Ministry for Primary Industries
Manatū Ahu Matua

Animal Products Notice

Specifications for Bivalve Molluscan Shellfish for Human Consumption

[Subtitle]

[Document Date]

Draft for Consultation

Issued under the Animal Products Act 1999

New Zealand Government

TITLE

Animal Products Notice: Specifications for Bivalve Molluscan Shellfish for Human Consumption

COMMENCEMENT

This Animal Products Notice comes into force on [Effective Date]

REVOCATION

This Notice revokes and replaces Animal Products (Specifications for Bivalve Molluscan Shellfish) Notice 2006, issued 31 May 2006.

ISSUING AUTHORITY

This Animal Products Notice is issued by the Director-General under sections 40 and 167(1)(g) of the Animal Products Act 1999, and after having complied with the matters in section 40(2).

Dated at Wellington this ... day of .....

Paul Dansted
Director, Animal and Animal Products
Ministry for Primary Industries
(acting under delegated authority of the Director-General)

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Contents

Draft for Consultation

Draft for Consultation

Draft for Consultation

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 amplifies 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.

The Animal Products (Specifications for Bivalve Molluscan Shellfish) Notice 2006 set specifications to give effect to the regulated control scheme for bivalve molluscan shellfish and to amplify the manner in which the requirements of that scheme were met.

This Notice updates and amends many of the clauses in the Animal Products (Specifications for Bivalve Molluscan Shellfish) Notice 2006 and reformats them in the new MPI requirements template.

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Who should read this Animal Products Notice?

This Notice specifies the requirements that must be met by persons involved in, and activities involving 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 store BMS;
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); or
b) regulation 20 (obligation of harvest operators to register); or
c) regulation 21 (obligation of relay operators to hold permit); or
d) regulation 22 (obligation of transport, sorting shed, and BMS depot operators to be listed); or
e) regulation 23 (duties of harvest operators); or.
f) regulation 25(2) or 25(3) (harvesting from growing area in certain circumstances); or
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, therefore, a breach of the specifications set out in this Notice may also be a breach of the Regulations.

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Document History

No.	Version Date	Section Changed	Change(s) Description
1	31 May 2006		
2	2017		New format and branding

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: Specifications for Products Intended for Human Consumption;
b) Fisheries Act 1996;
c) Food Act 2014;
d) Health Act 1956.

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Part 1: Requirements

1.1 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 water in the growing area, or in elevated *Escherichia coli* levels in BMS in the growing area

APC strategy means a sampling strategy that targets adverse pollution conditions

APO means an animal product officer

approved in relation to a growing area, means a growing area that is classified under Part 2 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 as part of retail, wholesale or processing

certified sampler means a sampler who holds a current certificate of competency issued under clause 14.4

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 as **conditionally approved** or **conditionally restricted**

global positioning system (GPS) is 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

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

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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 stormwater; 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), 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

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 as remote approved

restricted in relation to a growing area, means a growing area that is classified under Part 2 as restricted (but does not include a conditionally restricted area)

runoff means water that flows over the ground surface or though 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

selective in relation to a growing area, means a growing area that is classified under Part 2 as a selective growing area

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

Draft for Consultation

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:

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

SRS strategy means the systematic random sampling and date analysis strategy as set out in Schedule 3

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

(2) Any term or expression that is defined in the Animal Products Act 1999, Animal Products (Ancillary and Transitional Provisions) 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.

Draft for Consultation

1.2 Records

(1) Any 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; and
b) readily accessible and available for inspection by an 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 may be classified by the Director-General or an APO into 1 of 6 classifications, based on a sanitary survey, before being listed by MPI.

(2) Different rules apply to each classification, as set out in clause 2.2 and the rest of this Part.

(3) The rules applying to unclassified areas are in clause 2.3.

(4) Every listed classified growing area is reviewed annually by an APO to check whether it has the right classification, and the classification may be reviewed at other times.

2.2 Classifications

(1) Growing areas may be classified into 1 of the following classifications in Table 1:

Table 1: 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 prepared?
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	Selective	Only those where the final product is the adductor muscle, roe, or adductor muscle and roe (such as scallops)	Yes	No

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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 a minimum of 6 months before harvest for human consumption.

(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 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; and
b) a harvest control plan, in accordance with Part 6; and
c) if the area is classified as conditionally approved or conditionally restricted, a conditional area management plan, in accordance with Part 4.

(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 in accordance with Part 7.

(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 MPN of the water 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 APC strategy, an APO must use at least the most recent 15 samples covering at least the last 3 years of sampling from each primary sample station to calculate the bacteriological standard described in clause 2.6 (2) b).

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 in accordance with Part 7.

(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

Draft for Consultation

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 sewer overflows; and

c) the APC strategy is used, at each primary sample station:

i) the faecal coliform median MPN of the water 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; and

d) the SRS strategy is used, at each primary sample station:

i) the faecal coliform median MPN of the water does not exceed 14 per 100 ml; and
ii) the estimated 90th percentile of the water does not exceed an MPN of 43 per 100 ml; and
iii) the *Escherichia coli* median MPN of the BMS does not exceed 230 per 100 grams; and
iv) the estimated 90th percentile of the BMS does not exceed an MPN of 700 per 100 grams.

(3) For growing areas under the APC strategy, an APO must use at least the most recent 15 samples covering at least the last 3 years of sampling from each primary sample station to calculate the bacteriological standard described in clause 2.7 (2) c).

(4) 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) d).

(5) Samples collected during a tidal stage must be used to classify the growing area, if a particular tidal stage increases:

a) the faecal coliform concentration of the water 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 APC 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:

a) only if, before being made available for human consumption, the BMS is subject to processing or relaying; and
b) unless the area is closed in accordance with Part 7.

(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) the growing area is affected by non-point source pollution, it:

i) is impacted only by randomly occurring, intermittent events ; and
ii) is not impacted by discharges from sewage treatment facilities or combined sewer overflows; and

Draft for Consultation

c) where the APC strategy is used, at each primary sample station:

i) the faecal coliform median MPN of the water samples does not exceed 88 per 100 ml and not more than 10% of the samples exceed 260 per 100 ml; and
ii) 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; and

d) where the SRS strategy is used, at each primary sample station:

i) the faecal coliform median MPN of the water does not exceed 88 per 100 ml; and
ii) the estimated 90th percentile of the water does not exceed an MPN of 260 per 100 ml; and
iii) the *Escherichia coli* median MPN of the BMS does not exceed 4,600 per 100 grams; and
iv) the estimated 90th percentile of the BMS does not exceed an MPN of 14,100 per 100 grams.

(3) For growing areas under the APC strategy, at least the most recent 15 samples covering at least the last 3 years of sampling from each primary sample station must be used to calculate the bacteriological standard described in clause 2.8 (2) c).

(4) For growing areas under the SRS 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) d).

(5) Samples collected during a tidal stage must be used to classify the growing area, if a particular tidal stage increases:

a) the faecal coliform concentration of the water 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 APC strategy can be used.

Draft for Consultation

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 for the area; or
b) unless the area is closed in accordance with Part 7.

(2) A growing area must 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 Selective growing area

(1) The only BMS that may be commercially harvested for human consumption from a growing area classified as selective 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 selective unless the area is closed in accordance with Part 7.

(3) A growing area must be classified as selective if a sanitary survey of the area finds that the only BMS that should be harvested for human consumption are those in 2.10 (1).

2.11 Annual 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 each growing area to reflect any changes in the growing area catchment.

(2) The annual review involves all of the following:

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 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 quality of the growing area water 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 15.3 (2) and any resulting actions taken under 15.3 (4);
e) summarising any heavy metal analyses and toxic substance assessment performed;
f) reviewing the adverse pollution conditions identified in the sanitary survey or subsequent annual reviews;
g) reporting on all relevant action taken by the APO in the past year, including any:

i) adjustment of harvest criteria; or
ii) reclassification; or
iii) additional water 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 review 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 review must show a completion date.

2.12 When growing area classification may be reviewed

(1) In addition to the annual review of classification, an APO must review the classification of a growing area if:

a) the area has been closed following of an outbreak of illness caused by something other than naturally occurring pathogens or biotoxins; or
b) BMS from the area are implicated in an epidemiologically confirmed foodborne outbreak of illness; or
c) the area is determined by an APO to be the source of a human pathogen; or

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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 water and shellfish bacteriological results; and
b) a field review of all existing 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 water 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 conducted in the 12 months before the reclassification.

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.

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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 prohibited zone that is:

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 a minimum of 6 months before harvest for human consumption.

(2) 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.

Draft for Consultation

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 sewerage 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 waste water 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.

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Part 4: Conditional area management plan

4.1 Conditional growing areas to have conditional area management plan

(1) This Part applies to all APOs and 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.

(2) Every conditional growing area must have a conditional area management plan prepared by an APO.

(3) The conditional area management plan is for the purpose of determining when the conditional growing area will be open or closed for harvest.

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) a description of the annual bacteriological monitoring plan (as described in clause 8.2) for water and BMS, including numbers and frequency;
f) the predicted number of times, based on historical findings, that identified pollution events are expected to occur in a calendar year;
g) procedures for notifying an APO immediately if a trigger in a harvest criteria is met;
h) a detailed description of how the closed status will be implemented, including:

i) a clear statement that as soon as the triggers in the harvest criteria are exceeded, the growing area will be placed in the closed status; and
ii) the procedures and methods for notifying an APO and relevant growers and harvesters of the closure; and
iii) contingency arrangements for what happens at night, weekend and in the absence of key personnel; and

i) 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;
j) where relevant, a statement that the BMS must remain in the growing area for a period acceptable to an APO, if:

i) BMS are removed from the water for farm management purposes; and
ii) the area closes due to conditions described in the management plan before the BMS are placed back in the water.

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 may or 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

Draft for Consultation

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;
b) the bacteriological quality of the effluent;
c) the physical and chemical quality of the effluent;
d) the conditions which may cause plant failure;
e) the plant or collection system bypasses including pumping station overflow storage areas;
f) the effects of design, construction and maintenance procedures to minimise mechanical failure, or overloading;
g) provisions for monitoring and inspecting the waste water treatment plant.

4.4 Annual review of plan

(1) An APO must conduct an annual review of the conditional area management plan and include it in the annual review 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.

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4.5 Consultation on conditional area management plan

(1) During the preparation of a conditional area management plan, an APO must consult with:

a) growers and harvesters, or representatives of growers or 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 water or BMS quality 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 may, if he or she considers it would be useful, consult during any review of a conditional area management plan.

Part 5: Marine biotoxin management

5.1 All growing areas to have marine biotoxin management plan

(1) This Part applies to all APOs and 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.

(2) Every classified growing area must have a marine biotoxin management plan prepared by an APO.

(3) The marine biotoxin management plan for a growing area must be prepared for the purpose of identifying the conditions:

a) when the area must be closed for biotoxin contamination; and
b) when it may be reopened.

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;
b) the boundary, name and number of the growing area;
c) the species of commercial shellfish within the growing area;
d) the location and GPS (or other identification acceptable to a shellfish specialist) of the primary and any secondary BMS and phytoplankton sample stations;
e) relevant local, regional, and national agency and personnel contact details;
f) the routine monitoring programme for BMS and phytoplankton;
g) the criteria and actions to be taken to increase sampling in accordance with the marine biotoxin action plan in clause 5.7 when toxigenic phytoplankton in growing area water or biotoxins in BMS are detected;
h) hydrographic details showing predominant currents and circulatory patterns which may affect the movement of phytoplankton in or adjacent to the growing area;
i) the marine biotoxin test methods used for the respective biotoxin groups;
j) management procedures in place for the use of screen test methods if confirmatory testing is required;
k) management procedures that address the testing of BMS following phytoplankton trigger levels being exceeded;
l) procedures for notifying phytoplankton and biotoxin results from the laboratory to APOs and growers and harvesters operating in the growing area;
m) procedures and draft letters for growing area closure and reopening;
n) procedures for the recall and/or detention of BMS product resulting from a marine biotoxin closure;
o) the procedure for opening seasonal growing areas, including scallop and dredge oyster fisheries, prior to the commencement of harvesting.

5.3 Annual review of marine biotoxin management plan

(1) An APO must conduct an annual review of the marine biotoxin management plan and include it in the annual review of the growing area under Part 2.

(2) The annual marine biotoxin review must include the following matters:

a) a copy of the monitoring programme at the start of the year under review;
b) a discussion, rationale and results supporting any changes made to the marine biotoxin monitoring programme during the year;

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c) a summary of the phytoplankton activity including trigger levels that have been exceeded and whether there was compliance with trigger level requirements;
d) where applicable, discussion on results which suggest that amendments to the trigger levels or other aspects of the phytoplankton action level table in Table 2 are required;
e) a summary of the BMS monitoring programme, including the reports specified in clause 7.4;
f) a summary of timeliness and condition of samples on arrival at the laboratory;
g) a statement that the marine biotoxin action plan has been complied with;
h) confirmation that the details in the marine biotoxin management plan are up to date.

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 the there are no, or only minor, changes proposed.

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5.5 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; and
b) seawater, tested for the phytoplankton listed in Table 2 (unless equivalent management procedures are considered acceptable to a shellfish specialist).

(2) The selection of sample stations must be based on all of the following:

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

Table 2: Phytoplankton Action Level Table

Phytoplankton Species	Marine Biotoxin	Level in composite sample to trigger BMS flesh testing[1] Cells per litre (c/L)
Alexandrium minutum	PSP	100
Alexandrium ostenfeldii	PSP	100
Alexandrium catenella	PSP	100
Alexandrium pacificum	PSP	100
Alexandrium tamarense	PSP	100
Gymnodinium catenatum	PSP	100
[2]*Pseudo-nitzschia australis* [2]*Pseudo-nitzschia pungens* [2]*Pseudo-nitzschia multiseries*	ASP	100,000
[2]*Pseudo-nitzschia turgidula* [2]*Pseudo-nitzschia fraudulenta* [2]*Pseudo-nitzschia delicatissima* [2]*Pseudo-nitzschia pseudodelicatissima* [2]*Pseudo-nitzschia multistriata*	ASP	500,000
[3]*Karenia brevis*	NSP	1,000
Karenia brevisculata	NSP	10,000
[4]*Karenia/Karlodinium/Gymnodinium* Group	NSP	250,000
Dinophysis acuta	DSP	500
Dinophysis acuminata	DSP	1,000
Prorocentrum lima	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 3 most toxic species (*P. australis, P. multiseries* 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 5 less toxic species exceeds 500,000 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.*

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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 milligrams saxitoxin equivalent per kg
Amnesic Shellfish Poison (ASP)	20 mg per kg of domoic acid
Neurotoxic Shellfish Poison (NSP)	0.8 mg brevetoxin-2 equivalents per kg
Diarrhetic Shellfish Poison (DSP)	The maximum level of okadaic acid, dinophysistoxins[1] and pectenotoxins[2] must be 0.16 mg of okadaic acid equivalents per kg
Azaspiracid Shellfish Poison (AZP)	The maximum level of AZA1, AZA2 and AZA3 must be 0.16 mg per kg of azaspiracid equivalents per kg

[1] Okadaic acid and dinophysistoxins: a hydrolysis step is required in order to detect the presence of esterified Okadaic Acid group toxins.

[2] Pectenotoxins include PTX1 and PTX2.

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, with no regular testing of water for phytoplankton.

(2) An APO may authorise a reduced programme of BMS flesh testing on the basis of a review of all BMS and 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) The reduced programme that an APO may authorise must comply with the following:

a) if a toxin listed in Table 3 has not been detected in BMS during the review period, then the toxin must be tested for at least monthly; and
b) if a toxin listed in Table 3 has been detected in BMS below the maximum permissible level, then that toxin must be tested for at least every 14 days; and
c) if a toxin listed in Table 3 has been detected in BMS at a level above the maximum permissible, then that toxin must be tested for at least weekly; and
d) in every case, water from the growing area must be tested for the phytoplankton listed in Table 2 at least weekly; and
e) the BMS testing programme must stand on its own, with phytoplankton testing being a support system.

(4) An APO may decrease the frequency of the testing in subclause (3) for seasonality if, for the growing area and adjacent coastal marine areas, on at least 5 annual occasions, it is demonstrated that there are clear differences in marine biotoxin activity between the seasons.

(5) A further reduced frequency of BMS flesh testing and testing of seawater for phytoplankton may be authorised by the Director-General if he or she is satisfied that the risks will be adequately addressed if applying a reduced frequency of testing.

5.7 Marine biotoxin action plan

(1) The marine biotoxin action plan applies to all growing areas and describes the steps leading to the opening or closing of a growing area as a result of marine biotoxin activity.

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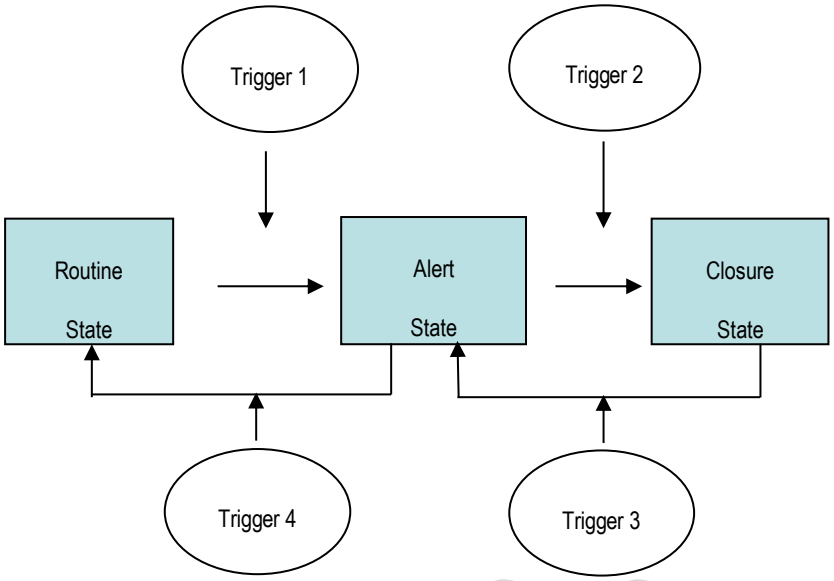
(2) The change of sampling frequency and spatial coverage from one level to another must be triggered by specific observations or combinations of observations already identified as triggering factors or triggering scenarios.

Figure 1: Marine biotoxin action plan



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In Figure 1:

a) **Routine state** is when the routine sampling programme, described in the marine biotoxin monitoring programme for the growing area, applies because marine biotoxin activity in the area is at or below background levels:

b) **Alert state** is the state when trigger levels of phytoplankton have been exceeded, or when biotoxins have been detected in BMS above the background level but below the maximum level.

c) **Closure state** is when biotoxins have been detected close to or above maximum limits, or there have been delays in obtaining samples or sample results:

d) **Trigger 1** occurs when:

   i) biotoxins are detected in BMS above background levels but below maximum level; or
   ii) toxic phytoplankton are present above trigger level.

e) **Trigger 2** occurs when:

   i) biotoxins are detected in BMS above maximum level; or
   ii) there are delays in sampling or receiving sample results.

f) **Trigger 3** occurs when:

   i) biotoxins are detected above background level but below maximum level; or
   ii) toxic phytoplankton are present above trigger level.

g) **Trigger 4** occurs when:

   i) toxic phytoplankton are detected below the trigger level; or
   ii) biotoxins are not detected in BMS, or are detected at or below background levels.

Part 6: Harvest control plans

6.1 All growing areas to have a harvest control plan

(1) This Part applies to all APOs, shellfish specialists and persons responsible for surveillance activities.

(2) Every growing area must have a harvest control plan prepared by an APO.

(3) 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) set out the written procedures describing the process for notifying harvest operators of the closure and opening of growing areas; and
e) record the names and addresses of all harvest operators operating in the area; and
f) record, if applicable, the name, position, or designation of the person or persons nominated by the operator as responsible for the day-to-day management of the harvest operations; and
g) record the name or unique identifier of each vessel and vehicle used in the harvesting operation; and
h) include any written agreement with other agencies that are likely to be conducting harvest control activities that describes their respective responsibilities; and
i) 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 BMS from another area; and
j) identify the frequency and nature of surveillance for each growing area; and
k) provide that the majority of the growing area is subject to surveillance; and
l) identify the surveillance personnel involved; and
m) record surveillance personnel contact details for both work hours and after work hours; and
n) record the type and frequency of reporting by surveillance personnel; and
o) identify any surveillance problems; and
p) record the methods used to inform APOs and others carrying out surveillance of the classification of the growing area and its status; and
q) identify any persons, other than harvest control APOs, who are entitled to perform specialist surveillance activities in the area; and
r) identify 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
s) 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.

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6.3 Surveillance requirements

(1) Harvest control plans must require that surveillance is carried out on all growing areas that are:

a) closed; or
b) conditional; or
c) restricted; or
d) have prohibited zones; or
e) used for relay.

(2) Where surveillance is required, the harvest control plan must require surveillance of the area:

a) at least once in every 30 day period; 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 that the majority of the growing area is monitored.

(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, wharfs 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, wharfs 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.

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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 and include it in the annual review of the growing area under Part 2.

(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; and
iii) times (e.g. night surveillance); and
iv) the number of days the areas were closed; and
v) 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.

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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 occur.

(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.

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 are responsible for an outbreak of illness; or
b) in the opinion of the APO, any emergency that may affect the public health quality 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 water or BMS from the area is exceeded; or
d) the level of biotoxin detected in BMS from the area is above the maximum permissible level described in Table 3 (Part 5); 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 outbreak of illness, 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 the area BMS; 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 ongoing evaluation process for any implicated pollution sources.

(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:

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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 clauses 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 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 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 water, 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 outbreak of illness 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 water, 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 water, 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 (Part 5) 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; and
g) cell counts of toxigenic phytoplankton listed in Table 2 (Part 5) are decreasing or static and below the trigger level stated in Table 2; and

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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 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 water and BMS samples taken to justify why the area was reopened.

(3) Every report under this clause must be attached to the annual review 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.

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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 water 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, water 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 APC strategy must target the adverse pollution conditions identified in the sanitary survey and any subsequent annual review reports.

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 annually under the APC 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 under the APC strategy from each primary sample station; or
b) a minimum of 6 samples per year must be collected under the SRS 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 water and 2 BMS samples must be collected annually from each primary sample station in the growing area; or
b) samples must be collected 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 annually under the APC 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 under the APC strategy from each primary sample station; or

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b) a minimum of 6 samples per year must be collected under the SRS 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 minimum frequency of:

a) 5 water and 5 BMS samples using the APC strategy; or
b) 6 water and 6 BMS samples using the SRS strategy.

(2) If the management plan for a conditional growing area is based on the operation and performance of a wastewater treatment plant, combined sewer overflow or other point sources of pollution, monthly water and monthly BMS samples must be taken from each primary sample station when the growing area is open.

(3) If the monthly water 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 Selective 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.

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8.6 Investigation of outbreaks of illness

(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 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 outbreak of illness

(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; 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 including:

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.

8.8 Investigation where human pathogens or chemical contaminants present

(1) This clause applies if clause 8.6 does not apply but:

a) human pathogens are detected in BMS; or
b) chemical contaminants are detected in BMS.

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(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 of the classification of the growing area; and
b) may close the area in accordance with Part 7.

8.9 Triennial 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; and
b) consideration of the risk of toxic substances being present in BMS.

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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.

(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) Every relay operating procedure must include all of the following matters:

a) the species and quantity of BMS to be relayed;
b) the source growing area of the BMS to be relayed;
c) the contaminant that the relay is intended to reduce to the background level of BMS in the relay growing area;
d) information on the quality of the water and BMS from the source growing area;
e) information on the quality of the water and the BMS indigenous to the relay growing area. This must include, where relevant species-specific critical values for:

i) water temperature; and
ii) salinity; and
iii) turbidity; and
iv) other environmental factors which may affect the natural cleansing process of the BMS species to be relayed;

f) BMS and water monitoring procedures (including calibration) to identify if critical environmental values in the relay growing area may be approached;
g) the name of the certified sampler;
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;
i) the method of transport to the relay growing area;
j) a map of the relay growing area showing the actual relay area;
k) the design and management of contaminant reduction studies;
l) the time of the year when the relaying may occur;
m) the method of marking the part of the growing area used for relaying;
n) the method of holding the relay BMS in the relay area, such as on sticks or in containers;
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;
p) the name and address of the harvest operator as shown in the register of harvest operators;
q) any other requirements an APO considers necessary for local conditions.

(2) If relaying for less than 14 days is applied for, the relay operating procedure must include:

a) representative BMS sampling, as described in clause 9.5 (2) b) before relay and on the last day of the relay, for the contaminant; and
b) monitoring acceptable to a shellfish specialist of critical environmental parameters such as water temperature, salinity and turbidity.

(3) The portion of the relay operating procedures which is constant during all relaying operations may be set out in a standard operating procedure.

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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 must be at least 14 consecutive days if environmental conditions are suitable for purification.

(5) Despite clause 9.3 (4), the relay period may be reduced to a minimum of 5 days by the APO, if contaminant reduction studies in accordance with clause 9.5 demonstrate that the reduced time is adequate to ensure contaminant reduction.

(6) The relay period commences when the last BMS has been placed in the relay area.

(7) 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 pump (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.

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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) address environmental and spatial factors which may affect the cleansing of the BMS; and
b) include a study of a minimum of 5 samples:
    i) taken by a certified sampler; and
    ii) each sample must contain at least 12 individual BMS; and
    iii) with 4 of the samples being taken from the approximate 4 corners of the relay area; and
    iv) the 5th sample from the approximate centre of the relay area or at an equivalent depth and spatial coverage considered acceptable to a shellfish specialist; and
c) adequately demonstrate whether, after the completion of the relay period, the contaminant has been reduced to the background level for BMS in the growing area; and
d) include the results of representative samples taken before and after relaying 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
e) include details of depth of water and stratification in the relaying area; and

f) include such daily water 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) 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 water and BMS quality for restricted areas; and

c) the relay period exceeds 60 days.

9.6 Records to be kept by relay operator

(1) Relay operators must keep records of:

a) relay operating procedures; and
b) analytical results; and
c) the details of each relay and harvest; and
d) reports and results of contaminant reduction studies; and
e) the receiver of the relayed BMS.

(2) Relay operators must obtain and keep a harvest declaration that complies with Part 11 from the harvester of the BMS sent for relay.

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Part 10: Wet storage

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

(1) BMS may only be harvested for wet storage:

a) from open areas that are approved, remote approved or conditionally approved; or
b) from 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 pump (feed) normally.

(4) Containers must be frequently cleaned and be maintained in a manner that ensures water flow is not impeded by fouling.

(5) Wet storage may only take place in growing areas that meet the requirements of the classification of the area.

(6) BMS that are stored in a growing area must meet the requirements for BMS harvested in that growing area in the open status.

(7) 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.

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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 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 to 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 Verification of harvest vessels and vehicles

(1) An application to the Director-General for registration as a harvest operator must be accompanied by a verification report 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 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, an APO must verify compliance of each harvest vessel or vehicle shown on the register at least once every 12 months.

(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.

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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 quality of the BMS.

(2) 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.

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 acceptable quality; 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 that are not channelled, graded or adequately drained; and
e) animals that may contaminate BMS are not to be brought on harvest vessels or vehicle; 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 are:

    i) shaded from the sun; or
    ii) sprayed with water of acceptable quality; 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; and

i) the requirements of clause 13.4 is complied with in relation to the harvesting, transporting and unloading of BMS.

(2) In this clause, water is of acceptable quality in relation to harvested BMS if:

a) it is potable water; or
b) water of no less quality than the water from the area from which the BMS was harvested.

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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 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 any vessel assisting a harvest vessel within 500 m 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;
b) the growing area number or other identification acceptable to a shellfish specialist;
c) any relevant authority identifier;
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 statement 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 declaration documents 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;
b) the name of the harvest operator, as specified in the register of harvest operators;
c) any relevant authority identifier;
d) the growing area number where the BMS are harvested from;
e) the date and start time of harvest;
f) the date and finish time of harvest;
g) the species and quantity of BMS and, if the BMS were relayed, the relay lot number;
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;

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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;
j) the signature of the harvest operator.

(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.

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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 a verification report on each sorting shed or depot proposed to be used with BMS by the applicant.

(2) The applicant must not be listed unless the 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 quality (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 vermin proof and have tight-fitting doors, lids and access ways; 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:

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a) an inventory is maintained, using harvest declaration information, of all incoming and outgoing BMS; and
b) BMS are labelled correctly at all times while in the sorting shed or depot; and
c) the harvest declaration contains the sorting shed or depot information required by clause 11.9 (3); and
d) a copy of the harvest declaration is retained as a record by the operator.

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.

(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.

(2) If a mechanical refrigeration unit is used it must have a calibrated thermostat that is visible from the outside of the depot.

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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 a verification report on each transportation unit proposed to be used with BMS by the applicant.

(2) The applicant must not be listed unless the 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, 13.3 and 13.4.

(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 and constructed 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) Animals that may contaminate BMS must not be allowed in or on transportation units.

(5) BMS containers on transportation units must be:

a) kept clean with water of acceptable quality (as per clause 11.4 (2)); and
b) provided with effective drainage, if necessary.

(6) Other cargo must not be placed on or above BMS unless the BMS are packed in sealed, crush-resistant, waterproof BMS containers.

(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) Transport operators must ensure that all persons transporting BMS have been trained in how to ensure that specifications of the RCS are complied with.

13.3 Temperature control of BMS during transportation

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

(2) Temperature measuring devices used to measure temperatures in transportation units must be calibrated and be located to measure the internal temperature of the unit at its warmest point.

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(3) If mechanical refrigeration units are used, the units must be:

a) equipped with automatic controls; and
b) capable of maintaining the ambient air temperature in the loaded transportation unit at 7°C or cooler.

13.4 Keeping BMS cool during transportation

(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:

a) any transportation units that the BMS are put into must be pre-chilled to 7°C or cooler; and
b) there must be a continued downward trend in the BMS temperature until they reach an internal temperature of 10°C or cooler; and
c) the temperature of any place where BMS are stored, whether in a transportation unit or at premises, must be continuously maintained at 7°C or cooler.

(3) The provision of adequate quantities of visible ice in or on a BMS container is sufficient compliance with the requirement to continuously maintain the temperature at 7°C or cooler.

(4) At any point of transfer, such as at a vehicle docking facility, BMS must not remain continuously out of refrigeration for more than 2 hours.

(5) BMS must not be left unattended or unprotected (such as in an unlocked transportation unit) at a:

a) wharf; or
b) public place; or
c) any other place outside a building.

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13.5 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:

a) all BMS transported by the courier are transported in a transport unit provided by a listed transport operator; and
b) the courier ensures that:

i) the BMS are kept at a temperature of 7°C or cooler; and
ii) the BMS are protected from damage and contamination; and
iii) opportunities for substitution are prevented.

Part 14: Sample taking

14.1 When APC or SRS strategy used

(1) The APC strategy may be used where there is point source pollution or non-point source pollution in a growing area.

(2) The SRS 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 responsibility for sampling includes:

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 of samplers

(1) Samplers must be:

a) trained and audited by or under the supervision of an APO; and
b) certified by an APO.

(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 and demonstrate competency in all of the following:

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 care and use of instruments and equipment used in sampling activities;
d) the correct method for taking water and BMS samples for microbiological analyses. Samples can be taken by a variety of methods including:

i) net haul; or
ii) hose; or
iii) Van Dorn; or
iv) grab methods for phytoplankton analyses; or
v) BMS samples for marine biotoxin analyses; or
vi) BMS and water samples for heavy metal and other toxic substance analyses; or
vii) other samples such as sediment and mussel rope for specific analyses;

e) the significance of the number of BMS to be collected including the variation in microbiological, marine biotoxin and heavy metal levels between individual BMS;
f) the correct method for taking measurements such as temperature and salinity;
g) the correct method for completing the sample submission form and the sample label;

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h) the correct method for the storage and despatch of samples to the laboratory;
i) the significance of following correct procedures;
j) the classification and status of growing areas;
k) marine biotoxin management;
l) the patchiness of harmful algae blooms;
m) the significance of phytoplankton monitoring and trigger levels;
n) aseptic sampling procedures for sampling for microbiological analyses;
o) the relevant collection method of BMS samples depending on the growing area characteristics such as dredge, intertidal or longline grown BMS;
p) the nature and whereabouts of pollution sources identified in the sanitary survey report;
q) making and recording field (including sea, land and meteorological) observations that may affect the quality of the water or BMS;
r) the consequences of errors in sampling for public health and for growers and harvesters;
s) the significance of timing in APC sampling;
t) the significance of monthly sampling under adverse pollution conditions;
u) the significance of sampling on pre set dates under the SRS system;
v) the amount of chilling material required to effectively chill the samples;
w) the organisation and management of sampling runs;
x) occupational health and safety requirements.

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 2 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 or by a person designated by the Director-General who was not involved in the decision to revoke the permit. Section 162(3) – (8) of the Act 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

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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;
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;
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;

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;
e) pack the sample using packaging that is durable, leak proof and free from contaminants;
f) place samples for microbiological and biotoxin analyses promptly into a chilled container at a temperature of cooler than 10°C;
g) complete the sample submission form in writing and sign it:

i) as soon as practicable after taking the sample; and
ii) before despatching the sample to the laboratory;

h) promptly despatch 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 and the relevant APO;
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) 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

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iv) the date and time of sampling.

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Part 15: Laboratories

15.1 Only recognised laboratories to analyse samples

(1) Samples taken for the purpose of the RCS may only be analysed by a recognised laboratory.

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;
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;
c) that the sampler who took the sample is certified under clause 14.4;
d) the sample provided is suitable for the particular test required;
e) the sample packaging is intact;
f) there are no visible signs of contamination of the sample;
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;

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 a temperatures cooler 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.

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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 4.

Table 4: Test timeframes

Sample	Tested for	Start Time
Microbiological and marine biotoxin samples	• Microbiological purposes. • Phytoplankton monitoring. • Marine biotoxins, using bioassay methods. • Marine biotoxins, using non-bioassay methods.	Testing must start within 24 hours from sample collection, subject to clause 15 (1) (b).
Microbiological and marine biotoxin samples	• Microbiological purposes. • Phytoplankton monitoring. • Marine biotoxins, using bioassay methods. • Marine biotoxins, using non-bioassay methods.	Testing may start within 48 hours, but only if: • significant transport delays have occurred; and • the delay is documented; and • the temperature requirements in clauses 15.3 (1) h) and 15.5 (1) 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
BMS	Marine biotoxins, using bioassay methods	Testing and reporting must be completed within 4 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
BMS	Microbiological purposes	Testing and reporting must be completed within 3 working days after sample received by laboratory
Seawater	Phytoplankton monitoring	Testing and reporting must be completed within 24 hours after sample received by laboratory

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(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.

(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 biotoxin methods, 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 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 (Part 5).

(4) Marine biotoxin results in the test reports must clearly show:

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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; and
b) faecal coliform levels in seawater greater than 14 MPN per 100 ml; and
c) levels of phytoplankton greater than the trigger levels stated in Table 2 (Part 5); and
d) levels of marine biotoxins in BMS greater than the maximum permissible levels shown in Table 3 (Part 5).

15.9 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:

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 calendar year; and
d) the proposed ILCP schedule indicating the testing rounds of participation for each assay and matrix for the coming calendar year; and
e) the laboratory third party International Accreditation New Zealand (IANZ) accreditation schedule for the coming calendar 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.

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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;
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 transporter records.

(4) Minimum frequencies must be set taking into account all of the following:

a) the stability of the equipment;
b) the nature of the measurement;
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.

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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) confirmed as or suspected of suffering from or being a carrier of a disease as described in section A, Part 1 of Schedule 1 of the Health Act 1956 that is likely to be transmitted through BMS; or
b) confirmed as or suspected of suffering from or being a carrier of another disease or condition of public health concern, including verocytotoxin-producing or shiga-toxin-producing *Escherichia coli*, that is likely to be transmitted through BMS; or
c) suffering from boils, sores, infected wounds or any other condition that cannot be adequately prevented from becoming a source of contamination.

(2) 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:

a) clause 17.2 (1) a) or b), must follow the exclusion and clearance criteria in Table 2.4, Appendix 2 of the Ministry of Health Communicable Disease Control Manual 2012, or any update to that Manual where specified for a particular disease or condition; and
b) clause 17.2 (1) a), if no exclusion and clearance criteria are specified for hepatitis A or cholera, must not resume work in that role until, in the view of a medical practitioner, the person is no longer likely to contaminate the BMS; and
c) clause 17.2 (1) a), if no exclusion and clearance criteria are specified for listeriosis or acute gastroenteritis, must be excluded from resuming their food-handling duties until 48 hours of being symptom free have passed; and
d) clause 17.2 (1) b), must not return to BMS handling duties until, in the view of a medical practitioner, the person is no longer able to contaminate the BMS, unless exclusion and clearance criteria specified in clause 17.2 (2) a) apply and are complied with.

(3) A person who handles BMS, or any other person who may affect the suitability of BMS for processing or fitness for intended purpose, who suffers from a condition described in clause 17.2 (1) c) 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.

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Schedule 1 – Sanitary survey

1. Sampling for sanitary survey before classification

(1) The collection of BMS and water samples by an APO or certified sampling officer 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 water or BMS quality in the growing area, a minimum of 30 water and 30 BMS samples, collected under various environmental conditions over a minimum of 12 months, must be taken from primary sample stations.

(3) For a growing area managed under the APC strategy, a minimum of 15 of the samples in subclause (2), for water and BMS respectively, must be taken under 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 water and 15 BMS samples taken under the APC strategy must be taken from primary sample stations, except where SRS strategy is applied.

2. Minimum sanitary survey requirements

(1) Sanitary survey and classification work must follow the format in Table 1A 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.

Table 1A: Sanitary Report Format

Heading	Content
1. General	(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	(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: 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: a) each associated authority identifier of the permit or registration to farm or harvest BMS; and 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

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Heading	Content
	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. (5) BMS resources, including: 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. (6) Harvest practices in the region, including: 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	(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. (2) Personnel involved and time period, including survey plan - procedures for: a) shoreline survey; and b) sampling of water 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	(3) Distance from each potential pollution source to the growing area. (4) For each potential pollution source in the catchment identified as likely to affect the growing area,: 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. (5) Evaluate all lakes drains, ditches, streams, rivers and other watercourses in the catchment for potential effects on the growing area. (6) Explore all visible discharge points, including:

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Heading	Content
	a) domestic wastes shown on maps, including: i) the presence of septic tanks in the catchment and, if adjacent to the shoreline or watercourses, detail on effluent disposal; and 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: 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) chlorination or ultraviolet treatment details; and ix) backup equipment; and x) hours of attendance and alarms; and xi) calculation of prohibited zone; and c) operational effectiveness of discharge points, including: i) breakdowns/emergency discharge and non-compliance with resource consent history over the last 3 years; and ii) bypassing; and iii) chlorination 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) Stormwater, including: i) combined disposal systems; and ii) drainage ditches, pipes and runoff; and e) industrial wastes. (7) Radionuclides, including a copy of the latest letter from the National Centre for Radiation Science on the status of radiation. (8) Agricultural practices, including: a) use of fertilisers; and b) use of herbicides, pesticides; and c) animal waste treatment systems. (9) Whether toxic substances are likely to adversely affect the growing area. (10) Wildlife (resident and migratory) and domestic animals, including: a) numbers, types, seasonality and whereabouts shown on a map; and

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Heading	Content
	b) unfenced access of animals to watercourses and growing areas. (11) Silviculture practices. (12) Boat traffic and the presence of houseboats. (13) Marinas in or adjacent to growing area, including marina dilution calculations in accordance with Schedule 2. (14) Potential for cyanotoxin contamination. (15) Non-point pollution sources. (16) Summary of pollution sources, including faecal loading estimates.
5. Hydrographic and meteorological characteristics	(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: 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: 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: 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: 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: 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: a) volumes; and b) seasonality; and

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Heading	Content
	c) time taken for river to rise and fall after heavy rains 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: a) velocity and direction; and b) tidal; and c) effect 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) effects 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.
6. BMS and water quality studies	(1) Map of growing area showing primary and secondary sample stations for all samples, including water and BMS for: a) microbiological sampling; and b) marine biotoxin and phytoplankton sampling. (2) Sampling plan and justification for frequency and location, including: a) water and BMS for microbiological sampling; and b) water 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 toxic phytoplankton history in the growing area and adjacent growing areas. (3) Description of the proposed annual monitoring programme, including: 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: a) statistical criteria demonstrating compliance with bacteriological standards; and b) advanced statistical tests; and c) results presented in summary table.

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Heading	Content
	(8) Presentation of results including: a) by meteorological conditions; and b) by hydrographic conditions; and c) by pollution events.
7. Land based aquaculture facilities	(1) In addition to all the other requirements in this Schedule: 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	(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: 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. (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. (3) Management plans for conditional areas must be included with the sanitary survey report.
9. Conclusions	(1) Classification, including: 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 classified areas and prohibited zones. (2) The management plan for conditional areas. (3) Recommendations for further studies.

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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) a slip occupancy rate for the marina; and
b) an actual or assumed rate of boats which will discharge untreated waste; and
c) occupancy by persons per boat; 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 boat rate by investigation in specific areas or sites, an APO must assume a minimum occupancy rate of 2 persons per boat.

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Schedule 3 – Systematic random sampling (SRS) 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 (SRS strategy) may be used in place of the adverse pollution condition sampling strategy (APC 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 an SRS 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 an SRS 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;
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 SRS strategy, then the previous 15 adverse pollution condition (APC) 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 SRS strategy, their results must replace chronologically the APC samples (i.e. sample 31 replaces sample 1, sample 32 replaces sample 2, etc.) until all APC samples have been eliminated; and
ii) growing area classifications may be maintained under APC 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, Most Probable Number (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 SRS 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 SRS 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]

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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) multiplying the standard deviation in (1) by 1.28;

(3) adding the product in (2) to the arithmetic mean;

(4) taking 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:

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

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Schedule 4 – Harvesting and transport time-temperature protocol

(1) MPI has established average monthly maximum air temperatures for growing areas by averaging the last 15 years' maximum monthly temperatures for BMS growing regions.

(2) BMS must be placed under temperature control in accordance with Tables S4A – S4C.

Table 4A: Time allowed from harvest to temperature control

Action Level	Average Monthly Maximum Air Temperature	Maximum hours from harvest to temperature control
Level 1	<10°C	36 Hours
Level 2	10°C – 15°C	24 Hours
Level 3	>15°C – 27°C	18 hours
Level 4	>27°C	12 Hours

Table 4B: Mean daily maximum temperature statistics in C° (Based on data 1999 – 2014)

Location	J	F	M	A	M	J	J	A	S	O	N	D
Kaitaia	24	25	23	21	19	17	16	16	17	18	20	22
Kerikeri	24	25	23	21	19	17	16	17	18	19	21	23
Dargaville	24	24	23	21	18	16	15	16	17	18	20	22
Whangarei	24	24	23	21	19	16	16	16	18	19	21	23
Port Fitzroy	24	24	23	21	18	16	15	16	17	18	20	22
Warkworth	23	23	22	20	18	15	14	15	16	18	19	21
Waiheke Island	24	25	23	21	18	16	15	16	17	18	20	22
Whitianga	24	24	23	20	18	16	15	16	17	18	20	22
Whakatane	24	24	23	20	18	15	14	15	17	18	20	22
Port Taharoa (Kawhia)	23	24	23	20	18	16	15	15	16	17	19	21
Gisborne	24	24	23	20	18	15	14	15	17	19	21	23
Napier	24	23	22	19	17	15	14	15	17	19	20	23
Palmerston North	23	24	22	19	16	14	13	14	16	17	19	21
Wellington	21	21	20	17	15	13	12	13	15	16	18	20
Motueka, Riwaka	23	24	22	19	17	14	13	15	16	18	20	22
Pelorus Sound, Crail Bay	22	22	21	18	16	13	13	14	16	17	19	21
Blenheim	24	24	22	19	16	14	13	14	16	18	20	23
Akaroa	22	22	21	18	15	13	12	13	16	17	19	21
Dunedin, Musselburgh	19	18	18	15	13	11	11	11	14	15	16	17
Stewart Is	17	17	16	15	12	11	10	11	13	13	15	16
Chatham Island	19	19	18	16	14	12	11	12	14	15	16	18

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Table 4C: Temperature recording sites - Growing area regions

Location	Growing Area Regions
Kaitaia	Whangaroa Harbour and further north
Kerikeri	Bay of Islands and south to Whangarei
Dargaville	Kaipara
Whangarei	Whangarei Harbour
Port Fitzroy	Great Barrier Island
Warkworth	Mahurangi Inlet
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

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Tables 4B and 4C must be read together to determine the application of the time-temperature matrix in Table 4A for each growing area.