



New Zealand Fishing Industry Agreed Implementation Standards

IAIS 005.1 Shellfish Quality Assurance Circular

1995

Prelims

Issue 25

November 2003

Table of Contents

New Zealand Fishing Industry Agreed Implementation Standards

Prelims

1 Introduction

- 1.1 Subject Matter of the Circular
- 1.2 Scope
- 1.3 Background
- 1.4 Definitions
- 1.5 References

2 Administration

- 2.1 Regulatory Requirements
- 2.2 Records Kept by New Zealand Food Safety Authority
- 2.3 Records Kept by Industry
- 2.4 Laboratory Standards

3 Control of Growing Areas

- 3.1 Regulatory Requirements
- 3.2 Sanitary Survey of Growing Areas
- 3.3 Classification of Growing Areas
- 3.4 Approved Areas
- 3.5 Remote Approved Areas
- 3.6 Conditionally Approved Areas
- 3.7 Restricted Areas
- 3.8 Conditionally Restricted Areas
- 3.9 Prohibited Areas
- 3.10 Polyculture
- 3.11 Marine Biotxin Control

4 Relaying

- 4.1 Regulatory Requirements
- 4.2 Shellfish Available for Relaying
- 4.3 Conditions for Relaying
- 4.4 Relaying Areas

4.5 The Relaying Process

4.6 Harvest of Relayed Shellfish

5 Harvesting, Handling and Transport of Shellfish

5.1 Regulatory Requirements

5.2 General Requirements

5.3 Surveillance of Harvesting

5.4 Design of Vessels and Vehicles

5.5 Harvesting

5.6 Shellstock Packaging and Labelling from Harvest to Fish Packing House

5.7 Shellstock Sorting Sheds

5.8 Vessels and Vehicles Used for the Transport of Shellstock

5.9 Requirements for the Care of Shellstock during Transport

5.10 Arrival at the Fish Packing House

6 Wet Storage

6.1 Regulatory Requirements

6.2 Application

6.3 Requirements for Wet Storage

6.4 Water Quality

6.5 Care of Shellfish

6.6 Records

7 Depuration

7.1 Regulatory Requirements

7.2 Application

7.3 Standards and Licensing

7.4 Commissioning a Depuration Plant

7.5 Harvesting for Depuration

7.6 Process Water Standards

7.7 Shellfish Standards

7.8 Depuration Unit Trays

7.9 The Depuration Process

7.10 Cleaning and Sanitising Plant and Equipment

7.11 Quality Assurance

8 Processing

8.1 Regulatory Requirements

8.2 Premises

8.3 Packing, Processing and Shucking

8.4 Heat Shocking

8.5 Repacking

8.6 Labelling

Appendix I

Approved Laboratories for Microbiological Analyses

Appendix II

Approved Laboratories for Marine Biotxin Analyses

Appendix III

Minimum Requirements For Performing Shoreline Surveys In Shellfish
Growing Areas

Appendix IV

Model Sanitary Survey Report

Appendix V

Systematic Random Sampling Strategy

Appendix VI

Protocols for Reviewing the Classifications of Areas Implicated in Shellfish-
Related Illnesses

Appendix VII

Minimum Requirements and Standard Format for a Conditional Area
Management Plan

Appendix VIII

Model Forms for Shellfish Relaying

Appendix IX

Model Harvesting and Transport Report

Appendix X

Model Surveillance Reports

Appendix XI

Model Shellfish Harvesting Declaration

Appendix XII

Harvesting and Transport Time-Temperature Protocol

Appendix XIII

Model Depuration Process Report

Appendix XIV

Commissioning a Depuration Plant

Appendix XV

Shellfish Growing Areas Classified for Harvest for Human Consumption in
Accordance with the Requirements of IAIS 005.1

Disclaimer

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Website

A copy of this document can be found at: <http://www.nzfa.govt.nz/animalproducts/index.htm>

Promulgatory Statement

This circular:

is issued pursuant to Regulation 19 of the Fish Export Processing Regulations 1995

may be referred to as the Shellfish Quality Assurance Circular 1995

comes into force in November 2003

applies to all shellfish growing areas supplying shellfish to fish premises

applies to all licensees of fish premises

applies to all harvesters and transporters of shellfish from commercial growing areas.

(Signed)

Tony Zohrab
Director (Animal Products)
(acting pursuant to delegated authority)

Owen Symmans
for
Seafood Standards Council

Explanatory Note

This circular is issued under the Fish Export Processing Regulations 1995.

This note and other explanatory notes found boxed in bold italics are not part of the circular, but are intended to explain the circular.

The circular sets out certain “industry agreed implementation standards” concerning processing fish.

To comply with the standards relating to shellfish set out in Regulation 10, Part II, Part IV and Part VI of the First Schedule to the Regulations, you must either comply with this circular or have an alternative proposal approved by the Director (Animal Products) under delegation from the Director-General of Agriculture and Forestry.

You must still comply with any other relevant law or by-law.

If you have any questions about this circular, you should ask your local Inspector.

Amendments

Suggestions are welcomed for alterations, deletions or additions to this circular to improve it or to make it better suited to the needs of the fishing industry and inspection staff.

Suggestions should be forwarded to the co-ordinator, together with reasons for the change and any relevant experimental or documentary data.

Amendments do not become part of a circular until they have been issued pursuant to the Fish Export Processing Regulations 1995, along with an amendment form. Amendments are numbered in sequence.

Amendments to the circular can be identified by the issue number in the page header and a background screen over the changes which have been made. Deletions are marked with a background screen appearing where the entry has been deleted.

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Amendment Record

It is important that this circular is kept up-to-date by the prompt incorporation of amendments.

To update this circular when you receive an amendment, remove the appropriate outdated pages, destroy them, and replace them with the pages from the new issue. Complete instructions will be given on the covering letter accompanying the amendment. File the covering letter at the back of the circular and sign off and date this page.

Issue No.	Date	Initials	Issue No.	Date	Initials
1	Aug 1998	MAF Reg	21		
2	29.9.95		22	30.1.01	
3			23	04.02	
4	3.5.96		24		
5	17.10.96		25	10.03	NZFSA
6	04.97		26		
7			27		
8			28		
9	25.3.98		29		
10			30		
11	1.10.99		31		
12			32		
13			33		
14			34		
15			35		
16			36		
17			37		
18	12.7.00		38		
19			39		
20			40		

1 Introduction

Issue 25

November 2003

1.1 Subject Matter of the Circular

This circular sets out the general criteria for attaining the shellfish quality assurance standards referred to in **Regulation 10, Part II, Part IV and Part VI of the First Schedule to the Regulations.**

1.2 Scope

1.2.1

This circular applies to bivalve shellfish harvested in New Zealand and processed through a fish packing house. Whilst intended principally for shellfish destined for export sale, the standard has been designed in such a way as to be easily adopted by the New Zealand Food Safety Quality under New Zealand food safety legislation as a mandatory requirement for shellfish for sale in New Zealand.

1.2.2

This circular applies to all bivalve shellfish grown in New Zealand for human consumption, including all species of clams, cockles, geoducks, mussels, oysters, pipis, scallops and tuatuas. When the final product is the adductor muscle only, or muscle with roe on only, shellfish shall be excluded from the requirements of this circular, except for the requirements for toxic substances, marine biotoxins and labelling and record keeping requirements in Sections 2.3, 5.6.4, 5.6.5, 5.6.6, 5.10.1, 5.10.2 and 8.6.

1.2.3

All other FIICC circulars also apply, where relevant, to the shellfish procedures to which this circular applies (this is particularly relevant for the requirements for fish packing houses); but where there are more specific requirements in this circular than in other circulars the requirements of this circular take precedence.

1.2.4

This circular shall apply to all commercial shellfish activities for the export market, including the growing, harvesting, relaying, depurating, heat shocking, processing, manufacturing, transporting, labelling and storing of shellfish, and the laboratory examination of growing waters and shellfish.

1.2.5

This circular describes the minimum standards for the export of shellfish from New Zealand. It does not describe the standards required by particular foreign governments.

Information on the specific requirements of particular foreign countries are available in IAIS 002.4 and overseas market access requirements.

1.3 Background

1.3.1

Bivalve shellfish receive special consideration in food safety law throughout the world because:

- Bivalves are filter-feeding shellfish. In their aquatic environment, they can filter and accumulate to hazardous levels pathogenic micro-organisms, viruses, protozoa, helminths, marine biotoxins or toxic substances, and become naturally contaminated with autochthonous micro-organisms such as the *Vibrio spp.*
- No thermal process is generally applied to the shellfish prior to sale to eliminate pathogens.
- Microbial multiplication is likely to occur if time and/or temperature abuse occurs between harvest and sale. For example, a recent study has shown a 10-100 fold increase of *Vibrio vulnificus* between harvesting and processing, with greater increases in the numbers of *Vibrio parahaemolyticus*.
- Raw molluscan shellfish receive the second highest hazard rating for all foods (International Commission on Microbiological Specifications For Food (ICMSF) and the National Advisory Committee on Microbiological Criteria For Foods, HACCP Report).

- An increasing number of studies are showing the presence of pathogens in waters and shellfish when (faecal) coliforms are either absent or present in low numbers. Foremost amongst these studies are those conducted in New Zealand on viral contamination of wastewaters, sediments and shellfish. These findings are of concern because they suggest that the risk of disease may sometimes be underestimated by (faecal) coliform densities.

1.3.2

This circular has been prepared at the request of the shellfish industry, with the purpose of developing a New Zealand standard which will provide consumers, the shellfish industry, foreign governments and New Zealand regulatory agencies with an assurance of the safety of shellfish grown, harvested, transported and processed in New Zealand.

1.3.3

In 1980 a memorandum of understanding was signed between the United States Food and Drug Administration (USFDA) and the New Zealand Ministry of Agriculture and Fisheries (MAF). The memorandum affirmed the intention of the Ministry of Agriculture and Fisheries to assure that molluscan bivalves exported to the United States were safe and wholesome and had been harvested, transported, processed and labelled in accordance with the USFDA National Shellfish Sanitation Programme (NSSP).

1.3.4

In the 1980 memorandum, the then Meat Division of the Ministry of Agriculture and Fisheries agreed to a co-operative agreement with the Fisheries Management Division to control shellfish harvesting practices. This agreement was annulled by the Fisheries Management Division in 1988, and the control of harvesting practices was undertaken by the Meat Division of the Ministry and the then Department of Health.

1.3.5

The 1980 memorandum also contained a memorandum of understanding between the Ministry of Agriculture and Fisheries and the Ministry of Health. This placed the responsibilities for the sanitary survey, classification and monitoring of shellfish growing areas with the Ministry of Health. The DOH memorandum is still in effect.

1.3.6

As a result of the 1980 memorandum, all shellfish growing areas which provided shellfish for export and the majority of the shellfish growing areas which provided shellfish for sale in New Zealand were classified under the NSSP. Although it was mandatory for all export shellfish to be harvested from classified growing areas, it was not mandatory for shellfish for sale in New Zealand to be harvested from classified growing areas. This caused concern to the shellfish industry, the Ministry of Agriculture of Fisheries and the Ministry of Health, and in 1988 the shellfish industry formally requested through the Shellfish Sanitation Committee that the New Zealand Food Regulations 1984 be amended to require this. The industry also asked that a New Zealand standard be designed which could apply to all commercial shellfish grown and harvested in New Zealand, irrespective of whether it was destined for the New Zealand or export market.

1.3.7

In December 1991, Amendment No. 5 to the New Zealand Food Regulations 1984 was passed. This requires that shellfish grown and harvested for the domestic market meet the requirements of the NSSP manuals and became effective on 1 January 1993.

1.3.8

The Third Schedule of the Resource Management Act 1991 provided a further standard designed specifically for shellfish growing water quality, and it is expected that all IAIS 005 classified growing areas will be classified under this act as Class SG.

1.4 Definitions

In this circular, unless the context requires otherwise, the following definitions apply:

Acceptable means acceptable to the Seafood Standards Council.

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

Adverse pollution conditions means conditions determined by changes in meteorological, hydrographic, seasonal and point source pollution conditions that have been historically demonstrated to unfavourably impact on a particular growing area. Examples are unusual

climatic conditions, long periods without rain, unusually hot temperatures, consecutive days of light rainfall, heavy rainfall, tidal effects, salinity and wind effects.

Adverse pollution sampling strategy means a water quality sampling programme designed to target the adverse pollution conditions described in the growing area management plan.

Air gap means the unobstructed vertical distance through the free atmosphere between the lowest opening from any pipe or tap supplying water to any tank, plumbing fixture, container or other device, and the flood level rim of the receptacle.

Approved means approved in writing by the Inspector or officer for the time being responsible for ensuring that requirements are met under the Health Act 1956, the Meat Act 1981, the Food Act 1981.

Approved area means the classification by the Ministry of Agriculture and Forestry of a shellfish growing area for growing or harvesting shellfish for direct sale. The classification of an approved area is determined through a sanitary survey conducted by an authorised health officer in accordance with Section 3 of this circular. An approved shellfish growing area may be temporarily made a prohibited area, e.g. when a flood, storm or marine biotoxin event occurs.

Approved depuration process (ADP) means a process which places shellfish harvested from conditionally approved or restricted areas into a controlled aquatic environment selected by the processor and approved by the Inspector as adequate to effectively reduce the level of contaminants in the shellfish.

Approved heat shock process means the process selected by the processor and approved by the Inspector to heat shock shellfish to facilitate shucking.

Aquaculture means the controlled production of molluscan shellfish in natural and artificial systems. Components of aquaculture may overlap with other activities covered in this circular such as relaying, transplanting, wet storage, depuration, growing water classification and labelling.

Authorised health officer means a person employed by a District Health Board as a health protection officer or a person with other acceptable public health experience who is employed by the Ministry of Agriculture and Forestry or a District Health Board to perform specified duties to ensure the requirements of this circular are complied with.

Backflow means the flow of water or other liquids, mixtures or substances into the distributing pipes of a potable water supply from any other source.

Central file means the file system in the New Zealand Food Safety Authority.

Closed area means a growing area where the harvesting of shellfish is temporarily or permanently not permitted. A closed area status may be placed on any of the five classified area designations: approved, remote approved, conditionally approved, restricted or conditionally restricted.

Community health specialist means a medical practitioner with a special qualification in public health employed by a District Health Board as a community medicine specialist or a medical officer of health.

Conditionally approved area means the classification by the Ministry of Agriculture and Forestry of a shellfish growing area which meets approved area criteria for a predictable period. The period is conditional upon established performance standards specified in a management plan. The classification of a restricted area is determined through a sanitary survey conducted by an authorised health officer in accordance with Section 3 of this circular. A conditionally approved area becomes a closed area when the area does not meet the approved growing area criteria.

Conditionally restricted area means the classification by the Ministry of Agriculture and Forestry of a shellfish growing area which meets restricted area criteria for a predictable period. The period is conditional upon acceptable performance standards specified in a management plan. The classification of a restricted area is determined through a sanitary survey conducted by an authorised health officer in accordance with Section 3 of this circular. A conditionally restricted growing area becomes a closed area when the area does not meet the restricted area criteria.

Controlled purification - see "deputation".

Cross connection means any physical connection or arrangement between two otherwise separate piping systems, which might result in the contamination of potable water supplies.

Delivery centre means a shellfish quality assurance programme cost centre developed at the request of the shellfish industry to ensure compliance with this circular in a cost-effective manner. The delivery centre comprises representatives of the shellfish industry, the Ministry of Agriculture and Forestry and the District Health Boards.

Depuration means the process that uses a controlled aquatic environment to reduce the level of contaminants in live shellfish.

Depuration plant means a licensed premises, containing one or more depuration units, which submits shellstock to an approved depuration process.

Depuration unit means a tank or series of tanks supplied by a single depuration process water system.

District Health Board (DHB) means an organisation established as a District Health Board under the New Zealand Health and Disability Act 2000.

Dry storage means the storage of shellstock out of water.

Fish packing house means any premises that is for the time being licensed by the New Zealand Food Safety Authority for the processing, packing, wet storing or depuration of fish or shellfish.

Fish premises means any licensed premises, i.e. any fish packing house or any fishing vessel or premises approved under Regulation 21 of the Fish Export Processing Regulations 1995.

Growing area means a marine or freshwater area which supports or could support live shellfish.

Harvester means a person who takes shellfish by any means from a growing area.

Heat shock means the process of subjecting shellstock to any form of heat treatment prior to shucking to facilitate the removal of the meat from the shell.

ICSS List means a list of packing houses which are licensed by the New Zealand Food Safety Authority for the export of shellfish to the United States of America and which are listed in the Food and Drug Administration Interstate Certified Shellfish Shippers List.

Inspector means a person appointed by the Ministry of Agriculture and Forestry as an inspector for the purposes of the Meat Act 1981.

Lot of shellfish means shellstock harvested from a particular area (e.g. marine farm) at a particular time (i.e. no more than 1 day).

Marina means any water area with a structure (wharf, basin, floating wharf, etc.) which is used for berthing or otherwise mooring vessels and is constructed to provide temporary or permanent berthing for more than 10 boats.

Marine Biotoxin Management Board means the board of management, comprising representatives of the Ministry of Agriculture and Forestry, Ministry of Health, Public Health Commission and the New Zealand Fishing Industry Board, whose primary role is to manage the New Zealand marine biotoxin management programme.

Marine biotoxins means poisonous compounds accumulated by shellfish feeding on toxin-producing dinoflagellates or diatoms, or on seawater containing toxins produced by such organisms.

Ministry of Health means the previous Department of Health.

Mixing means the act of combining different lots of shellfish.

Most probable number (MPN) means the statistical estimate of the number of bacteria per unit volume and is determined from the number of positive results in a series of fermentation tubes.

National Shellfish Sanitation Programme (NSSP) means the shellfish programme for the certification of shellfish shippers as described in the United States Food And Drug Administration (FDA) National Shellfish Sanitation Programme Manual Of Operations, Part I and II.

New Zealand Marine Biotoxin Management Plan means the plan developed and managed by the Marine Biotoxin Management Board to minimise the risk to consumers from hazardous levels of marine biotoxins in New Zealand shellfish and fish products.

New Zealand Shellfish Quality Assurance Programme (NZSQAP) means the NZFSA/Ministry of Agriculture and Forestry/shellfish industry/District Health Board programme which provides assurance of the safety and wholesomeness of New Zealand grown commercial shellfish.

NZFSA means the New Zealand Food Safety Authority.

Open coastal water means coastal water that is remote from estuaries, fiords, inlets, harbours and river mouths; and is at least 1 kilometre offshore or at a distance offshore approved by an authorised health officer.

Person means any individual, partnership, corporation, association or other legal entity.

Point source (of pollution) means any discernible single source such as any pipe, ditch, channel, tunnel or conduit that carries pollution.

Polyculture means the cultivation of molluscan shellfish species with other non-molluscan species in a common aquaculture system.

Process batch means a quantity of shellfish used to fill each separate depuration unit.

Process water means the water in depuration tanks during the time that the shellfish are being depurated, or the water in wet storage tanks during the time the shellfish are being wet stored.

Processor means a person who depurates, heat treats, manufactures, processes, shucks, packs or repacks shellfish.

Prohibited area means a growing area where there is no current sanitary survey or where the sanitary survey or other monitoring programme indicates that faecal material, pathogens or toxic substances may reach the area in excessive concentrations. Any taking of shellfish for human consumption from such areas is prohibited.

Relaying means the transfer of shellfish from restricted areas and conditionally approved areas (when closed due to harvesting criteria being exceeded) to approved or conditionally approved areas for natural biological cleansing using the ambient environment as a treatment system.

Regional shellfish specialist means a person employed by MAF with the designation "regional shellfish specialist" to provide specialist advice and direction on shellfish quality assurance matters.

Regulations means the Fish Export Processing Regulations 1995, and a reference to a regulation is to a provision of the Regulations.

Remote approved area means a growing area that has no human habitation in the catchment, is not affected by any actual or potential pollution sources and has been classified by the Ministry of Agriculture and Forestry for growing or harvesting shellfish for sale. The classification of an approved area is determined through a sanitary survey conducted by an authorised health officer in accordance with Section 3 of this circular. A remote approved area may be temporarily made a prohibited area, for instance when a flood, hurricane or toxic substance spillage occurs.

Restricted area means a growing area classified by the Ministry of Agriculture and Forestry as an area from which shellfish may be harvested only by special permit and then subjected to an effective purification process such as relaying or depuration. The classification of a

restricted area is determined through a sanitary survey conducted by an authorised health officer in accordance with Section 3 of this circular.

Sampling officer means a person approved by the District Health Board to take water and shellfish samples for the purposes for the compliance with the growing area requirements of this circular.

Sanitary survey means the evaluation, in accordance with the requirements of Section 3 of this circular, by an authorised health officer, of all actual and potential pollution sources and environmental factors which may affect shellfish growing water quality.

Shellfish means all edible species of molluscan bivalves such as oysters, clams, geoducks, scallops, tuatuas, pipis and mussels, either shucked or in the shell, fresh or frozen, whole or in part or processed. The definition does not include spat (defined below).

Shellstock means shellfish in the shell.

Shoreline survey means a survey of the shoreline of the growing area catchment conducted by an authorised health officer according to the requirements in Appendix III.

Shucked shellfish means shellfish from which one or both shells have been removed.

Sorting shed means a building or structure where shellstock are handled directly after harvesting to enable separation of shellstock for farm management, transplanting, relaying, or culling for transport to a fish packing house.

Spat means juvenile shellfish which are taken for the purposes of ongrowing. The spat of oysters shall be no longer than 40 mm; the spat of scallops shall be no longer than 50 mm; the spat of cockles shall be no longer than 20 mm; the spat of green-lipped mussels/greenshell mussels shall be no longer than 40 mm; the spat of blue mussels shall be no longer than 30 mm; and the spat of Pacific oysters shall be no longer than 37 mm.

Systematic random sampling means a method of water sampling and data analysis (as described in Appendix V) which may be applied to a growing area which is not impacted by point source pollution.

Temperature control means management of the environmental temperature of molluscan shellfish by means of ice, mechanical refrigeration or other approved means which will lower the internal body temperature of the animal to or will maintain it at 10 °C or less.

Toxic substance means a toxic compound occurring naturally or added to the environment that may be found in shellfish for which a regulatory tolerance limit has been established or

which the New Zealand Food Safety Authority determines to be hazardous. Examples of naturally occurring toxic substances are marine biotoxins and trace elements geologically leached from the environment, such as mercury, zinc and copper; examples of added substances are agricultural pesticides, polynuclear aromatics from oil spills and polychlorinated biphenyls.

Transaction record means a form used to document each purchase or sale of shellfish at the wholesale level.

Transplanting means the regulated movement of shellfish under market size from one growing area to another for aquaculture purposes.

Your local Inspector means the Inspector who inspects your premises or the Inspector's deputy.

Wet storage means the temporary storage of shellfish from approved or conditionally approved growing areas, intended for marketing, in containers or floats in natural bodies of water or in tanks containing natural or synthetic seawater.

All words and expressions defined in Regulation 2 of the Fish Export Processing Regulations 1995 have the same meanings when used in this circular except where the context requires otherwise.

1.5 References

The main references used in the development of this circular were:

- Bird, P. *Management Plan for the New South Wales Oyster Program*. New South Wales Department of Health, Sydney, August 1990.
- Codex Alimentarius Commission. *Recommended International Code of Hygienic Practice for Molluscan Shellfish*. CAC/RCP 18 - 1978, 2nd Edtn, 1983.
- Council Directive 91/492/EEC. *Health Conditions for the Production and Placing on the Market of Live Bivalve Molluscs*. Official Journal of the European Communities, 15 July 1991.
- Council Directive 91/493/EEC. *Health Conditions for the Production and Placing on the Market of Fishery Products*. Official Journal of the European Communities, 22 July 1991.

- McBride G.B., Cooper A.B., Till D.G. *Microbiological Water Quality Guidelines for Recreation and Shellfish Gathering Waters in New Zealand*. DSIR Water Quality Centre Consultancy Report 6211, prepared for the Department of Health, June 1991.
- Memorandum of Understanding between the United States Food And Drug Administration, Department of Health and Human Services, and the New Zealand Ministry of Agriculture and Fisheries, 14 October 1980.
- Memorandum of Understanding between the Ministry of Agriculture and Fisheries and the Health Department relative to the certification of export shellfish, February 1981.
- *Provisional Microbiological Water Quality Guidelines for Recreational and Shellfish-Gathering Waters in New Zealand*. Public Health Services, Department of Health, Wellington, 1992.
- United States Department of Health and Human Services, *National Shellfish Sanitation Programme Manual of Operations, Parts I and II*. US DHHS, Washington, 1993.
- World Health Organisation. *Guide to Shellfish Hygiene*. WHO Offset Publication No. 31. WHO, Geneva, 1976.

2 Administration

Issue 25

November 2003

2.1 Regulatory Requirements

The regulations state:

“Every licensee shall keep such records as will enable the licensee, the Director General, or any Inspector to readily ascertain -

- a. The nature, quantity, and source of any fish or fish product handled in the fish premises;
and
- b. The date on which each container of fish or fish product was packed; and
- c. Where unpacked fish or fish product in the premises has been held at some other fish premises, the identity of those other fish premises; and
- d. Compliance with the requirements or the certification requirements of any foreign country to which any fish or fish product handled in fish premises has been or is to be exported;
and
- e. Such other details as may be required by the Director-General for purposes of these regulations and notified to the licensee”.

Under **Regulation 10** the records required to be kept are laid down in Sections 2.2-2.3.

2.2 Records Kept by New Zealand Food Safety Authority

2.2.1

New Zealand Food Safety Authority shall keep and maintain a central file containing copies of the records and documents of the New Zealand shellfish quality assurance programme, including:

- laboratory evaluation records;

- individual growing area reports (e.g. sanitary surveys, management plans, surveillance, transport, closure, harvesting criteria adjustments, reclassification and annual evaluation reports);
- Interstate Certified Shellfish Shippers premises evaluation reports;
- summaries of shellfish foodborne illness reports;
- enforcement action reports;
- marine biotoxin monitoring data, notices and reports;
- New Zealand Shellfish quality assurance programme evaluation reports by foreign governments;
- all data, criteria and protocols relating to the operation of a restricted area such as depuration and relaying reports, harvesting permits and harvesting control records;
- all data, procedures and reports for heat shocking;
- all data, procedures and reports on wet storage;
- all approval documentation for sorting sheds;
- approvals for mixing of shellfish;
- all approvals required by this circular.

2.2.2

The Inspector shall keep and maintain at delivery centre level a file containing copies of the relevant records, documents and reports described in Section 2.2.1 for each growing area administered by the delivery centre.

2.3 Records Kept by Industry

Complete, accurate and legible shellfish transaction records shall be kept for at least 2 years in a permanently bound ledger book, or another method approved by the Inspector, by each packing house, marine farmer, harvester and person authorised to take shellfish under the Fisheries Act 1983 or 1996. Such records shall include:

- all information necessary to trace all purchases and sales of shellfish back to their growing area source;
- dates of harvesting of shellfish, and of their arrival at licensed premises, shucking, packing and despatch.

2.4 Laboratory Standards

2.4.1

The approved methods as recommended by the National Shellfish Sanitation Programme shall be followed in the bacteriological examination of shellfish, shellfish waters, process water and water used for processing.

2.4.2

The approved edition of the United States Food and Drug Administration (USFDA) *Bacteriological Analytical Manual* shall be followed for the examination of shellfish for *Vibrio parahaemolyticus* and for virological examination of shellfish waters and shellfish.

2.4.3

The approved editions of the manuals of the APHA and the Association of Official Analytical Chemists shall be followed for the examination of shellfish, shellfish waters, process water and water used for processing for chemical and physical analyses.

2.4.4

Analytical methods approved by the New Zealand Food Safety Authority, shall be used for the examination of shellfish for marine biotoxins. The seafood industry agreed guideline, 'A Guide for the Validation and Approval of New Marine Biotxin Test Methods', must be followed by laboratories seeking approval to use a new marine biotoxin test method. To view this guide [click here](#).

2.4.5

Laboratories performing marine biotoxin or microbiological examinations for the New Zealand Shellfish Quality Assurance Programme shall be evaluated by a United States Food and Drug Administration-certified New Zealand laboratory evaluation officer at least every 3 years and receive written approval from NZFSA prior to performing marine biotoxin or microbiological examinations required by this circular.

2.4.6

A schedule of approved laboratories for microbiological examinations is shown in Appendix I.

2.4.7

A schedule of approved laboratories for marine biotoxin examinations is shown in Appendix II.

2.4.8

All laboratories performing analyses to support the New Zealand Shellfish Quality Assurance Programme using methods described above must have International Accreditation New Zealand accreditation for the tests performed or have an approval in writing from the Programme Manager (Seafood), NZFSA.

3 Control of Growing Areas

Issue 25

November 2003

3.1 Regulatory Requirements

The regulations state:

“Fish declared by the Director-General to be subject to this clause under regulation 5(2) of these regulations and received into a product area of fish premises shall have been grown in or taken from a place for which there is an approved monitoring programme to show that the place is not contaminated at the time of catching or harvesting”.

Under **Clause 4, Part IV, First Schedule to the Regulations**, the requirements for an approved monitoring programme are laid down in Sections 3.2 - 3.11.

3.2 Sanitary Survey of Growing Areas

3.2.1

MAF shall maintain a list of the following which have in place an approved monitoring programme:

- marine farm leases and licences issued under the Marine Farming Act 1971;
- permits and authorisations to take shellfish for sale issued under the Fisheries Act 1983 or 1996.

3.2.2

The sanitary survey of a growing area is the most important requirement of this circular. A sanitary survey addressing the factors outlined in Appendices III and IV shall be conducted by an authorised health officer for each shellfish growing area. A report shall be prepared for each growing area in accordance with the minimum requirements and in the standard format shown in Appendix IV.

3.2.3

Shellfish shall not be harvested from a growing area until the sanitary survey has been completed and the sanitary survey report containing a recommended classification and harvesting criteria has been approved by the regional shellfish specialist.

On completion of the sanitary survey and classification, the sanitary survey shall be maintained in accordance with the requirements of this circular to maintain the “approved monitoring programme” status.

3.2.4

Each sanitary survey shall:

- include a shoreline survey conducted according to the minimum requirements outlined in Appendix III;
- identify and evaluate all actual and potential sources of pollution which may affect the quality of the water and/or shellfish in the growing area;
- determine whether each potential pollution source is likely to have a direct or indirect impact on growing area water quality;
- assess the effectiveness and reliability of sewage treatment systems which may affect the growing area;
- ascertain the levels of toxic substances in shellfish;
- determine the effects on the growing area quality of small sources of pollution such as boats, feral and domestic animals, birds, penguins and seals;
- evaluate any meteorological and hydrographic effects and geographic characteristics that may affect the distribution of pollutants over the growing area to determine their maximum effect on the water quality;
- include the collection of growing water and shellfish samples and their analysis for bacteriological quality.

The number and location of sampling stations selected shall be adequate to produce the data necessary to effectively evaluate all point and non-point sources of pollution, including all freshwater discharges into the growing area catchment. The collection of samples shall provide adequate data to form a profile for periods defining adverse pollution conditions

which reflect adverse meteorological, hydrographic, seasonal and point sources of pollution to assure that the requirements for the respective classifications of growing areas are met. It is expected that the collection of such data will cover a period of at least 12 months to ensure that all seasonal factors are addressed. The collection of samples for the sanitary survey shall also demonstrate the time taken for the faecal coliform MPN levels of the polluted waters to return to 14/100 ml or less and the faecal coliform MPN levels of the shellfish to return to 300/100 g or less.

In an area not previously classified a minimum of 30 samples shall be collected from each sample station. The 30 samples shall be collected under various environmental conditions whereby adverse conditions and the impact of their interrelationships can be determined.

3.2.5

A complete sanitary survey, including a full shoreline survey, shall be conducted on each classified shellfish growing area (apart from those classified as prohibited) at least once every 12 years.

3.2.6

To maintain the sanitary survey and classification of a growing area, each sanitary survey shall be reviewed annually in writing by an authorised health officer and the classification and harvesting criteria evaluated to assure their validity.

The written annual evaluation shall include:

- an analysis of the laboratory results of at least the last 15 water samples where the adverse pollution condition sampling strategy is used or at least the last 30 water samples where the systematic random sampling strategy is used (see Appendix V for further details);
- an evaluation of pollution sources identified during the shoreline survey;
- the documentation of all newly identified, actual or potential pollution sources, and an evaluation of their effect on the growing area;
- further water quality, hydrographic or field work considered necessary by an authorised health officer;
- a determination of the correctness of the classification and harvesting criteria.

3.2.7

A heavy metal analysis and toxic substances assessment shall be conducted at least every 3 years and a report included in the annual evaluation.

3.2.8

An authorised health officer may reduce the number of samples to be analysed in Section 3.2.5 for growing areas classified as remote approved (see Section 3.3).

3.2.9

A report shall be prepared by an authorised health officer for each sanitary survey, reclassification, adjustment of harvesting criteria and annual evaluation.

3.3 Classification of Growing Areas

3.3.1

The MAF shall classify all commercial growing areas into one of the following categories based on the information contained in the sanitary survey report:

- approved
- remote approved
- conditionally approved
- restricted
- conditionally restricted
- prohibited.

3.3.2

The classification shall be consistent with the public health intent of the classification criteria described in this circular.

3.3.3

A full sanitary survey report is not required for an area to be classified as prohibited.

3.3.4

All commercial growing areas which have not been subject to a sanitary survey shall be classified as prohibited.

3.3.5

Where the adverse pollution condition sampling strategy is used for a growing area, the classification shall be based on a minimum of the last 15 water samples collected under adverse pollution conditions from each sample station in the growing area. (For areas not previously classified, Section 3.2.3 shall apply.) Where the systematic random sampling strategy is used for a growing area classification, the strategy shall comply with the requirements of Appendix V.

3.3.6

Areas adjacent to each sewage plant outfall and any other waste outfall of public health significance shall be classified as prohibited. The prohibited area shall be large enough to provide sufficient time to stop harvesting before a non-permitted discharge could travel through the prohibited area to an area classified as approved, conditionally approved, restricted or conditionally restricted.

3.3.7

Each reclassification of a growing area shall be supported by an adequate sanitary survey and a reclassification report which shall include comment on the analysis of the water quality data obtained after the existing classification and/or harvesting criteria.

3.3.8

Where a growing area at any time does not comply with the sanitary requirements of the designated classification, it shall be immediately closed by an authorised health officer and the harvesting criteria and classification reviewed.

3.3.9

A growing area may be closed by an authorised health officer following a public health emergency such as a broken sewer pipe, the presence of pathogens, toxic substance spillage, storm, flood or any other event which in the opinion of the authorised health officer may affect the public health quality of the growing water or the shellfish.

3.3.10

When shellfish from a growing area are implicated in an epidemiologically confirmed foodborne outbreak involving two or more persons, the authorised health officer shall promptly review the classification of the growing area in accordance with the protocol described in Appendix VI.1.

3.3.11

When pathogens are identified in shellfish from a growing area, the authorised health officer shall use the protocol in Appendix V I.2 to review the classification of the area.

3.3.12

A report shall be prepared by an authorised health officer on each reopening of an area temporarily closed due to an emergency such as a broken sewer pipe, extreme sea or weather conditions, marine biotoxins, the presence of pathogens, failure to meet performance standards, etc. The report shall include water quality data and, if necessary, shellfish quality data, to demonstrate that the existing classification and harvesting criteria are complied with.

3.4 Approved Areas

3.4.1

An approved area shall not be contaminated with faecal coliform levels exceeding those in Section 3.4.3 and shall not contain pathogens or hazardous concentrations of toxic substances or marine biotoxins.

3.4.2

The sanitary survey shall comply with the requirements of Section 3.2.

3.4.3

The bacteriological quality of every sample station in the growing area shall meet one of the following standards:

- When the adverse pollution condition sampling strategy is used, the faecal coliform median MPN of the water shall not exceed 14/100 ml, and not more than 10% of the samples shall exceed an MPN of 43/100 ml for a five tube decimal dilution test at each sample station in the growing area. For the annual growing area review, this determination shall be based on a minimum of 15 water quality samples collected from each station in the approved area under adverse pollution conditions.
- When the systematic random sampling strategy is used, the faecal coliform median MPN of the water shall not exceed 14/100 ml, and the estimated 90th percentile shall not exceed an MPN of 43/100 ml for a five tube decimal dilution test at each sample station in the approved area. This determination shall be based on a minimum of 30 water quality samples collected from each sample station in the growing area in accordance with the requirements of Appendix V.

3.4.4

To maintain an approved area classification:

- The sanitary survey shall be reviewed annually as required by Section 3.2.6.
- Growing area water samples shall be taken according to Section 3.4.5 and the analytical results shall comply with the requirements in Section 3.4.3.

3.4.5

Where pollution of the growing area is from point sources, five samples shall be taken from each sample station under adverse pollution conditions throughout the year. In growing areas affected by non-point sources of pollution, five samples per year shall be taken as described above; or, if the growing area is being managed under the systematic random

sampling strategy, six samples shall be taken from each sample station throughout the year according to the systematic random sampling strategy described in Appendix V.

3.4.6

Harvesting of shellfish may take place at any time in an area classified as approved, providing a temporary prohibition classification or closure (e.g. for oil spills, marine biotoxins) is not in place.

3.5 Remote Approved Areas

3.5.1

A remote approved area shall have no human habitation in the growing area catchment and shall not be impacted upon by any actual or potential pollution sources.

3.5.2

A remote approved area shall meet the approved area requirements specified above except that the numbers of samples stated in Section 3.4.5 for adverse pollution conditions may be varied at the discretion of an authorised health officer.

3.5.3

A remote approved area situated in open coastal water may have the number of samples specified in Section 3.2.4 varied at the discretion of an authorised health officer.

3.5.4

Harvesting of shellfish may take place at any time in an area classified as remote approved, providing a temporary prohibition classification or closure (e.g. for oil spills, marine biotoxins) is not in place.

3.6 Conditionally Approved Areas

3.6.1

A conditionally approved area shall meet the approved area criteria for a reasonable period of time but may be subject to periods of intermittent microbiological pollution. The factors determining these periods shall be known, shall be predictable and shall not be so complex as to preclude a reasonable management approach.

3.6.2

A management plan shall be developed for every conditionally approved area by the Inspector according to the requirements in Appendix VII.

3.6.3

To maintain a conditionally approved classification:

- The area shall comply with the management plan.
- Upon annual inspection, critical pollution sources shall comply with the requirements of a conditionally approved area.
- Water quality samples shall be taken at least monthly from each sample station throughout the year, when the area is open for harvesting, under the adverse pollution condition strategy for areas affected by point source pollution. For areas affected by non-point source pollution, either the above shall apply or six samples shall be taken in accordance with the systematic random sampling strategy described in Appendix V.
- The results of the water samples collected when the area is open for harvest shall comply with Section 3.4.3.
- An annual review shall be conducted in accordance with Section 3.2.6.

3.6.4

Shellfish shall only be harvested from a conditionally approved area when it meets the approved area requirements in Section 3.4.3, i.e. in accordance with the harvesting criteria.

3.6.5

When a conditionally approved area does not comply with the approved area requirements in Section 3.4.3, it shall be immediately closed to shellfish harvesting. Immediately means as soon as reasonably possible and shall not exceed 24 hours.

3.6.6

Harvesting from a conditionally approved area when it is closed is not permitted except for the purposes of depuration or relaying. For these purposes, the requirements of Sections 3.7, 3.8 and 4 shall be complied with prior to relaying.

3.7 Restricted Areas

3.7.1

A restricted area shall not be subject to levels of pollution that cannot be reduced to acceptable levels by depuration or relaying.

3.7.2

The sanitary survey and water quality monitoring of restricted areas shall be conducted and maintained in the same manner and frequency as for approved areas.

3.7.3

The faecal coliform median MPN of the water shall not exceed 88/100 ml, and not more than 10% of the samples shall exceed an MPN of 260/100 ml for a five tube dilution test for each sample station in the growing area. When the systematic random sampling strategy is used, the faecal coliform median MPN of the water shall not exceed 88/100 ml and the estimated 90th percentile shall not exceed an MPN of 260/100 ml for a five tube decimal dilution test at each sample station in the growing area.

3.7.4

Shellfish quality specifications for use in classifying an area as restricted shall be established by an authorised health officer. These shall be based on the purification effectiveness

studies which have determined the bacteriological requirements for depuration or relaying of the shellfish.

3.7.5

Shellfish shall only be harvested from restricted areas in compliance with the requirements for depuration or relaying.

3.7.6

To maintain the restricted area classification, the sanitary survey shall undergo an annual review in accordance with the requirements of Section 3.2.6 of this circular.

3.8 Conditionally Restricted Areas

3.8.1

A conditionally restricted area shall meet the restricted area classification criteria for a reasonable period of time but may be subject to intermittent periods of increased pollution. The factors determining these periods shall be known, shall be predictable and shall not be so complex as to preclude a reasonable management approach.

3.8.2

A management plan for every conditionally restricted area shall be developed by an inspector according to the requirements in Appendix VII.

3.8.3

To maintain a conditionally restricted classification:

- The area shall comply with the management plan.
- Upon annual inspection, critical pollution sources shall comply with the requirements of a conditionally restricted area.
- Water samples shall be taken at least monthly when the area is open for harvesting, under the adverse pollution condition strategy for areas affected by point source

pollution, or six samples shall be taken by the systematic random sampling strategy described in Appendix V.

- Water samples collected when the area is open for harvest shall meet the standards in Section 3.7.3.
- The sanitary survey shall undergo an annual review in accordance with the requirements of Section 3.2.6 of this circular.

3.8.4

Shellfish shall not be harvested for human food use from a conditionally restricted area when it is closed except with the written approval of an Inspector.

3.9 Prohibited Areas

3.9.1

A shellfish growing area shall be classified as prohibited when any of the following conditions apply:

- There is no current sanitary survey or annual evaluation report to support the existing classification.
- A sanitary survey or marine biotoxin surveillance report indicates that pollution sources may unpredictably contaminate the shellfish.
- The area is so contaminated with toxic substances, faecal matter, pathogens or marine biotoxins that the shellfish are considered by an authorised health officer to be excessively contaminated.

3.9.2

Shellfish growing areas adjacent to sewage treatment plant outfalls or other waste discharge outfalls of public health significance shall be classified as prohibited. The size of the prohibited area shall be determined using the following minimum criteria:

- pollution source details (e.g. location of discharge, flow rate of discharge, plant performance and quality of discharge);

- 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;
- characteristics of the adjacent shellfish growing area (e.g. water quality required for classification of the area, identifiable landmarks for area boundaries and expected decay rate of pollutants).

3.9.3

An authorised health officer shall approve the methodology for applying the above criteria.

3.9.4

No shellfish shall be taken from a prohibited area for human food use.

3.9.5

Spat taken from prohibited areas for ongrowing shall 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 food use. In addition, the shellfish in adjacent approved or conditionally approved areas shall be adequately separated so as to avoid contamination.

3.10 Polyculture

3.10.1

Shellfish may be grown in a polyculture situation provided that a written operational plan has been developed and approved by the Inspector. The plan shall include the following details:

- the specified site and boundaries in which shellfish culture activities are to be conducted;
- the species of shellfish to be cultured and harvested;
- the source and species of other organisms to be cultured and harvested;
- the method of farming, including data on structures used;

- the procedures used to ensure that no poisonous or deleterious substances are introduced into the operations;
- a description of how the water quality of water in the culturing site shall be monitored and maintained;
- information on the microbiological and chemical quality of shellfish harvested from the culturing site.

3.10.2

Before a site is approved for polyculture, a sanitary survey shall be conducted in accordance with the requirements of Section 3.2.

3.10.3

The site of the polyculture farm shall be classified and this classification maintained in accordance with Section 3.3.

3.10.4

The polyculture site shall be inspected at a frequency determined by the Inspector, but not less than once every 6 months, to check compliance with the operational plan.

3.10.5

Procedures for the monitoring of pathogens, animal drugs and other poisonous substances resulting from the polyculture operations shall be developed and approved by the Inspector. In addition, molluscan shellfish harvested from polyculture operations shall be either relayed or subjected to depuration when the above agents are determined to exist at levels of public health significance.

3.11 Marine Biotxin Control

3.11.1

Each growing area shall conduct a marine biotoxin monitoring programme in accordance with the requirements of the New Zealand Marine Biotxin Management Plan.

3.11.2

The authorised health officer, in consultation with the Inspector and the shellfish industry, shall develop a marine biotoxin management plan for each growing area which adequately addresses the requirements of the New Zealand Marine Biotoxin Management Plan and which clearly identifies the agencies responsible for and the procedures necessary to:

- identify algal and diatom blooms,
- initiate growing water, seawater and shellfish sampling,
- detain shellfish,
- prevent commercial harvesting from closed or prohibited areas,
- recall shellfish.

3.11.3

Each growing area management plan shall include a map of the growing area showing the position of the marine biotoxin sample points in relation to the growing area.

3.11.4

The authorised health officer shall immediately close a growing area when the level of biotoxin in the shellfish is sufficient to cause a health risk as described below.

Toxin	Amount that must not be exceeded in the edible portion:
Paralytic Shellfish Poison (PSP)	80 micrograms saxitoxin equivalent/100g
Amnesic Shellfish Poison (ASP)	20 ppm 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 shall 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 shall be 1 mg of YTX equivalents/kg
Azaspiracid Poison (AZP)	The maximum level of AZA1, AZA2 and AZA3 shall be 0.16 mg kg ⁻¹ of azaspiracid equivalents/kg.

1. okadaic acid and dinophysistoxins: an hydrolysis step may be required in order to detect the presence of DTX3
2. pectenotoxins include PTX1 and PTX2

3.11.5

A shellfish growing area closed due to marine biotoxins shall not be reopened until the authorised health officer has determined that each of the requirements for reopening, as stated in the New Zealand Marine Biotoxin Management Plan, have been adequately addressed.

3.11.6

Marine biotoxin analyses required by this section shall be conducted in accordance with the requirements of Section 2.4 of this circular.

3.11.7

A report shall be prepared by the authorised health officer on each closure and reopening event due to marine biotoxins. The report shall fully document the data, environmental conditions and factors leading to the decisions and a copy shall be attached to the annual growing area report.

3.11.8 Procedures for the release of shellfish detained or recalled for marine biotoxin reasons are specified in IAIS 003.7.

4 Relaying

Issue 25

November 2003

4.1 Regulatory Requirements

The regulations state:

“Fish declared by the Director-General to be subject to this clause under regulation 5(2) of these regulations and received into a product area of fish premises shall have been grown in or taken from a place for which there is an approved monitoring programme to show that the place is not contaminated at the time of catching or harvesting”.

Under **Clause 4, Part IV, First Schedule to the Regulations**, the approved monitoring programme is laid down in Sections 4.2-4.6.

4.2 Shellfish Available for Relaying

Shellfish may be harvested for relaying from:

- approved areas when they are closed in accordance with Section 3.11.4;
- conditionally approved areas when they are closed because of harvesting criteria or marine biotoxins, provided that the area meets the restricted area classification criteria and the requirements of Sections 3.7 and 3.8 of this standard have been complied with;
- restricted areas at any time;
- conditionally restricted areas when the areas comply with the restricted area water quality.

Relaying requirements do not apply to the transplanting of shellfish from one part of a growing area to another part of the same growing area.

4.3 Conditions for Relaying

4.3.1

Each person harvesting shellfish for relaying shall possess a permit to relay issued by the Inspector. The permits shall be non-transferable and shall be issued only for a specific relaying operation according to the approved operating procedures described in Section 4.3.2. The Inspector may revoke the permit when operating procedures are not complied with. The permit shall have an expiry date which is no longer than 1 year after the date of the permit. Model forms for relaying procedures are provided in Appendix VIII.

4.3.2

Written relaying operating procedures shall be developed by the relayer and approved by the Inspector. The procedures shall include:

- the source and species of shellfish to be relayed;
- information on the quality of the shellfish and the growing water prior to harvest for relaying purposes;
- information on the quality of the water and the shellfish indigenous to the relaying area;
- information on the quality of relayed shellfish after purification;
- the time of the year when the relaying may occur;
- the method of marking the growing area used for relaying;
- the method of transport to the relaying site;
- the method of holding the relayed shellfish at the relaying site;
- the method of maintaining adequate separation between different lots of relayed shellfish and between relayed shellfish and shellfish which has not been relayed;
- how the permitted harvester will maintain and file records with the Inspector;
- the issuing of permits to relay by the Inspector.

Note that the portion of the operating procedures which is constant during all relaying operations may be set forth in a standard operating procedure. The procedure shall be reviewed at least annually by the Inspector.

4.3.3

Adequate records shall be maintained and submitted to the Inspector by the relaying permit holder. The information and the frequency with which it is to be submitted shall be specified in the relaying permit. These records may include results of microbiological analyses on each lot of relayed shellfish before and after the relaying period, the period of relaying, the date of harvest, the source and quantity of relayed shellstock, and the purchaser and quantity purchased. This may best be accomplished by assigning lot numbers to incoming shellfish and carrying the lot number through the relaying process.

4.3.4

All relaying operations shall be effectively supervised by the Inspector.

4.4 Relaying Areas

4.4.1

Areas in approved, remote approved or conditionally approved growing areas that contain relayed shellfish shall be located and marked so that they may be readily identified. In addition, the shellfish in adjacent approved or conditionally approved areas shall be adequately separated from the relayed shellfish so as to avoid contamination.

4.4.2

Relayed shellfish shall be held in the approved, remote approved or conditionally approved areas for a sufficient period of time under suitable environmental conditions to assure purification. The bacteriological quality and marine biotoxin level of the shellfish after relaying shall attain the same quality as the same species already in the relay area. The time required for purification will normally be determined by water temperature, salinity, initial quality, species of shellfish and the ability of the shellfish to cleanse themselves. This period shall be at least 14 consecutive days when environmental conditions are suitable for

purification unless shorter periods are demonstrated to be adequate according to the procedures in Section 4.5.2.

4.4.3

Water temperature, salinity and any other critical variables identified in the area to be used for relaying shall be determined at a frequency approved by the Inspector when it is known that the limiting values may be approached and when the minimum relaying period is approached.

4.4.4

Adequate studies shall be conducted to establish the effectiveness of contaminant reduction to the satisfaction of the Inspector.

4.5 The Relaying Process

4.5.1

Shellfish shall be relayed only according to the approved operating procedures and the conditions of the relaying permit.

4.5.2

Purification times of less than 14 days may be approved by the Inspector provided that adequate data are first produced to justify the shorter periods. These data shall include:

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

4.5.3

Where shellfish are relayed in containers, the shellfish shall be culled, washed and placed in clean containers which allow the free flow of water to the shellfish. The depth and configuration of shellfish in containers shall allow the shellfish to pump (feed) normally.

4.5.4

The identity of lots of relayed shellfish shall be maintained and the containers correctly labelled. Each lot shall be kept separate from other lots to prevent cross-contamination and mixing.

4.6 Harvest of Relayed Shellfish

Relayed shellfish shall be harvested only after the harvester has verified that operating procedures have been complied with and signed a Declaration of Harvest of Relayed Shellfish form (as described in Appendix VIII; Form VIII.3).

5 Harvesting, Handling and Transport of Shellfish

Issue 25

November 2003

5.1 Regulatory Requirements

5.1.1

The regulations state:

“Fish declared by the Director-General to be subject to this clause under regulation 5(2) of these regulation and received into a product area of fish premises shall have been grown in or taken from a place for which there is an approved monitoring programme to show that the place is not contaminated at the time of catching or harvesting”.

Under **Clause 4, Part IV, First Schedule to the Regulations**, the approved monitoring programme is laid down in Sections 3.2-3.11.

5.1.2

The regulations also state:

“No fish or fish products shall be received into the product area of fish premises -

- b. If, since the time of catching or harvesting, the fish or fish products have not been handled, held, and transported in an approved manner so as to prevent deterioration and to protect it from contamination; or
- c. If the fish or fish products have not been labelled or identified in an approved manner”.

Under **Clause 1 (b) and (c), Part IV, First Schedule to the Regulations**, the approved manner for handling, holding and transporting shellfish is laid down in Sections 5.2-5.10, and for labelling shellfish in Section 5.6.

5.1.3

The regulations also state:

“Fish and fish products shall be maintained under approved temperature regimes while being transported or stored”.

Under **Clause (2), Part VI, First Schedule to the Regulations**, the approved temperature regimes for transport or storage of shellfish are laid down in Sections 5.2-5.10.

5.2 General Requirements

5.2.1

No person shall harvest, handle or transport shellfish for human consumption except according to the requirements of this circular.

5.2.2

All land and water transport vehicles used for shellstock transport shall be constructed, operated, cleaned and maintained so as to prevent contamination, deterioration or decomposition of the shellstock.

5.2.3

A list of all shellfish harvesters and road transport operators shall be kept by the Inspector and updated annually.

5.2.4

All harvesting vessels and road transport vehicles shall be inspected at least annually and approved in writing by the Inspector. A model report form is provided in Appendix IX.

In special circumstances, such as transporting shellfish from isolated rural areas, an Inspector may approve a method of transport (e.g. in an enclosed sanitary design chilled container with a specified transport firm), rather than approving a particular vehicle.

5.3 Surveillance of Harvesting

5.3.1

The Inspector shall monitor each growing area to ensure compliance with harvesting criteria, closures and harvesting, storage in sorting sheds, relaying, labelling, handling and transport requirements. A model surveillance report form is provided in Appendix X.1.

5.3.2

A surveillance plan to address the above requirements shall be developed by the Inspector for each growing area and reviewed each year.

5.3.3

The surveillance plan shall address the prevention of illegal harvesting of shellfish from growing areas and shall include details about the personnel and agencies involved and the nature and frequency of surveillance.

5.3.4

A surveillance report shall be prepared by the Inspector each year for each growing area and shall contain details of the surveillance activities performed during the preceding year. The report shall be included in the annual growing area report. A model annual surveillance report is shown in Appendix X.2.

5.4 Design of Vessels and Vehicles

5.4.1

Decks and storage areas on vessels shall be designed and constructed to prevent bilge water or polluted water from coming into contact with shellfish.

5.4.2

Where the vessel or vehicle deck is not channelled, graded or adequately drained, the shellstock shall be stored a minimum of 25 mm off the deck.

5.4.3

Human body wastes shall not be discharged from harvest vessels while in or adjacent to growing areas.

5.4.4

Where toilets are provided on harvest vessels, hand sanitising facilities shall also be provided. Toilets and hand sanitising facilities shall be designed, located and operated to prevent the contamination of growing areas and adjacent waters and be of a type approved by the Inspector. Everyone shall sanitise their hands after using the toilets.

5.5 Harvesting

Where necessary, shellstock shall be washed using water of an approved area quality under pressure to remove mud, bottom sediments, detritus and seaweed during or as soon as practicable after harvesting. Shellstock shall not be washed with recirculated water unless this has been approved by the Inspector.

5.6 Shellstock Packaging and Labelling from Harvest to Fish Packing House

5.6.1

Containers for the transport and storage of shellstock shall be clean and constructed from impervious easily cleanable materials.

5.6.2

Bags or sacks shall not be reused for shellfish unless constructed of an impervious material approved by the Inspector. Prior to such bags or sacks being reused, they shall be effectively washed, then sanitised by soaking in a solution containing at least 50 ppm and not more than 200 ppm of free available chlorine for 30 minutes or by using an equivalent

sanitising method approved by the Inspector. Where the Inspector considers it necessary, the bags/sacks shall be rinsed with potable water or clean seawater to prevent the sanitiser from contaminating the shellfish.

The sanitised bags shall be protected from contamination prior to reuse.

5.6.3

Bags, sacks or other containers used to contain shellstock shall only be labelled with:

- words or statements required by this circular;
- a description of the contents of the container.

5.6.4

Each bag, sack or container of shellstock shall be labelled at the time of filling with a durable and legible waterproof harvest label that is affixed to the exterior of the container.

5.6.5

The harvest label shall contain the following information:

- the name or licence number of the harvester,
- the Ministry of Fisheries licence/lease/permit/authorisation number,
- the date of harvest.

In the case of dredge oysters (*Ostrea chilensis*) harvested from the Challenger dredge oyster fishery, the label shall also contain the growing area number.

5.6.6

A harvest declaration shall also accompany consignments of shellstock to the fish packing house and this shall contain the following information:

- the name or licence number of the harvester;
- the Ministry of Fisheries licence/lease/permit/authorisation number;

- the date and starting time of harvest;
- the species and quantity of shellfish;
- the licence number and name of the destination packing house;
- the signature of the harvester or picker;
- the shellfish have been harvested in accordance with the requirements of this circular.

A model shellfish harvest declaration form is provided in Appendix XI.I. (The declaration may be adapted for the harvesting of shellfish for depuration.)

5.6.7

Each marine farmer, harvester, person authorised to take shellfish under the Fisheries Act 1983 and packing house manager shall keep a record of the above information for at least 2 years to allow for traceback investigations.

5.7 Shellstock Sorting Sheds

5.7.1

Shellstock harvested for sale shall not be stored overnight in a sorting shed unless this has been approved by the Inspector.

The purpose of approving the overnight storage of shellstock in sorting sheds is to address the difficulty of transporting shellstock to packing houses when the times of tides limit transport arrangements.

5.7.2

The Inspector may grant an approval when satisfied that the following conditions have been met in a written agreement:

- The name and contact details of the person responsible for managing the sorting shed shall be stated.

- The times of tides that overnight storage is permitted for and transport departure times the following day shall be specified.
- Shellstock shall only be stored overnight when transport to a packing house is inhibited by the times of tides.
- Shellstock shall not be stored in a sorting shed for more than 24 hours.
- Dogs, cats and other animals shall not be permitted into the sorting shed.
- The shellstock shall be stored in a room, compartment or container that:
 - ⇒ is vermin-proof,
 - ⇒ has tight fitting doors/lids/accessways,
 - ⇒ has flooring/structures that prevent shellstock from coming into contact with shellstock liquor,
 - ⇒ is not used to store petrochemicals or other materials that may contaminate the shellstock,
 - ⇒ is constructed of materials which, in the opinion of the Inspector, are unlikely to contaminate the shellstock,
 - ⇒ complies with the requirements of Section 5.9.
- Arrangements shall have been made between the Inspector and the sorting shed manager for access by the Inspector at any reasonable time to the sorting shed and harvest/storage records.
- All shellstock which has been harvested for sale, and is to be stored overnight in a sorting shed, shall be labelled in accordance with the requirements of Section 5.6.5 prior to the overnight storage.

5.7.3

In granting approval, the Inspector may specify any conditions relating to the storage requirements or record keeping that are considered necessary.

5.7.4

MAF shall provide fish packing houses with a list of approved sorting sheds.

5.8 Vessels and Vehicles Used for the Transport of Shellstock

5.8.1

Any vessel or vehicle which has been used to transport toxic substances, livestock or any other goods which may contaminate or adversely affect shellstock shall be decontaminated and/or sanitised to the satisfaction of the Inspector prior to transporting shellstock.

5.8.2

Animals or birds shall not be permitted in or on vessels or vehicles on which shellstock is transported.

5.8.3

Shellstock shall not be transported with other cargo unless the shellstock is separated from the other cargo by impervious horizontal partitioning or isolated by another method approved by the Inspector. No other cargo may be placed on or above the shellstock unless the shellstock are packed in sealed, crush-resistant impervious containers.

5.8.4

Mechanically refrigerated and frozen transport units shall be equipped with calibrated thermostats and indicating thermometers which accurately measure the temperature in the unit. The refrigerated transport units shall be capable of holding the unit at a temperature of 7° C or less.

5.8.5

The transport unit shall be designed so that it is easily cleaned and will not allow contamination of the shellstock.

5.9 Requirements for the Care of Shellstock during Transport

5.9.1

Shellstock which are harvested or transported on a vessel for more than 6 hours shall be shaded from the sun or sprayed with water of approved area quality or chilled with ice or covered with clean wet sacks or subjected to other measures agreed to in writing by the Inspector to prevent an unacceptable increase in temperature and/or bacterial levels.

5.9.2

All shellstock harvested for sale and not intended for wet storage or depuration shall be placed under temperature control in accordance with the protocol specified in Appendix XII. Once placed under temperature control, the shellstock storage area or conveyance shall be continuously maintained at 7 °C or cooler until final sale to the consumer or until processing (except for points of transfer such as loading docks; here product shall not remain out for periods of more than 2 hours).

Where the conveyance is a harvesting vessel, the provision of adequate quantities of visible ice in or on the container of shellstock will be sufficient compliance for continuously maintaining temperature control.

5.9.3

Once the shellstock has been placed under temperature control, there shall be a continued downward trend in its temperature until the product reaches an internal temperature of 10° C or cooler.

5.9.4

Shellstock harvested for depuration, relaying, processing or packing shall not be left unattended or unprotected at a wharf or public place or outside.

5.9.5

Shellstock harvested for depuration, relaying, processing or packing shall be protected from contamination from the point of harvest to the fish packing house, depuration plant or relaying area.

5.10 Arrival at the Fish Packing House

5.10.1

On arrival at the fish packing house the following details shall be checked and recorded in the permanent records of the packing house:

- shellfish declaration details,
- labelling of containers,
- the hygienic status of the containers,
- compliance of the shellfish with the harvesting criteria,
- condition of shellfish, i.e. clean, alive, damaged,
- the shellstock internal temperature.

The person undertaking the check shall sign the record.

5.10.2

Shellstock shall not be accepted into a packing house if:

- The containers of shellstock do not have proper identification and harvesting tags are not labelled in accordance with Section 5.6.5 and are not accompanied by the harvest declaration required by Section 5.6.6.
- Where the labelling or harvest declaration requirements are incomplete or missing, the shellstock may be accepted into the packing house providing:
 - ⇒ the shellstock concerned is kept separate from other shellstock;
 - ⇒ the Inspector is notified within 24 hours of the consignment and the deficiency; and

⇒ the product is not processed until approved by the Inspector.

- The shellstock has not been stored under the temperature control requirements stated in Section 5.9.2.
- The temperature of shellstock which has been harvested for more than 24 hours exceeds 16° C.
- The shellstock has not been grown, harvested, handled or transported according to the requirements of this circular.
- The shellstock is not alive (except where approved by the Inspector).
- Any shellstock stored in a sorting shed overnight has not been stored in accordance with the requirements of Section 5.7.

Where shellstock arrives at a packing house in contravention of these criteria, the manager shall advise the Inspector within 24 hours.

6 Wet Storage

Issue 25

November 2003

6.1 Regulatory Requirements

The regulations state:

“No fish or fish products shall be received into the product area of fish premises -

(b) If, since the time of catching or harvesting, the fish or fish products have not been handled, held and transported in an approved manner so as to prevent deterioration and to protect it from contamination”.

Under **Clause 1(b), Part IV, First Schedule to the Regulations**, the approved manner for wet storage of shellfish is laid down in Sections 6.2 - 6.6.

6.2 Application

Wet storage may be used for the temporary storage of shellfish while awaiting processing for sale, for desanding or for improving palatability characteristics such as salinity. Wet storage requirements shall not apply to transplanting shellfish. Shellfish for wet storage shall be harvested only from approved or conditionally approved areas (when open for harvesting) and shall be harvested, labelled and transported according to this circular.

6.3 Requirements for Wet Storage

6.3.1

Each wet storage site, facility or premises shall be licensed by the New Zealand Food Safety Authority, and shall comply with the applicable parts of IAISs 001 and 003.

6.3.2

Each onshore wet storage facility shall comply with the following design, construction and operating requirements:

- Effective barriers shall be provided to prevent the entry of birds, animals and vermin into the area and above the wet storage tanks.
- The construction of floors, walls and ceilings and installation of lighting, plumbing and sewage disposal systems shall comply with the applicable provisions of IAIS 001.
- Storage tanks and related plumbing shall be fabricated of non-toxic materials and shall be easily cleanable. The construction of tanks shall allow for easy access for cleaning and inspection, self-drainage and comply with the product-contact surface requirements of Section 11.1 of IAIS 001.2. The design and installation of plumbing shall allow for regular cleaning and sanitising, as specified in the operating procedures, to prevent contamination of the tank and water.
- The design, dimensions and construction of storage tanks shall allow for adequate clearance between shellfish and the tank bottom.
- Shellfish containers, if used, shall have an impervious mesh-type construction which allows water flow to all shellfish in the containers.

6.3.3

The site, facility and plant shall be evaluated and approved annually by the Inspector, on the basis of an evaluation of the nearshore site or the facilities plan and operating procedures for an onshore operation submitted by the licensee, and an inspection of the storage site, facility and plant. Factors to be considered include, but are not limited to, the following:

- the sanitary survey of the nearshore storage site, with special consideration of potential intermittent sources of pollution;
- the location of nearshore storage sites and floats;
- a plan giving the design of the onshore storage facility, the source of water to be used for wet storage, and details of any water treatment system (all plans for construction or remodelling of onshore wet storage facilities shall be approved by NZFSA prior to commencing construction);
- the purpose of the wet storage operation, such as holding, conditioning or salinisation, and any relevant physiological factors of the shellfish species that may affect design criteria.

6.3.4

Nearshore areas used for wet storage shall meet the approved or conditionally approved area classification requirements whenever shellfish are being held there for direct marketing. Harvesting from conditionally approved areas shall only take place when the area meets the approved area water quality requirements.

6.4 Water Quality

6.4.1

Process water shall not adversely affect the sanitary quality of the stored shellfish.

6.4.2

In recirculating wet storage systems or systems using source water with a lesser quality than approved areas, a water treatment system shall be used which provides enough water of adequate quality to carry out the intended purpose of the wet storage operation. The minimum quality of the source water prior to treatment shall be that for a restricted area. Treated water entering the wet storage tanks shall have no detectable levels of total coliform bacteria as measured by any of the approved laboratory tests for the analysis of total coliform bacteria in seawater.

6.4.3

When recirculating water is used, a water treatment effectiveness study shall be conducted to determine that the system will consistently produce water with no detectable levels of total coliform bacteria under normal operating conditions. Thereafter, the frequency of routine sampling for such systems shall be at least weekly. In the event that a single sample contains any detectable levels of total coliforms, as measured by an approved test for total coliforms, daily sampling shall be instituted immediately until the problem is identified and demonstrated to be corrected.

6.4.4

The wet storage water treatment effectiveness study shall consist of five sets of three samples from each treatment unit. Samples shall be collected at the outlet of the water

treatment unit or at the point where the treated water enters the holding tank. In addition, one sample per day of untreated water will be collected and analysed. These samples shall be collected daily for 5 days and analysed by an approved test for total coliforms. Any positive sample of treated water shall constitute a failure of the effectiveness study, which shall be repeated after corrections have been made.

6.4.5

The effectiveness of treatment shall be confirmed whenever more than 10% of the water volume is added from an unapproved area or each time new ultra violet bulbs are installed. A set of three samples of treated water and one sample of untreated water shall be collected in one day to reaffirm the effectiveness study.

6.4.6

When corrections to the treatment are required because positive sample results are found in a sample of treated water, the effectiveness of the correction shall be demonstrated by the collection of three samples of treated water and one sample of untreated water in one day following the correction.

6.4.7

For water receiving ultra-violet disinfection, turbidity shall not exceed 20 nephelometric turbidity units (NTU).

6.4.8

Water of approved growing water quality may be used in wet storage tanks without disinfection if the system is a continuous flow-through one and provided the nearshore water source used for supplying the system meets the approved area water quality criteria at all times.

6.4.9

Salt added to increase salinity or produce synthetic seawater shall be food-grade salt.

6.5 Care of Shellfish

6.5.1

While awaiting storage in a wet storage facility or area, shellfish shall be protected from physical or thermal abuses which may reduce the effectiveness of the wet storage process.

6.5.2

Shellfish shall be thoroughly washed with water meeting approved area standards, and culled to remove dead, broken or cracked shellfish prior to wet storage in tanks. Due to the adverse effects of culling on mussel physiology, mussels may be culled after wet storage, subject to the approval by the Inspector as specified in the operating procedures.

6.5.3

Shellfish from different harvest areas shall not be mixed during wet storage in tanks. If more than one harvest lot of shellfish are being held in wet storage at the same time, each harvest lot shall be individually identified throughout the wet storage process.

6.5.4

Bivalve molluscs shall not be mixed with other seafood species in the same tank. Where multiple tank systems use a common water supply system for bivalve mollusc and other seafood species, process water shall be effectively disinfected prior to entering the tanks containing bivalve molluscs.

6.6 Records

The wet storage licensee shall maintain complete and accurate records which will enable each lot of shellstock to be traced back to the wet storage location and classified growing area. Results of water samples and other required tests and traceback records shall be maintained for a minimum of 2 years.

7 Depuration

Issue 25

November 2003

7.1 Regulatory Requirements

The regulations state:

“All fish shall be processed in accordance with approved processes carried out in accordance with any conditions attached to that approval.

All steps in any approved process, including packing, shall be performed without unnecessary delay and under conditions (including time and temperature parameters) that minimises the possibility of contamination or deterioration of fish or fish products”.

Clauses 20 and 21, Part II, First Schedule to the Regulations, require all fish to be processed in accordance with an approved process. The approved process for depuration of shellfish is laid down in Sections 7.2 - 7.11.

7.2 Application

7.2.1

Depuration is intended to reduce the number of pathogenic organisms that may be present in shellfish which have been harvested from moderately polluted areas to such levels that the shellfish will be acceptable for human consumption without further processing.

Depuration is neither intended to reduce contamination in shellfish from heavily polluted areas nor to reduce the levels of toxic substances which shellfish may have accumulated from their environment.

7.2.2

Shellfish harvested for depuration shall only be harvested from growing areas that have a classification of conditionally approved, restricted or conditionally restricted or any other area approved by an authorised health officer.

7.3 Standards and Licensing

Each depuration plant shall comply with the applicable parts of IAIS 001 and be licensed by New Zealand Food Safety Authority.

7.4 Commissioning a Depuration Plant

7.4.1 Requirement for process studies

Each depuration plant shall develop an approved depuration process (ADP) based upon a comprehensive study of the effectiveness of the depuration plant operations (including at least ten full trials, with additional trials being required if the commissioning of the plant is based on trials which do not encompass the winter and summer seasons). A report shall be prepared for each approved depuration process. The recommended format for this report is shown in Appendix XIII.

7.4.2 Scope of depuration process studies

The development of the depuration process shall take into account the following principles and procedures.

It shall be demonstrated through depuration process studies that the shellfish will consistently meet the end-point criteria specified in Section 7.11.5. The studies shall include an examination of the following critical variables:

- shellfish species,
- seasonal effects,
- growing water temperature,
- salinity,
- dissolved oxygen (DO),
- turbidity,
- growing water classification,
- process water standards,

- process water treatment,
- shellfish tray clearances,
- water hydraulics,
- depuration times,
- incoming shellfish quality,
- end-point criteria,
- plant process monitoring,
- sanitation procedures,
- growing area shellfish quality.

Where environmental conditions vary in the growing area, in the depuration source water or at the depuration plant, the studies shall encompass those conditions.

Comprehensive depuration studies shall be undertaken to demonstrate the maximum allowable zero-hour level of faecal coliforms in the shellfish in the plant. The maximum zero-hour level of faecal coliforms shall be such that the end-product criteria are consistently met.

Shellfish used in depuration trials shall be disposed of by:

- destruction or non-food use;
- relaying in accordance with Section 4;
- release for sale, provided the trial batch has been sampled in accordance with a sample plan approved by the Inspector and the sample results comply with the requirements of Section 7.11.5.

Copies of all depuration studies shall be held in the central file.

7.4.3 Nature of depuration process schedule studies

The following process schedule studies are required:

- A minimum of one dye study shall be conducted in each depuration unit to demonstrate process water circulation (see Appendix XIV).

- The turbidity of the raw process water shall be determined for all hydrologic and environmental conditions under which the process may operate.
- A minimum of one study using spiked untreated process water containing an estimated 88 faecal coliforms /100 ml shall be conducted to determine the efficiency of the water treatment unit. The samples to determine the effectiveness shall be taken from the treatment unit outlet immediately after the spiked water has passed through the treatment unit, on the first circulation (see Appendix XIV).
- At least one study using contaminated shellfish shall be conducted when each depuration unit in the system contains the optimum quantity of shellfish to assist in setting shellfish entry standards and mid-point standards, and to provide evidence that end-point standards will be met (see Appendix XIV).
- After each study the depuration system shall be sanitised with water containing 50 ppm available chlorine (or an equivalent disinfectant approved by New Zealand Food Safety Authority) by circulating the sanitising solution through the system with the treatment unit on for at least 30 minutes. After draining the sanitising solution from the units, the system shall be flushed with potable water to remove all traces of sanitiser.

7.4.4 Depuration process approval

Each depuration process shall be approved by the Inspector prior to the start of commercial operations.

7.4.5 Routine monitoring

Once the plant is commissioned, routine monitoring of the process shall continue in order to ensure that end-product criteria consistently are met (see Section 7.11).

7.5 Harvesting for Depuration

Shellfish shall not be harvested for depuration unless the Inspector has issued a special permit to the licensed marine farmer or person authorised under the Fisheries Act 1983 or 1996 to take shellfish. The permit shall specify the term of the permit, the conditions under which harvesting for depuration may occur, container labelling requirements and the growing areas to which the permit applies. A copy of the permit shall also be held at the depuration plant.

Product arriving at a depuration plant shall be accompanied by a shellfish harvest declaration (a model form is in Appendix XI).

7.6 Process Water Standards

7.6.1

The process water shall meet the physical, chemical and microbiological parameters required for the health and normal physiological activity of the shellfish.

7.6.2

A minimum of 5.0 mg/l of dissolved oxygen shall be maintained throughout the depuration system.

7.6.3

Treated water at the point of entry into the depuration unit shall contain no detectable coliform organisms.

7.6.4

The salinity parameters shall be established by the depuration process studies.

7.6.5

The temperature range shall be established by the depuration process studies.

7.6.6

Maximum turbidity levels of the source water prior to treatment and the process water at the depuration unit exit point shall not exceed 20 nephelometric turbidity units.

7.6.7

The pH of the water shall be in the range 7.0-8.4.

7.6.8

The depuration plant shall have on site or at a readily accessible designated place calibrated equipment to measure:

- dissolved oxygen,
- pH,
- temperature,
- turbidity,
- salinity,
- flow rate.

7.6.9

The flow rate of process water in each tank shall be a minimum of 107 l/min/m³ of shellfish unless the ADP studies show a lesser flow rate provides effective depuration and the flow rate is approved by the Inspector.

7.6.10

The minimum volume of process water in each depuration unit for cockles and oysters shall be 6400 l/m³ of shellfish based on the total tank capacity, unless the Inspector approves a lesser volume, based on approved depuration process studies. Minimum volumes for other shellfish species shall be determined by depuration process studies and approved by the Inspector.

7.6.11

Where process water is recirculated, the process water must be changed between each depuration batch.

7.6.12

Where a depuration plant contains a water treatment system the treatment shall not leave residues that may interfere with the depuration process, or the physiology or wholesomeness of the shellfish.

7.7 Shellfish Standards

7.7.1

Shellfish shall be thoroughly washed prior to depuration to remove mud, sand and other surface contaminants and culled to remove dead, broken and cracked shellfish.

7.7.2

The maximum level of faecal coliforms in shellfish entering a depuration plant shall be determined by the ADP studies. In any event, shellfish from the areas specified in Section 7.2.2 shall not have levels in excess of 3000 faecal coliforms /100 g of flesh except with the approval of the Inspector, based on the approved depuration process studies.

7.7.3

Different shellfish species shall not be processed in the same unit unless the approved depuration process studies demonstrate that the depuration requirements for each species are compatible.

7.7.4

Shellfish shall be handled and stored in such a manner that their physiological activity is not adversely affected and bacteriological quality does not deteriorate.

7.7.5

Shellfish which require depuration shall not be held in the same storage room as shellfish that have been depurated or which do not require depuration unless the method of storage and labelling has been approved by the Inspector. This method and approval shall be attached to the depuration process report required by Section 7.4.1.

7.7.6

Containers of shellfish which have undergone depuration shall not be stored in the same room as shellfish which have been harvested according to approved or conditionally approved area criteria unless the containers are distinctively marked or labelled and stored in a marked separate part of the room.

7.7.7

Shellfish shall be thoroughly washed and culled after depuration to remove surface contaminants and culled to remove dead, broken, cracked or gaping shellfish.

7.7.8

Different lots of shellfish shall not be mixed. If more than one lot is being depurated at the same time, then the identity of each lot shall be maintained from harvest through to final packing.

7.8 Depuration Unit Trays

7.8.1

Shellfish trays shall be impervious, easily cleaned and designed to allow adequate flow through the mesh.

7.8.2

The maximum depth of shellfish in trays shall not exceed three layers for oysters. For other species the depth shall be determined by scheduled depuration process studies and approved by the Inspector.

7.8.3

Shellfish in depuration units shall have a minimum cover of 50 mm of water, and the shellfish shall be not less than 25 mm off the base of the unit.

7.8.4

Depuration unit trays shall not be used for purposes other than depuration unless approved by the Inspector.

7.9 The Depuration Process

7.9.1

The depuration units shall not be filled with water until all the trays have been placed in the units.

7.9.2

If spawning occurs in the units during depuration, the process shall be stopped, the tanks drained and the shellfish removed or the process started at zero hour again. If the process is restarted at zero hour to depurate the spawned shellfish, multiple end-point sampling shall be performed irrespective of any exemptions the plant may have and the shellfish shall not leave the plant until the sample results are available and they demonstrate that the end-point criteria have been complied with.

An Inspector may exempt dredge oysters (*Ostrea chilensis*) from the requirement to restart the depuration process where less than 5% of the oysters are spawning and the depuration unit has a management plan for inspecting all oysters at the completion of depuration and removing all spawned/spawning oysters. Such an exemption shall not exempt the need to hold the shellfish until the sample results are available.

7.9.3

The depuration time shall be determined by the approved depuration process studies and shall be no less than 48 hours unless the Inspector is satisfied that the end point will be consistently met and authorises shorter depuration times down to a minimum of 36 hours. Some species of shellfish (e.g. cockles) may require more than 48 hours depuration time.

7.9.4

Shellfish shall not be removed from the depuration units until all the water has been drained from the units.

7.10 Cleaning and Sanitising Plant and Equipment

7.10.1

Adequate facilities shall be provided for the proper washing, cleaning and sanitising of equipment, utensils and the building.

7.10.2

All equipment and utensils utilised in the depuration plant shall be maintained in a clean condition.

7.10.3

All shellfish and seawater contact surfaces shall be cleaned and sanitised after each use or at the frequencies below:

- Process units, trays, containers and racks shall be cleaned, sanitised and rinsed before each depuration operation.
- The process unit, including the depuration system piping network, shall be cleaned and sanitised at least once a week or once every three depuration operations.
- The seawater storage tanks shall be cleaned and sanitised at least once a week or once every three depuration operations or at a frequency approved by the Inspector.
- The cleaning and sanitising procedures shall be specified in the ADP report.
- The washing and culling areas and pre-depuration storage areas shall be thoroughly washed and sanitised after each use.

7.11 Quality Assurance

7.11.1

A routine monitoring programme shall be developed as part of the approved depuration process and applied to demonstrate compliance with source water, process water and end point criteria.

7.11.2

An adequate number of shellfish samples shall be collected from representative locations within the unit and submitted for microbiological analyses prior to, during and after depuration according to the following minimum schedule:

- from at least 1 in 10 consecutive process batches; or
- where more than 28 days pass between depurating batches of shellfish, during the first process batch.

7.11.3

More intensive sampling of specific lots may be required by the Inspector when the shellfish are from a new growing area and the effectiveness of depuration of shellfish from that area has not been established, or when growing water quality or shellfish quality is highly variable, or when end-product quality is at times marginal or unsatisfactory.

7.11.4

Raw process water and treated process water, other than water from areas of approved growing water quality, shall be tested on each day of use to determine compliance with the critical parameters specified in Section 7.6 and to demonstrate that the water treatment units are operating effectively.

7.11.5

The number and siting of samples required to confirm compliance with end point criteria will be based on information in the approved depuration process. The following table shows the maximum allowable end point faecal coliform levels for oysters and clams for each process batch.

End point criteria

No. of samples	Geometric mean not to exceed (faecal coliforms /100 g)	One sample may exceed (faecal coliforms /100 g)
1	-	-
2	75	-
3	45	-
4	20	-
5	20	45
10	20	70

7.11.6

The continuing evaluation of the depuration plant performance and process efficiency shall be measured on the basis of end-point shellfish sampling using the geometric mean and an upper 10% level (i.e. no more than 10% of the samples analysed shall exceed this value) for the species listed in the table below. In determining these values, all of the end-point data from each group of ten consecutive batches is used. For plants processing less than ten batches in a 3-month period, if any one sample exceeds the upper 10% level or if the geometric mean is in excess of the value specified, the plant does not comply with this standard.

End point criteria for plant performance evaluation

Species	Geometric mean (faecal coliforms /100 g)	Upper 10% (faecal coliforms /100 g)
Hard clam	20	70
Oyster	20	70

8 Processing

Issue 25

November 2003

8.1 Regulatory Requirements

8.1.1 The regulations state:

“All fish shall be processed in accordance with approved processes carried out in accordance with any conditions attached to that approval.

All steps in any approved process, including packing, shall be performed without unnecessary delay and under conditions (including time and temperature parameters) that minimises the possibility of contamination or deterioration of fish or fish products”.

Clauses 20 and 21, Part II, First Schedule to the Regulations, require all fish to be processed in accordance with an approved process. Specific requirements for shellfish are laid down in Sections 8.2 - 8.5.

8.1.2

The regulations also state:

“All containers of fish, fish products, or fish byproducts intended to be exported from New Zealand shall be labelled in an approved manner.

All containers of fish or fish products transferred to, or between fish premises or from fishing vessels (including shellfish harvesting barges) to fish premises shall be labelled or identified in an approved manner”.

Under **Clauses 1 and 2, Part V, First Schedule to the Regulations**, the approved manner of labelling shellfish is given in Section 8.6.

8.2 Premises

8.2.1

Shellfish entering a fish packing house shall:

- have only been harvested from an approved or remote approved or conditionally approved area when open, or taken from a sorting shed, a wet storage facility, a depuration plant or from a source approved by the Inspector;
- be inspected on arrival at the fish packing house in accordance with the requirements of Section 5.10.

8.2.2

Shellfish from different lots shall be kept separate during processing and packing unless the Inspector has approved a shellfish mixing management plan. Such a management plan shall address the conditions for mixing and how the shellfish from different harvest areas and different days of harvest will be identified.

8.3 Packing, Processing and Shucking

8.3.1

Shellfish shall be handled during packing, processing and shucking in such a manner that they will not be subjected to contamination or unacceptable increases in temperature and/or bacterial levels. The measures which shall be taken to achieve this shall include:

- Where shellfish are processed in a room or area where other fish processing operations are performed, adequate measures shall be taken to ensure that there is no likelihood of the fish or shellfish product being contaminated by the other operations via splash, personnel, dual use of appliances or any other means.
- Shellstock shall be inspected immediately prior to shucking to ensure it is alive, clean, wholesome and not badly damaged.
- Shellfish shall be stored at a sufficient height off the floor or in such a location that contamination from floor water, splash water or foot traffic does not occur.

- The shucking operation shall be separated from other processing operations by adequate barriers or space.
- Shucking and packing operations shall be carried out in separate rooms or in adequately separated areas so that there is no likelihood of the shucked product or packing room equipment being contaminated by splash or by other means from adjacent areas.
- Precautions shall be taken to prevent food-contact surfaces of shucked shellfish containers from coming into contact with splash liquid or product handlers or their clothing.
- Shucked shellfish shall be delivered to the packing room within 1 hour of being shucked or prechilled and placed in temporary refrigeration at 7°C or cooler for no more than 2 hours.
- During shucking and packing, shellfish shall be examined for naturally occurring materials such as shell pieces and non-edible components. Such materials shall be removed.
- Shucked shellfish shall be thoroughly drained, cleaned as necessary and packed promptly after delivery to the packing room. The packing process shall be scheduled and conducted so that all meats are chilled to an internal temperature of 7°C or colder within 2 hours of delivery to the packing room.
- Shellfish meat which is packed into containers larger than 5 litres shall be prechilled to 7°C or colder prior to packing in the container.
- Shucked shellfish containers shall be completely emptied at the packing room and not returned to the shucking room unless washed and sanitised.
- Shucked shellfish shall be packed in clean containers fabricated from safe materials. Returnable containers shall be acceptable for interplant shipment of shucked shellfish only and shall be sealed during such transport. The shellfish from returnable containers shall be repacked into proper single-use containers.
- Containers of shucked shellfish shall be closed promptly after filling and when not in immediate use.
- Skimmer tables and other packing equipment shall be located so that they will not receive drainage from the delivery window or contamination from shucking room equipment and utensils.

- Shuckers and other unauthorised persons shall not be permitted entry into the packing room or area for any purpose except in a small operation where an employee may work in both the packing and shucking room. In such cases, the employees shall put on a clean apron or other outer clothing, sanitise their footwear before entering the packing room and thoroughly wash their hands with an approved sanitiser after entering the room.
- Shucked shellfish shall be packed only into containers labelled in accordance with Section 8.6.

8.3.2

Ice used in direct or indirect contact with shellstock or shucked shellfish shall be:

- manufactured in a premises licensed by MAF or a territorial local authority;
- of potable water quality;
- manufactured, stored, handled and transported in such a manner that it will not become contaminated;
- inspected on arrival at a packing house when delivered from another premises, and rejected if delivered in a manner which may have permitted contamination or if contamination (e.g. from dust, chemicals, foreign matter) is evident.

8.3.3

Shucked shellfish intended to be marketed in a chilled state shall not be permitted to leave the packhouse unless the temperature of the shucked shellfish is 4° C or colder. This temperature shall be maintained during transport and storage.

8.3.4

Live shellfish intended to be marketed in a live chilled state shall not be permitted to leave the packhouse unless the temperature of the shellfish is 10°C or colder. This temperature shall be maintained during transport and storage.

The licensee may apply to the Director (Animal Products) for a derogation from this requirement for shellfish destined for the domestic market. Derogation will only be

considered when the shellfish are stored in the packing house for less than 12 hours and are maintained under temperature control at all times while in the packing house.

8.3.5

Shellfish which are to be frozen shall be arranged to ensure rapid freezing and shall be frozen a temperature of -18°C or colder, with shellfish frozen solid within 12 hours from the start of the freezing process. Frozen shellfish shall be held at -18°C or colder during storage and transport.

8.4 Heat Shocking

8.4.1

Each licensed premise which heat shocks shellfish shall develop a heat shock process schedule based upon a comprehensive study of the process. A report on the studies shall be prepared for each heat shock process and shall address such critical factors as the type and size of shellfish, time of exposure to heat, internal shellfish temperature and process temperature, type of heat process, water to shellfish ratios, size of process equipment, measurement devices and their calibration, shell removal techniques, post-heat shock chilling techniques, packing and storage procedures, cleaning and sanitising of heat process equipment.

8.4.2

Each heat shock process schedule shall be approved by the Inspector prior to the start of commercial operations.

8.4.3

All shellstock shall be washed with pressurised potable water or water of approved growing area quality and culled of badly damaged and dead shellstock prior to heat shocking. Shellstock shall be protected from contamination during and after washing.

8.4.4

The heat shock process shall not result in an increase in microbiological levels in the shellfish.

8.4.5

The operator of the heat shock process shall be familiar with the heat shock process schedule and shall not operate the heat shock appliance unless in accordance with the approved heat shock process schedule.

8.4.6

Either the heat shock process schedule shall be posted in a conspicuous location near the heat shock process appliance or the process approval shall contain the names of the operators who are familiar with and have been trained in the requirements of the heat shock process schedule.

8.4.7

Heat shocked shellfish shall be cooled to 7°C or less within 2 hours of being heat shocked and shall be cooled to 4°C or less within 4 hours of being heat shocked.

8.4.8

Where a water tank heat shock process is used, the tank shall be completely drained and rinsed in such a manner that all the sediment and detritus are removed at 3 hour intervals or at a frequency agreed in writing by the Inspector. The tank shall be drained, washed and sanitised at the end of each day's operation or more frequently if required by the Inspector.

8.5 Repacking

8.5.1

Repacking is the process of removing shellfish from one package and placing them in another package.

8.5.2

Shellfish for repacking shall originate only from a licensed packing house, a depuration plant or a wet storage facility.

8.5.3

Where repacking of shellstock occurs, the following procedures shall be complied with:

- Where the shellstock has been previously refrigerated, the shellstock shall be transported under refrigeration.
- Full records shall be kept according to Section 2.3.
- Shellstock shall not be mixed during repacking.
- Only clean, alive, or chilled, or frozen shellfish shall be repacked.

8.5.4

Where repacking of shucked shellfish occurs, the following procedures shall be complied with:

- Shucked shellfish shall not be repacked when the temperature of the shellfish exceeds 4°C or the temperature of the frozen shellfish is warmer than -18°C at the time of receipt or the packages are not labelled according to Sections 5.6 and 8.6.
- Only shellfish which has originated from a licensed packing house and been kept in export-licensed premises shall be repacked.
- Full records shall be kept according to Section 2.3.
- The internal temperature of shucked shellfish shall not exceed 4°C during storage or repacking operations.
- Shucked shellfish from different lots shall not be mixed during the repacking operation.
- If during repacking further processing occurs, using a process given specific approval pursuant to IAIS 003.5 Section 3 (e.g. smoking, marinating, freeze drying), then the temperature requirements set out above may be replaced by the temperatures specified in the process approval.

8.5.5

Each package containing repacked product shall be labelled according to IAIS 004 and be labelled with the repacker's licence number.

8.6 Labelling

In addition to the requirements of IAIS 004, containers of shellfish are required to be labelled as below.

8.6.1

Either containers of shellfish leaving the packing house shall be labelled with:

- the growing area lease, licence, permit number,
- the date of harvest,
- the type and quantity (e.g. number, weight) of shellfish;

or the Inspector may approve the use of a lot number labelling system to replace the date of harvest and harvest area, provided that packing house records are adequate to enable traceback to the specific harvest dates and harvest areas. The approval shall specify how this will be achieved.

8.6.2

Where reshipping (i.e. the purchase and resale of shellfish without repacking) occurs, the original labels on shucked shellfish and shellstock shall be maintained on the product containers. The labelling information shall not be altered or removed, nor the product mixed with other shellfish, resorted or repackaged. The name of the reshipper shall be added to the package.

Appendix I

Approved Laboratories for Microbiological Analyses

Issue 25

November 2003

The following laboratories have been approved in accordance with Section 2.4 of this circular:

- **AgriQuality Lab Network**
131 Boundary Road
Blockhouse Bay
Auckland
Postal Address: PO Box 41, Auckland
Contact: Brenda Whitfield
Phone: 64 09 626 6026
Fax 64 09 627 9750
- **Cawthron Institute**
98 Halifax Street East
NELSON
Postal address: Private Bag 2, NELSON
Contact: Ron Fyfe
Phone: 64 03 548 2319 or 0800 809 898
Fax: 64 03 546 9464
- **Waikato Environmental Health Laboratory Ltd (Envirolab Waikato)**
Knox Street
HAMILTON
Postal address: PO Box 52, HAMILTON
Contact: Gordana Alexsic
Phone: 64 07 834 0712
Fax: 64 07 834 0758

- **Gribbles Analytical Laboratories**

35 O'Rorke Road

Penrose

AUCKLAND

Postal Address: PO Box 12-545, Penrose, AUCKLAND

Phone: 64 09 579 2669

Fax: 64 09 579 9044

- **Citilab**

10 Tahuna Road

DUNEDIN

Postal Address: PO Box 781, DUNEDIN

Contact: Graham Mason

Phone: 64 03 455 7940

Fax: 64 03 455 7940

Email: citilab@bigfoot.com

Appendix II

Approved Laboratories for Marine Biotxin Analyses

Issue 25

November 2003

The following laboratories have been approved in accordance with Section 2.4 of this circular:

- **AquaBiotox - Laboratory (AgriQuality NZ/ Crop and Food)**
AgriQuality Lab Network
131 Boundary Road
Blockhouse Bay
AUCKLAND
Postal Address: PO Box 41, AUCKLAND
Contact: Cliff Bancroft
Phone: 64 09 626 6026
Fax: 64 09 627 9750
Biotxin Analyses Approved: ASP/PSP/DSP/NSP
- **Cawthron Institute (Cawthron/ Crop and Food)**
98 Halifax Street East
NELSON
Postal Address: Private Bag 2, NELSON
Contact: Paul McNabb/ Patrick Holland
Phone: 0800 809 898
Fax: 64 04 546 9464
Biotxin Analyses Approvals ASP/PSP/DSP/NSP
- **Food Evaluation Unit, Crop and Food Research**
Food Industry Science Centre
Batchelar Road
PALMERSTON NORTH 5301
Postal Address: Private Bag 11-600
Contact: Aaron Miller
Phone: 64 06 353 0962
Biotxin Analyses Approved: PSP/DSP/NSP (mouse bioassay only)

Appendix III

Minimum Requirements For Performing Shoreline Surveys In Shellfish Growing Areas

Issue 25

November 2003

III.1 The boundaries of the shoreline survey area shall be determined by a field investigation of the area topography and the proximity of individual properties to the growing area. This should identify for examination only those properties where the potential discharges of wastes (raw sewage, kitchen wastes, laundry wastes, agricultural wastes, etc.) may affect growing water quality.

III.2 The location of each property with a pollution source adversely affecting the growing area shall be clearly shown on a map of the survey area.

III.3 If the property has a pollution source adversely affecting a growing area, it shall be classified into one of the two categories below concerning its impact on water quality.

Direct impact

A pollution source having direct impact is defined as one which directly discharges into the growing area.

An attempt should be made to quantify the volume of the discharge.

Indirect impact

A pollution source having an indirect impact is defined as any waste discharge which reaches the growing area in a roundabout way.

An attempt should be made to quantify the volume of the discharge.

III.4 All sanitary, industrial or agricultural sources of pollution shall be marked on a map of the survey area.

III.5 All farms with animals shall be evaluated. The evaluation shall include the number and type of animals and, where relevant, the type and effectiveness of waste treatment systems.

III.6 All marinas shall be evaluated according to Section 3.2.8 of Appendix IV.

III.7 The survey shall comment on flocks of waterfowl and on populations of wild animals such as deer, seals, penguins and possums. An estimate of their number, seasonality and effect on the growing water quality shall be provided.

III.8 Drains, ditches, streams and other watercourses shall be evaluated

III.9 Any other potential source of pollution which in the surveyor's opinion might influence water quality shall be evaluated and reported on.

III.10

The surveyor shall provide a comprehensive map of the survey area identifying the location of each pollution source found

Appendix IV

Model Sanitary Survey Report

Issue 25

November 2003

The following outline of a sanitary survey report has been included to illustrate the wide variety of factors that have to be taken into account during the planning, execution and documentation of a complex growing area sanitary survey. Each sanitary survey report shall be written in a similar format to this model and all applicable factors listed below shall be considered in planning, conducting and writing the report. The model is also useful as a checklist to determine what survey information should be collected, to promote national uniformity in survey report preparation and to aid in defending classification decisions when challenges arise.

1. Summary

- 1.1 What, when, where and why descriptions
- 1.2 Allocation of a unique growing area name and number
- 1.3 Abstracts of results and activities
- 1.4 Conclusions
- 1.5 Recommendations
- 1.6 Actions

2. Background Information

- 2.1 **Purpose, objectives, goals and reason** for the survey/study
- 2.2 **General description of area** including maps and, if available, aerial photographs. Map showing location in New Zealand, location in region and specific water area
- 2.3 **History of shellfish programme for the growing area.**
 - 2.3.1 Summary of sanitary survey history
 - 2.3.2 Previous or recommended classification(s)

- Legal description
- Maps showing situation of growing area, houses, farms, land use, marinas, wharves
- Colour photographs, e.g. showing growing area, tide in, tide out

2.3.3 Resources

- Shellfish species
- Distribution (map)
- Abundance
- Actions

2.3.4 Harvest practices

- Commercial
- Recreational
- List of lease, licence and authority owners
- Wet storage facilities (map)
- Seasonality
- Landings
- Relaying
- Depuration

3. **Pollution Source Survey**

3.1 Survey procedures

3.1.1 Personnel involved and time period.

Survey plan - procedures for:

- shoreline reconnaissance
- sampling
- sampling stations, map references, how determined

- collection methods and practices
- analytical methods
- laboratories.

3.2 Identification and evaluation of pollution sources

Exploration of all visible discharge pipes

3.2.1 Domestic wastes (maps)

- Septic tanks: statement on presence in catchment and, if adjacent to shoreline/watercourses, more detail on effluent disposal. Attach house-to-house inspection form to sanitary survey report
- Number and distribution
- Soil suitability
- Holding and pump-outs, where disposed
- Impact on growing area
- Treatment plants/package plants/lagoons
- Location
- Size and capacity, both operational and design
- Type of treatment
- Outfall location
- Pumping station(s): show on map and explain emergency provisions
- Bypasses
- Chlorination
- Backup equipment
- Hours of attendance and/or alarms
- Operational effectiveness:

- ⇒ breakdowns
- ⇒ bypassing
- ⇒ chlorination practices
- ⇒ strength/quality of effluent
- Acknowledgment of responsibility
- Emergency notification procedures
- Location of sewer pipes if near to growing area

3.2.2 Stormwater

- Combined
- Drainage ditches, pipes and runoff

3.2.3 Industrial wastes

3.2.4 Radionuclides

3.2.5 Agricultural practices

- Fertilisers
- Pesticides
- Dairy shed wastes

3.2.6 Wildlife and domestic animals

- Unfenced access of animals to growing areas

3.2.7 Boat traffic and the presence of houseboats

3.2.8 Marinas

The impact of marinas shall be calculated on the following assumptions:

- the occupancy rate of the marina
- an assumed percentage of boats which will discharge untreated waste
- an occupancy rate of at least 2 persons per boat

- a discharge rate of 2×10^9 faecal coliforms per persons per day
- the wastes are completely mixed in and around the marina
- closure is based on a theoretical calculated faecal coliform count (MPN) of 14/100 ml
- closure is based on the volume of water in the vicinity of the marina.

3.2.9 Non-point pollution sources

4. Hydrographic and Meteorological Characteristics (maps)

4.1 Physiography (description of body of water)

4.1.1 Physical description: width, length and depth

4.1.2 Channels

4.1.3 Rivers

4.1.4 Passes

4.2 Tides

4.2.1 Type

4.2.2 Amplitude

4.2.3 Tidal exchange rate

4.3 Rainfall and runoff

4.3.1 Amount, summary of last 5-10 years

4.3.2 Seasonal variation

4.3.3 Frequency of significant rainfalls

4.3.4 Rain gauge reference points

4.3.5 Heaviest fall in last 5 years

4.4 Winds

4.4.1 Strength

4.4.2 Directions

- 4.4.3 When/seasonality
- 4.4.4 Effect of wind in tidal estuaries, harbours and inlets
- 4.5 River discharges
 - 4.5.1 Volumes
 - 4.5.2 Seasonal
 - 4.5.3 Discussion on time for river to rise and fall after heavy rains and time for rains to reach river gauge
 - 4.5.4 River height gauges
- 4.6 Currents
 - 4.6.1 Tidal
 - 4.6.2 Wind driven
 - 4.6.3 Flood
 - 4.6.4 Times
 - 4.6.5 Dispersion and dilution
 - 4.6.6 Effects of ocean currents on growing areas in bays, harbours and inlets
- 5. Water Quality Studies**
 - 5.1 Description of programme
 - 5.1.1 Sample stations (maps), reason for selection
 - 5.1.2 Minimum sampling plan required under adverse conditions including comment on wet weather surveys, time taken for bacteriological levels in water to return to 14 faecal coliforms/100 ml and time taken for shellfish to return to 300 faecal coliforms/100 g.
 - 5.1.3 Sample collection, handling and transport
 - 5.1.4 Analytical procedures
 - 5.1.5 History of algal and diatom blooms in or adjacent to growing areas
 - 5.2 Data presentation (tables)

5.3 Data analysis

5.3.1 IAIS statistical criteria

5.3.2 Advanced statistical tests

5.3.3 Data presented in summary table

5.3.4 Include full calculations and statistics

5.4 Present results on:

5.4.1 Overall conditions

5.4.2 By meteorological conditions

5.4.3 By hydrographic conditions

5.4.4 By pollution events

6. Interrelationships of the Previous Factors

Discussion of how actual and potential pollution sources, wind, tide, rainfall, etc., affect or may affect the growing area water quality. The discussion shall include the following points:

- Pollution sources as affected by meteorological conditions
- Pollution sources as affected by hydrographic conditions
- Potential pollution sources which may occur due to seasonal conditions such as holidays, stock sales and festivals
- Adverse conditions caused by meteorological events
- Adverse conditions caused by hydrographic factors
- Explanation of the causes of data variability
- **Data analysis and discussion on the interrelationships of the above factors in relation to their effects on the quality of the growing water and shellfish.**

7. Management Plans

Management plans of conditionally approved and conditionally restricted areas shall be included in the sanitary survey report in accordance with Sections 3.6.2, 3.8.2 and Appendix VII.

8. Conclusions

8.1 Recommended classification and harvesting criteria

8.1.1 Classification of area for respective criteria

8.1.2 Maps

8.2 Recommendations

8.2.1 Monitoring schedule and stations, etc.

8.2.2 Comments, suggestions for future work

Appendix V

Systematic Random Sampling Strategy

Issue 25

November 2003

V.1 Background

V1.1

When classifying shellfish 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).

V1.2

The requirements of Section 3.2 of this circular shall be complied with to establish that the growing area is not affected by point-source pollution.

V1.3

Prior to a systematic random sampling strategy being used, the sampling plan shall be filed in the central file.

V.2 Requirements for the Use of a Systematic Random Sampling Strategy

V2.1 The following sampling requirements shall be fully complied with:

- Sample collection shall be scheduled sufficiently far in advance to support the premise that collection is random with respect to environmental conditions such as rainfall, wind, etc. Systematic random sampling shall be applied.
- A minimum of six samples per station shall be collected per year. If conditions are judged hazardous to crew safety at the scheduled time of sampling, samples shall be collected as soon after that as possible.

- A minimum of 30 of the most recent samples collected at each station shall 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 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 shall 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. 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.
- If a tidal stage is found to increase bacteriological concentrations in the growing area, the tidal conditions that cause the effect shall be used as the basis for the sample plan.
- For the purpose of mathematical calculations, MPN values that signify the upper and lower range of sensitivity for that test shall be increased or decreased respectively by one significant number.

V2.2

The annual evaluation shall 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.

V.3 Bacteriological Standards

V3.1 Approved areas

The bacteriological quality of every sampling station in an approved area shall meet the following standard:

- The faecal coliform median MPN of the water shall not exceed 14/100 ml and the estimated 90th percentile (see Section V.4) shall not exceed an MPN of 43/100 ml for a five tube decimal dilution test (or an MPN of 49/100 ml for a three tube decimal dilution test).

V.3.2 Restricted areas

The bacteriological quality of every sampling station in a restricted area shall meet the following standard:

- The faecal coliform median MPN of the water shall not exceed 88/100 ml and the estimated 90th percentile shall not exceed an MPN of 260/100 ml for a five tube decimal dilution test (or an MPN of 300/100 ml for a three tube decimal dilution test).

V.4 Background to the Use of the Ninetieth Percentile

V4.1

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

V4.2

Each delivery centre has 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 shall be used to calculate the estimated 90th percentile.

V4.3

The public health concern is that although many waters may meet the IAIS median, and percentage factor criteria, some shellfish growing water sampling stations still display a considerable level of variation in a distribution of sampling results. In such a situation, the risk to the shellfish-consuming public has been a concern, since sampling data of this type may indicate that the shellfish growing waters are intermittently polluted.

V4.4

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" was not intended to allow for variation in the data caused by changes in environmental conditions at the time of sampling. The "percentage factor" was 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 (230 or 330 MPN per 100 ml) allow a somewhat greater degree of variation than that attributable to the MPN test alone. The presence of wide swings in water quality that result from changing environmental conditions are not endorsed by the water quality criteria.

V4.5

The 1965 revision of Part I of the NSSP 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 $70 \times 3.3 = 230$.

V4.6

The dilemma facing the shellfish growing water evaluator is how to distinguish between the inherent variation of the MPN test and that resulting from intermittent environmental conditions that degrade water quality. It is not intended that shellfish growing waters be classified that are polluted 10% of the time.

V4.7

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 shellfish may be exposed to enormous quantities of pollution. In this situation, the determination of conformity for a randomly collected set of growing water 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 waters.

V4.8

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 shellfish growing water 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.

V.5 Guideline for Estimating the Ninetieth Percentile

V5.1 The estimated 90th percentile shall be obtained from the following equation:

$$\text{Est. 90th} = \text{antilog} [(s_{\log})1.28^* + x_{\log}]$$

Where

s_{\log} = the standard deviation of the logarithms of the MPN values comprising the data set

x_{\log} = the mean of the logarithms of the MPN values comprising the data set (also known as the log mean or the arithmetic average of the logarithms). The geometric mean is the antilog of x_{\log} .

* This value is obtained from the normal standard derivation.

V5.2 Other instructions

- For the purpose of the mathematical calculations, MPN values that signify the upper or lower range of sensitivity for that test shall be increased or decreased one significant number. (MPN scores are reported in the form of two significant numbers.) For example, a MPN value of “less than 2” shall be decreased by 1 to 1.9 to indicate the lower level of sensitivity of the five tube MPN test.

In a similar manner, 2.9 shall be used to indicate the MPN value of “less than 3” for the three tube MPN test and a MPN value of 1700 shall be used to indicate the MPN value “greater than 1600” for the five tube MPN test.

- Logarithms may be rounded to three decimal places.
- Antilogs of log MPN calculations may be rounded to the next lower integer (0 decimal places), e.g. antilog (0.556) = 3.
- The standard deviation of the log MPN data shall be calculated in the following manner:

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

V.6 Application of the Guideline

V6.1 Example 1

- Convert the MPN values to logarithms:

Obs	MPN	log ₁₀	Obs	MPN	log ₁₀
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

- Calculate the geometric mean and standard deviation:

Median = 3.6
 Percentage greater than 43 = 3.3 %
 Geometric mean (antilog x_{\log}) = antilog (0.834) = 6

Log standard deviation (s_{log}) = 0.506

- Calculate the estimated 90th percentile using the above equation:

Est. 90th = antilog ($(s_{log}) 1.28 + x_{log}$)
 = antilog ($(0.506)1.28 + 0.834$)
 = antilog (1.482)
 = 30

- 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 circular for an approved growing area.

V.6.2 Example 2

- Convert the MPN values to logarithms:

Obs	MPN	\log_{10}	Obs	MPN	\log_{10}
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

Calculate the geometric mean and standard deviation:

- Calculate the geometric mean and standard deviation:

Median = 2.0
 Percentage greater than 43 = 6.6%
 Geometric mean (antilog x_{log}) = antilog (0.788) = 6
 Log standard deviation (s_{log}) = 0.737

- Calculate estimated 90th percentile using the above equation:

$$\begin{aligned} \text{Est. 90th} &= \text{antilog} ((s_{\log})1.28 + x_{\log}) \\ &= \text{antilog} ((0.737)1.28+0.788) \\ &= \text{antilog} (1.731) \\ &= 53 \end{aligned}$$

- 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 stormwater 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.

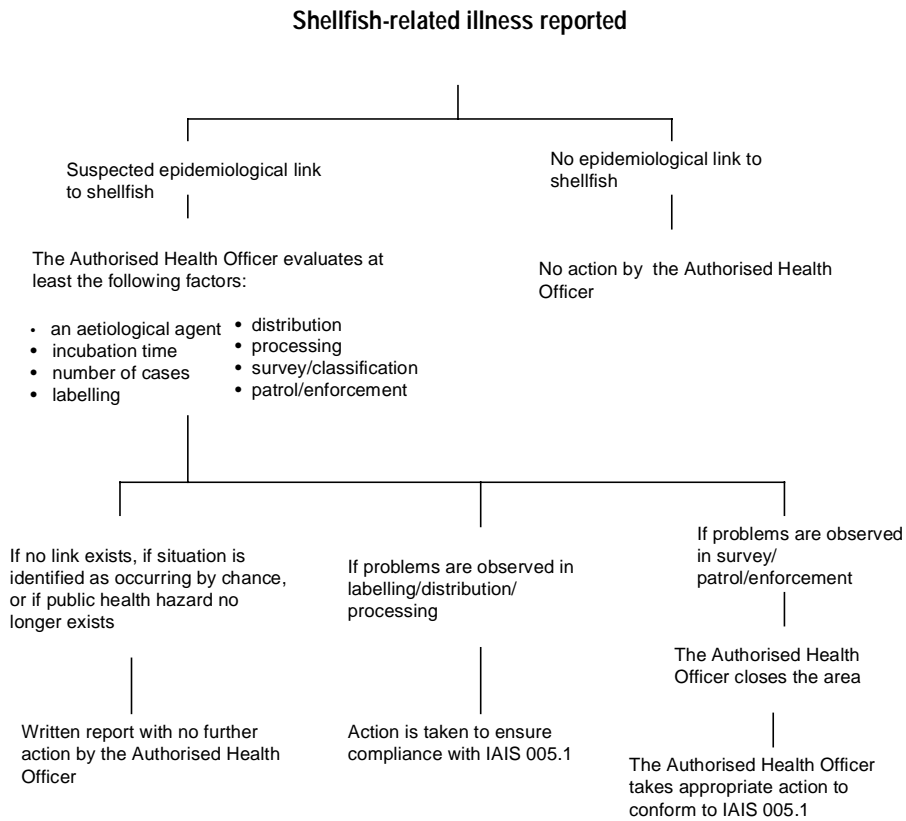
Appendix VI

Protocols for Reviewing the Classifications of Areas Implicated in Shellfish-Related Illnesses

Issue 25

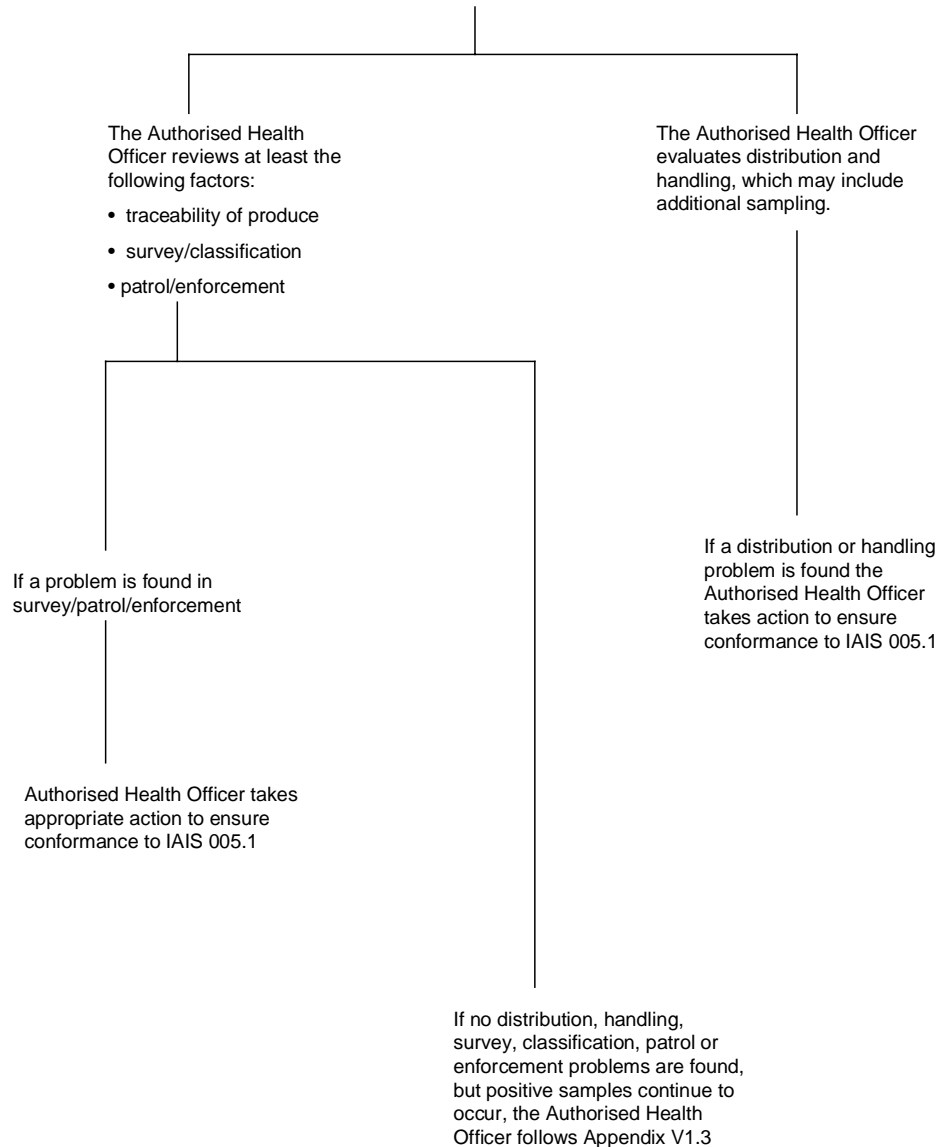
November 2003

VI.1 Protocol for Reviewing the Classification of Areas When Shellfish-Related Illnesses are Reported.

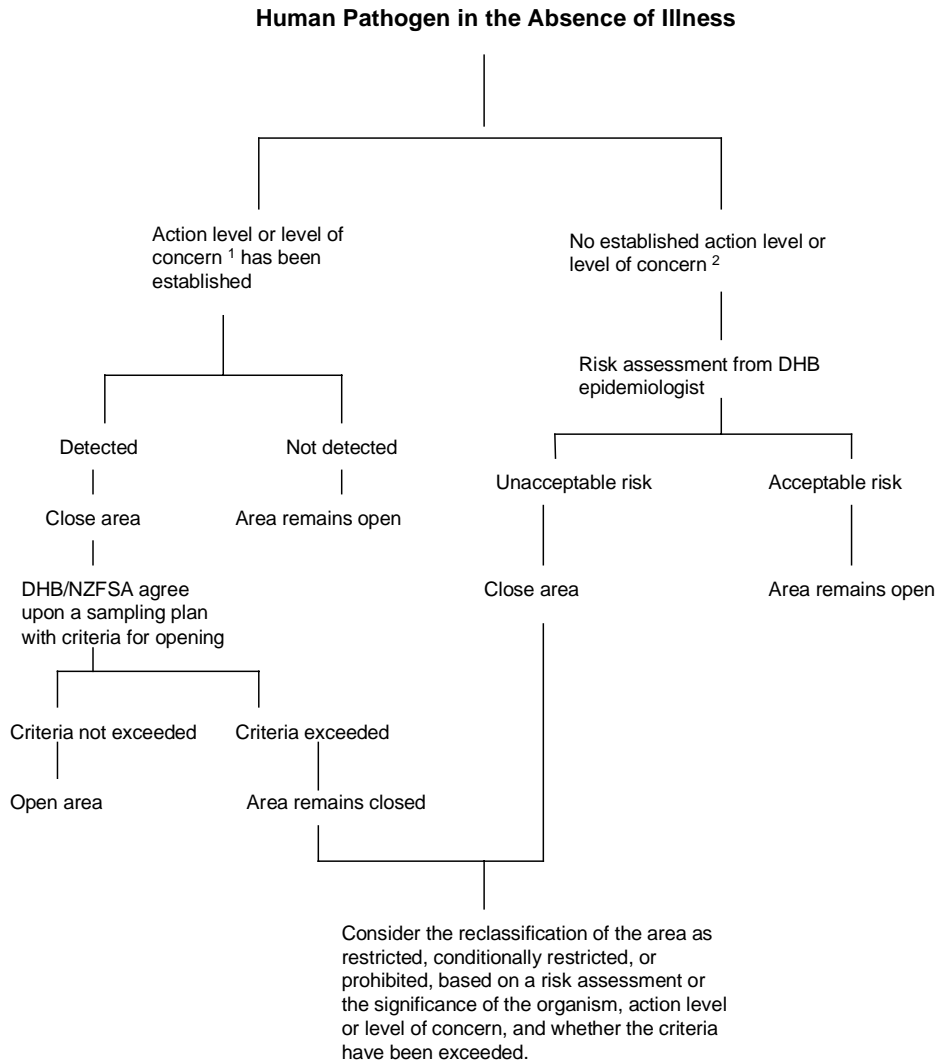


VI.2 Protocol for Reviewing the Classification of Areas With Positive Pathogen Results In Shellfish Meat Samples

Human pathogens isolated in meat sample from a growing area



VI.3 Protocol for Reviewing the Classification of Areas With Positive Pathogen Results in the Absence of Illnesses



Notes:

1. The Ministry of Health established Microbiological Reference Criteria (October 1994) for certain microbial pathogens to provide guidance in assessing the safety of molluscan shellfish.
2. In the absence of a microbiological reference criterion, the Authorised Health Officer will consider the action required on a case-by-case basis.

Appendix VII

Minimum Requirements and Standard Format for a Conditional Area Management Plan

Issue 25

November 2003

VII.1 A written management plan shall be developed by the Inspector for each conditionally approved and conditionally restricted area with the assistance of the shellfish industry and local agencies such as local and regional councils, crown health enterprises, rainfall station readers and wastewater facility operators.

The purpose of and conditions in the management plan for each conditionally approved and conditionally restricted area shall be understood and agreed upon in writing by all parties involved. Failure of any one party to agree shall be sufficient justification for NZFSA, if it believes the failure of agreement is of significance, to reclassify an area as prohibited.

VII.2 The management plan shall include:

1. A general description of the conditionally managed area including a map showing area boundaries.
2. A description of factors determining the growing area's suitability for being classified conditionally approved or conditionally restricted.
3. A description of predictable pollution events that cause closure, including:

3.1 Wastewater treatment facility performance standard based on:

- ⇒ Peak effluent flow
- ⇒ Bacteriological quality of the effluent
- ⇒ Physical and chemical quality of the effluent
- ⇒ Bypasses
- ⇒ Design, construction, and maintenance to minimise mechanical failure or overloading
- ⇒ Provisions for verifying and monitoring efficiency of the wastewater treatment plant and the feedback system for addressing inadequate treatment.

3.2 Meteorological or hydrological events:

- ⇒ Specific meteorologic and/or hydrologic events that will cause the area to be closed.
- ⇒ Data and a discussion concluding that these specific meteorologic and/or hydrologic events are predictable, so that the operation of the conditional area has a meaningful basis.
- ⇒ The predicted number of times such an event will occur within year based on historical findings.

3.3 Seasonal events, e.g:

- ⇒ Marina closures
- ⇒ Seasonal rainfall
- ⇒ Waterfowl migration

4. Implementation of a conditional area closure

4.1 Notification of management plan violations

- ⇒ The agency or agencies responsible for notifying the Inspector of a management plan violation
- ⇒ The response time between a violation of the management plan and notification of the Inspector
- ⇒ Procedures for prompt notification

4.2 Implementation of a closure

- ⇒ The response time between notification of a management plan violation and legal closure
- ⇒ How the shellfish industry is notified
- ⇒ How surveillance personnel are notified

4.3 Enforcement of closure

- ⇒ Which agency is responsible
- ⇒ Response time between legal closure and patrol agency notification

⇒ Adequacy of enforcement during closure

5. Criteria necessary for reopening a conditional area after a pollution event

The authorised health officer shall establish the following control elements to define reopening criteria:

- Procedures to determine that the pollution event has ended
- A time interval sufficient to permit the area to flush itself, i.e. exchange a sufficient volume of water to disperse or assimilate the pollutant loading
- Shellfish feeding activity sufficient to achieve natural cleansing shall be determined by documented water quality and shellfish studies.
- The time interval sufficient to permit the shellfish to cleanse themselves naturally. The elapsed time can begin only after the completion of the period required for the area to flush.

6. A synopsis of the effectiveness of the closure procedures and co-operation between involved agencies.

Appendix VIII

Model Forms for Shellfish Relaying

Issue 25

November 2003

Form VIII.1: Application to Relay Shellfish

Applicant Details

Name:

Company:

Postal Address:

Fax No. Phone No.

Relay Information

Shellfish species:

Lessee, licensee, permit holder, authorised person:

Growing Area No.:

Method of transport to the relaying site:

Lessee, licensee, permit holder, authorised person of the relaying site:

.....

Growing Area No. of the relaying site:

Method of marking the relaying area:

Method of marking relayed shellfish:

Time of year the relaying is proposed:

I am familiar with the requirements for relaying as stated in Section 4 of IAIS 005.1: *Shellfish Quality Assurance* and am satisfied that all other persons involved in the relay operation are also familiar with these requirements.

Signed Date

(Harvester)



Form VIII.2: Permit to Relay Shellfish

.....
.....
.....
.....

Further to your application to relay shellfish dated this permit number
authorises you to relay shellfish in accordance with the requirements specified in Section 4 of IAIS
005.1: *Shellfish Quality Assurance* and any conditions attached to this permit.

This permit is issued on the condition that you file with this office a declaration describing the relay
operations for each month of relay by the last day of the month.

This permit expires on and you are advised to reapply prior to
that date if you wish the permit to be renewed.

Signed Date
(Inspector)

Form VIII.3: Declaration of Harvest of Relayed Shellfish

<p>Permit Details</p> <p>Name:</p> <p>Company:</p> <p>Permit No.: Issue Date:</p> <p>Shellfish Species:</p> <p>Growing Area Details</p> <p>Licensee, lessee, permit holder, authorised person:</p> <p>Growing Area No.:</p> <p>Relay Area Details</p> <p>Licensee, lessee, permit holder, authorised person:</p> <p>Growing Area No.:</p> <p>Relay Operation Details</p> <p>Relay Lot No.: Relay Date:</p> <p>Quantity:</p> <p>Date of harvest from relay area:</p> <p>I am familiar with the requirements for relaying as stated in Section 4 of <i>IAIS 005.1: Shellfish Quality Assurance</i> and am satisfied that the shellfish have been relayed and harvested in accordance with the approved operating procedures.</p> <p>Signature Date</p> <p>(Harvester)</p>

Appendix IX

Model Harvesting and Transport Report

Issue 25

November 2003

Licence/Lease/Permit No.: _____			
Location: _____			
Licensee/Lessee/Permit Holder _____			
Compliance			
	Last Review	Current Review	Comment
1. Shellfish			
1.1 Accredited marine farm			
1.2 Farm open for harvesting			
1.3 Wash water approved			
1.4 Are alive and not damaged or gaping			
1.5 Are protected from sun, animals, etc.			
1.6 Product protected at wharf			
1.7 Is temperature control adequate			
1.8 Labelling affixed and correct			
1.9 Clean, safe containers			
2. Harvesting vessels			
2.1 Construction satisfactory, easy to clean			
2.2 Inspector has approved sewage disposal system			
2.3 Shellstock protected from drainage water			
2.4 Are in a clean sanitary condition			
3. Harvesting criteria			
3.1 Area open/closed			
3.2 Harvesting declaration complete as per Section 5.6.6			
3.3 Are relaying requirements being complied with?			
3.4 Are wet storage requirements being complied with?			
4. Vehicle transport			
4.1 Construction satisfactory and able to be kept clean			
4.2 Adequate temperature control			
4.3 Thermometer/thermostat present and calibrated			
4.4 Protection from contamination, dust, other cargoes, etc.			
5. Sorting Shed			
5.1 Compliance with Section 5.7			
Signed: _____			
(Inspector/Authorised Health Officer)			

Appendix X

Model Surveillance Reports

Issue 25

November 2003

X.1 Model Routine Surveillance Report

Date and Time:
Licensee, Lessee Permit No:
Growing Area Name and No:
Rainfall:
Area Open/Closed:
Delivery Centre:
Shellfish Species:
Harvesting Vessels Operating:
Closure Criteria:
Water Quality:
Boating Activity:
Shoreline Activity:
Comments:
Signed: (Inspector/Authorised Health Officer)

X.2 Model Annual Surveillance Report

Name of Growing Area:

Personnel Responsible for Surveillance:

Period that Surveillance Report covers:

Number of Days the Area was Closed:

Date and Reasons for Closures (routine management criteria or emergency closure):

.....
.....

Dates the Area was Monitored:

Methods of Monitoring:

Log of Complaints re Illegal Harvesting:

.....

Comments:

.....
.....
.....
.....

Signed: (Inspector/Authorised Health Officer)

Appendix XI

Model Shellfish Harvesting Declaration

Issue 25

November 2003

A shellfish harvest declaration shall accompany the consignment of shellfish to the fish packing house where it shall be retained on file. A copy shall be retained by the lease/licence/permit holder and/or harvester/picker.

I hereby declare that _____ (number) containers of _____ (type of shellfish) were harvested from _____ (lease/licence/permit) of Area _____ (number) at _____ (starting time) on _____ (date) in full compliance with the harvesting and handling requirements as stated in the *Shellfish Quality Assurance Circular 1995 (IAIS 005.1)*.

The shellfish were transported to:

.....
.....

(name of the destination packing house)

..... (premises number)

Signed: *Signature*

Name in block letters

Lease/licence/permit holder and/or harvester/picker

Date:

Appendix XII

Harvesting and Transport Time-Temperature Protocol

Issue 25

November 2003

XII.1

The SSC has established average monthly maximum (AMM) air temperatures for shellfish growing areas by averaging the last 5 years' maximum monthly temperatures for shellfish growing regions.

XII.2

Shellstock shall be placed under temperature control in accordance with the requirements in Tables XII.1 - XII.3.

Table XII.1: Time allowed from harvest to temperature control

AMM temperature (°C)	10	11-18	19-27	>27
Maximum time from harvest to temperature control (hours)	48	36	24	20

Table XII.2: Average monthly maximum air temperatures for growing areas

Site	J	F	M	A	M	J	J	A	S	O	N	D
A	29	28	26	24	21	20	19	18	20	23	23	27
B	28	28	26	24	21	19	19	17	20	23	24	27
C	28	28	26	23	20	18	17	18	19	22	22	26
D	26	26	25	23	21	23	18	22	19	21	22	20
E	27	28	26	24	20	19	18	18	20	22	22	25
F	29	28	26	23	20	18	17	17	19	23	23	27
G	28	28	27	22	19	17	16	18	19	22	23	27
H	27	26	24	22	19	16	16	16	18	21	23	24
I	27	26	24	23	18	16	16	18	21	23	24	25
J	24	23	21	20	16	15	16	15	17	20	24	24
K	27	27	26	24	21	19	18	18	19	22	25	27
L	28	29	27	25	21	20	18	19	20	23	23	27

A = Kerikeri

B = Whangarei

C = Warkworth

D = Port Fitzroy

E = Coromandel

F = Whakatane

G = Motueka

H = Pelorus Sound

I = Dunedin

J = Stewart Island

K = Kaitaia

L = Dargaville

(Musselburgh)

Table XII.3: Temperature recording sites - Growing area numbers

Site	Growing area number
A Kerikeri	204, 205, 206
B Whangarei	207, 212,
C Warkworth	301, 502, 503
D Port Fitzroy	411, 412, 413, 414, 415, 422, 423, 424
E Coromandel	606, 610, 612, 613, 614-1, 614-2, 615, 616-1, 616-2, 617-1, 617-2, 618
F Whakatane	701, 702
G Motueka	1507, 1522, 1523, 1530, 1531, 1532
H Pelorous Sound	1501, 1502, 1503, 1504, 1505, 1506, 1508, 1509, 1510, 1511, 1512, 1513, 1514, 1516, 1518, 1519, 1520
I Dunedin	1801, 1802, 1803

J	Stewart Island	1901, 1902
K	Kaitaia	201, 202, 214, 215, 218.
L	Dargaville	209, 211

Tables XII.2 and XII.3 shall be read together to determine the application of the time-temperature matrix in Table XII.1 for each growing area.

XII.3

Once placed under temperature control and until sale to the final consumer, the shellfish:

- shall be protected from contamination;
- shall be maintained at an environmental temperature of 7°C or less;
- shall not be permitted to remain outside temperature control for more than 2 hours at points of transfer such as loading docks or in the packing house prior to processing.

Appendix XIII

Model Depuration Process Report

Issue 25

November 2003

The following outline has been included to illustrate the wide variety of factors that have to be taken into account during the planning, testing, execution and documentation of a depuration process. Although it is not anticipated that each report will be organised in the same order as shown, it is recommended that all applicable factors listed in the outline be considered in planning, conducting trials and reporting on the verification studies.

1. Summary
 - 1.1. Name and address of plant and operator
 - 1.2. What, when, where and why descriptions
 - 1.3. Abstract of results and activities
 - 1.4. Conclusions
2. Background Information
 - 2.1 Depuration facility design
3. Shellfish Source
 - 3.1 Shellfish species
 - 3.2 Growing water characteristics, e.g. salinity and temperature ranges
 - 3.3 Growing area classification and harvesting criteria
 - 3.4 Harvesting methods
 - 3.5 Water and land transport
 - 3.6 Harvest permit details
 - 3.7 Labelling

4. Depuration Water Source

Water quality characteristics:

- microbiology
- salinity
- turbidity

5. Process Water

Parameters established by process verification studies such as:

- dissolved oxygen
- salinity
- temperature
- faecal coliforms
- pH
- turbidity
- flow rate
- unit and premises shellfish and water capacities

6. Results of Microbiological Analyses

6.1 Water circulation

6.2 Water treatment unit efficiency

6.3 Dye and spiked shellfish tests

Appendix XIV

Commissioning a Depuration Plant

Issue 25

November 2003

XIV.1 Water Treatment, Shellfish Quality and End Point Criteria Studies

The following are the types of studies required to demonstrate the effectiveness of water treatment, to set maximum microbiological quality levels of shellfish entering the depuration process and to demonstrate that end-point criteria will be consistently met.

Full details of all studies shall be included in the scheduled depuration process report.

XIV.2 Circulation

A demonstration of the adequacy of circulation in each unit, e.g. using dye tests.

XIV.3 Treatment Unit Efficiency by *Escherichia coli* Spiking

The effectiveness of the process water treatment unit shall be demonstrated as follows:

1. Calculate the total water volume capacity of the system, i.e. including the pipes, pump, treatment unit and operating tank volume.
2. Early in the morning on the day before the plant is to be tested, inoculate a trypticase soy agar (TSA) plate with an *Escherichia coli* culture known to ferment lactose with the production of gas in 24 ± 2 hours at 44.5 ± 0.2 °C.
3. At 1600 hours on the same day, inoculate a tube containing 10 ml of trypticase soy broth (TSB) by touching an inoculation needle on to the *Escherichia coli* TSA plate. Incubate the tube at 35 ± 0.5 °C for 18 hours.
4. On the day of the plant test, make a 10^{-4} dilution of the inoculated TSB culture from fresh TSB and keep this chilled until used. The quantity of the 10^{-4} dilution required will depend on the total volume (V) of the depuration unit calculated in Step 1.

$$\text{Quantity of dilution required} = \frac{V(\text{litres}) \times 88 \times 10^5}{2 \times 10^9}$$

This formula has been derived on the assumption that an 18 hour TSB culture of *Escherichia coli* prepared as described above contains 2×10^9 *Escherichia coli*/ml. This may vary between laboratories. Therefore, each laboratory is advised to occasionally prepare a series of at least five 18- hour TSB cultures as in Step 3 and to determine the average number of organisms using standard dilution and counting methods. The number of *Escherichia coli* /ml of 18-hour TSB culture for the laboratory should then replace the denominator in the above formula.

5. With all the shellfish trays empty but in place in the depuration unit, fill the system with seawater to maximum capacity with the treatment unit switched on. When full, turn off the seawater supply and switch the treatment unit off.
6. With the treatment unit off and the circulation pump on, pour the 10^{-4} dilution of *Escherichia coli* from Step 4 into the depuration tanks, taking care to distribute it as evenly as possible in the tanks. Circulate this spiked water through the system for at least 30 minutes.
7. After at least 30 minutes of circulation, take three 100 ml samples of the spiked water from the outlet point of the tank.
8. Switch on the water treatment unit and **immediately** after the spiked water has passed through the treatment unit on its first circulation, take three 100 ml samples of the treated spiked water from the outlet end of the treatment unit.
9. Chill both sets of samples immediately and test as soon as possible (within 6 hours) for faecal coliforms using the APHA five tube MPN test for seawater.
10. After the two sets of samples have been taken, sanitise the system with a 50 ppm available chlorine solution or an equivalent sanitiser (approved by MAF RA) by circulating the sanitising solution through the system for at least 30 minutes.

The untreated process water used in the test should ideally contain 88 faecal coliforms /100 ml, which is the maximum permissible median MPN level for water from a restricted growing area. This is also the standard for water which can be treated for use in a depuration plant.

No faecal coliforms should be detected in the treated water samples.

XIV.4 Depuration Process Efficiency

The effectiveness of the depuration process in meeting end point criteria shall be demonstrated. The following is an example of such a study.

1. Fill all tanks of the depuration unit with (washed, culled, etc.) shellfish to the maximum operating capacity as if running the plant under operating conditions.
2. Pack 10 shellfish per bag into 11 cleaned mesh containers and close with mailbag or other secure seals.
3. Measure clean seawater into buckets or other suitable containers, allowing 4 litres of seawater for every 10 shellfish. Any size or number of tanks or buckets can be used as long as the ratio of 4 litres of water to 10 shellfish is maintained.
4. Using the 18-hour TSB culture of *Escherichia coli* prepared in Step 4 of Section XIV.3, prepare 10 ml of the 10^{-4} dilution. Add to the seawater in the ratio of 0.5 ml of diluted culture to 4 litres of seawater. Mix well.
5. Place bagged shellfish into the spiked seawater so that the shellfish are not lying more than two deep. Leave undisturbed for at least 30 minutes.

If cockles are to be used for this test, it is important to ensure that Step 4 is carried out within 2 hours of high tide at the site from which the cockles were harvested.

6. Drain the buckets quickly and rinse the shellfish with clean seawater before use.
7. Pack one bag of shellfish into an insulated container with ice and transport it to the laboratory for testing within 6 hours.
8. The 0 hour sample should contain between 10^3 and 10^4 faecal coliforms per 100 g.
9. Distribute the other 10 bags evenly among the shellfish in the depuration tank(s). Position the bags in places where there may be dead spots in the tanks. Place some of the bags at the outlet end of the tank(s).
10. Fill the depuration unit with the treatment unit switched on. When the unit is full, turn off the water supply but leave the circulation pump and treatment unit on. Start timing the depuration cycle as soon as the water supply is turned off.
11. During the 48-hour cycle, monitor and record temperatures, salinity, flow, etc., at least every 12 hours.
12. After 48 hours of depuration, switch off the treatment unit and open the tank drains.
13. When the depuration tanks have drained, remove the 10 bags of shellfish, taking care to label where each one was positioned in the tank(s). Pack into insulated containers with ice, transport to the laboratory and test within 6 hours for faecal coliforms using APHA methods.

14. After removing the shellfish, clean and sanitise the depuration unit as in Step 10 of Section XIV.3.

Appendix XV

Shellfish Growing Areas Classified for Harvest for Human Consumption in Accordance with the Requirements of IAIS 005.1

Issue 25

November 2003

Refer to NZFSA website address below for the latest list.

<http://www.nzfsa.govt.nz/animalproducts/seafood/registers/sfishgrow.pdf>