders* as they relate to bivalve molluscs, including the schedule to Standard 4.2.1 of the *Food Standards Code*.

The implementation of pre- and post-harvest Manual standards is the responsibility of appropriate state and territory government agencies and industry. Each state and territory divides this responsibility according to documented administrative and procedural arrangements. Consequently, the Manual forms the basis upon which both the administration of state- and territory-managed shellfish programs and the implementation of producer-based operational procedures are audited.

The ASQAP Manual is noted in the *Food Standards Code* as the “National guideline for managing risks in the harvesting, relaying, depuration and wet storage of shellfish”. Seafood businesses must comply with the *Food Standards Code* as it relates to bivalve molluscs, including the requirements listed in the schedule to Standard 4.2.1 of the *Food Standards Code* for domestic sales and the *Export Orders* for export.

In addition to being produced in accordance with this Manual, shellfish that are intended for overseas markets must comply with all relevant requirements of the *Export Control Act 1982* and its subordinate legislation. Where specific importing country requirements apply, these must also be met as a condition of market access in order to achieve export certification. In these circumstances, i.e. where importing country requirements are different or supernumerary to these Manual standards, the Commonwealth Department of Agriculture will endeavour to convey to relevant parties details of the status and terms of entry involved.

This Manual does not limit an agency's or individual producer's capacity to establish additional procedures or controls, if considered necessary, to manage the food safety risks associated with bivalve mollusc production.

This Manual has been endorsed by a full meeting of the Australian Shellfish Quality Assurance Committee and then by the Implementation Sub-committee on Food Regulation.

*Editors Note: In an effort to identify changes, amendments or updates to this manual any such changes will be shown in red text until a new version supersedes a previous version at which point the red text will revert to black text.*

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## 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.

**APHA** means American Public Health Association.

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

**Central file** means the file system maintained by the SCA or Commonwealth Department of Agriculture, Water and Resources.

**Closed inactive status** means a condition that may apply to a harvest area where the commercial harvesting of shellfish is prohibited for a minimum of twelve months due to industry inactivity. The sanitary survey needs to be reviewed before re-opening.

**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.

**Coliform group** includes all of the aerobic and facultative anaerobic, gram negative, non-spore-forming rod shaped bacilli that ferment lactose with gas production within 48 hours at  $35 \pm 0.5^{\circ}\text{C}$ .

**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.

**Culling** means the physical removal of individual shellfish from a lot of shellstock which are dead and/or damaged. Culling may also mean the process of manually separating shellfish which have grown and fused together, typically achieved by blunt force.

**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.

**Depuration plant** means a facility, containing one or more depuration units, which submits shellstock to a depuration process.

**Depuration unit** means a tank, trays or boxes, arranged singularly or in series, supplied by a single water purification system.

**Escherichia coli (E.coli)** are aerobic, rod-shaped, motile, thermotolerant faecal coliforms (bacteria) that ferment lactose to produce acid and gas, and indole from tryptophan after incubation at 44.0 to 44.5 °C for 24 + hours.

**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.

**Lot** (of shellfish) means a single species of shellfish harvested from a particular harvest area (e.g. marine farm, oyster lease or designated wild shellstock and designated by a single harvest record number and harvested on a single day).

**Manual** means the *Australian Shellfish Quality Assurance Program Operations Manual*.

**Marina** means any water area with a structure (wharf, basin, floating wharf, etc.) which is used for berthing or otherwise mooring vessels and is constructed to provide temporary or permanent berthing for more than 10 boats.

**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.

**Mixing** means the act of combining different lots of shellstock or processed shellfish.

**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.

**NATA** means National Association of Testing Authorities.

**Non-point source of pollution** means pollution from sources related to the activities of humans and to natural processes in the catchment area(s), which are diffuse or dispersed. Such sources do not enter at discrete, identifiable locations. Examples of non-point sources include urban run-off, agriculture run-off, faecal pollution from domesticated animals and wildlife, sewage discharge from boats, dredging operations, mining (e.g. leaching) and silviculture practices.

**nm** means nautical miles.

**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.

**Off-shore** means at least three nautical miles from the nearest land mass and practicably free from the risk of contamination by pollution sources.

**On-growing** means the process whereby shellfish are moved to a classified area for a sufficient period to permit their development as a marketable product. The period is not less than 60 days.

**Open status** with respect to:

(a) 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.

(b) a *Restricted* or *Conditionally Restricted* harvest area means that shellfish may be harvested for depuration or relaying when the shellfish growing waters and the shellfish meet harvesting criteria as determined by the SCA and in the case of a conditional classification, as defined in the management plan for the shellfish growing area.

(c) where the provision of samples for analysis (including water, shellfish and other substances or things) is undertaken in accordance with the requirements for the shellfish harvest area or as determined by the SCA.

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

**Point source** means any discernible, confined and discrete conveyance including any pipe, ditch, channel, tunnel or conduit (which may include natural watercourses), which carries a pollutant or potential pollutant.

**Point source pollution** includes discharges from sewage treatment plants, pulp mills, food processing plants, sewage emergency overflow points and the like through any discernible single source such as any pipe, ditch, channel, tunnel or conduit.

**Process batch** means the total quantity of shellfish depurated in one operational cycle of the depuration plant.

**Process water** means the water in depuration tanks during the time that the shellfish are being depurated.

**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.

**Sentinel species** means a species in a given area which has been shown to indicate the sanitary status for other species.

**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.

**Shoreline survey** means a survey conducted by a competent authority to identify and record pollution sources within the catchment of a shellfish growing area which contaminate or have the potential to contaminate the water quality of a shellfish harvest area.

**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.

**Temperature control** means management of the environmental temperature of shellfish by means of ice, mechanical refrigeration or other approved methods, which will lower the internal body temperature of the animal to a required level in a designated time.

**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.

## SCOPE OF THE MANUAL

This Manual applies to all bivalve molluscan shellfish species commercially harvested or handled for the purpose of human consumption whether they are harvested from the wild or from marine or land-based aquaculture facilities. 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 SCA 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 bivalve molluscs.

Scallops with either the viscera or the roe or both left on must comply with Section 4: Marine Biotoxin Control. The SCA must have a biotoxin management plan to cover roe-on scallops that are harvested or landed in its jurisdiction.

## 1. ADMINISTRATION

### OUTCOME

#### General administrative processes exist to support effective implementation of the Manual

The outcome of this section will be achieved if:

- 1.1 The SCA only approves shellfish harvest areas for harvest when they have complied with the requirements of:
  - a) Section 2: Classification Process for Shellfish Harvest Areas;
  - b) Section 3: Classification Standards; and
  - c) Section 4: Marine Biotxin Control.
- 1.2 The SCA administers the *Shellfish Food Safety Program* and compliance to this manual and the *Food Standards Code* or new elements of a program and finds substantial conformance with this Manual prior to harvest taking place.
- 1.3 There are adequate resources and trained technical personnel to:
  - a) survey, classify and maintain the appropriate classification status of shellfish harvest areas;
  - b) control the harvesting of shellfish; and
  - c) regulate the post-harvest handling and/or treatment of shellfish, including, but not restricted to, relaying, depuration, storage, handling, packing and labelling.
- 1.4 A Memorandum of Understanding is developed between the Commonwealth Department of Agriculture and the agency or agencies responsible for assuring shellfish safety to define their respective responsibilities, if more than one agency is involved.
- 1.5 Legislation is administered which enables:
  - a) control of the harvesting of shellfish, including:
    - (i) the prohibition of harvesting from areas that are unclassified or closed
    - (ii) the surveillance of harvest areas
    - (iii) the prosecution of persons found to have illegally harvested;
  - b) control of shellfish relaying;
  - c) control harvesting of shellfish which are to be depurated;
  - d) prevention of the sale, shipment or possession of shellfish which cannot be identified as having been produced in accordance with this Manual or which may be unfit for human consumption, and the right to detain, seize or destroy such shellfish;
  - e) registration, inspection and determination of the compliance of shellfish handling premises with the legislation;
  - f) control of shellfish shipping conditions to protect against contamination;

- g) labelling of shellstock to provide accurate identification of the shellfish source;
- h) protection of shellfish from contamination during harvesting and post-harvest handling, processing and storage;
- i) effective control and purification of shellstock subject to depuration;
- j) collection of samples and application of appropriate tests necessary to:
  - (i) verify the appropriateness of the shellfish harvest area classification
  - (ii) determine product safety;
- k) suspension or cancellation of the registration of premises on the basis of illegal practices and unacceptable or insanitary conditions.

**1.6** Documented administrative procedures are implemented sufficient to:

- a) effectively control shellfish harvesting, transport and storage; and
- b) detain, condemn, seize and embargo shellfish considered unfit for sale.

**1.7** The following records are maintained in a central file and made available upon request:

- a) laboratory accreditations;
- b) for each harvest area: a comprehensive sanitary survey and up-to-date sanitary survey reports which include all data, results and relevant analyses: management plans, surveillance plans and reports; harvesting criteria notices and related information; and information relating to post-harvest handling and treatment;
- c) shellfish handling premises evaluation reports;
- d) biotoxin management plans, monitoring data and reports;
- e) all data, criteria and protocols relating to the operation of a *Restricted* area such as depuration and relaying reports, harvesting permits and harvesting control records;
- f) all licences and special licences issued;
- g) all data, criteria and protocols relating to the operation of wet storage;
- h) any approvals required by commonwealth or state legislation;
- i) a current list of all harvest areas within a jurisdiction and their classification category;
- j) shellfish foodborne illness reports;
- k) closures and re-opening notices;
- l) enforcement actions, where applicable; and
- m) SCA evaluation reports by, for example, Commonwealth Department of Agriculture, foreign agencies or internal audits.

## 2. CLASSIFICATION PROCESS FOR SHELLFISH HARVEST AREAS

### 2.1: Sanitary Survey

#### OUTCOME

**Sanitary surveys effectively and comprehensively determine the sanitary quality of shellfish harvest areas**

The outcome of this section will be achieved if:

- 2.1.1** A comprehensive sanitary survey has been undertaken to determine the appropriate classification standard for the area.
- 2.1.2** The comprehensive sanitary survey is comprised of the following steps:
  - a) a shoreline survey;
  - b) a survey of the bacteriological quality of the water;
  - c) bacteriological and chemical examination of shellfish;
  - d) a study and evaluation of the effect of any meteorologic, hydrographic and geographic characteristics in the growing area;
  - e) a determination made of the risk of biotoxin occurrence in shellfish;
  - f) recording and written evaluation analysis of the data from a) to e) above; and
  - g) a determination of the appropriate harvest area classification.
- 2.1.3** In addition to the general elements described above, the comprehensive sanitary survey report includes:
  - 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) a history of harvest area classification, such as the date of last survey and previous classification maps, if applicable;
  - e) a pollution source survey, including:
    - (i) identification and evaluation of pollution sources such as domestic wastes, stormwater, agricultural waste (farms, feedlots and slaughterhouse operations), wildlife areas and industrial wastes
    - (ii) a map or chart showing the location of major sources of actual or potential pollution
    - (iii) 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 was determined by shellfish or water samples;

- 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;
- j) a discussion regarding variability in the data and its cause(s);
- k) overall compliance with the relevant classification criteria;
- l) the harvesting/growing area's classification;
- m) a management plan, if classified as *Conditionally Approved* or *Conditionally Restricted*; and
- n) a description of future monitoring arrangements.

*Note: A comprehensive sanitary survey is not required to classify an area as Prohibited.*

## 2.2: Shoreline Survey

### OUTCOME

**Contamination sources which could adversely affect the water quality of a shellfish harvest area are identified and evaluated**

The outcome of this section will be achieved if:

- 2.2.1** The boundaries of the shoreline survey area are identified by in-field investigation and mapped accordingly.
- 2.2.2** The shoreline survey area and all data associated with it are identified by unique designation.
- 2.2.3** 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 are identified, evaluated and reported by qualified personnel.
- 2.2.4** The shoreline survey includes, where applicable:
  - a) an assessment of the reliability and effectiveness of sewage treatment plants or other waste treatment systems with respect to:
    - (i) the concentrations to be achieved
    - (ii) monitoring information which demonstrates what concentrations are achieved consistently
    - (iii) presence and operating history of overflow devices and infiltration in collection systems, flow equalisation, equipment redundancy, increased disinfection contact times, sand filtration and/or alternate power sources in terms of their reliability
    - (iv) the safeguards within the treatment system to assure its reliability
    - (v) the measures available to provide early warning in the event of system failure;
  - b) 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;

- c) an attempt to quantify the volume of any discharge;
- d) 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;
- e) a determination of poisonous or deleterious substances which may adversely affect the harvest area, including those that bioaccumulate;
- f) a consideration of the presence of domestic, wild animal or resident and migrating bird populations for possible adverse effects;
- g) a determination that each pollution source has a direct, indirect, or no impact on the shellfish harvest area; and
- h) how drainage patterns and hydrodynamic factors could affect the dispersal of potential pollution inputs.

### 2.3: Bacterial Sampling

#### OUTCOME

**Bacterial sampling is undertaken to supplement the findings of the shoreline survey**

The outcome of this section will be achieved if:

- 2.3.1 Sampling stations in the harvest area are sufficient in number and appropriately located so as to effectively evaluate all pollution sources.
- 2.3.2 Sampling is conducted so that the integrity of the samples is assured.
- 2.3.3 Testing of water samples enumerates the thermotolerant coliform bacteria indicator group.
- 2.3.4 Testing of shellfish samples enumerates *Escherichia coli* bacteria.
- 2.3.5 When a shoreline survey has identified actual or potential pollution sources which may have an impact on the water and shellfish quality, a minimum of 30 water and/or 30 shellfish sample rounds are collected under a range of environmental conditions which are expected to include the worst pollution conditions;

or

Where a shoreline survey has not identified actual or potential pollution sources which may impact on water quality, a minimum of 15 water sampling rounds and/or 15 shellfish sampling rounds are collected under a range of environmental conditions.

- 2.3.6 Shellfish and/or water samples, taken from around the perimeter of a closed safety zone, are analysed to verify the size and adequacy of the zone, where such a zone is necessary.

## 2.4: Chemical Assessment

### OUTCOME

**An evaluation is made of the potential for toxic substances to contaminate the shellfish**

The outcome of this section will be achieved if:

- 2.4.1 Information gathered in the shoreline survey is used to select the chemicals to be included in the initial chemical monitoring program.
- 2.4.2 The location of sampling sites reflects the chemical contaminant loading associated with point and non-point source discharges, the dispersion of any discharge plume and/or key drainage areas.
- 2.4.3 If applicable, the monitoring program includes the most heavily used pesticides in the watershed, particularly if these pesticides have a tendency to be bioaccumulated.
- 2.4.4 Sites with chemical concentrations in excess of acceptable levels listed in the *Food Standards Code* are immediately resampled in an intensive pattern to determine the extent of the contamination.



### 3. CLASSIFICATION STANDARDS

#### 3.1: General Principles for Classification of Harvest Areas

##### OUTCOME

**Harvest areas are correctly classified**

The outcome of this section will be achieved if:

**3.1.1** At any given time, each harvest area is given only one of the following classification categories in accordance with this Manual:

- a) *Approved Remote*
- b) *Approved*
- c) *Conditionally Approved*
- d) *Restricted*
- e) *Conditionally Restricted*
- f) *Nursery/Source*
- g) *Prohibited*

*Note: A comprehensive sanitary survey is not required in order to classify an area as Prohibited.*

**3.1.2** The harvest area may be classified using bacteriological data from water or shellfish samples. Where both shellfish and water data is available, the more conservative classification shall be used.

**3.1.3.** The bacteriological data from only one approved method of water and/or shellfish analysis is used for classification purposes.

**3.1.4** A harvest area which has sewage treatment plant outfall(s) or other point sources of public health significance within or adjacent to the harvest area has a Closed Safety Zone established adjacent to the outfall(s) which has been established in accordance with Section 3.8.2.

#### 3.2: Approved Remote Classification

##### OUTCOME

**A harvest area classified as *Approved Remote* is correctly classified**

The outcome of this section will be achieved if:

**3.2.1** A comprehensive sanitary survey determines that the area has no human habitation or any other actual or potential pollution sources with potential to impact the harvest area.

**3.2.2** The area meets *Approved* classification criteria for water and/or shellfish (See Section 3.3).

### 3.3: Approved Classification

#### OUTCOME

A harvest area classified as *Approved* is correctly classified

The outcome of this section will be achieved if:

- 3.3.1** A comprehensive sanitary survey determines that the harvest area is not subject to contamination from:
- human or animal faecal matter at levels that present an actual or potential public health hazard; or
  - pathogenic organisms, poisonous or deleterious substances and/or biotoxins exceeding the levels required by the *Food Standards Code*.
- 3.3.2** Where the harvest area is surveyed using a systematic random sampling strategy, the bacteriological water quality of every sampling station assessed using the full complement of samples (as specified in Section 2.3) meets the following criteria:
- the thermotolerant coliform median or geometric mean of the water sample results do not exceed:
    - MF - 14 per 100 ml and the Estimated 90<sup>th</sup> percentile does not exceed 21 per 100 ml; or
    - MPN - 14 per 100 ml and the Estimated 90<sup>th</sup> percentile does not exceed 43 per 100 ml for a 5 tube decimal dilution test, or 49 per 100 ml for a 3 tube decimal dilution test.

or

Where the harvest area is surveyed using the adverse pollution conditions sampling strategy, the bacteriological water quality of every sampling station assessed using the full complement of samples (as specified in Section 2.3) meets the following criteria:

- the thermotolerant coliform median or geometric mean of the water sample results do not exceed:
    - MF - 14 per 100 ml and not more than 10% of the samples exceed 21 per 100 ml; or
    - MPN - 14 per 100 ml and not more than 10% of the samples exceed 43 per 100 ml for a 5 tube decimal dilution test, or 49 per 100 ml for a 3 tube decimal dilution test.
- 3.3.3** The Estimated 90<sup>th</sup> percentile is obtained from: Est. 90<sup>th</sup> = antilog [(slog)1.28 + xlog]
- Where: *slog* = the standard deviation of the logarithms of the values comprising the data set
- xlog* = the mean of the logarithms of the values comprising the data set (also known as the log mean or the arithmetic average of the logarithms).
- ~ and if values used in the calculation signify the lower range of sensitivity, the value is decreased by 0.1 - for example, if the analytical result is "less than 2", the value 1.9 is used for the calculation.

Note: Logarithms may be rounded to three decimal places and antilogs of log calculations rounded to the next lower integer (ie no decimal places), eg antilog 0.553 = 3. The geometric mean is the antilog of  $x \log$ .

**3.3.4** Where the harvest area is surveyed, using the systematic random sampling or the adverse pollution conditions sampling strategy, the bacteriological shellfish quality at every sampling station assessed, using the full complement of samples as specified in Section 2.3, shall not exceed a median or geometric mean of 2.3 *E. coli* per gram of flesh and intravalvular liquid and not more than 10% of the samples shall exceed 7 *E. coli* per gram at each station.

### 3.4: Conditionally Approved Classification

#### OUTCOME

**A harvest area classified as *Conditionally Approved* is correctly classified**

The outcome of this section will be achieved if:

- 3.4.1** A comprehensive sanitary survey finds that the 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.
- 3.4.2** Bacteriological water and shellfish quality correlates with environmental conditions or other factors affecting the distribution of pollutants into the harvest area.
- 3.4.3** 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 Section 2.3.
- 3.4.4** A written management plan has been completed for the harvest area which contains all of the following:
  - a) a general description of the harvest area including a map showing boundaries;
  - b) a description of factors determining the area's suitability for being given a *Conditionally Approved* classification;
  - c) a description of predictable pollution events that cause closure, including when applicable:
    - (i) wastewater treatment facility performance standards based on:
      - peak effluent flow
      - bacteriological quality of the effluent
      - physical and chemical quality of the effluent
      - treatment plant and sewage collection system bypasses
      - design, construction and maintenance to minimise mechanical failure or overloading
      - provisions for verifying and monitoring efficiency of the wastewater treatment plant and the feedback system for addressing inadequate treatment

- (ii) meteorological or hydrological events such as:
  - specific events that will cause the area to be closed
  - data and a discussion concluding that these specific events are predictable, so that the operation of the area has a meaningful basis
  - the predicted number of times such an event will occur within a year, based on historical findings
- (iii) seasonal events such as:
  - marina closures
  - seasonal rainfall
  - waterbird migration;
- d) implementation procedures for a closure including:
  - (i) notification of management plan violations, including:
    - the agency or agencies responsible for notifying a management plan violation
    - the response time between a violation of the management plan and notification
    - procedures for prompt notification
  - (ii) implementation of a closure, including:
    - the response time between notification of a management plan violation and legal closure
    - how the shellfish industry is notified
    - how surveillance personnel are notified
  - (iii) enforcement of closure, including:
    - which agency is responsible
    - the response time between legal closure and patrol agency notification
    - adequacy of enforcement during closure;
- e) criteria necessary for re-opening the area after a pollution event, including:
  - (i) procedures to determine that the pollution event has ended
  - (ii) a time interval sufficient to permit the area to flush itself
  - (iii) shellfish feeding activity sufficient to achieve natural cleansing as determined by documented water quality and shellfish studies
  - (iv) the time interval sufficient to permit the shellfish to cleanse themselves naturally - elapsed time beginning only after the completion of the period required for the area to flush.

### 3.5: Restricted Classification

<p><b>OUTCOME</b></p> <p><b>A harvest area classified as <i>Restricted</i> is correctly classified</b></p>
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The outcome of this section will be achieved if:

- 3.5.1** A comprehensive sanitary survey finds that the harvest area is:
- a) subject to only a limited degree of pollution; and

- b) the level(s) 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.

**3.5.2** Where the harvest area is surveyed using a systematic random sampling strategy, the bacteriological water quality of every sampling station assessed using the full complement of samples (as specified in Section 2.3) meets the following criteria:

- a) the thermotolerant coliform median or geometric mean of the water sample results do not exceed:
  - (i) MF - 70 per 100 ml and the Estimated 90<sup>th</sup> percentile does not exceed 85 per 100 ml; or
  - (ii) MPN - 88 per 100 ml and the Estimated 90<sup>th</sup> percentile does not exceed a MPN of 260 per 100 ml for a five tube decimal dilution test, or 300 per 100 ml for a three tube decimal dilution test.

or

Where the harvest area is surveyed using the adverse pollution conditions sampling strategy, the bacteriological water quality of every sampling station assessed using the full complement of samples (as specified in Section 2.3) meets the following criteria:

- b) the thermotolerant coliform median or geometric mean of the water sample results do not exceed:
  - (i) MF - 70 per 100 ml and not more than 10% of the samples exceed 85 per 100 ml; or
  - (ii) MPN - 88 per 100 ml and not more than 10% of the samples exceed 260 per 100 ml for a 5 tube decimal dilution test, or 300 per 100 ml for a 3 tube decimal dilution test.

**3.5.3** The Estimated 90<sup>th</sup> percentile is obtained from: Est. 90<sup>th</sup> = antilog [(slog)1.28 + xlog]

*Where: slog = the standard deviation of the logarithms of the values comprising the data set*

*xlog = the mean of the logarithms of the values comprising the data set (also known as the log mean or the arithmetic average of the logarithms).*

~ and if values used in the calculation signify the lower range of sensitivity, the value is decreased by 0.1 - for example, if the analytical result is "less than 2", the value 1.9 is used for the calculation.

*Note: Logarithms may be rounded to three decimal places and antilogs of log calculations rounded to the next lower integer (ie no decimal places), eg antilog 0.553 = 3. The geometric mean is the antilog of xlog.*

**3.5.4** Where the harvest area is surveyed using the systematic random sampling or the adverse pollution conditions sampling strategy, the bacteriological shellfish quality at every sampling station located in the harvest area shall not exceed a median or geometric mean of 46 *E. coli* per gram of flesh and intravalvular liquid and not more than 10% shall exceed 141 *E. coli* per gram.

### 3.6: Conditionally Restricted Classification

#### OUTCOME

A harvest area classified as *Conditionally Restricted* is correctly classified

The outcome of this section will be achieved if:

- 3.6.1** A comprehensive sanitary survey finds that the 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.
- 3.6.2** Bacteriological water and shellfish quality correlates with environmental conditions or other factors affecting the distribution of pollutants into the harvest area.
- 3.6.3** 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 Section 2.3.
- 3.6.4** A written management plan has been completed for the harvest area which contains all of the following:
- a) a general description of the harvest area including a map showing boundaries;
  - b) a description of factors determining the area's suitability for being given a *Conditionally Restricted* classification;
  - c) a description of predictable pollution events that cause closure, including when applicable:
    - (i) wastewater treatment facility performance standards based on:
      - peak effluent flow
      - bacteriological quality of the effluent
      - physical and chemical quality of the effluent
      - treatment plant and sewage collection system bypasses
      - design, construction and maintenance to minimise mechanical failure or overloading
      - provisions for verifying and monitoring efficiency of the wastewater treatment plant and the feedback system for addressing inadequate treatment
    - (ii) meteorological or hydrological events such as:
      - specific events that will cause the area to be closed
      - data and a discussion concluding that these specific events are predictable, so that the operation of the area has a meaningful basis
      - the predicted number of times such an event will occur within a year, based on historical findings
    - (iii) seasonal events such as:
      - marina closures
      - seasonal rainfall
      - water bird migration;
  - d) implementation procedures for a closure including:

- (i) notification of management plan violations, including:
  - the agency or agencies responsible for notifying a management plan violation
  - the response time between a violation of the management plan and notification
  - procedures for prompt notification
- (ii) procedures for the implementation of a closure, including:
  - the response time between notification of a management plan violation and legal closure
  - how the shellfish industry is notified
  - how surveillance personnel are notified
- (iii) enforcement of closure, including:
  - which agency is responsible
  - response time between legal closure and patrol agency notification
  - adequacy of enforcement during closure;
- e) criteria necessary for re-opening a conditionally classified area after a pollution event, including:
  - (i) procedures to determine that the pollution event has ended
  - (ii) a time interval sufficient to permit the area to flush itself
  - (iii) shellfish feeding activity sufficient to achieve natural cleansing as determined by documented water quality and shellfish studies
  - (iv) the time interval sufficient to permit the shellfish to cleanse themselves naturally - elapsed time beginning only after the completion of the period required for the area to flush.

### 3.7: Nursery/Source Classification

#### OUTCOME

**A harvest area classified as *Nursery/Source* is correctly classified**

The outcome of this section will be achieved if:

- 3.7.1** 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 *Food Standards Code*.
- 3.7.2** The SCA has issued an authorisation for all relaying from a *Nursery/Source* area.
- 3.7.3** All shellfish are taken from the *Nursery/Source* area for on-growing in a classified harvest area for at least 60 days.
- 3.7.4** The SCA 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.
- 3.7.5** Shellfish transferred from *Nursery/Source* areas for on-growing must not be commingled and must be identified and kept separate from other shellfish in the destination harvest area until 60 days have lapsed.
- 3.7.6** The identity of lots of shellfish in the process of being transferred from *Nursery/Source* areas is maintained at all times; each lot is kept separate from other lots to prevent cross-contamination and mixing; and containers, when used, are correctly labelled.
- 3.7.7** Adequate records are maintained which include:
- a) the source and quantity of shellstock transferred from a *Nursery/Source* harvest area
  - b) the date of harvest from the nursery/on-growing harvest area
  - c) the period of on-growing.
- 3.7.8** Where shellfish are transferred from *Nursery/Source* areas in containers, the shellfish are culled, washed and placed in clean containers which allow the free flow of water to the shellfish.
- 3.7.9** The depth and configuration of shellfish in containers allow the shellfish to filter normally.
- 3.7.10** Shellfish growing equipment in harvest areas that contain relayed shellfish from *Nursery/Source* areas are located and marked so that they may be readily identified.
- 3.7.11** Shellfish located in receiving harvest areas are adequately separated from the relayed shellfish so as to avoid cross-contamination.

### 3.8: Prohibited Classification

#### OUTCOME

**A harvest area is classified as *Prohibited* when necessary**

The outcome of this section will be achieved if:

- 3.8.1** A harvest area is classified as *Prohibited* when shellfish are so highly or frequently contaminated that harvesting controls cannot be implemented to adequately ensure the protection of public health.
- 3.8.2** The size of an area classified as *Prohibited* because of its adjacency to a pollution source of public health significance or designated as a Closed Safety Zone is determined using:
- a) the volume and flow rate of the wastewater discharge;
  - b) the concentration and decay rate of the contaminants of public health significance in the wastewater discharged; and



- c) the wastewater's dispersion and dilution, and the time of waste transport to the area where shellfish may be harvested.

## 4. MARINE BIOTOXIN CONTROL

### OUTCOME

**Marine biotoxin food safety hazards are monitored and managed**

#### 4.1: General Marine Biotoxin Requirements

The outcome of this section will be achieved if:

- 4.1.1** A marine biotoxin risk analysis has been established for the harvest area and an appropriate marine biotoxin management plan approved by the SCA.
- 4.1.2** The biotoxin management plan includes:
- a) the responsibilities of all parties involved in the biotoxin management plan
  - b) hydrographic details describing predominant currents and circulatory patterns
  - c) species of shellfish cultured/harvested
  - d) sample sites
  - e) sampling frequencies
  - f) sampling methods
  - g) methods of analysis for water and shellfish samples
  - h) laboratories used for sample analysis
  - i) alert level/s and/or closure levels for toxic/potentially toxic algal species
  - j) potentially toxic algal species list
  - k) closure levels for toxins in shellfish flesh
  - l) actions to be taken by SCA when either alert levels are exceeded or toxins are found in shellfish below closure levels
  - m) closure procedures including closure criteria, notification of closures to marine farmers and relevant authorities, public announcements, management during closures, product recall
  - n) opening procedures including opening criteria, notification of opening to marine farmers and relevant authorities, public announcements, procedures for opening inactive or seasonal harvest areas
  - o) procedures for dealing with relayed and recalled product potentially (or known to be) contaminated with biotoxins
  - p) case definitions of toxic syndromes
  - q) an annual review
- 4.1.3** When biotoxin testing is undertaken all shellfish species grown in the harvest area are sampled to indicate the biotoxin status of the harvest area.

or

Where a sentinel species is used, adequate data should exist to confirm the sentinel species accumulates toxins at a faster rate.

- 4.1.4** The sampling sites must be representative of the harvest area, taking account of both benthic and suspended culture, where relevant.
- 4.1.5** Following a comprehensive risk analysis, biotoxin sampling must be undertaken at a minimum of monthly intervals. Where limited data exists to inform a comprehensive risk analysis, a minimum of weekly testing is required.
- 4.1.6** Biotoxin risk management must consider all toxins listed in the Food Standards Code. Where an approved risk assessment has determined that NSP is an unlikely risk in the harvest areas and algal testing is undertaken, no regular monitoring for NSP is required. Monitoring for NSP or marine biotoxins not listed in the Food Standards Code must occur when any evidence highlights a potential health risk for example causative algae identified in the harvest area or adjacent harvest areas, or epidemiological evidence of specific marine toxins.
- 4.1.7** Where a SCA has approved a sentinel site sampling program, supported by an approved risk assessment to cover the risk of biotoxins in multiple harvest areas within a connected water body, the sampling at the sentinel sites must meet the requirements of 4.1.6 and must be supported by regular algal sampling at all harvest areas.
- 4.1.8** The inputs into the biotoxin risk analysis to determine the sampling frequency may include 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.
- 4.1.9** The harvest area is placed in the closed status when the biotoxin levels in the shellfish exceed the levels prescribed in Standard 1.4.1 of the *Food Standards Code* or a lesser level as may be determined by the SCA; or phytoplankton levels exceed the closure trigger levels provided in the management plan in absence of shellfish flesh toxicity data; or samples as required by the SCA have not been taken.
- 4.1.10** For reopening following a closure caused by elevated toxins, all species must be shown to comply the *Food Standards Code* for the toxin of concern, with two tests that meet the *Food Standards Code* levels, sampled not less than one week apart.
- 4.1.11** If using biotoxin screen tests, appropriate risk management actions must be documented in the biotoxin risk management plan.
- 4.1.12** The SCA may exempt specific shellfish species from a biotoxin closure when sufficient data is available from flesh testing that indicates these specific shellfish species can be safely exempt.
- 4.1.13** Phytoplankton monitoring may provide an early warning of potential biotoxin contamination, often with results available before the shellfish tests. It can, therefore, act as a pre-emptive tool to trigger an action plan, delay harvest, or close an area thereby protecting human health.

## 5. MAINTAINING THE CLASSIFICATION STATUS

### 5.1: Classification Review and Reporting Requirements

#### OUTCOME

**The sanitary status of a harvest area is subject to continuous effective appraisal**

The outcome of this section will be achieved if:

- 5.1.1** The classification of a harvest area is re-evaluated:
- at least annually, in accordance with sections 5.1.2-5.1.6;
  - at least every three years, in accordance section 5.1.7;
  - within 90 days of the end of the period under review;
  - if identified as the source of marketed shellfish that have been tested and found to not comply with relevant standards and/or export regulations;
  - if implicated in any disease outbreak; and/or
  - if suspected to be the source of shellfish that may cause illness.
- 5.1.2** The harvest area classification re-evaluation identifies, records and assesses changes in conditions in the harvest area and determines if the current sanitary survey data is consistent with the current classification category.
- 5.1.3** The harvest area classification re-evaluation comprises a field observation of actual and potential pollution sources which may include:
- a drive-through survey;
  - observations made during sample collection; and
  - information from other sources, where relevant.
- 5.1.4** The harvest area classification re-evaluation includes:
- a review of the previous twelve months' sampling data;
  - a review, if applicable, of inspection reports and effluent samples collected from pollution sources;
  - a review, if applicable, of performance standards for various types of discharges that impact the harvest area;
  - a review, if applicable, of the biotoxin risk analysis and the associated biotoxin management plan;
  - a review, if applicable, of closure and opening dates and supporting information; and
  - a report which documents all findings.
- 5.1.5** If a re-evaluation indicates conditions have changed, or samples have indicated that the current management plan is not adequate, further investigation is made to determine the nature of the change.
- 5.1.6** If a harvest area is classified as *Conditionally Approved* or *Conditionally Restricted*, the re-evaluation also includes:

- a) an assessment of compliance with the management plan;
- b) a determination of the adequacy of reporting any failure to meet performance standards, and remedy;
- c) a review of the co-operation of the persons involved;
- d) a field inspection of critical pollution sources, if applicable; and
- e) a synopsis of the effectiveness of the closure procedures and co-operation between the agencies involved.

**5.1.7** In addition to 5.1.2 – 5.1.6, a triennial re-evaluation includes:

- a) statistical analysis and review of the water quality and/or shellfish samples collected since the area was given the current classification or the previous triennial review, whichever is the lesser;
- b) investigation of all pollution sources necessary to fully evaluate any changes in the sanitary conditions of the harvest area;
- c) analysis of the sanitary survey data and a determination that the existing harvest area classification is correct or needs to be revised in accordance with 5.2.1.5;
- d) immediate revision of the classification category for harvest areas which do not comply with the requirements of the current harvest area classification; and
- e) a review of the biotoxin data and harvest areas compliance with the marine biotoxin management plan.

**5.1.8** Any upward revision of a harvest area classification is supported by an adequate re-evaluation of the sanitary survey.

**5.1.9** If the sampling strategy for a harvest area is changed from an adverse pollution conditions sampling strategy to a systematic random sampling strategy and there are not 30 recent randomly collected samples from each sampling station:

- a) the previous 15 samples collected under adverse pollution conditions are used with the most recent random samples to meet the minimum 30 samples for a transition period not to exceed three years; and
- b) as additional random samples are collected, the random samples replace chronologically the samples collected under adverse pollution conditions (i.e. sample 31 replaces sample 1).

## 5.2: Sampling to Maintain the Classification Status

### OUTCOME

#### Harvest areas are sampled appropriately

### 5.2.1 Bacterial sampling

The outcome of this section will be achieved if:

- 5.2.1.1 All compliance monitoring samples are taken when the area complies with the open condition associated with the harvest area classification.
- 5.2.1.2 All samples are submitted to laboratories accredited with the National Association of Testing Authorities (NATA) for the specific methodology required.
- 5.2.1.3 The sampling strategy used for a harvest area is selected before sampling commences and justification provided for its use.

- 5.2.1.4 When a systematic random sampling strategy is used, sample collection is scheduled sufficiently far in advance to support random collection with respect to environmental conditions, and the schedule is documented in a central file.

*Note: If conditions at the time and date of scheduled sample collection are believed to be hazardous to the safety of the individuals assigned to collect samples, sample collection must be rescheduled and undertaken as soon as practicable.*

- 5.2.1.5 For a harvest area that has identified pollution sources which have an impact on the water quality:
  - a) samples are collected from every station in the harvest area at a minimum of five samples per annum when identified adverse pollution conditions are prevailing in the harvest area;
  - b) a minimum of the most recent 15 samples collected under adverse pollution conditions are used to calculate the median or geometric mean and percentage tolerance to determine compliance with the appropriate classification criteria.

- 5.2.1.6 When the area is:
  - a) sampled by an Adverse Pollution Conditions sampling strategy, a minimum of five samples per annum are collected from every station in the harvest area under the identified adverse pollution conditions. When the adverse pollution conditions have not occurred within a two month period, samples must be collected from every station to ensure an adequate annual spread of sampling. These samples count towards the required five samples. A minimum of the most recent 15 samples collected are used to calculate the median or geometric mean and percentage tolerance to determine compliance with the appropriate classification criteria.
  - or
  - b) sampled by a Systematic Random Sampling strategy, a minimum of six random samples per annum are collected from every station in the harvest area and a minimum of the most recent 30 samples collected are used to

calculate the median or geometric mean and the Estimated 90th percentile to determine compliance with the appropriate classification criteria. The bacteriological data should effectively evaluate all non-point sources of pollution that accurately reflect the current shoreline survey. This must include all tidal stages that are suspected of affecting the total or thermotolerant coliform levels.

- 5.2.1.7** If it is necessary to verify the boundary line separating adjacent harvest areas, to verify the appropriateness of a Closed Safety Zone or where environmental and geographic conditions preclude reliable correlation between water and shellfish quality, testing of shellstock is to be undertaken.
- 5.2.1.8** If a harvest area is classified as *Approved Remote*:
  - a) samples from every station in the harvest area are collected at a minimum of two samples per annum; and
  - b) a minimum of the most recent 15 samples collected are used to calculate the median or geometric mean and Estimated 90th percentile to determine compliance with *Approved* classification criteria.
- 5.2.1.9** If a harvest area is in the Closed Inactive status, a minimum of two samples per annum must be collected from every station in the harvest area.
- 5.2.1.10** Where the harvest area has been placed in the Closed Inactive status it must remain in this status for at least 12 months.
- 5.2.1.11** Before a closed inactive harvest area is re-activated, the appropriate number of the most recent samples shall be reviewed to confirm compliance with the area's classification.

## **5.2.2 Chemical sampling**

The outcome of this section will be achieved if:

- 5.2.2.1** Information collected during the comprehensive sanitary survey from sites with acceptable concentrations serves as a benchmark for comparison with future monitoring results to document trends in the increase or decrease of toxic substance accumulation in shellfish tissues.
- 5.2.2.2** The frequency of monitoring is scheduled and sampling implemented in accordance with that schedule.

## 6. HARVESTING CONTROLS AND SURVEILLANCE

### 6.1: Harvesting Controls

#### OUTCOME

Harvesting controls ensure shellfish safety and are commensurate with relevant classification criteria

The outcome of this section will be achieved if:

- 6.1.1** The boundaries of harvest areas are charted, described by GIS coordinates and marked by fixed objects or landmarks sufficient to allow successful prosecution of any illegal commercial harvesting activity.
- 6.1.2** Growers/harvesters are notified of the boundaries by dissemination of information with licences, publication or direct notification.
- 6.1.3** A harvest area is closed when:
  - a) shellfish contamination levels are above the maximum levels listed in the *Food Standards Code*;
  - b) pollution conditions exist that were not included in the database of pollution and environmental conditions used to classify the area;
  - c) a sewage spill has occurred that could potentially impact the harvest area;
  - d) there is evidence of harmful levels of chemical contamination in shellfish;
  - e) it is required by a relevant management plan;
  - f) the level of biotoxin(s) present in shellfish is sufficient to cause a public health risk;
  - g) phytoplankton counts in the water column exceed defined trigger levels; or
  - h) other information or public health risk indicates a necessity to do so.
- 6.1.4** Any elevated data from the bacteriological sampling program is investigated, whether from a single station or multiple stations and, if the harvest area is not closed as a result of this data, written justification is provided as to why the area has remained open.
- 6.1.5** A harvest area classified as *Conditionally Approved* meets the requirements of the *Approved* classification when open for the purposes of harvesting shellfish for direct human consumption.
- 6.1.6** A harvest area classified as *Conditionally Approved* meets the requirements of the *Restricted* classification when closed for the purposes of harvesting shellfish for direct human consumption but open to harvesting for depuration.
- 6.1.7** A harvest area classified as *Conditionally Restricted* meets the requirements of the *Restricted* classification when open for the purposes of harvesting shellfish for depuration.
- 6.1.8** A biotoxin management plan is implemented for all shellfish harvest areas in accordance with Section 4.



**6.1.9** If a biotoxin-related closure is applied selectively to shellfish species in a harvest area, there is adequate data to justify the selectivity and the biotoxin management plan documents the arrangements accordingly.

**6.1.10** A harvest area temporarily placed in the closed status is reopened only when:

- a) the original classification criteria are satisfied;
- b) sufficient time has elapsed to allow the shellstock to reduce to acceptable levels: pathogens, indicator organisms, biotoxins or other deleterious substances that may be present in the shellstock, and the shellstock have been demonstrated to be safe;
- c) for closures associated with an untreated or partially treated sewage discharge or an untreated sewage discharge from a community sewage system:
  - i. at least 21 days have passed since the end of the contamination event;  
OR
  - ii. shellstock samples, collected from representative locations in each harvest area (no sooner than seven days after the contamination has ceased), are found to have Male Specific Coliphage levels which do not exceed background levels or a level of 50 Male Specific Coliphage per 100 grams; and
- d) supporting information is documented in a central file.
- e) any State that has had outbreaks from pathogenic vibrio associated with bivalve shellfish or has been shown to have a high level of sporadic vibriosis associated with bivalve shellfish, should develop and implement a Vibrio Management Plan

**6.1.11** Shellfish are only harvested for depuration from areas that have a classification of *Approved, Approved Remote, Conditionally Approved, Restricted or Conditionally Restricted*. Shellfish are only harvested from Conditionally Restricted areas when they are in the open status.

**6.1.12** Shellfish are not harvested for direct consumption from Nursery/Source or Restricted areas.

**6.1.13** Shellfish are not harvested from a *Prohibited* area.

## 6.2: Surveillance and Licensing

### OUTCOME

**Surveillance and other administrative measures support harvesting controls**

The outcome of this section will be achieved if:

**6.2.1** The responsible agency maintains an effective program to ensure that shellfish are harvested only from areas in the appropriate status.

**6.2.2** The harvesting control program includes:

- a) surveillance activity;

- b) licensing of growers/harvesters for harvesting purposes;
  - c) enforceable legal penalties sufficient to encourage compliance; and
  - d) appropriate identification of areas where shellfish harvesting is prohibited.
- 6.2.3** At the time of issuance or renewal of a grower/harvester licence, each licensee is provided with:
- a) information which explains the public health risk associated with illegal harvesting of shellfish;
  - b) information describing the procedure used to notify growers/harvesters of changes in harvest area status or classification; and
  - c) if requested, a current, comprehensive, itemised listing of all harvest areas including their geographic boundaries and their classification.
- 6.2.4** A written surveillance plan, which includes inspection, record keeping, audit and reporting requirements, is implemented for all harvest areas and reviewed each year.
- 6.2.5** The surveillance plan addresses the prevention of illegal harvesting of shellfish and includes details about the personnel and agencies involved, and the nature and frequency of surveillance.
- 6.2.6** Surveillance activities aid compliance with management plan criteria and closure, relaying, shellfish identification, handling and transport criteria detailed in this Manual.
- 6.2.7** A surveillance report is prepared by the responsible agency each year and contains details of the surveillance activities performed during the preceding year.

## 7. POST-HARVEST HANDLING, STORAGE AND LABELLING PRIOR TO RECEIVAL OF SHELLSTOCK

### 7.1: Storage and Handling Practices

#### OUTCOME

**Post-harvest handling minimises contamination with and proliferation of micro-organisms and protects shellstock from deterioration**

The outcome of this section will be achieved if:

- 7.1.1** Shellstock, which are harvested and transported on a vessel and/or vehicle for more than four hours, are shaded from the sun and/or sprayed with water of *Approved* area quality, chilled with ice made with potable water, covered with clean wet sacks or subjected to other measures to prevent an unacceptable increase in temperature and/or bacterial levels.
- 7.1.2** Shellstock intended for consumption as raw product are placed under ambient refrigeration at 10°C or less within twenty four hours of being harvested.  
*Note: A higher temperature will be considered acceptable only if demonstrated, by scientifically-robust evidence, that such a (higher) temperature will not support unacceptable growth of human pathogens in the shellstock.*
- 7.1.3** At points of transfer, such as the loading dock, shellstock:
  - a) are protected from contamination; and
  - b) are not permitted to remain without ice, mechanical refrigeration or other approved means of lowering the internal body temperature of the shellstock to, or maintaining it at, 10°C or less for more than two hours.
- 7.1.4** Pressurised water of a standard which is at least equal to the approved water quality of the harvest area is used to remove mud, bottom sediments, detritus and seaweed from shellstock as soon as practicable after harvesting.
- 7.1.5** If shellfish are washed at the harvest area prior to harvest, trays holding the shellfish are above the water level to ensure that wash water cannot adversely affect adjacent shellfish.
- 7.1.6** Vessels and vehicles used to harvest and transport shellfish are properly constructed, operated and maintained to prevent contamination, deterioration and decomposition of shellstock.
- 7.1.7** Decks and storage bins are constructed and located to prevent bilge water or polluted water from coming into contact with the shellfish.
- 7.1.8** Bags or other containers used for storing shellstock are clean and fabricated from safe materials.
- 7.1.9** Vessels, vehicles and all the equipment coming into contact with shellfish during handling or transport are kept clean and provided with effective drainage.
- 7.1.10** When necessary, effective coverings are provided to protect shellfish from exposure to birds and adverse conditions.

- 7.1.11 Cats, dogs and other animals are not allowed on vessels or vehicles used for shellfish.
- 7.1.12 Human excreta is not discharged overboard from a vessel used in the harvesting of shellfish while the vessel is in, or is adjacent to, a shellfish harvest area.
- 7.1.13 Shellstock are transported in adequately refrigerated vehicles when they have been previously refrigerated or at times when ambient air temperature and time of travel are such that unacceptable bacterial growth or deterioration may occur.
- 7.1.14 When mechanical refrigeration units are used, the units are equipped with automatic controls.
- 7.1.15 Shellstock are not transported with other cargo unless:
  - a) they are separated from the other cargo by impervious horizontal partitioning or isolated by another acceptable method; and
  - b) the other cargo is not placed on or above the shellstock unless the shellstock are packed in sealed, crush-resistant impervious containers.

## 7.2: Shellfish Labelling

**OUTCOME**  
**Shellfish are adequately identified**

The outcome of this section will be achieved if:

- 7.2.1 Bags or containers of shellstock are identified with a durable tag or label that is affixed to the exterior of the bag or container or within the container.
- 7.2.2 Each bag or container of shellstock is tagged or labelled at the time of filling. If the shellfish are harvested at more than one location per voyage, each bag or container is tagged or labelled at the harvest area. If only harvesting from one harvest area per voyage then shellstock can be labelled at the farm's processing facility.
- 7.2.3 The tag or label remains affixed to each bag or container of shellstock until the bag or container is emptied.
- 7.2.4 The tag or label contains the following legible information:
  - a) the name of the grower/harvester;
  - b) the name of the harvest area;
  - c) the date of harvest; the type and quantity of shellstock; and
  - d) any other information required by the SCA (for example lease number).
- 7.2.5 If the shellstock are removed from the original bag or container for washing, grading, sorting or other processing, the processor:
  - a) keeps the identification tag or label for a minimum period of 90 days; and
  - b) maintains the lot identity of all shellstock during the processing.
- 7.2.6 During any intermediate stage of processing each lot of shellstock is separated and identified in a way that prevents mixing or misidentification.

## 8. RELAYING, DEPURATION AND WET STORAGE

### 8.1: Relaying

#### OUTCOME

#### Relaying controls ensure shellfish safety

The outcome of this section will be achieved if:

- 8.1.1** Shellfish are only harvested for relaying from areas when the level of contamination can be reduced to safe levels for human consumption.
- 8.1.2** Water temperature, salinity, initial quality, species of shellfish and the physiological ability of the shellfish to cleanse themselves determines the time required for purification, but this period is at least 14 days when environmental conditions are suitable for reduction of contaminants, unless shorter periods are demonstrated to be adequate.
- 8.1.3** When any of the harvest areas listed in Section 3.1.1 are closed due to an untreated or partially sewage discharge from a community sewage collection system, relayed shellstock must be held for at least 21 days since removal from the affected harvest area or the end of the discharge, whichever is shorter.
- 8.1.4** When any of the harvest areas listed in Section 3.1.1 are closed due to biotoxins, the shellstock must be relayed for at least 60 days unless testing shows they have been adequately cleansed of toxins, in accordance with [4.1.10](#).
- 8.1.5** When shellstock is sourced from unclassified areas they must be relayed for at least 60 days unless testing shows they have been adequately cleansed of all contaminants. Where heavy metal contamination or other chemical contamination is a concern, testing must demonstrate shellstock are safe for consumption.
- 8.1.6** A person harvesting shellfish for relaying possesses an authorisation to relay issued by the SCA which is:
  - a) non-transferable;
  - b) issued only for a specific relaying operations according to approved operational procedures.
- 8.1.7** The SCA 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.
- 8.1.8** Shellfish are relayed in accordance with the operational procedures and the conditions of the relaying authorisation. The authorisation should include:
  - a) All relayed product must be clearly marked to distinguish it as relay product during transport and on the farm during the relay period;
  - b) The identity of lots of relayed shellfish is maintained at all times;
  - c) Relayed shellfish are adequately separated from market ready shellfish so as to avoid cross-contamination;
  - d) The relaying authorisation holder maintains adequate records which include:
    - i. the period of relaying;

- ii. the date of harvest;
  - iii. the source and quantity of relayed shellstock;
  - iv. the purchaser and quantity purchased; and
  - v. where required by the SCA, the results of analyses on each lot of relayed shellfish before and after the relaying period;
- e) Where shellfish are relayed in containers, the shellfish are culled, washed and placed in containers which allow the free flow of water to the shellfish.
  - f) The depth and configuration of shellfish in containers allow the shellfish to pump normally.
  - g) Areas within the harvest area that contain relayed shellfish are located and marked so that they may be readily identified.
- 8.1.9** The responsible agency takes appropriate action, which may include revoking an authorisation, when the operational procedures are not complied with.

## 8.2: Depuration

### OUTCOME

**Shellfish are safe for human consumption after depuration**

The outcome of this section will be achieved if:

**8.2.1** The SCA:

- a) establishes a control plan for shellfish harvested for depuration;
- b) approves the design and construction of the depuration facility prior to its use;
- c) approves any subsequent changes to the depuration facility;
- d) confirms depuration operators are suitably trained;
- e) issues non-transferable licences to harvesters for the taking of shellfish from areas classified as *Restricted* or *Conditionally Restricted* when in the open status, or of the *Approved*, *Approved Remote* or *Conditionally Approved* classification when in the closed status, and specifies the limitations and conditions for harvesting shellfish, including requirements for the grower/harvester to keep records which:
  - (i) specify the date and amount of shellfish harvested from each shellfish harvest area; and
  - (ii) record the name of the depuration facility to which the shellfish were consigned or sold;
- f) regularly audits depuration activities and facilities; and
- g) prohibits the shipment of depurated shellfish if the depuration process is determined to be compromised.

**8.2.2** The following elements are addressed in the depuration control plan:

- a) the classification and status of the source harvest area;
- b) the shellfish species;

- c) water temperature (including process water temperature and the differential between harvest area and process water temperature;) the salinity of the process water;
- d) dissolved oxygen of the process water;
- e) turbidity of the process water;
- f) plant design and construction;
- g) water disinfection units; and
- h) a description of operational procedures and requirements including:
  - (i) protection of shellfish prior to depuration
  - (ii) handling shellfish prior to depuration
  - (iii) source water quality
  - (iv) shellfish source identification
  - (v) layout of shellfish within the plant
  - (vi) plant hydraulics
  - (vii) the depuration period
  - (viii) handling shellfish after depuration
  - (ix) cleaning and maintenance
  - (x) record keeping.

**8.2.3** The maximum allowable pre-depuration (zero hour) level of the indicator *E. coli* in shellfish to be depurated is determined according to:

- a) the environmental conditions in the harvest area;
- b) the constraints and limitations of depuration; and
- c) the physiological attributes of the species to be depurated.

**8.2.4** The SCA ensures that:

- a) the depuration plant conforms with specified design parameters and construction standards;
- b) all plans for the construction or alteration of a depuration plant are submitted to the responsible agency prior to the commencement of construction or alteration of the plant;
- c) the plant is operated by a person who has been trained to a level of expertise considered adequate;
- d) the plant is used only for the species listed on the depuration permit;
- e) product for depuration must meet the minimum microbiological requirements for restricted classification; and
- f) process monitoring and end product testing is conducted in accordance with the requirements established by the responsible agency.

**8.2.5** The SCA:

- a) provides written approval for the depuration plant if it is satisfactory, prior to its use for direct marketing of depurated shellfish or if there is any substantial modification to the depuration plant.

**8.2.6** The depuration operator:

- a) is trained to an adequate level of expertise;
- b) complies with the control plan covering the operation of depuration plants;

- c) complies with any other conditions imposed as a condition of registration of the plant or as a condition of a permit to operate the plant; and
  - d) maintains an adequate routine end product sampling program.
- 8.2.7** Pressurised water of a standard which is at least equal to the water quality of the harvest area is used to remove mud, bottom sediments, detritus and seaweed from shellstock as soon as practicable after harvesting and prior to depuration.
- 8.2.8** Wash water post depuration must comply with Section 7.1.
- 8.2.9** The SCA must consider animal and human health risks for toxic by-products of any disinfection process prior to approving any depuration system.

### 8.3: Wet Storage in On-Land Facilities

**OUTCOME**

**The safety and suitability of shellfish are maintained during wet storage at on-land facilities**

The outcome of this section will be achieved if:

- 8.3.1** Wet storage is practiced only by an approved operator in strict compliance with the provisions in a written approval for the wet storage activity provided by the responsible agency.
- 8.3.2** The SCA:
- a) approves the design and construction of the wet-storage facility prior to its use;
  - b) approves any subsequent changes to the wet-storage facility; and
  - c) inspects and evaluates each wet storage operation regularly.
- 8.3.2** Wet storage facilities have effective barriers to prevent entry of birds, animals and pests.
- 8.3.3** Storage tanks and related plumbing are self-draining, easily cleanable and fabricated from non-toxic, corrosion-resistant materials.
- 8.3.4** Shellstock are sourced for wet storage only from:
- a) areas in the open status that are classified as *Approved*, *Approved Remote*, *Conditionally Approved* or *Off-shore*. or
  - b) areas in the open status that are classified as *Restricted* or *Conditionally Restricted* areas after being subject to effective depuration.
- 8.3.5** The wet storage operator keeps complete and accurate records to enable a lot of shellstock to be traced back to the wet storage location and source of the shellstock.
- 8.3.6** At all times, shellstock are protected from physical, chemical, biological and thermal conditions that may compromise the shellstock's quality or survival during wet storage. Factors such as temperature, salinity and dissolved oxygen need to be considered.



**8.3.7** Shellstock are thoroughly washed with water meeting the *Approved* area classification or potable water standards and any dead and damaged shellfish are removed prior to wet storage.

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

**8.3.8** Shellstock from different harvest areas are not commingled during wet storage.

**8.3.9** If more than one lot of shellstock is being held in wet storage at the same time, the identity of each harvest area lot is maintained.

**8.3.10** The shellstock are not mixed with other non-shellfish species in the same tank. Where multiple tank systems use a common water supply system for the shellfish and other species, the wet storage water is effectively disinfected prior to entering tanks containing the shellstock.

**8.3.11** Adequate clearance between shellstock and the tank bottom is maintained to ensure that shellstock are not contaminated by material which accumulates on the bottom of the tank.

**8.3.12** Shellstock containers are designed and constructed so that they allow the free flow of water to all shellstock within the container.

**8.3.13** Water used in wet storage tanks is sourced from an area in the open status which meets *Approved* classification criteria or complies with 8.3.14.

**8.3.14** When the source of the wet storage water is not from an approved harvest area in the open status, the water source:

a) meets, at a minimum, the bacteriological criteria for the *Restricted* classification;

b) is continuously disinfected or otherwise treated so that it is safe and does not interfere with the shellstock's survival, quality or activity during wet storage; and

c) either

(i) is sampled and tested for the total coliform group daily following disinfection; and

(ii) has no detectable levels of the total coliform group per 100 ml of water after treatment.

or

(iii) is proven to be of a quality, following the disinfection treatment, to test negative for the total coliform group, under normal operating conditions, by a study that:

- includes three samples from each disinfection unit collected for five consecutive days at the outlet from the disinfection unit or at the inlet to at least one of the wet storage tanks served by the disinfection system;

- includes one sample daily for five consecutive days from the source water prior to disinfection;

- uses only an approved method to analyse the samples to determine total coliform levels;

- requires all samples of disinfected water to be negative for the total coliform group; and

- is repeated if any sample of disinfected water during the study is positive for the total coliform group.

**8.3.15** If the water described in 8.3.14 is disinfected by ultra-violet treatment, turbidity does not exceed 20 nephelometric turbidity units, measured in accordance with the current APHA edition of the *Standard Methods for the Examination of Water and Wastewater*.

**8.3.16** Results of water samples and other tests to determine the suitability of the water supply are maintained for at least two years.

**8.3.17** Disinfection units for the water supply are cleaned and serviced as frequently as necessary to ensure effective water treatment.

**8.3.18** The SCA must consider animal and human health risks for toxic by-products of any disinfection process prior to approving any wet storage system.

## 9. INVESTIGATION OF ILLNESS ASSOCIATED WITH SHELLFISH

### 9.1: Confirmed Outbreaks

#### OUTCOME

Cases of shellfish being the cause of, or having the potential to cause, illness are adequately investigated

The outcome of this section will be achieved if:

- 9.1.1** When a suspected shellfish-borne illness outbreak is reported, appropriate authorities investigate the proposed epidemiological link to determine if:
- a) the cause of the illness is transmitted by shellfish;
  - b) the incubation time between shellfish consumption and the outbreak of the illness is consistent with the known incubation time associated with the suspected aetiologic agent;
  - c) there is more than one case reported; and
  - d) laboratory confirmation of the aetiological agent exists.
- 9.1.2** If an aetiologically-confirmed outbreak is demonstrated to implicate a shellfish harvest area:
- a) the harvest area is promptly placed in the closed status and kept in that status until its correct classification is determined using current data;
  - b) any remaining shellfish from the same harvest area are detained and/or recalled; and
  - c) appropriate authorities, including public health authorities, are notified.
- 9.1.3** If the source of the implicated shellfish appears to be illegal harvesting from areas classified as *Restricted* or *Prohibited* or harvest areas in the closed status, surveillance and enforcement activities are increased in the implicated harvest areas.
- 9.1.4** If it is determined that the outbreak is caused by a problem associated with the labelling, distribution or processing of the shellfish, immediate steps are taken to correct the problem.

## 9.2: Human Pathogens in Shellfish Meat

### OUTCOME

Cases of shellfish being the cause of, or having the potential to cause, illness are adequately investigated

The outcome of this section will be achieved if:

- 9.2.1** If it is determined that human pathogens are present in shellfish meats at levels likely to cause illness, the harvesting, distribution and processing of the shellfish are investigated, additional meat samples collected if necessary, and the following factors relating to the shellfish harvest area reviewed:
- a) documentation to trace the shellfish to its source;
  - b) classification assigned to the harvest area and whether the sanitary survey data supporting that classification is current; and
  - c) the probability of illegal harvesting from areas classified as *Restricted* or *Prohibited*, or in the closed status.
- 9.2.2** When the established tolerance level for a particular pathogen isolate is known:
- a) the harvest area is closed when the maximum level is exceeded; and
  - b) the harvest area is reviewed to ensure the risk is managed.
- 9.2.3** A management plan based on shellstock exceeding established tolerance levels:
- a) meets all appropriate requirements for a management plan for the *Conditionally Approved* or *Conditionally Restricted* classification;
  - b) specifies the additional criteria associated with the particular pathogen isolate that the harvest area must meet to be in the open status of its classification;
  - c) documents the scientific basis for the additional criteria;
  - d) provides for periodic re-testing of the shellfish meats; and
  - e) provides for the harvest area to be placed in the closed status if the criteria are exceeded.
- 9.2.4** When an established tolerance level does not exist for the particular contaminant isolated, a risk assessment is undertaken to determine the public health significance of the contaminant. If it is determined that the levels are unacceptable, the harvest area is placed in the closed status of its classification.
- 9.2.5** If a harvest area is placed in the closed status in the circumstances referenced in 9.2.2 or 9.2.4 the SCA determines that:
- a) that status is maintained indefinitely; or
  - b) the area is reclassified to the *Nursery/Source*, *Restricted* or *Prohibited* classification; or
  - c) the area is reclassified to the *Conditionally Approved* or *Conditionally Restricted* classification and a management plan is established in accordance with this Manual.

- 9.2.6** When a shellfish harvest area continues to demonstrate the presence of human pathogen isolates in shellfish meats in the absence of reported illness, a risk assessment is performed to determine the correct classification category for the harvest area.
- 9.2.7** If it is determined that the harvest area is not properly classified, immediate action is taken to:
- a) change the classification category to the correct classification category; or
  - b) close the harvest area until the correct classification can be determined.
- 9.2.8** If it is determined that a problem exists in the distribution or processing of the shellfish, immediate steps are taken to correct the problem.

### **9.3: Toxic Substances in Meats**

#### **OUTCOME**

**Cases of shellfish being the cause of, or having the potential to cause, illness are adequately investigated**

The outcome of this section will be achieved if:

- 9.3.1** If it is determined that toxic substances such as heavy metals, chlorinated hydrocarbons or natural toxins are present in levels of public health significance in shellfish meats, the harvesting, distribution and processing of the shellfish are investigated and the necessary corrective action taken in accordance with the following:
- a) the harvest area is promptly placed in the closed status;
  - b) any remaining shellfish from the same harvest area in the distribution system are detained and recalled;
  - c) the harvest area is kept in the closed status until its correct classification is verified using current data;
  - d) when the harvest area appears to be improperly classified, the area is reclassified correctly using the current data; and
  - e) the appropriate authorities, including public health authorities, are notified.
- 9.3.2** If a harvest area continues to demonstrate the presence of toxic substances in the absence of illness, a risk assessment is performed to determine the correct classification of the area.

## 10. LABORATORY AND ANALYTICAL REQUIREMENTS

### OUTCOME

Laboratory systems, methods and processes are fit for purpose

#### Definitions:

**Inter-Laboratory Comparison Program** (or proficiency program or round robin test) means a program, primarily as part of laboratory QA/QC, that involves testing the same samples by different laboratories followed by a comparison of the results. The analytical method to be used is not generally specified.

**Inter-Laboratory Study (ILS)** means organisation and performance evaluation of a test method on the same set of samples by two or more laboratories in accordance with predetermined conditions. According to the purpose, the study can be classified as a collaborative study (performance of the method) or proficiency study (performance of the laboratories).

**Qualitative method** means an analytical method that identifies the presence of a substance on the basis of its chemical, biological or physical properties.

**Quantitative method** means an analytical method that determines the amount or mass fraction of a substance so that it may be expressed as a numerical value of appropriate units.

**Screen method** means a method that is used to detect the presence of a substance or class of substances at the level of interest.

**Single laboratory study** (in-house validation) means an analytical study involving a single laboratory using one method to analyse the same or different test materials under different conditions over a time interval. Single laboratory validation studies are the initial phase of determining the performance characteristics of a test method and are generally followed by an ILS or collaborative study to achieve international acceptance for the method.

- 10.1** Each laboratory that undertakes analysis of water or shellfish samples has accreditation to ISO/IEC 17025 from National Association of Testing Authorities or an equivalent body.
- 10.2** Testing laboratories undergo any additional evaluation or audit as required by the SCA.
- 10.3** Test results are reported promptly, clearly and consistently according to SCA requirements.
- 10.4** Microbiological methods must meet those specified in Table 1, or other methods validated in accordance with the protocol set out in the ISO 16140, or other internationally accepted similar protocol.

**Table 10.1.** Microbiological Methods

Test type	Method
<i>E. coli</i> in shellfish flesh	ISO16649-3 or an Australian Standard method
Thermotolerant coliforms in seawater	Australian Standard method, or the approved methods of the US National Shellfish Sanitation Program (NSSP)
Norovirus in shellfish flesh	ISO 15216
Hepatitis A virus in shellfish flesh	ISO 15216
MSC phage in shellfish flesh	Enumeration of male-specific RNA bacteriophages in bivalve molluscan shellfish. Cefas Standard Operating Procedure 1671

- 10.5** Marine biotoxin methods will detect the biotoxin groups specified in Standard 1.4.1. of the Food Standards Code.
- 10.6** Biotoxin quantitative methods must meet criteria for the Determination of marine biotoxins listed in Codex Standard 292: Standard for Raw and Live Bivalve Molluscs, and use current FAO toxicity equivalency factors (TEFs).
- 10.7** New marine biotoxin quantitative or semi-quantitative methods that have undergone validation in accordance with the Guidelines for Single-Laboratory Validation of Methods of Analysis (e.g. International Union of Pure and Applied Chemistry (IUPAC)) may be used as screening techniques whilst laboratories are working towards full inter-laboratory studies.
- 10.8** Qualitative screen methods for marine biotoxins and chemical contaminants are validated in accordance with the AOAC Guidelines for Validation of Qualitative Binary Chemistry Methods.
- 10.9** For new marine biotoxin methods, the method validation study should:
  - a) Ensure that all relevant toxin analogues (as listed in Codex Standard 292: Determination of marine biotoxins in the Standard for Raw and Live Bivalve Molluscs) in the group that is being tested are detected.
  - b) Include testing of samples with toxin profiles relevant to the region in which the tests will be used.

- 10.10** Appropriately validated qualitative marine biotoxin screen methods can be used in the following situations:
- a) To determine if a quantitative method should be undertaken on a sample from a closed area for re-opening purposes (i.e. to test the first of two samples collected to re-open areas);
  - b) For routine testing of harvest areas in the open status when risk is considered low.
- 10.11** Where the SCA uses phytoplankton identification and enumeration to maintain the open status of a harvest area, or to open or close a harvest area, then the laboratory must:
- a) have the demonstrated capacity, capability and experience to identify all potentially harmful marine species to a level required by the SCA and;
  - b) participate in a relevant annual marine phytoplankton proficiency program e.g. International Phytoplankton Intercomparison (IPI).
- 10.12** Methods to analyse chemical contaminants in shellfish flesh must meet current ISO methods, or other internationally accepted similar protocol.