



Regulated Control Scheme - Bivalve Molluscan Shellfish for Human Consumption

31 May 2022

TITLE

Animal Products Notice: Regulated Control Scheme - Bivalve Molluscan Shellfish for Human Consumption

COMMENCEMENT

This consolidated Animal Products Notice comes into force on 14 June 2022.

AMENDMENT AND CONSOLIDATION

This Animal Products Notice amends, and consolidates all amendments to, the Animal Products Notice: Regulated Control Scheme - Bivalve Molluscan Shellfish for Human Consumption made up to the commencement of this notice.

ISSUING AUTHORITY

This Animal Products Notice is issued by the Director-General under section 167(2) for the purposes of section 38(2)(a) of the Animal Products Act 1999.

Dated at Wellington this 31 day of May 2022.

[Signed]

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(acting under delegated authority of the Director-General)

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Introduction

This introduction is not part of the Animal Products Notice, but is intended to indicate its general effect.

Purpose

This Notice is issued for the purpose of specifying the requirements that must be met in relation to bivalve molluscan shellfish (BMS) harvested for human consumption.

This Notice supplements and gives effect to the general standards for bivalve molluscan shellfish in the Animal Products (Regulated Control Scheme – Bivalve Molluscan Shellfish) Regulations 2006.

Background

The stated purpose of the Animal Products (Regulated Control Scheme – Bivalve Molluscan Shellfish) Regulations 2006 is to identify, monitor, evaluate and manage the risks associated with the commercial growing, harvesting, sorting and transporting of bivalve molluscan shellfish for human consumption, and the risks associated with other related activities or conditions affecting the suitability for processing or fitness for intended purpose of bivalve molluscan shellfish.

Who should read this Animal Products Notice?

This Notice specifies the requirements that must be met by persons involved in, and for activities involving, bivalve molluscan shellfish (BMS) harvested for human consumption.

The following persons should read this Notice:

- a) persons with overall management or control of the growing of BMS for commercial purposes on marine farms or land-based farms or in the wild;
- b) persons with overall management or control of the harvesting of BMS for commercial purposes on marine farms or land-based farms or in the wild;
- c) laboratories, and persons in those laboratories, carrying out analysis of samples of BMS or associated things;
- d) persons who transport, sort or temporarily store BMS, prior to delivery to a primary processor;
- e) persons involved in undertaking specialist functions in relation to BMS under this scheme, such as samplers, recognised persons and animal product officers.

Why is this important?

BMS harvested under conditions that do not comply with this Notice could be ineligible for sale for human consumption, and may endanger human health if consumed. Growers, relay operators, harvest operators, sorting shed and depot operators, and transporters of BMS for human consumption are responsible for ensuring these requirements are met and that evidence of compliance is maintained.

For the purposes of section 135(1)(b) of the Animal Products Act 1999, a failure to comply with the following Animal Products (Regulated Control Scheme – Bivalve Molluscan Shellfish) Regulations 2006 is an offence:

- a) regulation 19 (obligations of growers);
- b) regulation 20 (obligation of harvest operators to register);
- c) regulation 21 (obligation of relay operators to hold a permit);
- d) regulation 22 (obligation of transport, sorting shed, and BMS depot operators to be listed);
- e) regulation 23 (duties of harvest operators);
- f) regulation 25(2) or 25(3) (harvesting from growing area in certain circumstances);
- g) any conditions imposed under regulation 38(3) or regulation 40 or regulation 46.

A person who commits an offence under the Act is liable to the penalty specified in section 135(3) of the Act.

This Notice elaborates on the requirements set out in the Regulations and therefore a breach of the specifications set out in this Notice may also be a breach of the Regulations.

Document History

No.	Version Date	Section Changed	Change(s) Description
1	31 May 2006		
2	2 August 2018	All	<ul style="list-style-type: none"> • New format and branding. • New “limited” classified areas introduced. • Yessotoxin deregulated. • New regulatory units for brevetoxins added. • New phytoplankton trigger levels added. • New species of phytoplankton added. • BMS sorting shed and depot requirements aligned. • Changes reflecting Animal Products Notice: Specifications for Laboratories. • Provision made for electronic harvest declarations. • Providing for courier transport of BMS. • Frequency of bacteriological testing in conditionally approved areas decreased. • More pollution source follow-up after illness outbreaks associated with growing areas required.
3	22 June 2021		<ul style="list-style-type: none"> • Remove Pectenotoxin as a regulated toxin, following a thorough assessment of its food safety risk. • Reinstate the previous laboratory methods clause that was omitted in the last amendment and list those methods that are approved by the Director-General. • Re-ordering clauses and wording changes for ease of use. • Changed the requirement for re-certification of samplers from 2 to 3 yearly.
4	9 July 2021		<ul style="list-style-type: none"> • Remove statement under background indicating the previous Notice was revoked and replaced.
5	31 May 2022	1.2, 5.3 Table 2, 6.2, 6.5, 6.7, 6.8, 7.2(1)(d), 8.7, 11.2(3) 11.9(1)(k), 12.3(2), 15.8(3) and Schedule 4.	<ul style="list-style-type: none"> • Amend Table 2 in relation to the strains and cell numbers of the phytoplankton <i>Pseudo-nitzschia</i> that can be present in seawater before testing BMS flesh for the biotoxin is carried out • Include risk management measures for <i>Vibrio parahaemolyticus</i> • Reduce frequency of harvest vessel verification • Include laboratory method for phytoplankton • Update average monthly maximum temperature statistics (Table S4B) in Schedule 4.

Other information

Bivalve molluscan shellfish for human consumption are also subject to other requirements, including the relevant requirements in the following legislation:

- a) Animal Products Notice: Production, Supply and Processing;
- b) Fisheries Act 1996;
- c) Food Act 2014;
- d) Health Act 1956.

Part 1: Requirements

1.1 Incorporation of material by reference

- (1) Under section 168 of the Animal products Act 1999, the following documents are incorporated into, and form part of, this Notice as standard works reference:
 - a) The current edition of Table 2.4 Pathogen or Disease-Specific Exclusion and Clearance Criteria for People at Increased Risk of Transmitting an Infection to Others, [Appendix 2 of the Ministry of Health Communicable Disease Control Manual](#).

1.2 Definitions

- (1) In this Notice, unless the context otherwise requires:

adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice

adverse pollution conditions, in relation to a growing area, means conditions caused by any meteorological, hydrological, salinity, tidal, turbidity, or seasonal condition, or by point source pollution or by some other event, that has historically resulted in elevated faecal coliform levels in seawater in the growing area, or in elevated *Escherichia coli* levels in BMS in the growing area

adverse pollution conditions strategy means a sampling strategy that targets adverse pollution conditions

annual classification review means the annual review required by clause 2.11

APO means an animal product officer

approved, in relation to a growing area, means a growing area that is classified under [Part 2 Classification of growing areas](#) as approved or remote approved (but does not include a conditionally approved area)

aquaculture means the cultivation of spat or BMS in a growing area

authority identifier means the current identification of any permit or registration under the Fisheries Act 1996, the Resource Management Act 1991, or any other Act, that relates to a growing area

background level means the concentration of a regulated substance, such as faecal coliforms, *Escherichia coli* or marine biotoxins, that provides a defensible reference point with which to evaluate the effect of a contamination event such as a marine biotoxin or catchment rainfall event

BMS container means any bag, sack, cage or other container that comes into direct contact with harvested BMS

BMS receiver means a person receiving BMS for retail, wholesale or processing

certified sampler means a sampler who holds a current certificate of competency issued under clause [14.4 sampler certification](#)

closed, in relation to a growing area, indicates that the status of the area is closed, which means that BMS must not be harvested from the area

conditional, in relation to a growing area, means a growing area that is classified under [Part 2](#) classification of growing area as **conditionally approved** or **conditionally restricted**

epidemiological association means a time, place or person associated with a BMS related illness outbreak based on a preliminary evaluation of data by an animal product officer prior to samples being taken for analysis (in accordance with the guidance provided in the current edition of "Procedures to

Investigate Foodborne Illness” published by the International Association of Milk, Food and Environmental Sanitarians, Inc)

GPS means the global positioning system, a system for determining position on the Earth’s surface

harvest criteria means the criteria set out in a conditional area management plan that determines whether a conditional growing area is to be open or closed

harvest declaration means the written declaration of the harvest details of the BMS, as required by clause [11.8 harvest declaration](#)

limited, in relation to a growing area, means a growing area that is classified under [Part 2 Classification of growing areas](#) as a limited growing area

lot, in relation to BMS, means a single type of bulk BMS harvested from a particular growing area during a single harvest duration of no more than 24 hours

marine biotoxin means any toxic substance produced by marine micro-organisms such as plankton and accumulated by BMS

MPI means the Ministry for Primary Industries

MPN means most probable number

non-point source means any source of pollution that is:

- a) not a point source; and
- b) diffused and dispersed such as:
 - i) agricultural farm runoff; or
 - ii) urban runoff or storm water; or
 - iii) sewage discharge from vessels; or
 - iv) dredging operations; or
 - v) silviculture practices

open, in relation to a growing area, indicates that the status of the area is open, which means that BMS may be harvested from the area in accordance with the area’s classification

pathogen means an organism such as a bacteria (e.g. *Salmonella* spp.), a virus (e.g. norovirus) or a parasite (e.g. *Giardia*, *Cryptosporidium*) that may cause disease in humans

point source, in relation to pollution, means a source of pollution that is discernible, confined and discrete, such as from a pipe, ditch, channel, tunnel or other conduit

primary sample station means a sample station used for the purposes of routine monitoring

prohibited zone means part of a growing area in which the commercial harvesting of BMS is prohibited, except as provided in [Part 3 Prohibited zones](#)

RCS means the regulated control scheme for BMS imposed by the Animal Products (Regulated Control Scheme – Bivalve Molluscan Shellfish) Regulations 2006, and includes the detailed specifications of that scheme as set out in this Notice

recognised laboratory means a laboratory that is recognised under section 101 of the Act

Regulations means the Animal Products (Regulated Control Scheme – Bivalve Molluscan Shellfish) Regulations 2006

remote approved, in relation to a growing area, means a growing area that is classified under [Part 2 Classification of growing areas](#) as remote approved

restricted, in relation to a growing area, means a growing area that is classified under [Part 2 Classification of growing areas](#) as restricted (but does not include a conditionally restricted area)

runoff means water that flows over the ground surface or through the ground directly or indirectly into drains, streams, rivers and lakes before reaching a coastal marine area

secondary sample station means a sample station used for the purposes of intensive monitoring

shellfish specialist means an APO who is designated by the Director-General as a shellfish specialist to provide specialist advice and direction on BMS matters relevant to the RCS

shoreline survey means a survey, by foot, vessel, aircraft, vehicle or other means, of the shoreline of a growing area catchment to determine and evaluate actual and potential pollution sources

spat means BMS that are within the minimum shell length for different types of shellfish as follows:

- a) dredge oyster (*Ostrea chilensis*) less than 40 mm in length;
- b) scallop (*Pecten novaezelandiae*) less than 50 mm in length;
- c) cockle (*Austrovenus stutchburyi*) less than 20 mm in length;
- d) Greenshell™ mussel (*Perna canaliculus*) less than 50 mm in length;
- e) blue mussel (*Mytilus galloprovincialis*) less than 30 mm in length;
- f) pacific oyster (*Crassostrea gigas*) less than 37 mm in length;
- g) geoduck (*Panopea zelandica*) less than 30 mm in length;
- h) other species at a length acceptable to a shellfish specialist

systematic random strategy means the systematic random sampling and date analysis strategy as set out in [Schedule 3 Systematic random sampling Strategy](#)

toxic substance means a compound that, if found in BMS in more than insignificant amounts, would render the BMS unfit for human consumption

transportation unit means a container, or part of a vessel or vehicle, in which BMS containers holding BMS are transported

V. parahaemolyticus *Vibrio parahaemolyticus*

Vp management plan means a plan, applied to a growing area, for limiting the likelihood that cases of vibriosis will result from the consumption of BMS harvested from that growing area, where the BMS is intended to be consumed raw (see clauses 6.7, 6.8, and 8.6(4))

vibriosis means a foodborne illness in humans caused by *V. parahaemolyticus*

- (2) Any term or expression that is defined in the Animal Products Act 1999, or Animal Products (Regulated Control Scheme – Bivalve Molluscan Shellfish) Regulations 2006, and used but not defined in this Notice, has the same meaning as in those Acts or Regulations.

1.3 Records

- (1) All records that a person is required under this Notice to make or keep must be:
 - a) kept (whether in hard copy or electronically) for at least 4 years or other period where provided for in this Notice; and
 - b) readily accessible and available for inspection by an animal product officer (APO), the Director-General, or any other person authorised (under the Act, the Regulations or this Notice) to have access to those records; and
 - c) retrievable within 2 working days.

Part 2: Classification of growing areas

2.1 Overview of classification system

- (1) Growing areas must be classified into one of the six classifications set out in clause 2.2.
- (2) Different rules apply to each classification, as set out in clauses 2.2, 2.6, 2.7, 2.8, 2.9 and 2.10.
- (3) The rules applying to unclassified areas are in clause 2.3.
- (4) Every listed classified growing area must be reviewed annually by an APO to check whether it has the right classification, and the classification may be reviewed at other times as set out in clause 2.12.

2.2 Classifications

- (1) Growing areas must be classified into one of the following classifications in Table 1:

Table 1: Growing area classifications

	Classification of growing area	Which commercial species of BMS may be harvested?	Do BMS require processing or relaying before human consumption?	Is a conditional area management plan required?
1	Remote approved	Any	No	No
2	Approved	Any	No	No
3	Conditionally approved	Any	No	Yes
4	Restricted	Any	Yes	No
5	Conditionally restricted	Any	Yes	Yes
6	Limited	Only those where the final product is the adductor muscle, roe, or adductor muscle and roe (such as scallops)	Yes	No

2.3 Unclassified areas

- (1) In unclassified areas:
 - a) the commercial harvest of BMS for human consumption is prohibited; but
 - b) BMS spat may be harvested from the area for the purpose of growing on for harvest for human consumption, but only if the growing on will be done in a classified growing area for a minimum of 6 months (or any shorter period determined by a shellfish specialist).
- (2) An area must be treated as unclassified if a sanitary survey:
 - a) has never been completed for it; or
 - b) has not been completed as required by clause 2.4.

2.4 Sanitary surveys

- (1) If a growing area is proposed to be classified, an APO must undertake an initial sanitary survey.
- (2) A sanitary survey of a classified growing area must be conducted by an APO at least every 12 years following the initial sanitary survey, unless the Director-General grants an extension (which may be of no more than 1 year).
- (3) Every sanitary survey must be done by an APO in accordance with [Schedule 1](#).

2.5 Plans required for classified areas

- (1) For each newly classified area and before harvest can occur, an APO must prepare:
 - a) a marine biotoxin management plan, in accordance with [Part 5 Marine biotoxin management](#); and
 - b) a harvest control plan, in accordance with [Part 6 Harvest control plans](#); and
 - c) if the area is classified as conditionally approved or conditionally restricted, a conditional area management plan, in accordance with [Part 4 Conditional area management plan](#).
- (2) Plans prepared for a growing area may be combined, provided that the combined plan contains all the information required of each separate plan.

2.6 Remote approved growing area

- (1) BMS may be commercially harvested for human consumption from a growing area classified as remote approved, unless the area is closed under [Part 7 Opening and closing growing areas](#).
- (2) A growing area may be classified as remote approved only if:
 - a) a sanitary survey finds:
 - i) there is no human habitation in the catchment of the growing area; and
 - ii) the growing area is not impacted by any actual or potential pollution sources; and
 - b) at each primary sample station:
 - i) the faecal coliform median most probable number (MPN) of the seawater samples does not exceed 14 per 100 ml, and not more than 10% of the samples exceed an MPN of 43 per 100 ml; and
 - ii) the *Escherichia coli* median MPN of the BMS samples does not exceed 230 per 100 grams and not more than 10% of the samples exceed an MPN of 700 per 100 grams.
- (3) For growing areas under the adverse pollution conditions strategy, in order to calculate the bacteriological standard described in clause 2.6 (2)(b), an APO must use no less than 15 of the most recent sample results from each of the primary sample stations.

2.7 Approved growing area

- (1) BMS may be commercially harvested for human consumption from a growing area classified as approved unless the area is closed under [Part 7 Opening and closing growing areas](#).
- (2) A growing area may be classified as approved only if:
 - a) a sanitary survey finds that the growing area:
 - i) is suitable for harvesting BMS for supply for human consumption without the need for relay, depuration or post-harvest treatment; and

- ii) is not subject to contamination from human or animal faecal matter at levels that, in the judgement of an APO, make the BMS unfit for human consumption; and
 - iii) is not contaminated with pathogenic organisms or toxic substances at levels unacceptable to a shellfish specialist; and
- b) the growing area is affected by non-point source pollution, it:
- i) is only impacted by randomly occurring, intermittent events; and
 - ii) is not impacted by discharges from sewage treatment facilities or combined sewerage overflows; and
- c) either:
- i) where the adverse pollution conditions strategy is used, at each primary sample station:
 - 1) the faecal coliform median MPN of the seawater samples does not exceed 14 per 100 ml, and not more than 10% of the samples exceed an MPN of 43 per 100 ml; and
 - 2) the *Escherichia coli* median MPN of the BMS samples does not exceed 230 per 100 grams and not more than 10% of the samples exceed an MPN of 700 per 100 grams; or
 - ii) where the systematic random sampling strategy is used, at each primary sample station:
 - 1) the faecal coliform median MPN of the seawater does not exceed 14 per 100 ml; and
 - 2) the estimated 90th percentile of the seawater does not exceed an MPN of 43 per 100 ml; and
 - 3) the *Escherichia coli* median MPN of the BMS does not exceed 230 per 100 grams; and
 - 4) the estimated 90th percentile of the BMS does not exceed an MPN of 700 per 100 grams.
- (3) For growing areas under the adverse pollution conditions strategy, in order to calculate the bacteriological standard described in clause 2.7 (2)(c)(i), an APO must use no less than 15 of the most recent sample results from each of the primary sample stations.
- (4) For growing areas under the systematic random sampling strategy, the 30 most recent randomly collected samples from each primary sample station must be used to calculate the median and 90th percentile to determine compliance with the standard described in clause 2.7 (2)(c)(ii).
- (5) Samples collected during a particular tidal stage must be used to classify the growing area, if that particular tidal stage increases:
- a) the faecal coliform concentration of the seawater in the growing area; or
 - b) the *Escherichia coli* level in the BMS.
- (6) If the growing area is affected by point source pollution only the adverse pollution conditions strategy can be used.

2.8 Restricted growing area

- (1) BMS may be commercially harvested for human consumption from a growing area classified as restricted only if:
- a) before being made available for human consumption, the BMS is subject to relaying, depuration or other post-harvest treatment; and
 - b) the area is not closed under [Part 7 Opening and closing growing areas](#).
- (2) A growing area must be classified as restricted if:

- a) there is a limited degree of pollution in the growing area, but a sanitary survey finds that the levels of contamination are such that BMS harvested from the area may be made fit for human consumption by:
 - i) relaying; or
 - ii) depuration; or
 - iii) other post-harvest treatment; and
 - b) either:
 - i) where the adverse pollution conditions strategy is used, at each primary sample station:
 - 1) the faecal coliform median MPN of the seawater samples does not exceed 88 per 100 ml and not more than 10% of the samples exceed 260 per 100 ml; and
 - 2) the *Escherichia coli* median MPN for BMS does not exceed 4,600 per 100 grams and not more than 10% exceed 14,100 per 100 grams; or
 - ii) where the systematic random sampling strategy is used, at each primary sample station:
 - 1) the faecal coliform median MPN of the seawater does not exceed 88 per 100 ml; and
 - 2) the estimated 90th percentile of the seawater does not exceed an MPN of 260 per 100 ml; and
 - 3) the *Escherichia coli* median MPN of the BMS does not exceed 4,600 per 100 grams; and
 - 4) the estimated 90th percentile of the BMS does not exceed an MPN of 14,100 per 100 grams.
- (3) However, if the limited pollution is non-point source but arises from discharges from sewage treatment facilities or combined sewerage overflows, the area may be classified as restricted only if the BMS is subject to relay or other processing (and not merely to depuration).
- (4) For growing areas under the adverse pollution conditions strategy, in order to calculate the bacteriological standard described in clause 2.8 (2) b) i), an APO must use no less than 15 of the most recent sample results from each of the primary sample stations.
- (5) For growing areas under the systematic random sampling strategy, the 30 most recent randomly collected samples from each primary sample station must be used to calculate the median and 90th percentile to determine compliance with the standard described in clause 2.8 (2) b) ii).
- (6) Samples collected during a particular tidal stage must be used to classify the growing area, if that particular tidal stage increases:
 - a) the faecal coliform concentration of the seawater in the growing area; or
 - b) the *Escherichia coli* level in the BMS.
- (7) If the growing area is affected by point source pollution only the adverse pollution conditions strategy can be used.

2.9 Conditionally approved and conditionally restricted growing areas

- (1) BMS may be commercially harvested from a growing area for human consumption that is classified as conditionally approved or conditionally restricted:
 - a) only in accordance with the conditional area management plan and the marine biotoxin management plan for the area; and
 - b) if the area is not closed under [Part 7 Opening and closing growing areas](#).
- (2) A growing area may only be classified as conditionally approved or conditionally restricted if:

- a) a sanitary survey finds that the growing area meets the criteria for classification as approved or restricted (as appropriate) for a reasonable period; and
- b) the factors determining that period are known, predictable and not so complex as to prevent a reasonable management approach.

2.10 Limited growing area

- (1) The only BMS that may be commercially harvested for human consumption from a growing area classified as limited is BMS where the final product is the:
 - a) adductor muscle; or
 - b) roe; or
 - c) adductor muscle and roe (e.g. scallops).
- (2) That kind of BMS may be commercially harvested from a growing area classified as limited unless the area is closed under [Part 7 Opening and closing growing areas](#).
- (3) A growing area may only be classified as limited if a sanitary survey of the area finds that the only BMS that should be harvested for human consumption are those identified in clause 2.10 (1).

2.11 Annual classification review of growing areas

- (1) On an annual basis, and within 60 working days of the anniversary of the date of the current sanitary survey, an APO must review and report on each growing area to reflect any changes in the growing area catchment.
- (2) The annual classification review involves all of the following (where applicable):
 - a) a field observation and evaluation of the pollution sources identified in the sanitary survey and their performance standards, if any. This may include:
 - i) a drive through survey; or
 - ii) observations made during sampling; or
 - iii) information from other sources; or
 - iv) in the case of sources previously implicated in illness outbreaks, a thorough re-evaluation;
 - b) identification of any new pollution sources and evaluating their effect on the growing area;
 - c) an evaluation of the seawater and BMS in the growing area with respect to the bacteriological standards for its classification;
 - d) reviewing the sampling activity, including laboratory notifications given to the APO under clause [15.3 \(2\)](#) and any resulting actions taken under clause [15.3 \(4\)](#);
 - e) summarising any heavy metal analyses and toxic substance assessments performed under clause [8.9](#);
 - f) reviewing the adverse pollution conditions identified in the sanitary survey or subsequent annual reviews;
 - g) reporting on all relevant actions taken by the APO in the past year, including any:
 - i) adjustment of harvest criteria; or
 - ii) reclassification; or
 - iii) additional seawater or BMS sampling; or
 - iv) hydrographic studies; or
 - v) emergency closures; or
 - vi) other work done by the APO to update the information in the sanitary survey for the area.
- (3) The annual classification review report must include:
 - a) a determination of whether the existing classification and, if applicable, the harvest criteria, are correct or should be changed; and

- b) the annual reviews of the marine biotoxin management plan, the harvest control plan, and the conditional area management plan (if any); and
 - c) any reports under clause 7.4 following a closure for an emergency situation; and
 - d) any other relevant written findings, evaluations and recommendations; and
 - e) the rationale for any decisions made to extend or split the growing area.
- (4) The annual classification review report must show a completion date.

2.12 When growing area classification to be reviewed

- (1) In addition to the annual classification review under clause 2.11, an APO must review and report on the classification of a growing area if:
- a) the area has been closed following an outbreak of illness caused by something in the growing area other than naturally occurring pathogens or biotoxins; or
 - b) BMS from the area are implicated in an epidemiologically confirmed foodborne illness outbreak; or
 - c) the area is determined by an APO to be the source of a human pathogen; or
 - d) human pathogens or chemical contaminants are detected in BMS and an APO determines, following an investigation under [Part 8](#), that the growing area is or is likely to be the source of the pathogens or chemical contaminants; or
 - e) the area is found to no longer comply with the conditions of its classification.
- (2) Any review of classification under this clause must include:
- a) a review of the growing area classification file records, including at least the last 3 years seawater and shellfish bacteriological results; and
 - b) a field review of all existing or new pollution sources; and
 - c) a review of actual and potential intermittent pollution sources, such as vessel waste discharge and wastewater discharge from treatment plant collection systems; and
 - d) a review of any related seawater and shellfish results.
- (3) Following a review under this clause, an APO may:
- a) retain or change the existing classification; and
 - b) make any changes necessary to the:
 - i) marine biotoxin management plan; and
 - ii) harvest control plan; and
 - iii) conditional area management plan (if any).

2.13 Upward revision of classification

- (1) Any revision of a growing area classification to a less restrictive classification must be supported by a sanitary survey, which may be done by way of updating the most recent sanitary survey of the area.

2.14 Extension of growing areas

- (1) If a new area is proposed to be added to an existing classified growing area, an APO must assess any pollution sources that may affect the new area and determine the need for:
- a) further sample stations; and
 - b) parallel sampling in both the new area and existing growing area.

Part 3: Prohibited zones

3.1 Identifying parts of growing areas as prohibited zones

- (1) Any part of a growing area may be declared by an APO to be:
 - a) an ongoing prohibited zone; or
 - b) a temporary prohibited zone.
- (2) The purpose of a prohibited zone is to prevent contaminated, or possibly contaminated, BMS from being harvested from a part of a growing area, while allowing the rest of the growing area to be harvested according to its classification.

3.2 Effect of prohibited zones

- (1) In a prohibited zone:
 - a) the commercial harvest of BMS for human consumption is prohibited; but
 - b) BMS spat may be harvested from the area for the purpose of growing on for harvest for human consumption, but only if the growing on will be done in a classified growing area for a minimum of 6 months.
- (2) Despite clause 3.2 (1) a shellfish specialist may:
 - a) authorise harvest from a prohibited zone for the purpose of processing or relay; and
 - b) impose conditions on any harvest.
- (3) An APO must ensure that every prohibited zone is identified on a map that forms part of the sanitary survey or any plan relating to the growing area.

3.3 Ongoing prohibited zones

- (1) Any part of a growing area must be declared to be an ongoing prohibited zone if a sanitary survey indicates that:
 - a) that part is adjacent to a sewage treatment plant outfall or other point source outfall of public health significance; or
 - b) there are pollution sources contaminating that part that are unpredictable; or
 - c) that part is contaminated with levels of human or animal faecal waste that are unacceptable to a shellfish specialist; or
 - d) that part is contaminated with toxic substances causing levels of contamination in BMS that are unacceptable to a shellfish specialist.
- (2) An ongoing prohibited zone may be declared without the need for a sanitary survey if a shellfish specialist determines that the area:
 - a) has been declared to be a temporary prohibited zone; and
 - b) is unlikely, before the next sanitary survey of the area, to be safe for the commercial harvest of any BMS for human consumption.

3.4 Temporary prohibited zones

- (1) An APO may declare part of a growing area to be a temporary prohibited zone if:
 - a) the growing area could be closed under clause [7.2](#); but
 - b) the APO is satisfied that:

- i) only part of the growing area is affected; and
 - ii) that area is able to be defined; and
 - iii) the risks associated with the reason for closure can be managed by declaring part of the growing area to be a prohibited zone instead of closing the whole area.
- (2) An APO must take all reasonable steps to immediately notify all interested persons when a part of an area is declared to be a prohibited zone, and must ensure that the boundaries of the zone are clearly identifiable.
- (3) An area ceases to be a temporary prohibited zone when:
 - a) a shellfish specialist determines that it should become an ongoing prohibited zone and the marine biotoxin and/or conditional management plan is amended to show it; or
 - b) the conditions in clause [7.3](#) are satisfied.

3.5 Size of prohibited zones for wastewater systems

- (1) A prohibited zone must be large enough to provide sufficient time for an APO to close any growing area around it before a discharge could travel beyond the prohibited zone.
- (2) For areas around major point source discharges, such as a sewage outfall, the minimum area of the prohibited zone is the area formed by a radius of 500 m around the outfall.
- (3) The criteria used to determine the size of a prohibited zone must include:
 - a) the volume, flow, rate, location of discharge, performance of the wastewater treatment plant and the microbiological quality of the effluent; and
 - b) the decay rate of the contaminants of public health significance in the wastewater discharged; and
 - c) the characteristics of the receiving water, including:
 - i) bathymetry; and
 - ii) current velocity; and
 - iii) net transport velocity; and
 - iv) water depth and volume; and
 - v) direction of flow; and
 - vi) water stratification; and
 - vii) tidal characteristics; and
 - viii) dilution rate; and
 - ix) likely dispersion; and
 - d) the wastewater's dispersion and dilution, and the time of waste transport to any area where BMS may be harvested; and
 - e) the location of the BMS resources, classification of adjacent waters and identifiable landmarks or boundaries.

Part 4: Conditional area management plan

4.1 Conditional growing areas to have conditional area management plan

- (1) Every conditional growing area must have a conditional area management plan prepared by an APO.
- (2) The conditional area management plan is for the purpose of determining when the conditional growing area will be open or closed for harvest under that plan but without limiting when it may be opened or closed for any other reason.

4.2 Content of conditional area management plan

- (1) Every conditional area management plan for a growing area must include all of the following:
 - a) harvest criteria, as described in clause 4.3;
 - b) an explanation of how the harvest criteria were determined;
 - c) a contingency plan for when critical measuring equipment, used to determine whether harvest criteria are met, is unable to accurately and reliably make the measurement;
 - d) calibration requirements for critical measuring equipment, in accordance with [Part 16](#);
 - e) identification of key personnel or positions with responsibilities under the plan;
 - f) a description of the annual bacteriological monitoring plan (as described in clause [8.2](#)) for seawater and BMS, including numbers and frequency;
 - g) the predicted number of times, based on historical findings, that identified pollution events are expected to occur in a calendar year;
 - h) procedures that the personnel or positions identified in paragraph e) must follow for notifying an APO immediately if the harvest criteria is exceeded;
 - i) a detailed description of how the closed status will be implemented, including:
 - i) a clear statement that as soon as the harvest criteria are exceeded, the growing area will be placed in the closed status; and
 - ii) the procedures and methods for the APO to receive notification, and for the APO to notify relevant growers and harvesters of the closure; and
 - iii) contingency arrangements for what happens at night, on weekends and in the absence of key personnel identified in the management plan; and
 - j) a statement of whether, if the area is in the closed status but meets the requirements for the restricted classification, BMS may be harvested for depuration, relaying, or post-harvest treatment.

4.3 Harvest criteria

- (1) Harvest criteria in the conditional area management plan for a growing area must identify the conditions under which an APO must open or close the area for the commercial harvest of BMS for human consumption.
- (2) The harvest criteria must identify:
 - a) the specific meteorologic, hydrologic, salinity or other events that trigger the area being closed; and
 - b) if there are seasonal events (such as boating, seasonal rainfall, or bird migration), the estimated duration of those events; and
 - c) the time necessary to reduce the faecal coliform levels in the growing area water, and the *Escherichia coli* levels in BMS, to background levels established by a sanitary survey after an area is closed.

- (3) Harvest criteria for growing areas affected by wastewater treatment plants must adequately address all of the following:
- a) the effects of peak effluent flow, average flow and infiltration flow; and
 - b) the bacteriological quality of the effluent; and
 - c) the physical and chemical quality of the effluent; and
 - d) the conditions which may cause plant failure; and
 - e) the plant or collection system bypasses including pumping station overflow storage areas; and
 - f) the effects of design, construction and maintenance procedures to minimise mechanical failure, or overloading; and
 - g) provisions for monitoring and inspecting the wastewater treatment plant.

4.4 Annual review of conditional area management plan

- (1) An APO must conduct an annual review of the conditional area management plan and include the report in the annual classification review report of the growing area described in clause [2.11](#).
- (2) The annual review must include:
- a) an evaluation of compliance with the plan; and
 - b) a determination of the adequacy of reporting of failure to meet performance standards; and
 - c) a review of the cooperation of the agencies and persons involved.

4.5 Consultation during preparation of conditional area management plan or review

- (1) During the preparation or review of a conditional area management plan, an APO must consult with:
- a) growers and harvesters, or representatives nominated by growers and harvesters, who operate or are likely to operate in the growing area; and
 - b) the individuals responsible for the operation of any wastewater treatment plants that impact the area; and
 - c) any other relevant agencies that may be involved in anything that affects or monitors seawater or BMS safety and wholesomeness in the growing area.
- (2) Consultation must include:
- a) an opportunity to comment in writing on a draft version of the plan; and
 - b) an opportunity, if requested, to meet and discuss the plan with the APO and other relevant parties; and
 - c) consideration by the APO of all comments and discussion; and
 - d) notification to relevant parties of the final version of the plan at least a week before it comes into effect.
- (3) An APO need not consult on a review of a conditional area management plan if there are no, or only minor, changes proposed.

Part 5: Marine biotoxin management

5.1 All growing areas to have marine biotoxin management plan

- (1) Every classified growing area must have a marine biotoxin management plan prepared by an APO.
- (2) The marine biotoxin management plan for a growing area must be prepared for the purpose of identifying the conditions when the area must be closed for biotoxin contamination, and when it may be reopened (but without limiting when it may be opened or closed for any other reason).

5.2 Content of marine biotoxin management plan

- (1) A marine biotoxin management plan must include all of the following:
 - a) a map of the growing area, showing the location and identification of each marine farm and wild BMS growing area, to which the plan applies; and
 - b) the boundary, name and number of the growing area; and
 - c) the species of commercial shellfish within the growing area; and
 - d) the location and GPS (or other identification acceptable to a shellfish specialist) of the primary and any secondary BMS and phytoplankton sample stations; and
 - e) relevant local, regional, and national agency and personnel contact details; and
 - f) the routine monitoring programme for BMS and phytoplankton; and
 - g) the increased sampling to be undertaken, in terms of sites, frequency and BMS species, when trigger levels of toxigenic phytoplankton in growing area seawater, or biotoxins above background levels in BMS, are detected; and
 - h) hydrographic details showing predominant currents and circulatory patterns which may affect the movement of phytoplankton in or adjacent to the growing area; and
 - i) the marine biotoxin test methods used for the respective biotoxin groups; and
 - j) management procedures in place for the use of screen test methods if confirmatory testing is required; and
 - k) management procedures that address the testing of BMS following toxigenic phytoplankton trigger levels being exceeded; and
 - l) procedures for notifying toxigenic phytoplankton and biotoxin results from the laboratory to APOs, growers, and harvesters operating in the growing area; and
 - m) procedures and draft letters for growing area closure and reopening; and
 - n) procedures for the recall and/or detention of BMS product resulting from a marine biotoxin closure; and
 - o) the procedure for opening seasonal growing areas, including scallop and dredge oyster fisheries, prior to the commencement of harvesting.

5.3 Marine biotoxin monitoring programme

- (1) The marine biotoxin monitoring programme that is part of the marine biotoxin management plan must set out the sample stations and frequencies for testing samples of:
 - a) BMS flesh, tested for the toxins listed in Table 3: Maximum permissible levels for marine biotoxins in BMS; and
 - b) seawater, tested for the toxigenic phytoplankton listed in Table 2: Toxigenic phytoplankton action levels in seawater (unless equivalent management procedures are considered acceptable to a shellfish specialist).
- (2) The location of sample stations must be based on all of the following considerations:

- a) the history of marine biotoxin and toxigenic phytoplankton activity in the growing area and adjacent coastal marine areas; and
- b) hydrographic effects such as retention zones, upwellings, inshore and offshore current flow patterns and tidal effects; and
- c) the accessibility of the sample station in all weather conditions when harvesting is likely to occur; and
- d) the need to locate the phytoplankton sample station as near as practicable to the BMS sample station; and
- e) the potential need to provide spatial and depth coverage for sampling of BMS and toxigenic phytoplankton.

Table 2: Toxigenic phytoplankton action levels in seawater

Phytoplankton species	Marine biotoxin group	Level in composite sample to trigger BMS flesh testing. ¹ Cells per litre (c/L)
<i>Alexandrium minutum</i>	PSP	100
<i>Alexandrium ostenfeldii</i>	PSP	100
<i>Alexandrium catenella</i>	PSP	100
<i>Alexandrium pacificum</i>	PSP	100
<i>Alexandrium tamarense</i>	PSP	100
<i>Gymnodinium catenatum</i>	PSP	100
² <i>Pseudo-nitzschia australis</i> ² <i>Pseudo-nitzschia pungens</i> ² <i>Pseudo-nitzschia multiseriata</i> ² <i>Pseudo-nitzschia multistriata</i>	ASP	100,000
² <i>Pseudo-nitzschia fraudulenta</i> ² <i>Pseudo-nitzschia delicatissima</i> ² <i>Pseudo-nitzschia pseudodelicatissima</i>	ASP	1,000,000
³ <i>Karenia brevis</i>	NSP	1,000
<i>Karenia brevisculata</i>	NSP	10,000
⁴ <i>Karenia/Karlodinium/Gymnodinium</i> Group	NSP	250,000
<i>Dinophysis acuta</i>	DSP	500
<i>Dinophysis acuminata</i>	DSP	1,000
<i>Prorocentrum lima</i>	DSP	500
Azadinium Group	AZP	30,000

¹ If the trigger level is exceeded, a BMS sample must be taken within 24 hours of notification of the trigger level and submitted for analysis for the relevant toxin.

² For *Pseudo-nitzschia* species, if the 100,000 c/L level is exceeded a DNA probe or BMS analysis for domoic acid must be performed.

BMS analysis for domoic acid must be performed if the combined percentage result from a DNA probe for the 4 most toxic species (*P. australis*, ²*P. multistriata*, *P. multiseriata* and *P. pungens*) exceeds 100,000 if applied to the original cell count (preserved seawater sample).

BMS analysis for domoic acid must be performed if the combined percentage result from a DNA probe for the 3 less toxic species exceeds 1,000,000 c/L if applied to the original cell count (preserved seawater sample).

If DNA probe speciation is not performed, the default trigger level of 100,000 c/L applies.

³ *Karenia brevis* has not been isolated in New Zealand to date.

⁴ The *Karenia*/*Karlodinium*/*Gymnodinium* group includes *Karenia bidigitata*, *Karenia mikimotoi*, *Karenia papilionacea*, *Karenia selliformis*, *Karlodinium micrum* and *Gymnodinium impudicum*.

Table 3: Maximum permissible levels for marine biotoxins in BMS

Toxin group	Amount that must not be exceeded in the edible portion
Paralytic Shellfish Poison (PSP)	0.8 mg saxitoxin dihydrochloride equivalent per kg
Amnesic Shellfish Poison (ASP)	20 mg domoic acid per kg
Neurotoxic Shellfish Poison (NSP)	0.8 mg brevetoxin-2 equivalent per kg
Diarrhetic Shellfish Poison (DSP)	0.16 mg of okadaic acid ¹ equivalent per kg
Azaspiracid Shellfish Poison (AZP)	0.16 mg of azaspiracid ² equivalent per kg

¹ Okadaic acid includes okadaic acid (OA), dinophysistoxins (DTX1 and DTX2). For okadaic acid and dinophysistoxins a hydrolysis step is required in order to detect the presence of esterified okadaic acid group toxins.

² Azaspiracid includes AZA1, AZA2 and AZA3.

5.4 Consultation during preparation of marine biotoxin management plan or review

- (1) An APO must consult with growers and harvesters, or representatives of growers or harvesters, who operate or are likely to operate in the growing area during:
 - a) the preparation of a marine biotoxin management plan; or
 - b) any review of a marine biotoxin management plan.
- (2) Consultation must include, at a minimum:
 - a) an opportunity to comment in writing on a draft version of the plan; and
 - b) an opportunity, if requested, to meet and discuss the plan with the APO and other relevant parties; and
 - c) consideration by the APO of all comments and discussion; and
 - d) notification to relevant parties of the final version of the plan at least a week before it comes into effect.
- (3) An APO need not consult on a review of a marine biotoxin management plan if there are no, or only minor, changes proposed.

5.5 Annual review of marine biotoxin management plan

- (1) An APO must conduct an annual review of the marine biotoxin management plan and include the report in the annual classification review report of the growing area under [clause 2.11](#).
- (2) The annual review of the marine biotoxin management plan must include the following matters:
 - a) the marine biotoxin monitoring programme that was in place at the start of the year under review; and
 - b) a discussion, rationale and results supporting any changes made to the marine biotoxin monitoring programme during the year; and
 - c) a summary of the toxigenic phytoplankton activity including trigger levels that have been exceeded and whether there was compliance with trigger level requirements; and
 - d) where applicable, discussion on results which suggest that amendments to the trigger levels or other aspects of the toxigenic phytoplankton action level table in Table 2 Toxigenic phytoplankton action levels in seawater are required; and
 - e) a summary of how the marine biotoxin monitoring programme was implemented and whether it was effective; and
 - f) a summary of timeliness and condition of samples on arrival at the laboratory; and
 - g) what increased sampling was undertaken in terms of sites, frequency and species; and
 - h) confirmation that the details in the marine biotoxin management plan are up to date.

5.6 Frequency of sample testing

- (1) The default testing programme for marine biotoxins in a growing area is for BMS flesh testing to be carried out weekly in accordance with [Part 14](#) for each biotoxin stated in Table 3 Maximum permissible levels for marine biotoxins in BMS, with no regular testing of seawater for toxigenic phytoplankton.
- (2) An APO may authorise a reduced programme of BMS flesh testing on the basis of a review of all BMS and toxigenic phytoplankton results for the growing area and surrounding areas from 1 January 1993 to the review date, including results from the marine biotoxin programme for non-commercial BMS.
- (3) Any reduced programme authorised under subclause (2) must comply with the following:
 - a) in every case, seawater from the growing area must be tested for the toxigenic phytoplankton listed in Table 2 Toxigenic phytoplankton action levels in seawater at least weekly; and
 - b) the BMS flesh testing programme must stand on its own, with toxigenic phytoplankton testing being a support system; and
 - c) if a toxin listed in Table 3 Maximum permissible levels for marine biotoxins in BMS has not been detected in BMS during the review period, then the toxin must be tested for at least monthly; and
 - d) if a toxin listed in Table 3 Maximum permissible levels for marine biotoxins in BMS has been detected in BMS below the maximum permissible level, then that toxin must be tested for at least every 14 days; and
 - e) if a toxin listed in Table 3 Maximum permissible levels for marine biotoxins in BMS has been detected in BMS at a level above the maximum permissible, then that toxin must be tested for at least weekly.
- (4) An APO may decrease the frequency of the testing authorised under clause 5.6 (2) for seasonality if, for the growing area and adjacent coastal marine areas, it is demonstrated that there are clear differences in marine biotoxin activity between the seasons.
- (5) The Director-General may authorise a further reduction in the frequency of testing required by this clause if he or she is satisfied that the risks will be adequately addressed if applying a reduced frequency of testing.

Part 6: Harvest control plans

6.1 All growing areas to have a harvest control plan

- (1) Every growing area must have a harvest control plan prepared by an APO.
- (2) The purpose of the harvest control plan for a growing area is to ensure that BMS are harvested:
 - a) only from growing areas that are open; and
 - b) in accordance with the requirements of the Regulations and the RCS.

6.2 Content of harvest control plan

- (1) Every harvest control plan must:
 - a) identify the growing area to which it applies; and
 - b) record the classification of the growing area; and
 - c) if the area is a conditional growing area, record the harvest criteria for the area; and
 - d) if the growing area is required to have a *Vp* management plan, include the *Vp* management plan; and
 - e) set out the written procedures describing the process for notifying harvest operators of the closure and opening of growing areas; and
 - f) record the names and addresses of all harvest operators operating in the area; and
 - g) record, if applicable, the name, position, or designation of the person or persons nominated by the harvest operator as responsible for the day-to-day management of the harvest operations; and
 - h) record the name or unique identifier of each vessel and vehicle used in the harvesting operation; and
 - i) include any written agreement with other agencies that are likely to be conducting harvest control activities that describes their respective responsibilities; and
 - j) record whether the growing area is used for wet storage or relaying and, if so, the procedures used to prevent relayed or wet stored BMS being mixed with resident BMS; and
 - k) identify the frequency and nature of surveillance in accordance with clause 6.3 for each growing area; and
 - l) provide that the majority of the growing area is subject to surveillance; and
 - m) identify the surveillance personnel involved; and
 - n) record surveillance personnel contact details for both work hours and after work hours; and
 - o) record the type and frequency of reporting by surveillance personnel; and
 - p) identify any surveillance problems; and
 - q) record the methods used to inform APOs and others carrying out surveillance of the classification of the growing area and its status; and
 - r) identify any persons, other than harvest control APOs (referred to in clause 6.6), who are entitled to perform surveillance activities in the area; and
 - s) identify surveillance activities for the transport route to get BMS from the source growing area to the place where it is taken for relay, depuration or post-harvest treatment; and
 - t) set out how the following are audited for compliance with the harvest control plan:
 - i) completing harvest documentation;
 - ii) labelling BMS;
 - iii) transporting BMS;
 - iv) wet storage activities;
 - v) relaying activities;
 - vi) sorting shed activities;
 - vii) BMS depot activities.

6.3 Surveillance requirements

- (1) Harvest control plans must require that surveillance is carried out on all growing areas that are closed or have a prohibited zone to ensure that BMS is not harvested from those areas.
- (2) Where surveillance is required, the harvest control plan must require surveillance of the area:
 - a) at least once in every 30 day period when the area is closed and/or has a prohibited zone; or
 - b) at a frequency authorised by a shellfish specialist in accordance with this clause.
- (3) Surveillance requirements in a harvest control plan must:
 - a) address the need for night, weekend and holiday surveillance; and
 - b) ensure that the majority of the growing area is subject to surveillance.
- (4) The frequency of surveillance specified in a harvest control plan may be increased by an APO if the APO has current evidence that illegal harvesting of BMS is occurring.
- (5) A shellfish specialist may authorise a harvest control plan to provide for less frequent surveillance if:
 - a) the growing area is geographically remote, sparsely populated or has limited access (because, for instance, it has no or very poor roads) such that the potential for harvesting and trading the BMS is severely restricted; and
 - b) the APO includes in the harvest control plan additional surveillance activities (such as at airports, wharves or with transporters) that are in lieu of traditional surveillance activities.
- (6) A shellfish specialist may authorise a harvest control plan to require surveillance at any appropriate interval if:
 - a) the growing area is closed to harvesting during traditional non-harvesting seasons; and
 - b) the APO includes in the harvest control plan additional surveillance activities (such as at airports, wharves or with transporters) that are in lieu of traditional surveillance activities.
- (7) For the purpose of calculating surveillance frequency:
 - a) no more than 2 surveillances can be counted in a 24 hour period and each must be a separate deliberate effort; and
 - b) if tidal, weather or other conditions prohibit harvesting on a particular day, that day is not included in the 30 day calculation.

6.4 When surveillance not required

- (1) Surveillance of a growing area is not required if:
 - a) there is no BMS production and the area has been depleted of BMS by harvesting, disease or other causes; or
 - b) harvest from the area is not economically feasible due to the cost of harvesting exceeding the market value of the product.

6.5 Review of harvest control plan

- (1) An APO must conduct an annual review of the harvest control plan (including any Vp management plan) and include the report in the annual classification review report of the growing area under [clause 2.11](#).
- (2) The review of the harvest control plan must include an annual surveillance report that:
 - a) includes details of the surveillance activities performed during the preceding year, including:
 - i) dates (e.g. week days and weekends); and
 - ii) personnel who carried out the surveillance; and

- iii) times (e.g. night surveillance); and
 - iv) the number of days the areas were closed; and
 - v) the number of days temporary or ongoing prohibited zones were in effect; and
 - vi) the activities stated in clause 6.2 (1)(s); and
- b) states whether the required frequency of surveillance was achieved; and
 - c) gives details of warnings issued; and
 - d) gives details of any activities referred for MPI investigation; and
 - e) gives details of any legal actions undertaken.
- (3) The review must update the details contained in the harvest control plan, and in particular the names and contact details of all people and organisations involved in the harvest that are identified in the plan.

6.6 Personnel involved in harvest control plan implementation

- (1) A shellfish specialist must train and certify certain APOs (known as **harvest control animal product officers**) in:
- a) harvest control plan design and implementation; and
 - b) growing area classification and harvest criteria; and
 - c) harvest control legislation.
- (2) Individuals who are not APOs may perform specified surveillance activities identified in a harvest control plan if they have undergone training acceptable to a shellfish specialist.

6.7 Consideration of *V. parahaemolyticus* risk

- (1) When a harvest control plan is developed the APO, assisted by a shellfish specialist, must consider the risk of cases of vibriosis occurring as a result of consuming BMS harvested from the growing area and intended to be consumed raw, on the basis of at least the following:
- a) the number of cases epidemiologically linked to consumption of BMS from the growing area:
 - b) any data on the levels and characteristics of *V. parahaemolyticus* in the growing area:
 - c) the water and air temperatures:
 - d) salinity:
 - e) harvesting and cooling practices:
 - f) the quantity and type of BMS harvested from that area.
- (2) The APO must require a *Vp* management plan to be prepared if the APO considers that it is likely that cases of vibriosis will occur as a result of consuming raw BMS harvested from the area at certain times or under certain environmental or other conditions.
- (3) (Note that an APO must consider the risk of vibriosis, and whether to require a *Vp* management plan, whenever there is an epidemiological association between a case of vibriosis and a growing area – see clause 8.7(4).)
- (4) When preparing a *Vp* management plan the APO must consult in the same way as consultation for a marine biotoxin management plan is done (see clause 5.4).

6.8 *Vp* management plan

- (1) Every *Vp* management plan must include all the following:
- a) the growing area and BMS species to which it applies:
 - b) the period when, or the specific harvest conditions (if known) that will trigger, the plan becoming operative, and ceasing to be operative:

- c) one or more of the following control measures, which must be applied when the *Vp* management plan is operative:
 - i) limiting the time from the start of harvest to when the BMS are placed under refrigeration or other form of temperature control to no more than 5 hours;
 - ii) limiting the time from the start of harvest to when the BMS are placed under refrigeration or other form of temperature control so that the levels of total *V. parahaemolyticus*, after initial cooling of the BMS to an internal temperature of 15°C, does not exceed the average levels from the harvest water at the time of harvest by more than 0.75 log, based on sampling or modelling;
 - iii) any other control measures that, based on scientific studies, are designed to ensure that cases of vibriosis are not reasonably likely to occur;
 - d) how the BMS will be cooled to an internal temperature of less than or equal to 10°C within 10 hours after the start of harvest;
 - e) how BMS will be returned to the growing area water for at least two tidal cycles (48 hours), or diverted for post-harvest processing under an RMP to control the *V. parahaemolyticus* hazard if the *V. parahaemolyticus* controls in the plan are not met;
 - f) the additional harvest declaration information that must be applied when the *V. parahaemolyticus* management plan is operating (see clauses 11.7 and 11.9).
- (2) The control measures in subclause (1)(c) override the requirement in clause 13.3(1) to place BMS under temperature control in accordance with Schedule 4.
- (3) In subclause (1), **start of harvest** means when the first BMS are taken from the water or, in the case of intertidal harvest, the time of first exposure.
- (4) Every *Vp* management plan must be reviewed by an APO:
 - a) annually, at the time the harvest control plan is reviewed; and
 - b) whenever BMS from the growing area is epidemiologically linked to a case of vibriosis.
- (5) When reviewing a *Vp* management plan, the APO must consider all the matters referred to in clause 6.7(1).
- (6) An APO may permit an operative *Vp* management plan to cease to be operative if the grower requests this and provides evidence, to the satisfaction of the APO, that there is no longer a risk of cases of vibriosis occurring as a result of consuming raw BMS from the growing area.

Part 7: Opening and closing growing areas

7.1 Non-emergency growing area closures

- (1) An APO must close a conditional area as soon as the criteria for closure identified in its conditional area management plan occurs.
- (2) An APO must close an area if:
 - a) a sanitary survey for the area has not been completed as required by [clause 2.4](#); or
 - b) the area does not comply with the requirements of its classification.
- (3) An APO may close an area if:
 - a) growers in the area ask for the area to be closed due to inactivity; or
 - b) the conditional area management plan for the area is under review; or
 - c) closure is necessary to determine the nature of any survey that may be required before the area is opened.
- (4) Nothing in this clause affects any automatic notification systems approved under Regulation 32(4).

7.2 Emergency reasons for growing area closures

- (1) An APO must close an area immediately if:
 - a) an investigation under [clause 8.6](#) confirms that pathogens or biotoxins from the growing area are responsible for an illness outbreak; or
 - b) in the opinion of the APO, any event that may affect the safety of the BMS in the area, such as:
 - i) a broken sewer pipe; or
 - ii) the detection of pathogens; or
 - iii) a toxic substance spillage; or
 - iv) storm or flood; or
 - c) testing confirms that the known tolerance level of a particular human pathogen in seawater or BMS from the area is exceeded; or
 - d) the level of biotoxin detected in BMS from the area is at or above the maximum permissible level described in Table 3 Maximum permissible levels for marine biotoxins in BMS; or
 - e) closure is required under the marine biotoxin management plan for the area.
- (2) If an area is closed because an investigation under [clause 8.6](#) confirms that pathogens in the area (other than those naturally occurring) are responsible for an illness outbreak, an APO must:
 - a) keep the area closed until:
 - i) a review of the classification using at least the last 3 years bacteriological results is completed; and
 - ii) a field review of all actual or potential pollution sources is completed; and
 - iii) the APO determines that the event that caused the contamination no longer exists and (following a contaminant reduction study under [clause 9.5](#)) that the pathogen is no longer present in BMS from the growing area; and
 - b) if the illness is consistent with viral aetiology, keep the area closed for 28 days from the end of the contamination event (unless a shellfish specialist determines that a greater or lesser time is required); and
 - c) implement an evaluation process for any implicated pollution sources until the pollution source has been eliminated or its effects adequately mitigated.

- (3) If an APO reasonably believes that an area has been impacted by a sewage event, the APO must keep the area closed for 28 days from the date of the end of the event, unless the shellfish specialist determines that a greater or lesser time is required.
- (4) An APO may also close an area if:
 - a) as a result of an investigation under [clause 8.6](#), an APO believes that the area is the source of the illness; or
 - b) the investigation outlined in [clause 8.6](#) cannot be completed within 24 hours; or
 - c) as a result of an investigation under [clause 8.8](#), an APO believes that the area is the source of the pathogen or chemical contamination; or
 - d) levels of toxigenic phytoplankton listed in Table 2 Toxigenic phytoplankton action levels in seawater are increasing; or
 - e) levels of biotoxin have been detected in BMS above background levels, but delays in collecting samples, analysing them, or receiving the results of testing mean that there is a risk that BMS containing levels of biotoxins greater than the maximum permissible level could be harvested; or
 - f) the trigger level for toxigenic phytoplankton listed in Table 2 Toxigenic phytoplankton action levels in seawater are increasing, but delays in collecting samples, analysing them, or receiving the results of testing mean that there is a risk that BMS containing levels of biotoxins greater than the maximum permissible level could be harvested; or
 - g) there are levels of faecal coliforms in growing area seawater, or levels of *Escherichia coli* in BMS, that are unacceptable to an APO.
- (5) If an APO closes an area on the grounds that the area is the source of an illness outbreak due to naturally occurring pathogens or biotoxins, the APO must:
 - a) follow the marine biotoxin management plan, if appropriate; and
 - b) collect samples for analysis relevant to the investigation, as necessary; and
 - c) keep the area closed until it has been determined that levels of naturally occurring pathogens or biotoxins are not a public health concern.

7.3 When closed growing areas may be opened

- (1) An APO may open a conditional growing area if the requirements for reopening the area, as set out in the conditional area management plan, are met.
- (2) Except as provided in clause 7.2 and this clause, an APO may open a closed area at his or her discretion.
- (3) An APO may open an area that was closed for any reason in clause 7.2 when:
 - a) the emergency condition or situation no longer exists and sufficient time has elapsed to reduce the contaminant that may be present in the BMS and seawater, or either of these as applicable, to background levels; or
 - b) studies are conducted in accordance with conditions acceptable to a shellfish specialist to establish that sufficient time has elapsed for the BMS and seawater, or either of these as applicable, to return to background levels.
- (4) If an area is closed under the marine biotoxin management plan, an APO may open the area in accordance with that plan if he or she is satisfied that:
 - a) longline aquaculture growing areas have been sampled at upper, middle and lower depth intervals or at depths where toxigenic phytoplankton are shown to have been stratified prior to or during the closure; and
 - b) intertidal growing areas have been sampled, at the low tide and high tide boundaries of the growing area where BMS are grown; and
 - c) each commercial species of BMS has been sampled; and
 - d) spatial sampling of the growing area has been conducted to the extent that patchiness of the causative harmful algae bloom has been adequately addressed; and

- e) levels of biotoxins listed in Table 3 Maximum permissible levels for marine biotoxins in BMS are decreasing or static; and
 - f) on at least 2 consecutive sampling occasions, at least 48 hours apart, BMS sample results are below the maximum permissible level stated in Table 3 Maximum permissible levels for marine biotoxins in BMS; and
 - g) cell counts of toxigenic phytoplankton listed in Table 2 Toxigenic phytoplankton action levels in seawater are decreasing or static; and
 - h) for the purpose of assessing the potential for re-occurrence of the toxicity, the hydrography of the growing area and any adjacent marine areas have been considered in conjunction with the patterns of toxigenic phytoplankton and BMS toxicity; and
 - i) no suspected or confirmed cases of human illness, notified to the Medical Officer of Health, have resulted from the consumption of BMS harvested from within or adjacent to the closed area on or after the date of collection of the first BMS clearance sample.
- (5) For the purposes of this clause, the information available to the APO must be adequate to make an informed and reasoned food safety decision.

7.4 Reports following closure for emergency

- (1) A report must be prepared by an APO whenever an area that was closed under clause 7.2 is reopened.
- (2) The report must include the results of any seawater and BMS samples taken to justify why the area was reopened.
- (3) Every report under this clause must be attached to the annual review report under [Part 2](#).

7.5 Declaring prohibited zones instead of closing whole growing areas

- (1) An APO may, instead of closing a growing area under clause 7.2, declare part of the growing area to be a temporary prohibited zone, as provided in [Part 3](#).
- (2) Clauses 7.3 and 7.4 apply with respect to a temporary prohibited zone in the same way as if the prohibited zone was a closed growing area.

Part 8: Sampling and investigating

8.1 Sample station location and focus for bacteriological testing

- (1) An APO must ensure that the location and number of seawater and BMS sample stations are adequate to allow the effective evaluation and routine monitoring of:
 - a) all actual and potential pollution sources that may have an impact on the bacteriological quality of the growing area; and
 - b) the bacteriological quality of the BMS in the growing area, taking into account the spatial and depth variability that may occur in the bacteriological content of each commercial species of BMS.
- (2) Where practicable, seawater sample stations and BMS sample stations must be located adjacent to actual or potential pollution sources.
- (3) Where multiple species of BMS are harvested from a growing area, each species must be sampled unless a particular species is identified as representative of all species harvested from that growing area by studies demonstrating equivalent uptake and depuration of contaminants.
- (4) The bacteriological sampling required to maintain the classification of a growing area using the adverse pollution conditions strategy must target the adverse pollution conditions identified in the sanitary survey and any subsequent annual review reports, and be timed to represent all seasons.

8.2 Requirements for annual bacteriological testing in different growing areas

8.2.1 Approved areas

- (1) For a growing area affected by point source pollution to maintain an approved classification, a minimum of 5 samples must be collected and tested per year under the adverse pollution conditions strategy from each primary sample station.
- (2) For a growing area that is not affected by point source pollution to maintain an approved classification:
 - a) a minimum of 5 samples per year must be collected and tested under the adverse pollution conditions strategy from each primary sample station; or
 - b) a minimum of 6 samples per year must be collected and tested under the systematic random sampling strategy from each primary sample station.

8.2.2 Remote approved areas

- (1) For a growing area to maintain remote approved classification:
 - a) a minimum of 2 seawater and 2 BMS samples must be collected and tested per year from each primary sample station in the growing area; or
 - b) samples must be collected and tested based on an alternative sampling plan accepted by a shellfish specialist.

8.2.3 Restricted areas

- (1) For a growing area affected by point source pollution to maintain a restricted classification, a minimum of 5 samples must be collected and tested per year under the adverse pollution conditions strategy from each primary sample station.
- (2) For a growing area that is not affected by point source pollution to maintain a restricted classification:

- a) a minimum of 5 samples per year must be collected and tested under the adverse pollution conditions strategy from each primary sample station; or
- b) a minimum of 6 samples per year must be collected and tested under the systematic random sampling strategy from each primary sample station.

8.2.4 Conditional areas

- (1) If the conditional area management plan for a conditional growing area is based on the effects of non-point sources of pollution (such as rainfall events, storm water runoff, and seasonal variations), samples must be taken from each primary sample station when the growing area is in the open status at:
 - a) a minimum of 5 seawater and 5 BMS samples per year using the adverse pollution conditions strategy; or
 - b) a minimum of 6 seawater and 6 BMS samples per year using the systematic random sampling strategy.
- (2) If the management plan for a conditional growing area is based on the operation and performance of a wastewater treatment plant, combined sewerage overflow or other point sources of pollution, monthly seawater and monthly BMS samples must be taken from each primary sample station when the growing area is open.
- (3) If the monthly seawater and BMS samples as required above cannot be collected due to environmental constraints, the monthly sampling requirement will be satisfied if:
 - a) the environmental constraints are noted in the annual growing area review; and
 - b) an additional sampling run is conducted the following month.

8.2.5 Limited areas

- (1) No bacteriological testing requirements.

8.3 Sampling for marine biotoxins

- (1) The requirements for sampling for marine biotoxins are set out in [Part 5](#).

8.4 Sampling when growing area is closed for a prolonged period

- (1) If an area is closed for a period exceeding one year, a shellfish specialist must:
 - a) determine the sampling required for the area to retain its existing classification; and
 - b) determine the sampling required before the area may be reopened.

8.5 Investigation and increased sampling following elevated bacteriological results

- (1) If a bacteriological result from a sample taken in an area exceeds the bacteriological standard for the classification of that area (as described in [Part 2](#)), an APO may:
 - a) increase the required sampling frequency and spatial coverage of the area; and
 - b) undertake a shoreline survey.
- (2) If an APO determines that an elevated bacteriological result can be attributed to an unusual event that is unlikely to recur, the result may be excluded from the classification and harvest criteria consideration. The rationale for excluding the result must be acceptable to a shellfish specialist and be included in the next annual review report.

8.6 Investigation of illness outbreaks

- (1) If BMS are implicated in an illness outbreak involving 2 or more persons not from the same household (or 1 person in the case of marine biotoxin poisoning or vibriosis or as a shellfish specialist determines relevant), an APO must determine, on the basis of a preliminary evaluation before samples are analysed, whether an epidemiological association exists between the illness and the BMS consumption.
- (2) The preliminary evaluation under subclause (1) must consider:
 - a) whether the disease has the potential or is known to be transmitted by BMS; and
 - b) each consumer's food history; and
 - c) BMS handling practices by the consumer and where applicable retailer; and
 - d) whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent.
- (3) If an APO has reason to suspect an epidemiological association between an illness outbreak and BMS consumption, the APO must initiate an investigation of the illness outbreak within 24 hours to determine whether the illness is likely to be:
 - a) related to the growing area; or
 - b) the possibility that the BMS were illegally harvested; or
 - c) the result of post-harvest contamination or mishandling.

8.7 Results of investigation of illness outbreak

- (1) If, within 24 hours, the investigation under clause 8.6 indicates that the illness is likely to be related to the growing area, or if the investigation cannot be completed within 24 hours, an APO must:
 - a) either close the area or declare part of it to be a prohibited zone, in accordance with [Part 7](#), unless the illness is vibriosis, in which case subclause (4) applies instead; and
 - b) notify a shellfish specialist that a potential health risk is associated with BMS harvested from the implicated area; and
 - c) as soon as practicable, pass on to a shellfish specialist information identifying the processors and exporters handling the implicated BMS; and
 - d) promptly initiate detention of product and prepare for a BMS recall; and
 - e) initiate a growing area review and report that includes, where applicable:
 - i) a thorough field review of all actual or potential pollution sources; and
 - ii) analysis of at least the last 3 years bacteriological results to determine if the classification and, if applicable, harvest criteria are appropriate.
- (2) If the investigation demonstrates that the illnesses are related to post-harvesting contamination or mishandling, the growing area need not be closed, but the APO must:
 - a) notify a shellfish specialist; and
 - b) initiate recall procedures.
- (3) If further investigation indicates that the growing area is not in fact the problem, the area must be reopened as provided in [Part 7 Opening and closing growing areas](#).
- (4) If the illness relating to the growing area is vibriosis, the following applies instead of subclause (1)(a):

Table 4: Actions in the event of vibriosis from commercial BMS

	Cases of vibriosis linked to commercial BMS from growing area	APO actions
(1)	(a) 1 to 4 cases detected over 30-day period.	(a) Investigate the growing area and check compliance with any operative <i>Vp</i> management plan. (b) Consider whether to impose harvest restrictions on BMS from the growing area that are intended to be consumed raw. (c) Consider the risk of vibriosis occurring and decide whether to require a <i>Vp</i> management plan for the growing area, applying clause 6.7, or amend any existing plan.
(2)	(a) 2 - 3 cases in a single harvest day; or (b) 5 to 10 cases over 30-day period.	(a) Investigate the growing area and check compliance with any operative <i>Vp</i> management plan. (b) Impose harvest restrictions on BMS from the growing area that are intended to be consumed raw for a minimum of 14 days from the date of the most recent reported case. (c) Consider the risk of vibriosis occurring and decide whether to require a <i>Vp</i> management plan for the growing area, applying clause 6.7, or amend any existing plan.
(3)	(a) 4 or more cases in a single harvest day; or (b) more than 11 cases in 30-day period.	(a) Investigate the growing area and check compliance with any operative <i>Vp</i> management plan. (b) Impose harvest restrictions on BMS from the growing area that are intended to be consumed raw for a minimum of 21 days from the date of the most recent reported case. (c) Consider the risk of vibriosis occurring and decide whether to require a <i>Vp</i> management plan for the growing area, applying clause 6.7, or amend any existing plan.

8.8 Investigation where human pathogens or chemical contaminants present

- (1) This clause applies if clause 8.6 does not apply and there is no illness outbreak but:
 - a) human pathogens are detected in BMS; or
 - b) chemical contaminants are detected in BMS.
- (2) If this clause applies, an APO must promptly undertake an investigation of the harvesting, distribution, and processing of the BMS in order to determine whether the growing area is the source of the pathogens or chemical contamination, by looking in particular at:
 - a) all post-harvest activity; and
 - b) the possibility that the BMS were illegally harvested.
- (3) If the APO determines that the growing area is, or is likely to be, the source of the pathogens or chemical contamination, the APO:

- a) must immediately initiate a review and report on of the classification of the growing area; and
- b) may close the area under [Part 7 Opening and closing growing areas](#).

8.9 Heavy metal analysis and toxic substance assessment

- (1) Every classified growing area must have conducted by an APO, at least every 3 years:
 - a) analysis of BMS for heavy metals identified in the sanitary survey; and
 - b) consideration of the risk of toxic substances being present in BMS; and
 - c) report findings in the annual review report.

Part 9: Relaying BMS

9.1 Relay permit

- (1) BMS must not be relayed unless an APO has issued a relay permit.
- (2) Any person may apply for a relay permit by applying in writing to an APO.
- (3) The application must include the applicant's relay operating procedure and the results at least of the first contaminant reduction study required by clause 9.5(2).
- (4) The permit must include conditions:
 - a) relating to the nature and frequency of information to be provided to the APO; and
 - b) requiring the relay operating procedures to be reviewed annually by an APO.

9.2 Relay operating procedures

- (1) The relay operator must have a relay operating procedure, which must include all of the following matters:
 - a) the species and quantity of BMS to be relayed; and
 - b) the source growing areas of the BMS to be relayed; and
 - c) identification of the contaminant that the relay is intended to reduce to the background level of BMS in the relay growing area; and
 - d) information on the bacteriological or chemical quality of the seawater and BMS from the source growing areas; and
 - e) information on the quality of the seawater and the BMS indigenous to the relay growing area. This must include, where relevant, species-specific critical values which may affect the natural cleansing process of the BMS species to be relayed, such as:
 - i) seawater temperature; and
 - ii) salinity; and
 - iii) turbidity; and
 - iv) other relevant environmental factors; and
 - f) BMS and seawater monitoring procedures (including calibration) to determine the species specific critical values in the relay growing area identified in e); and
 - g) the name of the certified sampler; and
 - h) the security of the BMS, from the time of harvest for relay to the time of relay, to prevent BMS from being illegally diverted to retail, wholesale or processing; and
 - i) the method of transport to the relay growing area; and
 - j) a map of the relay growing area showing the actual relay area; and
 - k) the design and management of contaminant reduction studies required by clause 9.5(2); and
 - l) the time of the year when the relaying may occur; and
 - m) the method of marking the part of the growing area used for relaying; and
 - n) the method of holding the relay BMS in the relay area, such as on sticks or in containers; and
 - o) how adequate separation will be maintained between different lots of relayed BMS and between relayed BMS and adjacent BMS which has not been relayed; and
 - p) the name and address of the harvest operator as shown in the register of harvest operators; and
 - q) any other requirements an APO considers necessary for local conditions.
- (2) The portion of the relay operating procedures which is constant during all relaying operations must be set out in a standard operating procedure.

9.3 Relay requirements

- (1) BMS must not be relayed into a growing area unless the growing area is approved, conditionally approved or remote approved.
- (2) Each relay lot kept must be uniquely identified by a lot number and be kept separate from other relay lots to prevent cross-contamination and mixing.
- (3) All parts of a growing area that contains relayed BMS must be marked by buoys, poles or other means so that relayed BMS are readily identified.
- (4) The relay period commences when the last BMS has been placed in the relay area.
- (5) Relayed BMS must not be harvested for human consumption until at least the end of their relay period.

9.4 Container relaying

- (1) Where BMS are relayed in containers, the BMS must be culled, washed and placed in clean containers in such a manner as to allow the seawater to flow freely and uniformly to all BMS in the container.
- (2) Containers used for relaying must be made of non-toxic materials.
- (3) The depth and configuration of BMS in containers must allow the shellfish to filter feed normally.
- (4) Containers must be frequently cleaned and maintained in such a manner as to ensure that adequate water flow is not impeded by fouling.
- (5) The identification of lots of relayed BMS must be maintained and every container must identify the lot it contains.

9.5 Contaminant reduction studies

- (1) A contaminant reduction study must be conducted by the relay operator to demonstrate that the relaying has cleaned the shellfish to the background level for BMS in the relay growing area.
- (2) The contaminant reduction study must:
 - a) be undertaken for BMS from each source growing area to be relayed; and
 - b) address environmental (e.g. seasonal) and spatial factors which may affect the cleansing of the BMS; and
 - c) include BMS samples that:
 - i) are taken by a certified sampler; and
 - ii) include a minimum of 1 BMS sample taken on the first day of the relay;
 - iii) include a minimum of 5 BMS samples taken on the last day of the relay;
 - iv) each contain at least 12 individual BMS; and
 - v) between them are representative of the whole relay area or lot being sampled; and
 - d) include monitoring acceptable to a shellfish specialist of critical environmental parameters such as seawater temperature, salinity and turbidity.
 - e) include the results of representative samples from at least 5 separate relays under a variety of seasonal and environmental conditions (4 of these studies may be conducted after the issue of the permit); and
 - f) include, where appropriate, details of depth of seawater and stratification in the relaying area; and
 - g) include such daily seawater temperature, salinity, turbidity, rainfall and other environmental factors determined to be critical by an APO, during the relaying period as required in the permit.

- (3) The relay operator must confirm the relay performance at least once every 12 years for BMS from each source growing area, by testing 12 shellfish that are representative across the relay area on the first and last day of relay.
- (4) An APO may waive in writing the requirements for a contaminant reduction study if:
 - a) only microbial contaminants are to be reduced; and
 - b) the BMS are relayed from any of the following:
 - i) a restricted area;
 - ii) conditionally restricted area when open;
 - iii) a conditionally approved area that, when closed, meets the bacteriological seawater and BMS standard for restricted areas; and
 - c) the relay period exceeds 60 days.
- (5) The operator must keep all records, methodology, analytical results and reports used to support or resulting from each contaminant reduction study until the relay performance has been revalidated.

9.6 Records to be kept by relay operator

- (1) Relay operators must keep records of:
 - a) the details of each relay and harvest in accordance with the relay operating procedures; and
 - b) the receiver of the relayed BMS.
- (2) Relay operators must obtain and keep a copy of the harvest declaration that complies with [Part 11](#) from the harvester of every lot of the BMS sent for relay.

Part 10: Wet storage

10.1 Harvesting, transport, and labelling of BMS for wet storage

- (1) BMS may only be harvested for wet storage from:
 - a) open areas that are approved, remote approved or conditionally approved; or
 - b) premises operating under a registered risk management programme for depuration, after the successful completion of depuration.
- (2) BMS that have not been grown on the seabed must not be wet stored on the seabed.
- (3) The requirements of [Part 11](#) and [Part 13](#) apply to the harvesting, transportation and labelling of BMS for wet storage.

10.2 Operation of wet storage

- (1) Different lots of BMS must not be mixed while in wet storage.
- (2) Containers used for wet storage must be made of non-toxic materials.
- (3) The depth and configuration of BMS in containers must allow the BMS to filter feed normally.
- (4) Containers must be frequently cleaned and be maintained in a manner that ensures water flow is not impeded by fouling.
- (5) BMS that are stored in a growing area must meet the requirements for BMS harvested in that growing area in the open status.
- (6) If a wet storage area is closed, any BMS in that area must be:
 - a) subjected to relay, depuration or post-harvest treatment before being made available for human consumption; or
 - b) held in the wet storage area until the growing area is reopened.

10.3 Record keeping

- (1) Every person responsible for harvesting BMS for wet storage, must complete and keep a harvest declaration that complies with [Part 11](#).
- (2) Every person responsible for wet storage must keep a copy of a harvest declaration that complies with [Part 11](#).
- (3) The harvest declaration must include sufficient detail to ensure that each lot of BMS can be traced back to its source growing area.

Part 11: Harvesting BMS

11.1 Harvest operator and others involved in harvesting

- (1) In this Part, a reference to the harvest operator includes a reference to any person nominated by the harvest operator as the person responsible for the day-to-day management of the harvesting operations.
- (2) The person nominated by a harvest operator to be the day-to-day manager of harvest operations must be confirmed in writing by the harvest operator.
- (3) The harvest operator must ensure that all persons working on harvest vessels and vehicles are adequately trained to ensure compliance with the RCS, and keep records of that training.

11.2 Initial and ongoing verification of harvest vessels and vehicles

- (1) An application to the Director-General for registration as a harvest operator must be accompanied by an initial verification report prepared by a recognised verifier on each harvest vessel or vehicle proposed to be used with BMS by the applicant.
- (2) The applicant must not be registered by the Director-General unless the initial verification report confirms that each harvest vessel or vehicle complies with the requirements of this Part.
- (3) After a person is registered as a harvest operator, the operator must ensure that a recognised verifier verifies compliance of each harvest vessel or vehicle shown on the register at least once every 2 years.
- (4) A harvest operator must notify a recognised verifier if a harvest vessel or vehicle shown on the register:
 - a) is no longer used by the operator; or
 - b) changes ownership.

11.3 Requirements for harvest vessels and vehicles and BMS containers

- (1) If considered necessary by an APO, a harvest operator must provide effective coverings on harvest vessels and vehicles to protect BMS from exposure to direct sunlight, birds, or other things or conditions that may affect the safety and wholesomeness of the BMS.
- (2) Unless exempted by the Director-General, a marine sanitation device, portable toilet or other sewage disposal receptacle must:
 - a) be provided in each harvest vessel to contain human sewage; and
 - b) be constructed of impervious, cleanable material; and
 - c) have a tight-fitting lid; and
 - d) be secured while on board and located to prevent contamination of BMS by spillage or leakage.
- (3) BMS containers must be designed and made of non-toxic materials that will not contaminate the BMS and must be kept clean.
- (4) Harvest operators must ensure handwashing and sanitising facilities are provided on all BMS harvest vessels and vehicles.

11.4 Use of harvest vessels and vehicles

- (1) Harvest operators working on a harvest vessel or vehicle must ensure that:
 - a) the vessel or vehicle is operated in such a way as to prevent contamination of BMS by bilge or other water; and
 - b) water that comes into direct or indirect contact with BMS is water of an acceptable standard; and
 - c) ice that comes into direct or indirect contact with BMS is manufactured, stored, handled and transported in such a manner that it will not become contaminated, and if delivered to a harvest vessel or vehicle, is inspected on arrival and rejected if delivered in a manner that may have permitted contamination or if contamination is evident; and
 - d) BMS are stored at a minimum of 25 mm off the deck on vessels or vehicles that are not channelled, graded or adequately drained; and
 - e) animals that may contaminate BMS are not to be brought on harvest vessels or vehicles; and
 - f) any equipment on board that may come into direct or indirect contact with BMS during handling or transport for relaying, depuration or post-harvest treatment is thoroughly cleaned before the vessel, vehicle or equipment is used to transport or handle BMS for direct trading; and
 - g) BMS containers that are bags or sacks are not reused unless they have been washed and sanitised by:
 - i) soaking in a solution containing between 50 and 200 parts per million free available chlorine for 30 minutes; or
 - ii) using any other method approved in writing by an APO; and
 - h) BMS that are harvested and transported on a harvest vessel or vehicle for more than 6 hours, measured from the time the first BMS are harvested, are:
 - i) shaded from the sun; or
 - ii) sprayed with water of acceptable standard; or
 - iii) chilled with ice; or
 - iv) covered with clean wet sacks; or
 - v) subjected to other measures approved by an APO to minimise BMS deterioration; or
 - vi) a combination of the above; and
 - i) the temperature control requirements of [clause 13.3](#) are complied with in relation to the harvesting, transporting and unloading of BMS.
- (2) In this clause, water is of acceptable standard in relation to harvested BMS if:
 - a) it is potable water; or
 - b) water of no less standard than the water from the area from which the BMS was harvested.

11.5 Dealing with human sewage

- (1) Portable toilets and other sewage disposal receptacles must:
 - a) be used only for the purpose intended; and
 - b) be maintained in a sanitary manner.
- (2) All persons on board a harvest vessel or vehicle must wash and sanitise their hands after using the toilet.
- (3) Harvest operators must ensure that human sewage is not discharged overboard from a harvest vessel or vehicle or any vessel or vehicle assisting a harvest vessel within 500 metres from a growing area boundary.

11.6 Washing BMS before retail, wholesale, or processing

- (1) The harvest operator is responsible for washing BMS before retail, wholesale or processing.
- (2) BMS must be washed reasonably free of mud, marine flora, bottom sediments and detritus as soon as practicable after harvesting.
- (3) Re-circulated water may not be used for washing BMS unless authorised in writing by an APO.

11.7 Labelling harvested BMS

- (1) Each container of BMS must be labelled at the time of filling with a durable, legible and waterproof harvest label fixed to the exterior of the container.
- (2) The harvest label must contain all of the following information about the harvest:
 - a) the name or unique identification number of the harvest vessel or vehicle used, as specified in the register of harvest operators; and
 - b) the growing area number; and
 - c) the relevant authority identifier (being the lease, licence, permit or authorisation number); and
 - d) the date of harvest.
- (3) A single label may be attached to a transportation unit if all the BMS containers in the unit are secured together by wrapping material, net or other means.

11.8 Harvest declaration

- (1) The harvest operator must complete and sign a harvest declaration for each lot of BMS.
- (2) The harvest declaration must be provided to the BMS receiver.
- (3) If the harvest declaration is given in hard copy:
 - a) the content must be clear, legible and indelible; and
 - b) any changes made to it after it is submitted must be made in indelible ink and be initialled and dated.
- (4) If the harvest declaration is made electronically:
 - a) the requirement for the declaration to be signed may be satisfied by the incorporation of a unique identifier in the electronic system; and
 - b) the BMS transporter operator (at the time of transport) and BMS receiver must be able, on request, to reproduce all the information required to be in the harvest declaration; and
 - c) the electronic system used must be capable of ensuring that the information submitted can be received and retained in a manner that meets the records requirements of the Regulations and [Part 1](#); and
 - d) the electronic system must be capable of recording when and by whom any changes are made after the harvest declaration is submitted.
- (5) A copy of the harvest declaration must be provided to each receiver, where a harvest lot is divided between a number of BMS receivers.
- (6) The harvest operator must ensure that all harvest declarations are sequentially numbered.

11.9 Content of harvest declaration

- (1) Every harvest declaration must include all of the following:

- a) the name or unique identification number of the harvest vessel or vehicle, as specified in the register of harvest operators; and
 - b) the name of the harvest operator, as specified in the register of harvest operators; and
 - c) the growing area number where the BMS are harvested from; and
 - d) the relevant authority identifier (being the lease, licence, permit or authorisation number); and
 - e) the date and start time of harvest; and
 - f) the date and finish time of harvest; and
 - g) the species and quantity of BMS and, if the BMS were relayed, the relay lot number; and
 - h) the name and street address, or the MPI unique identifier, of the BMS receiver or, in the case of relay, the receiving growing area; and
 - i) a statement that the BMS referred to in the harvest declaration have been harvested and handled in accordance with the requirements of the RCS; and
 - j) the signature of the harvest operator or the person nominated by the harvest operator in the harvest control plan; and
 - k) if the BMS are harvested from a growing area subject to an operative *V_p* management plan:
 - i) indicate that the growing area is subject to an operative *V_p* management plan; and
 - ii) state the controls (such as the time and temperature requirements) specified by that plan.
- (2) Where BMS are harvested from a relay area at the completion of relaying, the harvest date is the date the BMS were harvested from the relay area.
- (3) If BMS have been stored in a sorting shed or a BMS depot, the harvest declaration must state the time and date of entry into and departure from the facility.
- (4) If BMS are harvested from a restricted or conditionally restricted area for post-harvest treatment, the harvest declaration must identify the intended type of post-harvest treatment.

Part 12: Sorting sheds and BMS depots

12.1 Sorting sheds and BMS depots to be verified

- (1) An application to the Director-General for listing as a sorting shed operator or a BMS depot operator must:
 - a) identify each sorting shed or depot; and
 - b) be accompanied by an initial verification report prepared by a recognised verifier on each sorting shed or depot proposed to be used with BMS by the applicant.
- (2) The applicant must not be listed unless the initial verification report confirms that the sorting sheds and depots do or will comply with the requirements of this Part.
- (3) After a person is listed as a sorting shed operator or a BMS depot operator, the operator must ensure that, at least once in every 12 months, a recognised verifier checks the compliance of the sorting sheds and depots listed for that operator
- (4) An operator must not use a sorting shed or depot for BMS unless the shed or depot:
 - a) has been verified; and
 - b) is listed by MPI.

12.2 Requirements applying to both sorting sheds and BMS depots

- (1) Sorting sheds and depots must:
 - a) be provided with water of acceptable standard (as defined in [clause 11.4 \(2\)](#)); and
 - b) be constructed of materials that minimise contamination and deterioration of the BMS; and
 - c) be designed, constructed, and maintained in a way that permits easy and effective cleaning and sanitising; and
 - d) be pest proof and have tight-fitting doors and windows; and
 - e) have flooring or structures that prevent BMS from coming into contact with BMS liquor.
- (2) Operators of sorting sheds and depots must ensure that:
 - a) adequate steps are taken to exclude pests and other animals that may contaminate BMS; and
 - b) people who have access to the sorting shed or depot;
 - i) wear clothing that is not a source of contamination; and
 - ii) refrain from behaviour that could contaminate the BMS; and
 - c) the sorting shed or depot is:
 - i) not used to store petrochemicals or any other substances that may contaminate BMS; and
 - ii) is used only for washing, grading, or chilling BMS; and
 - iii) is operated within its capability and capacity; and
 - d) the sorting shed or depot and all associated equipment are cleaned regularly and sanitised where necessary; and
 - e) only maintenance compounds approved by the Director-General are used, and they are stored and maintained in a way that ensures they are not a source of contamination to the BMS; and
 - f) access is provided to an APO at any reasonable time.

12.3 Records and labels

- (1) The operator of a sorting shed or BMS depot must ensure that:
 - a) BMS can be tracked from its origin to the next recipient of the BMS;

- b) an inventory is maintained, using harvest declaration information, of all incoming and outgoing BMS; and
 - c) BMS are labelled in accordance with clause [11.7](#) while in the sorting shed or depot; and
 - d) the harvest declaration contains the sorting shed or depot information required by clause [11.9 \(3\)](#); and
 - e) a copy of the harvest declaration is retained as a record by the sorting shed or depot operator.
- (2) When BMS harvested from a growing area that is subject to an operative *Vp* management plan are stored, the depot operator must:
- a) meet any temperature or other requirements of the *Vp* management plan; and
 - b) record the temperature of the chiller, the time when all the BMS were placed in the chiller, the time the BMS reached 10°C or less at the slowest cooling point (if achieved within the depot), and the load out temperature of the BMS; and
 - c) provide the time and temperature records to the BMS receiver.

12.4 Particular requirements for sorting sheds

- (1) A sorting shed may be used only if circumstances determined by an APO (such as tide times or harvest times) delay the transport of BMS from landing to the next point of business.
- (2) BMS must not be stored in a sorting shed for more than 24 hours.
- (3) Sorting sheds may be provided with a refrigeration facility or some other means by which BMS can be subjected to temperature control to ensure compliance with the temperature control requirements of [clause 13.3](#).
- (4) If a mechanical refrigeration unit is used it must have a calibrated thermostat that is visible from the outside of the sorting shed.

12.5 Particular requirements for BMS depots

- (1) BMS depots must be provided with a refrigeration facility or some other means by which BMS can be subjected to temperature control to ensure compliance with the temperature control requirements of [clause 13.3](#).
- (2) If a mechanical refrigeration unit is used it must have a calibrated thermostat that is visible from the outside of the depot.

Part 13: Transporting BMS

13.1 Verification of transportation units

- (1) An application to the Director-General for listing as a transport operator must be accompanied by an initial verification report prepared by a recognised verifier on each transportation unit proposed to be used with BMS by the applicant.
- (2) The applicant must not be listed unless the initial verification report confirms that each transportation unit complies with the requirements of this Part.
- (3) A transport operator must maintain records of transportation units to demonstrate compliance with clauses 13.2 and 13.3.
- (4) A transport operator must ensure that a recognised verifier annually verifies:
 - a) the operator's records of transportation units; and
 - b) a selection of the operator's transportation units.
- (5) A transport operator must notify a recognised verifier if a transportation unit shown on the list of transport operators:
 - a) is no longer used by the operator; or
 - b) changes ownership.

13.2 Design, construction and operation of transportation units

- (1) Transportation units must be made of materials that will not contaminate BMS transported in them.
- (2) Transportation units and loading equipment must be designed, constructed and operated in a manner that minimises the risk of contamination of BMS.
- (3) If the deck of a transportation unit is not channelled, graded or adequately drained, the BMS containers in or on it must be stored a minimum of 25 mm off the deck.
- (4) BMS containers on transportation units must be:
 - a) kept clean with water of acceptable standard (as per clause [11.4 \(2\)](#)); and
 - b) provided with effective drainage, if necessary.
- (5) Other cargo must not be placed on or above BMS unless the BMS are packed in sealed, crush-resistant, waterproof BMS containers.
- (6) Animals that may contaminate BMS must not be allowed in or on transportation units.
- (7) If BMS are transported with any other material that may be a source of contamination, it must be:
 - a) separated from the source of potential contamination; or
 - b) protected in a manner that prevents contamination.
- (8) BMS in containers must not, be left unattended or unprotected (such as in an unlocked transportation unit), or be placed directly on the ground at a:
 - a) wharf; or
 - b) public place; or
 - c) any other place outside a building.
- (9) Transport operators must ensure that all persons transporting BMS have been trained in how to ensure that specifications of the RCS are complied with.

- (10) If a transportation unit provides the means by which BMS are refrigerated, the unit must be designed, constructed, equipped and operated to ensure that the required temperatures are achieved and maintained throughout transportation.

13.3 Temperature control of BMS

- (1) All harvested BMS, other than BMS intended for wet storage or depuration, must be placed under temperature control in accordance with [Schedule 4](#).
- (2) Once BMS are placed under temperature control:
- any transportation units that the BMS are put into must be pre-chilled to 7°C or cooler; and
 - there must be a continued downward trend in the BMS temperature until they reach an internal temperature of 10°C or cooler; and
 - the temperature of any place where BMS are stored, whether in a transportation unit or at premises, must be maintained at 7°C or cooler.
 - they must not be continuously out of temperature control for more than 2 hours.
- (3) The provision of adequate quantities of visible ice in or on a BMS container is sufficient compliance with the requirement to maintain the temperature at 7°C or cooler.
- (4) If mechanical refrigeration units are used, the units must be:
- equipped with automatic temperature controls; and
 - capable of maintaining the ambient air temperature in the loaded transportation unit at 7°C or cooler.
- (5) Temperature measuring devices used to measure temperature in transportation units must be calibrated and be located to measure the internal temperature of the unit at its warmest point.

13.4 Couriers

- (1) A courier who transports BMS is not a transport operator for the purposes of the RCS (and therefore does not have to be listed) if:
- all BMS transported by the courier are transported in a transport unit provided by a listed transport operator or harvest operator; and
 - the transport operator or harvest operator is satisfied that the courier can and will ensure that:
 - the BMS are kept in an ambient temperature of 7°C or cooler; and
 - the BMS are protected from damage and contamination; and
 - opportunities for substitution are prevented.

Part 14: Samples and sample taking

14.1 When adverse pollution conditions or systematic random sampling strategy used

- (1) The adverse pollution conditions strategy may be used where there is point source pollution or non-point source pollution in a growing area.
- (2) The systematic random sampling strategy may be used only where there is non-point source pollution in a growing area.

14.2 APOs responsible for sampling

- (1) The APO responsible for a growing area is responsible for ensuring that all sampling required by this Notice is performed in accordance with the requirements.
- (2) The APO's sampling responsibilities include:
 - a) training, certifying and listing samplers; and
 - b) checking the suitability of equipment used by the samplers; and
 - c) conducting an annual review of the sampling activity, including a review of the receipt of samples at a laboratory; and
 - d) identifying required sampling activities to be included in the marine biotoxin management plan and any conditional area management plan for the growing area.

14.3 Training and listing of samplers

- (1) Samplers must be:
 - a) trained and audited by or under the supervision of an APO; and
 - b) certified by an APO; and
 - c) included on the list of certified samplers.
- (2) A person must not be trained as a sampler unless an APO is satisfied that the person:
 - a) has adequate educational qualifications and training in scientific principles; and
 - b) is trustworthy, reliable and self-motivated; and
 - c) has declared whether the person has any actual or potential conflicts of interest and, if any, these are acceptable to an APO.
- (3) Samplers must be trained in all of the following where relevant:
 - a) the RCS and other legal requirements relating to sampling and the harvest of BMS;
 - b) the sampling requirements of the RCS, including the public health rationale for the sampling;
 - c) the consequences of errors in sampling, for public health and for growers and harvesters;
 - d) the care and use of instruments and equipment used in sampling activities;
 - e) the correct method for taking seawater and BMS samples aseptically for microbiological analyses;
 - f) the correct method for taking seawater and BMS samples for biotoxin analysis. Seawater samples can be taken by a variety of methods for phytoplankton analysis including:
 - i) net haul; or
 - ii) hose; or
 - iii) Van Dorn; or
 - iv) grab;

- g) the relevant collection method of BMS samples depending on the growing area characteristics such as dredge, intertidal or longline grown BMS;
 - h) the significance of the number of BMS to be collected including the variation in microbiological, marine biotoxin and heavy metal levels between individual BMS;
 - i) the correct method for taking BMS samples for heavy metal and other toxic substance analyses;
 - j) the correct method for taking measurements such as temperature and salinity;
 - k) the correct method for completing the sample submission form and the sample label;
 - l) the correct method for the storage and dispatch of samples to the laboratory;
 - m) the significance of following correct procedures;
 - n) the classification and status of growing areas;
 - o) marine biotoxin management;
 - p) the patchiness of harmful algae blooms;
 - q) the significance of toxigenic phytoplankton monitoring and trigger levels;
 - r) the nature and whereabouts of pollution sources identified in the sanitary survey report;
 - s) making and recording field (including sea, land and meteorological) observations that may affect the quality of the seawater or BMS;
 - t) the significance of timing in adverse pollution conditions strategy sampling;
 - u) the significance of monthly sampling under adverse pollution conditions;
 - v) the significance of sampling on pre-set dates under the systematic random sampling system;
 - w) the amount of chilling material required to effectively chill the samples;
 - x) the organisation and management of sampling runs;
 - y) occupational health and safety requirements.
- (4) Samplers must demonstrate competency, where relevant, in clauses 14.3 (3)(d), (e), (f), (g), (h), (i), (j), (k) and (l).

14.4 Sampler certification

- (1) An APO may issue a certificate of competency to a person who the APO considers is adequately trained and who has demonstrated adequate competency as a sampler.
- (2) A certificate of competency expires at the end of 3 years after the date it was issued.
- (3) A certificate of competency may be revoked before it expires if an APO is satisfied that the sampler has failed to comply with:
- a) the requirements of this Notice; and
 - b) in particular, the responsibilities set out in clause 14.5.
- (4) Before revoking a certificate of competency, the APO must:
- a) notify the certificate holder in writing of his or her intention, giving the reasons for that intention and the facts and assumptions on which it is based; and
 - b) give the certificate holder a reasonable opportunity, within the time specified in the written notice, to provide evidence, information and submissions as to why the permit should not be revoked.
- (5) After considering material (if any) supplied by the certificate holder, the APO must:
- a) make a final decision whether to revoke the certificate; and
 - b) as soon as practical, notify the certificate holder of the decision in writing, giving reasons and the facts or assumptions on which the decision is based, in the case of a decision to revoke the certificate.
- (6) A person whose certificate has been revoked under this clause may seek a review of the decision by the Director-General (section 162 (3)-(8) of the Animal Products Act 1999 applies in relation to any such review).

14.5 Responsibilities of certified samplers

- (1) Every certified sampler must:
 - a) follow the direction of an APO in relation to sampling; and
 - b) ensure that the equipment used during sampling is adequately calibrated and does not contaminate the sample; and
 - c) ensure that the sampling procedure does not result in contamination of the sample.
- (2) Certified samplers must follow all of the following procedures when taking samples:
 - a) identify, package and store samples without delay after the sample has been taken; and
 - b) on becoming aware that an unsuitable sample has been taken, notify the laboratory and APO within 24 hours by phone, followed up within 3 working days in writing; and
 - c) mark or clearly identify each sample package at the time of sampling in a manner that:
 - i) maintains the identity of the sample in a durable and legible manner; and
 - ii) allows clear and correct matching to any relevant records; and
 - iii) clearly identifies the place from which the sample was taken; and
 - d) individually pack each sample in packaging so that the sample does not contaminate any other sample or packaging material, and to prevent any error in identification of the sample; and
 - e) double bag the sample (unless it is a sample of seawater) and pack the sample using packaging that is durable, leak proof and free from contaminants; and
 - f) place samples for microbiological and biotoxin analyses promptly into a chilled container at a temperature of cooler than 10°C; and
 - g) complete the sample submission form in writing and sign it:
 - i) as soon as practicable after taking the sample; and
 - ii) before dispatching the sample to the laboratory;
 - h) promptly dispatch the sample to the laboratory in such a manner that the required times between sample collection and commencement of analysis as stated in [Part 15](#) can be complied with.

14.6 Sample submission forms

- (1) Certified samplers must ensure that a sample submission form accompanies each sample submitted to a laboratory.
- (2) The sample submission form must set out all of the following:
 - a) the name and contact details of the sampler;
 - b) the date and time the sample was taken;
 - c) the type of sample taken and the part of the sample to be tested;
 - d) the sample station code, name, GPS coordinates or other location identifier, and where applicable the nearest corresponding marine farm number;
 - e) the type of tests to be carried out;
 - f) date the sample was submitted to the laboratory;
 - g) a section for laboratory use only for the recording of:
 - i) date of arrival; and
 - ii) time of arrival; and
 - iii) sample condition; and
 - iv) flesh temperature; and
 - v) water temperature.

14.7 Labels of samples

- (1) Certified samplers must ensure that each sample is labelled.
- (2) The label must:
 - a) clearly identify the sample to which it relates; and
 - b) state, or allow the discovery of:
 - i) a unique sample number; and
 - ii) the name or number or sample station from which the sample was taken; and
 - iii) the sample type; and
 - iv) the date and time of sampling.

Part 15: Laboratories

15.1 Only recognised laboratories to analyse samples

- (1) Testing required for the purpose of the RCS may only be analysed by a recognised laboratory, unless;
 - a) the test is for norovirus and is carried out by a laboratory which has the required test within the scope of its accreditation; or
 - b) the test is for the purpose of monitoring environmental factors such as salinity, temperature, turbidity, or pH.

15.2 Phytoplankton testing qualification

- (1) A laboratory that conducts analyses of seawater samples for toxigenic phytoplankton must employ a phytoplankton taxonomist who has attended:
 - a) an Intergovernmental Oceanographic Commission Advanced Course in Phytoplankton Taxonomy; or
 - b) an alternative course approved by the Director-General.

15.3 Receipt of samples

- (1) When a recognised laboratory receives a sample, it must check all of the following:
 - a) that the sample is clearly marked or identified to allow it to be traced back to the sample submission form; and
 - b) that the information on the sample submission form is consistent with the sample and meets the requirements of clauses [14.6](#) and [14.7](#); and
 - c) that the sampler who took the sample is certified under clause [14.4](#); and
 - d) the sample provided is suitable for the particular test required; and
 - e) the sample packaging is intact; and
 - f) there are no visible signs of contamination of the sample; and
 - g) that the sample was received:
 - i) within 24 hours after sample collection; or
 - ii) if delivery was delayed, within 48 hours after sample collection, but only if the sample is determined to be still suitable for analysis by the laboratory; and
 - h) the sample temperature for marine biotoxin and microbiological samples is less than 10°C, unless:
 - i) sampling occurred on the same day; and
 - ii) the sample has not had adequate time if placed in a chilled container to reach temperatures lower than 10°C.
- (2) If any of the requirements of this clause are not met, or if the recognised laboratory considers the sample may not be suitable for testing, the laboratory must:
 - a) decide whether to analyse the sample or seek direction from an APO responsible for the growing area; and
 - b) record the details of the defect; and
 - c) notify the sampler and an APO within 1 working day of sample receipt; and
 - d) analyse as a priority any replacement sample.
- (3) The recognised laboratory must keep records of all notifications given to samplers and APOs under this clause.

- (4) APOs must keep records of action taken as a result of reported laboratory non-compliances.

15.4 Tracking systems

- (1) A recognised laboratory must ensure that there are written procedures detailing the laboratory sample tracking system, including details of sample transfer to laboratories that are subcontracted to perform analyses where applicable.

15.5 Sample temperature and storage

- (1) Marine biotoxin and microbiological samples at a recognised laboratory must be maintained at a temperature of less than 4°C until analysis is started.
- (2) Samples that may be involved with an official investigation must be stored until the Director-General notifies the laboratory in writing that the samples may be discarded.

15.6 Test timeframes

- (1) Recognised laboratories must ensure that samples are tested in accordance with Table 5.

Table 5: Test timeframes

Sample	Tested for	Start time
Microbiological and marine biotoxin samples	<ul style="list-style-type: none"> Microbiological purposes. Phytoplankton monitoring Marine biotoxins, using bioassay methods Marine biotoxins, using non-bioassay methods 	Testing must start within 24 hours from sample collection or start within 48 hours only if: <ul style="list-style-type: none"> significant transport delays have occurred; and the delay is documented; and the temperature requirements in clauses 15.3 (1) h) are met; and if the sample is of BMS, the sample is live
Sample	Tested for	Completion time
BMS	Marine biotoxins, using non-bioassay methods	Testing and reporting must be completed within 2 working days after sample received by laboratory
	Marine biotoxins, using bioassay methods	Testing and reporting must be completed within 4 working days after sample received by laboratory
	Microbiological purposes	Testing and reporting must be completed within 3 working days after sample received by laboratory
Seawater	Microbiological purposes	Testing and reporting must be completed within 5 working days after sample received by laboratory
	Phytoplankton monitoring	Testing and reporting must be completed within 24 hours after sample received by laboratory

- (2) A recognised laboratory may extend a test timeframe in accordance with any written approval given by the Director-General on the grounds that:

- a) the test method routinely requires longer periods; or
 - b) complex confirmatory procedures make a definitive time period difficult to estimate.
- (3) A recognised laboratory may extend a test timeframe for a particular sample or group of samples in accordance with any written approval given by a shellfish specialist on the grounds that:
- a) a technical failure has been encountered in the laboratory; or
 - b) there were transport difficulties with the sample; or
 - c) the laboratory is closed, for example for a public holiday.
- (4) Any request for an extension to the test timeframe, must describe:
- a) the test to be performed; and
 - b) the reason for extension; and
 - c) the revised suggested reporting time; and
 - d) any corrective actions that will be taken to resolve any technical failure.

15.7 Method performance

- (1) A recognised laboratory must have in place corrective actions and procedures to deal with, or remedy, the situation where a method fails to perform within the requirements of the method.
- (2) The laboratory must ensure that samples in the batch are re-analysed where:
- a) batch control values are outside the limits or requirements of the method performance standards; and
 - b) the laboratory considers this may affect the results.
- (3) If there is an unidentified test response for marine biotoxins, the laboratory must:
- a) notify the Director-General within 24 hours; and
 - b) investigate the response; and
 - c) if possible, identify the unknown compound.
- (4) The laboratory must provide the Director-General with a report of all unidentified test response findings once the investigation is complete.
- (5) The Director-General may direct a laboratory to:
- a) either:
 - i) undertake independent confirmation, at the laboratory or at another laboratory determined by the Director-General; or
 - ii) repeat the test of a sample, as long as the remainder of the sample is sufficient for that process; and
 - b) test samples in duplicates; and
 - c) send samples for testing to another laboratory, if the remainder of the sample is sufficient for that process.

15.8 Laboratory methods

- (1) A laboratory may only use the following methods for the testing of biotoxins:
- a) Cawthron method: QSM 20 Method 40.105: Determination of ASP, DSP and NSP (ADN) toxins in shellfish by LC-MS, JAOAC (2005) Int 88:761-772 (modified); and
 - b) Cawthron method: QSM 20 Method 40.122: Determination of paralytic toxins by HILIC-MS/MS. JAOAC (2015) Int 98(3) 609-621;
- (2) Despite clause (1), a laboratory may use any other method that in the view of the Director-General is at least equivalent to either of the methods in clause (1)(a) or (1)(b).

- (3) When analysing seawater samples for toxigenic phytoplankton, a laboratory must use an in-house method based on UNESCO Phytoplankton Manual (1978) and IOC Manual & Guides 55 (2010).
- (4) A laboratory may only use the MPI method: Enumeration of *Escherichia coli* in Molluscan Bivalve Shellfish, to test for *Escherichia coli* in BMS flesh.
- (5) A laboratory may only use the 4th edition of the American Public Health Association's Recommended Procedures for the Examination of Sea Water and Shellfish, for testing seawater for the faecal coliforms.
- (6) Despite clause (4), a laboratory may use any other method that in the view of the Director-General is at least equivalent to the method in clause (4).
- (7) When a laboratory wishes to apply for, or change, an approved test method, it must apply to the Director-General for approval prior to the use of the new or changed method.
- (8) On receipt of an application for clause (6) above, the Director-General may approve the application, require further information, or decline the application.
- (9) The Director-General may specify, by notice in writing, steps and conditions for the preparation and testing of samples for a particular method, and the laboratory must comply with the notice.
- (10) Where new toxins or metabolites are detected and determined by the Director-General to be of public health significance, the Director-General may determine the test methods for the new toxin or metabolite and the maximum permissible levels for the purposes of public health protection.

15.9 Reporting results

- (1) If required by the Director-General, a recognised laboratory must report analytical results and sample information into an MPI database within 24 hours after each result is confirmed.
- (2) The Director-General may specify the format of reporting.
- (3) Marine biotoxin results must be reported in the units described in Table 3 Maximum permissible levels for marine biotoxins in BMS.
- (4) Marine biotoxin results in the test reports must clearly show:
 - a) which toxins are required to be summed for each toxin group; and
 - b) the total level obtained for each of those toxin groups.
- (5) The laboratory must ensure that marine biotoxin results obtained below the limit of detection of the test method are reported as 'Not Detected'.
- (6) If any of the following results are obtained, they must be reported verbally (or by a method acceptable to a shellfish specialist) by the laboratory to an APO responsible for the relevant growing area (or a nominated representative) within 1 hour after confirmation of the result, and be confirmed in writing within 24 hours:
 - a) *Escherichia coli* levels in BMS greater than 230 MPN per 100 grams; or
 - b) faecal coliform levels in seawater greater than 14 MPN per 100 ml; or
 - c) levels of toxigenic phytoplankton greater than the trigger levels stated in Table 2 Toxigenic phytoplankton action levels in seawater; or
 - d) levels of marine biotoxins in BMS greater than the maximum permissible levels shown in Table 3 Maximum permissible levels for marine biotoxins in BMS.

15.10 Documentation and records

- (1) Every recognised laboratory must submit to the Director-General an annual report relating to the previous 12 month period.

- (2) The annual report must include all of the following:
- a) the number of samples tested, including the nature of the sample, the species of BMS, where applicable, and the method used; and
 - b) the number of samples received in a non-conforming state and the nature of the non-conformance; and
 - c) a summary of Inter-laboratory comparison programme (ILCP) activity including reports, results and any corrective actions, for the previous year; and
 - d) the proposed ILCP schedule indicating the testing rounds of participation for each assay and matrix for the coming year; and
 - e) the laboratory third party International Accreditation New Zealand (IANZ) accreditation schedule for the coming year; and
 - f) major non-conformances detected by IANZ or MPI audits; and
 - g) information the Director-General may require the laboratory to provide relating to the requirements of this Notice.

Part 16: Equipment calibration

16.1 Calibration and measuring equipment

- (1) Persons responsible for measuring equipment that is used to provide critical measurements (such as thermometers, salinity meters, rainfall gauges) must ensure that the equipment:
 - a) has the accuracy, precision and conditions of use appropriate to the task performed; and
 - b) is calibrated against any of the following:
 - i) a reference standard showing traceability of calibration to a national standard;
 - ii) international standard of measurement (where available);
 - iii) if no such reference standard exists, is calibrated on a basis that is documented in, or incorporated by reference into, the relevant sanitary survey or any growing area plan; and
 - c) is uniquely identified to enable traceability of the calibrations and to identify the calibration status.
- (2) Critical measurements are those measurements used for:
 - a) establishing whether harvest criteria are met; and
 - b) BMS storage temperatures in sorting sheds, BMS depots and transportation units; and
 - c) performance standards required for relay operations.
- (3) For each piece of measuring equipment used to provide critical measurements, or used as reference standards, minimum frequencies of calibration must be specified in the:
 - a) relevant sanitary survey; or
 - b) conditional area management plan; or
 - c) relay permit; or
 - d) transporter, depot or sorting shed procedures.
- (4) Minimum frequencies must be set taking into account all of the following:
 - a) the stability of the equipment; and
 - b) the nature of the measurement; and
 - c) the manufacturer's instructions.
- (5) Safeguards must be in place to prevent unauthorised adjustments to the calibration of the measuring equipment, including safeguards to prevent movement of the equipment that may invalidate calibration.

Part 17: Health of personnel

17.1 Operator coverage

- (1) The following operators must comply with clause 17.2:
 - a) harvest; and
 - b) transport; and
 - c) BMS sorting shed; and
 - d) BMS depot; and
 - e) relay.

17.2 Health

- (1) The operator must take reasonable measures to ensure that a person (including any visitor or contractor) does not handle BMS or enter an area where he or she may adversely affect the suitability of BMS for processing or fitness for intended purpose, if he or she is:
 - a) known to be or suspected of being infected with or a carrier of, an infectious disease in a communicable form, as described in the current addition of Table 2.4 Pathogen or Disease-Specific Exclusion and Clearance Criteria for People at Increased Risk of Transmitting an Infection to Others, Appendix 2 of the Ministry of Health Communicable Disease Control Manual 2012 that is likely to be transmitted through BMS; or
 - b) known to be or suspected of suffering from or being a carrier of another disease or condition of public health concern, that is likely to be transmitted through BMS; or
 - c) suffering from acute respiratory infection; or
 - d) suffering from boils, sores, infected wounds or any other condition that cannot be adequately prevented from becoming a source of contamination.
- (2) The operator must ensure that a person who handles BMS, or any other person who may affect the suitability of BMS for processing or fitness for intended purpose, after suffering from a disease or condition described in clause 17.2 (1) a) must follow the exclusion and microbiological clearance criteria in the current addition of Table 2.4, Appendix 2 of the Ministry of Health Communicable Disease Control Manual 2012, where specified for a particular disease or condition
- (3) The operator must ensure that a person who handles BMS, or any other person who may affect the suitability of BMS for processing or fitness for intended purpose must before resuming work, be assessed by a suitably skilled person, nominated by the operator, to confirm:
 - a) that the condition is no longer likely to contaminate the BMS; or
 - b) that the handler or other person is adequately protected from being a source of contamination.

Schedule 1 – Sanitary survey

1. Sampling for sanitary survey before classification

- (1) The number of BMS and seawater samples collected by an APO or certified sampler during a sanitary survey must provide adequate results to form a profile for periods defining adverse pollution conditions.
- (2) To classify an unclassified growing area where pollution sources have an impact on the seawater or BMS quality in the growing area, a minimum of 30 seawater and 30 BMS samples, collected under various environmental conditions over a minimum of 12 months, must be taken from each primary sample station.
- (3) For a growing area managed under the adverse pollution conditions strategy, a minimum of 15 of the samples in subclause (2), for seawater and BMS respectively, must be taken under a minimum of 5 adverse pollution conditions.
- (4) To classify an unclassified growing area where no pollution sources have an impact on the growing area, a minimum of 15 seawater and 15 BMS samples must be taken under the adverse pollution conditions strategy from each primary sample station, except where systematic random sampling strategy is applied.

2. Minimum sanitary survey requirements

- (1) Sanitary survey and classification work must follow the format in Table 1A Sanitary report format and all matters listed in Table 1A must be considered by an APO when planning, conducting and writing the sanitary survey and classifying a growing area.
- (2) However, in the case of a sanitary survey for an area that is proposed to be classified only as a limited growing area, the sanitary survey need only address the matters in:
 - a) item 2 (Background);
 - b) item 5 (Hydrographic and meteorological characteristics), paragraphs 2, 3 and 8; and
 - c) item 9 (Conclusions).

Table 1A: Sanitary report format

Heading	Content
1. General	<ol style="list-style-type: none"> (1) Purpose of the sanitary survey. (2) Allocation of a unique growing area name and number. (3) Conclusions. (4) Recommendations. (5) Actions.
2. Background information	<ol style="list-style-type: none"> (1) Purpose, objectives, goals and reason for the specific sanitary survey. (2) General description of the area including size of growing area, detailed legible scale maps and, if available, aerial photographs. Map showing location in New Zealand, location in region and specific growing area and adjacent areas. (3) History of classification of the growing area, including: <ol style="list-style-type: none"> a) summary of sanitary survey history of the growing area and growing areas in adjacent coastal marine areas; and b) previous classification(s) and harvest criteria from the inaugural to the current sanitary survey and classification. (4) Description of each growing area, including: <ol style="list-style-type: none"> a) each associated authority identifier of the permit or registration to farm or harvest BMS; and

Heading	Content
	<ul style="list-style-type: none"> b) maps showing situation of such matters as the growing area, houses, farms, land use, marinas, wharves, sample stations and potential pollution sources; and c) the catchment boundaries of each growing area; and d) the marine boundaries of each growing area - clearly marked on charts of sufficient scale and detail so as to adequately show the classified areas in relation to non-classified or prohibited zones; and e) colour photographs showing such matters as the growing area, tide in or tide out for intertidal growing areas and river flow directions in coastal marine areas. <p>(5) BMS resources, including:</p> <ul style="list-style-type: none"> a) species of BMS expected to be grown or harvested in the growing area; and b) distribution of BMS within the growing area shown on a map; and c) expected quantity of BMS to be harvested per season or calendar year. <p>(6) Harvest practices in the region, including:</p> <ul style="list-style-type: none"> a) commercial; and b) recreational; and c) wet storage areas; and d) relay areas; and e) land-based aquaculture facilities in the area; and f) seasonality of harvest; and g) landing areas for harvested BMS; and h) disposition of BMS from restricted areas and conditionally approved and conditionally restricted areas, if closed.
3. Pollution source survey	<p>(1) Shoreline survey procedures including conducting an in-the-field investigation to identify properties with the potential to have an impact on the growing area.</p> <p>(2) Personnel involved and time period, including survey plan - procedures for:</p> <ul style="list-style-type: none"> a) shoreline survey; and b) sampling of seawater and BMS; and c) sampling of pollution sources; and d) determination of sites for sampling stations; and e) GPS, map references or other identification of each potential pollution source; and f) sample collection methods and practices; and g) analytical methods; and h) laboratories used.
4. Identification and evaluation of pollution sources	<p>(1) Distance from each potential pollution source to the growing area.</p> <p>(2) For each potential pollution source in the catchment identified as likely to affect the growing area:</p> <ul style="list-style-type: none"> a) the location and GPS co-ordinates, or other identification acceptable to an APO, of the pollution source on a comprehensive map of the growing area catchment; and b) whether the pollution source has a direct or indirect impact on the growing area. <p>(3) Evaluate all lakes drains, ditches, streams, rivers and other watercourses in the catchment for potential effects on the growing area.</p> <p>(4) Explore all visible discharge points, including:</p> <ul style="list-style-type: none"> a) domestic wastes shown on maps, including: <ul style="list-style-type: none"> i) the presence of septic tanks in the catchment and, if adjacent to the shoreline or watercourses, detail on effluent disposal; and

Heading	Content
	<ul style="list-style-type: none"> ii) the house-to-house inspection form used for the sanitary survey; and iii) the number and distribution of septic tanks; and iv) the soil suitability for septic tank effluent disposal; and v) holding and pump-out sites where collected sewage is disposed of; and vi) the impact of septic tank use on the growing area; and b) treatment plants, package plants and lagoons, including: <ul style="list-style-type: none"> i) location; and ii) resource consents, or summary of conditions; and iii) size and capacity, both operational and design; and iv) type of treatment; and v) outfall location; and vi) pumping station: show on map and explain emergency provisions; and vii) bypasses; and viii) tertiary treatment details; and ix) backup equipment; and x) hours of attendance and alarms; and xi) calculation of ongoing prohibited zone; and c) operational effectiveness of discharge points, including: <ul style="list-style-type: none"> i) breakdowns/emergency discharge and non-compliance with resource consent history over the last 3 years; and ii) bypassing; and iii) treatment practices; and iv) strength or quality of effluent; and v) acknowledgment of responsibility; and vi) emergency notification procedures; and vii) location of sewer pipes if near to growing area; and d) Storm water, including: <ul style="list-style-type: none"> i) combined disposal systems; and ii) drainage ditches, pipes and runoff; and e) industrial wastes. <p>(5) Radionuclides, including a copy of the latest letter from the National Centre for Radiation Science on the status of radionuclides.</p> <p>(6) Agricultural practices, including: <ul style="list-style-type: none"> a) use of fertilisers; and b) use of agrichemicals; and c) animal waste treatment systems. </p> <p>(7) Whether toxic substances are likely to adversely affect the growing area.</p> <p>(8) Wildlife (resident and migratory) and domestic animals, including: <ul style="list-style-type: none"> a) numbers, types, seasonality and whereabouts shown on a map; and b) unfenced access of animals to watercourses and growing areas. </p> <p>(9) Silviculture practices.</p> <p>(10) Vessel traffic and the presence of houseboats.</p> <p>(11) Marinas in or adjacent to growing area, including marina dilution calculations in accordance with Schedule 2.</p> <p>(12) Potential for cyanotoxin contamination.</p> <p>(13) Non-point pollution sources.</p> <p>(14) Summary of pollution sources as point or non-point sources, including faecal loading estimates.</p>

Heading	Content
5. Hydrographic and meteorological characteristics	<ul style="list-style-type: none"> (1) Focus on and evaluate the effect of any hydrographic, meteorological and geographic characteristics of the growing area and catchment. (2) Maps showing hydrographic and meteorological characteristics. (3) Physiography (description of body of water), including: <ul style="list-style-type: none"> a) physical description: width, length and depth; and b) channels and ditches; and c) rivers, streams, watercourses, including cumec estimates; and d) passes; and e) stratification in the growing area including the effect on pollution distribution and marine biotoxin management. (4) Tidal influences, including: <ul style="list-style-type: none"> a) type; and b) amplitude; and c) tidal exchange rate; and d) effect of turbidity in the growing area on BMS cleansing activity. (5) Rainfall and runoff, including: <ul style="list-style-type: none"> a) summary of amount of rainfall and runoff over last 5 – 10 years; and b) seasonal variation; and c) frequency of significant rainfalls; and d) ground saturation influences on runoff; and e) the monitoring system used, for example, rain gauge, salinity meter, river height or flow gauge including: <ul style="list-style-type: none"> i) whether system telemetric or manually read; and ii) GPS reference points; and iii) details of auditing, reading, calibration, maintenance, notification and backup; and f) heaviest rainfalls in last 5 years. (6) Winds, including: <ul style="list-style-type: none"> a) strength; and b) directions; and c) when or seasonality; and d) effect of wind in tidal estuaries, harbours and inlets. (7) River discharges, including: <ul style="list-style-type: none"> a) volumes; and b) seasonality; and c) time taken for river to rise and fall after heavy rainfall and time taken for rains to reach river gauge, and to reach the growing area; and d) river heights; and e) gauges; and f) direction of river flow in growing areas and coastal marine areas. (8) Currents, including: <ul style="list-style-type: none"> a) velocity and direction; and b) tidal; and c) affects of tide on pollution in the growing area; and d) wind driven; and e) flood; and f) times; and g) dispersion and dilution; and h) affects of ocean currents on growing areas in bays, harbours and inlets. (9) Calibration and maintenance of equipment such as salinity buoys and river height gauges.

Heading	Content
6. BMS and water quality studies	<ul style="list-style-type: none"> (1) Map of growing area showing primary and secondary sample stations for all samples, including seawater and BMS for: <ul style="list-style-type: none"> a) microbiological sampling; and b) marine biotoxin and phytoplankton sampling. (2) Sampling plan and justification for frequency and location, including: <ul style="list-style-type: none"> a) seawater and BMS for microbiological sampling; and b) seawater and BMS for marine biotoxins and phytoplankton sampling; and c) heavy metals; and d) toxic substances; and e) rationale for spatial and depth coverage for microbiological and marine biotoxin samples; and f) consideration given to the marine biotoxin and toxigenic phytoplankton history in the growing area and adjacent growing areas. (3) Description of the proposed annual monitoring programme, including: <ul style="list-style-type: none"> a) adverse pollution condition sampling; and b) systematic random sampling; and c) sample stations (maps), reason for selection; and d) minimum sampling plan required under adverse conditions, including comment on wet weather surveys, time taken for bacteriological levels to return to the background level. (4) Sample collection, handling and transport. (5) Analytical procedures. (6) Results presentation (tables). (7) Results analysis with full calculations and statistics, including: <ul style="list-style-type: none"> a) statistical criteria demonstrating compliance with bacteriological standards; and b) advanced statistical tests; and c) results presented in a summary table. (8) Presentation of results including: <ul style="list-style-type: none"> a) by meteorological conditions; and b) by hydrographic conditions; and c) by pollution events.
7. Land based aquaculture facilities	<ul style="list-style-type: none"> (1) In addition to all the other requirements in this Schedule: <ul style="list-style-type: none"> a) discussion on the purpose of this facility, including a detailed description of the facility and all related appurtenances related to the operation of the facility, including scale plans; and: b) the species of BMS to be cultured; and c) management practices and operating procedures; and d) a description of the source of water, reticulation system, and water treatment processes or methods; and e) the nature of any feed provided for the BMS.
8. Interrelationships of the previous factors	<ul style="list-style-type: none"> (1) Discussion of how actual and potential pollution sources, for example wind, tide, rainfall, affect or may affect the growing area BMS and water quality. The discussion must include the following points: <ul style="list-style-type: none"> a) pollution sources as affected by meteorological conditions; and b) pollution sources as affected by hydrographic conditions; and c) potential pollution sources which may occur due to seasonal conditions such as holidays, stock sales and festivals; and d) adverse conditions caused by meteorological events; and e) adverse conditions caused by hydrographic factors; and f) explanation of the causes of results variability.

Heading	Content
	<p>(2) Results analysis and discussion of the interrelationships of the above factors in relation to their effects on the quality of the growing water and BMS.</p> <p>(3) Management plans for conditional areas must be included with the sanitary survey report.</p>
9. Conclusions	<p>(1) Classification, including:</p> <ul style="list-style-type: none"> a) the classification as described in clause 2.2; and b) the identification of adverse pollution conditions that sampling must target; and c) the harvest criteria for conditional areas; and d) the detailed maps showing the unclassified and classified areas and prohibited zones; and e) list pollution sources as point or non-point. <p>(2) The management plan for conditional areas.</p> <p>(3) Recommendations for further studies.</p> <p>(4) Anniversary date used for the annual growing area review.</p>

Schedule 2 – Marina dilution calculations

- (1) Marina means any water area with a structure (such as a dock, floating dock or permanently fixed moorings) which is used for:
 - a) docking or otherwise mooring vessels; and
 - b) constructed to provide temporary or permanent docking space for more than 10 vessels.
- (2) The dilution calculations must be based on the volume of water within and/or adjacent to the marina.
- (3) The dilution calculations must include:
 - a) berth occupancy rate for the marina; and
 - b) an actual or assumed rate of vessels which will discharge untreated waste; and
 - c) occupancy by persons per vessel; and
 - d) a faecal coliform discharge rate of 2×10^9 faecal coliforms per day; and
 - e) the assumption that the wastes are completely mixed in the volume of water in and around the marina.
- (4) If the dilution calculations predict a theoretical faecal coliform loading greater than 14 faecal coliform MPN per 100 ml, the waters adjacent to the marina must be made prohibited zones.
- (5) If the dilution calculations predict a theoretical faecal coliform loading less than or equal to 14 faecal coliform MPN per 100 ml, the waters adjacent to the marina may be classified as:
 - a) approved; or
 - b) conditionally approved.
- (6) If an APO chooses not to determine a specific occupancy per vessel rate by investigation in specific areas or sites, an APO must assume a minimum occupancy rate of 2 persons per vessel.

Schedule 3 – Systematic random sampling strategy

1. Background Requirements

- (1) In classifying growing areas that are not affected by point source pollution, a systematic random sampling and results analysis strategy may be used in place of the adverse pollution condition sampling strategy.
- (2) The requirements of [clause 2.4](#) must be complied with to establish that the growing area is not affected by point source pollution.
- (3) Prior to a systematic random sampling strategy being used, the sampling plan for the year ahead must be acceptable to a shellfish specialist.
- (4) The sampling plan must address designated alternate sampling days that may be used if needed for:
 - a) unsafe sample collection (boating) conditions; or
 - b) when the growing area is closed for microbiological reasons.

2. Requirements for the use of a Systematic Random Sampling strategy

- (1) The following sampling requirements must be fully complied with:
 - a) a minimum of 6 samples per station must be collected per year. If conditions are judged hazardous to crew safety at the scheduled time of sampling, samples must be collected as soon after that as possible in accordance with the alternative sampling days documented in the sampling plan;
 - b) the 30 most recent samples collected at each station must be used for the classification of a growing area:
 - i) a transition period may be required for some growing areas between the current adverse pollution condition method and that recommended here. Therefore, if a growing area does not have 30 samples collected under the systematic random sampling strategy, then the previous 15 adverse pollution condition samples may be used with the 15 most recent random samples to obtain a total sample size of 30. As more samples are taken under the systematic random sampling strategy, their results must replace chronologically the adverse pollution conditions samples (i.e. sample 31 replaces sample 1, sample 32 replaces sample 2, etc.) until all adverse pollution conditions samples have been eliminated; and
 - ii) growing area classifications may be maintained under adverse pollution conditions or the transition strategy described above until sufficient results are available to classify under systematic random sampling strategies;
 - c) if a tidal stage is found to increase bacteriological concentrations in the growing area, the tidal conditions that cause the effect must be used as the basis for the sample plan;
 - d) for the purpose of mathematical calculations, MPN values that signify the upper and lower range of sensitivity for that test must be increased or decreased respectively by 1 significant number.
- (2) The annual evaluation must include an analysis of laboratory results pertinent to the last 30 samples collected at each station in areas not affected by point sources.

3. Estimating the 90th percentile

- (1) Use of the systematic random sampling strategy involves calculating the estimated 90th percentile of the data. This statistic measures variability in the data and should not be exceeded by random pollution events if the growing area is properly classified. If an APO elects to employ the systematic random sampling strategy, the following guidelines must be used to calculate the 90th percentile:

a) Equation to be used:

Estimated 90th percentile value = Antilog [(slog) 1.28* + xlog]

Where:

slog = the base 10 logarithmic standard deviation

xlog = base 10 log mean

* The value 1.28 is obtained from the standard normal distribution.

Equation explained in words:

- (1) Calculate the arithmetic mean and standard deviation of the sample result logarithms (base 10);
- (2) Multiply the standard deviation in (1) by 1.28;
- (3) Add the product in (2) to the arithmetic mean;
- (4) Take the antilog (base 10) of the results in (3) to get the estimated 90th percentile.

(2) Other instructions for estimating the 90th percentile:

- a) For the purpose of the mathematical calculations, MPN values that signify the upper or lower range of sensitivity for that test must be increased or decreased 1 significant number (MPN counts are reported in the form of 2 significant numbers).
For example, a MPN value of "less than 2" must be decreased by 0.1 to 1.9 to indicate the lower level of sensitivity of the 5 tube decimal dilution MPN test.
Therefore it would follow that a MPN value of 1,700 must be used to indicate the MPN value "greater than 1600" for the 5 tube MPN test.
- b) Logarithms may be rounded to 3 decimal places.
- c) Antilogs of log MPN calculations may be rounded to the next lower integer (zero decimal places), e.g. antilog (0.556) = 3.
- d) The standard deviation of the log MPN data must be calculated in the following manner:

$$S_{\log} = \sqrt{\frac{\sum(x - \bar{x})^2}{n - 1}}$$

Schedule 4 – Harvesting and transport time-temperature protocol

- (1) MPI has established average monthly maximum air temperatures for growing areas by averaging the last 5 years' maximum monthly temperatures for BMS growing regions.
- (2) BMS must be placed under temperature control in accordance with Tables S4A – S4C.
- (3) Tables 4B and 4C must be read together to determine the application of the time-temperature matrix in Table 4A for each growing area.

Table S4A: Time allowed from harvest to temperature control

Action Level	Average monthly maximum air temperature	Maximum hours from harvest to temperature control
Level 1	≤18°C	36 hours
Level 2	19°C – 26°C	24 hours
Level 3	≥27°C	20 hours

Table S4B: Average monthly maximum temperature statistics in °C (based on data Jan 2017 – Dec 2021)

Location	J	F	M	A	M	J	J	A	S	O	N	D
Kaitia	25	25	24	21	19	17	16	16	17	19	21	23
Kerikeri	26	25	24	22	19	17	17	17	18	20	22	24
Dargaville	24	25	23	21	18	16	16	16	17	19	21	23
Whangarei	26	26	24	21	19	17	16	17	18	20	22	24
Warkworth	24	25	23	20	18	15	15	16	17	19	21	23
Waiheke Island	25	26	24	22	19	17	16	16	17	19	22	24
Whitianga	25	25	23	21	18	16	15	16	17	19	21	24
Whakatane	25	25	23	21	18	16	15	16	17	19	21	24
Port Taharoa (Kawhia)	22	23	22	19	17	16	15	15	15	17	19	22
Gisborne	26	25	23	21	18	16	15	16	17	20	22	24
Napier	26	25	23	21	18	15	15	16	17	19	22	24
Palmerston North	24	24	23	19	16	14	14	14	15	17	20	22
Wellington	22	22	20	17	16	14	13	14	14	16	18	20
Blenheim	26	25	22	19	16	14	14	15	16	19	21	23
Motueka, Riwaka	25	24	22	19	17	14	14	15	17	19	21	23
Pelorus Sd, Crail Bay	25	24	22	19	17	14	14	15	17	19	21	23
Akaroa	24	24	22	19	16	13	13	14	16	18	20	22
Dunedin, Musselburgh	20	19	18	16	14	11	11	12	14	15	17	19
Stewart Is	19	18	17	15	13	11	11	12	13	14	17	19
Chatham Island	20	20	19	17	15	13	12	13	14	15	18	20

Table 4C: Temperature recording sites - growing area regions

Location	Growing area regions
Kaitia	Whangaroa Harbour and further north
Kerikeri	Bay of Islands and south to Whangarei
Dargaville	Kaipara
Whangarei	Whangarei Harbour
Warkworth	Mahurangi Inlet (incl. Great Barrier Island)
Waiheke Island	Auckland, Clevedon, Waimangu Point, Waiheke Island
Whitianga	Coromandel
Whakatane	Opotiki
Port Taharoa (Kawhia)	Kawhia
Gisborne	Gisborne
Napier	Hawkes Bay
Palmerston North	Manawatu
Wellington	Wellington
Motueka, Riwaka	Tasman and Golden Bays
Pelorus Sound, Crail Bay	Marlborough Sounds
Blenheim	Cloudy and Clifford Bays
Akaroa	Canterbury
Dunedin, Musselburgh	Otago
Stewart Is	Southland, Stewart Island
Chatham Island	Chatham Island