



Food
Authority

NSW Shellfish Industry Manual

Requirements to comply with the
Seafood safety scheme of the Food Regulation 2010
and Standard 4.2.1 of the Food Standards Code

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Definitions

Approved harvest area means a shellfish harvest area classified as approved by the Authority for harvesting or collecting shellfish for direct marketing (without depuration).

Aquaculture means the controlled production of shellfish in natural and artificial systems.

Authority means the NSW Food Authority.

Batch means a quantity of shellfish harvested from the same harvest area on the same date

Closed safety zone means the part of a shellfish growing/harvest area which lies adjacent to a sewage outfall or other area of contamination and where cultivation of spat and harvesting of shellfish is prohibited.

Closed status means a condition that applies to a harvest area where the commercial harvesting of shellfish is temporarily prohibited. An area may be closed by the Authority or a local shellfish committee when the harvest area does not meet the criteria for the harvest area classification or for any other condition likely to affect food safety.

Co-mingling means the act of combining different batches of shellfish (NOTE: this is not permitted under Standard 4.2.1 of the *Food Standards Code*).

Conditionally approved means the classification of a shellfish harvest area that meets approved harvest area criteria as determined by the Authority for a predictable period. The period depends on established performance standards specified in the harvest area management plan. A Conditionally approved area is placed in the closed status by the Authority when the area does not meet the approved harvest area criteria (but may remain open as a restricted harvest area when operating under a dual harvest area management plan).

Conditionally restricted means the classification of a shellfish harvest area that meets restricted harvest area criteria as determined by the Authority, for a predictable period. The period depends on established performance standards specified in the harvest area management plan. A Conditionally restricted area is placed in the closed status by the Authority when the area does not meet the restricted harvest area criteria.

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

Depuration plant means a facility, containing one or more depuration units, which submits live shellfish to a depuration process

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 shellfish grow naturally or are grown by means of aquaculture and which has not been classified by the Authority

Growing on means the process where juvenile bivalve molluscs (spat) are further grown for a sufficient period to enable their development prior to sale.

Harvest area means an area that has been classified (or is undergoing classification) by the Authority for the purpose of growing and/or harvesting commercial quantities of shellfish and may include wildstock or aquacultured shellfish.

Harvester means a person who takes shellfish by any means for commercial purposes from a harvest area.

Harvest area management plan is the set of conditions recognised by the Authority under which the harvest area may have an open status.

Local shellfish committee means the committee appointed under clause 129 of the Food Regulation 2010.

Marine biotoxins means toxic compounds produced by species of phytoplankton and accumulated by shellfish.

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

Open status in respect to:

- **an Approved/Conditionally approved harvest area**, means that shellfish may be harvested for direct marketing without depuration when the shellfish are safe for human consumption as determined by the Authority and defined in the criteria detailed in the harvest area management plan;
- **a Restricted/Conditionally restricted harvest area**, means that shellfish may be harvested for depuration or relaying when the shellfish growing waters and the shellfish meet criteria as determined by the Authority and detailed in the harvest area management plan.

Primary production in respect to shellfish means:

- growing, cultivation, picking, harvesting, collection or catching of shellfish; or
- growing on of shellfish; or
- transportation or delivery of shellstock; or
- holding of shellstock.

Processing in respect to shellfish, for the purposes of this Manual means:

- depuration, wet storage and desanding (NOTE: testing requirements for further processed product such as opened shellfish are included in the *NSW Food Safety Schemes Manual*).

Product Record (PR) number means a unique number to identify the harvested shellfish at all times through the harvest and distribution chain. The Product Record number is contained in the Harvested Product Record Book issued to a seafood business by the Authority.

Prohibited area means an area from which shellfish cannot be harvested for human consumption.

Relaying means the transfer of shellfish from one harvest area to another harvest area for the reduction of contaminants in the shellfish.

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

Restricted area means a classification used to identify a harvest area from which shellfish may be harvested only with the approval of the Authority and then subjected to an effective purification process such as relaying or depuration.

Shellfish means bivalve molluscs, including cockles, clams, mussels, oysters, pipis and scallops, but does not include the following:

- scallops and pearl oysters where the only part intended for human consumption is the abductor muscle, and
- the spat of bivalve molluscs.

Shellstock means live shellfish in the shell

Spat means juvenile bivalve molluscs taken for the sole purpose of growing on, that is, the process where juvenile molluscs are further grown for a sufficient period to enable their development prior to sale (NOTE: If spat are harvested for human consumption then the requirements in Standard 4.2.1 of the *Food Standards Code* and the requirements in this Manual relating to shellfish apply).

Translocation means the movement of shellfish from areas where harvest is not permitted (unclassified, nursery, prohibited or closed areas) into a classified shellfish harvest area.

Transshipment means the processing of transferring live shellfish between harvest areas.

Wet storage means the temporary storage of shellfish in containers or tanks containing natural or artificial seawater for purposes other than depuration (may include desanding).

Wildstock means shellfish that grow in natural conditions without the application of aquaculture practices and are commercially harvested as a wild resource.

Introduction

The Authority has prepared the NSW Shellfish Industry Manual (the Manual) to specify certain requirements of the Seafood safety scheme under the Food Regulation 2010 and Standard 4.2.1 of the *Food Standards Code*.

The requirements in this Manual apply to all seafood businesses licensed under the Seafood safety scheme of the Food Regulation 2010 for:

- the cultivating, harvesting or collecting of shellfish
- the depuration and wet storage of shellfish
- the cultivating of spat

The requirements detailed within this Manual must be complied with as a condition of licence.

The Manual will be published on the Authority's website at www.foodauthority.nsw.gov.au

Licence holders will be notified in writing of any subsequent changes to the requirements listed in this Manual.

Contact us by:

Phone 1300 552 406

Fax 02 9647 0026

Email contact@foodauthority.nsw.gov.au

Part 1 – Licensing requirements of the Seafood safety scheme

A seafood business must be licensed

- 1.1) A seafood business must be licensed under the Seafood safety scheme of the Food Regulation 2010 for:
- the cultivating, harvesting or collecting of shellfish;
 - the depuration and wet storage of shellfish;
 - the cultivating of spat.

Must comply with the Food Standards Code

- 1.2) A seafood business that engages in the primary production or processing of shellfish must comply with Standard 4.2.1 – Primary Production and Processing Standard for Seafood of the Australia New Zealand Food Standards Code (Food Standards Code).
NOTE: Standard 4.2.1 does not apply to cultivation of spat, as spat does not fall within the definition of shellfish.

Must implement a food safety management system

- 1.3) A seafood business that engages in the primary production or processing of shellfish is required by Standard 4.2.1 of the Food Standards Code to implement a documented food safety management system that effectively controls the hazards.

Editorial note:

'Hazard' is defined in Standard 3.1.1 of the *Food Standards Code* as a biological, chemical or physical agent in, or condition of, food that has the potential to cause an adverse health effect in humans.

- 1.4) All records associated with the implementation of the food safety management system must be kept for a minimum of two years
- 1.5) A seafood business is taken to comply with Standard 4.2.1 of the Food Standards Code if it implements:
- (a) a food safety program as set out in Standard 3.2.1 of the *Food Standards Code*; or
 - (b) a food safety management system as set out in the Commonwealth Export Control (Processed Food) Orders; or
 - (c) the Codex Alimentarius Hazard Analysis and Critical Control Point System (HACCP) for food safety management as set out in Annex C to CAC/RCP 1-1969, revision 4 (2003); or
 - (d) any other Hazard Analysis and Critical Control Point (HACCP) based food safety management system recognised by the NSW Food Authority.

- 1.6) For the purposes of complying with Standard 4.2.1 of the Food Standards Code, a seafood business must also comply with:
- (a) the conditions of the ASQAP (Australian Shellfish Quality Assurance Program) Manual specified in the Schedule to Standard 4.2.1 of the *Food Standards Code*; and
 - (b) conditions recognised by the NSW Food Authority, which are the requirements specified in this Manual.

Part 2 – Responsibilities of local shellfish committees

Appointment of a local shellfish committee

- 2.1) The Authority will appoint a local shellfish committee, in accordance with clause 129 of the Food Regulation 2010.
- 2.2) The appointed local committee is responsible for helping the Authority administer the local program, with responsibilities listed in clause 130 of the Food Regulation 2010.

Compliance with the harvest area management plan

- 2.3) For each individual harvest area in a local program where shellfish are harvested or collected, the Authority will establish a risk-based classification and a written harvest area management plan which will stipulate:
- (a) the boundaries of the harvest area;
 - (b) the environmental conditions that must be met for the harvest area to be in the open status so shellfish can be harvested, collected or depurated (eg rainfall and salinity criteria);
 - (c) the communication pathway used to advise changes in the status of the harvest area. The communication pathway must include all appropriate stakeholders, including the Authority, the local shellfish committee and the licence holders;
 - (d) the identification of sites for the sampling of the environment in which the shellfish are harvested or collected (eg shellfish, water and biotoxin test sites);
 - (e) the pollution sources that may adversely affect the environment in which the shellfish are harvested or collected;
 - (f) a sampling plan specifying the frequency of shellfish and water sampling for microbiological indicators, phytoplankton, marine biotoxins and heavy metals;
 - (g) that all samples will be analysed at a laboratory facility approved by the National Association of Testing Authorities (NATA) or the Authority for the particular type of analysis to be undertaken.
- 2.4) The appointed local shellfish committee must ensure that a harvest area only remains in the open status when in compliance with the requirements of the applicable harvest area management plan.

Establish an effective communication pathway

- 2.5) The local shellfish committee must immediately activate the communication pathway to notify licence holders and the Authority that a harvest area has been placed in the closed status when:
- (a) required by the conditions stated in the harvest area management plan; or

- (b) limits established in the marine biotoxin management plan or *Food Standards Code* have been exceeded; or
 - (c) the Authority places a harvest area in the closed status due to a pollution event, algal bloom, illness event or any other conditions likely to affect food safety.
- 2.6) The local shellfish committee must not activate the communication pathway to notify licence holders that a harvest area has been placed in the open status until the Authority has instructed the local committee that it is safe to do so.

Compliance with environmental sampling requirements

- 2.7) The local shellfish committee, at the expense of the local program, must ensure it complies with the requirements for sampling and analysis as specified in Table 1 and by the harvest area management plan, and any additional sampling as notified by the Authority.
- 2.8) Where a harvest area is placed in the closed status due to the presence of marine biotoxins above the regulatory limits established in the marine biotoxin management plan or Standard 1.4.1 – Contaminants and Natural Toxicants of the Food Standards Code, the local shellfish committee must ensure that at least two samples of shellfish collected over a 14-day period demonstrate that the level of toxin does not exceed the relevant Maximum Level (ML) specified in the Food Standards Code.
- 2.9) The local shellfish committee must ensure that any person assigned responsibility for taking environmental samples for the purposes of complying with the harvest area management plan has undertaken training as required by the Authority.
- 2.10) In the event of a suspected or confirmed sewage contamination event, the local shellfish committee must:
- (a) immediately place the affected harvest area(s) in the closed status;
 - (b) inform all licence holders in the affected area;
 - (c) inform the Authority; and
 - (d) ensure that representative shellfish samples and water samples are collected immediately from as close to the spillage site as practical, or as directed by the Authority.
- 2.11) Failure by the local shellfish committee to ensure compliance with the requirements of the harvest area management plan may result in the Authority permanently placing the harvest area in the closed status or reclassifying the harvest area.

Table 1 – Environmental sampling requirements for shellfish harvest areas

Shellfish harvest area classified as Approved or Conditionally approved				
Product	What to test	Indicator	Standard	Frequency
Water	Water from designated test sites	Faecal coliforms	<u>Approved harvest area</u> : Not exceeding 14 cfu/100mL	As required by the harvest area management plan
Shellfish	Shellfish from designated test sites	<i>E. coli</i>	<u>Approved harvest area</u> : Not exceeding 2.3 cfu/g	As required by the harvest area management plan
Shellfish harvest area classified as Restricted or Conditionally restricted				
Product	What to test	Indicator	Standard	Frequency
Water	Water from designated test sites	Faecal coliforms	<u>Restricted harvest area</u> : Not exceeding 70 cfu/100mL	As required by the harvest area management plan
Shellfish	Shellfish from designated test sites	<i>E. coli</i>	<u>Restricted harvest area</u> : Not exceeding 10 cfu/g	As required by the harvest area management plan
All shellfish harvest areas				
Product	What to test	Indicator	Standard	Frequency
Water	Water from designated test sites	Phytoplankton	As per marine biotoxin management plan issued by the Authority	As required by the harvest area management plan
Shellfish	Shellfish from designated test sites	Marine biotoxins	As per Standard 1.4.1 of the <i>Food Standards Code</i>	As required by the harvest area management plan
Shellfish	Shellfish from designated test sites	Heavy metals	As per Standard 1.4.1 of the <i>Food Standards Code</i>	Once every 3 years, or as notified by the Authority

Part 3 – Requirements for cultivating and harvesting of spat and shellfish

General requirements

- 3.1) A seafood business must not harvest (includes collecting) shellfish in an area if it is known, or ought reasonably be known at the time, that the shellfish, if harvested in the area, may not be safe or suitable when sold for human consumption.
- 3.2) A seafood business must not cultivate spat, or cultivate, harvest or collect shellfish from an area designated by the Authority as a closed safety zone.
- 3.3) A seafood business harvesting shellfish must only operate in accordance with the conditions established in the applicable harvest area management plan and marine biotoxin management plan which have been authorised by the Authority.
- 3.4) A seafood business harvesting shellfish must comply with any change in status of the harvest area, regardless of whether that change in harvest area status has been implemented by the Authority or the local shellfish committee.
- 3.5) A seafood business must not harvest shellfish from any area placed in the closed status by the Authority or the local shellfish committee.

Requirements for direct harvest of shellfish (without depuration)

- 3.6) A seafood business harvesting shellfish for direct harvest must comply with Standard 4.2.1 of the Food Standards Code, such that shellfish for human consumption must only be harvested from an area that:
 - (a) has been classified by the Authority as:
 - i. Approved; or
 - ii. Conditionally approved; or
 - iii. Approved as remote; or
 - iv. Offshore; and
 - (b) is subject to a marine biotoxin management plan; and
 - (c) has an open status; or
 - (d) is undergoing classification and is approved by the Authority subject to conditions specified by the Authority in the harvest area management plan.

Requirements for harvesting for depuration or relaying

- 3.7) A seafood business harvesting shellfish for depuration or relaying must comply with Standard 4.2.1 of the Food Standards Code, such that shellfish for human consumption must only be harvested from an area that:
 - (a) has been classified by the Authority as:
 - i. Approved; or
 - ii. Conditionally approved; or
 - iii. Approved as remote; or
 - iv. Restricted; or
 - v. Conditionally restricted; and
 - (b) is subject to a marine biotoxin management plan; and
 - (c) has an open status for the purposes of depuration or relaying; or
 - (d) is undergoing classification and is approved by the Authority subject to

conditions specified by the Authority in the harvest area management plan.

Identification and traceability of harvested shellfish

- 3.8) A seafood business harvesting shellfish must have a system to enable the traceback of a harvested batch of shellfish to a date, time and location of harvest, such that:
- (a) Each batch of shellfish must be tagged or labelled at the time of harvest with a durable, legible and waterproof harvest label, which clearly identifies the following information:
 - i the date and time of harvest; and
 - ii the name of the harvest area from which the shellfish were harvested.

Records of shellfish harvest

- 3.9) For the purposes of complying with Clause 123 of the Food Regulation 2010, a seafood business harvesting shellfish must complete the required records of the harvest operations as soon as practicable (but within 24 hours) for each occasion in which shellfish are harvested:
- (a) the date and time of harvest;
 - (b) the name of the harvest area from which the shellfish were harvested;
 - (c) the business name and address of the grower/harvester/collector;
 - (d) the species of shellfish and quantity of each species harvested;
 - (e) a seafood business harvesting oysters must allocate and record a unique Product Record (PR) number to each batch, in accordance with the Harvested Product Record Book issued by the Authority;
 - (f) a seafood business harvesting shellfish other than oysters, must use a documented system that allocates a unique batch number for each batch.
- 3.10) The Harvested Product Record Book and food safety management system records must be available for audit by the Authority at all times.

Part 4 – Relay and translocation operations

- 4.1) Transhipment of shellfish by relay or translocation may only occur in accordance with Table 2.

Table 2 – Permitted transhipment of shellfish – relay and translocation

Relay of shellfish		
Permitted from:	Permitted to:	Minimum time before harvest
Approved or Conditionally approved harvest area in closed status, but must meet criteria for a Restricted area	Approved or Conditionally approved area	Shellfish must remain in destination harvest area for 14 consecutive days in the open status prior to harvest for human consumption ¹
Restricted or Conditionally restricted harvest area (in open status)		
Translocation of shellfish		
Permitted from:	Permitted to:	Minimum time before harvest
Any growing area (but not from a closed safety zone)	Any Approved, Conditionally approved, Restricted, Conditionally restricted, Remote or Offshore shellfish harvest areas	Shellfish must remain in destination harvest area for 60 days prior to harvest for human consumption

Relay operations

- 4.2) Relayed shellfish must be identified and kept separate from other shellfish already located in the destination harvest area.
- 4.3) The Authority may establish critical values for water temperature, salinity and any other environmental variables which may affect the natural treatment process in the area to which shellfish will be relayed. The harvest area to be used for the treatment process must be monitored with sufficient frequency to identify when limiting critical values might be approached.

Records of relay operations

- 4.4) For the purposes of complying with Clause 123 of the Food Regulation 2010, a seafood business undertaking relay of shellfish must keep adequate records of relay operations. This includes the completion of a Stock movement diary (or a method of record-keeping deemed equivalent by the Authority) which maintains the following information in an up-to-date fashion:
- The name of the harvest area from which the shellfish were relayed;
 - The date and time at which the shellfish were relayed from the harvest area;
 - The name of the harvest area to which the shellfish were relayed;
 - The date and time at which the shellfish were relayed to the harvest area;

¹ Shellfish can also be relayed between harvest areas with the same classification (in the open status) with no minimum time before they can be harvested, provided the business has a system for tracing the product to the original harvest area.

- (e) The species of shellfish relayed and the quantity of each species relayed.

Translocation operations

- 4.5) Translocated shellfish for growing on must not be comingled and must be identified and kept separate from other shellfish in the destination harvest area.
- 4.6) The Authority may implement additional requirements on translocation movements from specific growing 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.

Records of translocation operations

- 4.7) For the purposes of complying with Clause 123 of the Food Regulation 2010, a seafood business undertaking translocation of shellfish must keep adequate records of translocation operations which maintains the following information in an up-to-date fashion:
 - (a) the name of the area from which the shellfish were translocated;
 - (b) the date on which the shellfish were translocated from the area;
 - (c) the name of the harvest area to which the shellfish were translocated;
 - (d) the date on which the shellfish were translocated to the harvest area;
 - (e) the species of shellfish translocated and the quantity of each species translocated.
- 4.8) Records must be sufficient to allow the translocated shellfish to be identified in the destination harvest area by an independent auditor.

Part 5 – Post harvest temporary wet storage and depuration

Wet storage of shellfish

- 5.1) A seafood business using temporary wet storage must comply with Standard 4.2.1 of the Food Standards Code, such that the water used must be sourced from an area that:
- (a) has been classified by the Authority as:
 - i. Approved; or
 - ii. Conditionally approved; or
 - iii. Approved as remote; or
 - iv. Offshore; and
 - (b) is subject to a marine biotoxin management plan; and
 - (c) has an open status; or
 - (d) is of a suitable quality that will not adversely affect the safety and suitability of the shellfish; and
 - (e) is effectively disinfected or maintained during the course of the wet storage in such a way that it continues to satisfy the conditions specified in (a).
- 5.2) While awaiting placement in a wet storage operation, shellfish must be protected from physical, chemical or thermal conditions that may compromise the shellstock's survival, quality or survival during wet storage.

Records of wet storage

- 5.3) For the purposes of complying with Clause 123 of the Food Regulation 2010, a seafood business using temporary wet storage must keep complete and accurate records to enable a batch of shellfish to be traced back to the wet storage location, including:
- (a) the date and time at which wet storage commenced;
 - (b) the date and time at which wet storage ended;
 - (c) if the wet storage was carried out for the business by another food businesses, the licence number issued to the other business by the Authority;
 - (d) the name of the operator of the wet storage facility;
 - (e) the source water used for the wet storage.
- 5.4) Records must include details of the source of the shellfish and include the product record (PR) number or batch number of the shellfish, as appropriate.

Depuration of shellfish

- 5.5) Where shellfish are harvested from a Restricted or a Conditionally restricted harvest area and require depuration, the depuration must be carried out in compliance with the following conditions:
- (a) shellfish must be depurated for at least 36 hours and the method of disinfection used for depuration must be capable of achieving a minimum of a 99.9% kill rate (3 log reduction) of *Escherichia coli*;
 - (b) the operator of a depuration plant must be trained to a level of expertise considered adequate by the Authority;
 - (c) the water flow must be uniform across the width of the depuration tank;

- (d) where ultra-violet disinfection lamps are used to treat the water they must:
 - i. disinfect continuously during the depuration process;
 - ii. be capable of being easily serviced and replaced when its intensity (measured at 254 nm at 1 m) is below 80% of its original intensity as stated by the manufacturer;
 - (e) where ozone water disinfection units are used:
 - i. the concentration of ozone oxidants at the outlet of the contact chamber should be not more than 0.4 ppm and at the point of entering the tank must be no more than 0.1 ppm;
 - (f) each depuration unit must be operated in compliance with its depuration plant specification approved by the Authority, and the loading capacity of the unit must not be exceeded;
 - (g) shellfish must not be placed into baskets or fish boxes in a depuration plant with more than three shellfish on top of each other;
 - (h) shellfish must be evenly distributed throughout the tank or tray of the plant and not be subjected to undue water turbulence from aeration or circulation systems;
 - (i) no more than two layers of baskets of shellfish are to be stacked on top of each other within individual tanks, and these must be separated to prevent fouling of the lower layer (eg by corrugated sheeting overlapped in the direction of the water flow). A baffle must be used when two layers of baskets of shellfish are stacked on top of each other to ensure the water flow in the tank is even throughout its depth and width;
 - (j) the tops of the containers holding the shellfish should be at least 25mm under the water;
 - (k) all shellfish must be at least 25 mm above the base of the tank or corrugated sheeting during depuration to avoid contamination from the shellfish faeces.
- 5.6) Depuration plants must not be used for any purpose other than depuration, without the approval of the Authority.

Records of depuration

- 5.7) For the purposes of complying with Clause 123 of the Food Regulation 2010, a seafood business using depuration must keep complete and accurate records which maintain the following information in an up-to-date fashion:
- (a) the date and time at which depuration commenced;
 - (b) the date and time at which depuration ended;
 - (c) particulars that identify the depuration unit used for the depuration;
 - (d) the name of the operator of the depuration facility;
 - (e) the source of the water used for the depuration;
 - (f) a unique identifier of the batch of shellfish (eg PR number for oysters).
- 5.8) The following records and documents must be kept at the depuration plant site:
- (a) current Harvested Product Record Book for harvested shellfish;
 - (b) the food safety management system of the business;
 - (c) the depuration unit's approved specifications;
- 5.9) Each section of the Harvested Product Record Book must be completed at the time of each depuration activity by the operator.

Water quality for wet storage and depuration

- 5.10) Water used in wet storage and depuration tanks must not adversely affect the safety and suitability of the stored shellfish and must meet the criteria specified in Table 4 (see Part 6 of this Manual).
- 5.11) Water used for wet storage and depuration must be effectively disinfected or maintained during the course of the wet storage in such a way that it continues to meet the criteria specified in Table 4.
- 5.12) When a water source classified as other than Approved is used, a study must be performed by the business to demonstrate that the disinfection system will consistently produce water that tests negative for Coliforms in 100 mL under normal operating conditions.
- 5.13) For wet storage facilities that use a recirculating water system, a study must be undertaken by the business to demonstrate that the disinfection system will consistently produce water that tests negative for Coliforms in 100 mL under normal operating conditions.
- 5.14) Disinfection units for the water supply must be cleaned and maintained in accordance with manufacturer's instructions and as necessary to ensure effective water treatment.
- 5.15) Water used for depuration must be free from any contamination. The water must meet the microbiological criteria for a Restricted harvest area and be from a source area in the open status. The depuration plant water must be filled via the operating disinfection unit.
- 5.16) Containers or tanks used for carting water to the depuration plant must not be used for any other purpose which may result in contamination of the shellfish.
- 5.17) The water must be fully replaced between depuration batches.
- 5.18) Water temperature may need to be adjusted for optimal depuration and to reduce spawning and stress in the shellfish. Shellfish must be depurated at a temperature above 14°C.
- 5.19) Shellfish must not be depurated when the salinity of the depuration water, without added salt, is below 18 parts per thousand. The salinity of the water in the depuration tank may be raised by no more than 20% of the initial value by the addition of unrefined sea salt. (NOTE: Depuration salinities below harvest salinities may induce spawning: the best salinity is about 25 to 35 ppt).
- 5.20) A suitable hydrometer and thermometer must be used to measure temperature and specific gravity at the beginning and end of the depuration cycle, or when any change is made to the system throughout the cycle.
- 5.21) Water circulation and disinfection must continue for the entire depuration period.
- 5.22) The rate of water circulation must be not less than twice the total water volume of the depuration plant per hour.

Handling of shellfish for wet storage and depuration

- 5.23) Shellfish must be washed in accordance with the requirements of Clauses 7.5 and 7.6 of this Manual, and dead and damaged shellfish must be removed prior to wet storage or depuration.
- 5.24) If more than one batch of shellfish is being held in wet storage at the same time, the identity of each harvest area batch must be maintained.
- 5.25) Shellfish must not be mixed with other species in the same tank. Where multiple tank systems use a common water supply for shellfish and other species, the wet storage water must be effectively disinfected prior to entering the tanks containing the shellfish.

Handling shellfish before depuration

- 5.26) Shellfish for depuration must be harvested in accordance with the conditions of licence and requirements of the harvest area management plan.
- 5.27) Shellfish for depuration must be protected from extremes of temperature during transport and storage, and be transported and stored in accordance with the food safety management system of the business.
- 5.28) Shellfish must be in good health and not be stressed in any way which is likely to prevent them from functioning at their optimum capacity during depuration.
- 5.29) Shellfish must be cleaned to ensure maximum removal of mud and other debris without damage to the shell margin.
- 5.30) Pacific oysters which are gaping must be returned to the harvest area for at least 48 hours before depuration.
- 5.31) Depuration must be commenced:
 - (a) for Sydney rock oysters (*Saccostrea glomerata*), within seven days of being harvested.
 - (b) for Pacific oysters (*Crassostrea gigas*) and Flat oysters (*Ostrea angasi*), within two days of being harvested.
- 5.32) Undepurated and depurated shellfish must be kept separated in accordance with the food safety management system of the business.

Handling shellfish after depuration

- 5.33) Any foam or scum which may have accumulated on the water surface must be removed prior to draining the water.
- 5.34) The water in the depuration tank must be drained below the level of the shellfish before the shellfish are removed from the tank.
- 5.35) Containers used for holding depurated shellfish must be clean.
- 5.36) Depurated shellfish must be stored in a cool, dry area off the ground and in accordance with the business' food safety management system.
- 5.37) All equipment used for transporting and handling undepurated shellfish should be thoroughly cleaned before being used for transporting or handling depurated shellfish.

Breakdown of services

- 5.38) If there is a breakdown of services due to equipment failure or interruption of electrical supply of less than 6 hours duration, the period of depuration must be made up to the required 36 hour period following resumption of normal services. If a breakdown of services of more than six hours occurs, depuration of the shellfish must recommence from the beginning for the full 36 hours, or the shellfish must be returned to the harvest area.
- 5.39) Shellfish must be closely inspected for signs of gaping or weakness if the water circulation has failed for any period, and those found to be dead or dying must be removed and not sold for human consumption.
- 5.40) The nature and duration of the breakdown must be recorded in the Harvested Product Record Book.

Servicing equipment

- 5.41) Once shellfish have been removed, the tanks, trays, baskets and filters must be thoroughly cleaned prior to further use.
- 5.42) The tanks, containers used for carting water, water disinfection unit, pump, filter baskets, corrugated sheeting, conduits, baffles and associated plumbing must be cleaned in accordance with the food safety management system of the business. After cleaning, all items must be thoroughly rinsed with clean water.

Part 6 – Sampling and analyses

- 6.1) For the purposes of complying with Clause 121 of the Food Regulation 2010, a seafood business collecting or harvesting shellfish must comply with the sampling and analyses provisions outlined in Table 3 and Table 4.
- 6.2) The holder of a licence must ensure that every analysis is carried out in a laboratory approved by the National Association of Testing Authorities (NATA), or by the Authority, for the particular type of analysis to be undertaken.
- 6.3) A seafood business must notify the Authority when the analysis of a sample does not meet the standard specified in Table 3 or Table 4, orally within 24 hours and in writing within 7 days.

Table 3 - Analysis of harvested or collected shellfish

Product	What to test	Indicator	Standard	Frequency
Shellfish	Depurated shellfish from each depuration unit	<i>E. coli</i>	Not exceeding 2.3 cfu/g	Once each calendar month (for each month that the depuration unit is used)
Wildstock shellfish	Collected shellfish	<i>E. coli</i>	Not exceeding 2.3 cfu/g	As notified by the Authority
Wildstock shellfish	Collected shellfish	Marine biotoxins	As per Standard 1.4.1 of the <i>Food Standards Code</i>	As notified by the Authority

Editorial note:

The Authority recommends that testing of depurated shellfish is undertaken on the first batch of shellfish depurated in each calendar month to ensure compliance and avoid missing tests through unexpected harvest area closures.

Table 4 – Analysis of water used for wet storage and depuration

Product	What to test	Indicator	Standard	Frequency
Water used for wet storage of shellfish				
Wet storage source water before disinfection	Water	Faecal coliforms	Not exceeding 70 cfu/100mL	Monthly
Disinfected water entering wet storage tanks	Water (sample to be taken from spray bar)	Faecal coliforms	Not detected in 100mL	Monthly
Wet storage source water without disinfection	Water (<u>permitted from Approved harvest areas only</u>)	Faecal coliforms	Not exceeding 14 cfu/100mL	As required by the harvest area management plan
Water used for depuration of shellfish				
Water sourced outside a classified harvest area	Water	Faecal coliforms	Not exceeding 70 cfu/100mL	Monthly
Water disinfected prior to depuration	Water	Salinity	Greater than 18 parts per thousand	Prior to commencement of each depuration cycle
Water disinfected prior to depuration	Water	Temperature	Greater than 14°C	Prior to commencement of each depuration cycle
Water disinfected prior to depuration	Water (sample to be taken from spray bar)	Faecal coliforms	Not detected in 100mL	May be required by the Authority under specific circumstances (eg as a follow up to a failed test of depurated shellfish)
Water disinfected prior to depuration	Water	Turbidity	Not exceeding 20 nephelometric turbidity units (NTUs) ²	May be required by the Authority under specific circumstances

² Measured in accordance with the Standard Methods for the Examination of Water and Wastewater, 17 ed., APHA et al., 1989.

Part 7 – Food safety practices and general requirements

Handling of shellfish

- 7.1) Shellfish must be protected from:
- (a) contamination; and
 - (b) extremes of temperature.
- 7.2) Shellfish that are harvested and transported on a vessel and/or vehicle for more than four hours must be stored in a way that prevents an unacceptable increase in temperature and will not make the shellfish unsafe or unsuitable. Methods for achieving this include keeping shellfish:
- (a) shaded from the sun;
 - (b) sprayed with potable water;
 - (c) sprayed with water of a microbiological standard which is equal to or better than the harvest area;
 - (d) chilled with ice made from potable water;
 - (e) covered with clean wet sacks.
- 7.3) Pacific oysters, flat oysters and all other shellfish must be placed under refrigeration at 10°C or less within 24 hours of being harvested or completion of depuration.
- 7.4) Sydney rock oysters must be placed under temperature control as follows:
- (a) at 25°C or less within 24 hours of harvest; and
 - (b) at 21°C or less within 72 hours of harvest; or
 - (c) if harvested for depuration, after depuration is completed.

Washing shellfish

- 7.5) Shellfish must be cleaned to ensure maximum removal of mud and other sediments and debris as soon after harvesting as practicable.
- 7.6) When washing shellfish, the water must be of a microbiological standard which is equal to or better than the standard of the harvest area.

Labelling of packed shellfish

- 7.7) For the purposes of complying with Clause 124 of the Food Regulation 2010, a seafood business must ensure that any packaging containing shellfish ready for sale (whether wholesale or retail sale) bears a label that includes the following:
- (a) the name and address of the seafood business authorised by the licence;
 - (b) a unique identifier of the batch of shellfish (eg Product Record number);
 - (c) the name of the harvest area from which the shellfish were harvested;
 - (d) the date of the harvest;
 - (e) the species and quantity of shellfish;
 - (f) a statement indicating the conditions under which the shellfish should be stored (eg 'Keep refrigerated' for Pacific oysters and Mussels);
 - (g) the country of origin (eg 'Product of Australia' but not required if the word 'Australia' is included in the address in (a)).

Part 8 – Premises and equipment

Vessels and vehicles

- 8.1) Vessels used to harvest or transport shellfish must be properly constructed, operated and maintained to prevent contamination, deterioration and decomposition of the shellfish.
- 8.2) Decks and storage bins must be constructed and located to prevent bilge water or polluted water from coming into contact with the shellfish.
- 8.3) Bilge pump discharges must be located so that the discharge does not contaminate shellfish.
- 8.4) Vessel decks and storage bins used in the harvest or transport of shellfish must be:
 - (a) kept clean with potable water; or
 - (b) kept clean with water of a microbiological standard which is equal to or better than the harvest area; and
 - (c) provided with effective drainage.
- 8.5) Bags or other containers used for storing shellfish must be clean and fabricated from safe materials.
- 8.6) When necessary, effective coverings must be provided on harvest vessels to protect shellfish from exposure to the sun, birds and other adverse conditions.
- 8.7) Cats, dogs and other animals must not be allowed on vessels or any part of a vehicle where shellfish are stored.
- 8.8) Human excreta must not be discharged overboard from a vessel used to harvest or transport shellfish.
- 8.9) Shellfish must be transported in adequately refrigerated vehicles when the shellfish 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.
- 8.10) When mechanical refrigeration units are used, the units must be:
 - (a) equipped with automatic controls; and
 - (b) capable of maintaining the ambient air temperature in the storage area at:
 - i temperatures of 10°C or less if transporting Pacific oysters, Flat oysters, mussels or other temperature sensitive species of shellfish; or
 - ii temperatures of 21°C or less if transporting Sydney rock oysters.
- 8.11) Any ice used to cool shellfish during transport must meet potable water standards.

Building requirements for wet storage and depuration premises

- 8.12) Premises used for the wet storage or depuration of shellfish must:
- (a) be of a construction that allows for easy cleaning of floors, walls and ceilings;
 - (b) have adequate artificial lighting with adequate covers to prevent food contamination in the case of breakage;
 - (c) have adequate ventilation to allow surfaces to dry;
 - (d) have accessible toilet and hand washing facilities;
 - (e) have a potable water supply;
 - (f) have adequate pest control measures to ensure that pests are not present in the building;
 - (g) have surrounding grounds that are free from conditions that would provide harbourage for pests or inadequate drainage;
 - (h) have adequate security to prevent unauthorised access while it is in operation;
 - (i) have areas for separating depurated and undepurated shellfish;
 - (j) have fittings and plumbing that are non-toxic and are maintained in a condition that will not contaminate the shellfish;
 - (k) have shellfish trays that are impervious, easily cleaned and designed to allow adequate flow through the mesh.

NSW Food Authority
6 Avenue of the Americas
Newington NSW 2127
PO Box 6682 Silverwater NSW 1811
Phone 1300 552 406
Fax 02 9647 0026
www.foodauthority.nsw.gov.au