Animal Products (Specifications for Bivalve Molluscan Shellfish) Notice 2006

Under sections 40 and 167(1)(g) of the Animal Products Act 1999, I, Tim Knox Director New Zealand Standards issue this Notice for the purpose of setting specifications that:

(a) are specified, or contemplated by, or necessary, or desirable to give effect to the regulated control scheme for bivalve molluscan shellfish; and

(b) are necessary or desirable to amplify the manner in which the requirements of that scheme are to be met.

Signed at Wellington this 31st day of May 2006

Tim Knox

Director New Zealand Standards

New Zealand Food Safety Authority

(Acting under delegated authority)

Certified in order for signature

Lin Da Teoh

Solicitor

Legal Services

30 / 5 / 2006

Published by the Ministry of Agriculture and Forestry (New Zealand Food Safety Authority)

PO Box 2835, Wellington

Contents

Part 17 - Record keeping

Schedule 1

Schedule 2

Schedule 3

Schedule 4

Notice

1 Title

This Notice is the Animal Products (Specifications for Bivalve Molluscan Shellfish) Notice 2006.

2 Commencement

This Notice comes into force on 1 June 2006.

Part 1 - Preliminary provisions

3 Application of this Notice

(1) This Notice applies to all persons involved in, and activities involving BMS:
(a) on marine farms;
(b) in land based aquaculture facilities; and
(c) in the wild;

that are subject to the Animal Products (Regulated Control Scheme – Bivalve Molluscan Shellfish) Regulations 2006.

(2) In the case of BMS where the only final product is the adductor muscle, the adductor muscle and roe, or roe, Parts 2, 3, 4, 5 and 14 of this Notice shall not apply.

4 Interpretation

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

acceptable means acceptable to the regional shellfish specialist

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

adverse pollution condition (APC) means a state or situation caused by meteorological, hydrological, salinity, seasonal or point source discharge or other events that have historically resulted in elevated faecal coliform levels in growing area water or elevated *E. coli* levels in BMS in a particular growing area

adverse pollution strategy means a sampling strategy that targets adverse pollution conditions for each sampling occasion required by this Notice

anniversary date means the date that is shown on the current sanitary survey report unless an alternative date is acceptable

approved means a classification used to identify a growing area where harvest for commercial purposes is allowed without the need for relaying, depuration, or post harvest treatment

approved maintenance compound means any maintenance compound that is approved by the Director-General or listed in specifications made under the Act

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

background level means the concentration of a regulated substance, such as faecal coliforms, *E.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

background sample means a sample used in establishing a background level

BMS means all species of bivalve molluscan shellfish, including oysters, clams, mussels, and scallops

BMS depot means a depot, refrigerated container unit or other building or structure used for holding BMS in a temperature controlled environment prior to delivery to a processor, wholesaler or retailer.

BMS depot operator means a person who is the owner or other person in control of a business involving the holding of BMS in a depot

BMS receiver means a person receiving BMS as part of retail, wholesale or processing

BMS sorting shed means a building or structure where BMS are handled directly after harvesting to enable separation of BMS for farm management, wet storage, relaying or culling prior to transport to a processor, wholesaler or retailer

BMS sorting shed operator means a person who is the owner or other person in control of a business involving sorting BMS in BMS sorting sheds

closed area means a growing area where the harvesting of BMS is temporarily not allowed due to it being placed in the closed status

conditional growing area means a growing area with the classification of conditionally approved or conditionally restricted

conditionally approved means a classification used to identify a growing area that meets the criteria for the approved classification except where certain conditions exist as described in a management plan for that area

conditionally restricted means a classification used to identify a growing area that meets the criteria for the restricted classification except where certain conditions exist as described in a management plan for that area

container means any bag, sack, cage, conveyance or other receptacle used for containing BMS for holding, storage or transport

critical measurements include measurements, such as salinity, temperature and rainfall, taken in accordance with the requirements of this Notice

direct impact means, in relation to pollution, the pollution source has an immediate effect on the growing area

effective supervision means, in relation to relaying, acceptable supervision to ensure that no contaminated BMS is traded before the end of the relaying period

epidemiological association in relation to Part 13 of this Notice means a time, place or person associated with a BMS related illness outbreak based on a preliminary evaluation of data by an animal product officer prior to samples being taken for analysis (in accordance with the guidance provided in the current edition of “Procedures to Investigate Foodborne Illness” published by the International Association of Milk, Food and Environmental Sanitarians, Inc)

equipment includes the whole or any part of any device, instrument or apparatus that is used for taking measurements in accordance with the requirements of this Notice

floating structure means any wharf, dock, platform or floating structure used for vessel moorage; or any marina, anchored floating structure including floating homes, barges, platforms and vessels used for accommodation, fish processing or other purposes

geometric mean means the antilog (base 10) of the arithmetic mean of the sample result logarithm (base 10)

Global Positioning System (GPS) is a system for determining position on the Earth’s surface

growing area means any coastal marine area, and any land-based aquaculture facility used for the cultivation of BMS for commercial purposes, that —

(a) contains natural deposits of BMS harvested for commercial purposes; or
(b) is used for cultivation of BMS for commercial purposes;

harvest means the act of removing BMS, for wet storage, relay, retail sale, wholesale, or processing, from a growing area and its placement on or in a harvest vessel, vehicle or container

harvest area means a growing area that contains commercial quantities of BMS

harvest criteria means the closing and reopening criteria as determined by an animal product officer and specified in a management plan for a growing area with a conditional classification

harvest declaration means a written declaration of the harvest details of BMS that complies with the requirements of clause 61

harvest operator means a person who is the owner or other person in control of a business involving harvesting of BMS

harvest vessel means any vessel or vehicle used in the harvest of BMS for relay, depuration, wet storage, retail sale, wholesale or processing

harvestable day means a calendar day during which tidal, weather or other conditions make it possible to harvest BMS

immediate means within 24 hours

indirect impact means, in relation to pollution, a secondary impact on a growing area or the contaminant may reach the growing area in a roundabout way

label means any written, printed or graphic matter affixed to or appearing on or contained within any container of BMS

land based aquaculture facility means a facility designed, constructed and used for the commercial cultivation of BMS for commercial purposes

lot in relation to BMS, means a single type of bulk BMS harvested from a particular growing area during a single harvest

marina means any water area with a structure (such as a dock, basin, floating dock or permanently fixed mooring) which is —

(a) used for docking or otherwise mooring vessels; and
(b) constructed to provide temporary or permanent docking space for more than 10 vessels

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

mixing means the act of combining different lots of BMS

MPN means most probable number

non-point or **diffuse source** means a source of pollution, that is not point source, including agricultural farm runoff, urban runoff or stormwater, sewage discharge from vessels, dredging operations, silviculture practices and other sources which are diffuse and dispersed. Non-point source discharges enter surface waters in a diffuse manner and at intermittent intervals that are generally related to the occurrence of meteorological events

open area means a growing area where the harvesting of BMS is allowed due to it being placed in the open status by an animal product officer

pathogen means an organism such as bacteria (e.g. *Salmonella*), viruses (e.g. norovirus, hepatitis A virus), or parasites (e.g. *Giardia*, *Cryptosporidium*) that may causes disease in human beings

pest means an animal that may directly or indirectly contaminate the BMS

point-source means any identifiable, confined and discrete conveying source of pollution such as any pipe, ditch, channel, tunnel or conduit that carries pollution in the catchment of a growing area

polyculture means the cultivation of:
(a) two or more species of BMS; or
(b) BMS with other species of fish;

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

prohibited means a classification used to identify a growing area where the harvest of BMS for any purpose, except depletion or the gathering of spat for aquaculture, is not allowed

regional shellfish specialist means a person employed by the New Zealand Food Safety Authority with the designation "regional shellfish specialist" to provide specialist advice and direction on BMS matters relevant to the regulated control scheme

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

relay means to transfer BMS from a growing area to another growing area for the purpose of reducing pathogens or other contaminants by using the ambient coastal marine area environment or land based aquaculture facility as the treatment process and **relaying** has a corresponding meaning

remote approved means a classification used to identify a growing area that —
(a) meets the criteria for the approved classification; and
(b) has no human habitation in the growing area catchment; and
(c) is not impacted by any actual or potential pollution sources;

restricted means a classification used to identify a growing area where the BMS, following harvest, is subjected to a suitable and effective treatment process through relaying or depuration, or post harvest treatment

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

sampler means a person issued with a certificate of competency under clause 49 of this Notice

sanitary survey means the written evaluation report of all the environmental factors, including actual and potential pollution sources, that have a bearing on the quality of water or BMS in a growing area

secondary sample station means a sample station used for the purposes of intensive monitoring as a result of increased contaminant activity in a growing area, such as bacteriological or marine biotoxin activity; or a sample station used for the purposes of investigation

shellfish laboratory means a laboratory that performs analyses to demonstrate compliance with the requirements in this Notice

shellfish industry means the persons who, or organisation that, is considered (by the person carrying out the consultation) to represent that shellfish industry

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 length for different types of shellfish as follows:

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

suitable materials means articles or equipment or appliances manufactured from or composed of materials that may not reasonably be expected to, directly or indirectly, become a component of or otherwise adversely affect the characteristics of BMS

systematic random sampling strategy (SRS strategy) means a sampling strategy, based on a random yearly sample plan, which may be applied to a growing area which is not impacted by point source pollution, as described in Schedule 3

temperature control means management of the environmental temperature of BMS by means of ice, mechanical refrigeration or other means that is capable of lowering the internal body temperature of the shellfish to 10°C or cooler and maintaining the shellfish at that temperature or cooler

toxic substance means a toxic compound occurring naturally or added to the environment that may be found in shellfish and for which a regulatory tolerance limit has been established or which the Director General determines is hazardous

transport includes transport by road, rail, sea or air

transport operator means a person who is the owner or other person in control of a business involving transporting BMS by road, rail, sea, or air

transportation unit includes aircraft, vehicles, vessels, railway wagons, shipping containers, trailers and any other form of transport used in the transport of BMS

unacceptable means unacceptable to the regional shellfish specialist

unusual event means a “one-off” event that is unlikely to recur such as a sewage treatment works failure, a sewage pipeline break, a one in five year storm event or a failure to comply with a sampling protocol standard

vehicle means a contrivance equipped with wheels, tracks or revolving runners on which it moves or is moved; and includes a hovercraft

vessel means any description of a vessel

wet storage means the transfer and temporary storage of BMS, from a growing area to another growing area for the purposes of desanding, conditioning or storage prior to harvest for retail sale, wholesale or processing

(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, used, but not defined, in this Notice has the same meaning as in those Acts or Regulations.

Part 2 – BMS growing areas

5 Application and purpose of this part

(1) This Part specifies the requirements relating to sanitary surveys and the maintenance of sanitary surveys.

(2) This Part specifies the activities undertaken by animal product officers in relation to the classification of growing areas.

Sanitary survey of BMS growing areas

6 Initial sanitary survey

(1) A sanitary survey must be conducted and completed by an animal product officer for each growing area prior to —
- (a) the classification and listing of a growing area; and
- (b) the harvest of BMS for human consumption.

(2) A sanitary survey must be conducted and completed by an animal product officer at least once every twelve years.

7 Sanitary survey requirements

(1) The sanitary survey must identify by a unique name and number each growing area to which it applies and include the associated current identification of each permit or registration under the Fisheries Act 1996, Resource Management Act 1991, or any other relevant Act to commercially farm or harvest BMS in the growing area

(2) The sanitary survey must be conducted in accordance with the requirements in Schedule 1 and must include the data and results of the following —
- (a) a shoreline survey; and
- (b) a survey of the bacteriological quality of the water in the growing area and adjacent areas; and
- (c) a survey of the bacteriological quality of the BMS in the growing area; and
- (d) an evaluation of the effect of any hydrographic, meteorological and geographic characteristics of the growing area and catchment; and
- (e) an analysis of the data from the shoreline survey, the bacteriological survey and the hydrodynamic, meteorological and geographic evaluations; and
- (f) a determination of the appropriate growing area classification and, for conditionally approved and conditionally restricted areas, a determination of the harvest criteria.

(3) On an annual basis, and within 60 working days of the anniversary date, an animal product officer must review for each growing area the sanitary survey, classification, harvest criteria (where appropriate) and growing area activities as required in this Notice to reflect any changes in the growing area catchment. The annual review must include —
- (a) a field observation and evaluation of the pollution sources identified in the sanitary survey and their performance standards, if any. This may include a drive through survey, observations made during sampling and information from other sources; and
- (b) the identification of any new pollution sources and an evaluation of their effect on the growing area; and
- (c) an evaluation of quality of the growing area water and BMS in the growing area with respect to the bacteriological standards for its classification;
- (d) a review of the sampling activity; and
- (e) a summary of any heavy metal or toxic substance analyses performed; and

(f) a review of the adverse pollution conditions identified in the sanitary survey; and
(g) for conditional growing areas, additional review requirements as specified in clause 27; and
(h) the taking of any necessary action by an animal product officer such as adjustment of harvest criteria, reclassification, additional water or BMS sampling, hydrographic or any other work considered necessary by the animal product officer to maintain the sanitary survey; and
(i) the written findings, evaluations and recommendations, including a determination that the existing classification and harvest criteria are correct or require changing.

(4) The sanitary survey and the annual review must be conducted and signed by an animal product officer and 2 copies supplied to the relevant regional shellfish specialist.

(5) When a sanitary survey is incomplete or has not been completed within the 12 year period, or the annual review has not been completed within 60 working days of the anniversary date, a regional shellfish specialist must place the growing area in the closed status until the sanitary survey report or annual review, as the case may be, is completed, unless the Director-General has granted an extension.

(6) At least once every three years an animal product officer must conduct a heavy metal analysis and toxic substance assessment of BMS in each growing area.

8 Shoreline survey

(1) In conducting the shoreline survey, the animal product officer must —
(a) determine the boundaries, based on the catchment area topography, of each shoreline survey area; and
(b) conduct an in-the-field investigation which identifies properties with the potential to have an impact on the growing area; and
(c) identify, investigate and evaluate all potential sources of pollution which may affect the growing area; and
(d) determine the distance from each potential pollution source to the growing area; and
(e) determine the impact of each potential pollution source on the growing area under normal and adverse pollution conditions; and
(f) document for each potential pollution source in the catchment identified as likely to affect the growing area —
(i) the location and GPS co-ordinates or other acceptable identification of the pollution source on a comprehensive map of the growing area catchment; and
(ii) the determination that the pollution source has a direct or indirect impact on the growing area; and
(g) evaluate all farms with animals, including the number and type of animals, the access of animals to watercourses and the type and effectiveness of animal waste treatment systems; and
(h) determine the effects of domestic and wild animal populations, including resident or migrating bird populations, deer, seals, and penguins including estimation of numbers and seasonality; and
(i) evaluate all lakes drains, ditches, streams, rivers and other watercourses in the catchment for potential effects on the Growing Area; and
(j) assess the reliability and effectiveness of sewage or other waste treatment systems that may affect the growing area; and
(k) evaluate each human waste management system, including septic tanks, and determine if their intended purpose is met; and

(l) evaluate the potential for cyanotoxin contamination of BMS in the growing area; and
(m) determine if toxic substances are likely to adversely affect the growing area; and
(n) include the findings of the shoreline survey in the sanitary survey report.

Samples and sample stations

9 Water sample stations

(1) The animal product officer must ensure that the location and number of water sample stations are adequate to allow the effective evaluation and routine monitoring of all actual and potential pollution sources that may have an impact on the bacteriological quality of the growing area.

(2) Where practicable, water sample stations must be located adjacent to actual or potential pollution sources.

10 BMS sample stations

(1) The animal product officer must ensure that the location and number of BMS sample stations are adequate to allow the effective evaluation and routine monitoring of 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 multiple species of BMS are harvested from a growing area, each species must be routinely sampled unless a particular species is identified as an indicator species by studies demonstrating equivalent uptake and depuration of contaminants.

(3) Where practicable, BMS sample stations must be located adjacent to actual or potential pollution sources.

11 Sample stations for adjacent/extended growing areas

(1) For a newly identified growing area, that is adjacent to or extends an existing growing area, the need for further sample stations must be determined by an animal product officer following an assessment of pollution sources that may affect the new area.

(2) The animal product officer may require parallel sampling in the new area and existing area prior to the inclusion of the new area into the existing area.

(3) The rationale for the decisions made relating to sub-clauses 11(1) and (2) above must be included in the annual review for the growing area.

12 Classification sample number

(1) The collection of BMS and water samples during a sanitary survey must provide adequate data to form a profile for periods defining adverse pollution conditions. The profile must address adverse meteorological, hydrographic, tidal, turbidity and seasonal conditions and point sources of pollution to ensure that the requirements for the classification of growing areas are met.

(2) For a growing area where the sanitary survey shows that 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 to classify any growing area not previously classified.

(3) For a growing area managed under the adverse pollution strategy, a minimum of 15 of the samples in sub-clause (2) above, for water and BMS respectively, must be taken under the adverse pollution conditions.

(4) For a growing area where there are no pollution sources having an impact on the growing area, except where systematic random sampling is applied, the last 15 samples taken, when the area is open, under the adverse pollution strategy, must be used to classify any growing area not previously classified.

(5) The animal product officer must use the bacteriological data for water and BMS, from samples taken over the last 3 years under adverse pollution conditions except where systematic random sampling is applied, for the determination and review of classification.

Bacteriological standards for water and BMS

For guidance on interpretation of the 10% factor, refer to Schedule 2 Standard for remote approved growing areas

13 Standard for remote approved growing areas

(1) The growing area water and BMS must meet the following bacteriological standards at every sampling station in the growing area when the area is in the open status:

(a) the faecal coliform median MPN of the water samples must not exceed 14 per 100ml and not more than 10% of the samples must exceed an MPN of 43/100ml; and

(b) the *E coli* median MPN of the BMS samples must not exceed 230 *E coli* per 100g and not more than 10% of the samples must exceed an MPN of 700/100 grams.

(2) To maintain this classification a minimum of two water and two BMS samples must be collected annually unless the regional shellfish specialist considers an alternative sampling plan acceptable.

(3) Bacteriological data from water and BMS samples taken over the last 3 years when the area was in the open status must be used by the animal product officer to determine compliance with the bacteriological standards prescribed in clause 13(1) of this Notice.

14 Standard for approved growing areas affected by point sources

(1) The growing area water and BMS must meet the following bacteriological standards at every station in the growing area when the area is in the open status:

(a) the faecal coliform median MPN of the water samples must not exceed 14 per 100ml and not more than 10% of the samples must exceed an MPN of 43/100 ml at each sample station in the growing area;and

(b) the *E coli* median MPN of the flesh samples must not exceed 230 E *coli* per 100g and not more than 10% of the samples must exceed an MPN of 700/100 grams at each sample station.

(2) To maintain this classification a minimum of five samples must be collected annually under adverse pollution conditions from each sample station in the growing area.

(3) Bacteriological data from water and BMS samples taken over the last three years under adverse pollution conditions, when the growing area was in the open status, must be used by the animal product officer to calculate the median and percentage to determine compliance with the bacteriological standards prescribed in clause 14(1) of this Notice.

15 Standard for approved growing areas affected by non-point sources

(1) If a particular tidal stage increases the faecal coliform concentration of the water or the *E.coli* level in BMS, the animal product officer must use bacteriological data from samples collected during that tidal stage to classify the growing area.

(2) The growing areas described in clause 15(1) must —

(a) only be impacted by randomly occurring, intermittent events; and
(b) not be impacted by discharges from sewage treatment facilities or combined sewer overflows.

(3) The bacteriological quality of each sample station in the growing area must meet the standards in clause 14 (1) of this Notice.

(4) Where the systematic random sampling strategy is used, (calculated in accordance with Schedule 3) the faecal coliform median MPN of the water must not exceed 14 per 100 ml and the estimated 90th percentile must not exceed an MPN of 43 per 100ml and the *E.coli* median MPN of the BMS must not exceed 230 per 100g and the estimated 90th percentile (calculated in accordance with Schedule 2) must not exceed an MPN of 700 per 100g at each sample station.

(5) The estimated 90th percentile must be calculated by-
(i) calculating the arithmetic mean and standard deviation of the sample result logarithms (base 10); and
(ii) multiplying the standard deviation in (i) by 1.28; and
(iii) adding the product in (ii) to the arithmetic mean; and
(iv) taking the antilog (base 10) of the results in (iii) to get the estimated 90th percentile; and
(v) increasing or decreasing by one significant number the MPN values that signify the upper or lower range of sensitivity of the MPN tests in the 90th percentile calculation.

(6) Growing areas under the adverse pollution control strategy must meet the requirements in clauses 14(2) and (3) of this Notice to determine compliance with the standards described in clause 14(1)(a) and (b).

(7) Growing areas under the systematic random sampling strategy must be sampled at each primary sample station at a frequency of at least six samples per year. The 30 most recent randomly collected samples from each sample station must be used to calculate the median and 90th percentile to determine compliance with the standard described in clause 15 (4).

16 Standard for restricted growing areas affected by point sources

(1) The growing area water and BMS must meet the following bacteriological standards at each station in the growing area when the area is in the open status:
(a) the faecal coliform median MPN of the water samples must not exceed 88 per 100ml and not more than 10% of the samples must exceed 260 MPN per 100ml; and
(b) the *E coli* median MPN for BMS must not exceed 4,600 per 100 grams and not more than 10% must exceed 14,100 *E.coli*/100 grams .

(2) To maintain this classification a minimum of five samples must be collected annually under adverse pollution conditions from each sample station in the growing area.

(3) Bacteriological data from water and BMS samples taken over the last three years under adverse pollution conditions from each sample station when the growing area is in the open status must be used to determine compliance with the bacteriological standards described in clause 16 (1).

17 Standard for restricted growing areas affected by non-point sources

(1) If a particular tidal stage increases the faecal coliform concentration of the water or BMS the animal product officer must use bacteriological data from samples collected during that tidal stage to classify the growing area.

(2) The growing areas described in clause 17(1) must —
(a) only be impacted by randomly occurring, intermittent events; and
(b) not be impacted by discharges from sewage treatment facilities or combined sewer overflows.

(3) The bacteriological quality of each sample station in the growing area must meet the requirements in clause 16(1) of this Notice.

(4) Where the systematic random sampling strategy is used, (in accordance with Schedule 2) the water and BMS quality must meet the following bacteriological quality at every station in the growing area when the area is in the open status:
   (a) the faecal coliform median of the water samples must not exceed 88 per 100ml and the estimated 90th percentile must not exceed an MPN of 260 per a 100ml and
   (b) the *E.coli* median MPN for BMS must not exceed 4,600 per 100 grams and not more than 10% must exceed 14,100/100 grams .

(5) The estimated 90th percentile must be calculated by the method described in clause 15(5)

(6) Growing areas under the adverse pollution control strategy must meet the requirements described in clause 16(2) and (3) of this Notice to determine compliance with the standards described in clause 16(1)(a) and 16(1)(b).

(7) Growing areas under the systematic random sampling strategy must be sampled at each sample station at a frequency of six samples per year. The 30 most recent randomly collected samples from each sample station must be used to calculate the median and 90th percentile to determine compliance with the standard described in clause 16(1).

18 Standard for conditional growing areas

(1) The quality of water and BMS for conditionally approved growing areas in the open status must meet the bacteriological standards for an approved area.

(2) The quality of water and BMS for conditionally restricted areas in the open status must meet the bacteriological standards for a restricted area.

(3) When the 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, a minimum of monthly sets of water and BMS samples (when the Adverse Pollution Condition sampling strategy is used) or six (6) sets of water and BMS samples (when the Systematic Random Sampling strategy is used) must be taken from each primary sample station when the growing area is in the open status.

(4) When 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 BMS samples must be taken from each primary sample station when the growing area is in the open status

(5) When the monthly water and BMS samples specified in clause 18 (3) and (4) above cannot be collected due to environmental constraints, the monthly sampling requirement will be satisfied if the environmental constraints are noted in the annual growing area review and if an additional sampling run is conducted the following month.

(6) When a bacteriological result exceeds the bacteriological standard for the classification of a growing area as required in this Part of the Notice, the animal product officer may increase the sampling frequency and spatial coverage of the growing area.

(7) When an animal product officer determines that a 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 data must be acceptable to the regional shellfish specialist and included in the next annual report.

(8) The unusual event result stated in the above clause 18(7) must not preclude any requirement by the animal product officer for short term public health control measures to be implemented, such as placing the growing area in the closed status pending further investigation and/or conducting investigative sampling and shoreline survey work.

19 Adverse pollution control sample strategy

The animal product officer must target the adverse pollution conditions identified in the sanitary survey and subsequent annual review reports when conducting the bacteriological sampling required to maintain the classification of each growing area.

Part 3 - Growing area classification and status

20 Application and purpose of this part

(1) This Part applies to all growing areas.

21 General

(1) Every growing area that is subjected to a sanitary survey must be correctly classified, based on the current sanitary survey and the most recent annual review, as one of the following:
- (a) remote approved;
- (b) approved;
- (c) conditionally approved;
- (d) restricted;
- (e) conditionally restricted;
- (f) prohibited.

(2) The classification of a growing area must be consistent with the public health intent of the classification criteria described in this Notice.

(3) Any upward revision of a growing area classification must be supported by a sanitary survey conducted in the 12 months prior to the reclassification that demonstrates full compliance with the shellfish and water quality standards based on monthly sampling of shellfish and water under adverse pollution conditions or in accordance with the systematic random sampling strategy.

(4) When a growing area does not comply with the requirements of its classification, it must be immediately closed by an animal product officer and the classification (including harvest criteria for conditionally approved or conditionally restricted growing areas) reviewed.

(5) A growing area must be closed immediately by an animal product officer following a public health emergency such as a broken sewer pipe, the detection of pathogens, a toxic substance spillage, storm, flood or any other event which in the opinion of the animal product officer may affect the public health quality of the growing water or BMS.

(6) When BMS from a growing area are implicated in an epidemiologically confirmed foodborne outbreak the animal product officer must promptly review the classification of the growing area in accordance with the protocol described in Part 13.

(7) When pathogens are identified in BMS from a growing area, an animal product officer must use the protocol in Part 13 to review the classification of the area.

(8) A report must be prepared by an animal product officer on each reopening of an area temporarily placed in the closed status due to a public health emergency described in sub-clause (5). The report must include the results of any water and BMS samples taken, to demonstrate that the existing classification and harvesting criteria are complied with and the report attached to the growing area annual review.

Classification

22 Remote approved classification

(1) Growing areas may only be classified as remote approved when the following criteria are met —
- (a) A sanitary survey finds —
  - (i) that there is no human habitation in the catchment; and

(ii) that the growing area is not impacted by any actual or potential pollution sources.

(b) The quality of water and BMS in the growing area must meet the bacteriological standards for a remote approved area specified in clause 14.

23 Approved classification

(1) Growing areas may only be classified as approved when the following criteria are met —

(a) A sanitary survey finds that the growing area is —

(i) suitable for the trade of BMS without relay, depuration or post harvest treatment ; and

(ii) not subject to contamination from human or animal faecal matter at levels that, in the judgement of the animal product officer, present an actual or potential public health hazard; and

(iii) not contaminated with pathogenic organisms or toxic substances at unacceptable levels.

(b) The quality of water and BMS in the growing area meet the bacteriological standards for an approved area stated in clauses 14 and 15.

24 Restricted classification

(1) Growing areas may only be classified as restricted when the following criteria are met —

(a) A sanitary survey finds that —

(i) there is a limited degree of pollution in the growing area; and

(ii) the levels of faecal pollution, human pathogens or toxic substances are such that BMS can be made fit for human consumption by either relaying, depuration or post harvest treatment.

(b) The quality of water and BMS in a restricted growing area must meet the bacteriological standards for a restricted classification specified in clause 16 and 17 of this Notice.

(c) BMS must only be harvested from a growing area classified as restricted

(i) by special permit as required in clause 32 for relay; or

(ii) for depuration; or

(iii) for post harvest treatment;

and the harvest of BMS from a growing area classified as restricted must only take place under the effective supervision of an animal product officer.

25 Conditional classification

(1) Growing areas may only be classified as conditionally approved or conditionally restricted when the sanitary survey demonstrates that–

(a) the growing area will be in the open status of the conditional classification for a reasonable period of time, the factors determining this period are known, are identified in the sanitary survey or annual review, are predictable, and are not so complex as to preclude a reasonable management approach;

(b) each potential source of pollution that may adversely affect the growing area is identified, evaluated and its effect on the growing area discussed in the sanitary survey;

(c) the bacteriological quality of the growing area water and BMS correlates with environmental conditions or other factors affecting the distribution of pollutants into the growing area.

26 Other requirements for conditional classification

(1) For each conditional growing area, a written management plan must be developed by an animal product officer prior to the classification and must include-

(a) For management plans for growing areas affected by wastewater treatment plants, performance standards that adequately address the following matters —

(i) the effects of peak effluent flow, average flow, and infiltration flow; and
(ii) the bacteriological quality of the effluent; and
(iii) the physical and chemical quality of the effluent; and
(iv) the conditions which may cause plant failure; and
(v) the plant or collection system bypasses including pumping station overflow storage areas; and
(vi) the effects of design, construction, and maintenance procedures to minimise mechanical failure, or overloading; and
(vii) provisions for monitoring and inspecting the waste water treatment plant; and
(viii) establishment of an area in the prohibited classification adjacent to a wastewater treatment plant outfall in accordance with clause 29(4) of this Notice; and

any other matters that the Director-General considers necessary.

(b) For management plans for areas affected by pollution sources other than waste water treatment plants, performance standards that adequately address the following matters-

(i) identification of the specific meteorologic, hydrologic, salinity or other event that places the growing area in the closed status; and
(ii) discussion and data analysis, concluding that the effects on the growing area water and shellfish from these specific meteorologic, hydrologic, salinity or other events are predictable and that data are sufficient to establish meaningful performance standards or harvest criteria for the establishment and implementation of a management plan; and
(iii) for seasonal events such as boating or seasonal rainfall or bird migration, the performance standard must be based on identification of the seasonal event , including estimated duration; and
(iv) the predicted number of times, based on historical findings, that the pollution event is expected to occur in a calendar year; and
(v) harvest criteria such as salinity, rainfall, river height, that reliably predict when the criteria for conditional classification are met.

(c) For management plans based on a risk assessment made in accordance with Part 13 of this Notice, the following matters:

(i) harvest criteria which can be used to reliably determine when the growing area may be placed in the open status and BMS may be harvested;
(ii) procedures for immediate notification to an animal product officer when performance standards or criteria are not met.

(d) For all management plans-

(i) the determination of the harvest criteria must include studies that show the time interval necessary for the reduction of faecal coliform levels in growing area water and *E.coli* levels in the BMS to background levels; and
(ii) a contingency plan must be developed for when critical measuring equipment used to measure performance parameters is unable to accurately and reliably measure the performance standard; and
(iii) a description of the annual monitoring plan for water and BMS, including numbers and frequency; and
(iv) a detailed description of how the closed status for the conditional growing areas will be implemented, which must include;
(A) a clear statement that as soon as the harvest criteria are exceeded, the growing area will be placed in the closed status; and

(B) the procedures and methods for notifying the animal product officer and the shellfish industry of the closure, including contingency arrangements such as night, weekend and absences of key personnel.

(e) For management plans for conditionally approved areas -

(i) a statement as to whether BMS may be harvested for depuration or relaying or post harvest treatment when a conditional growing area in the closed status meets the requirements for the restricted classification; and

(ii) Where relevant, a statement that when pacific oysters are removed from the water for farm management purposes and the area closes due to conditions described in the management plan before the oysters are placed back in the water, the oysters must remain in the growing area for an acceptable period of time.

27 Re-evaluation of conditional areas

(a) The classification and harvest criteria of each conditional growing area must be re-evaluated by an animal products officer as part of the annual review. In addition to the requirements in clause 7(3), the re-evaluation must include:

(i) an evaluation of compliance with the management plan; and

(ii) a determination of the adequacy of reporting of failure to meet performance standards; and

(iii) a review of the cooperation of the agencies and persons involved.

28 Consultation requirements

(a) The management plan must be developed by the animal product officer in consultation with —

(i) the local shellfish industry; and

(ii) the individuals responsible for the operation of any wastewater treatment plants involved; and

(iii) any other relevant agencies involved in performance standards or other matters relating to the management plan.

(b) The purposes and conditions of the management plan must be understood and agreed upon in writing by the parties described in clause 28(a).

(c) Failure of any one party to agree on the conditions may constitute sufficient justification for an animal product officer to place the growing area into the closed status.

29 Prohibited classification

(1) Except for the harvest of spat for on growing, no person may harvest BMS from any area classified as prohibited unless that person ensures that BMS removed from such an area are effectively excluded from human consumption.

(2) A growing area, or part thereof, must be classified as prohibited if —

(a) No current sanitary survey exists; or

(b) A sanitary survey determines that —

(i) the growing area is adjacent to a sewage treatment plant outfall or other point source outfall of public health significance in accordance with sub-clause 4 below; or

(ii) the pollution sources contaminating the growing area are unpredictable; or

(iii) the growing area is contaminated with unacceptable levels of human or animal faecal waste; or

(iv) the growing area is contaminated with toxic substances causing the unacceptable levels of contamination in BMS.

(3) A growing area must be classified as prohibited if a risk assessment performed in accordance with Part 13 of this Notice indicates the BMS are not safe for human consumption.

(4) Sewage Treatment Plant and Point Source Outfalls

(a) When a sewage treatment plant outfall or any other point source outfall of public health significance is situated in or adjacent to a growing area an animal products officer must classify the area surrounding the outfall as prohibited.

(b) The prohibited area must be large enough to provide sufficient time for an Animal products officer to close the area to harvesting before a discharge could travel through the prohibited area to an area classified as approved, conditionally approved, restricted or conditionally restricted.

(c) For major point source discharges, such as a sewage outfall, a minimum prohibited area of 500 metres must be established in the growing area.

(d) The determination of the size of the area to be classified as prohibited adjacent to each outfall must include the following minimum criteria —

(i) the volume, flow rate, location of discharge, performance of the wastewater treatment plant and the bacteriological quality of the effluent; and

(ii) the decay rate of the contaminants of public health significance in the wastewater discharged; and

(iii) the characteristics of receiving water (e.g. bathymetry, current velocity, net transport velocity, water depth and volume, direction of flow, water stratification, tidal characteristics, dilution rate and likely dispersion); and

(iv) the wastewater's dispersion and dilution, and the time of waste transport to the area where BMS may be harvested; and

(v) the location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries.

(e) The size of the prohibited area must be determined using computerised steady-state simulation models such as the United States Environmental Protection Agency PLUMES Dilution models for Effluent Discharges or another model acceptable to the regional shellfish specialist.

(5) Spat taken from prohibited or unclassified areas for on-growing must be cultured for a minimum of 6 months in a growing area with a classification of approved, remote approved, conditionally approved, restricted, or conditionally restricted before being harvested for human consumption.

30 Status of growing areas

(1) Open status

The open status may be applied to any correctly classified growing area that is normally open for the purposes of harvesting BMS, subject to the limitations of the classification for the area.

(2) Closed status

(a) Any classified growing area may be placed in the closed status by an animal product officer for a limited or temporary period because of —

(i) an emergency condition or situation such as described in clause 21(5) of this Notice; or

(ii) the levels of biotoxins or toxic phytoplankton in concentrations of public health significance as stated in Part 6; or

(iii) unacceptable levels of faecal coliforms in growing area water or *E.coli* in BMS; or

(iv) failure to complete the 12 yearly sanitary survey, or annual review within 60 working days of the anniversary date; or

(v) conditions stipulated in the management plan of a conditionally approved or conditionally restricted area.

(vi) A request by the growers to place the area in a seasonal closure.

(b) Sampling requirements during a seasonal closure and prior to reopening must be acceptable to the regional shellfish specialist,

(3) Reopened status

(a) A growing area temporarily placed in the closed status as provided in sub-clause (2)(a) above may only be returned to the open status by an animal product officer when —

(i) the emergency situation or condition no longer exists and sufficient time has elapsed to reduce the *E.coli*, faecal coliforms, or toxic substances that may be present in the BMS and water or either of these as applicable, to background levels; and

(ii) studies are conducted in accordance with conditions acceptable to the regional 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.

(iii) if applicable, the requirements for reopening in clause 45(9) after biotoxin closure are met; and

(iv) if applicable, the requirements for reopening after conditional area closures in clause 26 are met.

Part 4 - Relaying of MBS

31 Application of this part

(1) This Part applies to relay operators, harvest operators, animal product officers, samplers and such persons must comply with the requirements of this Part.

32 General requirements

(1) BMS must not be relayed unless an animal product officer has issued a relay permit to the relay operator in accordance with the requirements in clause 33.

(2) BMS must not be relayed into a growing area unless the growing area is classified as approved, conditionally approved or remote approved.

(3) Each relay lot must be identified by a unique relay lot number.

(4) Each relay lot kept must be kept separate from other relay lots to prevent cross-contamination and mixing.

(5) Growing areas, or parts of growing areas containing relayed BMS must be marked by buoys, poles or other means so that relayed BMS are readily identified.

(6) That part of the growing area containing relayed BMS and an area an acceptable distance from the relayed BMS must be placed in the closed status by an animal product officer until the period of relay is completed in accordance with the conditions in the relay permit.

(7) Relaying requirements in this Part do not apply to the wet storage of BMS.

33 Conditions for relaying and application for relay permit

(1) The relay operator must apply to an animal product officer for a relay permit in accordance with the requirements of this Notice.

(2) The animal product officer may issue a relay permit for a period which must not exceed 12 months.

(3) The animal product officer may amend or revoke a relay permit when relay operating procedures are not complied with.

(4) The relay period must be at least 14 consecutive days when environmental conditions are suitable for purification, but may be reduced to a minimum of 5 days, by the animal product officer, when contaminant reduction studies demonstrate that the reduced time is adequate to assure contaminant reduction.

(5) A contaminant reduction study must be conducted by the relay operator to demonstrate the effectiveness of relaying in cleansing the shellfish of the contaminant to the background level for BMS in the relay growing area.

(6) The relay operator must develop a relay operating procedure and include this with the application for a relay permit to an animal product officer.

(7) The relay operating procedure must include the following matters —
- (a) the species and quantity of BMS to be relayed; and
- (b) the source growing area of the BMS to be relayed; and
- (c) the contaminant that the relay is intended to reduce to the background level of BMS in the relay growing area; and
- (d) information on the quality of the water and BMS from the source growing area; and
- (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 water temperature, salinity, turbidity and other environmental

factors which may affect the natural cleansing process of the BMS species to be relayed; and

(f) BMS and water monitoring procedures to identify when critical environmental values in the relay growing area may be approached; and

(g) the name of the certified sampler; and

(h) the security of the BMS from the time of harvest for relay to the time of relay to prevent BMS from being illegally diverted to retail, wholesale or processing;

(i) the method of transport to the relay growing area; and

(j) a map of the relay growing area showing the actual relay area and the proposed closure area around the relayed BMS; and

(k) the design and management of contaminant reduction studies; and

(l) the time of the year when the relaying may occur; and

(m) the method of marking the part of the growing area used for relaying; and

(n) the method of holding the relay BMS in the relay area - such as on sticks or in containers; and

(o) adequate separation between different lots of relayed BMS and between relayed BMS and adjacent BMS which has not been relayed; and

(p) the name and address of the harvest operator as shown in the register of harvest operators in accordance with regulation 35 of the regulations; and

(q) any other requirements an animal product officer considers necessary for local conditions.

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

(9) The relay operating procedure must be reviewed at least annually by the animal product officer.

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

(11) The animal product officer must specify in the relay permit the nature and frequency of information to be provided by the relay operator to the Animal product officer while the permit is in effect.

(12) All relaying operations must be effectively supervised by an animal product officer.

34 Record keeping

The relay operator must retain for a period of at least 4 years legible 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.

35 Contaminant reduction studies

(1) The contaminant reduction study must —

(a) address environmental, spatial and vertical factors which may affect the cleansing of the BMS; and

(b) include a study of a minimum of 5 samples (each sample must contain at least 12 individual BMS) being taken by a sampler, with 4 of the samples being taken from the approximate 4 corners of the relay area and the fifth sample from the approximate centre of the relay area, or at an equivalent depth and spatial coverage considered acceptable by the regional shellfish specialist; and

(c) adequately demonstrate that 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 critical environmental factors during the relaying period as required in the permit.

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

(a) representative BMS sampling, as described in clause 35(1)(b) of this notice before relay and on the last day of the relay, for the contaminant; and

(b) acceptable monitoring of critical environmental parameters such as water temperature, salinity and turbidity.

(3) An animal product officer 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 a conditionally approved, restricted or conditionally restricted area meeting the bacteriological water and BMS quality for restricted areas; and

(c) the relay period exceeds 60 days.

36 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 must be designed 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 the containers correctly labelled.

Part 5 - Wet storage of BMS

37 Application of this part

This Part applies to all persons involved in wet storage and the harvest of BMS after wet storage and such persons must comply with the provisions of this Part.

38 Source of BMS

(1) BMS intended for wet storage must only be harvested from an area classified as approved, remote approved when in the open status or conditionally approved or taken from a premises, operating under a registered Risk Management Programme for depuration, after the successful completion of the depuration

(2) BMS harvested for wet storage must be harvested, transported and labelled in accordance with the requirements of Parts 9 and 12 of this Notice.

39 Wet storage process

(1) Wet storage may be used for farm management purposes such as to store, condition or desand BMS.

(2) BMS which has not been grown on the seabed must not be wet stored on the seabed.

40 Containers used for wet storage

(1) Containers used for wet storage must be constructed of non toxic materials.

(2) The depth and configuration of BMS in containers must allow the BMS to pump (feed) normally.

(3) Containers must be frequently cleaned and maintained in such a manner as to ensure that adequate water flow is not impeded by fouling.

41 Wet storage areas

(1) Growing areas used for wet storage must meet all the requirements in this Notice for classified growing areas and the BMS must meet all the requirements in this Notice for BMS grown and harvested from a classified growing area.

(2) When a wet storage area classified as conditionally approved is placed in a status other than the open status, any BMS in wet storage in that area must be:
   (a) subjected to relay or depuration or post harvest treatment prior to human consumption; or
   (b) held in the wet storage site until the growing area is returned to the open status.

(3) Different lots of BMS must not be mixed while in wet storage.

42 Record keeping

(1) Persons involved in wet storage must keep complete and accurate records to enable each lot of BMS to be traced back to the source growing area.

43 Notification of wet storage operations

(1) Persons involved in the wet storage of BMS must notify an animal product officer in writing within 24 hours of the wet storage operation commencing of :
   (a) the source growing area and the wet storage growing area; and
   (b) the species and quantity of BMS being wet stored; and
   (c) a standard operating procedure including the documentation, harvesting transport and identification of BMS during the wet storage operation.

Part 6 - Marine biotoxin control

44 Application of this part

This Part applies to all animal product officers, samplers, growing areas 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.

45 Marine biotoxin management

(1) An animal product officer, in consultation with the shellfish industry, must develop and implement a marine biotoxin management plan for each growing area, in accordance with the requirements of this Notice.

(2) The purpose and conditions of the marine biotoxin management plan must be understood and agreed upon in writing by the animal product officer and the shellfish industry. The failure of any party to agree or a breach of the agreement or management plan by any party may be sufficient reason for the animal product officer to place the growing area in the closed status.

(3) The animal product officer must maintain the marine biotoxin management plan in a current and valid up to date state.

(4) The marine biotoxin management plan must include the following matters-
- (a) a map of the growing area, showing the location and identification of each marine farm and wild BMS growing area, to which the plan applies; and
- (b) the boundary, name and number of the growing area, if any; and
- (c) the species of commercial shellfish within the growing area; and
- (d) the location and GPS or other acceptable identification of the primary and secondary (where provided) BMS and phytoplankton sample stations; and
- (e) agency and personnel contact details at local, regional and national level in relation to regulatory, laboratory, shellfish industry, research matters; and
- (f) the routine monitoring programme for BMS and phytoplankton; and
- (g) the criteria and actions to be taken for increasing sampling in accordance with the marine biotoxin action plan in clause 46 when toxigenic phytoplankton in growing area water or biotoxins in BMS are detected; and
- (h) hydrographic details showing predominant currents and circulatory patterns which may affect the movement of phytoplankton in or adjacent to the growing area; and
- (i) the marine biotoxin test methods used for the respective biotoxin groups; and
- (j) management procedures in place for the use of screen test methods when confirmatory testing is required; and
- (k) management procedures that address the testing of BMS following phytoplankton trigger levels being exceeded; and
- (l) procedures for the notification of phytoplankton and biotoxin results from the laboratory to animal product officers and the shellfish industry; and
- (m) procedures and draft letters for growing area closure and re-opening; and
- (n) procedures for the recall and/or detention of BMS product resulting from a marine biotoxin closure; and
- (o) the procedure for opening seasonal growing areas, including scallop and dredge oyster fisheries, prior to the commencement of harvesting; and

(5) The animal product officer must conduct an annual review of the marine biotoxin management plan and append the annual review to the annual growing area review report. The annual marine biotoxin review must include the following matters —
- (a) a copy of the monitoring programme at the commencement of the year under review;
- (b) a discussion, rationale and data supporting any changes made to the marine biotoxin monitoring programme during the year;

(c) a summary of the phytoplankton activity including the exceeding of trigger levels and compliance with trigger level requirements;
(d) where applicable, discussion on data which suggest that amendments to the trigger levels or other aspects of the phytoplankton action level table in Table 6A are required;
(e) a summary of the BMS monitoring programme, including the reports specified in clause 45 (13);
(f) a summary of timeliness and condition of samples on arrival at the laboratory;
(g) compliance with the marine biotoxin action plan.

Table 6A – Phytoplankton Action Level Table (Cells per litre)

Phytoplankton Species	Martine Biotoxin	Level in composite sample to trigger flesh testing[1]
Alexandrium minutum	PSP	100
Alexandrium ostenfeldii	PSP	100
Alexandrium catenella	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
[4]*Karenia/Karlodinium/Gymnodinium Group*	NSP	250,000
Dinophysis acuta	DSP	500
Dinophysis acuminata	DSP	1,000
Prorocentrum lima	DSP	500
Gonyaulax cf spinifera	YTX	100
Protoceratium reticulatum	YTX	500

[1]When 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, when 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 when the combined percentage result from a DNA probe for the three most toxic species (*P. australis, P. multiseries and P. pungens*) exceeds 100,000 when applied to the original cell count (preserved seawater sample).

BMS analysis for domoic acid must be performed when the combined percentage result from a DNA probe for the five less toxic species exceeds 500,000 cells/l when 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 brevisulcata, Karenia mikimotoi, Karenia papilionacea, Karenia selliformis, Karlodinium micrum and Gymnodinium impudicum.*

(If there is evidence of fish kills in the coastal area, BMS analysis for toxins must be considered.)

(6) The animal product officer must immediately place a BMS growing area in the closed status when the level of biotoxin detected in the BMS is above the maximum permissible level described below in Table 6B.

Table 6B - 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/kg
Amnesic Shellfish Poison (ASP)	20 mg/kg of domoic acid
Neurotoxic Shellfish Poison (NSP)	20 Mouse Units (MU) per 100g
Diarrhetic Shellfish Poison (DSP)	The maximum level of okadaic acid, dinophysistoxins[1] and pectenotoxins[2] must be 0.16 mg of okadaic acid equivalents/kg
Yessotoxin Shellfish Poison (YSP)	The maximum level of YTX, 45 OH YTX, homo YTX and 45 OH-homo YTX must be 1 mg of YTX equivalents/kg
Azaspiracid Shellfish Poison (AZP)	The maximum level of AZA1, AZA2 and AZA3 must be 0.16 mg/kg of azaspiracid equivalents/kg

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

[2]Pectenotoxins include PTX1 and PTX2.

(7) The animal product officer may place a growing area in a closed status when toxigenic phytoplankton listed in Table 6A are increasing or levels of biotoxin have been detected in BMS below the maximum permissible level stated in Table 6B, as a precautionary measure to prevent the harvest of BMS which may contain biotoxins above the maximum permissible level stated in Table 6B, when delays in the collection of samples, conducting analyses or the receipt of results may allow the harvest of shellfish containing levels of biotoxins greater than the maximum permissible level.

(8) In relation to footnote 1 of Table 6A, where the BMS sample cannot be taken and submitted for analysis within 24 hours of the notification of the trigger level being exceeded, an animal product officer may extend the sample collection time to 48 hours to provide for unsafe environmental sampling constraints and if the BMS sample cannot be taken within this time, the animal product officer must close the growing area until such time as a BMS sample is taken, analysed and the results are below the maximum permissible level stated in Table 6B.

(9) For marine biotoxins for which cell counts of toxigenic producing phytoplankton or maximum permissible levels in BMS have not been established in this Notice, the Director General may determine the closure criteria.

(10) A growing area closed due to marine biotoxins under Clause 45 (6), (7) or (9) of this Notice must not be reopened until the animal product officer has determined that each of the following requirements have been adequately met —

(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;

(b) intertidal growing areas are sampled, at the low tide and high tide boundaries of the growing area where BMS are grown;

(c) each commercial species of BMS has been sampled;

(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;

(e) levels of biotoxins listed in Table 6B must be decreasing or static;

(f) on at least two consecutive sampling occasions, at least 48 hours apart, BMS sample results must be below the maximum permissible level stated in Table 6B;

(g) cell counts of toxigenic phytoplankton listed in Table 6A must be decreasing or static and below the trigger level stated in Table 6A;

(h) the hydrography of the growing area and adjacent marine areas is considered in conjunction with the patterns of toxigenic phytoplankton and BMS toxicity in assessing the potential for re-occurrence of the toxicity;

(i) no suspected cases of human illness, notified to the Medical Officer of Health, must 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;

(j) the information available must be adequate to make an informed and reasoned food safety decision.

(11) The animal product officer may exempt specific species of BMS from the marine biotoxin closure when data effectively demonstrates that the biotoxin has not been detected in the species prior to the closure at increasing levels below the maximum level.

(12) The animal product officer must ensure that an area reopened after a biotoxin closure undergoes intensive spatial and depth marine biotoxin and phytoplankton monitoring until such time as the level of biotoxin in the BMS and the levels of toxigenic phytoplankton are consistently below the background level.

(13) The animal product officer must prepare a report on each marine biotoxin closure and reopening. The report must —

(a) contain the data, analytical results, uptake and detoxification curves showing the relationship between the levels of toxigenic phytoplankton and the levels of toxin in the BMS, oceanographic and environmental conditions and all factors supporting the decisions; and

(b) be included in the annual marine biotoxin review report.

46 Marine biotoxin monitoring

(1) General requirements

(a) The animal product officer must design and implement a marine biotoxin monitoring programme for each growing area, as part of the marine biotoxin management plan.

(b) The marine biotoxin monitoring programme must include the sampling of water for the toxigenic phytoplankton listed in Table 6A (unless equivalent management procedures are considered acceptable by the regional shellfish specialist) and the sampling of BMS for the marine biotoxins listed in Table 6B.

(c) The marine biotoxin monitoring programme must be designed in accordance with this clause and the marine biotoxin action plan shown in Figure 6C.

(2) Selection and location of sample stations

(a) The selection of sample stations for BMS and phytoplankton must be based on the consideration of —

(b) the history of marine biotoxin and phytoplankton activity in the growing area and adjacent coastal marine areas; and

(c) hydrographic effects such as retention zones, upwellings, inshore and offshore current flow patterns and tidal effects; and

(d) the accessibility of the sample station in all weather conditions when harvesting is likely to occur; and

(e) the need to locate the phytoplankton sample station as near as practicable to the BMS sample station; and

(f) the need to provide spatial and depth coverage of BMS and toxigenic phytoplankton.

(3) Determination of the frequency of sampling

(a) Seawater must be sampled for the toxigenic phytoplankton listed in Table 6A from each growing area at least weekly, or at a frequency considered acceptable by the regional shellfish specialist.

(b) BMS, representative of each growing area, must be sampled at least weekly, or at a frequency considered acceptable by the regional shellfish specialist, for each of the marine biotoxins stated in Table 6B.

(c) In determining the frequency for sampling BMS for marine biotoxins, the animal product officer must ensure that the following criteria are met, unless otherwise approved by the Director General:

(i) the levels shown in the marine biotoxin action plan Figure 6C, under the different conditions;

(ii) the BMS testing programme must stand on its own, with phytoplankton testing being a support system;

(iii) all BMS and phytoplankton data from 1 January 1993 to the review date must be reviewed for the growing area and surrounding areas, including data from the marine biotoxin programme for non commercial BMS;

(iv) if a particular toxin has not been detected in BMS during the review period then the particular toxin must be tested for at a minimum of monthly intervals;

(v) if a particular toxin has been detected in BMS below the maximum permissible level then that particular toxin must be tested for at a minimum of once every 14 days;

(vi) if a particular toxin has been detected in BMS at a level above the maximum permissible level shown in Table 6B then that particular toxin must be tested for at least weekly;

(vii) the frequency determined on the above criteria may be adjusted for seasonality when, on at least 5 annual occasions, it has been demonstrated that there are clear differences in marine biotoxin activity between the seasons being differentiated for the growing area and adjacent coastal marine areas.

(4) Marine biotoxin action plan

(a) The marine biotoxin action plan describes the marine biotoxin management actions the animal product officer must take when marine biotoxin activity occurs in a growing area.

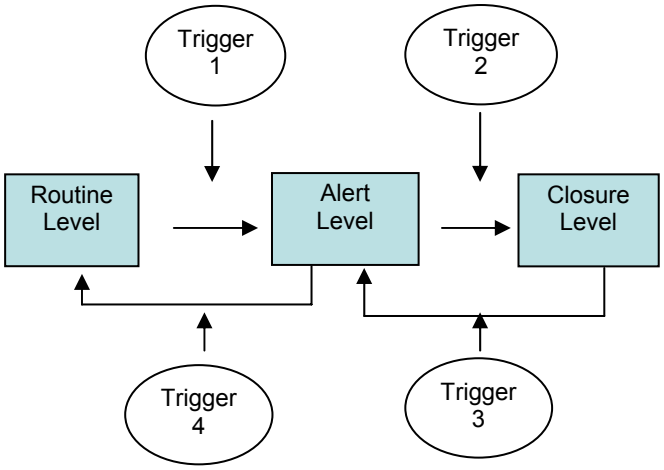
(b) Routine level means in accordance with clause 46(3) and during periods when there is no marine biotoxin activity.

(c) Alert level means when trigger levels are exceeded or levels of biotoxins are detected in shellfish below the maximum level and above the background level.

(d) Closure level means when biotoxins are observed in concentrations close to or exceeding maximum limits or when delays in obtaining samples or sample results occur.

(e) The change of frequency from one level to another must be triggered by specific observations or combinations of observations already identified as triggering factors or triggering scenarios (Figure 6C).

Figure 6C: Marine biotoxin action plan



Trigger 1:

- biotoxins detected above the background level but below the maximum level; or
- toxic phytoplankton present above trigger level.

Trigger 2:

- biotoxins detected above the maximum level; or
- delays in sampling or receipt of results.

Trigger 3:

- biotoxins detected above the background level but below the maximum level; or
- toxic phytoplankton detected above the trigger level.

Trigger 4:

- toxic phytoplankton detected below the trigger level; or
- biotoxins not detected or detected at a background level.

Part 7 – Sampling

47 Application of this part

(1) This Part applies to all persons responsible for carrying out sampling, including investigative and background sampling, required by this Notice and such persons must comply with the provisions of this Part.

(2) All sampling required by this Notice must be performed by a sampler certified under clause 49 of this Notice.

48 Responsibilities for sampling

(1) The animal product officer responsible for the growing area is responsible for ensuring that all sampling required by this Notice is performed in accordance with the requirements of this Notice. This includes —
- (a) the training, certification and listing of samplers and back up samplers; and
- (b) the suitability of equipment used by the samplers; and
- (c) an annual review of the sampling activity, including receipt of the samples at the laboratory; and
- (d) the inclusion of sampling activities in the growing area management plan.

49 Competency of samplers

(1) Every person carrying out sampling for the purposes of this Notice must have a certificate of competency issued by an animal product officer.

(2) Each sampler must be trained, certified as competent and audited by the animal product officer responsible for the sanitary survey, classification, marine biotoxin management and ongoing maintenance of the sanitary survey for the growing area.

(3) Prior to training and certification, each sampler must
- (a) demonstrate an adequate background in educational qualifications, scientific principles, trustworthiness, reliability and self motivation; and
- (b) declare any potential conflict of interest.

(4) The criteria for certification of samplers must include training and demonstrated competency in the relevant sampling areas, at least once every two years, in the following matters:
- (a) legislation, specifications and other requirements relating to BMS in relation to the regulated control scheme;
- (b) the sampling requirements of this Notice, 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; water samples by a variety of methods including net haul, hose, Van Dorn, grab methods for phytoplankton analyses; BMS samples for marine biotoxin analyses; BMS and water samples for heavy metal and other toxic substance analyses; and 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;
- (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 the shellfish industry;
(s) the significance of timing in adverse pollution condition sampling;
(t) the significance of monthly sampling under adverse pollution conditions;
(u) the significance of sampling on pre set dates for the systematic random sampling regime;
(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.

(5) The competency of the sampler must be reassessed by an animal product officer at least once every two years and a new certificate issued following successful reassessment.

50 Revocation of Certificate of Competency

(1) An animal product officer may revoke a certificate of competency issued under clause 49 if satisfied that the sampler has failed to comply with any relevant specifications or there has been a serious or repeated failure by the sampler to comply with the responsibilities specified in clause 51.

(2) Before revoking a certificate of competency, the animal products officer 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.

(3) After considering material (if any) supplied by the certificate holder under sub-clause (2)(b), the animal production officer must—
(a) make a final decision as to whether or not 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.

(4) 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, and subsections (3) to (8) of section 162 of the Act apply in relation to any such review.

51 Responsibilities of the sampler

(1) Every sampler must follow the direction of the animal product officer in relation to sampling.

(2) Every sampler must ensure that the equipment used during sampling is adequately calibrated and does not contaminate the sample.

(3) Every sampler must ensure that the sampling procedure does not result in contamination of the sample.

(4) Every sampler must identify, package, and store samples without delay after the sample has been taken.

(5) Every sampler who becomes aware that an unsuitable sample has been taken must notify the laboratory and animal product officer immediately by phone, followed up within 3 working days in writing.

(6) Every sampler must mark or clearly identify each sample package at the time of sampling in a manner that —
- (a) maintains the identity of the sample in a durable and legible manner; and
- (b) allows clear and correct matching to any relevant records; and
- (c) clearly identifies the place from which the sample was taken.

(7) Every sampler must —
- (a) individually pack each sample in packaging so that the sample does not contaminate any other sample or packaging material, and to prevent any error in identification of the sample; and
- (b) pack the sample using packaging that is durable, leak proof and free from contaminants; and
- (c) place samples for microbiological and biotoxin analyses immediately into a chilled container at a temperature of cooler than 10°C; and
- (d) 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.
- (e) 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.

52 Sample submission

(1) The sampler must ensure that a sample submission form accompanies each sample submitted to a laboratory and that it contains —
- (a) the name and contact details of the sampler and the relevant animal product officer; and
- (b) the date and time the sample was taken; and
- (c) the type of sample taken and the part of the sample to be tested; and
- (d) the sample station code, name, GPS coordinates or other acceptable location identifier, and where applicable the nearest corresponding marine farm number; and
- (e) the type of tests to be carried out; and
- (f) a section for lab use only for the recording of date of arrival, time of arrival, sample condition, flesh temperature and water temperature; and
- (g) any other information the Director-General may require.

(2) Each sample must be labelled and the label must clearly identify the sample to which it relates, and must state —
- (a) a unique sample number; and
- (b) the name or number or sample station from which the sample was taken; and
- (c) the sample type; and
- (d) the date and time of sampling.

unless other forms of labelling are considered acceptable.

Part 8 - Control of BMS harvesting

53 Application of this part

(1) This Part specifies the requirements undertaken by animal product officers in relation to the surveillance of growing areas and associated activities to ensure BMS are harvested in accordance with the requirements of the regulated control scheme

(2) This Part applies to all growing areas, animal product officers, regional shellfish specialists and persons responsible for surveillance activities.

54 Control of BMS growing areas

(1) General requirements

(a) An animal product officer must develop and implement a harvest control plan for each growing area to ensure that BMS are harvested only —

(i) From a growing area that is open for harvesting; or

(ii) For the purpose of relaying, depuration, or other post harvest treatment; and

(iii) By a vessel or vehicle specified in the register under regulation 35(d) of the regulations

(b) The harvest control plan must include surveillance activities for the audit of harvest documentation, transport of BMS, labelling of BMS, wet storage activities, relaying activities, sorting shed activities, BMS depot activities, and the transport of BMS from the source growing area for the purposes of relay, depuration or post harvest treatment.

(2) Surveillance of growing areas

(a) The animal product officer must ensure that surveillance of the following growing areas occurs at sufficient intervals to detect and/or deter illegal harvesting —

(i) growing areas classified as prohibited, restricted, conditionally restricted or conditionally approved based on a sanitary survey; and

(ii) growing areas in the closed status: and

(iii) growing areas used for relay.

(b) The surveillance activity must address the need for night, weekend, and holiday surveillance.

(c) Surveillance is considered adequate when the majority of an area is monitored.

(d) No more than two surveillances can be counted in a 24-hour period, and each must be a separate deliberate effort.

(e) If the animal product officer has current evidence that illegal harvest of BMS is occurring, the harvest control plan must be immediately re-evaluated and, if necessary, surveillance activity must be increased.

(f) The animal product officer may specify, in the harvest control plan, other persons who have undergone acceptable training, who may perform specified surveillance activities.

(3) Exceptions

Surveillance is not required under the following conditions-

(a) when there is no BMS production and the area has been depleted of BMS by harvesting, disease, or other causes; and

(b) when harvest from the area is not economically feasible due to the cost of harvesting exceeding the market value of the product;

(4) Frequency

(a) Each growing area must have surveillance at the frequency of one (1) time per 30 harvestable days when the area is in the closed status or prohibited except that when tidal, weather or other conditions prohibit harvesting on a particular day, that day is not included in the 30 harvestable day calculation.

(b) If the area is geographically remote, sparsely populated or has limited access such as no or very poor roads such that the potential for harvesting and marketing the BMS is severely restricted —

(i) the regional shellfish specialist may determine a surveillance frequency less than that required in sub-clause (4)(a) above; and

(ii) the animal product officer must include, in the harvest control plan, the additional surveillance activities such as airport, wharf, premises or transporter surveillance that will be used in lieu of traditional surveillance activities.

(c) Where the growing area is closed to harvesting during traditional non-harvesting seasons —

(i) the regional shellfish specialist must determine the frequency and nature of surveillance; and

(ii) the animal product officer must include in the harvest control plan, the additional surveillance activities such as airport, wharf, premises or transport surveillance and that will be used in lieu of traditional surveillance activities;

(5) Training

(a) The regional shellfish specialist must train and certify the harvest control animal product officers in the following:

(i) harvest control plan design and implementation; and

(ii) growing area classification and harvest criteria; and

(iii) harvest control legislation.

(6) Harvest control plan

(a) The animal product officer must prepare a harvest control plan for each growing area.

(b) The harvest control plan must be reviewed annually by the animal product officer and included in the growing area annual review report.

(c) Each harvest control plan must include the following-

(i) a list and description of each growing area to which it applies, including its classification, where surveillance is required and

(ii) the harvest criteria for conditional areas; and

(iii) the identification of growing areas where wet storage and relaying are carried out; and

(iv) the procedure used to prevent relayed or wet stored BMS being mixed with BMS from another area; and

(v) a written agreement, describing respective responsibilities, with other agencies that are likely to be conducting harvest control activities; and

(vi) the personnel, frequency and nature of surveillance for each growing area; and

(vii) surveillance staff contact details during work hours and after work hours; and

(viii) the name and address of the harvest operators and 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 (if applicable); and

(ix) the name or unique identifier of each vessel and vehicle used in the harvesting operation; and

(x) the written procedures describing the process of notifying harvest operators of the closure and re opening of growing areas; and

(xi) the methods used to inform animal product officers and others carrying out surveillance, of growing area classifications and status, and of any special activities undertaken in the area; and
(xii) an identification of any surveillance problems; and
(xiii) the type and frequency of reporting by surveillance personnel.

(7) Annual surveillance report —
(a) An annual surveillance report must be prepared by the animal product officer for each growing area and attached to the annual growing area review.
(b) The annual surveillance report must include the following-
(i) details of the surveillance activities performed during the preceding year including dates, personnel, times, week day, weekend, night surveillance activities, the number of days the areas were closed and the activities stated in clause 54(1)(b) above; and
(ii) confirmation that the required frequency of surveillance was achieved; and
(iii) details of warnings issued; and
(iv) details of any activities referred to the NZFSA Compliance and Investigation Group; and
(v) details of any legal actions undertaken.
(c) Must be included in the annual growing area review report.

Part 9 - Requirements for harvest operators, vessels and vehicles

55 Application of this part

(1) This Part applies to all harvest operators, vessels and vehicles used in the harvesting operation and to persons working on harvest vessels and vehicles and such persons must comply with the provisions of this Part.

(2) Harvest operators must comply with, and ensure compliance with, the relevant provisions of this Notice and the regulations.

(3) Clause 61(5) comes into force on 1 July 2007.

56 Registration and verification

(1) No person may use a vessel or vehicle for the harvest of BMS unless the name or unique identification number of each vessel and vehicle is shown on the register of harvest operators in accordance with regulation 35 of the regulations.

(2) A recognised verifier must conduct an inspection and prepare an initial verification report that addresses the requirements of this Part of the Notice not more than 3 months before the date of application for registration as a harvest operator.

(3) After initial registration, a recognised verifier must verify compliance, of each harvest vessel or vehicle with the requirements of this Notice, at least once every 12 months.

(4) The operator must notify a recognised verifier when a harvest vessel or vehicle is no longer used by the operator, including change of ownership, for the harvest of BMS.

57 Design of harvest vessels, vehicles, equipment and BMS containers

(1) The harvest operator must ensure that harvest vessels and vehicles are designed in such a way as to prevent contamination of BMS by bilge or other water.

(2) The harvest operator and persons working on the harvest vessels and vehicles must ensure that the vessels and vehicles are operated in such a way as to prevent contamination of BMS by bilge or other water.

(3) The BMS must be stored at a minimum of 25mm off the deck on vessels where the deck is not channelled, graded or adequately drained.

(4) When considered necessary by an animal product officer, the operator must provide effective coverings on harvest vessels and vehicles to protect BMS from exposure to direct sunlight, birds, or other conditions which may affect the quality of the BMS.

(5) Containers used for storing BMS must be clean and made from materials that will not contaminate the BMS.

(6) Bags or sacks must not be reused to contain BMS unless they are effectively washed and sanitised by soaking in a solution containing between fifty and two hundred parts per million free available chlorine for thirty minutes, or by using an equivalent sanitising method approved in writing by an animal product officer.

58 Operation of harvest vessels and vehicles

Harvest operators, persons nominated by the operator as responsible for the day-to- day management of the harvesting operations and persons working on harvest vessels and vehicles must ensure that-

(1) Water that comes into direct or indirect contact with BMS is potable water or water that meets the standard for an approved growing area as stated in clause 14; and

(2) 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

(3) Cats, dogs and pests are not allowed on harvest vessels or vehicle; and

(4) All 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 marketing; and

(5) All persons working on harvest vessels and vehicles are adequately trained in the requirements of this Notice; and

(6) BMS which are harvested and transported on a harvest vessel or vehicle for more than six hours must be shaded from the sun or sprayed with water of approved area quality while in the open status or chilled with ice or covered with clean wet sacks or subjected to other acceptable measures to minimise BMS deterioration; and

(7) The requirements of clause 73 are complied with in relation to the harvesting, transporting and unloading of BMS.

59 Disposal of human sewage from harvest vessels

(1) Human sewage must not be discharged overboard from a harvest vessel, or vessel assisting a harvest vessel unless the discharge occurs more than 500 metres from the growing area boundary.

(2) An acceptable marine sanitation device, portable toilet or other acceptable sewage disposal receptacle must be provided on each harvest vessel to contain human sewage, unless exempted by the Director General.

(3) Portable toilets and other acceptable sewage disposal receptacles must —
- (a) be used only for the purpose intended; and
- (b) be secured while on board and located to prevent contamination of BMS by spillage or leakage; and
- (c) be maintained in a sanitary manner; and
- (d) be constructed of impervious, cleanable material and have a tight fitting lid.

(4) Harvest operators must ensure that acceptable hand washing and sanitising facilities are provided on harvest vessels.

(5) All persons on board a harvest vessel must wash and sanitise their hands after using the toilet.

60 BMS washing

(1) The harvest operator is the primary person responsible for the washing of BMS prior to retail, wholesale or processing.

(2) BMS must be washed reasonably free of mud, marine flora, bottom sediments and detritus as soon after harvesting as practicable.

(3) Tanks and re-circulated water systems for washing BMS must be used only with the written approval of an animal product officer.

61 BMS identification and harvest declaration

(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 the following information:
- (a) the name or unique identification number of the harvest vessel or vehicle as specified in the register of harvest operators; and

(b) the growing area number or other acceptable identification; and
(c) the authority to farm or harvest BMS under the Fisheries Act 1996, Resource Management Act 1991 or any other relevant Act; and
(d) the date of harvest.

(3) A bulk unit of containers may be labelled with one harvest label provided that all containers in the unit are secured together by wrapping material, net or other acceptable means.

(4) Where the harvest lot is divided between a number of receivers, a copy of the harvest declaration must be provided to each BMS receiver.

(5) The harvest operator must ensure that all harvest declaration documents are sequentially numbered after 1 July 2007.

(6) The harvest declaration must not contain any corrections, erasures or alterations unless they are made in indelible ink, initialled and dated.

(7) The harvest operator or person nominated by the operator as responsible for the day-to-day management of harvesting operations must complete and sign a harvest declaration that must accompany each lot of BMS and be provided to the BMS receiver.

(8) The harvest declaration must include the following information in a clear indelible legible manner:
(a) the name or unique identification number of the harvest vessel or vehicle as specified in the register of harvest operators; and
(b) the printed name of the harvest operator as specified in the register of harvest operators; and
(c) the associated current identification of each permit or registration under the Fisheries Act 1996, Resource Management Act 1991, or any other relevant Act.; and
(d) the growing area number; and
(e) the date and start time of harvest; and
(f) the date and finish time of harvest; and
(g) the species and quantity of BMS; and
(h) in the case of BMS which has been harvested from the seafloor such as scallops, dredge oysters and dredge mussels, GPS or other acceptable harvest area identification must be stated on the harvest declaration; and
(i) the name and street address or NZFSA unique identifier of the BMS receiver; and
(j) a statement that the BMS referred to in the harvest declaration have been harvested and handled in accordance with the requirements of the BMS regulated control scheme; and
(k) the signature of the person nominated by the operator as responsible for the day to day management of the harvesting operations.

(9) Where the BMS have been wet stored, the harvest declaration must state the date the BMS was harvested from the wet storage area and identify the wet storage area as the harvest area.

(10) Where BMS are harvested for relay, the harvest declaration must identify the BMS as BMS harvested for relay by including the relay lot number in sub-clause (8)(g) above and in place of sub-clause (8)(i) above, the harvest declaration must state the growing area number and the associated current identification of each permit or registration under the Fisheries Act 1996, Resource Management Act 1991, or any other relevant Act of the relay site.

(11) Where BMS are harvested from a relay area at the completion of relaying, the harvest date must be the date the BMS was harvested from the relay area and the

harvest declaration must identify the BMS as relayed BMS by including the relay lot number in sub-clause (8)(g) above.

(12) Where the 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 time and date of departure from the facility.

Part 10 - Health of personnel

62 Application of this part

This Part applies to harvest operators, transport operators, BMS sorting shed operators, BMS depot operators and relay operators and such persons must comply with the provisions of this Part.

63 Health

(1) Every operator described in clause 62 must take reasonable measures to ensure that any person (including any visitor or contractor) who:

(a) is infected with, or a carrier of, an infectious disease in a communicable form as described in Section A, Part I, of the First Schedule of the Health Act 1956, and that it is likely to be transmitted through BMS; or

(b) is suffering from diarrhoea or vomiting; or

(c) is suffering from boils, sores, infected wounds or any other condition that cannot be adequately prevented from becoming a source of contamination;

must not work as a BMS handler or work in any sorting shed, depot or on any vessel or any area where he or she may contaminate the BMS unless the Medical Officer of Health confirms in writing that the medical condition of the person is not likely to contaminate the BMS.

Part 11 – BMS sorting sheds and depots

64 Application of this part

(1) This Part applies to BMS depot operators and sorting shed operators and such persons must comply with the provisions of this Part.

65 Listing of sorting sheds and BMS depots

(1) No person may use a BMS sorting shed or BMS depot unless the sorting shed or depot is listed under Part three of the regulations.

(2) Prior to listing, an animal product officer must conduct an inspection of each BMS depot and sorting shed and prepare an initial verification report that addresses the requirements of this Part.

(3) A copy of the initial verification report must accompany the application for listing.

(4) After initial listing of each BMS depot and sorting shed, an animal product officer must verify compliance of the listed depots and sorting sheds at least once every 12 months.

66 Requirements and Responsibilities of BMS sorting shed operators

(1) The BMS sorting shed operator must ensure that —

- (a) BMS are not processed, apart from washing, grading and chilling, in a sorting shed; and
- (b) sorting sheds are only used for the storage of BMS after harvest when conditions such as tide times, harvest times or other conditions determined by an animal product officer affect the transport of BMS from landing to the next point of business; and
- (c) persons who have access to the sorting shed—
  - (i) wear clothing that is not a source of contamination; and
  - (ii) refrain from behaviour that could contaminate the BMS; and
- (d) adequate steps are taken to exclude dogs, cats and pests; and
- (e) an acceptable inventory is maintained, using harvest declaration information, of all incoming and outgoing BMS; and
- (f) the sorting shed is provided with water of a sufficient quality such that it is not a source of contamination to the sorting shed or the BMS; and
- (g) the sorting shed and storage area are cleaned, and where necessary, sanitised; and
- (h) the sorting shed is operated within its capability and capacity; and
- (i) BMS is not stored in a sorting shed for more than twenty four hours; and
- (j) BMS is stored in a room, compartment or container that —
  - (i) is vermin proof; and
  - (ii) has tight fitting doors, lids, access ways; and
  - (iii) has flooring, structures that prevents BMS from coming into contact with BMS liquor; and
  - (iv) is not used to store petrochemicals, or other materials that may contaminate the BMS; and
  - (v) is constructed of materials which minimise contamination and deterioration of the BMS; and
  - (vi) where mechanical refrigeration is provided it is equipped with a calibrated thermostat and indicating thermometer and the indicating thermometer is visible from the outside of the sorting shed.
- (k) access is provided to an animal product officer at any reasonable time; and
- (l) BMS are labelled correctly at all times while in the sorting shed; and
- (m) the harvest declaration contains the sorting shed information stated in clause 61 of this Notice;

(n) a copy of the harvest declaration is retained by the sorting shed operator for a period of 4 years.

67 Requirements and Responsibilities of BMS depot operators

(1) The BMS depot operator must ensure that —

(a) BMS do not undergo any processing, apart from grading and chilling, in a BMS depot; and

(b) BMS depots are provided with —

(i) a refrigeration facility or some other means by which the BMS can be subjected to temperature control; and

(ii) water of a sufficient quality such that it is not a source of contamination to the BMS depot or the BMS; and

(c) BMS depots are designed, constructed and maintained to-

(i) permit easy and effective cleaning, and where appropriate, sanitising; and

(ii) minimise contamination and deterioration of BMS; and

(d) the BMS depot, facilities, equipment and essential services are cleaned and where necessary sanitised; and

(e) that cleaning and sanitising compounds are labelled, stored and maintained so as not to be a source of contamination; and

(f) only approved maintenance compounds are used within the BMS depot; and

(g) an acceptable inventory is maintained, using harvest declaration information, of all incoming and outgoing BMS; and

(h) the BMS depot is operated within its capability and capacity; and

(i) persons who has access to the BMS depot —

(i) wear clothing that is not a source of contamination; and

(ii) refrain from behaviour that could contaminate the BMS; and

(j) the BMS depot is equipped with a calibrated thermostat and indicating thermometer; and

(k) the temperature gauge used is visible from the outside of the depot; and

(l) appropriate steps are taken to exclude pests; and

(m) the harvest declaration contains the BMS depot information stated in clause 61 of this Notice;

(n) a copy of the harvest declaration is retained for at least 4 years.

Part 12 – Transport of BMS

68 Application of this part

This Part applies to transport operators, including harvest operators, from time of harvest to receipt at the primary processor or when the BMS are taken off the transport vessel or vehicle for retail or wholesale business and such persons must comply with the requirements of this Part.

69 Listing of transport operators

(1) No person may transport BMS unless that person is listed as a transport operator under Part 3 of the regulations.

(2) Prior to listing, an animal product officer must conduct an inspection and prepare an initial verification report, for each vessel or vehicle that the transport operator intends using for the transport of BMS, that addresses the requirements of this Part.

(3) A copy of the initial verification report must accompany the application for listing.

(4) After the initial listing of the transport operator, an animal product officer must verify compliance of each vessel or vehicle, used for the transport of BMS, with the requirements of this Notice at least once every 12 months.

70 Design and construction

(1) Transportation units, including vessels and vehicles, and loading equipment must be designed, constructed, equipped and operated to prevent contamination, deterioration and decomposition of the BMS.

(2) Where the deck of the transportation unit is not channelled, graded or adequately drained, the BMS must be stored a minimum of 25mm off the deck.

(3) Transportation units must be constructed from materials that will maintain the status of the BMS as suitable for processing or fit for intended purpose.

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

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

71 Hygiene and maintenance

(1) The hygiene and maintenance of the transportation unit and loading equipment must be such that contamination and deterioration of the BMS is minimised.

(2) Hygiene and behaviour of persons involved in the transportation of BMS must be such that contamination and deterioration of BMS is minimised.

72 Operation

(1) Trucks or other transportation units must be pre-chilled to 7°C when chilling of BMS has already commenced and when the ambient air temperatures are unacceptable.

(2) When mechanical refrigeration units are used, the units must be:
   (a) equipped with automatic controls; and
   (b) capable of maintaining the ambient air temperature in the loaded transportation unit at 7°C or cooler.

(3) The operator must ensure that cats, dogs, and pests are not allowed on the transportation unit.

(4) BMS storage containers on transportation units must be:
   (a) kept clean with potable water or growing area water meeting the approved area water quality in the open status; and
   (b) provided with effective drainage where appropriate.

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

(6) BMS that is transported with any other material that may be a source of contamination must be adequately separated from the source of potential contamination unless adequately protected in a manner that prevents contamination.

(7) Evidence of the maintenance of the refrigeration temperature during transportation must be available for verification by an animal product officer to ensure the suitability for fitness for intended purpose of the BMS is maintained.

(8) Determination of the BMS temperature and the taking of any samples must be carried out in such a manner that contamination of the BMS is minimised.

(9) The transport operator must ensure that persons transporting BMS are adequately trained and are aware of the relevant specifications.

73 Care of BMS

(1) All harvested BMS, not intended for wet storage or depuration, must be placed under temperature control in accordance with the protocol described in Schedule 4.

(2) Once BMS have been placed under temperature control, the BMS storage area or transportation unit must be continuously maintained at 7°C or cooler until processing or the BMS are taken off the transportation unit into the wholesale or retail business except for points of transfer such as loading docks in which case the BMS must not remain out of refrigeration for periods of more than two hours.

(3) The provision of adequate quantities of visible ice in or on the container of BMS on a vessel or vehicle will be sufficient compliance for continuously maintaining temperature control.

(4) When BMS has been placed under temperature control, there must be a continued downward trend in BMS temperature until the BMS reach an internal temperature of 10°C or cooler.

(5) BMS must not be left unattended or unprotected at a wharf, public place or any other place outside a building.

(6) BMS harvested for depuration, relaying, wet storage, processing, packing or entering wholesale or retail business must be protected from contamination and microbiological deterioration from point of harvest to reception at the processor, depuration plant, relay area, wet storage area or entering wholesale or retail business.

(7) The transport operator must ensure that all persons working on harvest vessels are adequately trained and are aware of the relevant specifications.

74 Record keeping

Transport operators must maintain records as required by Part 17 of this Notice.

Part 13 – Microbiological risk management

75 Application of this part

This Part applies to all growing areas and animal product officers.

76 Outbreaks of BMS related illness

(1) When BMS are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one person in the case of marine biotoxin poisoning or as the regional shellfish specialist determines relevant), the animal product officer must determine whether an epidemiological association exists between the illness and the BMS consumption, including —

(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.

(2) When an animal product officer has reason to suspect an epidemiological association between an illness outbreak and BMS consumption, an animal product officer must initiate an investigation of the illness outbreak immediately to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling.

(3) When the investigation outlined in clause 76(2) does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the animal product officer must —

(a) immediately place the relevant part of the growing area in the closed status; and

(b) notify the New Zealand Food Safety Authority that a potential health risk is associated with BMS harvested from the implicated growing area; and

(c) as soon as practicable, transmit to the New Zealand Food Safety Authority information identifying the processors and exporters handling the implicated BMS; and

(d) promptly initiate detention of product and prepare for a BMS recall .

(4) When the investigation outlined in clause 76(2) of this Notice demonstrates that the illnesses are related to post-harvesting contamination or mishandling, growing area closure is not required. However, the animal product officer must —

(a) notify the New Zealand Food Safety Authority; and

(b) promptly initiate recall procedures.

(5) When the investigation outlined in clause 76(2) of this Notice cannot be completed within 24 hours, the animal product officer must follow the closure procedure outlined in clause 76(3). If the investigation does not indicate a growing area problem, the area must be immediately reopened.

(6) Upon closing a growing area for illness causes other than naturally occurring pathogens or biotoxins, the animal product officer must review the growing area classification and determine if a growing area classification problem exists. The review must include at a minimum —

(a) a review of the growing area classification file records including at least the last three years water and shellfish bacteriological data; 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 water and shellfish bacteriological data subsequent to the illness outbreak.

(7) Upon closing an implicated portion of the growing area for naturally occurring pathogens and/or biotoxins, the animal product officer 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 growing area closed until it has been determined that levels of naturally occurring pathogens or biotoxins are not a public health concern.

(8) When the growing area is determined to be the source of the problem, the animal product officer must:
(a) maintain the growing area in the closed status until —
(i) s/he verifies that the area is properly classified and the harvest criteria are correctly set, using the last 3 years bacteriological data, in compliance with the requirements in this Notice; and
(ii) s/he has determined that the event which caused the contamination no longer exists and, based on a contaminant reduction study stated conducted in accordance with clause 35(1)(b) of this Notice, that the pathogen is no longer present in the growing area BMS; and
(b) keep the area closed for a minimum of 28 days from the end of the pollution source if the illness is consistent with viral aetiology; and
(c) prepare a written report summarising the findings of the investigation and actions taken and include this in the next annual growing area report.

77 Presence of human pathogens in BMS

(1) When human pathogens are detected in BMS, an animal product officer must investigate the harvesting, distribution, and processing of the BMS.

(2) Growing Area Investigation
(a) The animal product officer must review the following factors:
(i) the documentation to trace the BMS to its source; and
(ii) the classification and harvest criteria assigned to the growing area and whether the sanitary survey data supporting that classification is current; and
(iii) the probability of illegal harvesting from areas classified as restricted or prohibited, or in the closed status.
(b) The animal product officer may take no further action when it is determined that —
(i) the growing area is properly classified; and
(ii) no illegal harvesting is taking place; and
(iii) there is no reason to believe that the growing area is the source of the pathogens.
(c) When the animal product officer determines that the growing area is not properly classified or that the growing area is the source of the pathogen, the animal product officer must take immediate action to —
(i) change the existing classification to the correct classification; or
(ii) close the growing area until the correct classification can be determined.

78 Sewage events

(1) When an animal product officer reasonably believes that a growing area has been impacted by a sewage event, the growing area must be closed for 28 days from the date of the end of the event, unless the regional shellfish specialist determines that a greater or lesser time is required.

79 Risk management and tolerance levels

(1) Pathogen present

When a growing area continues to demonstrate the presence of human pathogen isolates in BMS in the absence of illness, the animal product officer must perform a risk assessment to determine the correct classification for an area.

(2) Established tolerance levels

(a) When the established tolerance level for a particular pathogen isolate is not exceeded, the animal products officer —

(i) must maintain a written summary of the finding and the data supporting the finding and include it in the annual review report; and

(ii) may leave the growing area in its present classification.

(b) When the established tolerance level for a particular pathogen isolate is known and there are no known outbreaks of BMS associated disease caused by that pathogen in a particular growing area, the animal product officer must —

(i) leave the growing area in the open status of its classification when the tolerance level is not exceeded; and

(ii) place the growing area in the closed status of its classification when the tolerance level is exceeded.

(c) When the established tolerance level is exceeded, the animal product officer may —

(i) maintain the growing area in the closed status of its current classification; and

(ii) reclassify the growing area to the restricted or prohibited classification; or

(iii) reclassify the growing area to the conditionally restricted classification and establish a management plan.

(d) Any management plan based on BMS exceeding established tolerance levels must —

(i) meet all appropriate requirements for a management plan for the conditionally approved or conditionally restricted classification; and

(ii) specify the additional criteria associated with the particular pathogen isolated that the growing area must meet to be in the open status of its classification; and

(iii) document the scientific basis for the additional criteria; and

(iv) provide for periodic retesting of the BMS ; and

(v) provide for the growing area to be placed in the closed status if the criteria are exceeded.

(3) Established tolerance levels not known

(a) When an established tolerance level does not exist for the particular pathogen isolated, the animal product officer must seek direction from the regional shellfish specialist and assess the public health significance of the levels of the pathogen found in the BMS. When the animal product officer determines that —

(i) the levels are acceptable, the growing area must remain in the open status of its classification; or

(ii) the levels are unacceptable, the growing area must be placed in the closed status of its classification.

(b) If a growing area is placed in the closed status, the animal product officer may elect to —

(i) maintain that status indefinitely; or

(ii) reclassify the area to the restricted or prohibited classification; or

(iii) reclassify the area to the conditionally restricted classification and establish a management plan.

80 Presence of toxic substances in BMS

(1) Upon determination that toxic substances, including heavy metals, chlorinated hydrocarbons, petroleum products or natural toxins are present at levels of public

health significance in BMS, the animal product officer must investigate the harvesting, distribution, and processing of BMS and take necessary corrective action in accordance with the procedures described in clause 77 of this Notice.

(2) When a growing area continues to demonstrate the presence of toxic substances in the absence of illness, the animal product officer must perform a risk assessment to determine the correct classification of the area. The risk assessment and subsequent risk management must follow the procedures outlined in clause 76 of this Notice.

Part 14 – Marinas

81 Application of this part

This Part applies to all marinas in or adjacent to growing areas except marinas covered by acceptable management plans.

82 Classification

(1) The area within any marina which is in or adjacent to a growing area must be classified as —
- (a) conditionally approved; or
- (b) conditionally restricted; or
- (c) prohibited.

83 Adjacent water

(1) Where growing area water adjacent to a marina classified under clause 82 of this Notice may be impacted by pollution associated with the marina, a dilution analysis must be used by an animal product officer to determine if there is any impact on adjacent waters.

(2) The dilution analysis must be based on the volume of water in the vicinity of the marina.

(3) The dilution analysis 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 analysis predicts a theoretical faecal coliform loading greater than 14 faecal coliform MPN per 100ml, the waters adjacent to the marina must be classified as prohibited.

(5) If the dilution analyses predict a theoretical faecal coliform loading less than or equal to 14 faecal coliform MPN per 100ml, the waters adjacent to the marina may be classified as —
- (a) approved; or
- (b) conditionally approved.

(6) If the animal product officer chooses not to determine a specific occupancy per boat rate by investigation in specific areas or sites, the animal product officer must assume a minimum occupancy rate of two persons per boat.

Part 15 - Shellfish laboratories

84 Application of this part

This Part applies to all laboratories and persons conducting analyses required by this Notice and such laboratories and persons must comply with the provisions of this Part.

85 General

(1) Each shellfish laboratory must ensure that —

(a) it has International Accreditation New Zealand (IANZ) accreditation to NZ/ISO/IEC 17025:1999 for the tests performed, or have an approval in writing from the Director-General; and

(b) it undergoes any other evaluation or audit as required by the Director-General; and

(c) where the laboratory conducts analyses of seawater samples for toxigenic phytoplankton, the laboratory employs a phytoplankton taxonomist who has attended an Intergovernmental Oceanographic Commission Advanced Course in Phytoplankton Taxonomy or, as an interim measure, an alternative course approved by the Director-General.

(d) it advises the Director-General immediately, whenever the laboratory is unable to comply with any specification contained within this Notice.

(e) it advises the Director-General immediately when a major non-conformance that may affect the sample result occurs.

86 Receipt of samples

(1) The laboratory must ensure that each sample and sample submission form is inspected at the time of receipt at the laboratory to ensure that —

(a) the sample is clearly marked or identified to allow it to be traced back to the sample submission form; and

(b) the information on the sample submission form is consistent with the sample and meets the requirements of clause 52 of this Notice; and

(c) a sampler certified under clause 49 has taken the sample; and

(d) the sample has been submitted to the laboratory within 24 hours of sample collection, or within 48 hours if there have been significant transportation delays involved; and

(e) the sample packaging is intact; and

(f) there are no visible signs of contamination of the sample; and

(g) the sample provided is suitable for the particular test required; and

(h) the sample temperature for marine biotoxin and microbiological samples is less than 10°C, unless sampling occurred on the same day and the sample has not had adequate time when placed in a chilled container to reach a temperatures cooler than 10°C.

(2) If any of the requirements of this clause have not been met, or if the laboratory considers the sample to be unsuitable for testing, the laboratory must:

(a) make a considered decision on whether to analyse the sample or seek direction from the animal product officer responsible for the growing area; and

(b) record the details of the defect; and

(c) notify the animal product officer within one working day of sample receipt; and

(d) analyse as a priority any replacement sample.

(3) The laboratory must ensure that a record is kept of all notifications to the sampler and the animal product officer when non-compliant samples have been submitted to the laboratory.

(4) The 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.

87 Sample temperature and storage

(1) The laboratory must ensure that all marine biotoxin and microbiological samples are maintained in the laboratory after sample receipt at temperatures 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.

88 Laboratory methods

(1) The laboratory must only use test methods, approved by the Director-General, on samples taken to meet the requirements of this Notice.

(2) When a laboratory wishes to modify or change an approved test method, it must apply to the Director-General for approval prior to the use of the changed method.

(3) On receipt of an application to change an approved method, the Director-General may approve the application, require further information on the proposed method change or decline the application.

(4) Applications to change an approved marine biotoxin method must include validation documentation and be submitted to NZFSA in accordance with the principles described in the current version of the Seafood Industry Agreed Guideline 'A Guide for the Validation and Approval of New Marine Biotoxin Test Methods'.

(5) The Director-General may specify, by notice in writing, steps and conditions for the preparation and testing of samples for a particular method, and the laboratory must comply with the notice.

(6) Where new toxins or metabolites are detected, and determined by the Director-General to be of public health significance, the Director-General may determine the test methods for the new toxin or metabolite and the maximum permissible levels for the purposes of public health protection.

89 Method performance

(1) The laboratory must ensure that each test method performs within the limits or requirements of the method performance standards determined by the laboratory.

(2) The laboratory must have in place corrective actions and procedures to deal with, or remedy, the situation where a method fails to perform within the set of limits and requirements.

(3) Where batch control values are outside the limits or requirements of the method performance standards and the laboratory considers this may affect the results, the laboratory must ensure that samples in the batch are re-analysed.

(4) If there is an unidentified test response for marine biotoxin methods, the laboratory must immediately notify the Director-General, investigate the response, and identify where possible the unknown compound.

(5) The laboratory must provide the Director-General with a report of all unidentified test response findings once the investigation is complete.

(6) The Director-General may direct a laboratory to —

(a) undertake independent confirmation, within the laboratory or at another laboratory determined by the Director-General, or repeat the test of a sample, if 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.

90 Test time frame

(1) The laboratory must ensure that microbiological and marine biotoxin sample analysis commences within a 24 hours from sample collection. When significant sample transportation delays have occurred and been documented, the analysis may begin within 48 hours of collection, provided that sample temperatures have been maintained as described in 86(1)(h) and 87(1) above, and that only live shellfish are selected for analysis.

(2) BMS samples which are analysed for marine biotoxins by 'non-bioassay methods', such as High Pressure Liquid Chromatograph, Liquid Chromatograph Mass Spectrometry (LC-MS) or Enzyme-Linked Immunosorbent Assay (ELISA) must be tested, and the result confirmed internally in the laboratory, where required, and the results reported within two working days of sample receipt at the laboratory.

(3) BMS samples which are analysed for marine biotoxins by 'bioassay methods' must be tested, and confirmed where required, within 4 working days of sample receipt at the laboratory.

(4) Seawater samples which are analysed for microbiological purposes must be tested and confirmed where required within 5 working days of sample receipt at the laboratory.

(5) BMS samples which are analysed for microbiological purposes or other purposes under this Notice must be tested and confirmed where required within 3 working days of sample receipt at the laboratory.

(6) Seawater samples which are analysed for the purpose of phytoplankton monitoring must be tested and confirmed where required within 24 hours of sample receipt at the laboratory.

(7) The laboratory may be given written approval from the Director-General to extend the test timeframe if —
(a) the test method routinely requires longer periods; or
(b) complex confirmatory procedures make a definitive time period difficult to estimate; or
(c) a technical failure has been encountered in the laboratory; or
(d) sample transport difficulties.

(8) In requesting an extension to the test timeframe, the laboratory must include information on —
(a) the test to be performed; and
(b) the reason for extension; and
(c) the revised suggested reporting time; and
(d) where applicable the corrective actions that will be taken to resolve the technical failure.

91 Reporting of result

(1) If required by the Director-General, each laboratory must report analytical results and sample information into a NZFSA database within 24 hrs (daily) of the result being confirmed and the Director-General may specify the format of reporting.

(2) The laboratory must ensure that where marine biotoxin results are reported the units must be expressed in units as described in Table 6B of this Notice.

(3) The laboratory must ensure that for marine biotoxin results the test reports clearly show which toxins are required to be summed for each toxin group, and the total level obtained for each toxin group requiring summing must also be shown.

(4) The laboratory must ensure that marine biotoxin results obtained below the limit of detection of the test method are reported as 'Not Detected'.

(5) The following results must be verbally communicated to the animal product officer responsible for the growing area, or their nominated representative, within 1 hour after confirmation of the analytical result and immediately confirmed in writing – *E.coli* levels in BMS greater than 230 MPN/100g; faecal coliform levels in seawater greater than 14MPN/100ml; levels of phytoplankton greater than the trigger levels stated in Table 6A and levels of marine biotoxins in BMS greater than the maximum permissible levels shown in Table 6B of this Notice.

92 Documentation and records

(1) The laboratory must ensure that all data relating to samples received during an analytical year is retained for a minimum period of 4 years from completion of that year.

(2) If any modification is made to any record required to be kept by the laboratory under these specifications, the documentation concerning that record must show:
- (a) the person who made the modification; and
- (b) the date of the modification; and
- (c) the reasons for the modification.

(3) The laboratory must submit an annual report to the Director-General within 60 days of the beginning of each calendar year. The 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 NZFSA audits; and
- (g) any other information the Director-General may require relating to the requirements of the regulated control scheme.

93 Participation in inter-laboratory comparison programme

(1) The Director-General may require participation of each shellfish laboratory in specific inter-laboratory comparison programmes and the laboratory must participate as required.

(2) The laboratory must ensure that any amendments to the inter-laboratory comparison programme schedule are forwarded to the Director-General as they occur during the course of the year.

(3) The laboratory must forward to the Director-General within 5 working days of obtaining the information a copy of its results and the report from the inter-laboratory comparison programme agency.

(4) If a laboratory has been alerted to a problem in an inter-laboratory comparison programme, the laboratory must, within 15 working days of the receipt of the notification, provide the Director-General with a report stating the reasons why the result occurred and the corrective action to be taken by the laboratory to prevent a recurrence of the problem.

(5) The laboratory must ensure that all inter-laboratory comparison programme test samples are handled, prepared and analysed in the same manner as samples

tested for the purposes of this Notice, unless the inter-laboratory comparison programme specifies otherwise.

(6) If an inter-laboratory comparison programme is not available for a particular matrix or test method other means must be used by the laboratory to determine laboratory proficiency as required by the Director-General.

Part 16 – Calibration

94 Application of this part

This Part applies to equipment used for measuring for the purposes of this Notice.

95 Calibration and measuring equipment suitability

(1) Measuring equipment, such as thermometers, salinity meters, rainfall gauges, that are used to provide critical measurements, must —

(a) have the accuracy, precision and conditions of use appropriate to the task performed; and

(b) be calibrated against a reference standard showing traceability of calibration to a national or international standard of measurement (where available), or (if no such reference standard exists) be calibrated on a basis that is documented in, or incorporated by reference into, the sanitary survey; and

(c) be uniquely identified to enable traceability of the calibrations and to identify the calibration status.

(2) Minimum frequencies of calibration must be specified in the sanitary survey report for each piece of measuring equipment used to provide critical measurements, or used as reference standards, taking into account the following (as appropriate) –

(a) the stability of the equipment; and

(b) the nature of the measurement; and the manufacturer's instructions.

(3) The equipment operator must have safeguards in place to prevent unauthorised adjustments to the calibration of the measuring equipment, including movement of the equipment where this may invalidate calibration.

Part 17 - Record keeping

96 Application of this part

This Part applies to all persons required to keep records under this Notice, and such persons must comply with the provisions of this Part.

97 Record keeping

(1) Operators and other persons as required in this Notice to make records must retain records to demonstrate that the requirements of this Notice have been met.

(2) Records must be —

(a) accessible to an animal products officer and the Director-General and any other person authorised by the Director-General; and

(b) retained for a period of at least 4 years or other period where provided in this Notice; and

(c) retrievable within 24 hours.

(3) Documentation of BMS movement must be such that trace back to the original growing area can be conducted.

Schedule 1

Minimum sanitary survey requirements

Sanitary survey and classification work must follow the format in clause (1) and all matters listed in clauses (2) to (9) must be included in the planning, conducting and writing of the sanitary survey.

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 current identification of each permit or registration under the Fisheries Act 1996, Resource Management Act 1991 or any other relevant Act in the growing area; 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
- (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 areas; 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
- (a) species of BMS expected to be grown 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
- (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 when closed.

3 Pollution source survey

(1) Survey procedures.

(2) Personnel involved and time period including-
- (a) survey plan - procedures for:
  - (i) shoreline reconnaissance; and
  - (ii) sampling of water and BMS; and
  - (iii) sampling of pollution sources; and
  - (iv) determination of sites for sampling stations; and
  - (v) GPS, map references or other acceptable identification of each potential pollution source; and
  - (vi) sample collection methods and practices; and
  - (vii) analytical methods; and
  - (viii) laboratories used.

4 Identification and evaluation of pollution sources

(1) Exploration of all visible discharge points.
- (a) domestic wastes shown on maps including-
  - (i) discussion on 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.
- (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 area (cf clause 26).
- (c) operational effectiveness:
  - (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.
- (d) stormwater:
  - (i) combined disposal systems; and
  - (ii) drainage ditches, pipes and runoff.
- (e) industrial wastes.

(f) radionuclides, including a copy of the latest letter from the National Radiation Laboratory on the status of radiation.
(g) agricultural practices including-
  (i) use of fertilisers; and
  (ii) use of herbicides, pesticides etc; and
  (iii) dairy shed waste disposal methods.
(h) wildlife and domestic animals:
  (i) numbers and whereabouts shown on a map; and
  (ii) unfenced access of animals to watercourses and growing areas.
(i) silviculture practices.
(j) boat traffic and the presence of houseboats.
(k) non-point pollution sources.

5 Hydrographic and meteorological characteristics shown on maps

(1) Physiography (description of body of water) including-
  (a) physical description: width, length and depth; and
  (b) channels; 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.

(2) Tidal influences including-
  (a) type; and
  (b) amplitude; and
  (c) tidal exchange rate; and
  (d) currents including velocity and direction; and
  (e) effect of turbidity in the growing area on BMS cleansing activity.

(3) Rainfall and runoff including-
  (a) amount, summary of last 5-10 years; and
  (b) seasonal variation; and
  (c) frequency of significant rainfalls; and
  (d) discussion on ground saturation influences on runoff; and
  (e) discussion on the rain gauge system/salinity system/river height system including whether telemetric or manual. GPS reference points. Details of auditing, reading, calibration, maintenance, notification, deputy gauge readers etc; and
  (f) heaviest rainfalls in last 5 years.

(4) Winds including-
  (a) strength; and
  (b) directions; and
  (c) when or seasonality; and
  (d) effect of wind in tidal estuaries, harbours and inlets.

(5) River discharges including-
  (a) volumes; and
  (b) seasonality; and
  (c) discussion on time for river to rise and fall after heavy rains and time for rains to reach river gauge and the time 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.

(6) Currents including-
  (a) tidal; and
  (b) effect of tide on pollution in the growing area; and
  (c) wind driven; and

(d) flood; and
(e) times; and
(f) dispersion and dilution; and
(g) effects of ocean currents on growing areas in bays, harbours and inlets.

(7) 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 sampling stations for all samples such as bacteriological water and BMS; marine biotoxin –BMS and phytoplankton.

(2) Sampling plan and justification for:
(a) water; and
(b) BMS; and
(c) phytoplankton; and
(d) BMS for marine biotoxins; and
(e) heavy metals; and
(f) other toxic substances; and
(g) rationale for spatial and depth coverage for bacteriological and marine biotoxin samples.

(3) Description of the proposed annual monitoring programme:
(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; and
(e) sample collection, handling and transport; and
(f) analytical procedures; and
(g) biotoxin and toxic algae history in and adjacent to the growing area.

(4) Data presentation (tables).

(5) Data analysis including-
(a) statistical criteria demonstrating compliance with bacteriological standards; and
(b) advanced statistical tests; and
(c) data presented in summary table; and
(d) include full calculations and statistics.

(6) 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-
(i) 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, 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, wind, tide, rainfall, etc., 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 data variability.

(2) Data analysis and discussion on the interrelationships of the above factors in relation to their effects on the quality of the growing water and BMS.

(3) Management plans of conditional areas must be included in the sanitary survey report.

9 Conclusions

(1) Classification

(a) the classification as described in clause 21 of this Notice; 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.

(2) The management plan for conditional areas.

(3) Recommendations for further studies.

Schedule 2

1 Interpretation of the 10% Factor

(1) The "10% above 43" criterion is not considered adequate to protect public health when known meteorological or hydrological events that occur intermittently are shown to adversely affect growing water quality. The "percentage factor" is not intended to allow for variation in the data caused by changes in environmental conditions at the time of sampling. The "percentage factor" is intended for use with a data set collected under uniform conditions, and is intended to reflect the inherent variation of the MPN methodology, although the current "10% not greater than" levels allow a somewhat greater degree of variation than that attributable to the MPN test alone.

(2) The dilemma facing the animal product officer is how to distinguish between the inherent variation of the MPN test and that resulting from intermittent environmental conditions that degrade water and BMS quality. It is not intended that shellfish growing waters be classified that are polluted 10% of the time i.e. in determining compliance with bacteriological standards, elevated bacteriological levels must not be associated with environmental conditions, particularly those that are described in conditional management plans as adverse pollution conditions.

Schedule 3

Systematic random sampling (SRS) strategy

1 Background

(1) In classifying growing areas that are not affected by point-source pollution, a systematic random sampling and data analysis strategy (SRS strategy) may be used in place of the adverse pollution condition sampling strategy (APC strategy).

(2) The requirements of clauses 7 and 8 of this Notice must be complied with to establish that the growing area is not affected by point-source pollution.

(3) Prior to a systematic random sampling strategy being used, the sampling plan for the year ahead must be acceptable to the regional shellfish specialist. The sampling plan must address unsafe sample collection (boating) conditions by designating an alternate sampling day or by allocating extra sampling days in the schedule that may be used when needed.

2 Requirements for the use of a systematic random sampling strategy

(1) The following sampling requirements must be fully complied with:

(a) A minimum of six 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) A minimum of 30 of the most recent samples collected at each station must be required for the classification of a growing area. 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. Growing area classifications may be maintained under APC or the transition strategy described above until sufficient data 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 one significant number.

(2) The annual evaluation must include an analysis of laboratory results pertinent to at least the last 30 samples collected at each station in areas not affected by point sources.

3 Background to the use of the ninetieth percentile

(1) The systematic random sampling strategy involves calculating the estimated 90th percentile. This guideline is provided to ensure uniformity in calculating the estimated 90th percentile.

(2) Animal product officers, in consultation with the shellfish industry, have the option to continue using directed sampling to capture adverse pollution conditions or to adopt

the SRS strategy. When the latter is employed to collect growing water samples, the method described below must be used to calculate the estimated 90th percentile.

(3) The public health concern is that although many waters may meet the median, and percentage factor criteria in the regulated control scheme, some growing area sample stations still display a considerable level of variation in a distribution of sampling results. In such a situation, the risk to the BMS-consuming public has been a concern, since sampling data of this type may indicate that the growing areas are intermittently polluted.

(4) The 1965 revision of Part I of the USFDA National Shellfish Sanitation Programme Manual of Operations discussed this point (page 11, footnote 6) by demonstrating that an MPN tolerance factor was involved in the derivation of the 230 MPN/100 ml (total coliform "percentage factor") value. This value, for use with growing waters with uniform bacterial densities, acknowledges that "the MPN determination is not a precise measure of bacterial concentrations". The footnote continues:

> *Thus, in repeated sampling from water having a uniform density of bacteria varying MPN estimates will be obtained. The use of the tolerance factor 3.3 (applicable only to 5 tube decimal dilution MPN's) is one method of recognizing this variation. For example, in a body of water in which the median concentration of coliform bacteria is 70 per 100 ml, 95% of observed MPN's will be between 20 and 230 per 100 ml; i.e. 70/3.3 = 21 and 70 x 3.3 = 230.*

(5) When environmental events (such as rainfall) produce unfavourable effects on water quality, the distribution may contain data points that vary widely from the geometric mean. Such a data set would probably contain upper outliers that represent periods when the BMS may be exposed to enormous quantities of pollution. In this situation, the determination of conformity for a randomly collected set of growing area samples from a particular station may become an arbitrary function of the mechanics of sampling (timing, frequency) rather than an actual characteristic of the growing area.

(6) The estimated 90th percentile will adjust for the random pollution events that may cause a data set to be skewed because of a few high MPN values. When growing area sampling data collected following intermittent pollution events are combined with data collected under normal conditions in one data distribution, variation is increased. The calculated estimated 90th percentile will reflect this variation. Therefore the estimated 90th percentile will allow for the use of an SRS, while protecting against the possibility of the existence of intermittent unfavourable conditions which can be as difficult to define as to identify and monitor.

4 Guideline for estimating the ninetieth percentile

(1) The estimated 90th percentile must be obtained from the following equation:

(a) Use of the systematic random sampling strategy involves calculating the estimated ninetieth 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. When the animal product officer elects to employ the systematic random sampling strategy, the following guideline must be used to calculate the ninetieth percentile.

(b) Est. 90th percentile value = Antilog [(slog) 1.28* + xlog]

Where:

slog = the base 10 logarithmic standard deviation

xlog = base 10 log mean

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

(2) Other instructions

(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 one significant number. (MPN counts are reported in the form of two significant numbers.) For example, a MPN value of "less than 2" must be decreased by 1 to 1.9 to indicate the lower level of sensitivity of the five tube decimal dilution MPN test.

Therefore it would follow that a MPN value of 1700 must be used to indicate the MPN value "greater than 1600" for the five tube MPN test.

(b) Logarithms may be rounded to three decimal places.

Antilogs of log MPN calculations may be rounded to the next lower integer (zero decimal places), e.g. antilog (0.556) = 3.

The standard deviation of the log MPN data must be calculated in the following manner:

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

5 Application of the guideline

(1) Example 1

(a) Convert the MPN values to logarithms:

Obs	MPN	Log10	Obs	MPN	log10
1	2.9	0.462	16	3.6	0.556
2	2.9	0.462	17	3.6	0.556
3	2.9	0.462	18	3.6	0.556
4	2.9	0.462	19	9.1	0.959
5	2.9	0.462	20	9.1	0.959
6	2.9	0.462	21	9.1	0.959
7	2.9	0.462	22	9.1	0.959
8	2.9	0.462	23	9.1	0.959
9	3.6	0.556	24	9.1	0.959
10	3.6	0.556	25	23	1.362
11	3.6	0.556	26	23	1.362
12	3.6	0.556	27	23	1.362
13	3.6	0.556	28	43	1.633
14	3.6	0.556	29	43	1.633
15	3.6	0.556	30	460	2.663

(b) Calculate the geometric mean and standard deviation:

Median = 3.6

Percentage greater than 43 = 3.3 %

Geometric mean (antilog xlog) = antilog (0.834) = 6

Log standard deviation (slog) = 0.506

(c) Calculate the estimated 90th percentile using the equation below:

Est. 90th = antilog ((slog) 1.28 + xlog)

= antilog ((0.506)1.28 +0.834)

= antilog (1.482)

= 30

(d) Interpretation of the result

The geometric mean is less than 14 and the estimated 90th percentile is less than 49 (three tube test). This station meets the criteria in this Notice for an approved growing area.

(2) Example 2

(a) Convert the MPN values to logarithms:

Obs	MPN	log10	Obs	MPN	log10
1	1.9	0.279	16	2.0	0.301
2	1.9	0.279	17	4.5	0.653
3	1.9	0.279	18	4.5	0.653
4	1.9	0.279	19	7.8	0.892
5	1.9	0.279	20	7.8	0.892
6	1.9	0.279	21	7.8	0.892
7	1.9	0.279	22	11	1.041
8	1.9	0.279	23	11	1.041
9	2.0	0.301	24	23	1.362
10	2.0	0.301	25	23	1.362
11	2.0	0.301	26	23	1.362
12	2.0	0.301	27	23	1.362
13	2.0	0.301	28	33	1.519
14	2.0	0.301	29	540	2.732
15	2.0	0.301	30	1700	3.230

(b) Calculate the geometric mean and standard deviation:

Median = 2.0

Percentage greater than 43 = 6.6%

Geometric mean (antilog xlog) = antilog (0.788) = 6

Log standard deviation (slog) = 0.737

(c) Calculate estimated 90th percentile using the above equation:

Est. 90th = antilog ((slog)1.28 + xlog)

= antilog ((0.737)1.28+0.788)

= antilog (1.731)

= 53

(d) Interpretation of the result

Although this station's geometric mean is less than 14, the standard deviation that resulted from the high values in this data set would lead one to conclude that water quality might have been adversely affected by storm water runoff or another intermittent pollution event. The estimated 90th percentile is 53 (greater than 43, five tube test). Therefore this station would not meet the criteria for an approved area.

Schedule 4

1 Harvesting and transport time-temperature protocol

(1) The New Zealand Food Safety Authority has established average monthly maximum (AMM) air temperatures for growing areas by averaging the last 5 years' maximum monthly temperatures for BMS growing regions.

(2) BMS must be placed under temperature control in accordance with the requirements in Tables 4A – 4C.

2 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	≤18°C	36 Hours
Level 2	19°C – 27°C	24 Hours
Level 3	≥ 27°C	20 Hours

3 Table 4B: Mean daily maximum temperature statistics in degrees Celsius

(Based on data for the period 1999 – 2003)

Location	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**
Kaitaia	24	24	23	21	19	17	16	16	18	19	20	22
Kerikeri	24	24	23	21	19	17	16	16	18	19	20	23
Dargaville	25	25	25	22	20	18	17	17	19	21	21	23
Whangarei Airport	24	24	23	20	19	17	15	16	18	19	20	23
Warkworth	22	23	22	20	18	16	14	15	17	18	19	20
Port Fitzroy	24	24	22	20	19	17	16	16	17	19	20	na
Coromandel	23	23	22	20	18	15	14	15	16	18	19	22
Whakatane Airport	24	24	23	20	18	16	15	15	17	19	20	23
Port Taharoa (Kawhia)	23	24	23	20	18	16	15	15	16	18	19	21
Gisborne Airport	24	24	22	20	18	16	14	15	18	19	20	23
Napier Airport	23	23	22	19	18	16	14	15	17	19	20	23
Nelson Park, Hastings	24	24	23	20	18	16	14	16	18	20	20	24
Palmerston North Airport	23	24	23	19	16	14	13	14	16	17	18	21
Riwaka, Motueka	23	23	22	18	17	14	13	14	16	18	19	22
Crail Bay, Pelorous Sound	22	23	22	18	16	14	13	14	16	17	18	21
Akaroa, Bank's Peninsula	22	22	21	17	16	14	12	13	16	17	18	22
Musselburgh, Dunedin	18	19	18	15	14	12	10	11	14	15	15	18
Oban, Stewart Island	17	18	16	14	13	11	10	11	13	14	14	17

4 Table 4C: Temperature recording sites - Growing area numbers

Site	Growing area number
Kaitaia	201, 202, 214, 215, 218, 220
Kerikeri	204, 205, 206, 221
Dargaville	208, 209
Whangarei	207, 212,
Warkworth	301
Port Fitzroy	411, 412, 413, 414, 415, 422, 423, 424
Coromandel	502, 503, 606, 610, 611, 612, 613, 614-1, 614-2, 615, 616-1, 616-2, 617-1, 617-2, 618, 619-1
Whakatane	701, 702
Port Taharoa	608
Motueka	1507, 1522, 1523, 1530,1531, 1532, 1533, 1534, 1535, 1536, 1537
Pelorous Sound	1501, 1502, 1503, 1504, 1505, 1506, 1508, 1509, 1510, 1511, 1512, 1513, 1514, 1516, 1518, 1519, 1520, 1521, 1566
Akaroa	1601, 1602
Dunedin	1801, 1802, 1803
Stewart Island	1901, 1902

Tables 4B and 4C must be read together to determine the application of the time-temperature matrix in Table 3A for each growing area.

Issued under section 167 of the Animal Products Act 1999.

Date of notification in Gazette:

This notice is administered in the Ministry of Agriculture and Forestry in the New Zealand Food Safety Authority.
