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REVIEW OF THE CURRENT TESTING PROTOCOLS FOR IMPORTED SEAFOOD PRODUCTS

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EXECUTIVE SUMMARY

This report is produced in response to the project brief issued by the Australian Quarantine and Inspection Service (AQIS) – the Terms of Reference and Expectations of the final report are in Appendix A. As outlined in the project brief, the aim of this project was to review the existing approach to the testing protocols for seafood imported into Australia and, following consideration of international practices and stakeholder opinion, to make recommendations for an optimal approach for food safety risk management and testing of imported seafood.

All food sold in Australia, be it domestic or imported, must meet Australian requirements and be safe and suitable for human consumption. AQIS is responsible for administering the requirements of the Imported Food Control Act 1992.

The Imported Food Inspection Scheme (IFIS) in Australia requires that risk foods be inspected at a rate of 100 percent of consignments for commodity: hazard combinations advised by Food Standards Australia New Zealand (FSANZ). This rate can ultimately reduce to 5 percent with a demonstrated history of compliance.

Australia relies chiefly on border inspection to assess food safety because it has no jurisdiction over process controls in exporting countries. However, assurances of the safety of certain types of risk seafood imported into Australia could be improved if production, catch and/or processing in the exporting countries were supported by through chain food safety programs. Such programs may already exist in some exporting countries, but may not necessarily form part of any voluntary certification arrangements in place with AQIS. The certain types of imported risk seafood referred to here are those that if produced or processed in Australia would require a through chain food safety management program in accordance with the Australian Seafood Primary Production and Processing Standard, and include seafood such as bivalve molluscs.

Internationally, a mix of risk management implementation strategies is typical. Product from countries with which agreements and/or memoranda of understanding are in place is often given less attention for inspection and analysis than product from countries that has no certification or compliance arrangements in place or has a history of problems. Several countries have recently, or are the process of, upgrading their management practices for assuring the safety of imported seafood. Both Canada and New Zealand have taken a similar approach in requiring that seafood importers be licensed and licensing conditions may be linked to quality management programs in the importing business. The United States is focussing more on a risk based prevention strategy and will make greater use of foreign certification arrangements and good importer practice guidelines. Some countries will use some form of agreements (MOU, MRA or certification agreements) with exporting countries, usually with the exporting country's competent authority. Most countries will also utilise some degree of risk-based testing or inspection on a similar basis to that practiced by AQIS in Australia where a good compliance record results in reduced inspection frequency.

Thus, the overarching recommendation of this report is that AQIS should implement a mix of risk management options for seafood imported into Australia. These options should be commensurate with the risk of the seafood and include the following key elements:

- Foreign government certification arrangements for certain risk seafood imported into Australia should be mandated, as per recommendation 48 of the report "One Biosecurity: A Working Partnership". The certain risk seafood referred to here are the kinds of seafood, such as bivalve molluscs, for which safety is best assured by through chain food safety control measures.
- Compliance agreements with importers of seafood.
- An inspection scheme that allows for flexibility in the type of test(s) conducted and has the capacity for responsiveness to emerging/perceived unsafe and/or unsuitable food.
- An enhanced role for FSANZ in assessing food safety risks to consumers and thus prioritise seafood food safety concerns for control and/or testing.

The benefits and limitations associated with the development of a licensing or registration scheme for importers should also be investigated by AQIS. Such a scheme could require importers to develop food safety and traceability systems to demonstrate compliance of their imported product to Australian requirements.

Work towards further development of foreign government certification arrangements for certain risk seafood that should require through chain safety assurances can occur immediately under existing legislation with voluntary participation of competent authorities of exporting countries. AQIS should continue to be responsible for stipulating and/or assessing equivalence of the food safety control measures to be met under such arrangements, in consultation with FSANZ. Legislative changes are necessary to mandate that foreign government certification is required for these certain types of risk seafood.

Similarly, importers of seafood will soon be able to voluntarily enter into compliance agreements with AQIS once amendments to the current ligislation are finalised.

The current process where FSANZ has the responsibility to assess food safety risks to the consumers and thus prioritise seafood commodity:hazard combinations for control and/or testing should remain the responsibility of FSANZ for any future food import regimen using a risk-based approach. Retaining FSANZ in this role also ensures the criteria and limits specified for imported foods are consistent with those developed for domestic food.

Data collection and consolidation, such as the existing Coordinated Food Survey Plan and FSANZ Australian Total Diet Study should strengthen imported seafood surveillance and intelligence gathering activities to support FSANZ in their risk assessment activities and role in advising AQIS on emerging and or perceived hazards.

The advantages of implementing new elements or strengthening of existing elements (recommendations 1–6 detailed below) would be:

- Greater assurances of food safety for certain risk seafood where through chain food safety control measures are applied.
- Improved demonstration that imported seafood meets the Australian requirements for domestic seafood, especially in circumstances where through chain measures are required under the Seafood Primary Production and Processing Standard.
- Incentive for all seafood importers to enter into compliance agreements, but more specifically those importing risk seafood. This approach would provide importers with responsibility and flexibility to demonstrate compliance to Australian requirements and may include a through chain approach to also provide greater assurance of food safety.

- More effective surveillance activities (sharing of costs and limited resources) through strengthening of existing food safety networks and obtaining more value from imported food analysis and surveys. FSANZ or the relevant network would keep a watching brief on international testing activities to inform and advise AQIS on the relevance of these activities on Australian imported seafood testing.
- Capacity for border responses to emerging or perceived unsafe and/or unsuitable seafood

The recommended approach of this report for greater use of foreign government certification and compliance agreements is in line with that of Beale et al., 2008 in their report “One Biosecurity: A Working Partnership“ with respect to imported food safety. They recommended that risk return principles be applied and the current performance based Imported Food Inspection Scheme be continued.

ABBREVIATIONS

ABARE	Australian Bureau of Agricultural and Resource Economics
AQIS	Australian Quarantine and Inspection Service
CAC	Codex Alimentarius Commission
CDC	Center for Disease Control and Prevention
CFIA	Canadian Food Inspection Agency
Code	Australian Food Standards Code
EC	European Commission
COAG	Council of Australian Governments
DAFF	Department of Agriculture Forestry and Fisheries
DoHA	Australian Government Department of Health and Ageing
EU	European Union
EFSA	European Food Safety Authority
FRSC	Food Regulation Standing Committee
IFIS	Imported Food Inspection Scheme
IFN	Imported Food Notices
IFP	Imported Food Program
ISC	Implementation Sub-Committee of FRSC
INFOSAN	International Food Safety Authorities Network
FAO	Food and Agricultural Organisation
FSANZ	Food Standards Australia New Zealand
HACCP	Hazard Analysis Critical Control Point
MOU	Memorandum of Understanding
MRA	Mutual Recognition Agreement
MRL	Maximum Residue Limit
NRS	National Residue Survey
NZFSA	New Zealand Food Safety Authority
PPPS	Primary Production and Processing Standards
PSP	Paralytic shellfish poison
UK	United Kingdom
USA	United States of America
USFDA	United States Food and Drug Administration
WHO	World Health Organization

GLOSSARY

Agencies refers to the various public bureaus within the tiers of Government e.g. Primary Industry, Agriculture, Health etc. and other representative private groups within the health, food and animal sectors.

Consignment means food of a particular kind that comprises one or more batches imported by the same owner at the same time and described by a single line in an import entry (Imported Food Control Regulations, 1993).

Equivalence is the capability of different inspection and certification systems to meet the same objectives. (Codex, 2007)

A **hazard** is a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Inspection is the examination of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, in order to verify that they conform to requirements. (Codex, 2007)

A **lot**, as defined by AQIS, is a quantity of a food prepared or packed under essentially the same conditions (ordinarily from a particular preparation or packing unit and during a particular time ordinarily not exceeding 24 hours).

Monitoring is used to describe observing a situation for any changes that may occur over time.

Surveillance is used to describe the systematic ongoing collection, collation and analysis of data and the timely dissemination of information to those who need to know so that action can be taken.

Requirements are the criteria set down by the competent authorities relating to trade in foodstuffs covering the protection of public health, the protection of consumers and conditions of fair trading. (Codex, 2007)

Risk analysis is a process consisting of three components: risk assessment, risk management and risk communication. (Codex, 2007)

Risk assessment is a scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment and (iv) risk characterization. (Codex, 2007)

Risk management is the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures. (Codex, 2007)

Shipment means one or more consignments imported by the same owner at the same time described by one import entry (Imported Food Control Regulations, 1993).

REVIEW OF THE CURRENT TESTING PROTOCOLS FOR IMPORTED SEAFOOD PRODUCTS

1 BACKGROUND

The Australian Government's 2007 election commitment document (O'Brien, 2007) identified challenges for the Australian fishing industry including the ongoing decline in volume and gross value of Australian fisheries production. Conversely, the volume of seafood imports is growing and is expected to increase threefold in the next 40 years to meet Australia's growing demand from the current import level of 200,000 tonnes per year. In addition, whilst the gross value of seafood imports has increased, their price in relation to quantity has decreased which in turn has forced down prices of Australian produce. This has resulted in a negative impact on Australian seafood businesses. More recent data (Australian Bureau of Agricultural and Resource Economics, ABARE, 2009) confirms that while the total volume of Australian fisheries production has increased only 1 percent since 1998–1999, the gross value of production has fallen 22 percent and this has predominantly been driven by the lower values of lobster, prawns, abalone and tuna.

Although seafood imports have increased in volume over the past decade, the value of imported edible fisheries products decreased by over 4 percent in 2007–2008 to $1.13 billion compared to the previous year. A large fall in the volume of fresh, chilled or frozen prawns from 26 tonne to 18.7 tonne (2.8 percent) was observed between 2006–2007 and 2007–2008. During the same periods, the volume of edible fish imports increased by about 2.5 percent and crustaceans and molluscs (other than fresh, chilled or frozen prawns) increased in volume by over 9 percent. (ABARE, 2009). However, looking at longer trends, the value of fisheries imports (including edible and non edible) has risen by 12 percent since 2003–2004 driven by substantial increases in canned crustacean and mollusc imports and higher prices for whole fish and canned fish products.

Sixty five percent ($715 million) of the value of imports in 2007–2008 was due to finfish imports, with crustaceans and molluscs contributing the remaining $417 million of import value. The lower value products including frozen fish fillets, canned fish and frozen prawns dominated the range of imported seafood. In the main, the Australian fisheries exports comprise the higher value products such as rock lobster, tuna and abalone.

In 2005–2006, Thailand and New Zealand were the major sources of Australian seafood imports comprising about 30 and 15 percent of the total volume imported, respectively. Between 2000 and 2006 there were three to four fold increases in the value of imports from China and Vietnam, respectively (ABARE, 2007). In 2007–2008 Thailand remained the major source of edible fisheries imports (valued at $295 million or 26 percent of total value, or 30 percent of total volume, of edible imported fisheries products) followed by New Zealand (17–18 percent of total value and volume), Vietnam (about 13 percent of total value and volume) and China (12–13 percent of value and volume) (ABARE, 2009). Canned fish (mainly tuna) accounted for over 60 percent of the value and volume of the edible seafood imported from Thailand while frozen fish fillets and fresh and chilled whole fish dominated the imports (49 percent of volume, 56 percent of value) from New

Zealand. Prawns, canned crustaceans and molluscs dominated the fisheries products imported form Vietnam and China.

Fifty importers were responsible for importing the 14,313 consignments (see Glossary for definition) of seafood into Australia from January to December 2008 (AQIS, personal communication, 2009), with five importers responsible for over 32 percent of these consignments.

Food that is imported into Australia must meet requirements that address both quarantine and food safety concerns. The Australian Quarantine and Inspection Service (AQIS) has operational responsibility for administering the requirements with which imported food must comply. Foods imported into Australia must first be cleared by AQIS as meeting quarantine requirements before any food safety requirements are addressed.

An election commitment of the new Australian federal government (O'Brien, 2007) was to:

- review the provisions of the Australian Food Standards Code (The Code) relating to seafood to ensure they adequately address the known risks, and to
- review existing testing protocols for seafood imports and consider any measures necessary to improve the food safety standards of seafood products.

This commitment stemmed from a perception that the testing performed under the Imported Food Inspection Scheme (IFIS) might be lagging behind international standards and best practices.

The legislation applying to imported food is The Imported Food Control Act (1992) and associated Regulations as described later in Section 3.3. The Imported Food Control Act predates the Model Food Act (2000), with the latter providing a framework around which the various States and Territories can implement their own legislations around uniform food standards. The Model Food Act includes provisions:

- to ensure food is both safe and suitable for human consumption,
- to prevent misleading conduct in connection with the sale of food,
- to provide for the application of the Code.

The review of the provisions of the Code relating to seafood, identified above, was conducted by FSANZ (FSANZ, 2009c) and is discussed under section 3.2 below.

AQIS called for expressions of interest to conduct the review of existing testing protocols for seafood imports. CSIRO (formerly Food Science Australia, a joint venture formed between the CSIRO Division of Food Science and Technology and the Department of Primary Industries Victoria) was commissioned to conduct this review. The terms of reference for this review are listed in Appendix A.

1.1 One Biosecurity: A Working Partnership (Beale et al., 2008)

In 2008, the Minister for Agriculture, Fisheries and Forestry, the Hon. Tony Burke MP, appointed a Panel to conduct an independent review of Australia's current quarantine and biosecurity arrangements. This review was to include, but was not limited to, the functions of Biosecurity Australia and the Australian Quarantine and Inspection Service.

A trend in the recommendations of the Panel's report, "One Biosecurity: A Working Partnership" (also referred to here as ***the Beale Review***; Beale et al., 2008), was that risk-return principles be adopted through the continuum (Box 1). The authors, in noting some negative biosecurity events over recent years, acknowledged the timeliness of the commissioning of their report into Australia's quarantine and biosecurity systems, recognising international adoption of a continuum approach. Ultimately, a more efficient biosecurity system would encompass a risk management approach with effort focussed "before and behind borders" and resources allocated to those areas identified as delivering the greatest return (from a risk management perspective). Areas requiring development may include:

- building intelligence networks,
- adopting the principles of regionalisation and compartmentalisation,
- shifting the emphasis from 'not known to have' pests and diseases to 'known not to have' those pests and diseases when accepting imports from a country or region,
- securing food chains and applying new technologies.".

One of the Panel's eighty four recommendations was that:

- *the primary biosecurity functions currently within AQIS, Biosecurity Australia and Product Integrity, Animal and Plant Health Division should be brought together in a statutory authority—the* ***National Biosecurity Authority****"* (recommendation 16).

Although the *Beale Review* focussed on quarantine and biosecurity arrangements, there was some commentary on food safety issues (*Beale review* sections 5.2.4 and 7.4.3). Importantly, the authors state that:

- *"Risk-return principles should also be applied to imported foods. The Panel recommends that the current performance-based approach to border sampling and analysis arrangements be continued."*

Two key recommendations relevant to food safety were made (commentary on these is in Box 2):

- *Beale Review* recommendation 47 – "*The Authority should enter into* ***compliance agreements to recognise formally the food safety management systems of importing businesses****. These arrangements should provide for a power of audit, inspection, suspension or removal of approvals, and penalties where appropriate for breaches."*

The review noted that the capacity to accredit and audit food supply chain safety systems of importers should also extend to their product providers.

- *Beale Review* recommendation 48 – *"The National Biosecurity Authority should be empowered to require in specific circumstances, as a condition of entry to the Australian market, that* ***importers provide certification by the exporting country's competent government authorities*** *that Australian food safety standards are met."*

BOX 1

One Biosecurity: A Working Partnership (Beale et al., 2008)

Covering letter to the Minister

"Managing biosecurity risk is …. not just about controls at the border. 'Quarantine' has a largely defensive connotation associated with isolation. It is time to move to the broader concept of 'biosecurity' with an emphasis on managed risk, not zero risk, and from a border preoccupation to encompass fully pre-border and post-border measures. :

The Commonwealth has Constitutional powers to assume a much broader biosecurity reach. To manage the increasing biosecurity risks, the Commonwealth needs to take an assertive national leadership role underpinned by a strong partnership with the states and territories, businesses and the community. Modern and more comprehensive legislation is necessary…….

Australia's biosecurity system will be most effective if resources go to those areas of greatest return from a risk management perspective. The mandatory Increased Quarantine Intervention targets should be replaced by a system closely aligned to risk return and backed by a comprehensive approach to quality management, verification and audit. There is a need to increase national resources for pre-border risk management and post-border monitoring, surveillance and management of national priority exotic pests and diseases."

BOX 2

Food safety risks (Section 7.4.3; Beale et al., 2008)

Risk-return principles should also be applied to imported foods. The Panel recommends that the current performance-based approach to border sampling and analysis arrangements be continued. In addition, the National Biosecurity Authority needs to have the capacity to accredit and audit food supply chain safety systems of importers including their product providers. The National Biosecurity Authority should be empowered to require, as a condition of entry to the Australian market, that importers provide certification by the exporting country's competent government authorities that Australian food safety standards are met.

The Panel considers that, providing food safety management systems meet Australian standards, importing food businesses could be regulated by the National Biosecurity Authority through compliance agreements. These arrangements should be analogous to those under the Quarantine Act 1908 and should provide for a power of audit, inspection, suspension or removal of approvals, and penalties where appropriate for breaches of the compliance agreement. There should be consultation with state food safety authorities to ensure mutual recognition and avoid duplication.

As noted earlier, the Panel is concerned that Australia's imported food legislation does not empower Australia to require competent authority certification of imported foods from the exporting country. This is particularly an issue where safety can only be assured by the application of food safety management systems during production and processing. As with certification processes under the Quarantine Act 1908, the Australian authorities should reserve the right to review and accredit, and subsequently audit, these certification arrangements (see Chapter 8).

Further cooperation with New Zealand in harmonising measures for imported food control is desirable. This is particularly relevant given that the Trans Tasman Mutual Recognition Arrangement facilitates free trade between Australia and New Zealand.

Beale Review Recommendations

47 The Authority should enter into compliance agreements to recognise formally the food safety management systems of importing businesses. These arrangements should provide for a power of audit, inspection, suspension or removal of approvals, and penalties where appropriate for breaches.

48 The National Biosecurity Authority should be empowered to require in specific circumstances, as a condition of entry to the Australian market, that importers provide certification by the exporting country's competent government authorities that Australian food safety standards are met."

2 METHODOLOGY

2.1 Background familiarisation and project direction

Familiarisation with the project background was undertaken by review of documents and websites supplied by DAFF/AQIS and identified in discussion with AQIS and FSANZ staff.

Documents supplied by DAFF/AQIS and FSANZ included:

- FSANZ Review of Provisions in the Australia New Zealand Food Standards Code as they relate to Imported Seafood, March 2009
- National Food Incident Response Protocol, May 2007
- Seafood import testing data, 1 January to 31 December 2008

2.2 Review of Australian and International seafood import requirements and testing

For each country investigated, the following aspects have been considered:

- Food safety policy overview.
- Agency conducting risk assessments to support food safety policy.
- Risk management options available.
- Requirements of risk management options. Agency responsible for development
- Risk management options used. Agency responsible for implementation.

2.3 Stakeholder consultation

As part of this review, input was also sought from key stakeholders, including agencies with responsibility for human health and food regulatory activities as well as relevant industry sectors. Stakeholder representatives were interviewed by phone or in person where practicable. As far as possible, stakeholder consultation has occurred with representatives of peak bodies.

In total, over 20 stakeholders were invited for interview. The profile of stakeholders included government agencies (10; no response from 2 others), peak bodies (6) and food companies/importers (2; no response from 4 others).

Stakeholder interviewees were provided with a written background to the project and a series of questions in advance of the interview to allow preparation (see Appendix B).

The questions were designed by CSIRO (in consultation with AQIS) to explore stakeholder views on the anticipated key issues:

- Regulatory requirements necessary for the sale and/or import seafood in Australia
- Safety and compliance of seafood
- Gaps in the system for importing seafood into Australia
- Options for improvements to systems for imported seafood
- Border testing of imported food
- Certification arrangements and compliance agreements
- Surveillance and gathering industry intelligence

The comments were summarised under headings relating to the key issues of the exercise. Anonymity has been maintained in the presentation of the stakeholder comments.

2.4 Reporting

Reporting was undertaken through the following means:

The Consultant met with AQIS representatives by telecon (15 May, 9 June, 22 October, 4 November, 17 November and 1 December 2009) and face to face (21 July 2009).

A report was prepared and submitted:

1. Draft report dated 31 August 2009 was submitted.
2. Another draft report was submitted on 13 November 2009 following feedback from AQIS.
3. The final draft report was submitted on 14 December 2009 following feedback from AQIS.
4. Final report is submitted on 22 December 2009 following final feedback from AQIS.

3 CURRENT APPROACH TO REGULATION AND RISK MANAGEMENT OF SEAFOOD IMPORTED INTO AUSTRALIA

3.1 The Australian Food Regulation Model

The Australian Food Regulation Model comprises four groups that are responsible for food regulation policy development through standards setting to implementation (Australian Government Department of Health and Ageing, 2009). These four groups and their roles are:

i. The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) – policy development

- Comprises Ministers from all Australian States and Territories and the New Zealand Government and other Ministers from related portfolios (Primary Industries, Consumer Affairs etc) if nominated by their jurisdictions.
- Develops domestic food regulation policy in the form of policy guidelines.
- Requires members to bring a "whole of government" view by balancing the need to ensure public health and safety, with the need to produce and deliver food to the public efficiently, with minimal regulation.

ii. The Food Regulation Standing Committee (FRSC) – policy development

- Comprises the heads of Departments for which the Ministers represented on the Council have portfolio responsibility. Food Standards Australia New Zealand and the President of the Australian Local Government Association attend as observers.
- Co-ordinates policy advice to the Ministerial Council, ensuring a nationally consistent approach to the implementation and enforcement of food standards.
- Advises the Ministerial Council on the initiation, review and development of FRSC activities.

iii. Food Standards Australia New Zealand (FSANZ) – standards setting

- Develop all domestic food standards based on scientific/technical criteria, consistent with Ministerial Council policy.
- Advise AQIS on the risk categorisation of foods for the purpose of inspection under Imported Food Inspection Scheme (IFIS)

iv. The Implementation Sub-Committee (ISC) established in 2003 – policy implementation

- Comprises nominees from States and Territories, New Zealand, AQIS, FSANZ, DoHA, DAFF and Australian Local Government Association
- Sub-committee of FRSC, develops and oversees the implementation and enforcement of food regulations and standards to ensure consistency between jurisdictions, regardless of whether food is sourced from domestic producers, export registered establishments or from imports.
- ISC activities relevant to AQIS activities have included the development of:
    - a Co-ordinated Food Survey Plan for Australia and New Zealand (see section 3.5) that is aimed at achieving co-ordination of and consistency in survey activities across jurisdictions, including New Zealand. The Chemical Residues in Aquacultured Fish Survey (refer to section 3.5) was

the first survey to go through the full national coordinated cycle from planning to completion and outcome management. The Food Surveillance Network continues to be an active and an effective forum for implementing the survey plan.

- the National Food Incident Response Protocol (the Protocol) which provides guidance to ISC member agencies for responding to a range of national food incidents in a timely, appropriate, consistent and coordinated manner, thus formalising the current approach (see section 3.6)

3.2 Current provisions of the Australia New Zealand Food Standards Code (the Code) pertaining to seafood

Imported food must meet the requirements of the Code as is the case with food that is produced domestically. As summarised by FSANZ (2009c), the following requirements of the Code apply to seafood:

- Limits of residues that can be present in seafood from the use of agricultural and veterinary chemicals
- Maximum levels for certain potential chemical contaminants as per the contaminant standard
- Microbiological limits for known human pathogens and other microorganisms that are indicators for human pathogens
- Permissions to use certain additives in seafood as per the food additives standard. Maximum levels are prescribed for some permissions
- Labelling requirements that apply to all foods
- Primary production and processing standard for seafood which applies to seafood businesses, including seafood importers and seafood handlers.

Specifically, the relevant sections of the Code pertaining to seafood are:

- Standard 4.2.1. Primary Production and Processing Standard for Seafood (PPPS Seafood). The PPP Seafood Standard makes cross-reference to the Australian Shellfish Quality Assurance Program Operations manual for production practices and this manual refers back to Standards 1.4.1, 1.6.1, and 2.2.3 for limits on the criteria of microbiological, chemical and natural toxicants.
- Standard 1.3.1 Food Additives (specific to sulphur dioxide levels),
- Standard 1.4.1 Contaminants and Natural Toxicants,
- Standard 1.6.1 Microbiological limits for food, and

- Standard 2.2.3 Fish and Fish Products (compositional standard specific to histamine levels).

Although there are many limits specified for fish and fish products under the above Standards in the Code, only those food/hazard combinations identified by FSANZ through their risk assessment process as posing a high or medium public health risk are identified for high frequency control at the border as discussed under Section 3.3.1.

3.2.1 FSANZ 2009 review of provisions of the Australia New Zealand Food Standards Code (the Code) pertaining to imported seafood

In response to the Election 2007 Policy Document (O'Brien, 2007), FSANZ conducted a review of those provisions of the Code that relate to seafood to ensure that they adequately address the known risks (FSANZ, 2009c).

In their review, FSANZ describe the past and ongoing activities that are used to identify, assess and manage risks associated with imported seafood as well as challenge the appropriateness of risk categorisations. Previous reviews (2004 and 2007) of nominated testing requirements for risk categorised imported seafood, supported by surveillance data, confirmed the appropriateness of risk categorised foods and testing arrangements. Included in the ongoing strategies are:

- communication sharing arrangements with international regulatory agencies;
- participation in international forums such as Codex committees, FAO/WHO expert groups, INFOSAN and International Food Chemical Safety Liaison Group;
- imported food surveys carried out by AQIS in consultation with FSANZ;
- consultation with stakeholders; and
- changes in quarantine orders.

In consideration of the above, FSANZ concluded in this 2009 review that "…the standards in the Code are scientifically robust and provide an appropriate level of protection for the Australian consumers of seafood." FSANZ based their conclusion on the rigorous nature of the scientific analysis and the open and transparent consultation process applied. Whilst non compliance is observed from time to time, either through surveys or routine surveillance, further specific risk assessments conducted by FSANZ, some using data generated by surveillance activities (see section 3.5) have confirmed there were no significant public health and safety issues.

3.3 The Imported Food Program and food safety risk management options

The three legislative tiers relating to the import of foods into Australia are the Imported Food Control Act (1992; Australian Government Attorney-General's Department, Commonwealth of Australia Law, 2009), the Imported Food Control Regulations (1993) and the Imported Food Control Order (2001).

The object of the Act is "to provide for the compliance of food imported into Australia with Australian food standards and the requirements of public health and safety". Under the Act a number of options are available for managing the safety of food imported into Australia. These are:

- The Imported Food Inspection Scheme (IFIS)
- Foreign government certificates
- Quality assurance arrangements, and
- Compliance arrangements

3.3.1 The Imported Food Inspection Scheme

Clause 16 – allows for the establishment of an inspection scheme for imported food.

Under the Act, the Minister has the power to stop food at the border and inspect, or inspect and analyse, food. The Regulations under the Act set out "particulars of a food inspection scheme". In turn, the Regulations empower the Minister "…to make orders identifying the food of particular kinds as food of a kind that is required to be inspected, or inspected and analysed…" under the Food Inspection Scheme. Food "…may be subjected to microbiological, chemical or physical analysis, or any other kind of analysis, necessary to determine whether: (a) it poses a risk to human health; or (b) it complies with the Food Standards Code" (Regulation 29).

Under the Regulations, Part 3 Food Inspection Scheme, food may be classified as risk food, active surveillance food or random surveillance food for the purposes of determining inspection rates. The Minister may make orders reclassifying food only on advice from FSANZ with respect to the categories of risk and active surveillance food. Any food that is not risk food, active surveillance food or the subject of a holding order is, by default, random surveillance food.

The categorisation of foods is determined by FSANZ with foods being categorised as "risk" when they present a medium to high risk to public health. The two categories currently used, and into which seafood imports fall for food safety surveillance purposes, are "**risk**" and "**random**". No foods are currently specified by FSANZ in the active surveillance category.

The Imported Food Control Order (2001) identifies the "kind of food" specified as risk food under the Food Inspection Scheme of the Act. Therefore, these risk foods must be inspected, or inspected and analysed. The Order is a list of high level food categories that does not identify the potential hazard(s). For example, the Order lists

- crustaceans, including prawns, that are cooked (whether or not chilled or frozen), but are not canned;
- fish of the following kinds –
    - tuna, including canned tuna (whether dried or not);

- tuna products;
- mackerel and ready-to-eat finfish;

- marinara mix (whether or not chilled or frozen);
- molluscs bivalve (whether cooked or uncooked).

The Imported Food Notices (most recent being IFN 08/09; AQIS, 2009c) specify which tests apply and which Standard in the Code applies by providing the details of the potential hazards in the identified risk foods. Specific details are provided in Appendix C.

Food that fails to meet the requirements of the Code cannot be imported. It must be brought into compliance where possible or downgraded, re-exported or destroyed.

3.3.2 Foreign government certification

Clause 18 – allows for acceptance of certificates issued by foreign government instrumentalities – these arrangements are made with the competent authorities of countries that export to Australia. Such arrangements result in a reduced level of inspection under the IFP (AQIS, 2009b). As noted by Beale et al. (2008) AQIS is unable to mandate that foreign governments enter into certification arrangements, being "…voluntary on the part of the exporting country and …. developed only where AQIS is satisfied that appropriate risk management measures are enforced by the competent authority of the exporting country…"

Under certification arrangements the imported food, when accompanied by the appropriate documentation, will generally be released without inspection. The exceptions to this would include when inspection is required for audit inspection and analysis, or in cases where an AQIS authorised officer might have concerns about a particular consignment. The certification provides an assurance by the foreign government that the food is safe.

Regulation 32 details options for verifying the reliability of foreign government or quality assurance certificates by drawing consignments for sampling at no less than 5 percent of the certified consignment, auditing or conducting documentation checks.

3.3.3 Quality assurance arrangements

Clause 19 – allows for AQIS to enter into arrangements with persons conducting overseas food processing operations to approve that operation and that certificates issued by that person are recognised quality assurance certificates.

3.3.4 Compliance arrangements

Clause 35A – allows for AQIS to enter into compliance agreements with a person in connection with the application of particular procedures, keeping of records and supervision, monitoring and testing of the person's compliance with those procedures.

Entering into a compliance agreement is voluntary by the industry party (Other Party). However, once set up, the compliance agreement is a legally binding agreement between AQIS/the Commonwealth and the Other Party, and this requires the Other Party to perform specific tasks in an agreed manner (AQIS, 2005).

3.4 Imported Food Program food safety risk management options used

The safety of imported food is a responsibility shared across many Government agencies, with pre- and at border controls administered by AQIS under the Imported Food Control Act. Imported food must meet Australian food standards as is the case with food that is produced domestically, with post border controls managed by States and Territories through relevant state legislation (AQIS, 2009a).

3.4.1 The Imported Food Inspection Scheme implementation

As discussed previously (3.3.1) the AQIS testing regime at the border for imported food, the Imported Food Inspection Scheme (IFIS) is risk based with FSANZ advising on the risk categorisation of foods for the purpose of determining inspection rates under the IFIS.

3.4.1.1 Imported food risk list, seafood/hazard combinations and tests pertaining to seafood

The list of potential hazards for risk foods is determined and reviewed periodically by FSANZ and is specified in the Imported Food Notices. The most recent Imported Food Notice was released in August 2009 (IFN 08/09, AQIS, 2009c, with details relating to seafood in Appendix C, Table 2).

FSANZ (2007) reviewed the then Australian Imported Food Risk List as part of a trans-Tasman harmonisation project. FSANZ assessed the food/hazard combinations currently on Australia and New Zealand's risk lists using criteria for assessing risk food developed jointly by FSANZ, AQIS and the New Zealand Food Safety Authority (NZFSA). The review identified that a number of hazards posed a medium or high risk to consumers because post-import treatments would not sufficiently reduce the inherent risk of the products and recommended that AQIS should continue the current testing program (described in Appendix C, Table 2) for those food/hazard combinations.

An assessment of the suitability of the use of *E. coli* and standard plate counts as microbiological criteria was not included in the FSANZ 2007 review. This assessment is continuing with outcomes expected to impact on microbiological criteria in the Code as well as AQIS testing at the border. These tests are no longer specified in Standard 1.6.1 Microbiological Limits for Foods, Issue 103 (Appendix C, Table 3) but remain in the testing program specified on the imported food risk list (AQIS, 2009b and as listed in Appendix C, Table 2).

The Final Assessment Report Proposal P265 for the PPP Seafood standard also contains additional information to that currently identified in the Code and the 2007 review, about the Risk Ranking of Seafood for varying seafood commodity and hazard combinations.

3.4.1.2 Imported food random surveillance list, seafood/hazard combinations and tests pertaining to seafood

The IFIS stipulates that five percent of food consignments containing foods not identified as "risk" or "active surveillance" foods be randomly sampled for compliance to the Code.

Tests conducted on surveillance foods are nominated by AQIS. Details of the current testing regime for imported seafood are in Appendix C (Table 5).

Unlike risk category foods, AQIS can apply additional or alternate tests on random surveillance category foods where

- there may be reasonable grounds to believe that a food may not comply with the Code or may pose a risk to human health (AQIS, 2009c)
- advice is received from FSANZ which may occur following surveillance work as discussed under 3.5

3.4.1.3 Imported food inspection rates

Risk food: 100 percent of consignments (tightened rate) of risk food are inspected and analysed for the hazards specified in the Imported Food Notices. Once there is a demonstrated history of compliance of the foreign producer (five consecutive consignments), the inspection rate is reduced to 25 percent (normal rate) and then after a further 20 consecutive passes, the inspection rate is reduced to 5 percent (reduced rate). Any consignments of risk foods that fail result in a return to 100 percent testing of that product until a satisfactory compliance history is re-established.

Random surveillance food: is inspected at a rate of 5 percent of consignments.

Holding orders: If a random surveillance food fails, 100 percent of comparable suspect consignments are referred to AQIS and tested until satisfactory compliance has been demonstrated through five consecutive 'passes'.

Certification: Shipments of food imported with certification that is accepted by AQIS are inspected at the rate of 5 percent. Any failures may result in increased rate of inspection. Systemic non-compliance may lead to cancellation of the arrangement.

3.4.1.4 Imported Food Inspection Scheme testing results

Seafood is the single most tested commodity, accounting for 14.9 percent of tests applied to imported food during the period from July to December 2008, with a 98.4 percent compliance rate (AQIS, 2009d). The compliance rate for the analytical and other tests

applied to all imported food increases to 98.6 percent when labelling non-compliances are removed from the data.

More detailed data for January to December 2008 provided by AQIS for this report (AQIS, personal communication) showed that:

- there were 150 non-compliances for 5960 sets of analyses resulting in a 97.5 percent compliance rate for 14,313 seafood consignments.
- there were 3804 tests conducted under the risk category with 104 non-compliances resulting in 97.3 percent compliance
- there were 2052 tests conducted under the random surveillance category with 31 non-compliances resulting in 98.5 percent compliance
- there were 104 tests on product under holding order with 15 non-compliances (<86 percent compliance).

These compliance rates for risk and random surveillance seafood are the same as the result for tests applied to all imported food categories under the IFIS. A summary of non compliances for analytical testing of seafood imports for 2008 is provided in Table 1.

Histamine tests are conducted on all fresh, frozen, chilled, dried, salted, brined, smoked fish at the random rate (5 percent) and at 100 percent for tuna and mackerel (unless there is a good compliance history). Malachite green and fluoroquinolone tests are conducted on all fish at the random rate (5 percent), excluding ambient stable and/or significantly processed and/or wild caught. Nitrofuran and fluoroquinolone tests are conducted on all crustaceans (chilled or frozen, cooked or raw), excluding ambient stable and/or significantly processed and/or wild caught crustaceans at the random rate (Appendix C).

The compliance rate for the most frequently performed tests (histamine and flurooquinolone) is above the overall 2008 compliance rate for seafood of 97.5 percent. Additionally, no failures were observed for paralytic shellfish poison (PSP; 126 tests), domoic acid (108 tests), quinolones (22 tests) or penicillin (100 tests) for any imported seafood tested.

Thailand, New Zealand China and Vietnam provide the largest volumes of imported seafood into Australia. 2008 compliance rates were:

- Thailand
    - 99 percent compliance for all tests on seafood (804 total)
    - No non-compliances for fluoroquinolone (total 63 tests), malachite green (total 6 tests) or nitrofurans (total 86 tests)
    - Non compliances were 1 for *Vibrio cholerae* detected in cooked frozen prawns, 1 for sulphur dioxide in raw frozen prawns, 2 for standard plate count of frozen cooked prawns and mussels, 3 for histamines (396 tests) in dried or frozen fish, frozen fish and mackerel and 1 for composition of fish cake

- New Zealand
    - 98.9 percent compliance for all tests on seafood (378 total)
    - Non compliances were 2 for *Listeria monocytogenes* on smoked salmon and 2 for *Escherichia coli* in mussels and oysters
- Vietnam
    - 97.5 percent compliance for all tests on seafood (1404 total)
    - Non compliances were 17 for fluoroquinolones in basa and catfish, 10 for standard plate count of various products, 3 for malchite green in catfish, 2 for *E. coli* in oyster/mussel meat, 2 for *Vibrio* in cooked shrimp and 1 for Salmonella in cooked prawn.
- China
    - 98 percent compliance for all tests on seafood (859 total).
    - No non-compliances for histamine (total 21 tests) and fluoroquinolone (total 150 tests)
    - Non compliances were 1 for malachite green (total 13 tests), 3 for standard plate count (total 119 tests), 8 for nitrofurans (total 127 tests) 5 for composition (total number of tests not available)

It should be noted that the higher total number of tests conducted on imported seafood from Vietnam and China in comparison to Thailand and New Zealand can be related to the agreements (see section 3.4.3) in place with the latter two countries.

Table 1. Summary of non compliance for analytical testing of seafood (data provided by AQIS, personal communication). (#) is the number of non-compliances for type of food or country of origin. # = 1 if no number is specified in brackets.

Test type	Number of non compliant /compliant results	Compliance rate (%)	Type of non-compliant food	Country of origin
Histamines	36/1598	97.7	Dried fish (16); mackerel (3); tuna (3); other (14)	Sri Lanka (23); Indonesia (3); Thailand (3); Fiji; Italy; Japan; Korea, Myanmar, Norway; South Africa
Nitrofurans	8/519	98.5	Prawns or shrimp (8 total)	China (8)
Fluoroquinolones	17/1241	98.6	Frozen basa and catfish	Vietnam (17)
Malachite green	4/228	98.2	Giant catfish, frozen (3); fish fillets, frozen	Vietnam (3); China
Sulphur dioxide	1/75	98.7	Prawns (raw, breaded, frozen)	Thailand
E. coli	8/121	93.4	Clam, mussel and oyster, (dried, frozen) and other bivalve molluscs (8 total)	Hong Kong (2); New Zealand (2); Vietnam (2); Taiwan; Korea
Listeria monocytogenes	17/379	95.5	Smoked fish (10); dried fish (2); mackerel (2); brined sprats; salmon	Denmark (7); Japan (4); New Zealand (2); Norway (2); Russia; USA
Salmonella	3/308	99.0	Prawns (2);crab (1)	Indonesia; Taiwan; Vietnam
Staphylococci	1/306	99.7	Crab meat, frozen	Indonesia
Vibrio cholerae	3/219	98.6	Prawns, cooked and frozen	Vietnam (2); Thailand
Standard plate count	33/580	94.3	Crab, canned (8); prawns, frozen (6); bivalve molluscs, dried (8); crab, frozen, mussels/lobster (6); other (3)	Vietnam (10), Malaysia (7), Hong Kong (4), China (3), Indonesia (3), Taiwan (2), Thailand (2), Japan, Korea
Composition	19/27	29.6	Prepared roe (6); squid salad (5); Bonito (2); dried fish (4); fish cake; crispy dilis	Japan (11); China (5); Phillipines; Taiwan; Thailand
Total tests	**150/5960**	**97.5**		
Number of consignments	**14,313**			

3.4.2 The Trans Tasman Mutual Recognition arrangement

The Trans Tasman Mutual Recognition Arrangement was developed to mutually recognise regulatory standards adopted by either country. The Arrangement allows goods produced or imported into New Zealand (that meet New Zealand's requirements) to be also sold in Australia.

Risk food remains subject to the Imported Food Control Act under the Australian Trans-Tasman Mutual Recognition Act 1997 (Australian Government Attorney-General's Department, 2009b). All random surveillance food and all dairy products from or imported through New Zealand are not subject to the IFIS.

Consequently Australia partly depends on the activities of New Zealand authorities in regards to food safety.

Certification by the NZFSA is accepted by AQIS for risk category seafood. The certification arrangement is verified through 5 percent testing

3.4.3 Foreign government certification arrangements with Australia

Currently, certification arrangements exist with the following countries and competent authorities (AQIS 2009b):

- New Zealand – New Zealand Food Safety Authority,
    - for non-viable uncanned salmon, including smoked salmon
    - fish or fish products, including risk fish, crustaceans and molluscs
- Thailand – Ministry of Agriculture and cooperatives – Department of Fisheries, for cooked chilled/frozen crustaceans, molluscs and other seafood products. The seafood must be sourced from one of the establishments approved by the Thailand Department of Fisheries and will be subject to a reduced level of testing. The list of approved establishments is available from the AQIS website http://www.daffa.gov.au/aqis/import/food/fish-processing. Any seafood that is not sourced from the approved establishments in Thailand will be subject to the usual level of testing under the IFIS.
- Canada – Canadian Food Inspection Agency, for all seafood products. Note that in 2008, 43 tests were conducted on Canadian imported seafood with no failures recorded.
- India – Export Inspection Council of India, for fishery products. Note that in 2008, 35 tests were conducted on Indian imported seafood with no failures in compliance.
- Malaysia – Ministry of Health Malaysia (and approved laboratories only) for all risk food

Arrangements are agreed following the assessment of the underpinning food safety system and approval of the documentation to accompany consignments. AQIS officers

check that the documentation accompanying consignments complies with the agreed attestations. If certificates and any other associated documentation are not provided or incorrect the food will be subject to the routine inspection or inspection and analysis under the IFIS.

3.5 Food surveillance/monitoring of seafood by AQIS, FSANZ and other government agencies

AQIS, with the co-operation of importers, conducts some non regulatory surveys. Budgetary constraints restrict the number and scope of this work. The information collected can inform risk assessments conducted by FSANZ as well as providing data to assist in determining the most appropriate analysis for surveillance foods.

Imported seafood has been included in two Australian surveys.

Australian states and territories participated in a nationally coordinated survey of chemical residues in domestic and imported aquacultured fish during 2005. This was prompted by overseas reports of the presence of unapproved antimicrobial chemicals in aquacultured finfish and undertaken as part of the Coordinated Food Survey Plan (see section 3.1). The aim of this survey was to determine if residues of antimicrobials and other substances are present in both local (total 14 samples) and imported (total 46 samples) aquaculture product. AQIS was not directly involved in the survey.

Fifty four of the 56 chemicals screened in the survey were not detected in any of the samples. Malachite green and leucomalachite green were detected at trace levels of <0.14 mg/kg in three Australian aquacultured fish (one Rainbow Trout and two Silver Perch) and seven Basa fish samples imported from Vietnam (39 percent non-compliance rate from Vietnam).

Neither malachite green and leucomalachite green are approved for use in Australia and therefore they should not be detected in seafood. Although their presence indicates non-compliance, FSANZ concluded that the low reported levels of malachite green residues in aquacultured fish would not pose a public health risk following a risk assessment conducted in response to the 2005 residue survey. Nevertheless, AQIS included malachite green in the testing regime in aquacultured fish under the random surveillance category (Table 5).

In another survey of antimicrobial and pesticide residues in imported seafood conducted by AQIS from April 2006 to March 2007, some imported seafood products were shown to contain low-level residues of antimicrobial compounds that did not comply with Standard 1.4.2 of the Code. FSANZ subsequently conducted a risk assessment of the AQIS survey data considering estimated dietary exposures and found that there were no major safety concerns associated with the residues detected. Nevertheless, AQIS added several antibiotics (penicillin, fluroquinolones and quinolones) to the testing conducted under the random surveillance category (Table 5). AQIS have since removed penicillin and quinolones based on good compliance history.

AQIS also participates alongside state and territory authorities in national surveys coordinated under the Implementation Sub-Committee (ISC) Food Surveillance Network.

3.6 National Food Incident Response Protocol

A National Food Incident Response Protocol exists in Australia for the purpose of outlining "arrangements for consistent and collaborative responses across jurisdictions to food incidents that involve a potential or actual problem with a food sold within two or more Australian States or Territories".

The Protocol provides guidance to member agencies of the ISC of which AQIS is a member agency. FSANZ is the central notification point for action under this Protocol.

In 2008–2009 there was a high profile incident that led to a response under the Protocol whereby imported food (dairy products from China) was considered to be a potential food safety risk to Australian consumers. This came about following the adulteration of dairy-based infant formula with melamine in China, leading to kidney stone illnesses and deaths in infants.

Emergency powers with respect to food are detailed in the jurisdiction's food legislation (commonly the Food Act). Other required actions during a national food incident may be enacted under the relevant health, quarantine, agriculture, trade practices or environmental legislation.

4 INTERNATIONAL APPROACHES TO IMPORTED SEAFOOD SAFETY MANAGEMENT AND SURVEILLANCE

4.1 Agencies, role and overview

The **New Zealand** Food Safety Authority (NZFSA) sets policies, criteria and procedures to monitor the safety of imported food for human consumption.

The **United States** Food and Drug Administration (US FDA) is responsible for the safety of all food except for meat, poultry and some egg products which are regulated by the United States Department of Agriculture, Food Safety and Inspection Service (FSIS). The US FDA is not authorized under the law to approve, certify, license or otherwise sanction individual food importers, products, labels or shipments.

The **Canadian** Food Inspection Agency (CFIA) is responsible for the administration and enforcement of the Fish Inspection Act and Fish Inspection Regulations. The Department of Fisheries and Oceans (Inspection and Enforcement Directorate) is responsible for the registration of fish processing establishments and the inspection and certification of fish and fishery products prepared for export. Health Canada Food Branch conducts risk assessments and sets limits, establishes policies and standards.

The **UK** Food Standards Agency (FSA), an independent Government Department responsible for enforcement support, advice and audit of enforcement activity with respect to local authority food safety and standards controls including some imported products of animal origin (POAO) and food not of animal origin (non-POAO). This the Competent Authority (CA) for fish and fishery product imports from non-European Union countries to the UK, primarily concerned with and public health aspects of food, contamination of food and the Rapid Alert System for Food and Feed.

The **European** Commission's Directorate-General for Health and Consumer Protection (SANCO) is responsible for food safety in the European Union (EU). Their import rules for fishery products seek to guarantee that all imports fulfil the same high hygiene and consumer safety standards as products from the EU member States. The national, regional and/or local governments in EU countries apply the EU's health and consumer protection laws. The European Food Safety Authority (EFSA) provides risk assessment advice to the EU regarding food and feed safety. The EFSA works with national authorities and in consultation with stakeholders.

In **Japan**, the Ministry of Health, Labour and Welfare, (MHLW) Department of Food Safety is responsible for the safety of imported food and develops an Imported Foods Monitoring and Guidance Plan annually.

Several countries have recently upgraded their management practices for monitoring the safety of imported seafood. Both Canada and New Zealand have taken a similar approach with their new systems. The New Zealand system is currently awaiting legislative changes to allow full implementation.

Both Canada and New Zealand require that the importer be licensed and in the case of Canada, an importer that has a recognised and CFIA-audited quality management program in place is given less scrutiny. Further detail of New Zealand and Canadian practices are provided in the following sections. The other systems studied do not appear to require licensing but in the case of the U.S. the product must be stored in an approved facility on arrival. It is the importers responsibility to source wholesome product.

Most countries utilise risk-based testing or inspection on a similar basis to that practiced by AQIS in Australia where a good compliance record results in reduced inspection frequency. Further detail is provided in the following sections.

The EU does not appear to undertake regular sampling and testing other than documentary checks and a physical examination. In most cases sampling and testing is at the expense of the importer. In the UK, it is the importer's responsibility to ensure that food is safe and legal before they are purchased from producers and imported into the UK, however, there is no legal requirement for importers to arrange for chemical or microbiological analyses.

Some importing countries have memoranda of understanding (MOUs) or some other form of agreement with some exporting countries (usually with the exporting country's competent authority) that result in reduced or no sampling and testing for product from that source. For example:

- NZFA accept assurances/certification for each consignment from certain exporting countries.

- USA has MOUs with some countries that enable them to certify their facilities and reduce the risk status of the products.

- In Canada, inspection effort is reduced through MOUs or mutual recognition agreements (MRAs) with other countries having reliable inspection schemes – see section 4.4.

- The EU maintains a large list of countries and EU-approved establishments within those countries from which seafood may be sourced. Exporting countries must have a competent authority which is responsible for official controls throughout the production chain. The competent authorities in the approved countries are formally recognised by the EU and the EU's audit regime chooses a selection of EU approved establishments. This is a pre-requisite for the country to be eligible and authorized to export to the EU. For all fishery products, countries of origin must be on a positive list of eligible countries for the relevant product.

- The UK has a second list of countries that are not EU-approved (as per previous point) but may, through a bilateral agreement, export to the UK

4.2 International trends in imported seafood safety management

If any trend can be observed in overseas practice, it is to place more responsibility on the importer and for the importer to be licensed and have a quality management system in place. The activities are overseen by the competent authority employing a risk management approach.

Canada has a licensing system for importers and this is linked to quality management systems. Importers that have a quality management plan (QMPI importers) take more responsibility for the quality of their product and are subject to reduced product inspection.

As discussed below, New Zealand propose to implement a system whereby all New Zealand importers will be required to also be licensed and have in place a food safety management system, the complexity of which will relate to the "level of regulatory interest" that the business falls into.

Sampling and testing on a performance basis is still the main means of monitoring imported seafood quality where no certification arrangement or compliance agreement is in place. As sampling and testing on a risk-management basis is still conducted in Canada and NZ, it may be difficult see what licensing importers achieves although licensing of importers would allow the food safety authority to monitor and audit the importing business' quality program.

Overall internationally, a mix of risk management implementation strategies is typical. Product from countries with which agreements and/or MOUs are in place is given less

attention for inspection and analysis than product from countries that has no certification or compliance arrangements in place or has a history of problems.

4.3 New Zealand legislation, imported seafood safety management, clearance and surveillance

The legislation that currently covers food imported into New Zealand is the Food Act 1981. It applies to any food sold or supplied with any meal for consumption as well as imported food at the border. A new Act is being developed as part of the Domestic Food Review (NZFSA, 2009a) and this is likely to replace the New Zealand 1981 Food Act and the 1974 Food Hygiene Regulations (NZFSA, 2009c).

Under the current Act, the Minister for Food Safety is empowered to issue foods standards. Currently, those that apply to importers and imported food are:

- Food (Prescribed Foods) Standard 2007
- Food (Importer Listing) Standard 2008
- Food (Importer General Requirements) Standard 2008
- Australia New Zealand Food Standards Code
- All other general food standards.

Foods that are considered to present a risk to consumers are termed prescribed foods (referred to as risk food in Australia) and are subject to control. All other food is subject to free trade providing it meets other import requirements including biosecurity. A prescribed food is not permitted into New Zealand unless an importer can satisfy a food Act Officer that the food complies with the Food Act 1981 and relevant standards and regulations under the Act. The options available (NZFSA, 2009b) under the import requirements for specific foods may include one or more of the following options:

- Acceptance of recognised assurances/certification – This is a pre-clearance arrangement where government to government agreements exist. Under such arrangements, document checks are always conducted and verification of compliance is conducted via sampling and testing at a reduced rate in comparison to clearances where no certification is provided.
- Clearance sampling and testing on arrival in New Zealand – As is the case with Australia, the sampling frequency for prescribed foods is based on the compliance history of an importer for that prescribed food and the frequency of sampling and inspection reduces with good compliance history. A Mutual Recognition Arrangement between New Zealand and USA means that sampling and testing of products from the USA is at the rate of 1 in every 10 shipments.
- Multiple Release Permits (MRPs) – MRPs are specific to importer, broker, food type and supplier and may be issued for a defined time period. They can be issued if an imported food is:

- inadvertently captured by the tariff codes because the classification system is not designed specifically around New Zealand's imported food controls or

- from particular suppliers under an arrangement agreed to by the importer and NZFSA.

A MRP issued for certain prescribed foods that require approved assurances/ certification will specify the documentation and frequency of inspection required.

New Zealand tests the following prescribed seafood for the following hazards. The notable difference between analyses conducted by the NZFSA on prescribed foods and AQIS analyses of risk foods are tests for metal contaminants and heavy metals including mercury and pathogenic viruses.

- Bivalve molluscan shellfish (cooked and raw) including clams, cockles, mussels, oysters and scallops – metal contaminants that exceed the maximum level, biotoxins, pathogenic bacteria and pathogenic viruses
- Crustaceans (cooked and raw) including shrimps and prawns – metal contaminants that exceeds the maximum level, pathogenic bacteria
- Finfish in waters from the tropics world-wide, the extreme south eastern US (including south Florida), and the Bahamian region. Barracuda, amber jack, horseye jack, black jack, other large species of jack, king mackerel, large groupers and snappers and mackerel and barracuda in waters from mid to north eastern Australia – ciguatoxin contamination
- Manufactured and minced fish (surimi and marinara mix) – pathogenic bacteria
- Puffer fish and fugu – tetrodotoxin
- Shark and dog fish – the presence of spoiled product
- Sword fish, marlin and shark species – mercury that exceeds the maximum level
- Tuna, mahi mahi, blue fish, sardines, amberjack, mackerel and herrings – histamines (as evidence of spoiled product)

Failing product must be brought into compliance by the importer by reprocessing or destroyed. Failing product can also be re-exported back to the country of origin or to a third country where the country of origin or third country confirms acceptance of the product.

The aim of the proposed New Zealand Food Act mentioned above is to "reduce the prescriptive nature of the existing system and move to an outcomes-based regulatory system" (NZFSA, 2009a). It is proposed that there will be one of three levels of regulatory intervention, Food Control Plans, National Programmes or Food Handler Guidance, applied to domestic (and imported as detailed below) foods and these are determined on the levels of risk the food and/or its production process poses to the consumer.

For imported foods, the four components of the system under the proposed new Act will include (NZFSA, 2009a):

1. the import management decision-making framework.

    - This determines the level of regulatory interest (high, medium or low) that NZFSA will take in a particular food. There will be different import requirements that will be commensurate with the regulatory interest level.

2. the import programme for importers of foods of low, medium or high regulatory interest.

    - Low regulatory interest food importers will operate under a National Imported Food Programme that will require compliance to activities such as registration, record keeping and communication.

    - Medium regulatory interest food importers will operate under a Food Control Plan that will require compliance to management of and recording the steps ensuring the food safety and suitability of their products. Operators will need to be aware of any food standards that apply to their products, and options for pre-clearance.

    - High regulatory interest food importers will also operate under a Food Control Plan, but will only be able to import from countries/regions that have established pre-clearance arrangements with NZFSA. The aim of this approach is to manage the food safety risks off shore and/or at the appropriate point in the production chain

3. monitoring and review; and

4. communication mechanisms.

The proposed changes are expected to provide substantial benefit in the consistency of approach to regulation of import and domestic activities for businesses. Food importers will need to be registered and imported foods are expected to be brought more into line with the proposed new domestic food regime, particularly with respect to the three levels of regulatory interest. An importer required to have a Food Control Plan for their domestic activities (for handling high regulatory interest foods) can integrate their import plan into the Food Control Plan, thus reducing duplication. Improved recognition of international agreements is also an expected benefit under the proposed new Act.

4.3.1 New Zealand food safety surveillance

Under the current New Zealand system, there is only limited monitoring of “low risk” foods and this is usually conducted under specific food safety projects as strategic monitoring and information gathering. Under the proposed new Act, the NZFSA will use “The Scanning List” to increase surveillance of particular foods above the level used under the regulatory interest level. It is proposed that “scanning” will precede the addition of foods being put on the Scanning List, and may include monitoring food imports at the border, intelligence gathering and specific projects or programs (NZFSA, 2007)

NZFSA monitoring programmes are listed below and the NZFSA makes the results of these surveys available from their website (www.nzfsa.govt.nz):

- New Zealand Total Diet Survey
- National Chemical Residue Programme
- Dairy Residue Monitoring Programme
- Food Residue Surveillance Programme
- Marine Biotoxin Monitoring Programme
- National Microbiological Database
- *Trichinella spiralis* monitoring
- Targeted surveys

A survey of land-based farmed seafood conducted by the NZFSA in 2008 as part of its Food Residue Surveillance Programme included testing of shrimp, prawns and crabs. There were no detectable levels of residues from antimicrobial drugs (triphenylmethylene dyes, nitrofurans, chloramphenicol, sulfonamides, and tetracyclines) found in 30 random samples of imported land based aquaculture products (ILBA) from Thailand, Vietnam, India, Japan, China and Peru.

Some samples of land-based aquaculture products from China that were examined in 2007 were found to have residues but at such low levels there was no risk to human health.

4.4 Canadian imported food safety inspection and surveillance

Under the CFIA strengthened import program product source can be allocated to one of three levels of inspection and sampling.

1. Annual sampling. Product of normally good order is sampled at a rate of 5 percent.

2. Mandatory inspection list (MIL) – when product sampled at the 5 percent rate fails, it is added to the MIL and stays there until four consecutive lots have passed.

3. Enhanced inspection list (EIL) – product on this list has been identified as potentially unsafe and is inspected at 100 percent.

The Canadian approach to inspection of imported seafood is similar to Australia in that a risk based approach is used by the CFIA to determine inspection frequency of imported seafood. A separate body, Health Canada, is responsible for conducting the risk assessments that support the determination of hazard:commodity combinations for inspection. The frequency of inspection of imported seafood is based on the food safety risk, the history of compliance of a particular product, the history of compliance of the processor, and the country of origin of the product. An inspection rate of 100 percent is

applied to seafood imported from processors who have never exported those products to Canada before. Five percent is the minimum rate of analysis for food safety inspections and this can be achieved with a history of good compliance. CFIA can respond to emerging problems relating to particular products, processors and/or exporting countries by increasing inspection rates to 100 percent. Failing product must be brought into compliance by the importer or destroyed. Further consignments from that foreign processor will be subject to inspection at 100 percent until four consecutive shipments are compliant.

As with Australian seafood a much broader range of microbiological and chemical limits are specified in the Product Inspection Standards and Methods Manual for domestic seafood than is tested for on imported seafood [specifically Bacteriological Guidelines for Fish and Fish Products, Appendix 2 (http://www.inspection.gc.ca/english/fssa/fispoi/man/samnem/app2e.shtml) and chemical contaminants and toxins is listed for fish and fish products as per the Canadian Guidelines for Chemical Contaminants and Toxins in Fish and Fish Products, Appendix 3 (http://www.inspection.gc.ca/english/fssa/fispoi/man/samnem/app3e.shtml)].

Canada tests the following imported seafood species risk groups for the following hazards:

- scombroids – histamine
- predatory fish – contaminants/heavy metals, therapeutants (farmed production only)
- predatory/scombroid fish – contaminants/heavy metals, therapeutants (farmed production only), histamine
- salmonids – contaminants/heavy metals, therapeutants (farmed production only)
- crustaceans – therapeutants
- molluscan shellfish – marine toxins, sanitary waters
- tropical reef fish – marine toxins
- other fish – therapeutants

The notable difference between analyses conducted by the CFIA and AQIS are tests for heavy metals including mercury.

4.5 United States imported food safety management

Food can be imported into the United States without prior approval by the FDA, but prior notice of the food importation must be given and the facilities that produce, store and/or handle the products must be registered with the FDA. Inspection by the FDA occurs at the US border.

The Food Safety Inspection Service (FSIS) does not manage the food safety of fruits, vegetables or seafood. Seafood products imported into the USA are regulated by the FDA using a mix of management options including foreign manufacturer inspections,

inspections of importers, and inspection of surveillance samples of imported goods at the border. The choice of management option is risk based with “high priority” products, and foreign processors or importers of high priority products given the most attention.

An interagency working group released an action plan in 2007 that contained 14 recommendations that were developed to improve the safety of imported foods (Interagency Working Group on Import Safety, 2007). The strategic framework on which the action plan is based shifts the emphasis for import safety from intervention at the border to a risk-based prevention with verification model. Recommendations in the action plan included implementation of foreign certification arrangements (Plan recommendation 2), promoting Good Importer Practices (Plan recommendation 3), create an interactive import-safety information network (Plan recommendation 8) and expand laboratory capacity and develop rapid testing methods for swift identification of hazards (Plan recommendation 9).

The USA is in the process of actioning the report recommendation through strengthened enforcement, international discussions and agreements and enhanced information sharing (Interagency Working Group on Import Safety, 2008). A memorandum of agreement (MOA) between the FDA and China’s General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) requires AQSIQ to establish a registration and certification system to ensure food and feed exported from China to the United States meets FDA requirements. The US has been in discussion with other Asian countries (India, Vietnam and Singapore) with respect to food import safety and providing technical assistance. Two draft guidance documents are in preparation. One on good importer practices will facilitate importer compliance with federal laws and regulations. The other will lay out the standards third-party certification programs for FDA-regulated products should meet to be eligible for recognition. A new computer-based system will allow better targeting of higher risk exporters and products.

4.6 Japanese imported food safety management and surveillance

Japan uses a risk based approach to food safety management. Risk assessment occurs under the Food Safety Basic Law (2003) and risk management under the Food Sanitation and other laws. Imported foods are inspected by 31 quarantine stations placed across Japan under the central government.

The MHLW develops the Imported Foods Monitoring and Guidance Plan annually, the purpose of which “is to promote intensive, effective and efficient monitoring and guidance for the purpose of further ensuring safety with regard to imported foods.”

5 BEST PRACTICE FOOD IMPORT CONTROL SYSTEMS

5.1 Codex guidelines for food import control systems

The approach of the Codex guidelines general recommended characteristics of food import control systems (Codex Alimentarius, 2003; detailed in Appendix D) are in summary:

- clearly defined responsibilities for the competent authority or authorities;
- requirements for imported food that are consistent with requirements for domestic foods;
- clearly defined and transparent legislation and operating procedures;
- precedence to the protection of consumers;
- provision of the importing country for recognition of the food control system applied by an exporting country's competent authority;
- uniform nationwide implementation;
- implementation that ensures the levels of protection achieved are consistent with those for domestic food.

5.2 Risk based "through chain" food safety systems

Domestically and internationally, "through chain" food safety systems have become the recognised and accepted approach to producing safe food. It is widely acknowledged that it is more efficient and economical to manage food safety hazards where they might occur at the various points along the food production and/or processing chain, from paddock to plate or farm to fork, rather than solve the problem at the end. In 1993, the Guidelines for the Application of HACCP system were adopted by the FAO/WHO Codex Alimentarius Commission (World Health Organisation, 2009). Codex guidelines, standards and other documents are the reference points for food safety requirements in international trade.

Thus, monitoring and border testing of imported food is no longer considered as the only form of food safety control due to the worldwide recognition of "through chain" food safety and quality management systems. The United States Food and Drug Administration (USFDA, 1995) provides a sound summary in the following:

> *A functioning HACCP system reflects an understanding of the wide range of hazards to which seafood may always be subject and provides for a systematic application of the preventive controls necessary to minimize the occurrence of those hazards. It is the most effective and efficient way known of ensuring food safety as a matter of design.*

The current approaches of many developed countries are more focussed on integrated, through chain approaches to food safety, from farm to fork, incorporating feed production, primary production, food processing, storage, transport and retail sale. As preventative food safety controls become more stringent in developed countries, they must be based on sound science and applied equally to domestic and imported products if food safety is not to become a barrier to international trade, especially with developing countries (Frohberg et al., 2006). Thus, demonstration of equivalence between importing and exporting countries is also important and may not necessarily require that specific practices be identical, but that the effect or outcome of regulation achieves the same food safety goals.

Australia has been working towards the implementation of this through chain approach for domestic food production through the Primary Production and Processing Standards (PPPSs) since 2002 when the Australia and New Zealand Food Regulation Ministerial Council gave FSANZ responsibility to extend its evidence-based standard-setting process to the primary production sector. The first PPPSs developed were for the seafood (Standard 4.2.1 gazetted on 26 May 2005; FSANZ, 2009b) and dairy industries (Standard 4.2.4 gazetted on 5 October 2006). Primary production and processing requirements are currently being assessed for the egg industry, poultry meat industry, dairy (raw milk products), seed sprouts and meat and meat products.

While all foods imported into Australia must meet the requirements of the Code and the Seafood PPPS, the system in place to assess compliance is the IFIS which relies on inspection or inspection and testing at the border. The border inspection under the IFIS may not necessarily ensure compliance of imported foods with the Seafood PPPS. The Seafood PPPS can only apply to the production and processing of seafood in Australia, but could form the basis for foreign government certification arrangements.

5.3 Food import control systems – certification arrangements and compliance agreements

Codex (Codex Alimentarius, 2003) state that “Official and officially recognized inspection and certification systems are fundamentally important and very widely used means of food control systems”. Codex also note that “A substantial part of the worldwide trade in food depends upon the use of inspection and certification systems.”

In respect of the ability to recognise exporting country food control systems, Codex (2003) details that:

> *“Food import control systems should include provisions for recognition as appropriate of the food control system applied by an exporting country’s competent authority. Importing countries can recognise the food safety controls of an exporting country in a number of ways that facilitate the entry of goods, including the use of memoranda of understanding, mutual recognition agreements and equivalence agreements and unilateral recognition. Such recognition should, as appropriate, include controls applied during the production, manufacture, importation, processing, storage, and transportation of the food products, and verification of the export food control system applied.”*

The ability to recognise equivalence of through chain food safety and other control systems of exporting countries would also provide greater assurance that imported seafood complied with the Australian seafood PPPS, particularly for high risk seafood that requires a through chain preventative approach for the highest assurance of safety. Demonstration of equivalence of exporting country systems to the Australian seafood PPPS and the Code would be required under certification arrangements. AQIS should also be able to stipulate the conditions of the certification arrangement. This in turn may result in a decreased rate of IFIS border testing of risk foods, opening up opportunities (resources) for alternative surveillance activities, the ability to conduct surveys and further compliance checks.

In respect of a food import control system that ensures the levels of protection achieved are consistent with those for domestic food, Codex (2007) further details that:

> *"As an importing country has no direct jurisdiction over process controls applied to food manufactured in another country, there may be a variation in approach to the compliance monitoring of domestic and imported food. Such differences in approach are justifiable provided they are necessary to ensure that the level of protection achieved is consistent with that of domestically produced food."*

5.4 Advantages and limitations of current Australian practices

The majority of the current Australian practices for control systems for seafood imports are in line with the characteristics recommended by Codex (2003 and summarised under 5.1).

Advantages of the current Australian imported seafood program include:

- A **risk based approach to identification of risk foods**. The FSANZ risk assessment process to identify the risk foods to be subject to inspection at the border is based on sound science and widely accepted risk assessment principles.
- **Provision for recognition of exporting country food control systems** under Clauses 18 and 19 and 35A of the Act allowing foreign government certification, certification by approved overseas operations or compliance agreements, respectively.
    - Australia has foreign government certification arrangements with New Zealand and Thailand. These countries combined are responsible for approximately 45 percent of the seafood imports into Australia, although not all seafood may be covered by the arrangements. For example, if seafood is sourced from an establishment in Thailand that is not approved under the certification arrangement, it is subject to the usual inspection under the IFIS.
- An **inspection scheme that allows testing of risk foods** at the border and ongoing surveillance of non risk group foods. Border testing provides data on product compliance.

Equally, **limitations of the current Australian imported seafood program** include the following:

- **Entering into foreign government certification arrangements** with exporting countries **or compliance agreements** with importers is voluntary on the part of the other party. This limitation was noted in the Beale report.

- **An end point inspection scheme**. Under the current IFP, the primary means of checking the safety of imported seafood relies on a government run, end point, product test regime. The capacity of end product testing is limited in its ability to ensure practices that aim to ensure food safety are applied through the production/processing chain. While this may be achieved through foreign government certification arrangements, these are voluntary.

- **Consistency between requirements for imported and domestic foods.** Australian states and territories require food business, including importers, to comply with the relevant standards. The jurisdictions are able to demand production controls are implemented on domestic establishments, but have limited capacity to demand that importers prove that they have similar assurances for imported food.

- **Inspection rate for random surveillance** restricted to 5 percent of consignments. There is no capacity to reduce this to zero for very low risk products or increase the rate for surveillance of emerging or perceived hazards.

- **Limited ability to react to a food safety alert or incident**. The Imported Food Control Act is inflexible particularly in the mechanism to categorise risk food within the IFIS. AQIS apply their tests on advice from FSANZ and this can result in a lack of responsiveness to a food safety incident. There is no provision for AQIS to conduct higher rate inspections outside of the scheme, or a category of inspection within the scheme that would enable efficient and appropriate response to food safety alert and incidents. The current National Food Incident Response Protocol specifies FSANZ as the central notification point for an emergency response once food has entered the country.

6 STAKEHOLDER COMMENTS

This section draws out the key trends in the stakeholder comments. The comments provided by the stakeholders included those that were qualitative, anecdotal and, in some circumstances, perceptions and personal opinion. Some comments also related to trade issues. Some comments may not be factually correct, but have been included here or in Appendix E to demonstrate the sentiment of the individual or stakeholder group. The stakeholder comments presented as either direct quotes or paraphrased (for summary purposes) are presented in Appendix E.

6.1 Stakeholder comments – Imported seafood safety and compliance

There was overall agreement amongst all of the stakeholder groups that imported seafood is safe and complies with Australian requirements. Peak bodies noted in particular that imported seafood has a very high compliance rate.

However, some stakeholders from peak bodies and domestic producers reported that some seafood could be imported under the guise of alternative product tariff codes, thus avoiding some safety and/or compliance checks. If this continues to happen, the potential exists for breaches in both biosecurity and food safety. Stakeholders noted that this also demonstrates the tactics that some importers will use in an attempt to avoid border inspections.

Questions also arose of hormones and/or antibiotics that might be acquired through feed. A food company/importer noted that no non-compliance should occur if the antibiotics or other chemicals are used as per the product label. A peak body stakeholder noted that improvements in aquaculture are occurring very quickly and antibiotic use is in rapid decline.

A number of stakeholders indicated that there were instances of labelling non-compliances at retail level. Opinions were received from domestic producers and domestic producer peak bodies that labelling on imported seafood is inadequate, at times misleading and observations at retail level indicate that imported product is being sold as Australian product to achieve a higher price.

6.2 Stakeholder comments – Imported seafood safety gaps and deficiencies and suggestions for improvement

Government stakeholders noted that a significant gap as it relates to seafood safety is that Australia (AQIS) cannot prevent entry of a food where there is a known problem that is not captured under existing import requirements. Even temporary suspensions at the border are not possible in such situations. This also relates to gaps in surveillance activities that were also identified but are drawn out under 6.4.

Comments and opinions were received from government agencies, domestic producers and their representing peak bodies that related to the inconsistency between the enforcement of requirements for domestic seafood production and processing and those for imported seafood. Concerns were about the inability to enforce a through chain food safety program requirement on higher risk products such as bivalve molluscs. Some concerns (mainly from industry and peak bodies) related to the Australian restrictions on chemical and antibiotic use placed on domestic producers which could not be applied to product being imported, except in the form of a border test.

Government stakeholders also noted that there are deficiencies in analytical test capabilities, especially with respect to virus detection.

Gaps exist in the mechanisms for setting MRLs where there is no limit in the Code. FSANZ may/should amend the Code to recognise international MRLs (peak body).

Government stakeholders suggested that improvements to the food import system could be made with a mix of quality assurance programs, certification programs and end product testing. Licensing of importers, similar to the proposed NZ arrangements, should be considered.

6.3 Stakeholder comments – Food import control systems – certification arrangements and compliance agreements and risk based "through chain" food safety systems

There was general support from government and industry sectors and peak bodies for foreign government certification arrangements and importer compliance agreements. Future food safety management is inevitably going to require options for product compliance or certification at the point of exit. Concerns from peak bodies and importers and food companies related to ensuring that any government to government certification arrangements were established to ensure equivalence.

Peak bodies stated that the aim of food import compliance regulation should be to get the big importers onto compliance agreements and this will in turn free up resources to focus on smaller importers.

Compliance agreements with importers may be cumbersome to set up, but have the capacity in the long term to be cost effective and will build relationships with importers.

6.4 Stakeholder comments – border testing, surveillance and industry intelligence

Government stakeholders noted the inflexibility and unresponsiveness of the IFIS for risk foods and random surveillance. The poor response capability for risk category foods is because if information arises on potential, perceived or emerging hazards, AQIS cannot target that commodity:hazard combination unless advice is received from FSANZ. Additionally, whilst AQIS has flexibility to change tests on foods in the random surveillance category, there is no flexibility to increase testing rates beyond the 5 percent rate. The State and Territory jurisdictions comments relating to this issue appear to stem from the fact that they become responsible for non-compliant food once past the border. However, the flexibility to change the tests in the random surveillance category could be a useful mechanism to conduct rolling surveillance whereby certain tests be conducted for set periods of time to gather data on perceived, emerging or other hazards. Rolling surveillance would provide more useful information to the industry and government agencies than continually testing for the same thing and obtaining 98 percent compliance.

Of apparent particular concern to some stakeholders from the government sector is that, whilst identification of target foods for testing under the IFIS is risk based, the rate of testing of foods is performance based – there is a decrease in testing of the of the identified risk foods if high level compliance is achieved and an increase in testing if non-compliance is in evidence.

Peak bodies also noted the constraints on AQIS to act, especially compared to State and Territory jurisdictions that can test whatever they like. Some peak bodies commented that the IFIS is good with respect to the process with respect to “green lane” for good compliance history, while others commented that border testing is somewhat out of date and that the IFIS was developed at a time whereby end point testing was still regarded as an effective way of checking food safety.

Food companies/importers felt that end point testing is somewhat tokenistic and that they would prefer to see money spent on broader screening.

Stakeholders used various sources for their industry intelligence including existing formal and informal networks, customer relations, e-alerts, e-newsletter and their respective peak bodies. Stakeholders agreed that there should be a more coordinated approach to surveillance and more robust networks for sharing information.

7 AN OPTIMAL APPROACH TO SEAFOOD IMPORT PROGRAM AND SURVEILLANCE ACTIVITIES FOR AUSTRALIA

7.1 SUMMARY OF RECOMMENDATIONS

Overarching recommendation (refer to 7.2)	AQIS should implement a mix of risk management options for seafood imported into Australia. These options should be commensurate with the risk of the seafood and include the following key elements: • Foreign government certification arrangements for certain risk seafood imported into Australia. The certain risk seafood referred to here are the kinds of seafood , such as bivalve molluscs, for which safety is best assured by through chain food safety control measures. • Compliance agreements with and/or licensing of importers of risk seafood. • An inspection scheme that allows for flexibility in the type of test(s) conducted and has the capacity for responsiveness to emerging/perceived unsafe and/or unsuitable food. • An enhanced role for FSANZ in assessing food safety risks to consumers and thus prioritise seafood commodity:hazard combinations for control and/or testing.
Recommendation 1 (refer to 7.3)	AQIS should make greater use of foreign government certification arrangements with exporting countries. Such arrangements should be developed with countries that export certain "risk" seafood to Australia, in which the food safety hazards can only be controlled through the production chain and end product testing may not assure product safety. Such arrangements should specifically require satisfactory demonstration of through chain controls during the seafood production/processing chain.
Recommendation 2 (refer to 7.3)	AQIS should initiate action, in consultation with other agencies as appropriate, on the need to modify imported food legislation to enable AQIS to mandate the requirement for foreign government certification for certain "risk" imported seafood.
Recommendation 3 (refer to 7.4)	AQIS should make greater use of compliance agreements with importers of seafood, particularly "risk" seafood. Under compliance agreements, the importers would be responsible for ensuring that they import seafood that meets Australian requirements. Importers should have flexibility to demonstrate product compliance e.g via a through chain food safety system of their suppliers.

Recommendation 4 (refer to 7.4)	AQIS should initiate action, in consultation with other agencies as appropriate, on the need to modify legislation to enable AQIS to enter into compliance agreements with importers of seafood.
Recommendation 5 (refer to 7.5)	AQIS should initiate consultation as appropriate with other agencies, in respect of licensing/registration of importing operations at Federal or State/Territory level. A licensing/registration arrangement might require importers to develop food safety and traceability systems (commensurate with the risk of the seafood being imported), which in turn, will allow for auditing/monitoring of an importer's compliance to these systems. Requirements of a licensing/registration arrangement could encompass all importers.
Recommendation 6 (refer to 7.6)	AQIS should retain an inspection scheme to conduct surveillance of imported seafood (other than commodity:hazard combinations identified as high risk and subject to certification arrangements). The inspection scheme should: i. be based on advice from FSANZ that takes into account their monitoring of emerging issues and incidents; ii. continue to allow for flexibility in the type of test(s) conducted as is the case for random surveillance at present, but supported in the future by consultation with relevant stakeholders; iii. have capacity for responsiveness to newly recognised or perceived hazards or in an emergency to a perceived unsafe or unsuitable food. An additional category of inspection under the Act could allow for efficient and appropriate response to these issues, and; iv. have capacity to include a pre-planned coordinated surveillance program. Options to be considered could be similar to the FSANZ-designed Total Diet Survey and other FSANZ coordinated surveys and enable compliance checking of targeted commodities for a defined period. Emerging and/or perceived threats are likely to be identified and/or monitored under such a program.

7.2 A mix of management options commensurate with the food safety risk

Over arching recommendation

AQIS should implement a mix of risk management options for seafood imported into Australia. These options should be commensurate with the risk of the seafood and include the following key elements:

- Foreign government certification arrangements for certain risk seafood imported into Australia. The certain risk seafood referred to here are the kinds of seafood , such as bivalve molluscs, for which safety is best assured by through chain food safety control measures.
- Compliance agreements with and/or licensing of importers of risk seafood.
- An inspection scheme that allows for flexibility in the type of test(s) conducted and has the capacity for responsiveness to emerging/perceived unsafe and/or unsuitable food.
- An enhanced role for FSANZ in assessing food safety risks to consumers and thus prioritise seafood commodity:hazard combinations for control and/or testing.

A best practice system that uses **a mix of risk management options for seafood imported into Australia that are commensurate with the risk of the seafood** would be both effective in assuring food safety and efficient for clearance of seafood imported into Australia. The following key elements would be included:

- Foreign government certification arrangements for certain risk seafood imported into Australia.
- Compliance arrangements with importers of seafood, particularly “risk” seafood
- An inspection scheme that allows for flexibility in the type of test(s) conducted and has the capacity for responsiveness to emerging/perceived unsafe and/or unsuitable food.

These elements provide improvements to the current IFP by requiring that foreign government certification arrangements be mandated for certain risk seafood imported into Australia and more specifically for risk seafood where through chain measures are necessary to provide greatest assurances of food safety. Encouraging all seafood importers to enter into compliance agreements, but more specifically those importing risk seafood, would also provide improvements to the IFP in that this approach provides importers with responsibility and flexibility to demonstrate compliance to Australian requirements and this may be a through chain approach.

This recommended approach relating to greater use of foreign government certification and compliance agreements is in line with that of Beale et al., 2008 in their report “One Biosecurity: A Working Partnership“ with respect to imported food safety. They recommended that risk return principles be applied and the current performance based

Imported Food Inspection Scheme be continued, while a new National Biosecurity Authority be empowered to require that importers provide certification from the exporting country's competent government authorities and the capacity to enter into and audit compliance agreements with including their product providers.

The benefits and limitations associated with the development of a licensing or registration scheme for importers should also be investigated by AQIS. Such as scheme could require importers to develop food safety and traceability systems to demonstrate compliance of their imported product to Australian requirements, similar to the proposed New Zealand system.

The current process in the IFP where FSANZ has the responsibility to assess food safety risks to the consumers and thus prioritise seafood commodity:hazard combinations for control and/or testing should remain the responsibility of FSANZ for any future food import regime using a risk-based approach. Retaining FSANZ in this role also ensures the criteria and limits specified for imported foods are consistent with those developed for domestic food.

Consideration should be given to options, including the use and development of existing networks and/or an enhanced FSANZ role, for obtaining more value from imported food analysis and surveys. An additional category of seafood added to the imported food legislation (Imported Food Control Regulations, Part 3) might offer an option that would provide capacity for AQIS to respond to emerging or perceived unsafe and/or unsuitable food at the border.

7.3 Foreign government certification arrangements with exporting countries for certain risk seafood

Recommendation 1

AQIS should make greater use of foreign government certification arrangements with exporting countries. Such arrangements should be developed with those countries that export certain "risk" seafood to Australia, for which the food safety hazards are best controlled through the production chain and end product testing may not assure product safety. Such arrangements should specifically require satisfactory demonstration of through chain controls during the seafood production/processing chain.

Recommendation 2

AQIS should initiate action, in consultation with other agencies as appropriate, on the need to modify imported food legislation to enable AQIS to mandate the requirement for foreign government certification for certain "risk" imported seafood.

It is recommended that foreign government certification arrangements be developed with those countries, in particular, that export certain "risk" seafood into Australia for which the food safety hazards are best controlled through the production chain.

This approach for certain risk seafood will provide greatest assurance of the safety of the imported seafood (such as bivalve molluscs) for which through chain systems are internationally recognised as the most appropriate means to control food safety. Additionally, the responsibility for management of the food safety risks is placed on operators through chain with emphasis on practices and procedures from pre-harvest production and/or catch through to arrival at Australia's border. End product testing may not provide the best assurance of the safety as test methodology for some contaminant is not reliable and sampling alone can only provide a certain degree of confidence in measures of safety.

Requiring a systematic approach to food safety during primary production for imported seafood provides consistency with the Australian Primary Production and Processing Standard for Seafood (PPPS; FSANZ, 2009b) that requires a through chain food safety management system for bivalve molluscs. .

Under existing imported food legislation, foreign government certification arrangements with exporting countries are only set up on voluntary agreement from the other party. The ability to enter into certification arrangements with foreign governments should be made a requirement in the future for importing certain "risk" seafood into Australia. The certification arrangements developed and agreed between AQIS and the exporting country should be such that demonstration of through chain controls of food safety are required and are consistent with requirements of the Australian Seafood PPPS and the Code. This should in turn result in reduced border testing under the IFIS.

Therefore, changes to the imported food legislation are necessary to mandate that foreign government certification arrangements be developed for certain risk seafood. As a consequence, changes made to the imported food legislation may impact on those imported risk foods (other than seafood) that require through chain approaches to food safety.

The current Regulations under the Act allow for the incidence of inspection of imported food to be varied if there is an accompanying recognised foreign government certificate so the capacity to vary inspection and testing rates of imported risk seafood entering under such aforementioned certification is in place and appropriate.

A secondary level of development of foreign certification arrangements should be encouraged with those countries exporting other "risk" seafood to Australia, but such arrangements can continue to be voluntary by the participating country as is currently the case with the IFP.

7.4 Compliance agreements with importers for practices and procedures for risk seafood

Recommendation 3

AQIS should make greater use of compliance agreements with importers of seafood, particularly "risk" seafood. Under compliance agreements, the importers would be responsible for ensuring that they import seafood that meets Australian requirements. Importers should have flexibility to demonstrate product compliance e.g via a through chain food safety system of their suppliers.

Recommendation 4

AQIS should initiate action, in consultation with other agencies as appropriate, on the need to modify legislation to enable AQIS to enter into compliance agreements with importers of seafood.

It is recommended that AQIS encourages seafood importers to enter into compliance agreements, particularly for importers of "risk" seafood into Australia (such as foods of the kind identified in the Imported Food Control Order). Under these agreements, the importers would be responsible for ensuring that they import seafood that meets Australian requirements. Importers would also have flexibility to demonstrate product compliance, for example, via a through chain food safety system of their overseas operation and/or suppliers. This in turn provides consistency with the Australian PPPS by placing emphasis on practices and procedures from pre-harvest production and/or catch through to arrival at Australia's border and should result in reduced border testing under the IFIS.

Under existing legislation, entering into compliance agreements by seafood operations and their suppliers can be done on voluntary agreement from the other party.

The ability to enter into compliance agreements with importers is anticipated early in 2010.

7.5 Licensing or registration arrangements for importers of seafood

Recommendation 5

AQIS should initiate consultation as appropriate with other agencies, in respect of licensing/registration of importing operations at Federal or State/Territory level. A licensing/registration arrangement might require importers to develop food safety and traceability systems (commensurate with the risk of the seafood being imported), which in turn, will allow for auditing/monitoring of an importer's compliance to these systems. Requirements of a licensing/registration arrangement could encompass all importers.

Benefits that a licensing/registration arrangement could be expected to and developed to deliver would be:

- an efficient mechanism for overseeing and communicating with seafood importers
- further harmonisation of regulatory requirements for Australian domestic and imported seafood, particularly if licensing required demonstration of specific food safety control and traceability systems.
- further harmonisation of regulatory requirements between Australia and New Zealand
- reduced border testing for compliant low and medium risk seafood.

7.6 An inspection system for surveillance of low to medium risk food and with response capacity

Recommendation 6

AQIS should retain an inspection scheme to conduct surveillance of imported seafood (other than commodity:hazard combinations identified as high risk and subject to certification arrangements). The inspection scheme should:

i. be based on advice from FSANZ that takes into account their monitoring of emerging issues and incidents;

ii. continue to allow for flexibility in the type of test(s) conducted as is the case for random surveillance at present, but supported in the future by consultation with relevant stakeholders;

iii. have capacity for responsiveness to newly recognised or perceived hazards or in an emergency to a perceived unsafe or unsuitable food. An additional category of inspection under the Act could allow for efficient and appropriate response to these issues, and;

iv. have capacity to include a pre-planned coordinated surveillance program. Options to be considered could be similar to the FSANZ-designed Total Diet Survey and other FSANZ coordinated surveys and enable compliance checking of targeted commodities for a defined period. Emerging and/or perceived threats are likely to be identified and/or monitored under such a program.

It is recommended that AQIS retain an inspection system for surveillance of low to medium risk seafood. The current arrangement whereby FSANZ conducts the risk assessments and prioritises seafood commodity:hazard combinations for control and/or testing must be retained. This ensures that the criteria and limits specified for imported foods are based on sound science and are consistent with those developed for domestic food. The current surveillance inspection system could be strengthened by the use of existing and/or development of new networks to keep a watching brief over international commodity:hazard testing regimen. Working with AQIS and FSANZ, the network would regularly review and recommend updates to Australian border testing protocols and other planned ongoing surveillance activities in response to international intelligence and testing activities.

The flexibility currently available to AQIS with respect to choice of tests applied to random surveillance foods must be maintained. An inspection system of food classified as random surveillance at a rate of five percent of consignments should be maintained under existing legislation. Without changes to legislation, there is scope to apply additional or alternate tests under the Imported Food Notices that specify the tests that are applied to random surveillance category foods at the five percent rate. However, AQIS should investigate opportunities to improve the capacity of surveillance testing for responsiveness to emerging or newly recognized hazards or perceived unsafe and/or

unsuitable food at the border. This responsiveness could be developed through consultation with FSANZ as the risk assessor or food safety surveillance networks.

Product inspection and testing, for the purposes of audit checks and product compliance against relevant standards of the Code, should be retained in any modified surveillance system.

The National Food Incident Response Protocol (refer to section 3.6) offers an existing framework for a nationally coordinated response for product available for sale within two or more Australian States or Territories. An additional category of inspection implemented under the imported food legislation (Imported Food Control Regulations, Part 3) could encompass emergency surveillance activities at the border in the event of perceived or actual food safety hazards. This could provide a mechanism for an efficient and appropriate border response by AQIS to these issues, but should also be enacted under efficient and appropriate advice (mechanisms to be developed) from relevant national, state or territory agencies. This would differ from the category of active surveillance that is currently not used and in the process of being removed from legislation.

Routine surveillance testing and survey data will benefit food safety intelligence networks and continue to inform FSANZ in their risk assessments. Surveillance systems should be in response to industry intelligence or used to gather data on potential hazards not specifically identified as a risk to public health. Consideration should be given to options, including the use and development of existing networks, for obtaining more value from imported food analysis and surveys. Additional benefits are that emerging and/or perceived threats are likely to be identified and/or monitored under such a program. Also developing an ongoing planned surveillance scheme will build capability in test methods where it may previously not have existed with a view to making that capability available should ongoing testing be required in the future.

Therefore, **it is recommended** that AQIS give consideration to developing a pre-planned coordinated surveillance program in consultation with relevant agencies and/or under existing frameworks. It is noted that FSANZ is a collection point of food surveillance data, compliance test data and survey data from various public health units and agencies in Australia and New Zealand. Development and/or further formalisation of pre-planned and prioritised imported seafood surveillance activities by AQIS could occur through the Coordinated Food Survey Plan, an initiative of ISC. This mechanism has been used in the past in the survey of chemical residues in domestic and imported aquacultured fish (section 3.5).

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NON REFERENCED INFORMATION SOURCES

Guidance documents and reference sources for international comparisons

New Zealand

Importing - Food Importer Standards Guidance. This document describes the NZFSA's clearance procedures for all food imported into New Zealand. Importers should note the definition of food under the Food Act 1981 is very broad and includes ingredients and anything intended to be mixed or added to any food (or food related products).

This guidance document does not specify how importers must comply with the requirements of the Standards, but provides examples to help identify ways to comply.

http://www.nzfsa.govt.nz/importing/food-importer-standards-guidance/

Canada

The Good Importing Practices For Food (GIP) is a voluntary code of practice to be used as a guideline for Canadian importers.

USA

Regulatory procedures manual

http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm

UK

Imported food and enforcement

http://www.food.gov.uk/foodindustry/imports/enforce_authorities/

Roles and responsibilities of Government authorities

http://www.food.gov.uk/foodindustry/imports/enforce_authorities/roles

Guidance Document – Key questions related to import requirements and the new rules on food hygiene and official food controls (European Commission

Health & Consumer Protection Directorate-General, 2006)

EU

Guidance Document – Key questions related to import requirements and the new rules on food hygiene and official food controls (European Commission

Health & Consumer Protection Directorate-General, 2006)

http://ec.europa.eu/food/international/trade/interpretation_imports.pdf

APPENDIX A – PROJECT TERMS OF REFERENCE AND EXPECTATIONS OF THE FINAL REPORT

TERMS OF REFERENCE

In reviewing the current seafood testing protocol, the review should:

1. note the Food Standards Australia New Zealand (FSANZ) review of provisions of the Australia New Zealand Food Standards Code (the Code) pertaining to seafood;
2. identify the current approach to testing imported seafood in both the risk and random surveillance categories as required to meet the Imported Food Control Act 1992 and compare this approach against domestic and international practices;
3. recommend measures for imported seafood that can be implemented immediately under existing imported food legislation and other measures that would reflect best practice for imported seafood;
4. identify any changes to imported food legislation that would be required to deliver best practice seafood clearance;
5. identify relevant validated test methods, if there is laboratory capability to undertake relevant testing and any gaps; and
6. consult with stakeholders including FSANZ, the National Measurement Institute, the National Association of Testing Authorities, state and territory food regulators and the seafood sector (domestic and imported) on the adequacy of the current seafood testing protocols.

EXPECTATIONS OF THE FINAL REPORT

In reporting the outcomes and recommendations, the review should:

1. identify the current approach to testing imported seafood in both the risk and random surveillance categories required to meet the Imported Food Control Act 1992;

2. recommend measures for best practice (i.e. effective and efficient) clearance of imported seafood including, if appropriate, reference to offshore, quality assurance and system based approaches;

3. develop, as part of point 2 above, a regime for testing that checks the compliance of seafood against the relevant standards of the Code that can be accommodated under the existing Imported Food Inspection Scheme.

4. A proposed testing regime should prioritise seafood commodity:hazard combinations, noting the review by FSANZ of provisions of the Code for seafood and the responsibility for FSANZ to identify medium to high risks.

5. A proposal to introduce new testing methods must consider Australian and international recognition of the effectiveness of these methods and the capability of the Appointed Analysts to accommodate these methods; and

6. identify any legislative changes to the Imported Food Control Act 1992 that would be required to deliver the recommended seafood testing program.

APPENDIX B – STAKEHOLDER INTERVIEW BACKGROUND PAPER

Review of Current Testing Protocols for Seafood Imports

Stakeholder interview background paper

PROJECT BRIEF:

An election commitment of the new federal government was to review existing testing protocols for seafood imports and consider any measures necessary to improve the food safety standards of imported seafood products.

AQIS called for expressions of interest to conduct a review of current testing protocols for seafood imports. Food Science Australia (a joint venture formed between the CSIRO Division of Food Science and Technology and the Department of Primary Industries Victoria) was successful in tendering to conduct the review. The Food Science Australia consultancy team includes members of the Food Safety and Quality Theme in Sydney, Melbourne and Brisbane.

As part of the review, input is sought from key stakeholders, including agencies with responsibility for human health and food regulatory activities as well as relevant industry sectors. You have been identified as a key person with whom to consult.

The Food Science Australia consultancy team is seeking stakeholder opinion (via phone or face-to-face interviews) on the Imported Food Inspection Scheme (IFIS) and this approach to determining food safety and compliance of imported seafood with respect to:

1. Domestic regulatory requirements as defined under the Australia New Zealand Food Standards Code (the Code), including the Primary Production and Processing Standard for Seafood 4.2.1. and approaches to determining equivalence of these arrangements.
2. Alternative types of survey or testing plans or alternative approaches that could be applied to imported seafood, particularly for low risk random surveillance category foods (see project background, below).
3. Recognition of overseas certification as equivalent to the IFIS by appropriate whole of chain assurances and/or testing of product batches at point of departure rather than at point of entry.
4. International arrangements in countries maintaining similar expectations of food safety for imported seafood (e.g. USA, UK, NZ, Canada or Japan).
5. Views on what is considered best practice (i.e. effective and efficient) clearance of imported seafood including, if appropriate, reference to offshore, quality assurance and system based approaches.

SCOPE OF INTERVIEW:

We anticipate that depending on your stakeholder role and interests in imported seafood there will be a range of responses. However, to provide some consistency in the scope of the interview, a number of questions (intended to be relatively open), have been formulated to assist respondents in collecting any necessary information prior to interview.

1. What do you understand to be the regulatory requirements to sell seafood in Australia? What do you understand to be the requirements for imported seafood?

2. Are you aware of unsafe or non-compliant seafood that is manufactured overseas and imported into Australia?

3. Are you aware of information/evidence of market failure associated with imported seafood in other countries?

4. Do you believe there are current gaps and deficiencies in the existing seafood import testing arrangements? If so, what are they? (e.g. commodity-hazard combinations, test methods applied, sampling regimes, insufficient procedures to address emerging hazards).

5. Do you have suggestions for improvements to existing seafood import testing arrangements? (e.g. safety assurance systems, certified testing at point of exit).

6. Do you have relevant information on seafood production manufacturing processes overseas (including use of chemicals) that should be considered in a testing regime?

7. What sources of information do you access to stay abreast of knowledge of possible concerns associated with imported seafood from specific origins and also the methodologies used to identify occurrence or rate of incidence of the concern?

8. What options in your opinion could be employed to improve imported seafood safety and compliance with the Code? (These options may include changes that are low cost and easy to implement, or broader changes with a higher cost and a significant deviation from the current situation)? What are the benefits? What are the impediments? (e.g. restrictive legislation and/or Ministerial policy guidance, Office of Best Practice Regulation constraints)?

The following is a brief background to assist you in preparation for the discussion.

Thank you for agreeing to be interviewed and we look forward to talking with you.

PROJECT BACKGROUND:

Provisions of the Code pertaining to seafood

The relevant sections of the Code, (http://www.foodstandards.gov.au/thecode/foodstandardscode/index.cfm) pertaining to seafood are:

- Standard 4.2.1. Primary Production and Processing Standard for Seafood (PPP Seafood),
- Standard 1.3.1 Food Additives (specific to sulphur dioxide levels),
- Standard 1.4.1 Contaminants and Natural Toxicants,
- Standard 1.6.1 Microbiological limits for food, and
- Standard 2.2.3 Fish and Fish Products (compositional standard specific to histamine levels).

The PPP Seafood Standard makes cross-reference to the Australian Shellfish Quality Assurance Program Operations manual for production practices and this manual refers back to Standards 1.4.1, 1.6.1, and 2.2.3 for limits on the criteria of microbiological, chemical and natural toxicants. A guide to the standard is provided in the link http://www.foodstandards.gov.au/_srcfiles/Safe%20Seafood%202edn-WEBwc%20.pdf and risk ranking of seafood and hazards in attachment 10 of FSANZ P265, 2005 (http://www.foodstandards.gov.au/_srcfiles/P265_Seafood_PPPS_FAR.pdf).

Current approach of Risk and Random Surveillance of Imported Foods Inspection Scheme (IFIS) as defined by Imported Food Control Act, 1992 and Imported Food Control Regulations, 1993.

AQIS has operational responsibility for inspection and sampling of food as it reaches the Australian border and is known as the IFIS. FSANZ advises AQIS of the level of public health risk posed by foods and the IFIS testing regime is based on that advice, targeting foods that pose a medium to high risk to public health and safety. The legislation underpinning these roles is expanded in a memorandum of understanding (MOU; as explained in Attachment 9, FSANZ P265, 2005) between FSANZ and AQIS. AQIS can apply holding orders on importers of seafood as a result of non-compliant products under the specifications of the IFIS. An explanation of the application of the IFIS by AQIS is provided in the link http://www.daff.gov.au/aqis/import/food/inspection-scheme.

The AQIS Imported Food Notices define the sampling and testing regimes for operation of the IFIS as follows.

i. *Risk* categorised. Food that pose a medium to high risk to public health. At point of entry, the Australian Customs Service refers 100% of these foods to AQIS for inspection against the hazards determined by FSANZ. Risk categorised seafood includes finfish, crustaceans, molluscs and other aquatic invertebrates. Inspection rate reduces upon good compliance. The hazards identified by FSANZ are listed in the Imported Foods notice 03/08, (issued 7 August 2008, http://www.daff.gov.au/__data/assets/pdf_file/0005/762908/ifn-03-08.pdf)

ii. *Random Surveillance* categorised. These foods are subject to referral to AQIS at a rate of 5% of shipments and are inspected against specific standards. The standards AQIS tests imported food against under random surveillance are listed in the Imported Foods notice 03/09, (issued 20 May 2009, http://www.daff.gov.au/__data/assets/pdf_file/0003/1127451/ifn-03-09.pdf).

APPENDIX C – PROVISIONS OF THE CODE PERTAINING TO SEAFOOD

Imported food risks list and tests pertaining to fish and crustaceans, molluscs and other aquatic invertebrates ALSO preparations of meat, of fish or of crustaceans, molluscs or other aquatic invertebrates (AQIS, 2009c).

Table 2. Summary of imported food risks list and tests, limits, Code reference and test method pertaining to fish and crustaceans, molluscs and other aquatic invertebrates ALSO preparations of meat, of fish or of crustaceans, molluscs or other aquatic invertebrates (adapted from AQIS, 2009b).

Food Category	Analytical tests required	Maximum limit	Code Standard ref.
Fish – tuna and mackerel whole, filleted or further processed, whether dried or not. All tuna and mackerel with or without other ingredients. **Includes:** §Ambient stable sealed packages (with or without additives, such as onion, tomato, oil, salt, chilli flavourings or garnishes). Exclusions: AQIS, 2009b ** typical imported risk fish genera	Histamine *Listeria monocytogenes* testing may be an additional test for fish of these species (see 'Fin Fish' category below).	200 mg/kg Table 3	2.2.3 1.6.1

Food Category	Analytical tests required	Maximum limit	Code Standard ref.
Fin Fish – ready to eat processed finfish (including vacuum packed), other than [§]ambient stable sealed packages of finfish All ready-to-eat processed finfish with or without other ingredients. **Includes:** (Including vacuum packed) whole or portions of cooked, smoked, smoke flavoured, dried, pickled, salted and fermented finfish (ready-to-eat). Exclusions: AQIS, 2009b	*Listeria monocytogenes* Histamine may be an additional test added to fish of this type (see 'Fish' categories above)	Table 3	1.6.1
Marinara mix (seafood mix) Marinara mix that is: • raw or cooked or blanched, and • chilled or frozen, with or without the addition of additives. Exclusions: AQIS, 2009b	*Coagulase positive Staph* *E. coli* *Salmonella* Standard plate count Paralytic shellfish poison Domoic acid If there is no shellfish component, (ie. no bivalve molluscs), then Paralytic shellfish poison and Domoic acid are not required.	Table 3 Table 4 Table 3 Table 4 0.8 mg/kg 20 mg/kg	1.6.1 1.6.1 1.6.1 1.6.1 1.4.1 1.4.1

Food Category	Analytical tests required	Maximum limit	Code Standard ref.
Crustaceans - cooked (chilled or frozen) Cooked and chilled or cooked and frozen crustaceans (whole or portions) with or without other ingredients. **Includes:** crab, crayfish and lobster (peeled or unpeeled). Exclusions: AQIS, 2009b	*Coagulase positive Staph* *Salmonella* Standard plate count ***Vibrio cholerae*** is an additional test to prawns and shrimp when cooked (chilled or frozen) – see category below	Table 3 Table 3 Table 4	1.6.1 1.6.1 1.6.1
Prawns and Shrimp - cooked (chilled or frozen) Cooked and chilled or cooked and frozen prawns and shrimp (whole or portions) with or without other ingredients. **Includes:** prawn and shrimp (peeled or unpeeled). Exclusions: AQIS, 2009b	*Coagulase positive Staph* *Salmonella* Standard plate count *Vibrio cholerae* Prawns or shrimp have additional tests at the random rate.	Table 3 Table 3 Table 4 Table 3	1.6.1 1.6.1 1.6.1

Food Category	Analytical tests required	Maximum limit	Code Standard ref.
Bivalve Molluscs other than scallops that have not been processed. Whole or portions of bivalve molluscs other than scallops that **have not** been processed **Includes:** bivalve molluscs (e.g. oysters, mussels, clams, cockles) with or without additives or preservatives. **Includes**: frozen half shelled oysters or mussels Exclusions: AQIS, 2009b	*E. coli* Standard plate count Paralytic shellfish poison Domoic acid ***Listeria monocytogenes*** may be an additional test to molluscs of this type (see 'Mollusc' category below) **NOTE:** User Guide to Standard 1.6.1 states "Processing of molluscs includes such treatments as smoking, drying and marinating but does not include physical measures such as half shelling".	Table 4 Table 4 0.8 mg/kg 20 mg/kg	1.6.1 Table 4 1.4.1 1.4.1

Food Category	Analytical tests required	Maximum limit	Code Standard ref.
Bivalve Molluscs that **have** been processed other than by depuration / cleaning Whole or portions of bivalve molluscs that **have** been processed other than by depuration / cleaning. **Includes:** bivalve molluscs (e.g. oysters, mussels, clams, cockles, scallops) with or without additives or preservatives. **Includes:** bivalve molluscs that **have** undergone a process as defined in Code Standard 3.2.2: "chopping, cooking, drying, fermenting, heating, pasteurising, thawing and washing, or a combination of these activities" Exclusions: AQIS, 2009b **Note** – **DO NOT APPLY** the *E coli* test to scallops	*E. coli* Standard plate count Paralytic shellfish poison Domoic acid *Listeria monocytogenes* **NOTE:** User Guide to Standard 1.6.1 states "Processing of molluscs includes such treatments as smoking, drying and marinating but does not include physical measures such as half shelling".	Table 4 Table 4 0.8 mg/kg 20 mg/kg Table 3	Table 4 Table 4 1.4.1 1.4.1 1.6.1

[§]**Ambient stable sealed packages**:

The following processed food that falls within these statements below would be exempt from microbiological testing:

"Ambient stable sealed packages" refers to food that meets **all 3** of the following criteria

1. hermetically sealed containers (such as metal cans, glass jars or bottles, flexible pouches or rigid containers) and
2. stable (not perishable) over a long shelf life when stored at ambient (room) temperature and
3. refrigeration prior to opening is not required.

These attributes indicate that the food has undergone a heat treatment to render the food commercially sterile and has been packaged to maintain the stability of the food.
Note: dried foods are not included

****Risk fish genera**

The following list is intended to be a guide only to assist importers in identifying genera of fish that are risk category fish.
Importers must ensure that risk category fish are correctly identified in the Customs import entry and upon request from AQIS officers.
Where AQIS officers are unsure if a particular fish is a risk fish they should contact their regional Food Safety Manager for advice and or clarification.

Mackerel of the following genera:

Auxis, Acanthocybium, Gempylus, Grammatorcynus, Nealotus, Rastrelliger, Scomber, Scomberomorus, Sarda, Tunnus, Gasterochisma melampus

Tuna of the following genera:

Thunnus, Euthynnus, Katsuwonus, Allothunnus, Cybiosarda, Gymnosarda, Pelami

Table 3. Microbiological limits applying to seafood from the Australian Food Standards Code Standard 1.6.1 Microbiological Limits for Food (Issue 103).

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Food	**Microorganism**	**n**	**c**	**m**	**M**
Cooked crustacea	Coagulase-positive staphylococci/g	5	2	10^2	10^3
	Salmonella/25 g	5	0	0	
	SPC/g	5	2	10^5	10^6
Raw crustacea	Coagulase-positive staphylococci/g	5	2	10^2	10^3
	Salmonella/25 g	5	0	0	
	SPC/g	5	2	$5x10^5$	$5x10^6$
Ready-to-eat processed finfish, other than fully retorted finfish	*Listeria monocytogenes*/g	5	1	0	10^2
Bivalve molluscs, other than scallops	*Escherichia coli*/g	5	1	2.3	7
Bivalve molluscs that have undergone processing other than depuration	*Listeria monocytogenes*/ g	5	0	0	

n means the minimum number of sample units which must be examined from a lot of food as specified in Column 3 of the Schedule in this Standard.

c means the maximum allowable number of defective sample units as specified in Column 4 of the Schedule.

m means the acceptable microbiological level in a sample unit as specified in Column 5 of the Schedule.

M means the level specified in Column 6 of the Schedule, when exceeded in one or more samples would cause the lot to be rejected.

defective sample unit means a sample unit in which a micro-organism is detected in a sample unit of a food at a level greater than m.

micro-organism means a microbiological agent listed in Column 2 of the Schedule.

SPC means standard plate count at 30℃ with an incubati on time of 72 hours.

A lot of a food fails to comply with this Standard if the –

(a) number of defective sample units is greater than c; or

(b) level of a micro-organism in a food in any one of the sample units is more than M.

Table 4. Additional microbiological limits for imported seafood from Imported Food Notice 08/09 Issued: 28 August 2009

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Food	**Microorganism**	**n**	**c**	**m**	**M**
Bivalve molluscs, other than scallops	SPC /g	5	1	10^5	5×10^5
Bivalve molluscs that have undergone processing other than depuration	*Escherichia coli*/g	5	1	2.3	7
	SPC /g	5	1	10^5	5×10^5

Table 5. Summary of imported food random list and tests, limits, Code reference and test method pertaining to fish and crustaceans, molluscs and other aquatic invertebrates ALSO preparations of meat, of fish or of crustaceans, molluscs or other aquatic invertebrates (adapted from AQIS, 2009c).

Food Category	Analytical tests required	Maximum limit	Code Standard ref.
Fish – including fish fillets and other fish meats – fresh, chilled or frozen			
All fresh fish, fish fillets and other fish meat not on the risk list	Histamine Specific types of fish are also risk foods (refer Table 2 above)	200 mg/kg	2.2.3
All fish whether chilled or frozen, cooked or raw. **Excludes**: [§]ambient stable sealed packaged fish or fish which have undergone significant processing such as dried, battered, crumbed, marinated or mixed seafood. **Excludes:** consignments with specific government certification that declares the seafood as wild caught or words to this effect such as not from farmed or aquaculture sources.	Malachite green Fluoroquinolones *Compounds tested	ND ND	1.4.2 1.4.2
Fish – **- dried, salted or in brine;** **- smoked whether or not cooked before or during the smoking process;** **- flours, meals and pellets**			
All fish and fish meal not on the risk list	Histamine Specific types of fish are also risk foods (refer Table 2 above)	200 mg/kg	2.2.3

All smoked fish whether chilled or frozen **Excludes**: §ambient stable sealed packaged fish or fish which have undergone significant processing such as dried, battered, crumbed, marinated or mixed seafood. **Excludes:** consignments with specific government certification that declares the seafood as wild caught or words to this effect such as not from farmed or aquaculture sources.	Malachite green Fluoroquinolones #Compounds tested.	ND ND	1.4.2 1.4.2
Crustaceans **– in shell or not** **- fresh, chilled or frozen** **- dried, salted or in brine** **- cooked by steaming or boiling**			
All raw / uncooked crustaceans – whether chilled, frozen, dried or salted **Excludes:** comminuted products such as fish balls, dim sims etc containing prawns.	Sulphur dioxide Cooked prawns and shrimps are also risk foods (refer Table 2 above)	100 mg/kg	1.3.1
All crustaceans whether chilled or frozen, cooked or raw. **Excludes**: §ambient stable sealed packaged crustaceans or crustaceans which have undergone significant processing such as dried, smoked, battered, crumbed, marinated or mixed seafood. **Excludes:** consignments with specific government certification that declares the seafood as wild caught or words to this effect such as not from farmed or aquaculture sources.	Nitrofurans Fluoroquinolones #Compounds tested	ND ND	1.4.2 1.4.2

Molluscs (including snails) and other aquatic invertebrates other than crustaceans **– in shell or not** **- fresh, chilled or frozen** **- dried, salted or in brine** **Includes**: bivalve molluscs, cephalopod molluscs (eg. cuttlefish, octopus, squid)	No analytical tests Some bivalve molluscs are also risk foods (refer Table 2 above) *Imports of unopened bivalve molluscs and live snails are restricted by Quarantine*		

[§] **Ambient stable sealed packages**: Refer to description following Table 2

[#] **Compounds tested**

Malachite green – malachite green, leucomalachite green

Nitrofurans – furaltadone, furazolidone, nitrofurantoine, nitrofurazone

Fluoroquinolones – Ciprofloxacin, enrofloxacin, gatifloxacin, levofloxacin, moxifloxacin, norfloxacin, ofloxacin, sarafloxacin

APPENDIX D – GENERAL CHARACTERISTICS OF FOOD IMPORT CONTROL SYSTEMS (CODEX)

GENERAL CHARACTERISTICS OF FOOD IMPORT CONTROL SYSTEMS (Codex GL 47–2003)

Food import control systems should have the following main characteristics:

Requirements for imported food that are consistent with requirements for domestic foods

i. Requirements are commonly expressed as end-point standards with specific limits and complementary sampling regimes. These requirements may consist of standards, provisions for sampling, process controls, conditions of production, transport, storage, or a combination of these.
ii. The extent and stringency of requirements applied in specific circumstances should be proportionate to risk, noting that risk may vary from one source to another because of factors such as specific and/or similar situations in the region of origin, technology employed, compliance history, etc. and/or examination of relevant attributes of a sample of products at import.
iii. As far as possible, requirements should be applied equally to domestically produced and imported food. Where domestic requirements include process controls such as good manufacturing practices, compliance may be determined or equivalence confirmed by auditing the relevant inspection and certification systems and, as appropriate, the facilities and procedures in the exporting country..

Clearly defined responsibilities of competent authority or authorities

iv. The competent authority(ies) involved in any of the imported food inspection functions at the point or points of entry, during storage and distribution and/or at point of sale, should have clearly defined responsibilities and authority. Multiple inspection and duplicative testing for the same analyte(s) on the same consignment should be avoided to the extent possible.
v. Some countries, for example those that are part of a regional economic grouping, may rely on import controls implemented by another country. In such cases, the functions, responsibilities, and operating procedures undertaken by the country which conducts the imported food control should be clearly defined and accessible to authorities in the country or countries of final destination with the aim of delivering an efficient and transparent import control system.
vi. Where the competent authorities of an importing country use third party providers as officially recognised inspection bodies and/or officially recognized certification bodies to implement controls, such arrangements should be conducted in the manner discussed in CAC/GL 26-1997, Section 8, Official Accreditation. The functions that can be conducted by such providers may include:
- sampling of target consignments;
- analysis of samples;
- compliance evaluation of relevant parts or all of a quality assurance system that may be operated by importers in order to comply with official requirements.

Clearly defined and transparent legislation and operating procedures

vii. The object of legislation is to provide the basis and the authority for operating a food import control system. The legal framework allows for the establishment of the competent authority(ies) and the processes and procedures required to verify the conformity of imported products against requirements.
viii. Legislation should provide the competent authority with the ability to:
- appoint authorised officers;
- require prior notification of the importation of a consignment of a foodstuff;

- require documentation;
- inspect, including the authority to enter premises within the importing country, physically examine the food and its packaging; collect samples and initiate analytical testing; inspection of documentation provided by an exporting country authority, exporter or importer; and verification of product identity against documentary attestations;
- apply risk-based sampling plans, taking into consideration the compliance history of the particular food, the validity of accompanying certification, and other relevant information;
- charge fees for the inspection of consignments and sample analysis;
- recognize accredited or accredit laboratories;
- accept; reject; detain; destroy; order to destroy; order reconditioning, processing, or re-export; return to country of export; designate as non-food use;
- recall consignments following importation;
- retain control over consignments in transit during intra-national transport or during storage prior to import clearance; and,
- implement administrative and/or judicial measures when the specific requirements are not satisfied.

ix. In addition, the legislation may make provisions for:

- licensing or registration of importers;
- recognition of verification systems used by importers;
- an appeal mechanism against official actions;
- assessing the control system of the exporting country; and
- certification and/or inspection arrangements with competent authorities of exporting countries.

<u>Precedence to the protection of consumers</u>

x. In the design and operation of food import control systems, precedence should be given to protecting the health of consumers and ensuring fair practices in food trade over economic or other trade considerations.

<u>Provision of the importing country for recognition of the food control system applied by an exporting country's competent authority</u>

xi. Food import control systems should include provisions for recognition as appropriate of the food control system applied by an exporting country's competent authority. Importing countries can recognise the food safety controls of an exporting country in a number of ways that facilitate the entry of goods, including the use of memoranda of understanding, mutual recognition agreements and equivalence agreements and unilateral recognition. Such recognition should, as appropriate, include controls applied during the production, manufacture, importation, processing, storage, and transportation of the food products, and verification of the export food control system applied.

<u>Uniform nation-wide implementation</u>

xii. Uniformity of operational procedures is particularly important. Programmes and training manuals should be developed and implemented to assure uniform application at all points of entry and by all inspection staff.

<u>Implementation that ensures the levels of protection achieved are consistent with those for domestic food</u>

xiii. As an importing country has no direct jurisdiction over process controls applied to food manufactured in another country, there may be a variation in approach to the compliance monitoring of domestic and imported food. Such differences in approach are justifiable provided they are necessary to ensure that the level of protection achieved is consistent with that of domestically produced food.

APPENDIX E – STAKEHOLDER COMMENTS

Stakeholder comments presented on the following pages are either direct quotes or paraphrased to make them more concise.

Regulatory requirements to sell and/or import seafood in Australia

Stakeholder views on the regulatory requirements to sell and/or import seafood in Australia were canvassed in the context of question 1 of the Stakeholder Interview.

TABLE 6. Stakeholder views on regulatory requirements to sell and/or import seafood in Australia

Key viewpoint	Example comments
Largely effective	
Government	FSANZ write standard and then States/Territories and (imported food) can implement It is a good system that AQIS is able to include other items (not specified by FSANZ) in their random surveillance
Peak bodies	At the border all imported food is required to comply with the Code. Importers are allowed to relabel food prior to inspection. There are certain tests that AQIS do, some importers may not be aware of additional tests. Anecdotal "head in sand" I won't ask about other tests that might need to be done.
Food companies/ importers	AQIS tests company's imports with costs borne by the company Tuna and mackerel tested for histamines Histamines tests are done on other seafood regardless of species and source. Tuna – major source is Thailand, agreement with Government
Largely ineffective	
Government	
Peak bodies	
Food companies/ importers	Equivalence (level playing field) – standards that apply here in Australia should also apply to imports. Requirements of the seafood PPP should be expected for imported seafood

Safety and compliance of seafood

Stakeholder views on safety and compliance of seafood were canvassed in the context of question 2 and question 3 of the Stakeholder Interview.

TABLE 7. Stakeholder views on safety and compliance of seafood

Key viewpoint	Example comments
Unsafe or non compliant	
Government	Aware of incidents of cholera in white bait from Indonesia. Also histamine in seafood from Indonesia Histamine continues to appear relatively frequently What can we do about overseas practices such as temperature abuse which results in histamine formation?
Peak bodies	There is always going to be some failure until it is discovered. No in general terms. Seafood is a highly traded commodity and any identifiable problems get sorted. There are genuine issues in aquaculture.
Food companies/ importers	Know that "fiddling" does get done. If you know x number of samples per batch are tested, then make sure that there is one batch per container.
Domestic producer	Apparent absence of oversight and scrutiny of imported seafood from the countries of origin. In Australia any shortcomings in Australian seafood production can expect to be raised by any of national, State, Territory agencies, consumer organisations and/or the media. With imported products from some countries no such alert system exists. From some countries one has the feeling that some producers will attempt to push the boundaries on products until they are found out. As processors and exporters we are not allowed to use antibiotics and hormones in our production processes. This is not the case with imported products. Concerned that labelling on imported seafood is inadequate and at times misleading. Domestic operations are required to meet standards in print size and product disclosure and ask that those standards be enforced on imported seafood. Biosecurity restrictions on imported prawns demonstrated that some producers/wholesalers were prepared to undertake actions designed to circumvent the arrangements (as in marinading, then importing prawns then washing marinade off and repackaging as fresh prawn flesh). Marinades (which are supposed to stop white spot and yellow head), but if marinade doesn't impregnate the prawn, there is no protection from these diseases and a potential quarantine risk. Product is getting in through the back door. Similar activities could occur in relation to contaminants in imported seafood in the absence of a stronger regulatory regime, a commitment to 100% testing where appropriate and a declaration that 0% is the acceptable level for hormones and antibiotics in imported seafood. Non compliance in areas not related to food safety such as net weights

TABLE 7. Stakeholder views on safety and compliance of seafood	
	(short weights) labelling, etc. White spot intervention showed that claims of marinated and/or crumbed seafood were cleverly used to get around import (quarantine) restrictions. Whilst this is a quarantine issue, it is inferred that the same tactics could be used to avoid import restrictions on food safety issues. People can get around labelling and other issues, so why can't they get around food safety matters. China has a diverse spread of standards with their testing. Questions arise of hormones/antibiotics especially acquired through feed. Japan is good at checking hormone/antibiotic residues – Japan detected hormones in Chinese prawns which were rejected by Japan resulting in cheap prawns flooding the markets in other countries. Markets denied access because the imported foods don't meet the importing country's food safety requirements. Failures in Bangladesh seafood. Collapse in Ecuador due to white spot. Penicillin is not allowed in Australian produced product so why is it permitted in imported product?
Compliant	
Government	Not seen major problems with imported seafood nor aware of ongoing problem (2 comments)
Peak bodies	No specific intelligence on non-compliance. Seafood **IS** safe e.g antibiotics 350 tests, 7 failures, but low levels Post border surveys – seafood sits at/near best end Something driving improvements in aquaculture is that it is getting better really quickly. Now not using antibiotics. People are investing in farms are doctors/lawyers that have the capital to invest to achieve sustainability. Seafood has a very high compliance rate. AQIS review of a couple of years ago detected some residues but not at hazardous levels. Raised issue of oxytetracycline (Thai prawns). Raised discussion of how to set MRLs for levels where there is not limit in the Code. FSANZ may amend the Code to allow for overseas agricultural practices and amend Code to recognise international MRL's (Codex). Ocean wild caught vs aquaculture causes a problem where hazard is never going to be present in an ocean caught. Perhaps a certificate of origin can solve the problem. Then there are also wildly exaggerated claims taking time away from genuine concerns. While there is a high compliance, tendency is to focus on larger importers – the more you import, the more likely you're going to be inspected. Not just AQIS, but others will test e.g. Woolies, State Food Authorities, and less likely you are to fail. The aim of food import compliance regulation should be to get big

TABLE 7. Stakeholder views on safety and compliance of seafood	
	importers onto compliance agreements thus allowing for focus on smaller importers.
Food companies/ importers	No non-compliance likely if permitted antibiotics and/or chemicals are used as per label.

Gaps and deficiencies and improvements to existing seafood import testing arrangements into Australia

Stakeholder views on gaps and deficiencies in the system and thus improvements for importing seafood into Australia were canvassed in the context of question 4 and question 5 of the Stakeholder Interview.

TABLE 8. Gaps and deficiencies and improvements in seafood import testing identified by stakeholders	
Key gaps	**Example comments**
General	
Government	Aware of potential limitations of the current system and that improvements can be made Deficiencies in laboratory capability to detect norovirus and viral contamination is a common problem with seafood. Some gaps in having a good knowledge of what is coming in – AQIS needs better systems to capture details of what is coming in Need to get information from customs, deficiencies in descriptions to get the full picture to then target problem areas Need to communicate (two way) with industry about knowledge of potential problems so that AQIS can then target area or products. However, this needs to be real with real data – not perceived No comments on gaps observed in existing testing, but gaps in analytical test capability, particularly for viruses IFIS doesn't have the capability to implement third party country review. Bivalve molluscs require a food safety plan for export – this is an equivalency issue with what is required for import. Inconsistency (rather than non compliance) between local and imported produce that both present the same food safety issues
Peak bodies	Gaps and deficiencies are not in the system but are on the ground. Way out on performance indicators. Importers are bothered by the fact that there are two standards that they have to meet – domestic seafood is not tested for anything. The people delivering the program are through the import clearance area. AQIS are dependent on referrals from the Australian Customs IT system. Imports are classified according to the Customs tariff and then

TABLE 8. Gaps and deficiencies and improvements in seafood import testing identified by stakeholders	
	entries are referred to AQIS. But tariff headings are very broad and as a result, it is often very difficult for AQIS to capture the food it wants to inspect (as intended under the policy). Industry accepts that testing needs to be done, but a lot of money is spent on testing. Can it be better spent/more efficiently elsewhere? Such as on surveys? More efficiently?
Food companies/ importers	Look at species being tested for histamine – sometimes it is irrelevant to test for histamine in some species. Better off to look at the species that are going to develop histamine rather than blanket histamine testing. (***author's note*** *6 failures for histamine in random surveillance, 30 failures in risk category*)
Domestic producer	Gatekeeper role has insufficient procedures. The importance of equivalence in standards so that the same standards we are required to meet in our catching and processing are reflected in seafood products being imported into Australia. At present this is not the case.
Responsiveness, especially to emerging hazards	
Government	No flexibility to be reactive to an event beyond 5% tests If new information arises that something is a risk, without that information or without a standard in the Code, AQIS cannot target a food or increase testing (2 comments) Australia cannot prevent entry where there's a known problem (making food unsafe or unsuitable) that is not captured under existing import requirements. For example, melamine levels detected in product in 2008 year were not unsafe levels, but the presence of melamine was identified as unsuitable. AQIS could not respond to this to stop product getting in. Even temporary suspensions are not possible
Peak bodies	Insufficient procedures to address emerging hazards at the border. The melamine issue brought this to attention, even though it was handled well by authorities in Australia. FSANZ keep a watching brief on overseas situations and better communication between international organisations.
Food companies/ importers	
Domestic producer	Concern that testing applies to only 5% of an imported product line. This is an insufficient level below the 100% Australian consumers could expect. How would the authorities have handled the melamine milk powder matter by testing only 5% and waiting for a problem to surface?
Antimicrobials, hormones and chemicals	
Food companies/	Greatest risk is probably the antimicrobials. For example, in Vietnam the

TABLE 8. Gaps and deficiencies and improvements in seafood import testing identified by stakeholders	
importers	top 3 antimicrobials on sale are not on the Vietnamese hit (test) list. Banned antimicrobials are on the hit list, so why bother testing? Why not test for permitted antimicrobials and chemicals to ensure that they are being used correctly and do not exceed permitted levels and cover the banned antimicrobial or chemical on the certificates of analysis? There should be a broader screen done as is done for vegetables.
Domestic producer	An assurance by FSANZ and AQIS that the presence of hormones and antibiotics (substances such as penicillin) are below a critical level/ MRLs, fails to provide any comfort or assurance to Australian consumers. Firstly they are justified in asking why those contaminants are present in seafood and secondly such an approach ignores the cumulative effect of contaminants in the human body. We refer to cancer patients undergoing treatment and expectant mothers and ask if it is sufficient that they could also be exposed to contaminants in the form of hormones and antibiotics in imported seafood.
Water testing – Domestic producer	Water testing (equivalence). Monthly tests are required for all water access points in Australia. What requirements are expected of overseas producers for their water glazes?
Consumers – Domestic producer	Where does the consumer go if they think they have a problem with product? State Authority responsibility, but consumer doesn't necessarily know that. They must be able to voice an opinion.
Inspections – Domestic producer	AQIS should inspect on a regular basis, the factories, production facilities, etc to check the quality of the facilities. Retailers can, and do, but AQIS can't

Border testing of imported food

During interviews with stakeholders, a number of comments were gathered relating to border testing of imported food as presented below.

TABLE 9. Stakeholder views on border testing of imported food	
Key viewpoint	**Example comments**
Largely effective	
Government	
Peak bodies	No problems with the process of the IFIS and the testing that is done. Risk and random surveillance is good. However, there are problems with the practice of sampling – container of product with something "down the back" and not documented can sneak in thus companies could be evading quarantine. They can also use a loophole in legislation in product description e.g. highly processed prawns e.g. dim sims, etc. companies "sneaking" prawns in under the guise of marinated. This is bad practice as it can affect exemptions for everyone.

TABLE 9. Stakeholder views on border testing of imported food	
	Border testing allows “green lane” for good compliance Testing should go into hands of exporter. This pushes requirements from importers so that there is a level playing field.
Food companies/ importers	
Largely ineffective	
Government	Inflexibility issues – melamine example – intelligence says that there’s a problem. AQIS can’t test because there is no Code requirement. Therefore product gets past the border and states/territories must test then identify the problem, then FSANZ does risk assessment, then identify melamine as a hazard, then AQIS can act. The whole process is time consuming and not very responsive.
Peak bodies	There are significant constraints that the Imported Food Control Act places on AQIS and their ability to act is far more constrained than that of a state health department that can sample whatever food it likes. The legislation is quite antiquated and was drawn up at a time when end-point testing was still regarded as an effective way of checking food. It is mainly about setting up a mechanism for inspecting imports. There is scarcely any policy direction and as little flexibility. Rates of inspection are fixed and AQIS may sample only those foods that fall under the Imported Food Inspection Scheme. This means that AQIS just can not inspect and sample whatever food it considers it should on health grounds, but must also bring its activities in line with a rigid Act.
Food companies/ importers	End point testing is somewhat tokenistic. End point testing should be done on case by case basis. Would prefer to see testing money spent on broader screening. Their company is no different to other importers in that they rely on AQIS to do their QC testing. This is the only testing that is done, which is a very poor situation in this stakeholder’s opinion. If their company implemented what might be considered a more extensive system to assure safe seafood then they would be at a marked disadvantage.

Certification arrangements and compliance agreements

During interviews with stakeholders, a number of comments were gathered relating to certification arrangements and/or compliance agreements as below.

TABLE 10. Stakeholder views on certification arrangements and compliance agreements

Key viewpoint	Example comments
Largely effective	
Government	If agreements are in place, this allows for inspection and investigation based on intelligence (of potential hazards). This could result in closer/better communication between AQIS and importer. Compliance agreements are a more rigorous method than testing. Any certification arrangements must be at a high level – government to government and subject to periodic review
Peak bodies	Food Import Compliance Agreement (FICA) is a system recognising an importers own control systems and procedures. AQIS has been trying to get them in place. Government support in practice but reluctance to move implementation quickly. Compliance at point of exit The future is going to have to go in the direction of compliance at the point of exit. Equivalence ratings need to be sorted out. Australia should start agreeing on international standards and established third party certification that is already in place Thailand has the capacity to test for near everything/anything that Australia can ask for. Quality assurance systems in some Thai operations can demonstrate traceability back to brood stock and source of feed.
Food companies/ importers	Our trawlers are inspected, our crew trained in catching and product handling, our processors trained and supported. Australian consumers should be given an assurance that the same standards apply to imported products. Certification – if proceed down this path then industries need guarantees that the person providing that meets Australian equivalent requirements Take away message is full traceability of potential hazards through the food chain. Ability for AQIS to apply PPP and equivalence AQIS offers choice to importers for requiring that supplier has appropriate compliance agreement which is audited or continue end product tests. Smaller importers tend to keep end product tests while larger importers tending to use compliance agreements. Could move to require that all imports come from AquaGAP farm or HACCP approved premises. Many producers/processors in most countries have QAP in place so rely on certification/documentation. Make sure that seafood is appropriately test overseas by an appropriately accredited facility.

TABLE 10. Stakeholder views on certification arrangements and compliance agreements	
Largely ineffective	
Government	Australia is too slow with import compliance agreements
Peak bodies	Overseas certification would be used more by seafood industry. Stakeholder questioned the robustness of certification – if exporting country government provides certification, then that consignment will only be tested at Australian border at the rate of 5%. Government to government certification needs closer examination to ensure equivalence. More can be done with overseas certification.
Food companies/ importers	

Options for improvements to systems for imported seafood

Stakeholder views on options for improvements to systems for imported seafood were canvassed in the context of question 8 of the Stakeholder Interview.

TABLE 11. Stakeholder views on options for improvements to systems for imported seafood	
Key improvement	**Example comments**
General	
Government	Suggest mixture of quality assurance (QA) programs, certification programs and end product testing. Flexibility of random category could be a useful mechanism to do rolling surveillance over time. NZ moved to more of a certification system – licence importers, rely on certification and mandate certification European system can suspend imports. AQIS can't do this – can only test and then fail the product. Can't stop product coming in Move to safety assurance systems, auditing and compliance arrangements have the potential in long term and will be cost effective. Work with importers, build capacity and relationships. More resources required for education – a guidance approach is required, not a "stick" approach. Guide overseas suppliers to better approaches and improve overseas industries It is not just about policing. Improvements could be made more around strategic information and communication with importers and brokers. A strategic, proactive program of communication of what is required such as workshops with importers. If you have assurances from suppliers

TABLE 11. Stakeholder views on options for improvements to systems for imported seafood	
	then you might get tested less. If not, then you might get tested more. Can consultation be built into FSANZ regular review of risk list?
Peak bodies	With the predicted increase from the current level of 200 K tonnes of imports to 500K tonnes by 2025, one can predict that AQIS will struggle to inspect and/or test that increased volume AQIS needs to get out, start the conversation about co-regulation Industry groups need advice from government to say how things are going to dovetail. Industry should work under a code of practice and businesses should comply with code – build this into company business systems. Discounted product on the market because of bad practice such as added water, not 100% product, short weights, polyphosphates. Fish substitution issues have gone away so not so much of an issue now. Trade should be freed up by Codes of Practice, business systems, and professional people in place in companies
Food companies/ importers	Risk based testing system.
Domestic producer	Focus on the importance of traceability and assurances that people aren't getting around the system by opening and repacking as if it was from the exporting country.
Equivalence / parity	
Government	How can we be sure of equivalency if we had compliance agreements?
Food companies/ importers	Imported seafood must comply to the same standards that Australian producers must meet. It is not about restricting trade, it is about better benefits in better business practices throughout the industry and educated public and producers.

Surveillance and industry intelligence

Stakeholder views on surveillance and industry intelligence were canvassed in the context of question 6 and question 7 of the Stakeholder Interview.

TABLE 12. Stakeholder views on surveillance and gathering industry intelligence

Key viewpoint	Example comments
General	
Government	
Peak bodies	Some years ago, perception that seafood wasn't safe – testing for antibiotics showed low levels, but still hit the media, costing the industry tens of millions of dollars. AQIS are quite controlled/disciplined in the information that they put out If intelligence says there's an issue, many in industry say government is not responsive and can't act quickly. However, the responsiveness of government to meet early on the melamine issue was well received and shows responsiveness.
Food companies/ importers	
Domestic producer	Need to go back to producers and know how much of each chemical, farm by farm, processor by processor. For example, cadmium in EU because population may be accumulating from various sources, not just seafood.
Surveillance	
Government	Rolling surveillance would be more useful than the same testing year after year and finding 98% compliance. Importers are dissatisfied as they pay. Rolling surveillance can work on intelligence and current information on newly identified and perceived hazards. Potential problems moving to a rolling surveillance system – who would design and develop such as system? AQIS could collaborate with States and Territories to develop a rolling surveillance over time and to be informed by intelligence. Also, the labs doing the testing are appointed on basis of doing a particular test at a point in time. Rolling surveillance may require laboratories to be continually developing and/or changing methodologies. Better linkages including use of surveillance information and industry intelligence in developing risk lists Need industry intelligence on what is the next big issue – what chemicals are other countries using New Zealand uses a more strategic monitoring and information gathering approach. A strategic and targeted approach in response to industry intelligence into the future with money has been set aside to conduct strategic surveys. A scanning list – a perceived problem based on intelligence, information or an identified problem somewhere else. "Flags" can be put up at border using tariff codes (same as in Aust) and

TABLE 12. Stakeholder views on surveillance and gathering industry intelligence	
	samples taken for surveillance. This approach was used for melamine investigations – emergency response.
Peak bodies	Constraints the Imported Food Control Act places on AQIS. For example, in the survey of imported seafood, the importers donated the samples that were analysed, and in the melamine case, AQIS was heavily constrained in how it went about inspecting foods of possible concern. Information on failures should be taken notice of and more information on random surveillance to the industry would be good – does it add up to much? Should AQIS use surveys rather than test and find nothing? AQIS should review testing – do not test for everything, every time. Test for something specific and thoroughly for specific period of time.
Food companies/ importers	Would prefer to see testing money spent on broader screening (repeat comment). Even though agreements are in place (e.g. Thailand) are in place, it still gets audited.
Intelligence sources	
Government	All stakeholders should work together – linkages for information sharing should be better developed Various sources of intelligence and/or collaborators to assist AQIS– food surveillance network, implementation subcommittee (ISC), Europeans (rapid alert) Information sources include FSANZ info on issues and various reports; FSNET, pick up on what the overseas issues are and are they likely to occur in Australia Rumour surveillance – local and international, robust networks, including direct links with networks and associates, also anecdotal. Examples include: newspapers, ProMed alerts, Eurosurveillance and Health Canada, Salmserve, OzFoodNet network, Communicable Disease Network Australia Intelligence needs to be more proactive but not in an alarmist way. Be informed and constructive. Prawn farms in South America have dry out phase – use formaldehyde to kill prawn viruses – there could be concern about formaldehyde entering the food chain.
Peak bodies	Imported Food Consultative Committee is a good source of intelligence. AQIS or FSANZ are good at providing information. Any information usually gets around the industry – people talk, people share. AQIS should provide more information on foods that fail – stakeholder was not sure of the level of detail available – problem? source? If there is failure, the importer and overseas government are told – no one else might know so no one can take evasive action. Imported food is only a small area (5%) of AQIS activity and often gets looked at by senior people unless it comes to the Minister's attention and appears to be a low priority politically.

TABLE 12. Stakeholder views on surveillance and gathering industry intelligence	
	Maybe something that needs to be set up. Information portal
Food companies/ importers	Industry intelligence and having people "on the ground" in their exporting countries – visiting places and having procurement people on the ground
Domestic producer	Mostly customer relations rather than published information. If an issue arises with seafood safety Australian producers have FSANZ, AQIS, Dept Ag etc. following up. Then also FDA and EU are good information sources.

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