Australian Shellfish Quality Assurance Program

Export Standards

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AUSTRALIAN QUARANTINE AND INSPECTION SERVICE

Department of Agriculture, Fisheries and Forestry

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Foreword

The Australian Shellfish Quality Assurance Program (ASQAP) is a government-industry co-operative program designed to assure the food safety of shellfish managed in accordance with its operational guidelines. The Australian Shellfish Quality Assurance Program ***Export Standards*** comprise the ASQAP-based procedures and administrative practices necessary to meet legislative requirements prescribed by Orders under the ***Export Control Act, 1982***, and to satisfy the food safety expectations of importing countries. These ***Export Standards***, therefore, encapsulate core criteria for determining the export-eligibility of shellfish intended for overseas markets.

The implementation of pre-harvest and some post-harvest ***Export Standards*** are principally a responsibility of appropriate State and Territory government agencies. By contrast, post-harvest ***Export Standards***, such as those relating to depuration, storage, handling and labelling, are largely the responsibility of shellfish producers. Consequently, the ***Export Standards*** form the basis upon which both the administration of State- and Territory-managed shellfish programs and the implementation of producer-based operational procedures are audited.

In addition to being produced in accordance with these ***Export Standards***, shellfish that are intended for overseas markets must comply with all other 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 and in order to achieve export certification, if applicable. In these circumstances, ie where importing country requirements are different or supernumerary to these ***Export Standards***, the Australian Quarantine and Inspection Service will endeavour to convey, to relevant parties, details of the status and terms of entry involved.

The Australian Shellfish Quality Assurance Program ***Export Standards*** embody minimum effective regulation but do not limit an agency's or individual producer's capacity to establish additional procedures or controls if considered necessary to ensure shellfish safety.

Contents

Chapter 1 Administration

SECTION 1 - General administration

OUTCOME
General administrative processes exist to support effective implementation of the *Export Standards*.

The outcome of this section will be substantially achieved if:

1.1 AQIS evaluates the administration of a shellfish food safety program, or new elements of a program, and finds substantial conformance with these ***Export Standards*** prior to exports taking place.

1.2 There are adequate resources and trained technical personnel to:

a) survey and classify shellfish harvesting 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.

1.3 A Memorandum of Understanding is developed between AQIS and the agency or agencies responsible for assuring shellfish safety to define their respective responsibilities.

1.4 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 export.

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

a) laboratory evaluation records and related information;
b) comprehensive sanitary survey and update sanitary survey reports which include all data, results and relevant analyses; management plans, surveillance plans and reports; harvesting control notices and related information; and information relating to post-harvest handling and treatment;
c) shellfish handling premises evaluation reports;
d) shellfish foodborne illness reports;
e) biotoxin contingency plans, monitoring data, closures and re-opening notices, and reports;
f) 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;
g) all licences and special licences issued;
h) all data, criteria and protocols relating to the operation of wet storage;
i) any approvals required by commonwealth or state legislation; and
j) a current list of all harvesting areas within a jurisdiction and their classification category.

1.6 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 harvesting areas, and
   iii) the prosecution of persons found to have illegally harvested;
b) control of shellfish relaying and the harvesting of shellfish which are to be depurated;
c) prevention of the sale, shipment or possession of export-intended shellfish which cannot be identified as having been produced in accordance with these *Export Standards* or which are otherwise unfit for human consumption, and to detain, seize or destroy such shellfish;
d) registration, inspection and determination of the compliance of shellfish handling premises with regulations;
e) control of shellfish shipping conditions to protect against contamination;
f) labelling of shellstock to provide for accurate identification of the shellfish source;
g) protection of shellfish from contamination during harvesting and post-harvest handling, processing and storage;
h) effective control and purification of shellstock subject to depuration;
i) collection of samples and conduct of appropriate tests necessary to:
   i) verify the appropriateness of shellfish harvesting area classification, and
   ii) determine product safety.

1.7 Laboratories performing analytical microbiological, chemical and biotoxin examinations are accredited with the National Association of Testing Authorities (NATA) for the specific type of analysis, evaluated in accordance with the NATA laboratory evaluation program and participate in the NATA proficiency testing program.

Chapter 2
The comprehensive sanitary survey & classification

SECTION 2 - The shoreline survey

OUTCOME
Contamination sources which could adversely affect the water quality of a shellfish harvesting area are identified and evaluated.

The outcome of this section will be substantially achieved if:

2.1 The boundaries of the shoreline survey area are identified by in-field investigation and mapped accordingly.

2.2 The shoreline survey area and all data associated with it are identified by unique designation.

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 harvesting area are identified, evaluated and reported by qualified personnel.

2.4 The shoreline survey includes, where applicable:

a) an assessment of the reliability and effectiveness of sewage 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, and
   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 harvesting 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 growing area, including those that are bioaccumulatable;

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 harvesting area; and

h) how drainage patterns and hydrodynamic factors could affect the dispersal of potential pollution inputs.

Note: A pollution source has a direct impact if it would immediately affect the water quality of a shellfish harvesting area, whereas an indirect impact is secondary in nature or might eventually reach the harvesting area in a roundabout way.

SECTION 3 - Bacteriological sampling

OUTCOME
Bacteriological sampling is undertaken to supplement the findings of the shoreline survey.

The outcome of this section will be substantially achieved if:

3.1 Sampling stations in the growing area are sufficient in number and appropriately located so as to effectively evaluate all pollution sources.

3.2 Sampling is conducted so that the integrity of the samples is assured.

3.3 Testing of water samples enumerates either the total coliform or faecal coliform bacteria indicator group.

3.4 When a shoreline survey has identified pollution sources which may have an impact on the water quality:

a) a minimum of 30 water samples are collected under a range of environmental conditions which are expected to include the worst pollution conditions; and

b) the bacteriological results are used to calculate the median or geometric mean and percentage tolerance or Estimated 90th percentile to determine compliance with the appropriate classification criteria;

or

Where a shoreline survey has not identified any pollution sources which may impact on water quality:

c) a minimum of 15 water samples are collected under a range of environmental conditions; and

d) the bacteriological results are used to calculate the median or geometric mean and the Estimated 90th percentile to determine compliance with the appropriate classification criteria.

3.5 The Estimated 90th percentile is obtained from: Est. 90th = 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.

3.6 Shellstock are sampled and tested for a coliform indicator, particularly where environmental and geographic conditions preclude reliable correlation between water and shellfish quality.

3.7 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.

SECTION 4 - Chemical and biotoxin/phytoplankton sampling

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

The outcome of this section will be substantially achieved if:

4.1 Information gathered in the shoreline survey is used to select the chemicals to be included in the initial chemical monitoring program.

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.

4.3 If applicable, the monitoring program includes the most heavily used pesticides in the watershed, particularly if these pesticides have a tendency toward bioaccumulation.

4.4 Sites with chemical concentrations in excess of acceptable levels are immediately resampled in an intensive pattern to determine the extent of the contamination.

4.5 The presence of biotoxins and/or potentially toxic phytoplankton is determined through a monitoring program, which takes account of seasonal variability and the capacity of toxic algae that have been previously unknown in the area to appear.

SECTION 5 - Methods of analysis

OUTCOME
Approved methods are used during the analysis of water and shellfish samples.

The outcome of this section will be substantially achieved if:

5.1 The method used for the enumeration of faecal or total coliforms in water samples is in accordance with:

a) the *Recommended Procedures for the Examination of Seawater and Shellfish*, 4th Edition, 1970, The American Public Health Association, Inc.; or

b) the relevant Standard published by Standards Australia; or

c) an alternative method which has been determined to be equivalent to an Australian Standard or to a Joint Australian/New Zealand Standard (in a specified matrix) in accordance with the Australian/New Zealand Standard *Guide To Determine The Equivalency Of Microbiology Test Methods, 1999*.

5.2 The Australian Standard method AS 1766, *Methods for the Microbiological Examination of Food*, is used for analysis of shellfish samples.

5.3 The method used for the examination of samples for biotoxin and chemical contaminants is in accordance with:

a) the *Recommended Procedures for the Examination of Seawater and Shellfish*, 4th Edition, 1970, The American Public Health Association, Inc.; or

b) any other method approved under the *Export Control Act 1982* and its subordinate legislation.

SECTION 6 - The comprehensive sanitary survey

OUTCOME
Sanitary surveys effectively and comprehensively determine the sanitary quality of shellfish harvesting areas.

The outcome of this section will be substantially achieved if:

6.1 The comprehensive sanitary survey for a harvesting area includes the collection, recording and evaluation of environmental, bacteriological and chemical data and results from:

a) a shoreline survey;
b) a survey of the bacteriological quality of the water;
c) the 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) an analysis of the data from a) to d) above;
f) a determination made of the risk of biotoxin occurrence in shellfish; and
g) a determination of the appropriate harvesting area classification.

6.2 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 harvesting areas;
c) a location map or chart showing the harvesting area(s);
d) a history of harvesting area classification, such as the date of last survey and (a) previous classification map(s), if applicable;
e) the 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) the 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) a map of water quality sampling stations, and the sampling plan and its justification;
h) tables containing analytical statistics , including the number of samples, median or geometric mean and the respective variability factors;
i) a discussion regarding variability in the data and its cause(s);
j) overall compliance with the relevant classification criteria;
k) the harvesting/growing area's classification;
l) a management plan, if classified as Conditional Approved or Conditional Restricted; and
m) a description of future monitoring arrangements.

6.3 Either the faecal coliform water quality bacteriological criteria or the total coliform water quality bacteriological criteria are used to classify a shellfish harvesting area.

Note: A comprehensive sanitary survey is not required in order to classify an area as Prohibited or Off-shore.

SECTION 7 - Classification

OUTCOME
Harvesting areas are correctly classified.

The outcome of this section will be substantially achieved if:

7.1 At any given time, each harvesting area is given only one of the following classification categories on the basis of the completion of a comprehensive sanitary survey conducted in accordance with these *Export Standards*:

a) Approved
b) Approved Remote
c) Conditional Approved
d) Restricted, or
e) Conditional Restricted

Note: A comprehensive sanitary survey is not required in order to classify an area as Prohibited or Off-shore.

7.2 The bacteriological data from only one approved method of water analysis is used for classification purposes.

7.3 A harvesting area is classified as Prohibited where a comprehensive sanitary survey has not been satisfactorily completed, or shellfish are so highly or frequently contaminated that harvesting controls cannot be implemented to adequately ensure the protection of public health.

7.4 A growing area which has (a) sewage treatment plant outfall(s) or other point source outfall(s) of public health significance within or adjacent to the harvesting area(s) has (a) Closed Safety Zone(s) established adjacent to the outfall(s), the location(s) of which has/have been established in accordance with clause 13.2.

SECTION 8 - The Approved classification

OUTCOME
A harvesting area classified as Approved is correctly classified.

The outcome of this section will be substantially achieved if:

8.1 A comprehensive sanitary survey correctly determines that the harvesting area is not subject to contamination from:

a) human or animal faecal matter at levels that present an actual or potential public health hazard; or

b) pathogenic organisms, poisonous or deleterious substances and/or biotoxins exceeding relevant standards.

8.2 Where the growing area was surveyed using a systematic random sampling strategy, the bacteriological water quality of every sampling station, located in the growing area so as to be indicative of the sanitary quality of the defined harvesting area, meets the following criteria:

a) the faecal coliform median or geometric mean of the water sample results does not exceed:

i) MF - 14 per 100 ml and the Estimated 90th percentile does not exceed 21 per 100 ml; or

ii) MPN - 14 per 100 ml and the Estimated 90th 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

b) the total coliform median or geometric mean of the water sample results does not exceed 70 per 100 ml and the Estimated 90th percentile does not exceed 230 per 100 ml for a 5 tube decimal dilution test, or 330 per 100 ml for a 3 tube decimal dilution test when analysed by the MPN method;

or

Where the growing area was surveyed using the adverse pollution conditions sampling strategy, the bacteriological water quality of every sampling station, located in the growing area so as to be indicative of the sanitary quality of the defined harvesting area, meets the following criteria:

c) the faecal coliform median or geometric mean of the water sample results does not exceed:

i) MF - 14 per 100 ml and not more than 10 percent of the samples exceed 21 per 100 ml; or

ii) MPN - 14 per 100 ml and not more than 10 percent 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; or

d) the total coliform median or geometric mean of the water sample results does not exceed 70 per 100 ml and not more than 10 percent of the samples exceed 230 per 100 ml for a 5 tube decimal dilution test, or 330 per 100 ml for a 3 tube decimal dilution test when analysed by the MPN method.

8.3 The Estimated 90th percentile is obtained from: Est. 90th = 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.

SECTION 9 - The Approved Remote classification

OUTCOME
A harvesting area classified as Approved Remote is correctly classified.

The outcome of this section will be substantially achieved if:

9.1 A comprehensive sanitary survey determines that the area has no human habitation and it is not impacted by any actual or potential pollution sources.

9.2 The area meets Approved classification criteria.

SECTION 10 - The Conditional Approved classification

OUTCOME
A harvesting area classified as Conditional Approved is correctly classified.

The outcome of this section will be substantially achieved if:

10.1 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.

10.2 Bacteriological water quality correlates with environmental conditions or other factors affecting the distribution of pollutants into the harvesting area.

10.3 The area will meet Approved classification criteria when open to harvesting for direct human consumption.

10.4 A written management plan has been completed for the harvesting area which contains all of the following:

a) a general description of the harvesting area including a map showing boundaries;

b) a description of factors determining the area's suitability for being given a Conditional 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, and
- 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, and
- how surveillance personnel are notified,

iii) enforcement of closure, including:
- which agency is responsible
- the response time between legal closure and patrol agency notification, and
- 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, and
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; and

f) a synopsis of the effectiveness of the closure procedures and co-operation between the agencies involved.

SECTION 11 - The Restricted classification

OUTCOME
A harvesting area classified as Restricted is correctly classified.

The outcome of this section will be substantially achieved if:

11.1 A comprehensive sanitary survey finds that the harvesting 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.

11.2 Where the growing area was surveyed using a systematic random sampling strategy, the bacteriological water quality of every sampling station, located in the growing area so as to be indicative of the sanitary quality of the defined harvesting area, meets the following criteria:

a) the faecal coliform median or geometric mean of the water sample results does not exceed:

i) MF - 70 per 100 ml and the Estimated 90th percentile does not exceed 85 per 100 ml; or

ii) MPN - 88 per 100 ml and the Estimated 90th 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

b) the total coliform median or geometric mean of the water sample results does not exceed 700 per 100 ml and the Estimated 90th percentile does not exceed a MPN of 2300 per 100 ml for a five tube decimal dilution test, or 3300 per 100 ml for a three tube decimal dilution test when analysed by the MPN method;

or

Where the growing area was surveyed using the adverse pollution conditions sampling strategy, the bacteriological water quality of every sampling station, located in the growing area so as to be indicative of the sanitary quality of the defined harvesting area, meets the following criteria:

c) the faecal coliform median or geometric mean of the water sample results does not exceed:

i) MF - 70 per 100 ml and not more than 10 percent of the samples exceed 85 per 100 ml; or

ii) MPN - 88 per 100 ml and not more than 10 percent 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; or

d) the total coliform median or geometric mean of the water sample results does not exceed 700 per 100 ml and not more than 10 percent of the samples exceed 2300 per 100 ml for a 5 tube decimal dilution test, or 3300 per 100 ml for a 3 tube decimal dilution test when analysed by the MPN method.

11.3 The Estimated 90th percentile is obtained from: Est. 90th = 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.

11.4 Suitable shellfish quality criteria are established for shellfish that are to be relayed or for shellfish that are to be depurated.

SECTION 12 - The Conditional Restricted classification

OUTCOME
A harvesting area classified as Conditional Restricted is correctly classified.

The outcome of this section will be substantially achieved if:

12.1 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.

12.2 Bacteriological water quality correlates with environmental conditions or other factors affecting the distribution of pollutants into the harvesting area.

12.3 The area will meet Restricted classification criteria when open to harvesting for relaying or depuration.

12.4 A written management plan has been completed for the harvesting area which contains all of the following:

a) a general description of the harvesting area including a map showing boundaries;

b) a description of factors determining the area's suitability for being given a Conditional 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
- 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, and
      - 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, and
      - how surveillance personnel are notified;
   iii) enforcement of closure, including:
      - which agency is responsible
      - response time between legal closure and patrol agency notification, and
      - adequacy of enforcement during closure;

e) criteria necessary for re-opening a conditional 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, and
   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; and

f) a synopsis of the effectiveness of the closure procedures and co-operation between the agencies involved.

SECTION 13 - The Prohibited classification

OUTCOME
A harvesting area is classified as Prohibited when necessary.

The outcome of this section will be substantially achieved if:

13.1 A sanitary survey finds that the area is:
   a) adjacent to a sewage treatment plant outfall or other point source outfall with public health significance;
   b) contaminated by (an) unpredictable pollution source(s);
   c) contaminated with faecal waste so that the shellfish may be vectors for disease microorganisms;
   d) affected by algae which contain biotoxin(s) sufficient to cause a public health risk; or
   e) contaminated with poisonous or deleterious substances whereby the shellfish may be adulterated.

13.2 The size of an area classified as Prohibited because of its adjacency to an outfall 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 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.

SECTION 14 - The Off-shore classification

OUTCOME
A harvesting area classified as Off-shore is correctly classified.

The outcome of this section will be substantially achieved if:

14.1 A harvesting area is designated as Off-shore only when:

a) the area is at least 3 nm from land; and

b) it is determined that the area is not impacted by any actual or potential pollution sources.

14.2 A biotoxin management plan that includes tissue testing and/or phytoplankton counts is implemented in the harvesting area.

14.3 If considered necessary, testing is undertaken to confirm that shellstock are being handled hygienically prior to and during landing.

Note. Harvesting areas designated as Off-shore are exempt from all other provisions of Chapter 2 of these Export Standards, with the exception of Section 5, unless contra-indicated or stated otherwise.

Harvesting areas designated as Off-shore are also exempt from:

- *Chapter 3 (Section 15), except clauses 15.1c), d) & e) and 15.2;*
- *Chapter 4, Section 17;*
- *Chapter 5, Section 19; and*
- *Chapter 6, Section 22, except that the shellfish must be adequately identified:*
  - *i) to permit trace-back of product;*
  - *ii) as to its type and quantity; and*
  - *iii) by the date on which it was harvested.*

Chapter 3
Maintaining a classification

SECTION 15 - Classification review and update

OUTCOME
The sanitary status of a harvesting area is subject to continuous effective appraisal.

General

The outcome of this part will be substantially achieved if:

15.1 The classification of a harvesting area is re-evaluated:

a) at least annually, in accordance with the *Export Standards* for annual review;
b) at least every three years, in accordance with the *Export Standards* for triennial review;
c) if implicated in any disease outbreak;
d) if identified as the source of shellfish that have been tested and found to not comply with relevant standards and/or export regulations; and/or
e) if suspected of the potential to be the source of shellfish that will cause illness.

15.2 The re-evaluation is conducted in an expeditious manner and addresses all pertinent factors.

15.3 An annual re-evaluation identifies, records and assesses changes in conditions in the growing area and determines if the current sanitary survey data is consistent with the current classification category.

15.4 An annual re-evaluation comprises a field observation of actual and potential pollution sources which may include:

a) a drive-through survey;
b) observations made during sample collection; and
c) information from other sources, where relevant.

15.5 An annual re-evaluation includes:

a) a review of the previous twelve months' sampling data;
b) a review, if applicable, of inspection reports and effluent samples collected from pollution sources;
c) a review, if applicable, of performance standards for various types of discharges that impact the harvesting area; and
d) a report which documents all findings.

15.6 If an annual re-evaluation indicates conditions have changed, further investigation is made to determine the nature of the change.

15.7 If a harvesting area is classified as Conditional Approved or Conditional Restricted, the annual re-evaluation also includes:

a) an assessment of compliance with the management plan;
b) a determination of the adequacy of reporting of failure to meet performance standards;
c) a review of the co-operation of the persons involved; and
d) filed inspection of critical pollution sources, if applicable.

15.8 A triennial re-evaluation includes:

a) statistical analysis and review of the water quality samples collected since the area was given the current classification or the area was previously reviewed, whichever is the lesser;

b) investigation of all pollution sources necessary to fully evaluate any changes in the sanitary conditions of the harvesting area;

c) analysis of the sanitary survey data and a determination that the existing harvesting area classification is correct or needs to be revised; and

d) immediate revision of the classification category for harvesting areas which do not comply with the requirements of the current harvesting area classification.

15.9 Any upward revision of a harvesting area classification is supported by an adequate re-evaluation sanitary survey.

15.10 If a harvesting area appears to be improperly classified, the area is reclassified correctly using current data.

Bacteriological sampling

The outcome of this part will be substantially achieved if:

15.11 The water sampling strategy used for a harvesting area is selected before sampling commences and justification provided for its use.

15.12 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 may be rescheduled and undertaken as soon as practicable.

15.13 Except under the conditions stipulated in clauses 15.16 and 15.19, for a harvesting area that has identified pollution sources which have an impact on the water quality:

a) water samples are collected from every station in the growing area at a minimum of 5 samples per annum when identified adverse pollution conditions are prevailing in the growing 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.

15.14 Except under the conditions stipulated in clauses 15.16 and 15.19, where there are no identified point sources of pollution present that affect a harvesting area and the area is:

a) sampled by an Adverse Pollution Conditions sampling strategy ~

a minimum of 5 water samples per annum are collected from every station in the growing area under the identified adverse pollution conditions and 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 5 random water samples per annum are collected from every station in the growing 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 faecal coliform levels.

15.15 The Estimated 90th percentile is obtained from: Est. 90th = 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.

15.16 If a harvesting area is classified as Conditional Approved and is sampled according to a Systematic Random Sampling strategy, a minimum of 12 samples are collected per annum and all attempts are made to spread the collection of these samples over a 12 month period.

15.17 If the sampling strategy for a harvesting area is changed from an Adverse Pollution Conditions 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 (eg sample 31 replaces sample 1).

15.18 If necessary, for example to verify the boundary line separating adjacent harvesting 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 undertaken.

15.19 If a harvesting area is classified as Approved Remote:

a) water samples from every station in the growing area are collected at a minimum of 2 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.

Biotoxin/phytoplankton sampling

The outcome of this part will be substantially achieved if:

15.20 Representative samples of shellfish and/or water are collected during all harvest periods from indicator stations at intervals determined to be appropriate on the basis of risk, and assayed for the presence of toxins, or toxic or potentially toxic phytoplankton species.

Chemical sampling

The outcome of this part will be substantially achieved if:

15.21 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.

15.22 The frequency of monitoring is scheduled and sampling implemented in accordance with that schedule.

Methods of analysis

The outcome of this part will be substantially achieved if:

15.23 The approved methods referenced in Section 5 are used for the bacteriological, chemical and biotoxin analyses of water and shellfish samples.

Chapter 4
Harvesting controls & surveillance

SECTION 16 - Harvesting controls

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

The outcome of this section will be substantially achieved if:

16.1 The boundaries of harvesting 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.

16.2 Growers/harvesters are notified of the boundaries by dissemination of information with licences, publication, or direct notification.

16.3 A harvesting area is closed when:

a) pollution conditions exist that were not included in the database of pollution and environmental conditions used to classify the area;

b) a datum or data from any water sampling station(s), located in a growing area so as to be indicative of the sanitary quality of the defined harvesting area, exceed(s) the highest value in the current data set for that harvesting area;

c) required by a relevant management plan;

d) the level of biotoxin(s) present in shellfish is sufficient to cause a public health risk;

e) phytoplankton counts in the water column exceed defined trigger levels; or

f) other information or public health risk indicates a necessity to do so.

16.4 Any unusual data from the bacteriological sampling program is investigated, whether from a single station or multiple stations and, if the harvesting area is not closed as a result of this data, written justification is provided as to why the area has remained open.

16.5 If coliform levels in any sampling station exceed the relevant median or geometric mean of the bacteriological water sampling criteria of a harvesting area's classification and the area is not closed, the dataset for the harvesting area is (re)analysed to verify the area's classification.

16.6 A harvesting area classified as Conditional Approved meets the requirements of the Approved classification when open for the purposes of harvesting shellfish for direct human consumption.

16.7 A harvesting area classified as Conditional 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 relaying or depuration.

16.8 A harvesting area classified as Conditional Restricted meets the requirements of the Restricted classification when open for the purposes of harvesting shellfish for relaying or depuration.

16.9 A biotoxin management plan is implemented for all shellfish harvesting areas in accordance with the *Model Australian National Marine Biotoxin Management Plan,* Cawthron Report No. 646, November 2001.

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

16.11 A harvesting 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; and

c) supporting information is documented in a central file.

16.12 Shellfish are only harvested for depuration from areas that have a classification of Approved, Approved Remote, Conditional Approved, Restricted or Conditional Restricted, or for relaying from areas that have a classification of Approved, Approved Remote, Conditional Approved, Restricted, Conditional Restricted or Off-shore, when in the correct harvesting status.

16.13 Shellfish are not harvested from a Prohibited area.

SECTION 17 - Surveillance and licensing

OUTCOME
Surveillance and other administrative measures support harvesting controls.

The outcome of this section will be substantially achieved if:

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

17.2 The harvesting control program includes:

a) surveillance of harvesting areas;

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.

17.3 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 harvesting area status or classification; and

c) when requested, a current, comprehensive, itemized listing of all harvesting areas including their geographic boundaries and their classification.

17.4 A written surveillance plan, which includes inspection, record keeping, audit and reporting requirements, is implemented for all harvesting areas and reviewed each year.

17.5 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.

17.6 Surveillance activities ensure compliance with management plan criteria, and closure, relaying, shellfish identification, handling and transport criteria detailed in these *Export Standards*.

17.7 A surveillance report is prepared by the responsible agency each year and contains details of the surveillance activities performed during the preceding year.

Chapter 5
Relaying, depuration & wet storage

SECTION 18 - Relaying

OUTCOME **Relaying controls ensure shellfish safety.**
The outcome of this section will be substantially achieved if: **18.1** Shellfish are only harvested for relaying from: a) an Approved, Approved Remote, Conditional Approved or Off-shore area when closed due to the presence of biotoxin(s) in the shellfish or toxic phytoplankton in the water; b) a Conditional Approved area when closed in accordance with the criteria detailed in the management plan, provided that the area meets the Restricted classification criteria; or c) a Restricted or Conditional Restricted area when in the open status. **18.2** The responsible agency implements written relaying operational procedures which include: a) the source and species of shellfish to be relayed; b) information on the quality of the shellfish and/or the growing water prior to harvest for relaying purposes; c) information on the quality of relayed shellfish after purification; d) the time of the year when the relaying may occur; e) the method of marking the harvesting area used for relaying; f) the method of transport to the relaying site; g) the method of holding the relayed shellfish at the relaying site; h) the method of maintaining adequate separation between different lots of relayed shellfish and between relayed shellfish and shellfish which have not been relayed; i) how the permitted grower/harvester will maintain and file records; j) the issuing of permits to relay. **18.3** Shellfish are relayed in accordance with the operational procedures and the conditions of the relaying permit. **18.4** The responsible agency takes appropriate action, which may include revoking a relaying permit, when the operational procedures are not complied with. **18.5** The responsible agency periodically audits relaying operations.

18.6 The relaying permit holder maintains adequate records which include:

a) results of microbiological analyses on each lot of relayed shellfish before and after the relaying period, except where the shellfish were relayed due to the presence of biotoxin(s) in the shellfish;
b) the period of relaying;
c) the date of harvest;
d) the source and quantity of relayed shellstock; and
e) the purchaser and quantity purchased.

18.7 A person harvesting shellfish for relaying possesses a permit to relay which is:

a) non-transferable;
b) issued only for a specific relaying operation according to approved operational procedures; and
c) issued for a set period of time with reviews being undertaken on an annual basis.

18.8 Harvesting areas that contain relayed shellfish are located and marked so that they may be readily identified.

18.9 Shellfish located in receiving harvesting areas are adequately separated from the relayed shellfish so as to avoid cross contamination.

18.10 The identity of lots of relayed shellfish is maintained at all times, each lot kept separate from other lots to prevent cross-contamination and mixing, and containers, when used, are correctly labelled.

18.11 Relayed shellfish are held in receiving harvesting areas for a sufficient period of time, under suitable environmental conditions, to ensure purification.

18.12 Studies are conducted by the responsible agency to establish the effectiveness of contaminant reduction.

18.13 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 consecutive days when environmental conditions are suitable for purification, unless shorter periods are demonstrated to be adequate.

18.14 Purification times of less than 14 days are approved only if adequate data are first produced to justify the shorter period(s) and these data include:

a) the results of representative samples taken before and after relaying from at least ten lots of shellfish;
b) details of depth of water and stratification in the relaying area;
c) purification times used for each lot; and
d) daily water temperature, salinity and rainfall measurements recorded during the relaying period.

18.15 Water temperature, salinity and any other critical variables identified in the area to be used for relaying are determined when it is known that the limiting values may be approached and when the minimum relaying period is approached.

18.16 Where shellfish are relayed in containers, the shellfish are culled, washed and placed in clean containers which allow the free flow of water to the shellfish.

18.17 The depth and configuration of shellfish in containers allow the shellfish to pump normally.

SECTION 19 - Depuration

OUTCOME
Shellfish are safe for human consumption after depuration.

The outcome of this section will be substantially achieved if:

19.1 The responsible agency:

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) certifies depuration operators;
e) issues special licences to harvesters for the taking of shellfish from areas classified as Restricted or Conditional Restricted when in the open status, or of the Approved, Approved Remote or Conditional 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 harvesting 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.

19.2 The following elements are addressed in the depuration control plan:

a) the classification and status of the harvest area;
b) the shellfish species and source;
c) the initial (zero hour) level of *E. coli* in shellfish;
d) harvest area water temperature;
e) operational water temperature;
f) the salinity of the harvesting area and the process water;
g) dissolved oxygen of the process water;
h) turbidity of the source water;
i) plant design and construction;
j) water disinfection units;
k) 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, and
    x) record keeping.

19.3 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 harvesting area;
b) the constraints and limitations of depuration; and
c) the physiological attributes of the species to be depurated.

19.4 The responsible agency ensures that:

a) 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 meets the initial (zero hour) level of *E. coli* which cannot be exceeded in the undepurated shellfish in order to ensure achievement of end product standards; and
f) process monitoring and end product testing is conducted in accordance with requirements established by the responsible agency.

19.5 The responsible agency:

a) provides written approval for the depuration plant if it is satisfactory, prior to its use for direct marketing of depurated shellfish and if there is any substantial modification to the depuration plant; and
b) issues certification to the depuration operator if appropriately qualified.

19.6 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.

SECTION 20 - Wet storage

OUTCOME
The safety and suitability of shellfish are maintained during wet storage.

The outcome of this section will be substantially achieved if:

20.1 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.

20.2 Wet storage facilities have effective barriers to prevent entry of birds, animals and pests.

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

20.4 Shellstock are sourced for wet storage only from areas in the open status that are classified as Approved, Approved Remote, Conditional Approved or Off-shore, or Restricted or Conditional Restricted areas and subject to effective depuration.

20.5 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.

20.6 At all times, shellstock are protected from physical, chemical or thermal conditions that may compromise the shellstock's quality or survival during wet storage.

20.7 Shellstock are thoroughly washed with water meeting the Approved area classification or potable water standards and culled to remove dead and damaged shellfish prior to wet storage in tanks.
Note: Due to the adverse effects of culling on mussel physiology, culling of mussels may be done after wet storage.

20.8 Shellstock from different harvesting areas are not commingled during wet storage.

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

20.10 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.

20.11 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.

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

20.13 Water used in wet storage tanks is sourced from an area in the open status which meets Approved classification criteria or complies with clause 20.14.

20.14 When the source of the wet storage water is not an area which meets Approved classification criteria, 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 coliform group daily following disinfection; and

ii) has no detectable levels of the 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 coliform group, under normal operating conditions, by a study that:

- includes five sets of 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 coliform levels
- requires all samples of disinfected water to be negative for the coliform group and
- is repeated if any sample of disinfected water during the study is positive for the coliform group.

20.15 If the water described in clause 20.14 is disinfected by ultra-violet treatment, turbidity does not exceed 20 nephelometric turbidity units, measured in accordance with the *Standard Methods for the Examination of Water and Wastewater*, 17ed., APHA *et al*, 1989.

20.16 Results of water samples and other tests to determine the suitability of the water supply are maintained for at least two (2) years.

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

20.18 Each wet storage operation is inspected and evaluated at least annually.

Chapter 6
Post-harvest handling, storage and labelling

SECTION 21 - 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 substantially achieved if:

21.1 Shellstock which are harvested and transported on a vessel and/or vehicle for more than 4 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.

21.2 Shellstock intended for consumption as raw product are placed under ambient refrigeration at 10ºC 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.

21.3 At points of transfer, such as the loading dock, shellstock are:

a) protected from contamination; and

b) 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, 10ºC or less for more than 2 hours.

21.4 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.

21.5 If shellfish are washed on the lease prior to harvest, trays holding the shellfish are above the water level to ensure that wash water cannot adversely affect adjacent shellfish.

21.6 Shellstock are not washed with recirculated water.

21.7 Vessels and vehicles used to harvest and transport shellfish are properly constructed, operated and maintained to prevent contamination, deterioration and decomposition of shellstock.

21.8 Decks and storage bins are constructed and located to prevent bilge water or polluted water from coming into contact with the shellfish.

21.9 Bags or other containers used for storing shellstock are clean and fabricated from safe materials.

21.10 Vessels, vehicles and all the equipment coming into contact with shellfish during handling or transport are kept clean and provided with effective drainage.

21.11 When necessary, effective coverings are provided to protect shellfish from exposure to birds and adverse conditions.

21.12 Cats, dogs and other animals are not allowed on vessels or vehicles used for shellfish.

21.13 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 harvesting area.

21.14 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.

21.15 When mechanical refrigeration units are used, the units are:

a) equipped with automatic controls; and

b) capable of maintaining the ambient air temperature in the storage area at temperatures of 5^{o}C or less.

21.16 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.

SECTION 22 - Shellfish identification

OUTCOME
Shellfish are adequately identified.

The outcome of this section will be substantially achieved if:

22.1 Bags or containers of shellstock are identified with a durable waterproof tag or label that is affixed to the exterior of the bag or container.

22.2 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, each bag or container is tagged or labelled at the harvesting area.

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

22.4 The tag or label contains the following legible information:

a) the name of the grower/harvester;

b) the unique lease number;

c) the name of the harvesting area;

d) the date of harvest; and

e) the type and quantity of shellstock.

22.5 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.

22.6 During any intermediate stage of processing each lot of shellstock is separated and identified in a way that prevents mixing or misidentification.

Chapter 7
Aetiologic investigation

SECTION 23 - Investigation principles

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

Confirmed outbreaks

The outcome of this part will be substantially achieved if:

23.1 When a suspected shellfish-borne disease outbreak is reported, appropriate authorities investigate the proposed epidemiological link to determine if:

a) the disease is transmitted by shellfish;
b) the incubation time between shellfish consumption and the outbreak of the disease 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.

23.2 If an aetiologically-confirmed outbreak is demonstrated to implicate a shellfish harvesting area:

a) the harvesting area is promptly place 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 harvesting area are detained and/or recalled;
c) appropriate authorities, including public health authorities, are notified.

23.3 If the source of the implicated shellfish appears to be illegal harvesting from (an) area(s) classified as Restricted or Prohibited, or harvest areas in the closed status, surveillance and enforcement activities are increased in the implicated harvesting area(s).

23.4 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.

Human pathogens in meats

The outcome of this part will be substantially achieved if:

23.5 If it is determined that human pathogens are present in shellfish meats at a level likely to cause illness, the harvesting, distribution and processing of the shellfish are investigated and additional meat samples collected if necessary, and the following factors relating to the shellfish harvesting area reviewed:

a) the documentation to trace the shellfish to its source;
b) the classification assigned to the harvesting 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.

23.6 When the established tolerance level for a particular pathogen isolate is known:

a) the harvesting area is closed when the tolerance level is exceeded;

b) the harvesting area is reclassified to the Restricted or Prohibited classification, or to the Conditional Approved or Conditional Restricted classification and a management plan is established.

23.7 A management plan based on shellstock exceeding established tolerance levels:

a) meets all appropriate requirements for a management plan for the Conditional Approved or Conditional Restricted classification;

b) specifies the additional criteria associated with the particular pathogen isolate that the harvesting 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 retesting of the shellfish meats; and

e) provides for the harvesting area to be placed in the closed status if the criteria are exceeded.

23.8 When an established tolerance level does not exist for the particular pathogen isolated, the public health significance of the levels of the pathogen found in the shellfish is determined, and if it is determined that the levels are unacceptable, the harvest area is placed in the closed status of its classification.

23.9 If a harvesting area is placed in the closed status in the circumstances referenced in clause 23.8:

a) that status is maintained indefinitely;

b) the area is reclassified to the Restricted or Prohibited classification; or

c) the area is reclassified to the Conditional Approved or Conditional Restricted classification and a management plan is established in accordance with these *Export Standards*.

23.10 When a shellfish harvesting 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 harvesting area.

23.11 If it is determined that the harvesting area is not properly classified, immediate action is taken to:

a) change the classification category to the correct classification category; or

b) close the harvesting area until the correct classification can be determined.

23.12 If it is determined that a problem exists in the distribution or processing of the shellfish, immediate steps are taken to correct the problem.

Toxic substances in meats

The outcome of this part will be substantially achieved if:

23.13 If it is determined that toxic substances such as heavy metals, chlorinated hydrocarbons and 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 harvesting area is promptly placed in the closed status;

b) any remaining shellfish from the same harvesting area in the distribution system are detained and recalled;

c) the harvesting area is kept in the closed status until its correct classification is verified using current data;

d) when the harvesting 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.

23.14 If a harvesting 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.

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 faecal coliform or total coliform levels in a particular growing area. Examples may include unusual climatic conditions, rain after long dry periods, unusually hot temperatures, consecutive days of light rainfall, heavy rainfall, tidal effects, salinity and wind effects.

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

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

Closed status means a condition that may apply to a harvesting area where the commercial harvesting of shellfish is temporarily prohibited. A closed status may be placed on any of six classified harvesting area categories: Approved, Approved Remote, Conditional Approved, Restricted, Conditional 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° C ± 0.5°C.

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

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

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

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.

Faecal coliform group see thermotolerant coliforms.

Growing area means a marine or enclosed body of water (ie 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.

Harvesting 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.

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

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 as determined 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.

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 (eg leaching) and silviculture practices.

Off-shore means at least 3 nautical miles from the nearest land mass and practicably free from the risk of contamination by pollution sources.

Ongrowing means the process whereby shellfish are translocated 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, Conditional Approved or Off-shore harvesting area, means that shellfish may be harvested for direct marketing when the shellfish meet harvesting criteria and, in the case of the latter classification, as detailed in the relevant management plan for the area;

(b) a Restricted or Conditional Restricted harvesting area, means that shellfish may be harvested for depuration or relaying when the shellfish growing waters and the shellfish meet harvesting criteria and, in the case of the latter classification, as detailed in the relevant management plan for the area.

Point source means any discernible, confined and discrete conveyance including any pipe, ditch, channel, tunnel or conduit that 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 from Restricted or Conditional Restricted areas in the open status, or Approved, Approved Remote or Conditional Approved areas in the closed status to Approved, Approved Remote or Conditional Approved areas in the open status for the reduction of pathogens, or poisonous or deleterious substances that may be present, by using the ambient environment as a treatment process.

Remote shellfish area means a harvesting 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 harvesting 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.

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

Shellfish means all edible species of bivalve molluscs such as oysters, clams, scallops (except when the consumed product is only the adductor muscle), pipis and mussels, either shucked or in the shell, fresh or frozen, whole or in part or processed. The definition does not include spat.

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 harvesting area.

Spat means non-marketable juvenile shellfish which are taken for the purposes of ongrowing.

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 °C to 44.5 °C.

Toxic substance means a toxic compound occurring naturally or added to the environment that may be found in shellfish for which a regulatory tolerance limit has been established. Examples of naturally occurring toxic substances are marine biotoxins and trace elements geologically leached from the environment such as mercury, zinc and copper; examples of added substances are 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 natural bodies of water or in tanks containing natural or synthetic seawater. Wet storage may be used to remove sand or to add salt from or to the shellfish.