# Imported food requirement: Bivalve molluscan shellfish (BMS)

## Recent Updates

| Date | Location | Information |
|---|---|---|
| 17 August 2009 | 3.3 | Clarification of sampling for testing, BMS from all countries to be tested for Azaspriacid. |
| 1 July 2009 | All | Structure revised |

## 1.0 Scope

1.1 The purpose of this Imported Food Requirement is to provide administrative guidance to a Food Act Officer as to the matters they may take into consideration when determining whether they have been satisfied by a person who imports food into New Zealand that the food complies in all respects with-

(a) All relevant provisions of the Food Act 1981; and

(b) All relevant provisions of any regulations made pursuant to the Food Act 1981; and

(c) All applicable food standards.

Nothing in this Imported Food Requirement limits the powers of a Food Act Officer appointed under the Food Act 1981.

1.2 **Legislative basis:** Food (Prescribed Foods) Standard 2007

- Products covered under the scope of these requirements are Prescribed Foods for the purpose of import into New Zealand (Section 11P, Food Act 1981).
- No person may import these products into New Zealand unless that person has satisfied an officer that the food complies.

1.3 This Imported Food Requirement sets out clearance options and procedures for importers of prescribed foods that an importer may follow when aiming to satisfy a FAO that the food complies with the Food Act 1981.

1.4 These clearance options and procedures apply in addition to and after a prescribed food has gained clearance from MAF Biosecurity New Zealand. Importers should check those requirements at: MAF Biosecurity New Zealand.

1.5 **Products include:** Marine and freshwater **bivalve molluscan shellfish (BMS)**, including:

- Raw BMS
- Cooked BMS
- Ready-to-eat (RTE) BMS
- Canned BMS
- Dried BMS
- Products containing any of the above.

1.6 **Products excluded:**

- Molluscs that are not bivalves are excluded from this requirement 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 requirement. 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.

1.7 **Tariff codes targeted**

1.8 **Food safety hazard:** metal contaminants, biotoxins, pathogenic bacteria and pathogenic viruses.

1.9 **Import permitted with conditions from:**

The import and clearance requirements for BMS are currently undergoing change from a test-and-release procedure to the recognition of exporting country assurances. A transitional period for acceptance under test-and-release applies.

Imports of BMS from the following countries may be cleared on the basis of agreed assurances (pre-clearance arrangement) and if none have been agreed, on the basis of test-and-release procedures during the transitional period:

Australia, Canada, Chile, China, European Community, Japan, Korea, Peru, Thailand, United States of America, Vietnam.

At the conclusion of the transitional period (date to be further confirmed and communicated), imports will only be permitted from the following countries under any published conditions:

Australia, Canada, Chile, China, European Community, Japan, Korea, Peru, Thailand, United States of America or Vietnam.

1.10 All other countries are able to apply for a pre-clearance arrangement. Information on how a competent authority can apply is available online.

# 2.0 Importer Clearance Options

2.1 The clearance options and procedures in this Imported Food Requirement apply to **bivalve molluscan shellfish** and are in addition to clearance requirements detailed in the Import Clearance Procedure.

2.2 Importers must also meet the requirements of the Food (Importer Listing) Standard 2008 and the Food (Importer General Requirements) Standard 2008. Importers should also read and understand the Food Importer Standards Guidance before sourcing products to import.

2.3 For **BMS** products, importers have a responsibility under the Food (Importer General Requirements) Standard 2008 to ensure imports are of minimal risk of metal contaminants, biotoxins, pathogenic bacteria and pathogenic viruses that can be accumulated by BMS as a result of poor growing environment, management and harvesting conditions.

## Option 1 - Clearance sampling and testing on arrival in New Zealand

**Transitional arrangements:** Until pre-clearance arrangements are finalised, BMS from the countries listed below are sampled and tested in New Zealand. Procedures specific for BMS sampling and testing are outlined in the BMS import clearance procedure.

BMS will be sampled and tested for *Escherichia coli* and marine biotoxins.

Ready-to-eat BMS will also be tested for *Listeria monocytogenes*.

NZFSA is currently negotiating pre-clearance arrangements with the countries listed below:

- Chile
- China
- Japan

- Korea
- Peru
- Thailand
- Vietnam.

## Option 2 - Acceptance of recognised assurance / certification

Consignments with recognised pre-clearance arrangement may only be cleared in accordance with any conditions published. Such arrangements confirm that BMS are produced under a programme that manages the hazards associated with BMS and meets New Zealand's requirements for BMS. All conditions of the pre-clearance arrangement must be met before a product may be cleared for entry.

For the purposes of this document, origin includes where the BMS is grown, harvested, processed, manufactured and exported from.

NZFSA has pre-clearance arrangements with the countries listed below, which permit import of BMS into New Zealand:

**Australia** – Arrangement covers all BMS products originating and exported from Australia, and BMS imported into Australia for processing from third countries eligible to export that BMS to New Zealand. **Requirements to be met:** Agreed certification issued by the Australian Quarantine and Inspection Service (AQIS) is required for each consignment of BMS attesting that the product(s) listed are from AQIS registered premises. All types of BMS within a single consignment can be listed on one certificate.

**Canada** – Arrangement applies to the trade between Canada and New Zealand in fish and fishery products (including BMS). It does not cover the export of BMS imported into Canada from third countries. Fishery product means any product intended for human consumption derived in whole or in part from fish, including fish that have been processed in any manner, that when reduced to a dehydrated state, contains by weight 5% or more of fish. **Requirements to be met:** Agreed certification issued by the Canadian Food Inspection Agency (CFIA) must accompany each consignment of BMS.

**European Community** (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) – Agreement covers all types of BMS under this requirement originating and exported from the EC, and BMS imported into the EC from third countries eligible to export BMS to New Zealand.

**Requirements to be met:** Agreed certification issued by competent authorities of EC member states must accompany all imported consignments.

**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. **Requirements to be met:** in the interim, NZFSA will implement sampling and testing according to the BMS sampling and testing requirements contained in this document for US BMS products covered under the BMS Imported Food Requirements.

# 3.0 Clearance Procedures

## 3.1 Documentation checks

All consignments accompanied by NZFSA recognised assurances / certification from the relevant competent authority are subject to 100% documentation checks unless otherwise stated in the arrangement with the exporting country. The certification will be specified under each pre-clearance arrangement.

**Australia**

Specific requirements:

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

**Canada**

Specific requirements:

- Agreed certification issued by the Canadian Food Inspection Agency (CFIA) to accompany each consignment of BMS.

**European Community / European Union**

Specific requirements:

- Agreed certification issued by competent authorities of EC member states must accompany all imported consignments.

**United States of America**

Specific requirements:

- Documentary evidence that the consignment is of US origin.

## 3.2 Physical inspection

**Transitional arrangements:** Sampling and testing requirements apply to all consignments from countries that NZFSA is negotiating pre-clearance arrangements with. This will remain in place until an arrangement has been finalised.

**Pre-clearance arrangements:** 1% of imports with recognised assurances / certification will be verified against the accompanying documentation. Verification may include physical inspection and sampling and testing of the consignment. NZFSA reserves the right to review the testing rate.

## 3.3 Sampling and testing on arrival in New Zealand

**Transitional arrangements:** Sampling and testing requirements apply to consignments from countries that NZFSA is currently negotiating pre-clearance arrangements with and remain in place until an arrangement has been finalised. Samples may not be released for sale until final clearance is received from NZFSA.

**Pre-clearance arrangements:** Imports subject to pre-clearance arrangements may be sampled for the purposes of verification. Release of these products for sale prior to obtaining results is at the importers commercial risk.

**Samples:**

Sampling and testing should be in accordance with NZFSA's sampling and testing protocol .

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 = 6.
- Sample weight: A minimum of 500g of flesh per sample 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.
- A maximum of 5 samples (of approximately equal weight) per lot may be composited by the laboratory for *Listeria* testing.
- Samples for *E.coli* testing may not be composited.

- One sample per lot will be tested for marine biotoxins.

**Clearance criteria:**

Consignments will be monitored for *Escherichia coli*, *Listeria monocytogenes* and marine biotoxins according to the criteria and methodology set out in the table below. This is subject to review should new information become available.

| **Hazard** | **Product** | **Methodology to be applied by Laboratory**[1] | **Reject criteria** | **Justification for inclusion** |
|---|---|---|---|---|
| *Escherichia coli* | All product except retorted | Enumeration of *Escherichia coli* in BMS NZFSA method | REJECT lots that have excessive levels of E. coli/g (n=5, c=1, m=2.3, M=7)* | Hygiene indicator<br><br>NZ Standard |
| *Listeria monocytogenes* | 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 *L. monocytogenes*/25g (n=5, c=0, m=0)* | Hazard in RTE cooked product |
| Marine Biotoxins (see below) | All product | NOTE: Biotoxin samples may not be composited | REJECT lots where the following is found | (see below for each toxin) |
| Paralytic Shellfish Poisoning (PSP) | All product | AOAC mouse bioassay OR<br><br>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<br><br>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<br><br>NZ Standard |

| Hazard | Product | Methodology to be applied by Laboratory[1] | Reject criteria | Justification for inclusion |
|---|---|---|---|---|
| Neurotoxic Shellfish Poisoning (NSP) | All product but from East Coast USA ONLY<br><br>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<br><br>LC-MS method<br><br>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<br><br>LC-MS 0.8mg/kg for smoked product only | Hazard from environment<br><br>NZ Standard |
| Amnesiac Shellfish Poisoning (ASP) | All product | LC-MS method OR<br><br>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 |
| Azaspriacid (AZP) | All product | LC-MS method | AZP, when the toxin concentration equals or exceeds 0.16mg/kg of edible portion of BMS | Hazard from environment<br><br>NZ Standard |

**[1]Laboratories and methods must be listed by NZFSA.**

* where n= the minimum number sample units which must be examined from a lot of food, c = the maximum allowable number of defective sample units, m = the acceptable microbiological level in a sample unit and M = the level which when exceeded in 1 or more samples would cause the lot to be rejected.

Definition of Ready to Eat (RTE) for sampling and testing: RTE product includes:

- 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.

The following products are not classified as RTE product:

- uncooked BMS; and
- canned BMS; and
- dried shelf stable BMS products with a water activity (aw) of less than 0.9 (if requested importers must provide documented evidence of aw); 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).

**Reject criteria:**

Transitional arrangements:

- FAO may REJECT lots that exceed the reject criteria.
- FAO may reject any untested lots in the consignment.
- Procedures for rejected lots and untested lots are described in NZFSA's sampling and testing protocol.
- FAO will immediately notify NZFSA if any lots tested exceed the reject criteria.

Pre-clearance arrangements:

- FAO will immediately notify NZFSA if any lots tested exceed the reject criteria.
- FAO will manage the non-conformance under the coordination of NZFSA.

## 3.4 Management of non-compliant consignments

When clearance cannot be given because of non-compliance with import requirements, all determinations on disposition of non-complying consignments should be made in full consultation with NZFSA (or a representative nominated by NZFSA). This will facilitate appropriate corrective action and communication with relevant entities.

## 3.5 Contact details for border clearance agency

First stop for importers seeking more information.

Central Clearing House

NZFSA Verification Agency

Level 1, 96 New North Road, Eden Terrace, Auckland

PO Box 3540, Eden Terrace, Auckland

Email: imported.food@nzfsa.govt.nz

Fax: 09 909 6208

Phone: 09 909 6210 or 09 909 6211

To be notified of changes and updates to NZFSA's website, including import requirements, go to the NZFSA website Notifications page.

# 4.0 Information for Exporting Countries

BMS are a permitted import into New Zealand ONLY where the product originates from countries where NZFSA has negotiated a pre-clearance arrangement with the country's competent authority.

Imported BMS is expected to meet the same end product criteria as per New Zealand Standard requirements in the Animal Products (Specifications for Bivalve Molluscan Shellfish) Notice 2006.

## 4.1 Review of import standard and requirements for BMS

The New Zealand Food (Prescribed Foods) 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 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. The Food (Prescribed Foods) Standard and import requirements applying to BMS will be regularly reviewed as part of an ongoing programme reviewing all import standards and associated requirements.

**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.

- Consultation information
- WTO notification

## 4.2 Process to apply for pre-clearance

Pre-clearance arrangements confirm that BMS is derived from a regulated environment in the exporting country which manages hazards and meets New Zealand's requirements. 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.

The competent authority of an exporting country can apply to NZFSA for determination of a pre-clearance arrangement or for an equivalency assessment and determination of pre-clearance arrangement. Equivalency arrangements may or may not consider the country's import control system.

The application should be sent to:

Director Standards

New Zealand Food Safety Authority

PO Box 2835

Wellington 6140

New Zealand

Attention: Programme Manager (Import Systems)

Email: import.systems@nzfsa.govt.nz

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

1. Overseas country / commercial entity applies measures equivalent to New Zealand Standards
2. Overseas country / commercial entity comply with a food control system that NZFSA has determined as equivalent to New Zealand Standards.
3. Overseas country / commercial entity meets New Zealand Standards.

NZFSA will require that the competent authority of the exporting country provides assurances, through certification, as to the compliance or equivalence with New Zealand food safety requirements. NZFSA may undertake audits to review the arrangements. However, confidence could also be based on assessment of these systems by other competent authorities.

Note: Importers are encouraged to request their supplier to contact the competent authority in the exporting country to apply to NZFSA for assessment for a pre-clearance arrangement.

## 4.3 Contact point for SPS

One of the principal innovations of the World Trade Organisation Sanitary and Phytosanitary (WTO SPS) agreement (the agreement on the application of sanitary and phytosanitary measures) is a requirement for prior notification of SPS measures. Each WTO member is required to designate a single central government authority as responsible for implementing, on a national level, the notification requirements of the SPS agreement. In addition, each Member is required to establish

an Enquiry Point, which is responsible for the provision of answers to all reasonable questions as well as the provision of relevant documents.

The Contact Point for New Zealand can be contacted at:

NewZealand.SPS@maf.govt.nz

# 5.0 Tariff Codes Targeted

Prescribed foods are targeted at the border using the New Zealand Customs tariff code system.

A tariff code is a number used for Customs purposes to classify goods. An import agent or customs broker may be able to assist with interpretation of the tariff code.

Importers who are importing **BMS** under tariff codes not listed below should notify NZFSA Central Clearing House. CCH will notify NZFSA of the need to review the tariff codes targeted.

**Inadvertent captures**

As the tariff classification system is not designed specifically around the imported food regime, some food products may be inadvertently captured by the targeted tariff codes listed. If this is the case, products will not be subject to the requirements outlined in this document. Importers may apply to NZFSA for a multiple release permit (MRP) to facilitate clearance.

Products classified with the following tariff codes are captured under this requirement:

| **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 |