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Proposal to Amend Prescribed Food Standard
and Import Requirements for
Bivalve Molluscan Shellfish

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Table of Contents

1	Overview	3
2	Background	7
2.1	Background to hazards posed by BMS.....	7
2.2	History of monitoring imported BMS in NZ.....	7
2.3	Current import requirements	8
2.3.1	Standard Management Rule for Molluscs (excluding snails)	8
2.3.2	Standard Management Rule for Molluscs from Chile (excluding snails).....	10
2.3.3	Import requirements for Korean oysters.....	10
2.4	Imports from Australia.....	11
3	The need for change.....	12
3.1	Science and Risk Management Recommendations.....	13
4	Options for Future Management	15
4.1	Options considered by NZFSA	15
4.2	Analysis of options:	16
4.2.1	The “take no action (no change to the Food Standard)” and “enhance the border testing where exporting country programmes have not been recognised (amend Food Standard)” Options.....	16
4.2.2	The “officially assess and, if appropriate, recognise exporting country programmes... (amend Food Standard)” Option	17
4.2.3	Implications for industry.....	18
5	Proposal to Amend the New Zealand (Prescribed Foods) Food Standards 2002 and associated import requirements.....	18
5.1	Amendment of Standard	19
5.2	Amendment of import requirements.....	20
5.3	Border inspection requirements	21
5.4	Border Inspection Costs.....	23
6	Questions and Submission Form.....	23
	Appendix 1: Implications for Industry.....	25
	Appendix 2: Draft Standard Management Rule: Bivalve Molluscan Shellfish	27
1	Import Criteria Applying to Bivalve Molluscan Shellfish.....	28
1a	Products targeted:	28
1b	Clearance options:.....	31
1c	Border inspection procedures:.....	33
1d	Abbreviations:	35
	Appendix 3: Requirements and justification for amending the Prescribed Food Standard ...	40

1 Overview

This discussion paper invites comment on the proposal to amend the prescribed food standard, as it relates to Bivalve Molluscan Shellfish (BMS), to include viruses and to issue new import requirements for BMS. The proposed import requirements are intended to replace the current Standard Management Rules (SMRs) for Molluscs (excluding snails) and Molluscs from Chile (excluding snails). This is the first time the import requirements for BMS have been reviewed since molluscs became a Prescribed Food in 1996.

The proposed amendment to the New Zealand (Prescribed Foods) Food Standards 2002 is to more accurately reflect the food and hazards to be monitored. The Food Act 1981 allows for prescribed foods to be monitored for the condition or hazard described in relation to the food listed when imported, manufactured, stored, transported, prepared for sale, or sold in New Zealand. This allows for the introduction of import requirements, which must be met before the product can be sold in New Zealand.

When the Minister for Food Safety issues or amends a prescribed food standard he/she is required to consider a number of factors. These are outlined in Section 11E of the Food Act¹ and include the need to: protect public health; avoid unnecessary restrictions on trade; ensure consistency between New Zealand's food standards and those applying internationally; and ensure New Zealand's international obligations under agreements are met.

At present molluscs are monitored at the border for the presence of metal contaminants that exceed the permitted level, biotoxins, and pathogenic bacteria. It is proposed that viruses be added to the conditions listed for BMS. There are two main reasons for this proposed extension. A number of foodborne illness outbreaks in New Zealand resulting from norovirus infection in imported oysters has caused concern over recent years and import requirements put in place to address this issue have not been effective. In addition, the hazard identification and analysis process used during this review identified a number of other viruses as potential hazards in imported product.

¹ See section 5.1 and Appendix 3 of this discussion document

The proposed new SMR differs from the current SMRs in that emphasis is placed 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.

Consultation

Comments on these proposed new import requirements for BMS are being sought from importers, industry, key trading partners and other stakeholders. Submissions are invited from any interested party, whether representing organisations or acting as individuals. When sent on behalf of an organisation, the submission should include the position in the organisation of the person signing the submission and the extent of internal consultation undertaken in preparing the submission. All submission formats will be accepted. Please address the questions under the subject areas detailed in Page 23: Questions and Submission Form. However, you are welcome to comment on any additional matter relating to the proposed new Standard Management Rule and change to the Standard. This is the consultation draft. The final version of the Amendment to the New Zealand (Prescribed Foods) Food Standards 2002 may change after the consultation process.

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Closing date for submissions

The closing date is 10 January 2007.

Official Information Act

The Official Information Act 1982 (OIA) states that information is to be made available unless there are grounds for withholding it. Grounds for withholding information are in the OIA. Submitters may wish to indicate grounds for withholding information contained in their submission. Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information such as names or contact details to be withheld. NZFSA will take such indications into account when determining whether or not to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

Process after submissions

After analysing submissions, NZFSA will make recommendations to the Minister for Food Safety. If the Minister agrees, the amendment to the New Zealand (Prescribed Foods) Food Standards 2002 will be signed and gazetted to come into force mid March 2007. The new import requirements would apply from that date.

Process	Target Date
Public consultation	6 November 2006 – 10 January 2007
Analysis of submissions	31 January 2007
NZFSA submits recommendations to the Minister	9 February 2007
Notification appears in the New Zealand Gazette	Mid February 2007
New import requirements come into force	Mid March 2007

Disclaimer

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2 Background

2.1 Background to hazards posed by BMS

BMS are filter feeders, filtering up to approximately 30 litres per hour as they feed on the surrounding water. If toxic substances and pathogenic microorganisms are present in the growing area of the BMS, these hazards can 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 and metal pollutants and both marine and freshwater biotoxins (naturally produced toxic chemicals produced by microscopic marine algae (phytoplankton)). Some 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).

2.2 History of monitoring imported BMS in NZ

Imported BMS, such as clams, scallops, mussels and oysters, have been monitored as a high risk food for a number of decades. When the concept of Prescribed Foods was introduced into legislation in 1996, the Ministry of Health (which was then responsible for the imported food programme) undertook an assessment of the imported high risk foods that were being monitored. The assessment of BMS identified microbiological hazards, biotoxins and metals as hazards that needed to be monitored. As a result raw and cooked BMS were included in the prescribed food standards with these hazards listed as conditions able to be monitored. Import requirements for BMS were developed and included in the Standard Management Rule (SMR) for Molluscs (excluding snails) to ensure that product met the required standard and was free from the hazards identified as a potential risk.

In 1997 a separate SMR was developed for Chilean molluscs (excluding snails). This was in response to a number of foodborne illness outbreaks that occurred during the period June to December 1996 and were attributed to consumption of Chilean oysters. These outbreaks led the Ministry of Health (which was responsible until July 2002 for the imported food programme) to request that the Institute of Environmental Science and Research Communicable Disease Centre, evaluate the investigations and provide a consolidated report. In summary, the report concluded "...Overall, the epidemiologic results implicating Chilean oysters were not likely to be a result of chance or bias, and point to a real association between Chilean oysters and acute gastro enteric illness...". The Ministry

accepted the findings of the report and reviewed the import criteria for molluscs from Chile as a result of the findings.

In June 2004 action was taken to address a problem with Korean oysters; a number of confirmed and suspected cases of foodborne illnesses were attributed to Norovirus in Korean oysters. A decision was made to write to importers advising them of the problem and instructing them to label product that it must be cooked thoroughly if it was not already labelled in this way. Importers were also advised to provide their customers with a NZFSA-developed notice about handling potentially contaminated oysters. There have, however, been problems with the labelling requirement in that customers continue to eat/serve raw or undercooked Korean oysters and there have continued to be outbreaks of norovirus associated with these products.

2.3 Current import requirements

BMS are currently listed in the New Zealand (Prescribed Foods) Food Standards 2002. The list is set out in the table contained in clause 6 as follows:

Food	Conditions
Molluscs (cooked and raw) including clams, cockles, mussels, oysters and scallops	The presence of metal contaminants that exceed the maximum permitted level The presence of biotoxins The presence of pathogenic bacteria

The following is a brief overview of the current import requirements for imported BMS as set out in the SMR. For more specific details refer to NZFSA's website at www.nzfsa.govt.nz

2.3.1 Standard Management Rule for Molluscs (excluding snails)

The SMR for Molluscs (excluding snails) has remained unchanged since it was introduced in 1996.

Clearance options:

The current import requirements have several options for clearance:

- Recognition of overseas standards/systems: Where other countries measures, standards or systems have been recognised as meeting or equivalent to New Zealand's standards/systems then this has been reflected in NZFSA's import requirements for molluscs (excluding snails). In this regard products from the European Union (EU), Canada, the United States (US) and Australia are subject to confirmatory testing at the New Zealand border as laid down in the individual

agreement/memorandum of understanding (MOU)/arrangement made with each of these countries. The scope and frequency of this confirmatory testing can vary should problems arise.

- Multiple Release Permits (MRPs): Two types of MRPs are currently issued – firstly for importers bringing in BMS originating from countries with bilateral arrangements in place (EU, Canada, US, Australia), and secondly where importers are bringing in BMS from countries without such but there is a very good history of compliance with testing under the standard border testing regime. Only one MRP has been issued for countries without an arrangement and this covers retorted product. Border testing is required (as per testing requirements outlined below) under the conditions of this MRP but at a reduced rate. MRPs are reviewed annually and can be cancelled if conditions are not met.
- Standard border testing regime: BMS that are not cleared under an arrangement, or via a MRP, must be sampled and tested according to the standard border testing regime. The frequency of sampling is based on the sampling and testing history developed by each importer for a specific product. A 'specific product' means a product that is exactly the same i.e. the same size bottle/packet, variety, brand, and manufactured by the same company. As a compliant history is developed, the frequency of sampling and inspection is reduced for the importer for that specific product. This reduction is governed by the "switching rule", which follows the steps below:
 - Sampling initially starts out at the tightened level (where 100% or every consignment is sampled and tested) until 5 compliant consignments have been cleared, when:
 - Sampling is then lowered to the normal level (where 20% or 1 consignment in 5 is sampled and tested), until another 5 compliant consignments have been cleared, when:
 - Sampling is then lowered to the reduced level (where 10% or one consignment in 10 is sampled and tested).
 - The frequency of sampling returns back to the tightened level when a product is tested and found not to comply.

Sampling and testing requirements:

Where a consignment is flagged for testing then samples for analysis are taken for *Listeria monocytogenes* and marine biotoxins with the rates dependent on the clearance options

outlined above. Samples are taken for each specific type of product (e.g. same type of product, size packet, variety, brand, and manufactured by the same company). Where a consignment contains more than one lot, the number of lots to be sampled is calculated using a table that is standard for all prescribed foods. Consignments are rejected if test results of samples show:

- Presence of *Listeria monocytogenes* (chilled and frozen cooked products);
- Marine biotoxins that are above the required levels (for raw product - including live molluscs, cooked products - regardless of packaging, and dried products).

2.3.2 Standard Management Rule for Molluscs from Chile (excluding snails)

This SMR was introduced in the late 1990's and has remained unchanged since that time.

Border clearance options including sampling and testing requirements:

Chilean molluscs (excluding snails) must all meet the following requirements:

- Products must be sampled and consignments are rejected if test results show:
- The presence of *Listeria monocytogenes* (cooked products)
- Marine biotoxins that are above the required levels (for raw product - including live molluscs, cooked products - regardless of packaging, and dried products).
- The provision of acceptable evidence that enterovirus contamination (by workers on harvest vessels and at the processing premises) is being managed, prior to any consignments being shipped.
- In the absence of a finalised arrangement with Servicio Nacional de Pesca, the Chilean national marine and shellfisheries organisation, the provision of acceptable evidence that only molluscs harvested and packed in accordance with the USA National Shellfish Sanitation Programme (or an equivalent accepted by the NZFSA).

2.3.3 Import requirements for Korean oysters

In June 2004 additional import requirements were applied to Korean oysters. This was in response to a number of confirmed and suspected cases of foodborne illnesses from Norovirus in Korean oysters. While investigation of the illness cases clearly indicated that these resulted from consumption of raw oysters, it was not clear how the product became

contaminated with the virus. Importers of the contaminated product advised that exporters had informed them that the product was not intended to be eaten raw. As a result, a decision was made to inform importers to label product that it must be cooked thoroughly prior to consumption and provide their customers with a NZFSA-developed notice about handling potentially contaminated oysters. This did not prove to be effective and following three serious outbreaks of norovirus attributed to Korean oysters which had been served raw, NZFSA requested that Korea suspend all exports of this product until such time that New Zealand had confidence in the Korean systems and processes for the harvest and packaging of the product.

2.4 Imports from Australia

In 1995 the Australia and New Zealand Governments signed the Joint Food Standards Setting Treaty² and in 1997 the Trans-Tasman Mutual Recognition Arrangement (TTMRA). High risk (prescribed) foods were excluded from the scope of the TTMRA with the intention being to address this at some later stage. The Australian and New Zealand Governments are currently working on aligning our respective imported food inspection measures and removing the exclusion of high risk foods. This work includes developing, to the maximum extent possible, a common high risk (prescribed) food list for imports from third countries, common systems for food imports from third countries, and equivalency assessments of domestic programmes for high risk foods produced in Australia and New Zealand. If the Australian and New Zealand requirements for a particular high risk food are deemed equivalent, then this will enable these products to be traded freely across the Tasman.

Until the alignment work is completed the current import requirements applying to BMS exported from Australia will continue. These requirements are that BMS can be cleared where accompanied by certificates issued by the Australian Quarantine and Inspection Service (AQIS) attesting that the product is from AQIS registered premises. In the absence of such certificates product is required to be tested at the border under the standard border testing regime outlined under 'Clearance Options', third bullet point section 2.3.1.

² Formal title of the Treaty is *Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System*

3 The need for change

The decision to review the import requirements for BMS was made for the following reasons:

- As noted in the background section, the import requirements have not been reviewed since 1996 and there was clearly a need to assess them to ensure they reflect current scientific knowledge on the hazards associated with BMS.
- Since 1996 there have been a number of outbreaks of viral foodborne illness associated with imported BMS. The frequency and severity of these illness events has increased, particularly over the last 2-3 years. Norovirus³ is the predominant cause of gastroenteritis linked to shellfish consumption in New Zealand. Whilst Norovirus infections in the community have frequently been found to be associated with imported oysters, there is also the risk of more serious viral pathogens (e.g. Hepatitis A virus) being present in contaminated imported shellfish. The current import requirements are not therefore providing sufficient consumer health protection.
- The Imported Foods Review² recommended that:
 - Prescribed foods are regularly reviewed;
 - The imported food programme change its emphasis from relying on 'stand-alone' testing at the border to recognising exporting country programmes for managing food safety issues relating to imported foods. This approach being a more effective and consistent way of ensuring the safety of imported foods;
 - The imported food standards and requirements for particular foods should be equivalent to New Zealand standards for those foods; and
 - Risk-based or science-based assessments should be used in the review and development of import standards.
- There are inconsistencies in how importing countries are treated in relation to the current import management rules and other import requirements that are applied to specific countries.

³ Symptoms of Norovirus infection include headaches, nausea, vomiting, abdominal pain and diarrhoea.

- There has been a significant increase in BMS imports over recent years impacting on border arrangements.
- The current import requirements for BMS are not consistent with the requirements in place for New Zealand producers of BMS, which are required to operate under approved programmes.

3.1 Science and Risk Management Recommendations

The review of the import requirements discussed in this paper is based on work that was undertaken by NZFSA during 2005 and early 2006. The conclusions were:

1. Hazard ID and analysis

There are inherent hazards involved in the consumption of BMS, whether they are eaten raw or cooked. As filter feeders, the concentration of phytoplankton, bacteria, viruses and pollutants (e.g. metal compounds) from the immediate growing area, may result in unsafe food for the consumer. Potential hazards currently likely to occur in New Zealand BMS and in major countries exporting BMS to New Zealand were identified and compared. This updated previous work and identified emerging hazards associated with BMS that could impact on food safety in New Zealand.

The major hazards of concern for both domestic and international producers of BMS were those arising out of poor hygiene/sewage exposure to the growing beds (viruses, bacterial infections), and natural algal blooms resulting in elevated levels of biotoxins in the shellfish. *Vibrio spp*³ is also of concern for international producers of BMS, and is not associated with water pollution, but rather is naturally present in various areas.

2. Comparison between New Zealand import and domestic programmes, and the import requirements for BMS of New Zealand's major trading partners.

The New Zealand regulatory approach to managing potential hazards of BMS, the import requirements of importers of New Zealand BMS, as well as major exporters of BMS to New Zealand, were analysed and compared to identify differences.

Countries take a variety of regulatory approaches to the management of potential hazards in imported BMS. In general, New Zealand differs from other countries in the hazards that it

² *Strategic Review of Regulatory Arrangements Controlling the Importation of Foods and Food-Related Products into New Zealand: Final Report of the External Review Team, Nov 2004.* See: www.nzfsa.govt.nz

³ For example *Vibrio vulnificus*, *Vibrio parahaemolyticus*, *Vibrio cholera*

monitors. Australia has a similar approach to New Zealand in terms of recognition of certification and an option for testing product that cannot be imported via arrangements. Other countries appear to put more emphasis on acceptance of products imported under arrangements.

Other countries (e.g. Australia and the US) monitor imports of BMS for metals such as cadmium and lead. New Zealand has domestic BMS standards for metals that must be met by industry. Both cadmium and lead are naturally occurring in the environment and can become concentrated in BMS as they are filter feeders.

There is little information on the biotoxin hazards associated with freshwater BMS and very little product is produced commercially; as a result, regulators have not tended to include this food/hazard combination in imported food programmes and there are no known production and processing programmes operating overseas.

3. Proposals:

The proposal that resulted from this NZFSA work paper was that the import requirements for BMS be updated to reflect:

- All the food safety hazards identified internationally i.e. those arising out of poor hygiene/sewage exposure to the growing beds (viruses such as norovirus, bacterial infections), *Vibrio* spp, biotoxins and metal contaminants.
- That best practice for ensuring the safety of shellfish (as agreed internationally) is by introduction of a programme that assesses and manages the food safety hazards associated with growing, harvesting, transporting, processing and labelling of bivalve molluscs. Such a programme would include shellfish growing area catchment surveys and the evaluation of pollution sources accompanied by routine monitoring of the shellfish and water for biotoxins, toxic substances (including metal contaminants) and microorganisms.
- Recognition of systems that manage the growing, harvesting, transporting, processing and labelling (to ensure trace-back) of BMS e.g. employment of Good Agricultural Practice (GAP) and the Hazard Analysis Critical Control Point (HACCP) system, as this is the most effective way of managing food safety hazards associated with BMS.

4 Options for Future Management

4.1 Options considered by NZFSA

In relation to the amendment of the New Zealand (Prescribed Foods) Food Standards 2002 to include the presence of pathogenic viruses as conditions for BMS, NZFSA considered two options during the review of the import requirements for BMS:

1. Take no action and leave the Standard as originally drafted.
2. Amend the standard to include viruses.

Three options relating to the SMR for BMS were considered by NZFSA during the review of the import requirements for BMS. These were to:

1. Take no action and leave the current import requirements in place (refer to Section 2.3 for a summary).
2. Enhance the border testing programme where exporting country programmes have not been recognised. Product imported from countries that have not been recognised as complying with or equivalent to the New Zealand BMS standard (as proposed in option 2 above) would be subject to a significantly enhanced border testing programme for marine biotoxins, viruses, and pathogenic organisms. MRPs would be issued for importers who have developed a good history of compliance, and border testing adjusted commensurate with performance, although it would remain significantly more intensive than under options 1 or 3.
3. Officially assess and, if appropriate, recognise exporting country programmes that comply with or are equivalent to the New Zealand BMS standard. This option differs from the current import requirements in that it would require exporting countries to demonstrate that their programmes for managing the hazards associated with BMS comply with or are equivalent to the New Zealand BMS standard. A 'stand alone' border testing programme would not be available. Assessment and recognition of exporting country programmes would be undertaken using one of the following three methods:
 - i. Exporting country complies with the New Zealand BMS standard. This would be determined by direct assessment of an exporting country's programme. New Zealand would conduct in-country audits to confirm effective implementation.

- ii. Exporting country complies with another exporting country programme that NZFSA has determined as equivalent to the New Zealand BMS standard. An example of this would be product exported from third countries that is derived from EU or US registered growing/processing environments for growing, harvesting, transportation and processing of BMS in accordance with EU or US requirements. In this case New Zealand would primarily rely on results of US or EU audits to confirm effective implementation, but may also carry out audits of the exporting country programmes.
- iii. Equivalence assessment of the exporting country's measures against New Zealand's BMS standard based on Codex Alimentarius guidelines on equivalency. This equivalence may be formally recognised through some form of arrangement. New Zealand would conduct audits to confirm effective implementation in the exporting country.

In all cases consignment by consignment certification from the competent authority in the exporting country would be required, unless otherwise agreed with NZFSA.

Product imported under any of these three methods above, would be subject to confirmatory testing at rates determined between each country and New Zealand. These rates would be based on the confidence New Zealand has in the exporting country's programme. The determination of the specific country arrangements would take into account the matters discussed in the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) document *Principles and guidelines for imported foods based on Risk*.

(Refer: http://www.codexalimentarius.net/web/index_en.jsp)

4.2 Analysis of options:

4.2.1 The "take no action (no change to the Food Standard)" and "enhance the border testing where exporting country programmes have not been recognised (amend Food Standard)" Options

Both these options are considered unacceptable and were rejected by NZFSA for the following reasons:

- Taking no action would not address the public health risks that have been evidenced by numerous foodborne illness events associated with imported BMS and in particular those linked with viral contamination e.g. norovirus. Not including viruses

in the Food Standard means that New Zealand consumers will continue to be exposed to a known hazard.

- Enhanced testing at the border as a ‘stand-alone’ import measure does not adequately address the public health and safety concerns associated with the presence of potential hazards, namely viruses, pathogenic bacteria and marine biotoxins. Even extensive and rigorous testing will not provide the same level of confidence provided by the New Zealand BMS programme, and would also be commercially unviable in terms of the quantity of imported products which would be sampled. This argument is supported by the foodborne illness outbreaks which have occurred in New Zealand that have been confirmed as norovirus contracted after consumption of imported oysters that had been subject to a hundred per cent testing of consignments.
- Enhanced testing at the border as a ‘stand-alone’ import measure is not consistent with internationally agreed best practice, which requires the implementation of a BMS programme that actively monitors and assesses the shellfish and seawater for marine biotoxins, toxic substances and microorganisms.
- Neither of these two options is consistent with the current New Zealand BMS regulatory requirements. New Zealand producers do not have the option of replacing the current BMS programme’s requirements with a stand-alone testing programme.

4.2.2 The “officially assess and, if appropriate, recognise exporting country programmes... (amend Food Standard)” Option

This is NZFSA’s preferred option and was selected for the following reasons:

- The full range of known hazards associated with the growing, harvesting, transport and processing of BMS would be covered.
- The health and safety risk to New Zealand consumers would be more effectively managed as any BMS entering the country would have been part of a recognised exporting country programme to manage the full range of known associated hazards during growing, harvesting, transport and processing which complies with or is equivalent to, the New Zealand BMS standard.
- The process of assessing exporting country BMS programmes will ensure the full range of known hazards are effectively managed and, where appropriate, allow for additional measures to be applied to manage specific hazards.

- This option is consistent with the Imported Food Review recommendations, which are outlined in section 3.
- It provides for consistent food safety regulation of imported and New Zealand produced BMS.

4.2.3 Implications for industry

Data from Customs shows that very few importers source BMS product from countries with certification arrangements in place. Data also shows significant increases in BMS imports over recent years and therefore a significant demand for these products in New Zealand. Cost estimates of current import requirements show that costs are substantial. The main cost to business of the proposed changes will be the upfront cost of changing the source of the BMS imports. No estimate is made of this as it could vary widely between importers. On-going costs associated with verification of certification will vary with the country of export.

The proposed 12 month transition period will allow importers to spread these costs. These costs will also be offset to some degree by the removal of 'stand alone' border testing as a clearance option for BMS, which is more expensive to the importer than the proposed clearance option. Appendix 1 provides further information on the possible effects of introduction of the proposed standard on importers.

5 Proposal to Amend the New Zealand (Prescribed Foods) Food Standards 2002 and associated import requirements

As indicated in section four the preferred option for future management of imported BMS to New Zealand is to amend the New Zealand (Prescribed Foods) Food Standards 2002 and develop a new Standard Management Rule containing the amended import requirements.

5.1 Amendment of Standard

The amendment of the New Zealand (Prescribed Foods) Food Standards 2002 would involve removing the current listing for molluscs and replace it with the following, in the table contained in clause 6:

Food	Conditions
Bivalve Molluscan Shellfish (cooked and raw) including clams, cockles, mussels, oysters and scallops	The presence of metal contaminants that exceed the maximum permitted level The presence of biotoxins The presence of pathogenic bacteria The presence of pathogenic viruses

The change to the name from 'Molluscs' to 'Bivalve Molluscan Shellfish' is being made to more accurately reflect the scientific name for the range of foods. Pathogenic viruses are being included as a condition requiring monitoring as they are a hazard associated with BMS.

Before an amendment to a prescribed food standard can be issued the Minister must be satisfied that the requirements outlined in section 11E of the Food Act 1981 have been satisfied. These requirements are outlined below and a brief outline of the justification for each as it relates to this proposal for BMS is outlined in Appendix 3.

11E Preconditions for issuing food standard

1. In issuing any food standard, the Minister shall take into account the following:
 - a. The need to protect public health;
 - b. The desirability of avoiding unnecessary restrictions on trade;
 - c. The desirability of maintaining consistency between New Zealand's food standards and those applying internationally;
 - d. New Zealand's obligations under any relevant international treaty, agreement, convention, or protocol, and, in particular, under the Australia-New Zealand Joint Food Standards Agreement;
 - e. Such other matters as the Minister considers appropriate.
2. The Minister shall not issue any food standard unless the Minister is satisfied that appropriate consultation has been carried out with respect to the food standard, including (without limitation)-

- a. Adequate and appropriate notice of the intention to issue the food standard; and
- b. A reasonable opportunity for interested persons to make submissions;
- c. Adequate and appropriate consideration of any such submissions

5.2 Amendment of import requirements

See Appendix 2 for details of the Standard Management Rule for Bivalve Molluscan Shellfish which describes the proposed import procedures. The following provides a brief overview of the key changes that are proposed to the Standard Management Rule:

Import Options

Consignments of BMS arriving in New Zealand would only be cleared when they are derived from a BMS programme in the exporting country which manages the hazards associated with BMS and has been recognised as meeting New Zealand's requirements for BMS.

Exporting country programmes may either:

- i. Comply with New Zealand's BMS standard. This would be determined by direct assessment of a country's programme. NZFSA would conduct an audit(s) to confirm effective implementation in the exporting country.

OR

- ii. Comply with an exporting country programme which NZFSA has determined as equivalent to the New Zealand BMS standard. An example of this would be product exported from third countries which comes from EU or US registered growing environments and processing facilities, and which complies with the EU or US requirements. New Zealand would generally rely on the results of US and EU compliance auditing and may, from time to time, also perform audits of exporting country programmes.

OR

- iii. Be judged as applying measures equivalent to the New Zealand BMS standard. An example of this would be product imported to New Zealand from the EU which is covered by the EU/NZ Sanitary Agreement. NZFSA would conduct an audit(s) to confirm effective implementation in the exporting country.

Product imported under all three options would be required to be accompanied by individual consignment certification by the competent authority of the exporting country, unless otherwise agreed with NZFSA. Confirmatory testing would also be carried out at rates that

are commensurate with past performance and confidence in the exporting country's programme.

BMS from countries that had not been assessed via one of the methods outlined above would not be able to be imported into New Zealand.

Recognition of current exporting country programmes

Arrangements for foods that include marine BMS are in place with Canada, the US, the EU and Australia. These arrangements would continue to be recognised and imports of BMS from these countries would continue in accordance with those arrangements.

Transitional Provisions

Countries that are currently exporting BMS to New Zealand which do not have their BMS programme recognised as complying with, or equivalent to, the New Zealand BMS standard will be given 12 months from the date of introduction of the requirements to meet the new import requirements. This will enable the relevant competent authority in the country of export to apply to NZFSA for recognition of their programme in accordance with one of the three options outlined above.

5.3 Border inspection requirements

Certification and the product accompanying it, or product imported under an agreement which does not require certification, may be verified by physical inspection and/or confirmatory testing. Consignments will be checked and/or tested at the rate specified in arrangements and will be commensurate with past performance and confidence in the exporting country's programme. Consignments will be monitored for *Escherichia coli*, *Listeria monocytogenes* and marine biotoxins according to the microbiological and toxicological criteria and laboratory methodology set out in the table below. At this time consignments will not be specifically monitored for norovirus, which has resulted in recent foodborne illness outbreaks, as a viable test method is not currently available. Viruses such as *Vibrio* spp and metals will not be included in the monitoring of BMS at this stage as there is confidence in the BMS programmes in the countries that have pre-existing arrangements (US, Canada, EU and Australia).

Hazard	Product	Methodology to be applied by laboratories – labs 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 MBS 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 ready-to-eat (RTE) or RTE BMS product	Test methods identified in laboratory scheme established by DG of MAF	REJECT lots that have excessive levels of <i>L. monocytogenes</i> /25 g (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	Mouse assay AOAC method – HCl / aqueous fraction	(PSP), when the toxin concentration equals or exceeds 80 micrograms per 100g in the edible portion of raw BMS	Hazard from environment, NZ Standard
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	Recommended Procedures for the Extraction of Sea Water and Shellfish. 4th edition APHA, 1970 or LC-MS method for smoked product only	(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 Only known to be a hazard in East Coast of USA so product from other countries does not need to be subjected to confirmatory testing
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	Hazard from environment NZ Standard
Azaspiracid (AZP)	All product from the EU only	LC-MS method	AZP, when the toxin concentration equals or exceeds 0.16mg/kg of edible portion of BMS	Hazard from environment Only known to be a hazard in Europe so product from other countries does not need to be subjected to confirmatory testing NZ Standard

5.4 Border Inspection Costs

Costs are currently recovered under the Food (Fees and Charges) Regulations 1997. The current charges for clearance would continue to apply under the amended rule. These are:

Cost Recovered for	Cost (inclusive of GST)
Permit application & assessment	\$33.75
Sampling & inspection	\$18.28 per 15 minutes
Travel (distances over 40km)	\$0.62 per km

The cost of testing may vary between each laboratory and according to the number of lots sampled. Laboratories need to be approved by NZFSA to undertake the necessary analysis. Indicative costs of analysis per sample need to be obtained directly from the laboratory. The cost of any analysis is payable directly to the laboratory and is not recovered by NZFSA.

Note: The Food (Fees and Charges) Regulations 1997 are currently under review. This review will consider how costs associated with the assessment and recognition of exporting country programmes will be funded.

6 Questions and Submission Form

Your view? Answering the following questions will help us with our analysis.

Name:

Address:

Please comment under the following headings:

1. The consultation process.
2. The need for change

3. Options for future management:
 - a. Take no action
 - b. Officially assess and, if appropriate, recognise exporting country programmes that comply with, or are equivalent to, the New Zealand BMS standard.
 - c. Enhanced border testing programme in the absence of recognition of exporting country programmes
4. Proposal to Amend the New Zealand (Prescribed Foods) Food Standards 2002 and import requirements
5. Implications for industry
6. Border inspection requirements including draft Standard Management Rule
7. Any other comments.

Appendix 1: Implications for Industry

Parties Likely to be Affected

All importers of BMS will be affected by the proposed standard. The figures to date for 2006 indicate that most BMS product is imported from China and Korea. There are currently no arrangements in place with either country, although preliminary discussions have occurred with Korean authorities following the recent norovirus incident.

Table 1: Imports of BMS since 2003

Date	No Imports	No Importers	No Countries BMS originate from	Total Quantity (KG)	Comments
2003	22	14	8 countries	30,073	80% of all product imported from Thailand.
2004	204	53	20 countries	289,875	Significant increase in quantity, number of imports, importers, and countries from which sourced. 71% of all product imported from Thailand.
2005	159	35	16 countries	275,245	Slight decline in quantity being imported but still well up compared with 2003. Decline in number of importers. 57% of all product imported from Thailand, 26% from China.
2006 (Jan to June)	87	19	12 countries	797,405	Significant increase in quantity with 10 times more product imported from Korea compared to 2005 and doubling of quantity imported from China. 45% of all product imported from Korea, 39% from China

Additional Compliance Costs under Proposed Standard

Importers of BMS may incur additional up front costs under the proposed standard if they have to change the source of product. However, the proposed 12 month transition period will allow trade to continue under the current standard, and provide time for NZFSA to negotiate arrangements and/or importers with the time to effect a change of source of BMS.

It is difficult to calculate the additional costs for importers under the proposed standard. This is because, while the current costs of clearing product can be calculated (see Table 2 below for an example), the costs under the proposed standard are difficult to determine because sampling and testing will only be required to verify certification and will be set at a rate that reflects the arrangement with the country of export. The estimate of current costs illustrate

that the current ‘stand-alone’ border testing regime is costly and so the additional costs of sourcing product from countries with arrangements will be offset to some degree by the significant reduction in testing rates and associated costs.

Table 2: Estimate of an example of current costs to importers

	Cost		Cost per consignment based on an average of 3 lots sampled per consignment	Total \$ cost over 12 months based on 35 consignments imported ⁴	Total cost over 24 months based on 70 consignments imported ⁵
Permit application assessment	\$33.75		\$33.75	\$1,181.25	\$1,383.75
Sampling and inspection	\$18.28 per 15 minutes		1.75 hours = \$127.96	\$3,838.80	\$4,606.56
Travel	\$0.62 per km for distances over 40 km		Nil	Nil	Nil
Laboratory costs	<i>Listeria monocytogenes</i>	\$195 (5 samples)	\$585	\$17,550	\$21,060
	Biotoxins (PSP, domoic acid, NSP, DSP)	\$367.10	\$1,101.30	\$33,039	\$39,646.8
Total costs			\$1,848.01	\$55,609.05	\$66,697.11

⁴ Based on 6 different types of product (different product or product from different suppliers). Switching rules applied so 30 consignments tested assuming no non-compliances.

⁵ Assuming same 6 different types of product imported and no non-compliances then 6 consignments would be tested in the following year.

Appendix 2: Draft Standard Management Rule: Bivalve Molluscan Shellfish

Background Information

1. Import Criteria Applying to BMS
 - a. Products Targeted
 - b. Clearance Options
 - c. Border Inspection Procedures
 - d. Abbreviations

Background Information:

Summary of 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)). Some 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 assess and manages the food safety risks associated with growing, harvesting, transporting, processing and labelling of bivalve molluscs. Such a programme would include shellfish growing area 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 such a system, and countries exporting to New Zealand need to produce product of an equivalent food safety standard.

Review of these import requirements:

The import requirements for BMS were last reviewed in 2006, which was the first review since prescribed foods were introduced into legislation in 1996. The 2006 review changed the import requirements to ensure that all hazards were addressed and resulted in changes to the import requirements for BMS where emphasis is now placed on assessing exporting country BMS programmes to determine whether they comply with or are equivalent to New Zealand’s BMS programme, rather than solely relying on import testing at the border, which was the focus prior to this review.

In future, these import requirements will be regularly reviewed as part of an ongoing programme reviewing all import standards and associated requirements.

1 Import Criteria Applying to Bivalve Molluscan Shellfish

1a Products targeted:

Prescribed foods are targeted at the border using the New Zealand Customs tariff code system. Products classified with the following tariff codes are captured under this rule:

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 Molluscs, whether in shell or not, live, fresh, chilled, frozen, dried, salted or in brine . . . :	
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

Products included under this Rule:

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

RTE product **includes** for example:

- smoked BMS
- heat-shocked mussels
- cooked, then chilled, BMS
- processed BMS products (e.g.. seafood salad pieces)
- vacuum-packaged cooked BMS

Note: the following products are excluded from the definition of RTE product:

- uncooked BMS
- canned BMS
- dried shelf stable BMS products with an aw of less than 0.9 (if requested importers must provide documented evidence of aw)
- BMS products that have a pH of less than 4.6 e.g. some marinated BMS may meet this criteria (if requested importers must provide documented evidence that pH is below 4.6)

Products excluded from this Rule:

Molluscs that are not bivalves are not monitored under this rule as they do not present the same hazards as BMS. This includes paua, abalone, octopus, squid, sea slugs, snails – regardless of packaging.

1b Clearance options:

There is only one option available for clearance of BMS captured under this Rule, which is:

Recognition of exporting country programmes:

Consignments of BMS arriving in New Zealand will only be cleared when it is confirmed that they are derived from a BMS programme in the exporting country which manages the hazards associated with BMS and has been recognised as meeting new Zealand's requirements for BMS. Exporting country programmes may:

- i. Comply with New Zealand's BMS standard. This would be determined by direct assessment of a country's programme. New Zealand would conduct in-country audits to confirm effective implementation in the exporting country.

OR

- ii. Comply with an exporting country programme that NZFSA has determined as equivalent to the New Zealand BMS standard. An example of this would be product exported from third countries that comes from the European Union (EU) or the United States of America (US) registered growing/processing environments for the growing, harvesting, transportation and processing of BMS in accordance with EU or US requirements. New Zealand would generally rely on results of US and EU compliance auditing and may from time to time also perform in-country audits of exporting country programmes.

OR

- iii. Be judged as applying measures equivalent to the New Zealand BMS standard. An example of this would be product imported from the EU which is covered by the EU/NZ Sanitary Agreement. New Zealand would conduct audits to confirm effective implementation in the exporting country.

Product imported under all three options is required to be accompanied by individual consignment certification by the competent authority of the exporting country, unless otherwise agreed. Confirmatory testing would also be carried out at rates that are determined between each country and New Zealand. These rates would be based on the confidence New Zealand has in the exporting country's programme.

BMS from countries that had not been assessed via one of the methods outlined above would not be able to be imported into New Zealand.

Existing arrangements:

Arrangements for importation of foods, including marine BMS, from Canada, the US, the EU and Australia were in place prior to the issue of this rule. These arrangements continue to apply.

Each arrangement is specific in terms of the scope of the product and the requirements which must be met. Certification may or may not be required depending on what has been agreed. Detail on border clearance for BMS foods imported under pre-existing arrangements contained in SMR Appendix 1.

Imports from third countries that come from EU or US Registration Systems:

NZFSA accepts consignments of marine BMS exported from third countries that are from EU or US registered growing areas/processing environments for growing, harvesting, transportation and processing of BMS that are open for harvesting (as per EU/US requirements for acceptability). Each consignment is required to be accompanied by recognised certificates from the competent authority attesting to the above i.e. the product has been grown, harvested, transported and processed in accordance with EU or US requirements.

Transitional Provisions of the import requirements:

Countries that are currently exporting BMS to New Zealand which do not have their BMS programme recognised as complying with, or equivalent to, the New Zealand BMS standard have 12 months from the date of introduction of this rule to meet the new import requirements. This transition period is to enable the relevant competent authority in the country of export to apply to NZFSA for recognition of their programme in accordance with one of the three options outlined above. Such countries will be able to import BMS during the transition period but product must be sampled and tested according to the general sampling requirements outlined in this SMR with the switching rule determining the rate of sampling and testing.

Process to apply for recognition of exporting country programmes:

Competent authorities of exporting countries can apply to NZFSA for either recognition of the exporting country's BMS programmes using one of the three options outlined at the beginning of this section, or to negotiate certification for product exported from third countries that come from EU or US registered growing areas/processing environments for growing,

harvesting, transport and processing that are open for harvesting (as per EU/US requirements for acceptability).

Applications should be sent to:

Tim Knox
Director NZ Standards
NZFSA
PO Box 2835
Wellington
New Zealand

Attention: Clare Stynes, Programme Manager (Import Systems)

Email: tim.knox@nzfsa.govt.nz and clare.stynes@nzfsa.govt.nz

The introduction of any new arrangements covering BMS will result in the Country Arrangements Listing, attached as Appendix 1 to this rule, being updated.

1c Border inspection procedures:

All consignments are cleared through the Auckland Central Clearing House (ACCH). The following inspection requirements will apply to all BMS entering New Zealand, any specific country arrangements that also apply are provided in Appendix 1 to this rule, Country Arrangements Applying to Imported BMS:

Documentation checks

All consignments require certification from the relevant competent authority and are subject to 100% documentation checks unless otherwise stated in the arrangement with the exporting country.

Physical inspections:

Certification may be verified by physical inspection and/or confirmatory testing. Consignments are to be inspected and/or sampled and tested annually at rates that are commensurate with past performance and confidence in the exporting country's programme the rate of no more than 2% of the total number of BMS consignments imported by each importer. Confirmatory testing will follow the requirements set out below in this section.

Sampling requirements:

General requirements:

Refer to the general sampling requirements for guidelines which apply to all high risk imported foods. These guidelines cover who is responsible for taking samples, products to be sampled, approved laboratories, costs associated with border inspection procedures and non-compliance procedures.

The following requirements also apply specifically to BMS covered by this rule:

- Number of lots to be sampled per consignment (a 'lot' is 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.

Microbiological and toxicological criteria and lab methodology for certification verification testing:

Hazard	Product	Methodology to be applied by laboratories – labs 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 MBS 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	Test methods identified in laboratory scheme established by DG of MAF	REJECT lots that have excessive levels of <i>L. monocytogenes</i> /25 g (n=5, c=0, m=0)	Hazard in RTE cooked product
Marine Biotoxins (see below)	All product	NOTE: Biotxin samples are not to be composited	REJECT lots where the following is found:	(see below for each toxin)
Paralytic Shellfish Poisoning (PSP)	All product	Mouse assay AOAC method – HCl / aqueous fraction	(PSP), when the toxin concentration equals or exceeds 80 micrograms per 100g in the edible portion of raw BMS	Hazard from environment, NZ Standard
Diarrhoeic	All product	LC-MS method	(DSP), when the	Hazard from

Shellfish Poisoning (DSP)			toxin concentration equals or exceeds 0.16mg/kg of edible portion of raw BMS	environment, NZ Standard
Neurotoxic Shellfish Poisoning (NSP)	All product but from East Coast USA ONLY	Recommended Procedures for the Extraction of Sea Water and Shellfish. 4th edition APHA, 1970 or LC-MS method for smoked product only	(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 Only known to be a hazard in East Coast of USA so product from other countries does not need to be subjected to confirmatory testing
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
Azaspiacid (AZP)	All product from the EU only	LC-MS method	AZP, when the toxin concentration equals or exceeds 0.16mg/kg of edible portion of BMS	Hazard from environment Only known to be a hazard in Europe so product from other countries does not need to be subjected to confirmatory testing NZ Standard

1d Abbreviations:

AOAC	Association of Official Analytical Chemists
BMS	Bivalve Molluscan Shellfish – for the purposes of this SMR this is any product that is covered under section 1.0
ESR	Environmental Science and Research
FAO	Food Act Officer
HPO	Health Protection Officer
ISO	International Organisation for Standardisation
MRP	Multiple Release Permit
PHU	Public Health Unit

RTE	Ready-to-eat
SMR	Standard Management Rule

SMR APPENDIX 1:

Country arrangements applying to imported BMS:

Australia

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

Products covered by this agreement:

- All BMS products covered under the BMS Rule.

Specific requirements:

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

- Agreed certification issued by the Australian Quarantine and Inspection Service (AQIS) attesting that the product is from AQIS registered premises.

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. The agreement applies to fish and fishery products originating and exported from Canada.

Products covered by this agreement:

- The definition of fish in the agreement includes BMS.
- The definition of fishery products in the agreement covers any product intended for human consumption derived in whole or in part from BMS, including BMS which has been processed in any manner, that when reduced to a dehydrated state, contains by weight 5 percent or more of BMS.

Specific requirements:

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

- Agreed certification issued by the Canadian Food Inspection Agency (CFIA) to accompany each shipment of product as defined above

European Union

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

‘EU/NZ: Council Decision on Sanitary Measures Applicable to Trade in Live Animals and Animal Products’ signed 17 December 1996.

Products covered by this Agreement:

- Covers all types of BMS covered by this SMR
- Covers BMS originating and exported from the EU, and BMS imported into the EU from third countries for re-export to New Zealand.

Specific requirements:

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

- Agreed Certification issued by competent authorities of EU member states must accompany all imported consignments.

See www.nzfsa.govt.nz/imported-food/eu-nz-vet/index.htm for information on the agreement, including certification and sampling and testing details and requirements.

United States of America

‘Cooperative Arrangement Between The Ministry of Agriculture & The Ministry of Health New Zealand & Department of Health & Human Services, The Food & Drug Administration, United States of America’. Signed 20 December 1995. The Arrangement covers fish and fishery products except fresh and fresh frozen (molluscan) shellfish and applies to food safety, wholesomeness, and labelling requirements for the fish and fishery products covered.

Products covered by this Arrangement:

- The definition of fish in the Arrangement includes BMS but excludes fresh and fresh frozen BMS where the following definitions apply:
- Fresh is defined in the Arrangement as unprocessed food that is in its raw state, and that has not been frozen or subjected to any form of thermal processing or any other form of preservation.

- Fresh Frozen is defined in the Arrangement as food that has been frozen quickly while still fresh.
- The definition of BMS products from the Arrangement covers any edible human food product consisting in whole of BMS or a product containing a portion of BMS, including BMS which has been processed in any manner, in which the characterising ingredient is BMS **with the exclusion of product consisting of or containing fresh and fresh frozen BMS.**
- Note: Fresh and frozen BMS are excluded from the Understanding with the United States and will be cleared if under the US Registration System. Option outlined in 2.2.

Specific requirements:

Requirements:

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

- No certification is required.

Appendix 3: Requirements and justification for amending the Prescribed Food Standard

Food Act 1981 requirements before making a Prescribed Food Standard and justification as it relates to the BMS proposal

Section 11E Preconditions for issuing food standard

Justification for amending the food standard is in bold under each requirement.

1. In issuing any food standard, the Minister shall take into account the following:
 - a. The need to protect public health;
There are inherent hazards associated in the consumption of BMS. As filter feeders, the concentration of phytoplankton, bacteria, viruses and pollutants from the immediate growing area may result in unsafe food for the consumer. Recent outbreaks of norovirus associated with imported oysters illustrate that there the current import requirements are not effective in protecting public health.
 - b. The desirability of avoiding unnecessary restrictions on trade;
The current import requirements applying to BMS, which are restrictive for some countries due to the inability to manage norovirus outbreaks administratively, will be replaced with the proposed standard enabling recognition of overseas programmes that meet or are equivalent to New Zealand's standard for BMS.
 - c. The desirability of maintaining consistency between New Zealand's food standards and those applying internationally;
International best practice for ensuring the safety of BMS is by introduction of a programme that assesses and manages the food safety hazards, including viruses, associated with growing, harvesting, transporting, processing and labelling of this food.
 - d. New Zealand's obligations under any relevant international treaty, agreement, convention, or protocol, and, in particular, under the Australia-New Zealand Joint Food Standards Agreement;
Pre-existing agreements with overseas countries relating to BMS will

continue to be recognised under this proposal. The joint standards developed under the Australia-New Zealand Joint Food Standards Agreement and specified in the Joint Australia New Zealand Food Standards Code do not apply to this proposal as they relate to composition and labelling. The proposal meets New Zealand's obligations under the World Trade Organisation.

- e. Such other matters as the Minister considers appropriate.

The proposal is consistent with the recommendations made under the Imported Food Review.

- 2. The Minister shall not issue any food standard unless the Minister is satisfied that appropriate consultation has been carried out with respect to the food standard, including (without limitation) -
 - a. Adequate and appropriate notice of the intention to issue the food standard; and
 - b. A reasonable opportunity for interested persons to make submissions;
 - c. Adequate and appropriate consideration of any such submissions

Adequate and appropriate consultation is to occur as per the timetable in this NZFSA public discussion document, which was issued on 10 November 2006 asking for comment on the proposal to amend the New Zealand (Prescribed Foods) Food Standards 2002 to allow for monitoring of BMS for viruses.