

Imported Food Requirements: Bivalve Molluscan Shellfish

From the 1st July 2009 NZFSA replaced this SMR with a standardised format for all Imported Food Requirements.

This version is obsolete. Refer to the current version.

1 RECENT UPDATES

Date	Section	Information
1 July 2009	All	Made obsolete refer to the Imported Food Requirement for Imported Food Requirement for Bivalve Molluscan Shellfish.
3 September 2008	5.2.2	Updated to include the receipt of pre-clearance application from Korea
29 August 2008	5	Updated status of country to country arrangements and transitional provisions removed
23 May 2008	6	Clarification of import conditions

2 INTRODUCTION

The imported food requirements for bivalve molluscan shellfish (BMS) implement the Food (Prescribed Foods) Standard 2007. Under this Standard BMS can be monitored for metal

contaminants, biotoxins, pathogenic bacteria and pathogenic viruses. The Food (Prescribed Foods) Standard 2007 can be found at: <http://www.nzfsa.govt.nz/policy-law/legislation/food-standards/index.htm>

The New Zealand Standard for BMS can be found online at http://www.nzfsa.govt.nz/animalproducts/legislation/notices/animal-material-product/shellfish/bmsrcsspecv-16_2_signed.pdf Imported BMS is expected to meet the same end product criteria as per New Zealand Standard requirements.

The imported food requirements apply following biosecurity clearance. BiosecurityNZ require that marine fisheries products for human consumption must be dead. Mollusca may be imported whether of marine or freshwater origin. Importers should contact Biosecurity New Zealand directly to check their full requirements – see www.biosecurity.govt.nz

3 BACKGROUND

[Attachment 1](#) contains background information regarding the hazards associated with BMS and review of the BMS Standard and the associated import requirements.

4 IMPORT CRITERIA

4.1 These import requirements apply to the following products:

Marine and freshwater BMS including live, raw, cooked, ready-to-eat (RTE), canned and dried BMS.

Note:

These foods are targeted at the border using the New Zealand Customs tariff code system. The tariff codes currently targeted for monitoring under this rule are contained in **Appendix 1**. It should be noted that the targeted tariff codes are subject to regular reviews and may change in future. Importers importing BMS covered by this standard under tariff codes that are not listed in **Appendix 1** should advise NZFSA as the targeted codes will need to be reviewed.

4.2 These import requirements do not apply to the following products:

All products other than those listed under 4.1.

Note:

Molluscs that are not bivalves are excluded from this standard as they do not present the same hazards as BMS. For example: paua, abalone, octopus, squid, sea slugs and snails are excluded – regardless of packaging.

Roe-off scallops i.e. traded as abductor muscle only (eviscerated and with the roe removed) are also excluded from this standard. This recognises that viruses, biotoxins and metal contaminants are concentrated in the gut and roe of scallops during feeding and removal of these parts ensures the product is free from these hazards.

5 IMPORT CLEARANCE

5.1 Generic Clearance Procedure

Generic clearance procedures apply to all food imported into New Zealand and can be found at: <http://www.nzfsa.govt.nz/imported-food/clearance/index.htm>

5.2 Clearance Procedure Specific to BMS: Pre-clearance arrangement

BMS is permitted to be imported from exporting countries ONLY where the NZFSA has negotiated a pre-clearance arrangement with the relevant countries Competent Authority. Pre-Clearance arrangements confirm that BMS are derived from a BMS programme in the exporting country which manages the hazards associated with BMS and meets New Zealand's requirements for BMS. Arrangements with exporting countries may vary according to the scope of the application and are specific to the recognised programme in operation in the exporting country.

5.2.1 BMS Pre-clearance Arrangements

Pre-clearance arrangements, which include the import of BMS, have been concluded with the following countries:

- Australia
- Canada
- European Community
- United States of America.

Each arrangement is specific in terms of scope (i.e. types of BMS covered by the arrangement) and import conditions that have been recognised as either meeting or

determined equivalent to New Zealand Standards (for example: certification checks and physical inspections).

See **Appendix 2** for details of each country's pre-clearance arrangement.

5.2.2 Countries that have applied for a pre-clearance arrangement

Countries that applied to NZFSA for a pre-clearance arrangement between 30 August 2007 and 30 August 2008 may continue to export BMS to NZ under import conditions which existed prior to 30 August 2008 until the determination of a pre-clearance arrangement is concluded (if applicable). Under these conditions imports of BMS will be sampled and tested according to sections 7.3 and 7.4 of this document.

The following countries have applied for a pre-clearance arrangement:

- Chile
- China
- Japan
- Korea
- Peru
- Thailand
- Vietnam

Where a pre-clearance arrangement has been determined Appendix 2 will be updated.

5.2.3 Countries that have not applied for a pre-clearance arrangement

Countries that have not applied to NZFSA for assessment of their BMS programme prior to the end date of the 30 August 2008 are unable to export BMS to New Zealand.

These countries are able to apply for assessment of their country's BMS programme at any time however, exports will not be permitted entry to New Zealand until the assessment is complete and a pre-clearance arrangement determined (if applicable).

5.2.4 Process to apply for Pre-clearance Arrangement (recognition of exporting country programmes)

NZFSA has developed a template application form to guide countries in their application. The template is included in Appendix 3.

Applications should be made in English in order to facilitate prompt assessment. Submissions in other languages can be accepted, however, delays in assessment may be experienced with third party translation services.

The application should be sent to:

Director Standards
NZFSA
PO Box 2835
Wellington 6140
New Zealand

Attention: Programme Manager (Import Systems)

Email: import.systems@nzfsa.govt.nz

The application must be submitted as one of the three types of arrangement considered by NZFSA:

1. Exporting country programme complies with New Zealand's BMS requirements.

Arrangement is determined through direct assessment of a country's programme. Programmes assessed under this part must either replicate New Zealand's production Standards in full, or where subparts of the programme deviate from New Zealand Standards, an equivalence determination of the subparts will be undertaken. New Zealand would conduct in-country audits to confirm effective implementation in the exporting country.

2. Exporting country programme is equivalent to the New Zealand BMS requirements (outcome based).

Arrangement is determined on the basis of an equivalence assessment of a country's BMS programme against the sanitary outcomes of the New Zealand production system. New Zealand would conduct audits to confirm effective implementation in the exporting country.

For example: under the New Zealand / EU Veterinary agreement Council Decision 97/132EC, New Zealand has recognised EU sanitary measures (including food controls) for BMS as equivalent to New Zealand BMS requirements.

3. Exporting country programme complies with another exporting country programme that NZFSA has determined is equivalent to the New Zealand BMS requirements.

Arrangement is determined on the basis of equivalence assessment of the exporting country's BMS programme against the previously determined equivalence of a third party programme that NZFSA has determined is equivalent to the sanitary outcomes of the New Zealand production system.

For example: An exporting country's growing, harvesting, transportation and processing of BMS meets EU or United States of America (USA) requirements. These growing/processing environments are registered and controlled by the EU or the USA Food and Drug Administration (USFDA) in the exporting country and operate to the same Standards which have been recognised as equivalent and applied in the EU and USA.

See **section 5.2.5** for exporting countries, with BMS programmes recognised as equivalent to New Zealand BMS requirements, which have registered/approved growing/processing areas in third countries.

New Zealand would consider EU and USFDA audits to confirm effective implementation in the exporting country and conduct audits independently as required.

5.2.5 Exporting Countries which have registered/approved BMS growing/processing areas in third countries

United States of America

Following conclusion of a pre-clearance arrangement with the exporting country, NZFSA will accept consignments of BMS exported from countries provided the BMS are from growing areas / processing environments in the exporting country that are registered by the USFDA for growing, harvesting, transportation and processing of BMS and that are open for harvesting (as per USFDA requirements for acceptability).

European Community

Following conclusion of a pre-clearance arrangement with the exporting country, NZFSA will accept consignments of BMS exported from countries provided the BMS are from growing areas / processing environments in the exporting country that are registered by the EC for growing, harvesting, transportation and processing of BMS and that are open for harvesting (as per EC requirements for acceptability).

6 IMPORT CONDITIONS

Import conditions apply to all BMS exported to New Zealand. Import conditions are specific to each pre-clearance arrangement with the Competent Authority of each country. These are specified in **Appendix 2**.

7 VERIFICATION MECHANISMS

7.1 Certification Checks

All BMS consignments must be accompanied by NZFSA recognised certification from the relevant Competent Authority, as agreed under each pre-clearance arrangement.

All consignments are subject to documentation checks of up to 100% as agreed under each pre-clearance arrangement.

7.2 Physical Inspections and Confirmatory Testing

Certification may be verified by physical inspection and/or confirmatory testing of the BMS. The rate applied is specific to each pre-clearance arrangement as specified in **Appendix 2**.

7.3 Sampling Requirements

Sampling and testing requirements apply to consignments of product from countries that have applied for a pre-clearance arrangement and remain in place until an arrangement has been finalised.

Generic sampling procedures are outlined in the generic clearance procedure which can be found on the NZFSA website at: <http://www.nzfsa.govt.nz/imported-food/clearance/index.htm>

The switching rule will determine the rate of sampling and testing as detailed in the generic clearance procedure.

The following requirements also apply specifically to BMS:

A 'lot' is the same product from the same supplier harvested on the same day.

Number of samples to take per lot: For BMS one sample per lot is sufficient provided it meets the requirements below.

Sample weight: A minimum of 500g of flesh is required for analysis. As a general guideline each sample unit should be made up of at least 12 BMS, but where BMS are of a smaller species a greater number may be required to make up the 500g sample.

7.4 Testing Requirements

In addition to testing of product from countries that have applied for a pre-clearance arrangement, consignments imported under a pre-clearance arrangement (see **Appendix 2**) will be monitored at a rate specific to each pre-clearance arrangement for *Escherichia coli*, *Listeria monocytogenes* and marine biotoxins according to the microbiological and toxicological criteria and laboratory methodology set out in the table below. This is subject to review should new information become available.

Table 1: Microbiological and Toxicological Criteria and Laboratory Methodology for Certification Verification Testing

Hazard	Product	Methodology to be applied by laboratories – labs & methods must be approved by NZFSA	Microbial and toxicological criteria (reject criteria)	Justification for inclusion
<i>Escherichia coli</i>	All product except retorted	Enumeration of <i>Escherichia coli</i> in BMS NZFSA method	REJECT lots that have excessive levels of <i>E. coli</i> /g (n=5, c=1, m=2.3, M=7)	Hygiene indicator NZ Standard
<i>Listeria monocytogenes</i>	Cooked RTE or RTE BMS product (see definition of RTE below)	Test methods identified in the NZFSA Laboratory Approval Scheme (LAS)	REJECT lots unless they have zero levels of <i>L. monocytogenes</i> /25g (n=5, c=0, m=0)	Hazard in RTE cooked product
Marine Biotoxins (see below)	All product	NOTE: Biotoxin samples are not to be composited	REJECT lots where the following is found	(see below for each toxin)
Paralytic Shellfish Poisoning (PSP)	All product	AOAC mouse bioassay OR HPLC-UV method	(PSP), when the toxin concentration equals or exceeds 80 micrograms per 100g in the edible portion of raw BMS	Hazard from environment NZ Standard

Hazard	Product	Methodology to be applied by laboratories – labs & methods must be approved by NZFSA	Microbial and toxicological criteria (reject criteria)	Justification for inclusion
Diarrhoeic Shellfish Poisoning (DSP)	All product	LC-MS method	(DSP), when the toxin concentration equals or exceeds 0.16mg/kg of edible portion of raw BMS	Hazard from environment NZ Standard
Neurotoxic Shellfish Poisoning (NSP)	All product but from East Coast USA ONLY The hazard is only known to occur in the Gulf of Mexico, Florida and North Carolina, so product from other countries does not need to be subjected to confirmatory testing	Recommended Procedures for the Extraction of Sea Water and Shellfish. 4th edition APHA, 1970 OR LC-MS method NB: Only LC-MS method must be used for smoked product	(NSP), when the toxin concentration equals or exceeds 20 mouse units (MU) per 100 g of edible portion of raw BMS LC-MS 0.8mg/kg for smoked product only	Hazard from environment NZ Standard
Amnesiac Shellfish Poisoning (ASP)	All Product	LC-MS method OR HPLC method	For domoic acid (ASP), when the toxin concentration equals or exceeds 20 ppm (i.e. 20 mg/kg) in the edible portion of raw BMS	NZ Standard

Hazard	Product	Methodology to be applied by laboratories – labs & methods must be approved by NZFSA	Microbial and toxicological criteria (reject criteria)	Justification for inclusion
Azaspiacid (AZP)	<p>All product from the EC only</p> <p>Only known to be a hazard in Europe so product from other countries does not need to be subjected to confirmatory testing</p>	LC-MS method	AZP, when the toxin concentration equals or exceeds 0.16mg/kg of edible portion of BMS	<p>Hazard from environment</p> <p>NZ Standard</p>

n = the minimum number of sample units which must be examined from a lot of food.

c = the maximum allowable number of defective sample units i.e. that have counts between 'm' and 'M'.

m = the acceptable microbiological level in a sample unit.

M = the level which when exceeded (i.e. the level is greater than M) in one or more samples, would cause the lot to be rejected.

Definition of Ready to Eat (RTE) for Microbiological Criteria and Laboratory Verification:

RTE product includes for example:

- smoked BMS; and
- heat-shocked mussels; and

- cooked, then chilled, BMS; and
- processed BMS products (e.g.: seafood salad pieces); and
- vacuum-packaged cooked BMS.

Note: the following products are **not classified as RTE** product:

- uncooked BMS; and
- canned BMS; and
- dried shelf stable BMS products with a water activity (a_w) of less than 0.9 (if requested importers must provide documented evidence of a_w); and
- BMS products that have a pH of less than 4.6 e.g. some marinated BMS may fall into this category (if requested importers must provide documented evidence that pH is below 4.6).

8 BIOSECURITY REQUIREMENTS

Biosecurity New Zealand has additional requirements for import of foods, including marine BMS, into New Zealand. These requirements are necessary in preventing unwanted pests and diseases from reaching New Zealand, and for controlling, managing or eradicating them should they arrive. Importers should contact Biosecurity New Zealand directly to check their requirements – see www.biosecurity.govt.nz.

Appendix 1 – Tariff Codes Applying to BMS

Products Targeted:

Products classified with the following tariff codes are captured under this standard.

However, if importers are importing BMS under other tariff codes they are required to notify NZFSA as these targeted tariff codes may need to be reviewed.

Tariff codes targeted for bivalve molluscan shellfish	
0307 Molluscs, whether in shell or not, live, fresh, chilled, frozen, dried, salted or in brine . . . :	
0307.10.00.02H	Live Rock Or Pacific Oysters
0307.10.00.11G	Whole Chilled Rock Or Pacific Oysters
0307.10.00.22B	Half-Shell Chilled Rock Or Pacific Oysters
0307.10.00.28A	Chilled Rock Or Pacific Oyster Meat
0307.10.00.31A	Frozen Whole Rock Or Pacific Oysters
0307.10.00.41J	Frozen Half-Shell Rock Or Pacific Oysters
0307.10.00.48F	Frozen Rock Or Pacific Oyster Meat
0307.10.00.49D	Rock Or Pacific Oysters Other i.e. Not Chilled Or Frozen
0307.10.00.52D	Live Dredge Oysters
0307.10.00.61C	Whole Chilled Dredge Oysters
0307.10.00.72J	Half-Shell Chilled Dredge Oysters
0307.10.00.78H	Chilled Dredge Oyster Meat
0307.10.00.81H	Whole Frozen Dredge Oysters
0307.10.00.91E	Half-Shell Frozen Dredge Oysters
0307.10.00.98B	Frozen Dredge Oyster Meat
0307.10.00.99L	Dredge Oysters Other i.e. Not Chilled Or Frozen
0307.21.00.01H	Live Scallops
0307.21.00.09C	Scallop Meat Fresh Or Chilled
0307.21.00.19L	Other Fresh Or Chilled Scallops
0307.29.00.01D	Frozen Scallops
0307.29.00.09K	Scallops Other i.e. Not Live Fresh Chilled Or Frozen
0307.31.00.02K	Live Mussels
0307.31.00.11J	Whole Chilled Mussels
0307.31.00.21F	Half-Shell Chilled Mussels
0307.31.00.31C	Chilled Mussel Meat
0307.31.00.39J	Mussels Other i.e. Not Live Or Frozen

0307.39.00.01H	Frozen Whole Mussels
0307.39.00.09C	Frozen Half Shell Mussels
0307.39.00.19L	Frozen Mussel Meat
0307.39.00.21B	Freeze-Dried Mussel Powder
0307.39.00.29H	Mussels Other i.e. Not Live Fresh Chilled Or Frozen
0307.91.00.01C	Chilled Cockles
0307.91.00.09J	Chilled Tuatua
0307.91.00.19F	Other Chilled Clams
0307.91.00.29C	Other Chilled Molluscs
0307.91.00.38B	Molluscs Live Fresh Or Chilled Other Than Abalone (Including Paua)
0307.91.00.49H	Other Aquatic Invertebrates Live Fresh Or Chilled
0307.99.01.01F	Frozen Cockles
0307.99.01.09A	Frozen Tuatua
0307.99.01.19J	Frozen Other Clams
0307.99.01.29F	Other Frozen Molluscs
0307.99.01.39C	Other Molluscs Other i.e. Not Frozen
0307.99.11.00C	Other Frozen Aquatic Invertebrates
0307.99.19.00D	Other Aquatic Invertebrates Not Live Frozen Fresh Or Chilled
1605 Crustaceans, molluscs and other aquatic invertebrates, prepared or preserved	
1605.90.01.00E	Mollusc Pastes
1605.90.09.01D	Mollusc Pate
1605.90.09.09K	Other Mollusc Preparations
1605.90.19.01K	Mussels Prepared In Cans Or Jars
1605.90.19.09E	Oysters Prepared In Cans Or Jars
1605.90.19.19B	Scallops Prepared In Cans Or Jars
1605.90.19.29K	Other Molluscs Prepared In Cans Or Jars
1605.90.19.31A	Mussels Crumbed Or Battered
1605.90.19.39G	Mussels Powder Freeze Dried Capsules
1605.90.19.41J	Smoked Mussels Otherwise Packed
1605.90.19.49D	Mussels Otherwise Prepared Otherwise Packed
1605.90.19.51F	Smoked Oysters Prepared Otherwise Packed
1605.90.19.59A	Other Oysters Prepared Otherwise Packed
1605.90.19.69J	Scallops Prepared Otherwise Packed
1605.90.19.79F	Other Prepared Molluscs Otherwise Packed
1605.90.21.00F	Other Aquatic Invertebrates With Vegetables Etc In Cans Or Jars
1605.90.29.00G	Other Aquatic Invertebrates Other Than With Vegetables In Cans

	Or Jars
1605.90.39.00B	Other Aquatic Invertebrates Prepared And Otherwise Packed

Appendix 2 – Country Arrangements Listing for BMS

The countries listed below have a pre clearance arrangement with NZFSA which recognises the country's BMS programme as complying with or equivalent to New Zealand's BMS requirements.

Australia

Arrangement with Australia (in place until exemption for high risk foods is removed from the Trans-Tasman Mutual Recognition Arrangement).

Products covered by this Arrangement:

- All BMS products covered under the BMS Standard.
- Covers BMS originating and exported from Australia, and BMS imported into Australia for processing from third countries eligible to export that BMS to New Zealand.

Specific requirements:

The following specific requirements must be met for BMS cleared under this arrangement:

- Health certification issued by the Australian Quarantine and Inspection Service (AQIS) attesting that the product(s) listed are from AQIS registered premises; and
- Certification is required for each consignment of BMS. All types of BMS within a single consignment can be listed on one certificate; and
- 5% of BMS imports will be verified against accompanying certification (sampling and testing).

Canada

'Equivalency Arrangement on Control Measures for the Safety and Quality of Fish and Fishery Products' signed 29 April 1996 by Department of Fisheries and Oceans for Canada and Ministry of Agriculture & Ministry of Health for New Zealand.

Products covered by this Arrangement:

- The arrangement applies to the trade between Canada and New Zealand in fish and fishery products. It does not cover the export of BMS imported into Canada from third countries.
- Fish in the arrangement includes BMS
- Fishery products: means any product intended for human consumption derived in whole or in part from fish, including fish that has been processed in any manner, that when reduced to a dehydrated state, contains by weight 5% or more of fish.

Specific requirements:

The following specific requirements must be met for BMS cleared under this arrangement:

- Agreed certification issued by the Canadian Food Inspection Agency (CFIA) to accompany each consignment of BMS
- Arrangement allows performance verification that may take the form of checks on importation at an appropriate frequency.

European Community / European Union

(Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, The Netherlands, United Kingdom)

Council Decision 97/132/EC of 17 December 1996 on the conclusion of the Agreement between the European Community and New Zealand on sanitary measures applicable to trade in live animals and animal products.

Products included under this Agreement:

- All types of BMS covered by the BMS standard.

- Covers BMS originating and exported from the EC, and BMS imported into the EC from third countries eligible to export BMS to New Zealand.

Specific requirements:

- Agreed certification issued by competent authorities of EC member states must accompany all imported consignments. See <http://www.nzfsa.govt.nz/imported-food/eu-nz-vet/index.htm> for:
- Copy of agreed certification; and
- Certification requirement; and
- Verification requirements.

Importers of BMS from the EC may apply for a Multiple Release Permit (MRP) to facilitate the clearance process in consideration of the EU veterinary agreement.

Contact: Advisor (Food Service Sale and Import), Approvals Group, NZFSA

Ph: 04 894 2500

Email: approvals.fssi@nzfsa.govt.nz

United States of America

NZFSA has recognised the consumer safeguards provided by United States regime to manage the human health risks of BMS as equivalent to those provided by New Zealand's BMS Programme. However, formal recognition and implementation of this arrangement has not been finalised.

In the interim, NZFSA will implement sampling and testing according to sections 7.3 and 7.4 of this document for US BMS products covered under the BMS Imported Food Requirements.

The countries listed below have a pre clearance arrangement with NZFSA which recognises the country's BMS programme as complying with another exporting country programme that NZFSA has determined is equivalent to the New Zealand BMS requirements.

Note: no countries are currently recognised.

Appendix 3 Application Form Template

Part 1. Exporting Country:

Part 2. Identification of Competent Authority:

Part 3. Please provide details of countries BMS programme under the following categories of sanitary measures:

Level 1: Infrastructure:

*Including legislative base, competent authority, general statistics and administrative systems.
Example of required details below:*

Legislation:

1. Basic law: name and date it officially came into force
2. Relevant secondary and tertiary legislation (regulations, ordinances, specification etc. at national and regional level)

Competent authority:

1. Name and competencies (legislation, supervision etc.) of the Competent Authority (CA) at the national level. Competencies regarding public health aspects should be clearly presented. Include name and description of functions for other relevant CA's
2. Name and competencies of the services at the regional and local levels
3. Which tasks are carried out at the different levels (national/regional/local) and how is the control by the CA over the other levels organised, to guarantee a harmonised system in whole country
4. Staff number (senior staff and inspectors) at the central and the regional/local level

General statistics for country:

1. Annual production of each commercial species of BMS
2. Volume exported per annum, the main destinations, main species
3. List of approved harvest/factory vessels for BMS
4. Number of fishing vessels for cooking of BMS, if applicable
5. List of approved growing/harvest/production areas for BMS

6. Number of approved depuration/purification/post harvest treatment centres for BMS
7. Number of approved despatch centres for BMS
8. List of approved establishments processing BMS
9. List of species of interest in view of the export to New Zealand of BMS

Level 2: Programme design, implementation and monitoring:

Including documentation of systems, monitoring, performance, decision criteria and action, laboratory capability, transportation infrastructure and provisions for certification and audit. Example of required details below:

Laboratories:

1. Laboratories at the national level responsible for testing (Incl. microbiological, biotoxins and contaminants)
2. Laboratories at the regional/local level responsible for the testing
3. List of the types of analyses carried out by these laboratories. Are different laboratories responsible for different tests?
4. How is the supervision on the regional/local laboratories organised
5. Are the laboratories accredited or going to be accredited?
6. Are the laboratories taking part to inter-calibration tests?

Classification and monitoring of the production areas:

1. Classification of the growing/harvest/production areas

- 1.1 When was the classification done?
- 1.2 Criteria for the classification of the production areas (microbiological, chemical)
 - 1.2.1 Limits
 - 1.2.2 Frequencies
 - 1.2.3 Sampling methods
 - 1.2.4 Laboratory methods - please supply full details of method used for E.coli/faecal coliform analysis)
 - 1.2.5 Results - Analytical results for the previous 3 years, coded according to monitoring location and species, should be provided
- 1.3 Were the differences of species taken into account for the classification of the production areas?

1.4 What guarantees are put in place to ensure that no BMS are harvested outside the approved growing/harvest/production areas?

2. Monitoring of production areas

2.1 Monitoring of phytoplankton

- 2.1.1 Sampling method for collecting sea-water
- 2.1.2 Method for cell count (sedimentation, filtration)
- 2.1.3 Frequency of sampling
- 2.1.4 List of species targeted
- 2.1.5 Trigger levels for switching from "periodic monitoring" to "intensive sampling"
- 2.1.6 Frequency of "intensive sampling"
- 2.1.7 Criteria for return from "intensive monitoring" to "periodic monitoring"

2.2 Monitoring of the biotoxins

- 2.2.1 Sampling method
- 2.2.2 Sampling frequency
- 2.2.3 Laboratory methods

2.3 Sampling points

- 2.3.1 Number and distribution
- 2.3.2 How and why were they identified (oceanographic, climatic factors)?
- 2.3.3 Is there a difference for the sampling points between "periodic monitoring" and "intensive monitoring"?
- 2.3.4 Validation of the system

2.4 Do the authorities propose on-going controls directed at virus contamination? If so:

What approach is proposed? (Full details)

What analytical methods are to be used? (Please supply full details of methods)

What results are already available? (Provide details)

2.5 Maps with the location of the production areas:

A list of the areas proposed for export, maps of these areas to include details on scale showing growing area catchment boundaries, shellfish bed locations, species, monitoring points (each with an identification code), points of potential pollution sources population centres and location of corresponding sewage treatment system and effluent discharge point(s)

2.6 Closing/suspension of production areas

- 2.6.1 Criteria and limits for closing/suspending production areas
- 2.6.2 Criteria for re-opening production areas

- 2.6.3 Who is responsible for closure and re-opening of the production areas and what is the administrative procedure?
- 2.6.4 How is the closing/suspension of the production area communicated to shellfishers, harvesters and establishments?
- 2.6.5 What guarantees are put in place to ensure that no BM is harvested during the closing/suspension period of the production areas?

3. Requirements for transportation

Documents used during transport from the production area to the establishment

Time/temperature controls

4. Results of the monitoring programme

Please provide the results concerning the period from 1 January to 31 December for the most recent year

5. Checks on final product

Please provide information on official checks (sampling undertaken and analyses requested by the CA) on final products, own checks (undertaken by establishment management) and supervision (by the CA) of the own checks system

Control of processing establishments:

1. HACCP or quality systems of processing establishments
2. Design and construction of processing establishments
3. Approval procedure for establishments
4. Monitoring/supervision by CA
5. Traceability (incl. exclusion of non eligible/non classified product)
6. Closure/suspension/sanctions of processing establishments
7. Certification system

Level 3: Specific requirements:

Including requirements applicable to individual facilities (e.g. premise design), equipment, processes, procedures, tests (e.g. laboratory tests for micro and chemical hazards) and methods of sampling and inspection.

Please complete **part 4** for certification to be negotiated where your countries BMS programme complies with another exporting country programme that NZFSA has determined is equivalent to the New Zealand BMS standard.

Part 4. Please provide details of the BMS programme in your country that complies with another countries BMS programme that NZFSA has determined as equivalent. This must include audit reports.

Obsolete

Attachment 1 - Background

Hazards

Imported bivalve molluscan shellfish (BMS) such as clams, scallops, mussels and oysters have been monitored as a high risk food for a number of decades. There are potential hazards involved in the consumption of BMS, whether they are raw or cooked.

BMS are filter feeders, filtering up to some 30 litres per hour as they feed on the surrounding water. This means if toxic substances and pathogenic microorganisms are present in the growing area of the BMS, these hazards may accumulate in the shellfish and constitute a potential danger to human health when consumed. Examples of potential hazards that may be present include bacteria, viruses, chemical pollutants and marine biotoxins (naturally produced toxic chemicals produced by microscopic marine algae (phytoplankton)).

Management of Hazards

Some potential hazards can be managed by heat treatment of BMS (e.g. some viruses) while others may not necessarily be reduced to safe levels through any particular treatment (e.g. biotoxins). It is agreed internationally that best practice for ensuring the safety of shellfish is by introduction of a programme that assesses and manages the food safety risks associated with growing, harvesting, transporting, processing and labelling of bivalve molluscs.

Such a programme would include classification of shellfish growing areas based on catchment surveys and the evaluation of pollution sources accompanied by routine monitoring of the shellfish and growing water for marine biotoxins, toxic substances and microorganisms. New Zealand's regulatory programme is based on such a system.

To ensure the safety of BMS imported into New Zealand, countries exporting to New Zealand must produce product of an equivalent food safety standard to that of New Zealand's regulatory programme.

Review of import standard and requirements for BMS

The New Zealand (Prescribed Foods) Food Standard 2002 and import requirements for BMS were reviewed in 2006, the first review carried out since prescribed foods were introduced into legislation in 1996. The 2006 review changed the Standard to ensure that all hazards were addressed. It was recommended that new import requirements for BMS place emphasis on assessing exporting country BMS programmes to determine whether they

comply with or are equivalent to New Zealand's BMS programme, rather than relying solely on import testing at the border, which was the focus prior to this review. This Standard and import requirements applying to BMS will be regularly reviewed as part of an ongoing programme reviewing all import standards and associated requirements.

Obsolete