4-04
26 May 2004

DRAFT ASSESSMENT REPORT

PROPOSAL P265

PRIMARY PRODUCTION AND PROCESSING STANDARD FOR SEAFOOD

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:
21 July 2004
(See 'Invitation for Public Submissions' for details)

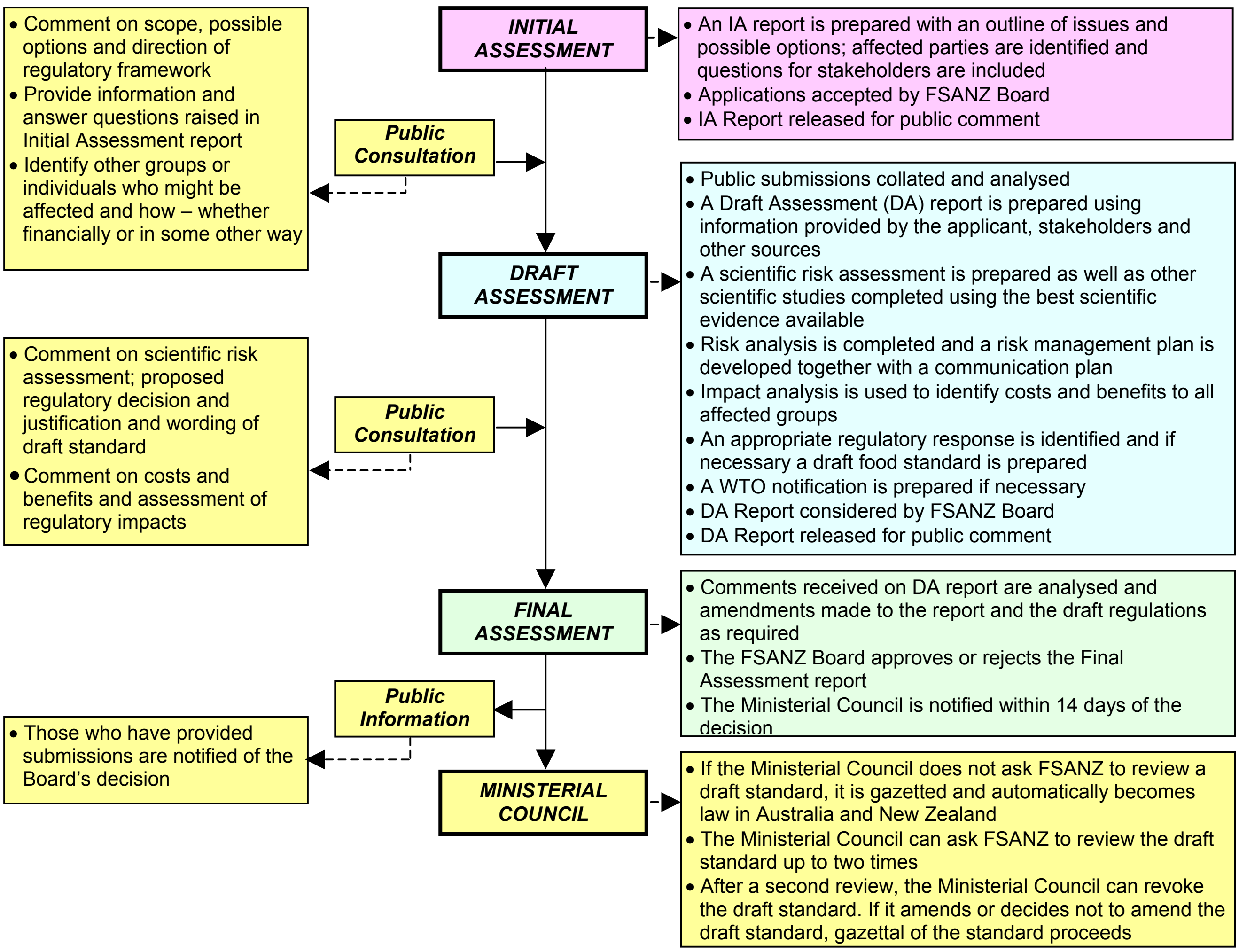
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* (the Code) is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared a Draft Assessment Report on Proposal P265; and prepared a draft variation to the Code.

FSANZ invites public comment on this Draft Assessment Report and the draft variation to the Code for the purpose of preparing a Final Assessment Report for the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Final Assessment for this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. For further details of section 10 of the FSANZ Act, refer to Attachment 1.

Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the FSANZ public register and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions should be received by FSANZ **by 21 July 2004.**

Submissions received after this date may not be considered unless the Project Manager has given prior agreement for an extension. Submissions may also be sent electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website or alternatively paper copies of reports can be requested from the FSANZ Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au including other general enquiries and requests for information.

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EXECUTIVE SUMMARY

This Report proposes, for the first time, that there be a single, national food safety standard for the primary production and processing of seafood.

Australia enjoys a high level of food safety protection but, like many other nations, we face the challenge of improving food safety. It is recognised that the risks from seafood are usually well managed and are therefore considered low. There are only a very small number of products that may present higher public health and safety risks.

Food-borne illness is a growing public health problem globally because of the increasing global trade in food, changes in the way food is produced and consumers' changing requirements. These changing patterns are causing new challenges in the way food safety is managed.

A recent study conducted by the food-borne illness surveillance network of Australia, OzFoodNet, estimates that there are 5.4 million cases of food-borne illness in Australia each year from a variety of foods. There is a need to ensure that there are appropriate strategies in place to effectively manage food safety across all food sectors in the current environment of global food trading and in light of the estimates of the incidence of food-borne illness.

A whole of government approach is now being taken in Australia to the management of food safety. Governments have agreed that food safety should be managed throughout the food supply chain. This approach aims to improve public health and safety and ensure that consumers continue to have the highest confidence in the safety of the food they consume.

FSANZ has been given responsibility for the development of food safety standards in the primary production and processing part of the food supply chain – in addition to its existing responsibilities for the manufacturing, retail and food service sectors. Under the FSANZ Act, the objectives for developing all food standards, in descending order of priority, are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

Seafood is one of the first industries to be examined in relation to a national approach to improving the primary production end of the food supply chain. The seafood industry itself has encouraged this early work.

Seafood is an important part of the diet for consumers in Australia and New Zealand. The sector is an important part of the Australian food industry - the fourth largest after beef, wheat and milk – with a considerable focus on exports.

This Draft Assessment Report outlines how industry and government currently achieve seafood safety in Australia – generally with a mixture of industry self-regulation, licensing schemes, and general and specific (albeit differing) State legislation. While providing a measure of assurance, this mix of arrangements, both voluntary and mandatory, creates some gaps in the management of food safety.

FSANZ has consulted widely in the development of this proposed Standard. A Standards Development Committee, consisting of representatives from State and Territory jurisdictions and New Zealand, and industry and consumer representatives, has carefully considered the results of committee discussions, opinion at public fora and written feedback from stakeholders on the Initial Assessment Report for this Proposal.

FSANZ, with assistance from the Seafood Standards Development Committee, has examined how to improve further the management of public health and safety issues in the sector in Australia. A number of options have been considered and these are outlined in the table below:

NATURE OF FOOD SAFETY CONTROL	**OPTION 1 Status quo**	**OPTION 2 Mgt of higher risk only**	**OPTION 3 Basic Safety Provisions + Mgt of higher risk**
Current arrangements:			
-General obligation under Food Acts to produce safe food	✓	✓	✓
-Food Std Code provisions (except for primary production)	✓	✓	✓
-State and Territory schemes (NSW, VIC)	✓	✓	
-Voluntary industry codes of practice	✓	✓	✓
General Provisions: Food safety practices applied to primary production end of seafood sector (similar to current hygiene requirements for the manufacturing, retail and food service sectors but tailored to seafood industry)			✓
Specific Provisions: Standard 3.2.1 (Food Safety Programs) or equivalent applied to higher risk activities of the seafood industry		✓	✓

States and Territories will be responsible for compliance with and enforcement of this Standard. Government costs may vary from State to State, but overall arrangements for industry will be more efficient by having a single national standard.

A regulatory impact analysis has been undertaken to consider which option provides the maximum public health protection, with least impost on industry. The preferred option is Option 3.

Option 3 is preferred as it provides a single set of national standards to protect public health and safety (the primary objective of the FSANZ standard setting process under section 10 of the FSANZ Act). It would do this by requiring an approach that is more rigorous for the higher risk products, which were identified from a review (risk ranking report) of the public health and safety risks associated with the consumption of seafood. The products include oysters and other bivalve molluscs (with some exceptions).

For seafood businesses producing bivalves[1], compliance with pre-harvest provisions of the Australian Shellfish Quality Assurance Program and the implementation of food safety programs for the post-harvest sector up to the beginning of the retail sector is proposed. Food safety requirements for retail and the food service sector are already covered under Chapter 3 of the Code.

For the majority of the seafood industry - that poses lower risk (medium and low risk categories according to the risk ranking report) – a basic set of food safety provisions (called general provisions) are proposed. Such provisions would include requirements to ensure that food is not contaminated during its production or handling, that adequate temperature control of food is maintained and that staff have the skills and knowledge about food safety that is necessary for the work they undertake. Some of the medium risk products may benefit from more specific risk management strategies. However, these may vary according to geographic/climatic and other factors, as well as existing jurisdictional and industry infrastructures.

For this reason, the proposed Standard does not prescribe a documented seafood safety management system for the lower risk products as for the high risk products. Nevertheless, the standard will require a seafood business to systematically examine all its primary production operations to identify potential seafood safety hazards and implement controls that are commensurate with the food safety risk The extent of hazard identification, implementation of control measures and verification required should also be commensurate with the level of food safety risk involved. This is most appropriately determined by State and Territory jurisdictions in consultation with industry, taking account of local environmental factors. Where possible, State and Territory jurisdictions should use national forums such as the Implementation Subcommittee (ISC) if the Food Regulation Standing Committee to develop nationally consistent approaches to verification.

The philosophy behind this approach is about taking a preventive approach to managing food safety hazards and for industry, at all parts of the food supply chain, to play their role in minimising such hazards. Option 3 proposes an approach based on risk – where risk is lower, the requirements are basic and where risks are higher, more significant requirements are proposed to manage food safety.

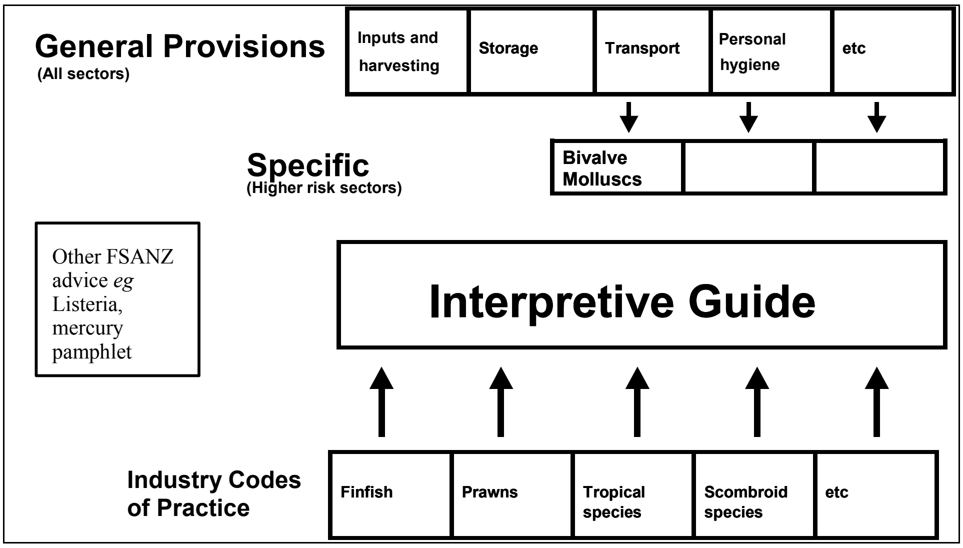
The recommended option is consistent with the decision of the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) in December 2003 – that food safety management approaches be based on risk and that food safety programs only be introduced where the benefits outweighed the costs of their implementation. In this regard, Ministers decided to require the introduction of food safety programs for oysters and other bivalves, up to the back door of the retail sector, following a cost benefit analysis undertaken as part of the National Risk Validation Project.

Specific recommendations are made in this Draft Assessment about implementation (effectively over a two year period) and a draft of the proposed Standard is included at Attachment 10.

[1] Bivalve molluscs means all molluscan bivalves with the exclusion of spat, and scallops and pearl oysters where the only part of the product consumed is the adductor muscle.

The Standard will be supported by an interpretive guideline for enforcement officers, developed by FSANZ, and industry developed guides to assist industry comply with the standard. The framework for Option 3 is outlined below.

Proposed Regulatory framework for food safety management in seafood



Consideration has also been given to fish names labelling requirements. While a comprehensive regulatory analysis has not been undertaken to support a case for mandating prescribed labelling of all fish species in all circumstances across the catching/production, processing, wholesale and retail sectors of industry, consultations have been undertaken with Standards Australia on the development of a national fish names standard for fish names.

To assist industry, FSANZ has facilitated discussions and agreements with various Australian government and industry agencies, to help develop an Australian Standard for fish names that could serve as a reference document for action under trade practices laws. Following implementation of these arrangements, further consideration will be given (through FSANZ's standards development processes) to whether any further coverage in the Code is required. While the document forms the second stage of public consultation in relation to the Seafood Primary Production and Processing Standard – it is the first outline of a proposed approach to improving the management of seafood safety in Australia.

All stakeholders are invited to comment on the proposed Standard – including its approach and practicality, potential implementation costs and the extent of changes required to current industry practice.

1. Introduction

1.1 Food safety is a public health issue

Food-borne illness is a significant public health issue. In Australia, a national survey of gastroenteritis during 2001-02[2] estimated that 5.4 million cases are due to contaminated food, resulting in the loss of 6.5 million days of paid work. This means that about one in four Australians get sick annually from eating unsafe food.

On the basis of these findings, together with costing data from a previous study[3], the Australian Government Department of Health and Ageing has estimated that food-borne illness comes at a substantial economic and social cost to the Australian community – estimated at $3.75 billion annually.

Food-borne illness impacts on health, consumer confidence in the food supply as well as on local and global trade in food. It is therefore important for consumers, industry, and governments that effective measures are put in place to ensure the safety of food.

The public is increasingly aware of the potential health risks posed by pathogenic microorganisms and chemical substances in the food supply. Such challenges to food safety must be met by a fully effective food safety system that protects public health, builds confidence of consumers in the food supply and has a positive effect on food trade. Such a system needs to have capacity to meet future challenges. Food safety regulation should also be sensitive to, and supportive of, the needs of the food industry. It should result in the lowest achievable regulatory costs on industry and facilitate industry innovation and growth. In order to achieve these dual aims of consumer protection and industry support, it needs to be based on sound scientific evidence and be commensurate with the risks.

Since 1996, international agreements have resulted in the World Trade Organization (WTO) being an interested party in the work of the Codex Alimentarius Commission (Codex), which is responsible for developing international food standards. Those agreements have significantly changed approaches to food safety by all WTO members, including Australia, as they oblige Member States to set health and safety standards on the grounds of protecting public health. Such standards must be justified by a sound, scientific risk assessment.

Australia's approach to food safety, modelled on international principles, addresses food safety across the entire food chain and manages hazards that pose a significant risk to public health. Australia takes a preventive approach to managing food safety and national standards are framed to achieve outcomes, rather than prescribe approaches, to provide businesses with flexibility in how they achieve the outcomes.

1.2 Australian food standards

The Code sets standards for chemical and microbiological safety, composition and labelling of food, approves new foods and foods using new technologies, and establishes food safety standards for the hygienic production and handling of food.

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[2] OzFoodNet Working Group (2003), *Food-borne disease in Australia: incidence, notifications and outbreaks. Annual report of the OzFoodNet network, 2002*, *Communicable Diseases Intelligence*

[3] Food Science Australia & Minter Ellison Consulting (2002), *National Risk Validation Project - Final Report*.

The existing food safety standards apply from processing and manufacturing through to the retail sector of the food chain. However, these food safety provisions do not apply to primary production.

In 2000, the Council of Australian Governments (COAG) agreed to major changes to the food regulatory system. As part of these changes, Food Standards Australia New Zealand (FSANZ) received a mandate to address food safety across the entire food chain where appropriate[4]. This facilitates a preventive approach to significant food safety risks across the food supply chain.

FSANZ must adhere to specific legislative requirements and guidelines when developing food standards, and receives policy guidance from the Ministerial Council.

Further details about the policy and regulatory framework for the development of food standards is contained at Attachment 1.

In December 2003, the Ministerial Council developed Ministerial Policy Guidelines for Food Safety Management in Australia, whereby food safety programs were made mandatory for identified highest risk sectors where the benefit to cost ratio justified their implementation. These Ministerial Guidelines identify specific high-risk business sectors where food safety programs should be made a mandatory regulatory requirement in accordance with Standard 3.2.1 of Chapter 3 of the Code. These were:

- food service in which potentially hazardous food is served to vulnerable populations (e.g. hospitals and nursing homes);
- producing, harvesting, processing and distributing raw bivalve molluscs
- catering operations serving food to the general public; and
- producing manufactured and fermented meat.

The Ministerial Council noted in its Guidelines that in relation to raw bivalve molluscs, FSANZ would address this sector in the Draft Assessment process for the primary production and processing Standard for seafood.

It is within this context that FSANZ is developing the first primary production and processing Standard for the seafood sector in Australia. The principle purpose of FSANZ's food standards is to protect public health and safety (and may also address consumer information needs) under the objectives for standard setting under the FSANZ Act. In developing this Standard, FSANZ must follow its statutory standard setting processes to implement the decision of the Ministerial Council in relation to bivalve molluscs.

[4] Primary production standards are not covered by the Treaty between Australia and New Zealand for the development of joint standards.

2. Background

2.1 The seafood sector

The seafood industry is the fourth largest sector of the Australian food industry (by value) after beef, wheat and milk. The gross value of production (GVP) during 2000-01 was $2.44 billion[5]. Since 1992, the GVP has increased, on average, by 10 per cent per annum[6]. Approximately 87 per cent of the value and 34 per cent of the edible volume of Australian seafood production is exported.

At 11 million square kilometres, the Australian fishing zone is the third largest in the world. Most wild fish stocks are fished at their optimal sustainable level, with aquaculture making an increasing contribution to the industry. Between 1991-92 and 2001-2, aquaculture was responsible for approximately 24 per cent of the total volume of seafood produced in Australia.

During 2001-02, 186,777 tonnes of seafood were produced in Australia, covering approximately 600 marine and freshwater seafood species. Approximately 66 per cent was consumed domestically, with the remainder exported. A further 144,474 tonnes were imported, mainly from Thailand and New Zealand.

Further details about the seafood sector, its nature and the value and volume of production, can be found at Attachment 2.

2.2 Development of a primary production and processing standard for seafood

Proposal P265 – Primary Production and Processing Standard for Seafood, was raised by FSANZ in December 2002 under its mandate to develop domestic standards for the primary production and processing of food.

Recently, some State Governments have developed seafood safety schemes to ensure that a 'boat to plate' (i.e. paddock to plate) approach to seafood safety was implemented across the seafood supply chain. However, other Governments are not yet at that point, leaving the primary production end of the domestic seafood chain largely unregulated.

The seafood sector is also increasingly aware that food safety issues are vital to the continued growth of the industry, and has developed a national voluntary seafood safety standard. The industry has also produced a number of guidance documents on food safety across a range of sectors. It is therefore considered an opportune time to move these developments forward nationally to further improve food safety outcomes.

As required by the Ministerial policy guidelines, a Standards Development Committee (SDC) was appointed in September 2002 by the FSANZ Board to assist in the development of the standard. The SDC contributes a broad spectrum of knowledge and expertise covering industry, government, research and consumers.

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[5] ABARE, Australian Fisheries Statistics 2003

[6] During 2002-03, although total production volumes rose to 249,000 tonnes, the GVP fell to $2.3 billion. This has been largely attributed to the lower export values for many species. Media Release 18 February 2004, Australian Seafood Industry Council.

Since December 2002, FSANZ, with the assistance of the SDC, has:

- considered the written submissions received in response to the public consultation on the Initial Assessment Report and conducted face-to-face consultations with stakeholders (see Attachments 3, 4 and 5);
- undertaken an evaluation of public health risks and identified sectors of the seafood industry that pose a potential high risk to safety;
- considered current strategies to manage those risks and determined what, if any, residual risks need to be managed;
- considered options for the management of these residual risks that aim to ensure the safety of seafood;
- conducted an impact analysis of the options to identify the option that meets the minimum effective regulation requirements that would effectively address public health and safety risks associated with seafood production;
- recommended a preferred option;
- considered the implementation of the preferred option; and
- drafted a proposed Standard consistent with the preferred option.

This Report forms the second part of public consultation in the process of developing a primary production and processing Standard for seafood. It takes into account the matters raised above and other deliberations of the Seafood SDC. Industry, government, agencies, consumers and other interested parties are invited to comment on these or any other matters relating to the development of a primary production and processing Standard for seafood.

2.3 Labelling of fish names

Ministers with responsibility for food regulation in Australia and New Zealand have stated that primary production standards should be developed to focus primarily on food safety matters and be complementary to, and not inconsistent with, the other chapters of the Code. These other sections of the Code contain generic and specific standards for all foods as well as standards for hygienic production of food. A primary reason for this separation of issues is that primary production standards will apply in Australia only and under the Treaty between Australia and New Zealand, the composition and labelling provisions of the Code apply in both Australia and New Zealand.

Labelling requirements for foods are determined following analysis against the objectives for standards set out in the FSANZ Act, COAG policy requirements for minimum effective regulation that is not anti-competitive and relevant Ministerial policy guidelines[7].

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[7] As set out in the Australia New Zealand Food Regulation Ministerial Council's *Overarching Policy Guideline On Primary Production And Processing Standards.* (Available on the web at http://www.foodstandards.gov.au/_srcfiles/ANZFRMC%20OVERARCHING%20POLICY%20GUIDELINE%

During the development of the primary production standard for seafood, some sectors of the fishing industry have advocated the need for mandatory labelling of fish names to prevent or limit consumer deception, a view that has also been supported by a major supermarket. Furthermore, the Australian Seafood industry Council (ASIC), the peak industry body for seafood, has incorporated the Australian Fish Names List in the industry voluntary standard. Part 1.2 – Labelling and other Information Requirements could be amended if a need were demonstrated, following a comprehensive analysis of the consumer risks, the regulatory options, and the likely costs and benefits to consumers, industry[8] and governments and public comment on the analysis. This analysis is required in the development of any standard in the Code to ensure that it receives Ministerial agreement and enforcement support by the States and Territories.

Discussions have also included reference to the existing protection consumers have against false and misleading claims in the various trade practices laws in Australia and New Zealand and the general principle of not duplicating legislation if this can be avoided.

In the meantime, following extensive discussions with industry (through the Seafood SDC), Standards Australia, the Australian Competition and Consumer Commission, the Australian Government Department of the Treasury (the agencies responsible for developing and administering Australia's consumer protection and business development laws) and with the Office of Regulation and Review, the following steps have been initiated by FSANZ and industry:

1. FSANZ and the seafood industry has entered into discussions with Standards Australia to develop an Australian Standard for fish names, based on the existing list of fish names developed by the fishing industry.

2. Preliminary discussions with the ACCC indicate that such a standard could be used as a reference document to assist in enforcement by the ACCC under the fair trading laws.

3. Once there is a formally recognised Australian Standard for fish names, consideration could be given to an Application to amend the Code to refer to the resulting Australian Standard on fish names. The nature of the reference (mandatory or voluntary; in all circumstances or only where there is a demonstrated health risk) would be determined at that time following FSANZ's normal assessment procedures.

This matter will be reported on further in the Final Assessment Report.

3. Current management strategies to address seafood safety

The safety of Australian seafood is controlled under a variety of schemes from primary production through processing, manufacture, wholesale, retail and food service. Regulatory and non-regulatory approaches are taken and these are outlined below.

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[8] Across the full range of industry, including catchers/producers, processors, wholesalers and retailers.

3.1 Domestic Production - regulatory requirements for food safety

3.1.1 Australia New Zealand Food Standards Code - adopted nationally under State/Territory legislation

Domestic seafood production and imported seafood sold in Australia are subject to the requirements of the Code, as adopted under State and Territory legislation. State and Territory governments enforce compliance with the Code under their Food Acts.

Management of the public health and safety risks and consumer information needs associated with wholesale trade, processing, manufacture, retail and foodservice of seafood products are covered by existing standards.

Chapter 1 of the Code specifies permissions for the use of food additives, processing aids and pesticides and also sets maximum limits for chemical and microbiological contaminants in seafood. There are also requirements for the labelling of seafood. Chapter 2 of the Code contains specific requirements for fish and fish products.

Chapter 3 of the Code contains provisions for the hygienic processing and handling of food, and voluntary provisions covering the application of Food Safety Programs to the processing and retail part of the food chain. The Food Safety Standards in Chapter 3 do not currently apply to the primary production of seafood, except where there is direct sale to the public or the seafood is substantially processed by the primary producer.
It should be noted that the point in the processing part of the food chain at which the Food Safety Standards apply is not the same in all jurisdictions. Generally, the standards do not apply on board vessels for activities such as gutting and filleting.

Attachment 6 provides a summary of these national standards impacting on seafood.

3.1.2 State and Territory regulations for the primary production of seafood

Different regulatory arrangements for seafood are in place in each of the States and Territories. These schemes are outlined in the sections below. (See also Table 1.)

Table 1: Seafood activities covered by food safety standards (Chapter 3) and State primary production food safety schemes

State/Territory	Seafood industry activities covered by	
	State/Territory Primary Production food safety schemes	**Food Safety Standards (Chapter 3) under the Code and State/Territory Food Acts**
New South Wales	▪ Capture/harvest to wholesale* ▪ Bivalve molluscs	Manufacturing, retail and food service
Queensland**	▪ Bivalve molluscs	Manufacturing, retail, food service
Victoria ***	▪ Capture/harvest, processing, wholesale, transport and retail fresh fish outlets ▪ Bivalve molluscs	Retailers selling cooked seafood
South Australia	▪ Bivalve molluscs	Gutting or filleting off-vessel or off-farm, bivalve molluscs from storage onwards (cleaning, grading, packing, shucking), wholesale, manufacture, retail, foodservice

Western Australia	▪ Bivalve molluscs	From land based seafood-processing facilities to retail sale. Shellfish - handled after harvest
Tasmania	▪ Bivalve molluscs	Shellfish - bagging, holding tanks, shucking. Finfish - filleting, thermal packaging, smoking and other manufacturing, retail sale and foodservice
Northern Territory	-	Wholesale, manufacture, retail, food service
Australian Capital Territory	-	Wholesale, manufacture, retail, food service

* State-based scheme under NSW Food Production (Seafood Safety Scheme) Regulation 2001.

** Initial/preparatory work on a Queensland Seafood Safety Scheme, which covers capture/harvest, gutting and filleting, shucking, boiling, freezing and wholesaling fresh fish. Note this scheme is not yet in place (pending outcome of the development of a national seafood standard)

*** Victorian scheme under the Seafood Safety Act.

3.1.2.1 New South Wales

The NSW seafood industry is regulated under the NSW Food Production (Seafood Safety Scheme) Regulation 2001. The original requirement for HACCP-based food safety programs[9] for all seafood businesses has subsequently been modified to match the rigor and complexity of the food safety systems, and the degree to which they are to be audited, with the level of risk to public health and safety.

For example, a food safety plan for a low risk business will not fully implement all HACCP principles and will only need to cover activities that impact on hygiene, sanitation and any necessary temperature controls. Roll-out of the system is being staggered, with the catch/harvest sector (excluding shellfish aquaculture), deemed to be mostly low-medium risk, being the first sector considered.

The NSW Food Production Regulation 2001 also incorporates a shellfish quality assurance program. Principles of the Australian Shellfish Quality Assurance Program (ASQAP) have been incorporated into the mandatory Shellfish Program to ensure safety in the consumption of bivalve molluscs.

3.1.2.2 Victoria

In Victoria, legislation for a new seafood safety system came into effect on 1 July 2003, with the exception of the wild catch and aquaculture sectors, which will come under the new legislation on 1 July 2004. The Seafood Safety Act extends the responsibilities of the Victorian Meat Authority (now called Primesafe) to cover the primary production, processing and retail sectors of the seafood industry. All seafood businesses must be licensed by Primesafe, and operate to approved food safety programs audited by Primesafe.

Seafood processors, wholesalers and retailers of fresh fish transferred from supervision under the Victorian Food Act to Primesafe on 1 January 2004. Victoria will adopt the national primary production and processing standard for seafood under this legislation.

In addition to the requirements imposed on primary production and processing of seafood under the proposed Seafood Safety Act, supermarkets and businesses engaged in retail sale of cooked seafood, such as fish and chip shops and restaurants, are required to implement a food safety program under provisions of the Food Act, 1984.

[9] HACCP – Hazard Analysis and Critical Control Point (HACCP) system – is a science based and systematic documented system that identifies specific hazards and measures for their control to ensure the safety of food.

3.1.2.3 Queensland

Queensland commenced consultation and development work on a seafood safety scheme, but is now waiting for the development (by FSANZ) and gazettal of the national primary production and processing Standard for seafood in the Code.

3.1.3 Australian Shellfish Quality Assurance Program (ASQAP)

The safe production of bivalve molluscs is effectively managed through a single management system, the ASQAP. ASQAP is a national program modelled on the United States Food and Drug Administration's National Shellfish Sanitation Program. The Program was initially developed to meet AQIS export requirements and adapted to local conditions by the Australian Shellfish Quality Assurance Advisory Committee (ASQAAC), to provide guidelines for the safe production and marketing of bivalve molluscs for domestic production.

Bivalve molluscs are filter feeders, extracting phytoplankton, bacteria and suspended organic and inorganic particles (including heavy metals, toxins, enteric pathogens and endogenous marine pathogens) from the surrounding water. Waters from which bivalves are harvested may be subjected to pollution from discharges of untreated or poorly treated human waste, direct discharges of industrial wastes and runoff from urban and agricultural areas. Bivalves have been associated with numerous outbreaks of human illness because of their ability to bio-accumulate pathogens and toxins derived from contaminated waters, and because they are often eaten raw or only lightly cooked with their gastrointestinal tract intact.

The most commonly used approach for managing these risks involves harvesting shellfish only from waters that are shown to be free from harmful contaminants or pathogenic microorganisms.

Federal, State and (sometimes) local government agencies share administrative responsibilities for the management of bivalves; sanitation controls for growing areas (including sanitary surveys and water classification); harvesting controls; and post-harvest processing and handling of bivalves consumed in Australia. ASQAP is administered on a co-operative basis by these agencies. For bivalves destined for export markets, AQIS administers sanitation controls for post-harvesting processing and handling of product.

In each State, the State Government regulates and manages the strict water and environmental monitoring provisions in the State program e.g. QSWAMP (Queensland Shellfish Water Assurance Monitoring Program), VSQAP (Victorian Shellfish Quality Assurance Program), TSQAP, SASQAP, NSWSQAP, WASQAP etc. Under these arrangements, there is a State Shellfish Control Authority (SSCA) that undertakes shoreline sanitation surveys, sanitation reviews, and risk management procedures.

Under ASQAP, harvest areas must be classified by the SSCA on the basis of the shoreline sanitary survey and an on-going water-sampling program. Production areas are classified as: *Approved*; *Approved conditional*; *Restricted*; *Restricted conditional*; and *Prohibited*. ASQAP also imposes controls on bivalve harvesting and ensures protection from contamination after harvesting.

The success of the program is based on continual and extensive monitoring of all commercial growing areas. It entails a precautionary approach, resulting in the closure of a harvesting area following a trigger event such as heavy rainfall or toxic algal bloom. Rainfall can flush microbiological and other pollution into harvesting areas and may also lead to conditions that encourage blooms of toxic phytoplankton.

Australian States and Territories also regulate bivalve safety through aquaculture licences, making it a condition of the licence to be part of the State shellfish quality assurance program. The approach under this system, while not embedded in the food regulation system, is recognised to be effective.

3.2 Voluntary industry standards and guidelines for domestic production

Many seafood businesses comply with voluntary industry guidelines and codes of practice developed by industry peak bodies to address seafood quality and safety issues. Examples of industry guidelines and codes of practice are listed in Attachment 7.

There are no data on the extent to which these guides are implemented by industry, but large operations and those that perceive a market advantage tend to implement and adhere to guidelines, while smaller, resource-constrained businesses are less likely to adopt them.

3.3 Imported seafood - regulatory requirements for food safety

Imported foods must meet the same standards as domestic foods.

At the border, the safety of imported seafood is regulated under the *Imported Food Control Act 1992* administered by AQIS. FSANZ and AQIS have joint responsibility for regulating the safety of imported food, with their roles defined by a memorandum of understanding. FSANZ is responsible for conducting risk assessment of imported food, and AQIS provides operational services at the border, including inspections, verifications and tests in line with FSANZ's advice and to ensure that imported foods comply with the Code.

Imported seafood that is currently classified as '*Risk*' food and therefore subjected to 100 per cent inspection levels, consists of the following:

- crustaceans, cooked and chilled or cooked and frozen. Includes cooked peeled prawns but excludes canned product that is commercially heat treated;

- fish (whole, filleted, further processed or dried), all shark (including Dogfish), *Rexea solandri* (Gemfish) and tuna;

- smoked vacuum packed fish and smoke flavoured vacuum packed fish;

- marinara mix - chilled or frozen, whether blanched or not. Excludes canned product that is commercially heat treated; and

- molluscs ready for consumption, whether chilled or frozen. Includes all bivalve molluscs such as mussels, clams, cockles and scallops. Excludes canned product that is commercially heat treated.

All other imported seafood products are included in the random surveillance category and inspected at a rate of 5 per cent. For further details on the current tests applied to imported seafood refer to Attachment 8.

FSANZ and AQIS are undertaking a review of the random and active surveillance categories. This review is considering existing limits in the Code, the risks to public health and safety and imported food data. The new imported food surveillance system is intended to reward those importers with a good history of compliance, and to allow greater flexibility in relation to inspection frequencies.

The involvement of domestic surveillance agencies in the review of imported food surveillance will result in a more inclusive consideration of issues and allow a greater integration of surveillance functions. It will also ensure that a broader range of information sources is considered when developing surveillance priorities.

The review of the imported foods random and active surveillance categories has been substantially progressed by FSANZ. In the next few months, proposals on inspection rates for classes of foods will be presented to State and Territories and industry for their comment. It is expected that implementation of the new, more flexible system will be in a phased approach with different rates of inspection being applied to some food categories by the end of 2004.

Importers can avail themselves of two mechanisms to reduce the level of inspection and testing at the border. These include (a) recognition of quality assurance arrangements and (b) certification provided by overseas governments (see below).

3.3.1 Recognised quality assurance arrangements

AQIS may enter into quality assurance arrangements with individual overseas manufacturers that are able to demonstrate that they operate to a HACCP based quality management system that ensures their products meet the requirements of the Code and other requirements of the *Imported Food Control Act 1992* and are therefore eligible for importation into Australia. Shipments from that company will be monitored by AQIS at reduced rates. To be eligible to enter into an agreement a company must be certified by a third party certification body to the ISO 9000 quality management standards and be able to meet requirements of relevant Codex Codes of Practice. There are currently no such agreements in place.

3.3.2 Certification provided by overseas governments

Australia has voluntary arrangements to accept assurances from a number of governments on the safety of the food exported to Australia. Food that is accompanied by certificates issued by these governments will generally be released with document inspection only and without routine inspection of the food. Inspections will only be carried out for verification checks of the certification arrangement or if AQIS has concerns about a particular consignment. The certification arrangements may apply to risk, active or random surveillance foods from any country and to risk foods from New Zealand under terms of the Trans-Tasman Mutual Recognition Arrangement.

Currently certification is provided for a range of foods, including seafood, from at least nine countries.

3.3.3 Monitoring for food safety by States and Territories

In addition to border inspection, States and Territories test imported food to ensure it meets requirements of the Code at the point of sale. States and Territories also undertake specific food surveillance surveys on food sold in Australia. These surveys cover domestically produced and imported foods. Specific surveys on fish and fish products have been undertaken (see Table 2).

Table 2: State and Territory surveys of fish and fish products sold in Australia (covers domestic and imported products)

Survey Title	State	Year	Foods
Listeria Monocytogenes in nil-tolerance products	QLD	1995	Smoked Fish Products
Heavy Metals/Pesticides in Brisbane River seafoods	QLD	1996	Seafood (Fish/Prawns)
Microbial quality of marinara mix	ACT	1997	Marinara mix
Biogenic amines in fish and fish products	ACT	1997	Fish and fish products
How safe are smorgasbord foods?	WA	1998	Cooked Prawns
Sulphur dioxide in cooked prawns	QLD	1999	Prawns
Mobile seafood vendor survey	NSW	2000	Seafood
Metal contamination of major NSW fish species	NSW	2001	Fin fish
Metal contamination of major NSW fish species	NSW	2001	Crustaceans
Metal contamination of major NSW fish species	NSW	2001	Molluscs
Histamines – Storage Conditions in Fish	VIC	2002	Finfish
Fish speciation, Cairns Public Health Unit	QLD	2002	Fish
Fish substitution survey	National	2003	Finfish
Shelf life of Sushi products Nigiri pieces and Nori rolls	VIC	2003	Fish products

These surveys may provide information on compliance with the Code at point of sale, hazards in seafood and in some instances insights into hazards that may commonly be associated with particular foods. In relation to any public health and safety impact arising from food/hazard combinations, this would need to be established through epidemiological investigations.

In 2000, the OzFoodNet project was established in Australia as a collaborative project between the Commonwealth and States and Territories to enhance the surveillance of food-borne diseases and to provide a means for facilitating the national investigation of and determine the causes of food-borne illness. It is anticipated that as a result of these activities and over time, Australia will have access to improved information about the sources of food-borne illness.

3.3.4 Enforcement of process standards for imported food

Consumers need to have confidence that the food they consume is safe, irrespective of its source. Mandatory national food standards in the Code apply to both domestically produced and imported foods. However, the mechanisms used to determine that food is safe may differ between domestic and imported foods.

For imported foods, the monitoring system aims to achieve the same outcome i.e. that only safe and suitable food is sold on the Australian market. The monitoring of imported foods often examines the end point of production and tests against agreed microbiological or chemical residual limits in the Code.

For example, instead of being able to check that specified processing requirements were applied during the production and processing of food, product safety is determined by testing, for example, for coagulase-positive staphylococci, salmonella, *E. coli* or histamine etc.

End point testing can have limitations in terms of being able to reliably ensure safe food outcomes. Therefore, FSANZ and AQIS, in conjunction with the States and Territories, have begun to examine systems that can more reliably monitor the safety of imported foods. It is expected that the Implementation Sub-Committee of the Food Regulation Standing Committee will consider the outcome of this work in 2004.

3.3.5 Importation of seafood from New Zealand

Seafood imported from New Zealand operates under the Trans Tasman Mutual Recognition Agreement. The Imported Food Control Act of 1992 applies the standards in the Code to risk categorised food imported from New Zealand.

3.4 Food safety and exported seafood

Seafood exports must comply with national legislation for export control administered by AQIS. This legislation includes the *Export Control Act 1982*, Export Control Prescribed Goods (General) Orders and more specifically the Export Control (Processed Foods) Orders. These provide Government-to-Government certification to assist in fulfilling importing country food safety requirements and trade description for seafood exports.

Export processing establishments (including some vessels) must be registered by AQIS and have, as a minimum, procedures to address the risks associated with the processing of different seafood products to assure an appropriate level of food safety. International market access for Australian fish product exports are facilitated and maintained through this process, and the country's competitive position as a supplier of safe products is enhanced.

AQIS systems for exported seafood are based on the auditing of processing of seafood managed under two approved arrangements. The two systems currently available are:

- *Approved Quality Assurance (AQA)* - based on the company having a fully documented quality management system (similar to ISO 9002 but including technical standards) audited by AQIS at least twice a year.

- *Food Processing Accreditation (FPA)* - a simpler system than AQA, requiring only documentation of a process flow chart and HACCP plan, and Good Manufacturing Practice (GMP), which is managed as part of a premise's registration. Registered establishments are audited at a frequency based on the risk rating of their products, past compliance with their documented system and legislative standards.

3.5 Summary of regulation of the Australian seafood sector

The existing regulatory arrangements for domestically produced, imported and exported seafood are summarised in Table 3.

There is no nationally consistent approach to seafood that obliges all of the industry to manage the safety of their product at the primary end of the food chain. The fragmented, and at times voluntary nature of existing management systems, creates gaps and an uneven approach to food safety.

Table 3:Seafood regulation in Australia

Sector ➔ Market ➔	PRIMARY PRODUCTION Catching Sector and Aquaculture	PROCESSING AND TRANSPORT	RETAIL AND FOOD SERVICE
Exports	Export Control (Processed Food) Orders - HACCP based-food safety programs required.	Export Control (Processed Food) Orders - HACCP based-food safety programs required.	Not applicable
Domestic seafood	Variable regulation: - NSW and Vic regulate primary production sector of the seafood chain requiring food safety programs. - Various industry food safety and quality assurance guidelines, schemes and codes. - Shellfish growers required to meet ASQAP requirements	State and Territory legislation (including requirements of Code). Requirement for good hygiene practices etc. - Considerable variation as to what point in the supply chain the Food Safety Standards apply. - Various industry food safety and quality assurance guidelines, schemes and codes.	State and Territory legislation (including requirements of Code). Requirement for good hygienic practices etc. - More consistent application except in Victoria, where food safety programs are mandatory. - Various industry food safety and quality assurance guidelines, schemes and codes.
Imported seafood	In country production requirements. - Some AQIS certification requirements in place *e.g.* fish products imported from Thailand.	In country production requirements. - Some AQIS certification requirements in place *e.g.* fish products from Thailand.	Imports are evaluated by AQIS against requirements of the Imported Food Inspection Scheme and the Code and inspected and tested for compliance to the Code. Seafood from New Zealand operates under the Trans Tasman Mutual Recognition Agreement and the Imported Food Control Act of 1992 applies the standards in the Code to risk categorised food imported from New Zealand.

4. Regulatory problem

Before Governments act to regulate any sector of business, it is necessary to describe what the regulatory needs are – 'the regulatory problem'.

4.1 Growing global burden of food-borne illness

Australia and most other countries in the world, as well as the World Health Organization (WHO)[10], recognise the increasing burden of food-borne illness worldwide. The growing burden of food-borne illness may be attributed largely to a rapidly changing global environment. The growth in global food trade – where food grown in one country can now be transported and consumed halfway across the world, changing patterns of food production and distribution, and evolving consumer preferences for food are some of the elements of the changing environment and it is likely that these will continue in the future.

[10] Brundtland, G.H. 'Food Safety – A World-Wide Challenge', Food Chain 2001, WHO Food Safety Strategy, 2001.

These changes create an environment that favours the emergence and re-emergence of new pathogens and contaminants in food, and the resulting food-borne illness in our population.

4.2 Impacts of food-borne illness in Australia

Consumers typically respond to outbreaks of food-borne illness in seafood by reducing their demand for seafood products. For example, following contamination of NSW oysters in 1997, NSW consumers immediately reduced their demand for oysters by 85 per cent. They also immediately reduced their demand for all seafood products by 30 per cent, indicating that consumers readily generalise a specific seafood risk to the broad category of seafood products[11].

However, despite consumers' immediate reactions to outbreaks of food-borne illness, demand for seafood recovers over time. Notwithstanding 24 outbreaks associated with raw-ready-to-eat seafood[12] during the 1990s, consumer demand for seafood has increased steadily over the medium term[13]. The implication is that while consumers immediately perceive costs when outbreaks of food-borne illness occur, these short-term costs are not sufficient to outweigh the perceived benefits of seafood to consumers over the medium-term.

Each outbreak of food-borne illness imposes an immediate cost on industry, by reducing sales revenues for the implicated product and with follow-on effects to the seafood industry more generally[14].

4.3 A new approach to food safety

In this environment, the effectiveness of the existing food safety management systems needs to be examined and strategies identified to further improve food safety management. Traditional food safety systems have tended to focus on testing food at the end of the food chain, often after an outbreak of food-borne illness or an incident has been reported. While this approach assists prosecution of offending parties, it rarely prevents food-borne illness.

The more recently introduced HACCP approach to food safety offers a preventive approach to food safety, but does not approach the management of food safety from a priority perspective, i.e. it makes little distinction between controlling hazards that translate into significant risks to public health as opposed to hazards that lead to a relatively low risk to public health. The HACCP system is relatively costly to implement, and in an environment of limited resources, may not be cost-effective for all food sectors or activities.

The Ministerial Council has recognised the need for Australia to develop a new approach to managing food-borne risks to human health. This approach includes a nationally consistent, whole-of-chain food safety management system that is preventive in nature, focuses on food safety outcomes rather than prescriptive requirements and identifies management systems that are commensurate with public health risks.

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[11] NRVP page 87.
[12] NRVP page 39.
[13] FRDC/Ruello and Associates, *op. cit.*
[14] As the NRVP case study of contaminated bivalve molluscs in NSW showed.

A nationally consistent, preventive approach has recently been adopted in Chapter 3 of the Code, specifying baseline food safety provisions for the hygienic production of food in the manufacturing and retail sectors. Chapter 3 also sets out voluntary provisions for food safety programs. As identified earlier, the Ministerial Council recently agreed that food safety programs should become mandatory for certain food sectors identified as posing a higher risk to public health, where food safety programs would be cost-effective.

However, the provisions in Chapter 3 do not apply to the primary production end of the food chain. For many industry sectors and activities, hazards introduced at the primary end of the food chain may not be able to be managed effectively further up the food chain, resulting in public health incidents. The effective management of hazards of public health significance at the primary end of the food chain makes the task of managing hazards in the later part of the food chain easier and more effective, resulting in safer food and improved public health outcomes.

Section 3.5 highlighted the inconsistent approaches being taken at the primary production end of the seafood supply chain in Australia. These gaps in the coverage of current regulation and industry compliance with voluntary management systems may have implications in terms of public health and safety. This will need to be considered in light of the inherent public health and safety risks presented by seafood and the current strategies used to minimise these risks.

4.4 Identification of public health and safety risks posed by seafood

The Risk Ranking Report (Attachment 9) qualitatively ranks the public health and safety risk posed by consumption of seafood in Australia. Overall the risks from seafood are usually well managed and are therefore considered relatively low. There are only a very small number of products that may present higher public health and safety risks.

The risk ranking compares the relative risks associated with the wide variety of seafood commodities available in Australia – domestically produced and imported. It takes into account the chemical and biological food safety hazards potentially present, and assigns each commodity or group of commodities to a broad relative risk category: low, medium or high.

The ranking brings together the available scientific and technical information on food safety hazards in seafood and identifies seafood commodities of higher priority for the development of risk management strategies. It provides a scientific basis for the development of a Primary Production and Processing Standard for seafood and informs other risk management approaches designed to protect consumers from seafood-borne illnesses.

4.4.1 Risk ranking method

FSANZ estimated relative public health risks by considering the severity of any adverse health effect resulting from the presence of a particular hazard in a seafood commodity, together with the likelihood of that adverse health effect occurring.

Estimates of the severity of illness due to the presence of hazards in seafood followed an internationally accepted procedure, which considers the duration of illness, likelihood of death and potential for ongoing adverse health effects.

Estimates of the likelihood of adverse health effects were based on:

- the link between the hazard and illness due to consumption of the particular seafood (epidemiological data);
- the prevalence and concentration or level of the hazard in seafood;
- patterns of consumption of the specific seafood (i.e. frequency of consumption, amount consumed);
- the impact of existing regulatory and non-regulatory risk management systems; and
- data and information on the following factors related to the properties of the hazard and the effect of production, processing and handling, particularly in terms of how they might influence hazard levels at the point of consumption:
  - the capacity for microbiological pathogens to survive or grow in the commodity;
  - any other relevant properties of the hazard (e.g. toxigenic or infectious dose);
  - the probable effect of production, processing and handling on the presence and level of the hazard; and
  - the likely effect of consumer handling (including cooking and product shelf life) on hazard levels.

Using a ranking matrix, FSANZ combined the severity and likelihood estimates into a broad relative risk estimate for each hazard that might be found in a seafood commodity (e.g. prawns) or group of similar commodities (e.g. oysters and other bivalve molluscs). An overall relative risk ranking for each commodity (or group of commodities) was then obtained by determining the highest relative risk ranking estimated for the commodity.

4.4.2 Future reviews of the risk ranking

The risk ranking is based on the best current knowledge and data. Such rankings are dynamic, with their evolution reflecting increasing knowledge about the hazards and the consumer's exposure to them. For example, the introduction of new technologies, modified production practices, and changes in management strategies may influence the need to review the rankings.

FSANZ will maintain a watching brief of the scientific literature and international activities, e.g. Codex Alimentarius, which may impact on the risk ranking. Where significant data gaps impacting upon the risk ranking process are filled by the results of ongoing scientific studies and surveys of the prevalence and levels of food safety hazards in seafood in Australia, the robustness of the risk rankings can be better assessed and the rankings may be further refined.

4.4.3 Food safety hazards in seafood

Seafood can contain food safety hazards derived from several different sources. Some of these hazards occur naturally in the environment in which seafood lives and grows and are unavoidable contaminants of seafood when it is harvested. Others are a consequence of the impact of human activities on the environment.

In the pre-harvest phase of production, feed components, veterinary drugs and other chemicals employed in aquaculture production may also present a public health risk.
In addition to these, food hazards can be introduced into seafood, or caused to increase to potentially hazardous levels, through direct contamination by food handlers and contaminated utensils and equipment and by inadequate handling (e.g. temperature abuse, cross-contamination, inadequate processing).

The extent to which any food safety hazard is likely to be present in seafood depends on a number of factors. These factors include the biology of the particular seafood species, its growing environment, and the conditions along its production and processing supply chain. Therefore, the broad biological classes of seafood species (bivalve and cephalopod molluscs, crustacea and finfish), and the public health risks posed by hazards associated with specific commodity groups within those classes, have been considered separately.

4.4.4 Summary of risk rankings

The relative risk rankings described in this report demonstrate the generally high level of safety of seafood products. Under current risk management practices – both voluntary and mandatory – public health risks are relatively low for the majority of seafood. A small number of commodities present a higher public health risk than other seafood, taking into account the impact of existing regulatory and non-regulatory risk management systems.

The Report concludes that the following seafood sectors are ranked in the higher relative risk category:

- oysters and other bivalve molluscs (except when the consumed product is only the adductor muscle, e.g. roe-off scallops) harvested from growing environments likely to be exposed to faecal contamination and/or not under a shellfish safety management scheme; and

- ready-to-eat cold-smoked finfish (and other ready-to-eat cold-smoked seafood products), when consumed by population sub-groups susceptible to invasive Listeriosis.

Table 4: Seafood commodities ranked as higher relative risk

Risk Ranking	Commodity	
High	Molluscs	- oysters and other bivalve molluscs
	Finfish	- cold-smoked (including other cold-smoked seafood)

4.4.4.1 Oysters and other bivalve molluscs

Oysters and other bivalve molluscs (except when the consumed product is only the adductor muscle, e.g. roe-off scallops) harvested from growing environments vulnerable to faecal contamination and/or not under a shellfish safety management scheme present a relatively high risk to public health, mainly due to the likelihood of illness caused by contamination with hepatitis A virus and algal biotoxins (particularly Neurotoxic Shellfish Poisoning [NSP]; and Amnesic Shellfish Poisoning [ASP]). These hazards are introduced in the pre-harvest phase of bivalve production.

This relatively high risk ranking is consistent with other studies based on recent epidemiological data that reflected a situation where inconsistent risk management systems were in place across Australia.

Food-borne illness due to oysters and other bivalve molluscs in Australia have resulted in a number of small outbreaks and sporadic cases due to *Vibrio* species and a few large outbreaks due to enteric viruses in oysters harvested from polluted and inadequately controlled waters.

While adoption of risk management strategies has improved the safety of bivalve shellfish in recent times, some risk remains. While monitoring of harvest waters for indicators of sewage pollution (e.g. faecal or total coliforms) helps to manage the risks due to enteric pathogens, bacterial and viral, it cannot predict levels of *Vibrio* species and enteric viruses in oysters. Oysters harvested from waters without a risk management system in place have a higher risk of contamination by algal toxins. Therefore, where oysters and bivalves are harvested from waters managed under a comprehensive shellfish safety scheme, such as the Australian Shellfish Quality Assurance Program (ASQAP), the risk is significantly reduced, notably, the likelihood of a food-borne illness is very low.

The risk rankings for oysters and other bivalves were the same regardless of whether they were to be cooked or eaten raw, as the hazards leading to the risk rankings are not greatly affected by the light cooking normally applied to these products.

4.4.2 Cold-smoked seafood

Ready-to-eat cold-smoked finfish (and other ready-to-eat cold-smoked seafood products) present a higher risk to public health relative to other seafoods due to the possibility of contamination with *Listeria monocytogenes* and the potentially severe illness it causes in at-risk population sub-groups such as pregnant women. *L. monocytogenes* is a ubiquitous organism often found in processing environments, and may also be present in fish at the time of harvest. Cold smoking is not a listericidal[15] process.

Recognition of the risks by both regulators and the industry has resulted in a high level of management of *L. monocytogenes* in Australia and a lower risk of illness to the general population. FSANZ has previously recognised the inherent risk to the general population due to *L. monocytogenes* in cold-smoked seafoods by including a microbiological limit standard for the organism in ‘ready-to-eat processed finfish, other than fully retorted finfish’ in the Code. When the food safety risks are managed such that cold-smoked seafoods meet this regulatory requirement, the relative risk ranking for the general population is low, although the relative risk ranking for susceptible populations (e.g. pregnant women, newborn and young children and the elderly) is high. FSANZ is currently reviewing its dietary advice to these at-risk sub-groups in order to manage their food safety risks due to *L. monocytogenes* from all food sources.

If the food safety risks are not properly managed, such that cold-smoked seafoods do not meet the microbiological limit standard for *L. monocytogenes*, the relative risk ranking is high for at-risk sub-groups and medium for the general population.

[15] A listericidal process is one which would normally involve heat processing, usually 70ºC for 2 minutes or equivalent, to achieve a 6D reduction in the pathogen load. The D value is the time required at a given temperature to destroy 90% of the population of a given microorganism.

This takes account of the relatively long shelf life of the product and the high standards of hygiene and sanitation in processing and good temperature controls across the food supply chain, up to and including the consumer, that is required to ensure the safety of the product.

4.4.3 Other seafood commodities

FSANZ ranked other seafood commodities as presenting a low or medium relative public health risk.

The vast majority of whole and filleted finfish was ranked in the low relative risk category. A few groups of fish species were ranked in the medium relative risk category:

- larger specimens of certain species of tropical and sub-tropical finfish, due to the potential for illness due to the accumulation of ciguatoxins; and

- large, long living or predatory fish, such as swordfish, shark/flake and some tuna, which tend to accumulate higher levels of methylmercury than other fish species. The ranking applies to the at-risk sub-population (the foetus) when the mother consumes mainly those species.

A medium ranking was also assigned to the following commodity groups (due to the listed hazards):

- univalve molluscs (e.g. abalone) and roe-off scallops (from algal biotoxins causing amnesic shellfish poisoning and paralytic shellfish poisoning);
- prawns (*V. cholerae* O1, *Salmonella* Typhi, arsenic);
- canned seafood (*Clostridium botulinum*);
- hot-smoked fish products (*C. botulinum*); and
- some whole and filleted finfish (arsenic).

In most cases, hazards linked to these medium risk commodities are already regulated in the Code (e.g. *Salmonella* in prawns, arsenic in finfish) or through longstanding and effective industry codes of practice (e.g. *C. botulinum* in low-acid canned foods).

Of the seafood commodities ranked in the medium risk category, prawns and some finfish (whole or as fillets) have been linked to several outbreaks of food-borne illness in Australia in recent years. For prawns, the associated food safety hazards have been primarily microbiological hazards, while for finfish, ciguatoxin, histamine fish poisoning and escolar wax esters account for the great majority of the outbreaks.

The majority of seafood commodities presented a lower risk to the general population. For some of these commodities, the limited consumption of the products was the main factor in leading to the conclusion that the likelihood of adverse health effects from associated hazards was very low. For others, the probable effects of downstream processing and consumer handling in reducing hazard levels were factors leading to a low likelihood of illness.

Table 5: Summary of selected seafood commodities including current risk management*.

Commodity	Hazard/Environment or species	Severity	Likelihood	Relative risk Ranking[1]	Current risk management
Raw Oysters	*V. vulnificus*	Serious	Likely	Medium	ASQAP/Ch 3[2]
	V. cholerae O1/O139	Severe	Unlikely	Medium	ASQAP/Ch 3[2]
	Noroviruses/Uncontrolled[3]	Moderate	Very likely	Medium	
	Noroviruses/Managed[4]	Moderate	Unlikely	Low	ASQAP
	Hepatitis A virus/Uncontrolled[3]	Serious	Very likely	**High**	
	Hepatitis A virus/Managed[4]	Serious	Unlikely	Low	ASQAP
	Algal biotoxins/Uncontrolled[3]	Severe	Likely	**High**	Ch 1
	Algal biotoxins/Managed[4]	Severe	Unlikely	Medium	ASQAP/Ch 1
	Arsenic, Cadmium, Lead	Severe	Unlikely	Medium	ASQAP/Ch 1
Cooked Oysters	*V. cholerae* O1	Severe	Unlikely	Medium	ASQAP/Ch 3[2]
	Noroviruses/Uncontrolled[3]	Moderate	Very likely	Medium	Ch 3[2]
	Noroviruses Managed[4]	Moderate	Unlikely	Low	ASQAP/Ch 3[2]
	Hepatitis A virus/Uncontrolled[3]	Serious	Very likely	**High**	
	Hepatitis A virus/Managed[4]	Serious	Unlikely	Low	ASQAP
	Algal biotoxins//Uncontrolled[3]	Severe	Likely	**High**	Ch 1
	Algal biotoxins/Managed[4]	Severe	Unlikely	Medium	ASQAP/Ch 1
	Arsenic, Cadmium, Lead	Severe	Unlikely	Medium	ASQAP/Ch 1
Cooked abalone /roe-off scallops	Algal biotoxins	Severe	Unlikely	Medium	Ch 1
Green prawns	*V. cholerae* O1[5]	Severe	Unlikely	Medium	Ch 3[2]
	Salmonella Typhi[5]	Severe	Unlikely	Medium	Ch 1/Ch 3[2]
	Arsenic	Severe	Unlikely	Medium	Ch 1
Cooked prawns	*V. cholerae* O1[5]	Severe	Unlikely	Medium	Ch 3[2]
	Salmonella Typhi[5]	Severe	Unlikely	Medium	Ch1/Ch 3[2]
	Arsenic	Severe	Unlikely	Medium	Ch 1
Chilled/ frozen whole fin fish and fillets	Mercury, Ciguatoxin[6]	Serious	Unlikely	Low	Ch 1/Advisory Notes
	Ciguatoxin/Tropical[7]	Serious	Likely	Medium	Advisory Notes
	Mercury/Predatory species[8]	Serious	Likely	Medium	Ch 1/Advisory Notes
	Arsenic	Severe	Unlikely	Medium	Ch 1
Canned fish products	*C. botulinum*[4,9]	Severe	Unlikely	Medium	GMP/GHP
	Arsenic	Severe	Unlikely	Medium	Ch 1
Cold-smoked fish products	*C. botulinum*[4,9]	Severe	Unlikely	Medium	GMP/GHP
	L. monocytogenes	Serious	Unlikely	Low[10]	Ch 1/Ch 3[2]/Advisory
	L. monocytogenes	Severe	Likely	**High**[10, 12]	Ch 1/Ch 3[2]/Advisory
	L. monocytogenes	Serious	Likely	Medium[11]	
	L. monocytogenes	Severe	Very likely	**High**[11, 12]	
Hot-smoked fish products	*C. botulinum*[4,9]	Severe	Unlikely	Medium	GMP/GHP

Footnotes for Table 5:

* Relative risk rankings are under constant review to identify emerging significant information.

1. Risk ranking reflects current practice for that commodity/seafood sector. The risk ranking is based on the severity of the hazard and an estimate of the likelihood of illness that takes into account various factors, including current risk management practices.
2. Chapter 3 provisions in the Code apply to the processing sector only.
3. Uncontrolled describes a growing environment not under a shellfish safety management scheme and/or likely to be exposed to faecal contamination. Includes growing waters adjacent to urban areas and rural habitation. In contrast, a growing environment considered pristine is unlikely to be exposed to faecal contamination. Pristine environments would typically include growing waters remote from human habitation and even if uncontrolled, present similar risk to managed waters for enteric pathogens. Algal toxins remain a risk for pristine environments.
4. **Where a food safety hazard is controlled under a management system/program, the likelihood of illness is very low.**
5. For product from intensive farming systems or estuarine harvest areas subject to human faecal contamination.
6. Majority of finfish present a low risk to consumers (Serious x Unlikely) due to mercury or ciguatoxin.
7. Ciguatoxin may be found in larger specimens of particular species of tropical and sub-tropical finfish from certain fishing areas. It is predominantly a problem in the recreational fishing sector (See Appendix 4, Table 19).
8. Predatory species – mercury is a problem in big, long living or predatory fish, such as swordfish, shark/flake and some tuna. These fish tend to accumulate higher levels of methylmercury than other species. The relative risk ranking is medium for the at-risk sub-population (the foetus) when the mother consumes mainly large, predatory or long-lived fish species.
9. Industry adherence to GMP, GHP and appropriate product formulation (*e.g.* pH, levels of salt, preservatives) control this hazard.

10. When correctly managed, the risk ranking is low for the general population (Serious x Unlikely), but high for at risk sub populations.
11. When not managed, i.e. processing, product handling and storage not adequately controlled, the risk ranking is medium for the general population and high for at risk populations.
12. *L. monocytogenes* is a severe hazard for at risk populations.

4.5 Examination of existing management systems and their control of identified risks

The previous section concludes that there are a small number of seafood commodities that may pose a higher relative risk to public health and safety when compared with other commodities in the seafood sector. It also concludes that the remaining seafood commodities pose a lower individual risk, but that when the risk is aggregated, these contribute significantly to the background incidence of food-borne illness associated with seafood.

It is noted that in identifying risks, use was made of the available epidemiological data. However, this data is limited due to significant underreporting (1 per cent of cases are estimated to be reported). With this in mind, well over 90 per cent food-borne illness related to seafood is likely to be unreported. However, the relative risk ranking took into account other information, as detailed previously, to develop a view of the overall risks posed.
The following section of the Draft Assessment Report further examines current management systems for higher risk sectors as well as the remaining sectors, to identify where these would benefit from application of additional or different risk management practices or a single integrated national scheme. Table 5 summarises current regulatory and food safety control measures in place for those seafood commodities ranked as either medium or higher relative risk.

4.5.1 Seafood ranked as high (relative to other seafood)

4.5.1.1 Oysters and other bivalve molluscs

Bivalves[16] were assessed as posing a higher relative risk to public health when harvested from growing environments likely to be exposed to faecal contamination and/or not under a shellfish safety management scheme.

The food safety of bivalves is controlled through State-based programs that utilise ASQAP as a guide to safe production and harvesting. All Australian producers must now comply with the State-based programs as a condition of their aquaculture licence.

State ASQAP programs adopt measures to prevent the growing and harvesting of bivalves from waters made unsuitable by the presence of biological or chemical hazards at levels likely to present a public health risk. These programs allow for the purification of bivalves from such waters, under certain conditions, through the application of techniques such as relaying and depuration. However, the vibrios, algal biotoxins and enteric viruses, in particular, tend to be removed ineffectively by these purification techniques, so that the higher inherent risk cannot be completely managed by these practices. Because of this, ASQAP prescribes the testing of bivalve flesh for biotoxins under certain circumstances, and requires temperature control to limit outgrowth of bacterial pathogens post-harvest.

[16] Bivalves molluscs means all molluscan bivalves with the exclusion of spat, and scallops and pearl oysters where the only part of the product consumed is the adductor muscle.

The State ASQAP programs are essential tools for the management of the safety of bivalve molluscs. It is clear that bivalve mollusc producers achieve a satisfactory level of safety for this inherently hazardous food through adherence to the requirements stated in ASQAP by the State Shellfish Control Authorities (SSCA). The use of very similar systems is mandated in many developed countries as the only recognised and effective means of producing safe bivalve molluscs. The control of waters from which the product is harvested is beyond the capacity of individual growers. Additionally, the current system ensures that the extensive sampling regime undertaken under the program is affordable for each grower.

The recent achievement of a national approach for industry compliance with the requirements set out in ASQAP for the safe production of shellfish has closed some of the gaps in the food safety management system for bivalves. The industry and the State regulators of the Program, through ASQAAC, have recommended to FSANZ that compliance with the pre-harvest requirements of ASQAP as well as biotoxins management plans be mandated in the Code and that food safety plans be mandated for certain post-harvest activities associated with these products. This aims to ensure that the current legislative basis for shellfish standards are based on food safety requirements, that States/Territories regulate shellfish safety through a nationally consistent standard and that there is a means to recognise ASQAAC as the body that maintains and updates ASQAP. Given the proven effectiveness of the ASQAP system, it would be appropriate to mandate compliance with requirements of the program as administered by the SSCA within the Code.

This approach would have the benefit of ensuring:

- an appropriate legislative basis by bringing it under the health umbrella;
- national consistency as all States would pick up the requirement uniformly and fully;
- once in the Code it would allow health portfolios to verify compliance by industry; and
- provide a mechanism for maintenance of guidelines that are essential for the safety of this food.

The development of mandatory documented risk management standards in the Code is consistent with the recent Ministerial decision and Guidelines on Food Safety Management Options in Australia.

In conclusion, the potential public health and safety risks associated with oysters and other bivalve molluscs are considered higher relative to other seafood and, therefore, voluntary or other non-regulated mechanisms to address this level of risk are not considered appropriate or sufficient to address the problem.

4.5.1.2 Cold-smoked finfish

Cold-smoked finfish (and other cold-smoked seafood products) were found to present a higher relative risk to public health for at-risk population sub-groups, due mainly to the severity of illness caused by contamination with Listeria monocytogenes. Listeriosis is a serious food-borne illness that affects susceptible populations and can lead to death. Because of its long incubation period (up to three months), it is often difficult to identify the food vehicle responsible for the illness.

Listeria is a ubiquitous organism in the environment and because the cold-smoking process does not contain a listericidal step, it is difficult to eliminate this pathogen from the product. Instead, strict adherence to good hygienic practices and proper maintenance of the processing environment are essential for controlling this organism. The long storage periods of the products at low temperatures favour the growth of the pathogen. Typically the shelf-life for vacuum packed cold smoked fish is up to 4 weeks at 5°C.

The Code sets a limit for *L. monocytogenes* in smoked fish and processors use this limit as one criterion for evaluating the safety of their products before release into the marketplace and in setting use-by-dates. Testing of products in the marketplace also contributes to recall of contaminated product. However, good hygienic practices and clean premises are essential tools in maintaining low levels of the pathogen in the product. These practices are already mandated for processing of this product in Chapter 3 of the Code.

In addition, FSANZ publishes and distributes information material to alert susceptible populations such as pregnant women to the high risk posed to them by this food. It must be concluded, however, that these current management strategies for *Listeria* in cold-smoked finfish leave a residual, albeit small, risk to public health.

One approach to manage the residual risks posed to public health by cold-smoked finfish would be to propose implementation of additional risk management systems. These could consist of a HACCP system or food safety program as described in the voluntary Standard 3.2.1 in the Code. It is clear that the risks lie mainly in the processing part of the food chain where the pathogen may be introduced, and also in the retail shop where *Listeria* growth may occur during the long shelf life of the product.

The implementation of HACCP or food safety programs would need to be justified by a positive benefit-cost ratio demonstrating that the burden would be clearly outweighed by the public health improvements. Such a benefit-cost study has not been done and until it is done, the proposal to mandate HACCP-based approach for this food would not meet with stakeholder agreement.

As the main sub-populations at risk are pregnant women and the elderly, improved education of these vulnerable populations may be the best approach, in the short-term, to manage the residual risk, combined with improved compliance and enforcement of the existing mandatory standards in Chapters 1 and 3 of the Code. FSANZ is currently reviewing the *Listeria* pamphlet for pregnant women to broaden its audience to the main vulnerable population groups at risk.
In summary, at this point in the standard development process, no additional regulatory requirements are proposed for cold smoked finfish.

4.5.2 Lower risk seafood

The majority of seafood commodities were ranked as presenting a lower public health risk than bivalve molluscs and cold-smoked finfish. The lower risk seafood products, when grouped together, do contribute to the overall level of food-borne illness and therefore have an impact on public health and safety.

Because of the continuing burden this will have on the community and the consequent costs it imposes, there is an argument for the introduction of basic measures, at low cost, across the seafood industry that would have a broad impact in improving public health and maintaining the high level of consumer confidence in the consumption of seafood.

The existing food safety provisions in the Code recognise that good hygienic practices and pre-requisite programs must apply to all food businesses (other than primary production) to ensure a basic level of food safety for all food. Codex, in its General Principles of Food Hygiene[17], also takes the approach that the primary production and processing of all food must meet basic requirements of food safety. The work of both the WHO and Codex indicates that reducing the hazards introduced at the primary end of the food supply chain will minimise food safety hazards at the later stages of the food chain.[18] The approach in Standards 3.2.2 and 3.2.3 of the Code that mandate minimum requirements for food safety do not apply to businesses in the primary production and processing sector - they apply to manufacturers through to retailers.

The various voluntary industry codes of practice and industry guidelines, in some cases, do pick up such requirements, but national consistency of coverage would be improved through the introduction of a single national scheme.

Therefore, there is a strong case to extend the basic food safety provisions of the Code throughout the primary production and processing supply chain to ensure there are basic food safety practices underpinning the production of all food, rather than at just one end of the supply chain. Some of the medium risk products may benefit from more specific risk management strategies; however, these may vary according to geographic/climatic and other factors, as well as existing jurisdictional and industry infrastructures. For this reason, the proposed standard does not prescribe a documented seafood safety management system for the lower risk products as for oysters and other bivalve molluscs. Nevertheless, the standard requires a seafood business to systematically examine all its primary production operations to identify potential seafood safety hazards and implement controls that are commensurate with the food safety risks. The extent of hazard identification, implementation of control measures and verification required should also be commensurate with the level of food safety risk involved. This is most appropriately determined by jurisdictions in consultation with industry, taking account of local environmental factors. Where possible, jurisdictions should use national forums such as the Implementation Subcommittee (ISC) of the Food Regulation Standing Committee to develop nationally consistent approaches to verification.
One example of a specific risk management strategy that is required is in relation to escolar (or rudderfish), where specific advice may be required at the retail and consumer level to advise people of the risk of consuming wax esters that are found in this fish.

5. Objective

The objective of the measures proposed in this draft assessment is to effectively address the public health and safety risks associated with seafood through the development of a single, nationally consistent, set of risk management measures that address food safety issues across the food chain, are preventive, outcomes-based and cost-effective.

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[17] Recommended International Code of Practice: General Principles of Food Hygiene, CAC/RCP 1-1969, Rev. 3-1997, Amd. (1999)
[18] WHO Food Safety Strategy, 2001.

6. Regulatory options

6.1 Scope of the Standard and Definition of Seafood

Any mandatory regulatory approach for managing public health risks associated with seafood will be defined by the scope of the standard and the definition of seafood. After consideration of issues raised by responses to the Initial Assessment Report and advice from the SDC and the Ministerial Council, it was determined that:

- The scope of the Standard should cover all aspects of primary production and processing, from harvest/capture (whether wild-catch or aquaculture) up to the point at which Chapters 1, 2 and 3 of the Code currently apply.

- The Standard should not cover indigenous/traditional fishers or recreational fishers, as the standard applies only if the seafood is intended for sale.

- The Standard should be outcome-based, developed by utilising a risk-based approach, with the level of regulatory intervention to be commensurate with the level of public health risk.

- The Standard should apply to both imported and domestically produced seafood, and should avoid duplication of existing food safety Standards, such as Standards 3.2.2 and 3.2.3.

Options 2 and 3 are considered to be feasible and address the objectives of this proposal. Option 1 is included in the Impact Analysis for comparative purposes.

Option 1: The status quo - continuing the current regulatory arrangements.
Option 2: A Primary Production and Processing Standard targeting high-risk seafood activities only.
Option 3: A risk-based Primary Production and Processing Standard to improve the overall safety of the seafood supply chain.

6.2 Option 1 – The status quo

The status quo option involves continuation of current State and Territory regulatory arrangements, including the obligation to produce safe food under the Food Acts, and application of the current provisions of the Code as administered and enforced by the States and Territories. This includes provisions applicable to seafood in Chapters 1, 2, and 3 of the Code. States and Territories and AQIS would continue to test for compliance against the Code and undertake other enforcement measures.

State-based standards for the primary production of seafood have been implemented in NSW and Victoria's scheme will commence for wild catch and aquaculture in 2004. It is likely that other States will develop their own standards if there is no nationally consistent standard. These schemes would continue to be enforced by States and Territories. The regulation of bivalve molluscs through aquaculture licensing arrangements would continue on a State-by-State basis.

The status quo would include the voluntary uptake of the Seafood Services Australia industry standard for seafood safety and the ongoing utilisation/implementation of various industry guidelines and codes of practice addressing seafood safety and quality (industry self-regulation).

6.3 Option 2 - A Primary Production and Processing Standard targeting high-risk seafood activities only

A Primary Production and Processing Standard addressing only high-risk seafood activities will require identified high-risk seafood sectors (bivalve molluscs) to implement written food safety management systems such as Standard 3.2.1. It will not contain general provisions for the primary production and processing sector.

In the case of seafood businesses producing bivalve molluscs, it will be mandatory to comply with pre-harvest provisions identified in the Australian Shellfish Quality Assurance Program to ensure that bivalve molluscs are harvested under conditions that assure their safety. In addition, these businesses will be required to implement food safety programs for the post-harvest sector up to the back door of the retail sector.

6.4 Option 3 - A risk-based Primary Production and Processing Standard to improve the overall safety in the seafood supply chain

A new Primary Production and Processing Standard to address food safety risks in two ways:

- basic hygiene requirements for all primary production of seafood; and
- a requirement for specific provisions for higher risk primary production of seafood.

This Standard would provide a single, nationally consistent and risk based approach to facilitate the safe production of seafood. Having a consistent approach to the management of food safety during seafood primary production will positively impact on safety across the seafood supply chain.

The Standard (Documented as Chapter 4 in the Code) would be divided into two main components as follows:

- ***General provisions*** which set out basic food safety requirements for the hygienic primary production and processing of seafood, and

- ***Specific provisions*** for higher risk primary production seafood sectors, requiring the implementation of food safety management systems.
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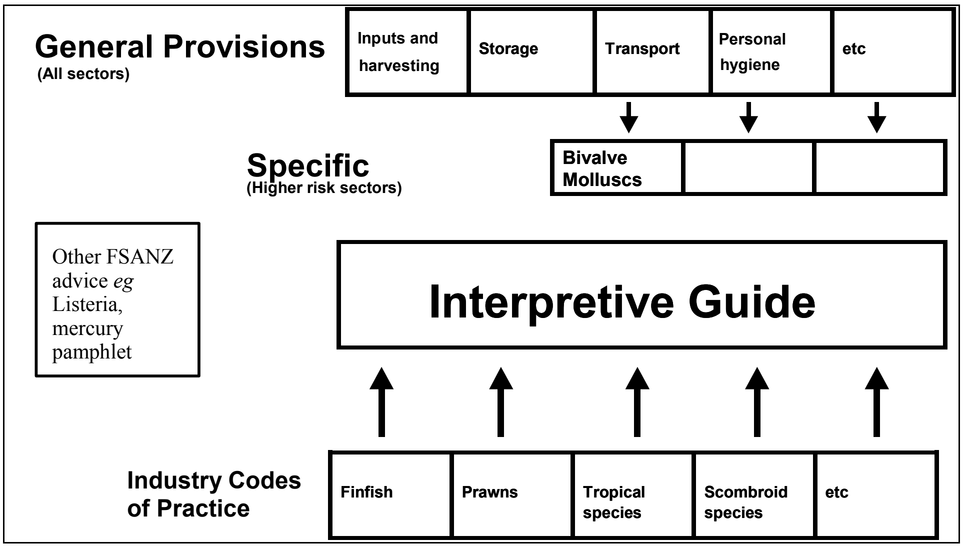
Figure 1 outlines the relationship between general provisions, specific provisions for higher risk sectors, and guideline documents that will assist regulators to interpret the Standard and industry to comply with the Standard.

Figure 1: Regulatory framework for food safety management in seafood



The general provisions are designed to minimise food safety hazards, and cover seafood primary production and processing activities that are not currently regulated under the Code. Such provisions are similar to the provisions in Chapter 3 of the Code (Standards 3.2.2 and 3.2.3), but tailored to the needs and situation of the seafood primary production sector. These provisions would include requirements to ensure that food was not contaminated during its production or handling, that adequate temperature control of the food is maintained, and that staff have the necessary skills and knowledge about food safety for the work they undertake. This option is intended to include simple on-vessel processing such as the gutting and filleting of finfish.

The specific provisions address identified higher risk seafood sectors, and require those seafood businesses to implement written food safety management systems such as Standard 3.2.1. In the case of seafood businesses producing bivalve molluscs, it will be mandatory to comply with pre-harvest provisions identified in the Australian Shellfish Quality Assurance Program. This will ensure that bivalve molluscs are only harvested under conditions that assure their safety. Additionally, these businesses will be required to implement food safety programs for the post-harvest sector up to the back door of the retail sector. This is consistent with the Ministerial decision of December 2003 on food safety management in Australia to only have requirements for food safety programs for sectors that have been identified as higher risk and where it has been demonstrated that the benefits will outweigh the costs. In this regard, Ministers agreed to specifically recommend the introduction of food safety programs for oysters and other bivalves following a benefit-cost analysis undertaken as part of the National Risk Validation Project.

Regulators will be assisted with enforcement by the development of an interpretive guide prepared by FSANZ, and industry will be assisted by tools such as guidelines and templates to comply with the standard. States will replace any existing standards with the new Primary Production and Processing Standard for Seafood (in the Code) and thus achieve a single, national, approach to food safety along the seafood supply chain.

6.5 Summary of options

The three options proposed above may be summarised as follows:

NATURE OF FOOD SAFETY CONTROL	OPTION 1 Status quo	OPTION 2 Mgt of higher risk only	OPTION 3 Basic Safety Provisions + Mgt of higher risk
Current arrangements:			
-General obligation under Food Acts to produce safe food	✓	✓	✓
-Food Std Code provisions (except for primary production)	✓	✓	✓
-State and Territory schemes (NSW, VIC)	✓	✓	
-Voluntary industry codes of practice	✓	✓	✓
General Provisions: Food safety practices applied to primary production end of seafood sector (similar to current hygiene requirements for the manufacturing, retail and food service sectors but tailored to seafood industry)			✓
Specific Provisions: Standard 3.2.1 (Food Safety Programs) or equivalent applied to higher risk activities of the seafood industry		✓	✓

The proposed options are considered further in the next section of the report where an impact (benefits versus cost) analysis of the various options is undertaken.

7. Impact analysis for seafood

FSANZ must consider the impact of various regulatory (and non-regulatory) options on all sectors of the community when it considers measures to mitigate public health and safety risks, including the seafood sector, governments, and consumers. The benefits and costs associated with any proposed amendment to the Code must be analysed using regulatory impact principles with the view to choosing the alternative with the maximum positive impact, whist minimising the regulatory burden on industry.

7.1 Affected Parties

The main stakeholders in the introduction of a new Standard are:

- Consumers - Australian consumers of seafood and the community.
- Seafood industry - Businesses involved in the primary production, processing, distribution and wholesaling of seafood products and those involved in the importation of seafood for the Australian market.
- Government - Government agencies (National, State and Territory, and Local) responsible for the enforcement of food safety regulations and for providing health care.

7.2 Option 1: the status quo

7.2.1 Benefits of Option 1

7.2.1.1 Consumers and the community

Australian households spend about 2.5 per cent of their food budgets on seafood products, which is about the same level as for poultry[19]. A study of consumer attitudes in Sydney and Perth found that the perceptions that fish is healthier than meat and that it adds variety to the diet were major factors influencing consumption. However uncertainty about safety and contamination, a lack of knowledge about seafood and high prices were major barriers to increased consumption[20]. Public health professionals also advocate seafood in the diet as a means to address obesity and as a good source of omega-3 fatty acids[21].

The consumption of seafood is valued by consumers and can confer considerable nutritional benefits. For example, fish is an excellent source of protein, is low in saturated fat, is a good source of some vitamins and is an excellent source of iodine.

7.2.1.2 Seafood industry

Apart from the current obligation in Food Acts to produce safe food, the regulatory regime of most State and Territory governments, with some exceptions, places few specific food safety requirements on seafood businesses in the primary production sector. Only NSW and Victoria, the smaller seafood production States, have put in place mandatory safety and hygiene regulations over the entire seafood supply chain.

In the other jurisdictions, hygiene and safety outcomes are mainly influenced by industry guidelines and codes of practice and by the regulation of export establishments (where these establishments also supply the domestic market) based on HACCP programs[22].

Industry bodies report that a significant majority of Australian seafood businesses do follow industry guidelines and codes of practice and incorporate good hygiene practices into their normal business operations[23]. The consequence of applying self-regulation is of commercial benefit to these businesses because good food safety practices enhance their capacity to meet market needs and achieve higher returns from their products[24].

Seafood businesses that meet food safety needs through a formal food safety program report additional benefits including: reduced wastage, lower maintenance costs, production savings, enhanced understanding of their own business and improved management practices[25].

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19 Australian Bureau of Statistics, 6535.0 *Household Expenditure Survey, Australia*.
20 FRDC/Ruello and Associates (September 2002) *Retail Trade and Consumption of Seafood*, pp 14
21 Mori, T. (2001). *A health promotion program incorporating fish for withdrawal of antihypertensive drugs in overweight hypertensives*, FRDC Project No. 2002/242, presented at Seafood Directions 2003. Also in FRDC (2001) *What's so healthy about seafood?*
22 For more information, visit Australian Quarantine and Inspection Service website - www.aqis.gov.au
23 Information provided by industry members of the Seafood Standard Development Committee (SDC), Seafood Services Australia and the Sydney Fish Market.
24 Information provided by industry, particularly the Sydney Fish Market.
25 NRVP feedback from focus groups, page 108.

7.2.1.3 Government

The current regulatory regime places few specific safety requirements for the hygienic production and processing of the seafood in most jurisdictions. Hence there is little pressure on Government enforcement resources.

7.2.2 Costs of Option 1

7.2.2.1 Consumers and the community

Current regulatory arrangements mean that some businesses are not required to undertake specific action to effectively manage food safety. The current Food Acts have a general obligation for primary producers to produce safe food – but does not give industry any guidance on these obligations. Where there is unmanaged risk, this gives rise to food-borne illness and imposes costs on consumers. Costs include personal distress, medical treatment, and time off work (patients and carers), with possible implications for forgone household income.

FSANZ estimates about 500,000 cases of food-borne illness could be attributed annually to seafood. Two studies published by the Food and Agriculture Organization (FAO)[26] reported that (i) seafood accounted for between 4.4 and 16.1 per cent of food-borne illness outbreaks in Western countries, in cases where the food vehicle for the outbreaks were known, and that (ii) seafood was reported to be involved in 10-25 per cent of food-borne disease outbreaks in developed countries. Based on this information, FSANZ estimates that 10 per cent of all food-borne illness in Australia might be attributable to seafood (approximately 500,000 cases annually). The seafood industry advise that over 1.1 billion seafood meals are consumed annually in Australia, thus the frequency of illness represents a very small fraction of the seafood meals consumed.

The direct cost of food-borne illness to the Australian community was estimated by the Allen Consulting Group to be $350 per case[27]. Hence, taking account of the 5.4 million cases of food-borne illness annually, discounting an estimated 20 per cent of cases for in-the-home contamination, provides an estimate of $150 million per year as the cost of food-borne illness to the Australian community associated with the consumption of seafood.

Raw-ready-to-eat seafood (oysters and other bivalve molluscs) was ranked in the top five high-risk food industry sectors in Australia by the National Risk Validation Project[28], on the basis of this sector's history of food-borne illness. The NRVP estimated the average cost of illness from eating raw-ready-to-eat seafood at $4.87 per meal, far higher (by a factor of 10) than the cost of any other high-risk food sector considered in the report[29].

[26] Martinez, I., James, D. and Loreal, H. (forthcoming) *Application of modern analytical techniques to ensure seafood safety and authenticity*, technical paper prepared by the Food and Agricultural Organisation of the United Nations. Cato, J.C. (1998) *Seafood Safety – Economics of Hazard Analysis and Critical Control Point programs*, FAO Fisheries Technical Paper – 381, Food and Agricultural Organisation of the United Nations.

[27] Allen Consulting Group (May 2002) *Food Safety Management Systems: costs, benefits and alternatives*.

[28] Food Science Australia & Minter Ellison Consulting (2002), *National Risk Validation Project*, Final Report (NRVP).

[29] NRVP page 87 and Appendix F.

Improvements in the risk management of bivalve molluscs since the NRVP collected this data imply that, currently, the costs to consumers should be lower than this estimate[30].

Consumers typically respond to outbreaks of food-borne illness in seafood by reducing their demand for seafood products. For example, following contamination of NSW oysters in 1997, NSW consumers immediately reduced their demand for oysters by 85 per cent. They also immediately reduced their demand for all seafood products by 30 per cent, indicating that consumers readily generalise a specific seafood risk to the broad category of seafood products[31].

However, despite consumers' immediate reactions to outbreaks of food-borne illness, demand for seafood recovers over time. Notwithstanding 24 outbreaks associated with raw-ready-to-eat seafood[32] during the 1990s, consumer demand for seafood has increased steadily over the medium term[33]. The implication is that while consumers immediately perceive costs when outbreaks of food-borne illness occur, these short-term costs are not sufficient to outweigh the perceived benefits of seafood to consumers over the medium-term.

<u>7.2.2.2 Seafood industry</u>

Each outbreak of food-borne illness imposes an immediate cost on industry, by reducing sales revenues for the implicated product and with follow-on effects to the seafood industry more generally[34]. A succession of outbreaks will repeatedly reduce industry sales revenues in the short term. In addition, small remote communities that derive a very substantial part of their income from fishing would be particularly vulnerable to outbreaks of food-borne illness. An adverse incident would have very serious implications for the economic base for these communities[35].

Apart from the bivalve mollusc sector, under current regulations, only seafood businesses in the primary production sector in NSW and Victoria incur compliance costs for food safety. These costs are very small.

Under current arrangements, the bivalve mollusc sector must pay the majority of the cost incurred by their SSCA who implement and examine requirements set out by the ASQAP in their jurisdiction.

<u>7.7.7.3 Government</u>

The current regulatory regime places few specified safety requirements on the primary production end of seafood supply chain in most jurisdictions. Hence there is little pressure on the resources of enforcement agencies. Only NSW and Victoria currently apply hygiene and safety regulation on the seafood industry from the production end of the chain; and only one seafood sector is regulated (through licensing arrangements and not under health legislation) by all jurisdictions: the sector producing oysters and other bivalve molluscs.

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30 See discussion of public health risk in earlier section of this report, the Regulatory Problem.
31 NRVP page 87.
32 NRVP page 39.
33 FRDC/Ruello and Associates, *op. cit.*
34 As the NRVP case study of contaminated bivalve molluscs in NSW showed.
35 NRVP page 83.

The public health system e.g. hospitals, provision of pharmaceuticals, etc contributes to the care of people with food-borne illness and hence any food-borne illness associated with seafood imposes cost on government.

7.3 Option 2 – A Primary Production and Processing Standard targeting high-risk seafood activities only

7.3.1 Benefits of Option 2

7.3.1.1 Consumers and the community

Consumers and the community will benefit from the greater assurance of the safety of the high risk seafood products: oysters and other bivalve molluscs. Outbreaks of food-borne illness have arisen from these high risk products in the past and imposed costs on consumers in the form of personal distress, incidents of death, costs of medical treatment, and time off work (patients and carers) which also implies some forgone household income. Under Option 2 the risk of future outbreaks will be minimised and hence the costs to consumers will be substantially reduced.

The benefits to the community of introducing food safety programs into the high risk bivalve mollusc industry were calculated by the National Risk Validation Project at $26.4 million per year[36]. These benefits mainly accrue from a nationally consistent approach to managing bivalve safety, through a system that doesn't permit opt-out by any State or Territory, and which enables food safety portfolios in all jurisdictions to audit the system.

7.3.1.2 Seafood industry

Improvement to the management of the safety for high risk seafood products will benefit industry because the recurring reductions in consumer demand and product sales that have resulted from incidences of food-borne illness, such as those that occurred as a result of the Wallis Lake outbreak, would be minimised under this option.

The consequence will be fewer incidents of food-borne illness and fewer highly visible outbreaks that have been a feature of the past and may still occur under the status quo.

The National Risk Validation Project showed that reductions in demand occur not only for the high risk product that caused the food-borne illness, but flow through to all seafood products. Ensuring that the safety of high risk products is appropriately managed on the basis of risk from boat to plate will improve safety overall and protect the sales revenues of the seafood industry. This is likely to have a positive impact on both the local and international markets.

Nationally consistent, mandatory requirements that ensure compliance with ASQAP and with food safety programs will contribute to a consistent record of safety for bivalves, thereby reducing the chance of something going wrong in one State and putting the entire sector at risk.

[36] NRVP page 7.

7.3.1.3 Government

The government sector may benefit from the material improvement in the safety of seafood products and fewer incidents of food-borne illness through lower utilisation of public health services. While this is a true benefit to government it may not translate into lower public expenditure. For example, public hospitals have an obligation to provide health care for the whole community and for a broad range of ailments and medical emergencies, and will respond to lower utilisation of their services from food-borne illness by providing quicker services to patients with other ailments. In practical terms the benefits to government could be negligible[37].

7.3.2 Costs of Option 2

7.3.2.1 Consumers and the community

This option will not impose costs on consumers or the community, over and above the costs incurred under the status quo.

7.3.2.2 Seafood industry

The impact of Option 2 limited to the high risk industry sector producing oysters and other bivalve molluscs. Businesses in this industry sector already comply with State based versions of ASQAP and, in some States, are required to have post harvest food safety programs. These requirements are administered by the States and Territories as a condition of obtaining an aquaculture licence. The additional costs on oyster growers and other primary producers in this sector as a result of this option will impact on those not already required to have food safety programs post harvest.

The effectiveness of ASQAP requirements in addressing the health and safety risks in the pre-harvest shellfish sector (including biotoxin testing) is recognised by all jurisdictions, although only recently by NSW. The cost of mandating compliance in the Code with specific pre-harvest requirements (stated in ASQAP) and food safety programs for the post-harvest activities is expected to be small, as compliance is mostly in place.

There will also be some additional compliance costs incurred further along the supply chain, for example by distributors and wholesalers, in meeting the requirements of a food safety program for these products.

7.3.2.3 Government

This option will not significantly expand the responsibilities of government enforcement agencies for the shellfish sector, as these arrangements already exist (e.g. ASQAP), and hence the impact on their resource requirements should be small.

[37] See discussion in the NRVP final report on page 79. The report states that any resources freed up in the health field because of lower incidence of food-borne illness will be used elsewhere (in the health field).

7.4 Option 3 - A risk-based Primary Production and Processing Standard to improve the overall safety in the seafood supply chain

7.4.1 Benefits of Option 3

7.4.1.1 Consumers and the community

Consumers benefit from the greater assurance of safety of the high risk seafood products of oysters and bivalve molluscs, as with the previous option.

In addition, Option 3 addresses safety risks comprehensively across the seafood industry so that consumers also benefit from greater assurance of the safety of all the lower risk products. This option will achieve a through-chain consideration of food safety, and eliminate gaps and inconsistencies in State and Territory approaches to the current management of seafood safety. It will improve on the status quo where there are inconsistencies in safety practices, particularly at the primary production and processing end of the seafood industry, and at the interfaces between the primary production and the processing sectors.

While the seafood industry has benefited from industry codes of practice and guidelines, these codes and guidelines are voluntary and a proportion of seafood businesses are not compliant with them[38]. The proposed standard would make a clear statement, obliging all seafood businesses involved in primary production and processing to achieve an appropriate level of hygiene and safety. Basic food safety requirements across these sectors of the industry will improve the safety of seafood products for consumers by reducing food-borne illness.

The international literature shows that the burden of food-borne illness attributable to seafood is sourced from a broad range of products, the high risk and the lower risk products.[39] The consequence of implementing a comprehensive set of management strategies under this option, including for the majority of seafood products that are lower risk, will be to significantly reduce the likelihood and severity of food-borne illness in the Australian population. The costs to consumers of food-borne illness – personal distress, medical treatment, and time off work (both patients and carers) which implies some foregone household income – will be reduced under this option and the greater assurance of the safety of all seafood products will benefit consumers.

Imported seafood products will be required to demonstrate an equivalent level of safety to domestically produced products. This measure will ensure that consumers can feel secure in the knowledge that all seafood, regardless of where it is sourced, meets the same level of food safety.

If the current cost of food-borne illness associated with seafood is estimated to be $150 million p.a. and the greater safety of the full range of seafood products under this option can reduce food-borne illness by between 20 and 50 per cent, then the benefit to the community would be in the range of $30 million to $75 million per year.

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[38] Information provided by industry members of the Seafood SDC.
[39] Martinez, James and Loreal, *op cit*, and Cato, *op. cit*.

7.4.1.2 Seafood industry

Industry will benefit from the reduction of the periodic disruptions to sales that occurred in the past in association with highly visible outbreaks of food-borne illness, because under this option (as with the previous option) these outbreaks will be further minimised.

This option also supports the widespread adoption of good hygiene practices, by all seafood businesses in all sectors of the industry. The minority of seafood businesses that currently do not follow industry codes of practice, and whose hygiene can be improved, will be required to comply with the new standard. Hence the level of food-borne illness associated with poor hygiene practices in the industry can be reduced. For consumers, this means fewer experiences of food-borne illness and a higher regard for the safety of seafood. Industry will benefit from the greater consumer satisfaction with the safety of seafood, which translates into a lift in demand for its products and higher sales.

7.4.1.3 Government

The government sector may benefit from the material improvement in the safety of seafood products under this option, compared with the status quo, because the lower incidence of food-borne illness should result in lower utilisation of public health services. While this is a true benefit to government, it may not translate into lower public expenditure. For example, public hospitals have an obligation to provide health care for the whole community and for a broad range of ailments and medical emergencies, and will respond to lower utilisation of their services from food-borne illness by providing quicker/enhanced services to patients with other ailments. In practical terms the benefits to government could be small[40]. However, government will benefit in terms of greater consumer confidence in the ability to ensure a safe food supply.

Mandating specific requirements for bivalve molluscs in the Code will provide government with a more appropriate legislative basis for regulation i.e. the approach is centred on food safety rather than existing aquaculture legislation that focuses on licensing rather than food safety. It will ensure a single, national approach to the safe production these higher risk products.

7.4.2 Costs of Option 3

7.4.2.1 Consumers and the community

This option will not impose costs on consumers or the community, over and above the costs incurred under the status quo.

It is considered that the additional compliance costs incurred by seafood businesses under this option are unlikely to be passed on to consumers. However, if it did occur, any increase would be minimal, as the wholesale price of seafood is frequently set by auction. Furthermore, industry bodies have advised that the majority of seafood businesses already undertake basic safety practices.

[40] See discussion in the NRVP final report on page 79. The report states that any resources freed up in the health field because of lower incidence of food-borne illness will be used elsewhere (in the health field).

Therefore, for these businesses, the proposed provisions would not adversely affect their operating costs and there would be no costs passed on to the consumers.

7.4.2.2 Seafood industry

The impact on producers of oysters and other bivalve molluscs under this option will be the same as under the previous option, essentially imposing some additional compliance costs where post harvest food safety programs are not yet in place.

In addition, this option mandates basic food safety obligations on all seafood businesses. The mandatory nature of the basic food safety obligations will be new for businesses in the primary production sector, with the exception of producers in NSW and Victoria. Fulfilling the basic food safety provisions required under this option is anticipated to have little impact on those seafood businesses which either supply the domestic market to the standards required under export controls or comply with the voluntary industry standards and codes of practice.

Advice from industry bodies such as Seafood Services Australia and the Sydney Fish Market indicates that the majority of seafood businesses already undertake basic safety practices as set out in industry codes of practice and guidelines to at least the level required under this option. For these businesses, the proposed provisions would not affect their operating costs.

Option 3 will impact on seafood businesses that do not comply with industry guidelines. The basic food safety provisions may require them to change work practices. The impact will vary across sectors of the industry. For example, fishing boat operators who undertake simple on-board processing, such as gutting, may only be required to change their work practices and provide basic temperature control. This imposes a once-off time cost on the operators to learn the new procedures, plus the cost of ice or other refrigeration.

Businesses that currently do not follow industry guidelines or do not focus on hygienic production would incur increased costs. The costs may be comparable to those experienced by NSW during the implementation of their State-based hygiene and safety regulations.

All NSW seafood businesses, up to the back door or retail, have paid a once-off registration fee of $100. SafeFood Production NSW is planning to introduce annual fees, to contribute to its costs of enforcement and auditing, but to date a fee structure has not been determined and the regulator is working closely with industry on this matter. Implementation of food safety regulations in this part of the seafood industry is being undertaken in stages.

The wildcatch sector has received support and assistance through several training workshops that explained the regulations and provided guidance specifically to the fishers on how to develop a food safety plan for their businesses. The cost to fishers was $65 to attend the workshops, plus their time necessary to apply the training to their business. The first audits of fishers commenced in November 2003. SafeFood Production NSW plans to continue implementation across the seafood industry, with the aquaculture and smoked fish sectors next in line. The compliance costs for these sectors will be similar to the wildcatch sector[41].

[41] Information supplied by Safefood Production NSW.

Victoria has enacted legislation for a through-supply-chain regulation of all seafood businesses. The legislation will come into force on 1 July 2004 for wildcatch and aquaculture businesses, at which stage they will be required to obtain a licence and demonstrate they are meeting the basic requirements of the Victorian Food Act. They will be required to prepare a food safety plan by the end of the first year. The regulator, Primesafe, proposed annual fees for businesses, dependent upon the level of annual throughput. Hence the fees are less costly for the smaller operators, although audit fees will be on top of this.[42] There is no advice at this stage on likely audit costs.

The examples above of the flow on costs to industry of States' recovery costs to implement food safety schemes are indicative. It should be recognised that costs to implement food safety schemes may vary across jurisdictions. However, having a single national standard will make for a more efficient process.

Businesses will be assisted to identify and comply with the requirements of the standard by following existing industry codes of practice and guidelines and other materials such as templates.

Other sectors of primary production that involve more substantial transformation of the seafood, or land-based operations such as aquaculture, may be required to install new services and equipment to meet basic hygiene requirements. The extent to which this option will require new equipment and add to industry costs is not known at present. However, it is presumed to be modest.

Question:

Can industry provide information and examples of the costs incurred by businesses as they change their operating procedures and implement good hygiene practices? In particular, how difficult is it for the smaller operators to implement good hygiene practices, especially where an industry code of practice is available to guide them?

7.4.2.2 Government

The new Standard will expand the responsibilities of government enforcement agencies at the primary production end of the seafood chain. The agencies have indicated that they are not expecting an increase in resources to address their new responsibilities and will respond to the situation by prioritising their efforts towards the higher risk areas[43]. A possible management option would differentiate between the lower risk businesses, that could be licensed but not systematically inspected, and the higher risk businesses that would be subject to rigorous enforcement[44].

Enforcement agencies will be assisted by the development of a guide developed by FSANZ, to aid in the interpretation of the standard.

42 Information supplied by Primesafe.
43 Information provided by government members of the Seafood SDC.
44 Suggestion made by a government member of the Seafood SDC.

Some jurisdictions are likely to be faced with a major effort in implementing the new Standard. The experience of SafeFood Production NSW, bearing in mind that it is one of the smaller seafood producing jurisdictions, is that implementation can be accomplished within existing resources, where assistance to specific sectors of industry is staged over a period of years.

The staged implementation of the regulations in NSW - focusing initially on the wild catch sector and progressing to the smoked fish and aquaculture sectors - means that SafeFood Production NSW could apply the regulations within existing resources. The cost of running the training workshops for fishers was covered by industry ($65 per fisher) together with a subsidy from the Australian Department of Agriculture, Fisheries and Forestry. Extending hygiene and safety regulations to the seafood industry in NSW did not, in practice, impose new costs on the NSW Government but will vary across States. It did incur costs on the Commonwealth government, and would result in additional costs if the program were rolled-out to other jurisdictions.

8. Conclusions

The existing system, as described in Option 1, includes regulation across the food chain for seafood in the two smaller jurisdictions, requirements in the Code, the current general obligation in Food Acts to produce safe food and a strong lead by the seafood industry to develop a voluntary food safety standard. However, it is clear that this approach can be further improved to minimise food safety risks and that arrangements under the status quo do not fully meet the objective of this proposal, to effectively address the public health and safety risks associated with seafood. Food-borne illness imposes costs on consumers, industry and governments, and while the current arrangements only partially manage the burden of food-borne illness estimated for seafood, they still contribute a net-benefit to the economy.

Option 2 will provide more benefits than the status quo by targeting businesses in the high risk bivalve mollusc sector, and requiring these businesses to manage their food safety risks through compliance with certain pre-harvest requirements and documented food safety programs for specified post-harvest activities. Consumers will benefit, in comparison with the status quo, from a greater assurance of the safety of these products and a reduction in incidents of severe food-borne illness. Industry also benefits because outbreaks of food-borne illness, which reduce sales of the high risk products and have flow on effects of reducing sales of other seafood products, will be minimised under this option. Additional industry compliance costs from this option are expected to be small. The impact of the targeted arrangements will be minimal on the sector because it must already comply with a comprehensive program and will require little change to satisfy the requirements of a food safety management plan program. However, it is expected to have an impact on food safety by ensuring that no opt-out of the current system is possible and that food safety portfolios are empowered to audit the sectors. In comparison with the status quo, Option 2 will more effectively achieve the objective of this Proposal.

Option 3 will provide all the benefits of the previous option but will also deliver additional higher value benefits because it will provide a single, consistent, national regulatory arrangement to manage seafood safety and the impost will be commensurate with the risks posed.

For the primary production and primary processing segment of the seafood industry, it will mandate basic food safety provisions and a requirement for businesses to systematically examine their operations to identify potential seafood safety hazards and implement controls that are commensurate with the food safety risks. It will also specifically address identified higher risk activities. It will deliver a material reduction in public health and safety risks and a greater net benefit by reducing food-borne illness in Australia, because it will require those businesses currently not adequately managing basic food safety to do so.

Consumers will benefit from the lower risk of food-borne illness and industry will minimise the periodic losses of sales revenues that have occurred following food-borne illness outbreaks. For the government sector, data on the new seafood regulations in NSW indicate that the introduction of food safety regulation into the seafood industry may be accomplished with minimal additional resources. However how jurisdictions implement the standard and the related costs incurred will vary.

Option 3 will impose new costs on businesses only where they do not currently manage food safety adequately. Note that it is expected that a significant majority of seafood businesses will meet or exceed these basic requirements and the new standard will, therefore, not affect their operating costs.

Overall, Option 3 will most effectively meet the objective of this proposal. It is superior to the previous option in that it has the capacity to deliver greater reductions in food-borne illness, as it will address a greater range of public health and safety risks in the seafood sector in comparison to Option 2. Additional compliance costs for industry appear to be small and, in comparison to the previous two options, Option 3 will provide superior net-benefits to the economy.

The preferred option is Option 3 (a Primary Production and Processing Standard - targeting higher risk activities and requiring minimum food safety requirements for lower risk activities/sectors), which combines general and specific provisions for seafood production and processing based on risk. This option is preferred because:

- it is consistent with the findings and conclusions of the scientific evaluation of public health and safety risk;
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- the risk management strategy is commensurate with the level of public health risk identified in the risk ranking document and is in harmony with the approach agreed to by the Ministerial Council;

- the need for basic food safety and hygiene requirement is consistent with the requirement for the manufacturing and retail sectors to meet good hygienic practice as defined in Chapter 3 of the Code – Food Safety Standards 3.2.2 and 3.2.3;

- it represents a minimum effective standard with the highest net benefit, and the risk management approaches and their verification are commensurate with the risks posed; and

- it is consistent with Codex in requiring that all food production meet basic requirements of good hygienic practice.

In conclusion, Option 3 is preferred because it achieves the objectives of:

- effectively addressing public health and safety risks, and demonstrates the highest net-benefits to the Australian community;
- improving national consistency in the management of seafood safety;
- improving food safety management across the seafood supply chain;
- providing a preventive approach to the management of food safety;
- providing outcomes-based standards to allow maximum flexibility for business; and
- being cost-effective as demonstrated in the regulatory impact assessment.

A draft of the proposed Primary Production and Processing Standard for Seafood, consistent with Option 3 is located in Attachment 10.

9. Recommendation

It is recommended that Option 3 (Primary Production and Processing Standard for Seafood as described in Attachment 10) be adopted. This option will manage food safety risks in two ways:

(a) the requirement to adopt basic food safety provisions for lower risk seafood; and

(b) more stringent food safety management requirements for higher risk seafood in the primary production and processing sector. Specifically, for bivalve molluscs there will be mandatory requirements to comply with pre-harvest provisions in the Australian Shellfish Quality Assurance Program so they are only harvested under conditions that assure their safety. In addition, businesses that deal with bivalve molluscs post-harvest up to (but not including) the retail sector will be required to implement food safety programs.

(c) a nationally agreed date for commencement of the Primary Production and Processing Standard for Seafood of one year from the date of gazettal is recommended. However, with provisions in the Code that allow for a compliance requirement of 12 months after gazettal of a variation to the Code, this means there is effectively a two year lead in period before businesses are required to comply.

This is also consistent with the decision by Ministers at their meeting in December 2003 where it was agreed that the implementation of national food safety management options for high risk businesses would be implemented by all States and Territories, no later than 2 years after gazettal of the standard.

10. Implementation, monitoring and review

Once accepted into the Code, the proposed Primary Production and Processing Standard for Seafood would become mandatory on a national basis. It would then be adopted into the appropriate legislation of each Australian State and Territory, providing each jurisdiction with the necessary legal basis for enforcement of the Standard.

Factors influencing successful implementation of the Standard include:

- implementation timeframe;
- provision of a suitable compliance timeframe for industry;
- implementation of appropriate audit management and inspection systems; and
- appropriate tools to provide assistance and guidance to industry (of which many currently exist).

Because of the non-prescriptive nature of the new seafood Primary Production and Processing Standard, interpretive documents are essential for enforcement officials (such as Environmental Health Officers) to assist with consistent implementation and for training organisations helping seafood businesses to meet the requirements of new standards. FSANZ will develop an interpretive guide to the Primary Production and Processing Standard to aid consistent interpretation of the standard by enforcement agencies. The guide will be developed in conjunction with jurisdictions and the Implementation Sub-Committee (ISC).

To a large extent, implementation is the responsibility of the States and Territories. The issue of how State and Territory legislation will apply to primary production (currently these are not considered to be food businesses) under the Model Food Act/State and Territory Food Acts is a matter that will need consideration. The Primary Products Working Group of the Food Regulation Standing Committee has undertaken responsibility for examining this matter further.

A qualitative review of the implementation of the Food Safety Standards (Chapter 3)[45] identified that the States and Territories were at different stages of implementation as a result of:

- dissimilar timing of adoption;
- diverse approaches to communicating with food businesses;
- widely different context of implementation; and
- different choices in aspects of implementation including inconsistencies in interpretation.

The Implementation Sub-Committee (ISC) of the Food Regulation Standing Committee is examining these issues.

The consistent implementation of the seafood standard will be facilitated nationally by ISC. ISC is charged with responsibility for overseeing cross-jurisdictional agreement on consistent approaches to implementing and ensuring compliance with food standards.

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[45] Campbell Research and Consulting (2003). Food Safety Standards Implementation Project. Report prepared for Dept of health and Ageing, Canberra, June 2003

ISC will have a major role in the implementation aspects of the standard to ensure consistent interpretation of issues related to the implementation and enforcement of the Standard, and to encourage cost-effective approaches to compliance and enforcement.

FSANZ will undertake baseline qualitative research on businesses in the seafood sector to determine awareness, knowledge and behaviour in relation to safe food handling, current regulations, sources of information and staff training. Follow up research will be undertaken at least two years after the standards are implemented in all States and Territories.

States and Territories will undertake routine surveillance of food for sale on the Australian market against the requirements of the Code as well as other specific surveillance activities.

11. World Trade Organization Notification

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

The proposed regulatory measures, the inclusion of a primary production and processing standard for seafood in Chapter 4 of the Code is likely to have an effect on trade for sanitary or phytosanitary reasons. Therefore a notification to the WTO under the SPS Agreement will be made by FSANZ.

Attachment 1

The Policy and Regulatory Framework for the Development of Food Standards

1. Policy and regulatory framework for food standards

A broad framework exists in Australia to guide the development of all food regulation. A review of regulatory arrangements in 1998 resulted in new arrangements for food regulation in Australia and New Zealand, agreed to by the Council of Australian Governments (COAG) in 2000[46]. These arrangements included the formation of the Ministerial Council that provides policy guidance to FSANZ to assist in the development of food standards.

The new structure also included the formation of a single agency, FSANZ, a bi-national authority that sets joint food standards for composition and labelling of food for Australia and New Zealand. It sets food safety standards in Australia, and from July 2002, also develops food standards for the primary production sector in Australia. FSANZ must adhere to specific legislative requirements and guidelines when developing food standards.

1.1 Council of Australian Governments

In Australia, there has been a major reorientation of the general regulatory framework and the processes for making regulations as well as to the framework for developing food regulation in Australia and New Zealand, and these have been endorsed by the Council of Australian Governments (COAG, 1997 and 2000[47]). The broader regulatory framework requires that regulation in Australia is pro-competitive, outcomes focussed, that the costs and benefits of any regulation are appropriately examined with the view to choosing the most effective alternative and that such regulation is regularly reviewed.

In 1997, the Prime Minister announced, in his statement *More Time for Business,* a review of food regulations in Australia[48]. The review aimed to examine the regulatory burden on business and to improve the clarity, certainty and efficiency of food regulatory arrangements, whist protecting public health and safety. Following a review of the recommendations, the Commonwealth, State and Territory Governments, through COAG, agreed on a national response to the Food Regulation Review. Included in the significant recommendations flowing from the review was the agreement to a national paddock to plate approach to food regulation to protect public health and safety. This included the formation of a single national agency, Food Standards Australia New Zealand (FSANZ), to set food standards and the formation of a new Ministerial Council, called the Australia New Zealand Food Regulation Ministerial Council, to consider all food safety matters from paddock to plate.

In 2000, a Food Regulation Agreement was signed by COAG, to put in place the new food regulatory arrangements. The Agreement aimed to:

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[46] Australian Government (2000). *Food Regulation Agreement* (Department of Prime Minister and Cabinet). http://www.dpmc.gov.au/docs/DisplayContents1.cfm?&ID=86

[47] Communique (1997). Council of Australian Governments Meeting. 7 June 1997. http://www.dpmc.gov.au/docs/DisplayContents1.cfm?&ID=82
Communique (2000). Council of Australian Governments Meeting. 3 November 2000. http://www.dpmc.gov.au/docs/DisplayContents1.cfm?&ID=85

[48] Howard, J. (1997). *More time for business*. Statement by the prime Minister, 24 March 1997. http://www.pc.gov.au/orr/reports/external/mtfb/mtfb.pdf

- provide safe food controls for the purpose of protecting public health and safety;
- reduce the regulatory burden on the food sector;
- facilitate the harmonisation of Australia's domestic and export food standards and their harmonisation with international standards;
- provide cost effective compliance and enforcement arrangements for industry, governments and consumers;
- provide a consistent regulatory approach across Australia through nationally agreed policy, standards, compliance and enforcement procedures;
- recognise the responsibility for food safety encompasses all levels of government and a variety of portfolios; and
- support joint Australia and New Zealand efforts to harmonise food standards.

The outcome of these arrangements has meant that for the first time in Australia, a single agency (FSANZ) develops all domestic food standards, including those for primary production and processing sectors.

The primary focus for these is on the protection of public health and safety. Under the Treaty arrangement with New Zealand, the promulgation of joint food standards for food hygiene measures is excluded. Therefore, primary production and processing standards under the Code will apply in Australia only.

1.2 *Food Standards Australia New Zealand Act 1991*

Under the FSANZ Act, the objectives for developing all food standards in descending order of priority are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to the:

- need for standards to be based on risk analysis using the best available scientific evidence;
- promotion of consistency between domestic and international food standards;
- desirability of an efficient and internationally competitive food industry; and
- promotion of fair-trading in food.

Food standards developed under the Act form part of the *Australia New Zealand Food Standards Code*, which the States and Territories in Australia adopt or incorporate within their food legislation without amendment. As part of the regulatory reforms, States and Territories have agreed to adopt new model food legislation as part of improving the consistency of food legislation across the country.

Food standards developed by FSANZ are also guided by overarching policy guidelines developed by the Ministerial Council and by the legislation under the FSANZ Act. In the case of Primary Production and Processing Standards, the overarching Ministerial guidelines specify higher order policy principles, which state they will:

- be a set of outcomes-based national standards for the relevant primary production and processing sectors/commodities;
- have a consistent regulatory approach across the Standards;
- be consistent with the s10 objectives of the FSANZ Act, recognising that the protection of public health and safety has priority;
- be consistent with the approach outlined in Chapter 3 of the Code
- be consistent with internationally recognised Codex standards, save where, after consideration of a risk assessment, it is clear that the relevant standard does not sufficiently protect public health and safety in Australia;
- address food safety across the entire food chain where appropriate;
- facilitate trade;
- be not more trade restrictive and comply with Australia's obligations under World Trade Organization agreements;
- ensure that the regulatory framework promotes consumer confidence;
- ensure the cost of the overall system should be commensurate with the assessed level of risks and benefits;
- provide a regulatory framework that applies only to the extent justified by market failure; and
- provide for collaborative action among enforcement agencies to optimise the use of resources and effectiveness.

2. Development of a Primary Production and Processing Standard for Seafood (Proposal P265)

Proposal 265 (P265) 'Development of a Primary Production and Processing Standard for Seafood' was raised by FSANZ in December 2002 under its mandate to develop domestic standards for the primary production and processing of food.

The seafood sector includes a number of products and activities that, unless well managed, may potentially have serious impacts on public health and safety. Recently, some State governments have developed seafood safety schemes to ensure that a 'boat to plate' (i.e. paddock to plate) approach to seafood safety was implemented across the seafood supply chain. However, other jurisdictions are not yet at that point, leaving the primary production end of the domestic seafood chain without mandated seafood safety schemes.

The seafood sector was also increasingly aware that food safety issues are vital to the continued growth of the industry, and was at an advanced stage of developing a national voluntary seafood safety standard. The industry has also produced a number of guidance documents on food safety across a range of sectors. It was therefore considered an opportune time to move these developments forward to a nationally mandated system.

As required by the Ministerial guidelines, a Standards Development Committee (SDC) was appointed in September 2002 by the FSANZ Board to provide advice to FSANZ on matters relevant to the standard development process. The SDC contributes a broad spectrum of knowledge and expertise covering industry, government, research and consumers.

In December 2002, the Board prepared a Proposal pursuant to section 12AA of the *Food Standards Australia New Zealand Act 1991* for the development of a Primary Production and Processing Standard for seafood.

The Board approved the Initial Assessment Report (Issues Paper) for release, agreed to seek public submissions, and directed the SDC to consider any available standards, including those developed by Seafood Services Australia Ltd, and the New South Wales and New Zealand Governments during its discussions and provision of advice on development of the mandatory national standard for seafood.

Since that time FSANZ, with advice from the SDC, has:

- considered the written submissions received in response to the public consultation on the Initial Assessment report;
- undertaken an evaluation of public health risks and identified sectors of the seafood industry that pose a potential high risk to safety;
- considered current strategies to manage those risks and determined, what if any, residual risks need to be managed;
- considered options for the management of these residual risks that aim to ensure the safety of seafood;
- conducted an impact analysis of the options to identify the option that meets the minimum effective regulation requirements , but effectively addresses any public health and safety risks associated with seafood;
- recommended a preferred option;
- considered the implementation of the preferred option; and
- drafted a proposed standard consistent with the preferred option.

This Report forms the second part of public consultation in the process of developing a Primary Production and Processing Standard for seafood. It takes into account the matters raised above and other deliberations of the Seafood SDC. Industry, government, agencies, consumers and other interested parties are invited to comment on these or any other matters relating to the development of a Primary Production and Processing standard for seafood.

Attachment 2

The Seafood Sector

1. Seafood sector

Seafood is an important part of the Australian diet. Domestic demand for seafood continues to grow: between 1991 and 1999, consumption of seafood in Australia increased by 12 percent (from 13.5 kg to 15.1 kg per capita)[49]. Australian households spend about 2.5 per cent of their food budgets on seafood products, which is about the same as expenditure on poultry[50]. The last few decades have also seen changes in the way Australians eat seafood, such as increasing consumption of sushi and smoked fish.

This increase in consumer demand is met to some extent by importing seafood products and by producing seafood through aquaculture. Approximately half of all seafood consumed in Australia is produced domestically and the other half is imported[51]**.** This means that any proposed food safety management systems for the primary production sector must adequately address food safety for imported as well as domestically produced seafood and must take into consideration the increasing trend for seafood to be produced through aquaculture.

1.1 Consumer attitudes to seafood safety

Public health professionals advocate seafood in the diet as a means to address obesity and as a good source of omega-3 fatty acids[52]. A study of consumer attitudes in Sydney and Perth found that the perceptions that fish is healthier than meat and that it adds variety to the diet were major factors influencing consumption. However uncertainty about safety and contamination, a lack of knowledge about seafood and high prices were major barriers to increased consumption[53].

The role of food safety systems is to minimise risks to public health, and in the process, to maintain consumer confidence in the food supply. Consumers have responded to outbreaks of food-borne illness in the past by reducing their demand for seafood. For example, following contamination of NSW bivalve molluscs in 1997, NSW consumers immediately reduced their demand for bivalve molluscs by 85 percent. They also immediately reduced their overall demand for seafood products by 30 percent, indicating that consumers readily generalise a specific seafood risk to all categories of seafood products[54]. Consumers also tend to respond by expressing a lack of confidence in the capacity of industry and government to ensure food safety, a situation that may also impact on trade.

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49 FRDC (2002). *Retail sale and consumption of seafood* (revised edition). Fisheries Research and Development Corporation (FRDC), Canberra.
50 Australian Bureau of Statistics, 6535.0 *Household Expenditure Survey, Australia*.
51 ABARE, (2003). *Australian Fisheries Statistics 2002*. FRDC, Canberra.
52 Mori, T. (2003) *A health promotion program incorporating fish for withdrawal of antihypertensive drugs in overweight hypertensives*, FRDC Project No. 2002/242
53 FRDC/Ruello and Associates (September 2002) *Retail Trade and Consumption of Seafood*, pp 14
54 NRVP page 87.

Other data, however, indicate that, despite a relatively short-term negative response to outbreaks of food-borne illness[55], there is solid demand for seafood over the medium term. For example, the share of seafood expenditure in household's food budgets was similar in 1993-94 to the share in 1998-99[56], indicating solid demand for seafood over the medium term. This demonstrates consumers perceive the benefits of seafood consumption to be greater than any risks associated with its consumption. Nevertheless, short-term negative responses can last up to a year and have a significant impact on some seafood producers or sectors, highlighting the importance of consumer confidence as an important issue for industry and government.

1.2 Nature of the industry

The Australian seafood industry markets a diverse range of approximately 600 marine and freshwater seafood species. The Australian fishing zone is 11 million square kilometres, the third largest in the world. Despite the size of the fishing zone, Australia is ranked 52nd in the world with respect to commercial tonnage. The industry ranges from tropical to sub-Antarctic, open ocean to estuarine, marine to freshwater, and operates in one of the world's cleanest environments

As the industry is geographically dispersed, it has a predominantly regional and rural workforce. In 2003, the Australian Bureau of Statistics reported 19 627 people directly involved in the wild catch, aquaculture, and processing sectors. Indirect employment in the commercial sector, and in compliance, transport, storage, wholesaling, and retailing, is considerably higher, and may approach 80 000 people[57]. A more detailed analysis of the industry was included in the Initial Assessment Report, released for public comment in December 2002.

The volume of seafood harvested from the wild is limited by the capacity of fish stocks. Most stocks are fished at their optimum sustainable level and there is little capacity to expand wild catch volume[58]. However, land and sea-based aquaculture is making an increased contribution to the seafood industry. Between 1991-92 and 2001-02, aquaculture produced approximately 24 percent of the total volume of seafood produced in Australia.

1.3 Value of the industry

The seafood industry is the fourth largest sector of the Australian food industry (by value) after beef, wheat, and milk. The gross value of production (GVP) during 2000-01 was estimated at $2.48 billion (adjusted figure)[59]. Since 1992, the GVP increased, on average, by 10 per cent per annum and aquaculture's share has risen from 15 per cent to 30 per cent.[60]

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55 NRVP page 39.
56 Australian Bureau of Statistics, 6535.0 *Household Expenditure Survey, Australia*.
57 FRDC (2000). *Investing for tomorrow's fish*. FRDC Research and Development Plan, 2000 to 2005. (FRDC, Canberra).
58 Australia Bureau of Rural Sciences, (2002). *Fishery status reports 2000-2001.* (A. Caton, ed.) DAFF, Canberra.
59 ABARE, (2003). *Australian Fisheries Statistics 2002*. FRDC, Canberra.
60 During 2002-03, although total production volumes rose to 249,000 tonnes, the GVP fell to $2.3 billion. This has been largely attributed to the lower export values for many species. Media Release 18 February 2004, Australian Seafood Industry Council.

Most species cultured in Australia are high unit value species such as southern blue fin tuna, Kuruma prawns, bivalve molluscs and Atlantic salmon. A breakdown of production by the Australian commercial fishing industry is shown in Figures 1 and 2.

Figure 1: State shares of fisheries production, by value (ABARE, 2003)

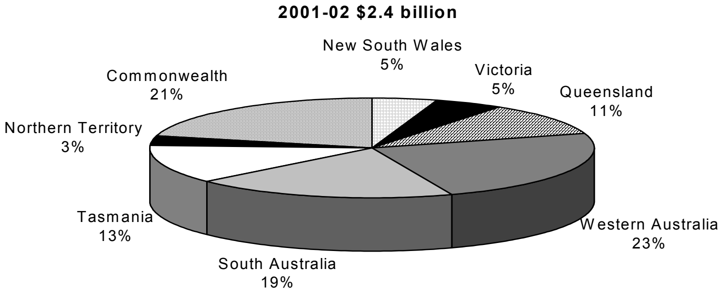
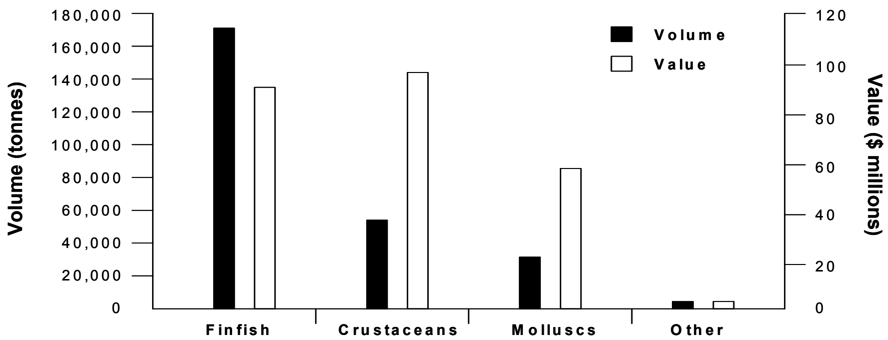


Figure 2: Australian seafood production (edible and non-edible), 2001-02 (ABARE, 2003)

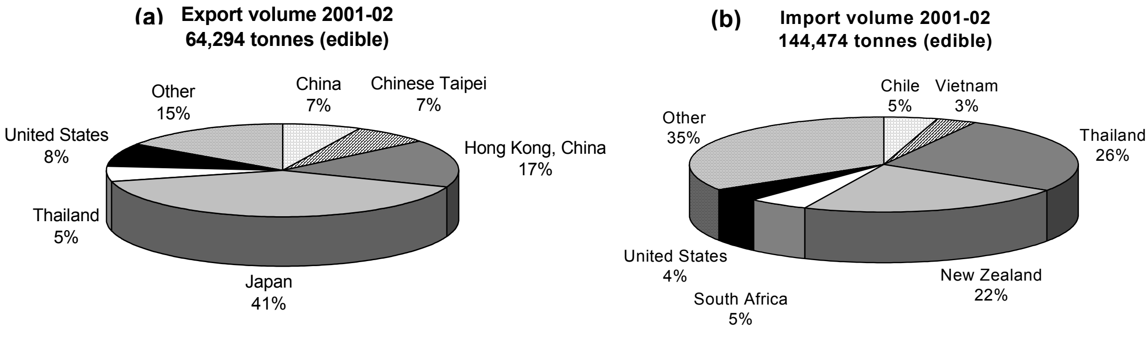


1.4 Volume produced by the industry

Of the 186,677 tonnes of seafood produced in Australia during 2001-02, approximately 66 per cent (122,383 tonnes) was consumed domestically. During 2001-02, Australia imported 144,474 tonnes of seafood, mainly from Thailand and New Zealand (Figure 3b), which represents approximately half the total seafood consumed in Australia per annum (by volume). By value, imported seafood represented 77 per cent of the total value of seafood consumed in Australia.

Thirty four percent by volume of domestically produced seafood is exported. The major export markets were Japan, Hong Kong, United States, China, Chinese Taipei, and Thailand, with these six markets making up 82 per cent of the total export volume (Figure 3a).

Figure 3: Volume of Australian edible fisheries exports (a) and imports (b) by country (ABARE, 2003)



In terms of the value of seafood produced in Australia, exports represented 87 per cent of total production. This comparison reflects Australia's position as an exporter of high value seafood species (e.g. rock lobster and abalone), with lower value species predominantly being traded in the domestic market.

Attachment 3

Consultation

FSANZ has a statutory obligation to consult with stakeholders in relation to food regulatory measures. This is undertaken through two rounds of public consultation: one following release of the Initial Assessment Report, and the other following the release of the Draft Assessment Report, as described on Pages (ii) and (iii).

In addition to statutory consultation, further consultative mechanisms have been built into the development process for the Primary Production and Processing Standard for Seafood. This reflects recognition of the need for close consultation with industry, regulators and consumers throughout the development of the Standard. This is considered particularly important as the setting of primary production and processing standards is a new function of FSANZ. Accordingly, in the early stages of standard development, the level of awareness of FSANZ processes in the community and within the primary production sector may be minimal.

In recognition of the need for broad and active consultation throughout the development of the seafood standard, FSANZ is committed to seeking stakeholder involvement via the following mechanisms:

- Seafood SDC - the role of the SDC is to provide input and advice from consumer, industry, government and research perspectives to FSANZ in the development of the standard;
- Working Groups - the Seafood SDC has established working groups to address the health risks associated with seafood, to facilitate risk assessment and to propose and assess risk management measures;
- Meetings coordinated by regulators in partnership with FSANZ, held in each of the jurisdictions, to exchange information and allow consultation with industry and other community members throughout the development of a seafood standard. Meetings have already been held in many jurisdictions;
- Regular progress updates posted on the Primary Production and Processing Standards section of the FSANZ web site;
- An electronic executive bulletin intended for CEOs and other executives of organisations with an interest in the development of a new national food primary production and processing standard for seafood; and
- Updates and progress reports included in a range of industry publications.

PUBLIC CONSULTATION

Written Submissions in Response to the Initial Assessment Report

A total of twenty-five written submissions were received by FSANZ in response to the Initial Assessment Report of Proposal P265. Submissions originated from a range of organisations and individuals representing industry sectors across the supply chain and all levels of government. A summary of the individual submissions is presented at Attachment 4.

A compilation of the responses to the specific issues raised for comment in the Initial Assessment Report is presented at Attachment 5. These issues mainly concerned:

- scope of the standard, including:

    - the inclusion of chemical and biological hazards within the standard and the Code as a whole;
    - at what point within the seafood industry the Standard should commence and cease to apply;
    - the position of ready-to-eat seafood under the Standard; and
    - the position of harvesting, handling and processing seafood on board fishing vessels under the standard;

- definition of seafood, including whether aquatic plants, reptiles and mammals should be regulated under the standard;
- scientific risk assessment process which underpins FSANZ's development of regulatory measures, and the provision of technical data for this purpose;
- suitability of existing standards, such as the industry-preferred voluntary standard (the Australian Seafood Standard), any State government standards and any international standards, to form the basis for the national mandatory standard; and
- options available to manage food safety risks, including:

    - costs and benefits of management options;
    - compliance and enforcement costs, mechanisms and concerns; and
    - the need for, and development of, guidelines.

The range of opinion on each of these issues is presented below, along with a short explanation of the approach taken in this Draft Assessment.

The scope of the Standard

A wide variety of opinions were expressed concerning the scope of the proposed standard. In general, submissions supported the principle of an outcomes based, non-prescriptive standard covering the entire seafood industry and focussed on food safety. Many expressed the view that the standard should impose requirements based on the level of public health risk posed by each industry sector. Some submissions supported a role for voluntary industry codes of practice and self-regulation. Divergent views were expressed by industry on the question of whether mandatory names for fish should be included in the standard.

In line with the Ministerial Council Guidelines, other policy advice and FSANZ's statutory objectives, the draft Seafood Standard (Attachment 10) put forward for comment in this Draft Assessment Report is an outcomes-based, non-prescriptive standard focussed on food safety. It covers the entire seafood industry to the extent determined by the level of public health risk posed by each industry sector and by the need to avoid duplication of, or inconsistency with, existing standards in the Code.

Inclusion of chemical and biological hazards within the Standard

Submissions highlighted a number of food safety hazards that were perceived as not being adequately addressed in the Code. These included allergens and physical hazards (e.g. fish bones), escolar wax esters, ciguatoxin and some microbial pathogens.

It was also suggested that maximum residue levels (MRLs) for pesticides and veterinary chemicals in seafood needed to be reassessed. A range of strategies to address these various hazards were suggested, including relying on interpretive or advisory guidelines to the standard, referencing relevant sections of other Chapters of the Code, and including specific provisions in the Seafood Standard. Industry generally preferred that the current provisions in Chapters 1 and 2 of the Code should be relied upon and simply referred to in the seafood standard.

The scientific evaluation and ranking of the public health risks posed by hazards in seafood in Australia (Attachment 9), conducted by FSANZ to underpin the development of suitable risk management strategies in the seafood sector, did not highlight any hazards that should be addressed by amendment to Chapters 1 and 2 of the Code. The draft Seafood Standard does not contain requirements concerning maximum levels of physical, chemical or microbiological hazards in seafood.

Certain hazards mentioned in submissions cannot routinely be assayed e.g. ciguatoxin, escolar wax esters. Maximum Residue Levels for pesticides and veterinary chemicals are (re)assessed on a routine basis by FSANZ, in conjunction with the Australian Pesticides and Veterinary Medicines Authority (APVMA), taking into consideration total dietary exposure from all food sources.

Coverage of the production and processing supply chain

Comments received on the coverage of the production and processing supply chain showed a broad range of opinion. Several submissions mentioned that the entire chain should be covered from harvest to retail, inclusive. However, others felt that it should only apply up to, but not including, the point of retail sale, or up to the point at which the Code currently applies. The question of whether the pre-harvest sector of aquaculture should be regulated also engendered varying opinions, with some believing that production inputs into aquaculture need to be covered by the standard.

The Seafood Standards Development Committee (SDC) advised that the seafood PPP Standard should cover all aspects of primary production and processing of seafood, from harvest/ capture (whether wildcatch or aquaculture) through to retail sale, to the extent determined by the level of public health risk posed by each industry sector.

The draft standard covers the pre-harvest sector to the extent that it requires seafood businesses to adopt an ‘inputs’ approach, using only inputs that do not contaminate seafood or adversely affect its safety and suitability.

Ready-to-eat seafood

The question of whether ready-to-eat seafood should remain covered under existing sections of the Code or be included in the Seafood Standard received comments supporting both views.

It is proposed that the primary production and processing of ready to eat seafood is covered in the draft seafood PPP Standard, to the extent determined by the level of public health risk posed by such products. Provisions elsewhere in the Code applying generally or specifically to such products will continue to apply.

Processing on board fishing vessels

The extent to which the standard should regulate seafood harvesting, handling and processing on board fishing vessels was the subject of many comments from submitters. Recommendations ranged from the view that no standard should apply, as the risks were low, to suggestions that food safety plans should be required. Mandating Good Hygienic Practice, addressing the risks through a voluntary code of practice and implementing a receival standard at the dock were also put forward as options. Several submissions advised that enforcing a standard on board vessels at sea would be difficult. The need for awareness programs or accredited food safety training was also raised.

The Seafood SDC advised that Good Hygienic Practices can and should be required of fishing vessels, including those only involved in harvesting and minor processing (such as gutting and gilling). The SDC recommended that the draft Standard require that fishing vessels must be constructed, maintained and used in ways that minimise the risks to the safety of seafood.

The definition of seafood

Most submissions agreed that the term 'seafood' should be defined so as to cover aquatic vertebrates and invertebrates including finfish, molluscs and crustaceans but excluding aquatic plants, reptiles and mammals. Three submissions suggested inclusion of aquatic plants within the definition, and one suggested inclusion also of aquatic reptiles and mammals, along with a suitable definition of the point at which they are considered to become seafood and thus subject to the provisions of the standard. Most submissions were in agreement that seafood taken for traditional purposes should also be excluded.

The Seafood SDC agreed that 'seafood' should be defined as 'all aquatic vertebrates and aquatic invertebrates, excluding amphibians, mammals and reptiles'. This definition excludes crocodile meat, seaweed and other aquatic plants, but includes ready-to-eat seafood. The SDC also recommended that the standard should not cover indigenous or traditional fishers, unless such seafood is offered for sale.

The scientific risk assessment process

The scientific risk assessment process, which underpins the FSANZ regulatory approach, received broad support. However, comments were received on the need to consider risk assessment work undertaken by others and to apply risk analysis in context. One submission suggested that the process seemed to be more appropriate to the establishment of food product standards. Some individuals identified that they were willing to provide data necessary for the risk assessment process, noting that significant data gaps existed. In one case, data could not be provided unless confidentiality could be assured.

In order to estimate and compare the relative risks associated with consumption of seafood in Australia, FSANZ prepared a risk ranking report (Attachment 9). It takes into consideration the multiple hazards potentially present, and assigns each commodity or group of commodities to a broad risk category: low, medium or high. Through this process, sectors of the seafood industry posing a higher public health risk were identified.

In compiling the risk ranking report, a wide range of literature and information from Australia and overseas was reviewed and evaluated. The report also drew on recent risk assessments that have been undertaken on Australian seafood.

Suitability of existing standards

Submissions generally suggested that existing voluntary regulations, codes of practice and guidelines should be recognised, in some form, under the standard. The suitability of using the industry-developed Australian Seafood Standard as a basis for development of the Primary Production and Processing Standard for Seafood was discussed, with views ranging across the spectrum. In general, most submissions suggested it would need modification or could be used, in part or in total, as a guideline to the standard.

Submissions also expressed the view that other regulations and standards, Australian and international, should be taken into account in developing the Seafood Standard, and parts used, as appropriate, in the standard or in the guidelines. The NSW Seafood Safety Scheme, the AQIS Export Control (Processed Food) Orders and the Codex Code of Practice for Fish and Fishery Products were mentioned as examples of existing measures that might be drawn upon.

FSANZ considered all appropriate existing seafood standards, regulations and codes of practice when developing the draft Seafood PPP Standard. Many of the principles upon which the industry-developed Australian Seafood Standard is based, also underpin the draft Standard.

Options available to manage food safety risks

Submissions canvassed options for appropriate food safety management systems. Implementation of HACCP-based systems and food safety plans for areas where the public health risk was judged to be highest received broad support, although questions regarding industry and government support and resourcing were raised. Industry were concerned about the criteria to be used for determining the extent to which HACCP-based food safety programs would be required of businesses. Voluntary codes of practice and non-regulatory guidelines were mentioned as being suitable where risks were low.

The proposed strategy for management of public health risks in the draft Seafood PPP Standard is based on a requirement for Good Hygienic Practice for all seafood businesses, supported by guidelines and industry codes of practice, and the implementation of HACCP-based systems (food safety plans) for areas where the public health risk is judged to be highest.

Compliance and enforcement issues

Industry bodies and representatives expressed concern regarding the impact of any standard on the industry and on practices within seafood businesses. In particular, industry expressed a desire to avoid unnecessary imposts and the potential for excessive cost-recovery revenue-raising by regulators at the expense of industry.

Industry and government submissions expressed the view that compliance and implementation costs associated with HACCP-based food safety plans were significant and had been under-estimated by FSANZ in the past. Information was provided detailing the costs of complying with current (HACCP-based) export certification schemes.

Industry also emphasised the need to avoid duplication of auditing and compliance activities (and hence costs) where a business supplied both domestic and export markets. Several submissions stated that businesses complying with export requirements should be deemed to comply with the domestic standard. Submissions also raised questions about the role, extent and system of audits that may be required under the standard.

A period of two to three years was generally nominated by industry as a preferred time frame for implementation of the Standard and for stock-in-trade provisions to apply. The need for government support to provide education and training was also raised.

Comment from government bodies covered issues including which level of government, and/or which government department, would have responsibility for regulation, implementation and enforcement of the standard. Audits were also discussed, incentive-based compliance schemes were generally supported, as was harmonisation with existing audit systems, such as those required by AQIS. Government bodies expressed a desire to avoid any duplication of current legislation, and to achieve genuine consistency on a national basis under the standard.

Once adopted into State and Territory legislation, enforcement of the Standard will become the responsibility of those jurisdictions. Policies regarding cost-recovery revenue-raising by regulators are set at that level of government in Australia.

FSANZ understands that a nationally agreed date for commencement of the Primary Production and Processing Standard will help to ensure national consistency, and will focus industry and regulators on the task at hand.

It is envisaged that a number of tools and resources will be developed to assist both industry and regulators in the implementation of the standard. A prime tool will be an interpretive guide to the Standard. This document will be developed by FSANZ in consultation with stakeholders. In addition, existing codes of practice developed and adopted by jurisdictions and industry, will provide further practical information. Existing codes of practice may be readily adapted to this purpose.

RESPONSES TO JURISDICTIONAL MEETINGS

In the period since commencing the development of a primary production and processing standard for seafood, consultation meetings have been held in the following jurisdictions: Tasmania, Victoria, Queensland, Western Australian, South Australia, New South Wales and the Northern Territory. Innovative strategies have included the use of video conferencing to engage distant communities in Western Australia (i.e. Broome, Karratha, Carnarvon, Albany, Geraldton, and Esperance).

Participants at each consultation were invited to provide their views orally, as well as through written submissions. Industry participants at the workshops focussed on the impact of any regulatory measures on their businesses, while regulators were interested in jurisdictional issues and the responsibilities.

These consultations were held during the period leading up to and following the release of the Initial Assessment Report and prior to the release of the Draft Assessment Report. In the lead-up to the release of the Draft Assessment Report, consultations have continued and have elicited valuable industry data and considerable feedback on support for the regulatory options being proposed.

IDENTIFICATION OF POTENTIAL NON-SCIENTIFIC RISKS

The development and implementation of good regulation can be influenced by a range of factors outside the potential hazards to the food supply that are evaluated in the scientific risk assessment. This broader set of risks typically includes factors such as community perceptions, political implications, regional implications and industry issues. In developing options for the regulation of the primary production and processing of seafood, FSANZ discussed this issue with State and Territory regulators, a consumer representative, and various members of the seafood industry. Such consultation assisted FSANZ to identify a range of non-scientific risks that, potentially, could affect the development and implementation of regulation for the seafood industry.

Consumer perceptions of seafood are ambivalent and pose a potential risk to the acceptance by consumers of any improvements to safety that new regulation may offer. A study of consumer attitudes revealed that, while consumers believe that seafood has some nutritional benefits, they lack sound knowledge about seafood products and are uncertain about the safety and possible contamination of seafood[61]. Furthermore, the study revealed that the correct labelling of fish was very important for 70% of consumers surveyed in Perth, and 73% of those surveyed in Sydney. Communication with consumers during the process of developing new regulation will continue to be important to foster greater consumer confidence.

Industry is concerned that implementation of any new regulation may bring with it large compliance costs, either through excessive regulation that is disproportionate to manage the hazards or through excessive government charges. Such concern, if not addressed, could result in a low level of compliance with new regulation and a lower level of benefit to the Australian community.

[61] FRDC/Ruello and Associates (September 2002), *Retail Sale and Consumption of Seafood*.

This concern can be addressed through a transparent process that demonstrates to all parties how the proposed regulatory measures relate to the scientific risk and provides benchmarks for industry to gauge the likely level of government charges.

The seafood industry contains a high proportion of small businesses, dispersed along rural and some remote coastlines, which potentially can make the implementation of any new regulation very difficult. Many regional communities are highly dependent on the continuing viability of their local seafood industry and may be resistant to change. These factors can be taken into account in the process of developing a new regulation, through a transparent process that demonstrates minimum effective regulation, and also the benefits to industry of consistently maintaining good hygiene and safety practices.

The staged approach to implementing food safety regulations in the NSW seafood industry indicates that regional dispersion of the industry need not be a barrier to the successful introduction of new regulations.

A further risk involves the potential for uneven implementation of a new regulation by the States and Territories. While each jurisdiction has responsibility to determine its priorities for enforcement, and the level of resourcing for its enforcement and auditing activities, there is nonetheless the issue that similar seafood activities anywhere in Australia should be subject to similar regulatory requirements.

The consequence of uneven implementation would be to reduce the credibility of the new regulation amongst industry, which would then be sceptical of its claims to be ‘nationally consistent’ and may doubt its other benefits. This risk can be addressed by clarity in the description of the new regulation, the provision of a comprehensive Interpretive Guide, and coordination between the jurisdictions in their implementation and enforcement of the Standard.

Attachment 4

Summary of Submissions

A public consultation period occurred from 18 December 2002 to 28 February 2003 for comment on the Initial Assessment of Proposal P265. During this period, 23 separate submissions were received by FSANZ. Two late submissions were also received.

The list of the submitters and a summary of their submissions is provided in the table below.

Organisation / Author (Abbreviation)	Summary / Major Points
Kanins Pty Ltd / Nigel Watt (Kanins)	• comments on the health and safety risks associated with treatment of Black Spot (melanosis) in uncooked prawns in Australia • notes that they believe there are serious health and safety problems with the current control practice involving dipping in sodium metabisulphite • suggested alternative is dipping in EverFresh (active ingredient 4-hexylresorcinol), free from health and safety concerns
Tasmanian Fishing Industry Council / Ralph Mitchell (TFIC)	• supports utilisation of the national industry seafood standard (SSA/ASIC application submitted to FSANZ) as appropriate within the standard, perhaps as interpretive guidelines • suggests marine plants should be included, while crocodile and mammalian meat should be excluded from the scope of the standard • chemical and biological hazards would not need to be listed specifically in the standard, rather they could be referenced from previous chapters of the Code • the seafood standard should regulate up to, but not including, point of retail sale • fishing vessels producing a live product that can demonstrate little or no significant risk of introducing a hazard should be exempt from a certified food safety plan – in line with the theory of minimal impost to industry • fishing vessels that process or store product on board may not have the facilities to accommodate regulatory inspectors on board, in which case the vessel skippers could be encouraged to obtain accredited training to cover food safety training on board • an awareness program would be a useful means of reinforcing the basics of food safety on board fishing vessels • suggests that a receival standard, whereby regulation/enforcement begins at the wharf (the receiver would be responsible for ensuring that seafood received from the vessel is safe to eat), may be used to encourage compliance together with lessening impost • any risk assessment process utilised in standard development needs to be specific to the situation to which it is being applied, particularly in the case of fishing vessels; a 'one size fits all' approach would be inappropriate • existing standards, such as TASQAP and the NSW Seafood Safety Scheme, should be incorporated into the interpretive guidelines as appropriate • the industry could utilise industry documents, such as ASIC's 'A Code of Conduct for a Responsible Seafood Industry' to provide objectives and principles, particularly where mandatory measures are ineffective

	• the seafood standard must apply equally to all seafood traded in Australia, regardless of its origin, in line with the WTO rules providing that a country cannot impose regulation on imports that do not apply domestically. • the time frame for standard implementation must be established through close consultation with industry, in accordance with the range of commodity types, business sizes, vessels and equipment, and communication skills involved in seafood production and processing in Tasmania • raises questions about the integrity of some aspects of the summary of the Wallis Lakes incident as an illustration of the cost to industry of risks associated with food-borne illness from seafood
Northern Territory Seafood Council (NTSC)	• supports the seafood standard as a means for providing consistency across Australia in regard to the safety of seafood • supports an outcome based, rather than a prescriptive standard, hence avoiding undue impost to industry and concurrently increasing consumer confidence in seafood • supports the SSA voluntary industry Australian Seafood Standard, as submitted to FSANZ • considers it essential that the seafood standard allow businesses to utilise solutions to any food safety risks as appropriate to the level of risk involved e.g. a HACCP plan or GMP may be appropriate in different situations • the seafood standard should cover from point of harvest through to point of retail • where there are already standards in place with which the retail sector must comply, the standard should refer to these rather than duplicate them • supports the SSA submission that the standard should recognise and reference the Australian Fish Names list • supports the SSA comment that the seafood standard must automatically recognise export establishments as complying with the standard
Seafood Export Consultative Committee (SECC)	Provides comments under two main headings: • incorporation of existing regulation into a PP&PS for seafood o raises concerns that state regulators would not have the capacity to implement and police a single standard, and that a single mandatory standard may duplicate existing regulation of seafood by AQIS o therefore the standard must contain provisions to recognise automatically export establishments as complying with the PP&P standard o or alternately that mutual recognition of audits by AQIS and each state regulator o AQIS should become a full member of the FSANZ SDC, given their extensive practical experience • the costs of existing regulation o current costs to industry are presented o duplication of existing regulation by State authorities would not be considered good value, or be accepted by industry
City of Unley / S. J. Sowter (Unley)	• raises the issue of which jurisdiction would be responsible for regulation and implementation of the seafood PP&P standard • suggests that production aspects would be best regulated by PIRSA • and processing aspects would be best regulated by the Department of Human Services
Food Technology Association of Victoria / David Gill (FTAV)	• the Technical Sub Committee of this association accepts the Issues Paper as presented and without further comment at this stage

Sontari Foods / Hope Kearney (Sontari)	• notes that food safety is a shared responsibility between the government (through FSANZ), industry, and the consumer • raises concerns about the definition of seafood – suggest that the standard should determine the point that aquatic product becomes food • notes that ABARE statistics regarding Australian seafood production volumes relate to green weight, hence there is an error in contribution of domestic consumption figures – imported seafood contributes around 65% to Australian seafood consumption volume • notes that importers may work with overseas suppliers who operate on strict codes of practice that are considerably tighter than those operating in Australia • agree that quality attributes and methodologies should not be enshrined in the code • believes that marine animals should be included in the standard • the seafood standard should apply through to point of sale, and should not exclude fishing vessels • upon consideration of the proposed SSA/ASIC standard, feels that a wider view is required for the Australian seafood sector than that of SSA, who does not engage with the considerable Australian seafood import sector • opposes formally incorporating the Australian Fish Names list into the standard, as suggested in the proposed SSA/ASIC standard • has considered the NSW Safe Food Production system and feels there are various deficiencies: • as the certificate is issued at time of payment of the fee, it is therefore easy to be deceived into thinking that a food safety plan actually exists • insufficient industry extension work has been undertaken by Safe Food NSW • audits are only authorised by Safe Food officers, passing over a wide range and high standard of commercial auditors • the program does not carry through to the consumer • notes that import legislation, although not perfect, seems to be working reasonably well
NT Government / John MacCartie (NT Govt)	• raises concerns regarding multiple audits – suggests that auditors need to be accredited to audit against more than one regime, or audit covering a lesser standard • questions whether consideration will be given to good corporate history e.g. an AQIS type bonus scheme • questions whether any national standard will have a national accreditation mark, or whether this will be left to individual jurisdictions • questions whether aquaculture and wildcatch ventures that sell at the door or over the gunwale will be subjected to the PP&PS or the Code • suggests that aquaculture be regulated from the start of culture • suggests that if the onus is on the supplier to sell safe food it will negate the need for heavy regulation of the primary production end of the chain

Seafood Council (SA) Ltd (SASC)	• the PP&PS should reference other parts of the Code where appropriate, further requirements should only be added where there are significant risks identified and public health benefits are greater than the cost of implementation • considers that the standard should not impose food safety regulations on businesses involved in the harvesting, handling and processing of seafood on board fishing vessels, as the public health risk relating to these activities is low • believes that a number of issues in the proposed SSA Standard need to be addressed prior to it being used to guide the national standard • specifically, the basis of the SSA Standard is the mandating of food safety programs for the whole seafood chain, whereas the Council believes that the standard should apply only to those elements of the chain that are at risk • believes that the principles underpinning ASQAP should be mandated through the Standard for all bivalve molluscs collected for human consumption • suggests that the Standard should not impose further requirements on sectors which are already meeting AQIS or other international requirements for food safety • believes that the industry should be encouraged to develop voluntary codes and that the Standard should provide for these to be mandated, or provided legislative recognition if requested by industry • believes there should be an option for sectors to demonstrate compliance with hygiene requirements by voluntary adoption of food safety programs with accredited third party auditors • does not support imposition of food safety programs on industry sectors unless there are strong public health reasons or there is strong industry support (and agreement by government) • considers that the frequency of audits should be appropriate to provide confidence that the system is under control, hence in the first instant there would be more frequent audits that would subsequently be reduced to an agreed level, with increased audits if there is evidence that the system is not under the level of control required
Environmental Health Unit, Queensland Health / Kerry Bell (Qld Health)	• concerned that there not be any duplication of existing legislation • current MRLs for seafood need revisiting: o current values have been derived in the main from mammalian studies o MRLs do not related directly to health issues particularly when considering the low level of seafood consumption in Australia o fish in particular metabolise fats at a much more rapid rate than mammals, therefore some residues can be purged within practical timeframes, as opposed to mammals • consistency is required between the states and the national standard in relation to the inclusion or exclusion of aquatic plants under the definition of seafood • questions whether the current Australian Standard for Hygienic Production of Crocodile Meat for Human Consumption is adequate • suggests that risk profiling is necessary to determine where higher standards are required, such as for ready-to-eat seafood, compared to seafood that has undergone a pathogen reduction step, such as cooking • suggests aquaculture products should be covered from production to point of retail sale

	• considers that a thorough Risk Assessment process has been applied within the Australian seafood industry, however some areas require attention, specifically aquaculture and chemical/pesticide residue accumulation as a consequence of prior land use • suggests there are various anomalies within the proposed SSA/ASIC Australian Seafood Standard • believes that food safety risks should be managed according to the degree of risk • audits should be seen as one of a suite of tools, there may be room to include incentive based compliance in the form of reduced frequency of audit, or other forms of rewarding good practice • the plethora of industry Codes of Practice available need to be reviewed for adequacy and equivalence
Tasmanian Salmonid Growers Association (TSGA)	• challenges the FSANZ assumption of the need for a PP&P Standard for seafood • alternately, believes that by removing the exemption for primary production in Chapter 3 of Code and qualifying the standards to allow for the conditions in primary production of seafood, would sufficiently cover food safety issues for seafood • believes that Chapters 1 & 2 of Code cover the hazards of concern, or could be easily modified to do so • the standard should clearly state the seafood species that the histamine requirements apply to, as TSGA members have experienced problems around testing for histamine – as this is expensive and has been demanded by customers and their auditors, despite it being irrelevant to cold-water salmon • duplication of standards should be avoided, and cost to industry minimised by any standard • consideration of controls at point of receipt of fish may be an alternative to fishing vessel inspection • risk assessment must be thoroughly and methodically applied to each seafood group before regulation is proposed • HACCP and Listeria monitoring programs are recognised as important for cold smoked salmon and any move to mandate food safety plans for these products would be welcomed • any technical data provided to FSANZ must be maintained in confidence, particularly in relation to individual company data • self-regulation is encouraged to be considered ahead of government regulation, for example the GMP guidelines produced by SSA and other industry Codes of Practice should be implemented, together with effective training of food handlers • expresses concern that any FSANZ proposals are not more onerous on Tasmanian processors than those in New Zealand, as the proposed standard will apply only in Australia

Centre for Food Technology, The Agency for Food and Fibre Sciences, QDPI / Clare Winkel (AFFS)	• fishing boats should not be required to have a full food safety plan unless processing occurs on board, otherwise they should only be required to implement Good Hygienic Practices • the information in the Safe Food NSW Seafood Safety manual should be used as the Australian Standard • believes that in relation to animals with high value to indigenous communities, such as turtles and dugongs, it is the preparation of these animals rather than their catching that carries food safety risks, and considers that this is covered by local health workers • the author refers to the ASS and makes the following comments: • the seafood industry should be asked only to comply with the current version of the Code, i.e.: sections 3.1.1, 3.2.2 and 3.2.3 • chilling temperature should remain between –1°C and 5°C, and the freezing temperature should remain at –18°C • Section 9 & 10 of the SSA/ASIC Standard, on operational hygiene and construction of premises, seems suitable for use in premises used for live fish and on trawlers • it is very necessary for harvesters to identify the date and place of the catch to enable identification of product caught in areas found later to be contaminated
SA Department of Human Services / Brian Delroy (SA DHS)	• in addition to those hazards already addressed in the Code, escolar, often sold as 'rudderfish', may need to be addressed in the Code • the seafood standard should not overlap with the matters covered by Chapters 1 and 2 of Code • the current definition of seafood within Code is considered adequate • the proposed standard should not cover aquatic plants, reptiles and mammals • the standard would ideally regulate activities on a fishing vessel, however as it is recognised that there are difficulties with enforcement; a code of practice may need to be developed to assist vessel operators • DHS has carried out numerous surveys concerning microbiological and heavy metal hazards in oysters, histamine in canned fish, micro in prawns etc., and can provide this information if requested • the SSA standard is seen as providing helpful input, but is not supported in its present form for a number of reasons, including that it appears to mandate the equivalent of Standard 3.2.1 of Code, and that it overlaps with Standard 3.2.2 and Chapter 1
South Australian Seafood Marketers and Processors Association Inc / Mark Cody (SASMPA)	• suggests that the seafood definition used by Codex would appear to be suitable • suggests that the scope must be the whole supply chain with emphasis on retail, hospitality sectors • the standard should apply specifically to those areas that pose a risk, and must pay regard to current arrangements, such as compliance with market driven and AQIS standards • notes that the risks associated with on-board processing in Australia are negligible, in contrast to those in New Zealand, due to their large scale processing vessels and foreign crews • notes that sushi and sashimi specialty shops need to be considered in the standard, as these represent raw, ready-to-eat seafood in a fast growing consumer market • recognise that a risk assessment process is vital in the standard development process, but also suggest that a different approach may need to be adopted for any 'external' or 'end-user' risks that are evident

	• suggest that caution should be exercised in interpreting health outcomes from epidemiological data in a simplistic model • believe that HACCP must be the base for all food safety management systems, and suggest that AQIS and existing supplier systems must be considered in any management system, and a tailored approach used taking into account whether a high or low risk is involved • believe that the cost of any proposed management system must be considered, for example duplicate audits must be avoided and there must be interstate consistency
Sydney Fish Market Pty Ltd / Bryan Skepper (SFM)	• believes the proposed standard should apply to all seafood that is produced or traded commercially in Australia, including seafood: o produced in Australia by commercial fishing or aquaculture o exported from, or imported into Australia o sold on the Australian domestic market • believes the proposed standard should not apply to: o recreational catch (unless sold for consumption) o seafood taken by Aboriginal or Torres Strait Island people for traditional or cultural reasons (excluding sale for consumption) o crocodile and seaweed • believes that the definition of seafood should not include crocodile and seaweed • believes that the standard should regulate the production of seafood through to the final retail sale, and that this should be further reinforced with a public education program • agrees that the proposed standard must be outcomes based, but suggests that fishing vessels may not require a full Codex HACCP system e.g. where risk to food safety is low, instead utilising other features • for such activities and products that carry a high food safety risk, a full HACCP plan would be warranted • risk assessment and profiling should rely on work that has already been undertaken by various authorities and the seafood industry • is prepared to assist where possible with the provision of technical data for incorporation into the scientific risk assessment process • the industry developed Australian Seafood Standard (SSA) should form the basis of a regulatory PP&P Standard as it was developed through an exhaustive consultative process, and most of the issues have already been debated and agreed during its development • believes that the work undertaken by Safe Food Production NSW should also be taken into account in development of a national PP&P Standard for seafood, as well as the issues raised in the 'Section 73' review into the Integration of the NSW Food Safety System (conducted by the Hon. John Kerin, published Nov. 2002) • believes the standard must be outcomes focused and based on food safety risk • where risk to food safety is demonstrated to be low, non-regulatory guidelines and codes of practice could be an effective means of achieving the overall outcome of providing safe seafood for customers • raises concern that multiple audits be imposed on industry by both government and other industry sectors, and therefore suggests that mutual recognition of audits by government agencies and acceptance of third party audits conducted by competent auditors must be considered o past audit performance of a seafood business must also be taken into account as well as the food safety risk profile of the business

	• Includes the following relevant points from the NSWSIC submission to the Kerin 'Section 73' Review: o food safety should be managed using a preventative approach based on through-chain risk management, with standards implemented in consultation and partnership with industry o believes that scientific risk assessment of food safety risks is needed for each industry and for each link in the chain, and that the management focus and costs should be directed towards those segments that present the greatest risk o suggests an increase in public good e.g. education and training, which must be supported by a significant increase in government contribution o believes that there should be a national approach aimed at eliminating inconsistencies between states
Master Fish Merchants' Association of Australia / John Roach (MFMAA)	• believes the proposed standard should apply to all seafood that is produced or traded commercially in Australia, including seafood: o produced in Australia by commercial fishing or aquaculture o exported from, or imported into Australia o sold on the Australian domestic market • believes the proposed standard should not apply to: o recreational catch (unless sold for consumption) o seafood taken by Aboriginal or Torres Strait Island people for traditional or cultural reasons (excluding sale for consumption) o crocodile and seaweed • believes that the definition of seafood should not include crocodile and seaweed • believes that the standard should regulate the production of seafood through to the final retail sale, and that this should be further reinforced with a strong, well funded public hygiene education program specifically aimed at handling of food for 'in home' consumption, as well as an education program for food service businesses • agrees that the proposed standard must be outcomes based, but suggests that fishing vessels may not require a full Codex HACCP system e.g. where risk to food safety is low, instead utilising other features • for such activities and products that carry a high food safety risk, a full HACCP plan would be warranted • risk assessment and profiling should rely on work that has already been undertaken by various authorities and the seafood industry • the MFMA is prepared to assist where possible with the provision of technical data for incorporation into the scientific risk assessment process • the industry developed Australian Seafood Standard (SSA) should form the basis of a regulatory PP&P Standard as it was developed through an exhaustive consultative process, and most of the issues have already been debated and agreed during its development • believes that the work undertaken by Safe Food Production NSW should also be taken into account in development of a national PP&P Standard for seafood, as well as the issues raised in the 'Section 73' review into the Integration of the NSW Food Safety System (conducted by the Hon. John Kerin, published Nov. 2002) • believes the standard must be outcomes focused and based on food safety risk • where risk to food safety is demonstrated to be low, non-regulatory guidelines and codes of practice could be an effective means of achieving the overall outcome of providing safe seafood for customers

	• raises concern that multiple audits be imposed on industry by both government and other industry sectors, and therefore suggests that: o mutual recognition of audits by government agencies and acceptance of third party audits conducted by competent auditors must be considered o past audit performance of a seafood business must also be taken into account as well as the food safety risk profile of the business
• Australian Institute of Environmental Health, South Australian Division / Michael Livori (AIEH SA)	• acknowledges that there are some areas of the food industry where sections are now not regulated in relation to food safety, such as seafood • agrees that an outcome-based standard focusing on food safety for sectors that are currently unregulated will help improve food safety • believe that the new standard should apply only to seafood production, including fishing, cultivating, growing and harvesting, • suggests further discussion and agreement is required with regard to enforcement and implementation • suggests that seafood production activities (including fishing, cultivating, growing, harvesting) would be best regulated by PIRSA, whereas regulation of activities involving substantial transformation of seafood (processing or storage on land prior to distribution) would fall within the jurisdiction of the local authority and the Department of Human Services • believe that all businesses involved in handling and selling seafood, including retail and businesses selling ready-to-eat seafood should remain covered under the current arrangements
Safe Food Queensland / John Burke (SFQ)	• believe that the current MRLs for seafood need to be revisited: o current values have been derived in the main from mammalian studies o MRLs do not related directly to health issues particularly when considering the low level of seafood consumption in Australia o fish in particular metabolise fats at a much more rapid rate than mammals, therefore some residues can be purged within practical timeframes, as opposed to mammals • believes the scope will inevitably involve some crossover into quality aspects, and regards this as not undesirable • supports the inclusion of aquatic plants, as they are already included in Queensland legislation • believes that crocodile processing contains inputs very similar to aquaculture inputs, and though already included in meat standards is not adequately dealt with there • believes that food safety objectives are still relevant to Native Rights, and that the seafood involved will generally have a low risk profile, and hence is best addressed through risk communication • believes that aquaculture should be covered from production inputs to point of retail sale • industry should be encouraged to fill the few existing gaps in the current Australian risk assessment data • one area that requires attention relates to residue accumulation as a consequence of prior land use in aquaculture • regards SSA's industry preferred standard as a good framework for a national standard, but perceives various anomalies in this standard • believes that food safety risk in the seafood industry should be managed according to the degree of risk • audits should be seen as one of a suite of tools, there may be room to include incentive based compliance in the form of reduced frequency of audit, or other forms of rewarding good practice • the plethora of industry Codes of Practice available need to be reviewed for adequacy and equivalence

Springs Smoked Salmon (Springs)	• believes the Code should be reviewed and readdressed, as it does not allow for health claims associated with the positive health benefits of Omega 3 oil content in certain fish products • all foods should come under the proposed food standard, as the current food standard addresses food consumed by humans • the standard should cover the entire seafood industry, as the quality and food safety status of the food is affected from the point of harvest, and any resulting processes will be carried through the processing and to the retail point • businesses carrying ready-to-eat seafood should be considered under the same food standard regulations as other food establishments, as they carry the same, if not higher, risks to the eating public • the regulation should address the activities on board fishing vessels at point of harvest, in the same manner as that of food processing establishments
New Zealand Food Safety Authority / Carole Inkster (NZFSA)	• no specific comments at this stage • a reference to the New Zealand standards for seafood provided
Simplot Australia Ltd (Simplot)	• raises concerns with the potential lack of harmonisation between Australian states and territories, New Zealand and other countries – this is relevant as a significant portion of seafood is caught internationally and may undergo a range of processes, hence necessitating a very broad approach • agrees with the principles of minimum effective regulation and an outcome based approach • welcomes legislation that promotes consumer understanding and acceptance of a highly skilled and sophisticated seafood industry is welcomed • raises concerns relating to any erosion of the trans-Tasman principle that may occur as a result of the seafood standard applying to Australia only • recommends that assessment is required of special techniques, the use of antibiotics, hormones and GM, • of particular note are the ongoing processes re mercury in 'predatory' fish – suggests that this be resolved through advisory guidelines • recommends that the scope of the standard follows that Codex Alimentarius Draft Code of Practice unless it is agreed that a particular section is too vague (such as micro standards) • believes that EU or FDA regulations are acceptable in such cases as they are accepted internationally for export / import • believes that issues of deceptive or misleading conduct should be left to the Trade Practices legislation to regulate and control • believes that an outcomes based approach is preferred • suggests that the seafood definition should be revisited to provide clarity for the various seafood groups, and that the definition should not include aquatic plants, reptiles and mammals • believes that the standard across the supply chain of aquaculture should commence at the point of harvest and end at point of sale • recommends an outcome based approach for harvesting, handling and processing of seafood at sea • suggests that businesses selling ready-to-eat seafood should remain covered by the PP&P standard with reference to Chapter 3 of the FSC • believes that the same standards that apply to land based processing of seafood should also apply to seafood aboard fishing vessels, and these should be based on HACCP principles • cold chain compliance throughout the supply chain is recommended

	• believes the FSANZ Risk Assessment process is acceptable, and does not recommend that prior studies be duplicated except where gaps are identified • attention should be given to particular allergen issues related to seafood where they are not covered by the Code • risks beyond microbiological factors must be addressed e.g. dangerous bones in a food product can be highly hazardous and may require specification in the standard • believes that Australia must create a single, comprehensive seafood standard so that any state and territory legislation can be repealed, and duplication for industry is avoided • considers that the standard should preferably have international recognition, especially from New Zealand • sees a need for greater awareness and training in the use of HACCP, especially in small business • believes that any import legislation should be based on Codex, and that strengthening of micro criteria should be in line with EU or FDA requirements if this is required • any legislation should not extend labelling obligation beyond those in the existing Code • suggests a three year compliance time frame, with a two year stock in trade provision • suggest that auditing should remain in the realm of market forces, and believes that non-compliance is already covered under provisions already in place under the Food Act • raise concern that the number of skilled auditors for seafood in Australia is very small • considers guidelines a vital support for any legislation, to provide clarity for industry and visibility throughout the primary production process for the public
South Australian Department of Primary Industries and Resources / Barry Windle (PIRSA)	• suggested hazards for which appropriate process controls should be implemented are: o scombrotoxin – histamine poisoning o microbiological, biotoxin and heavy metal contamination of shellfish o ciguatera toxins o Vibrio and prawns o ag and vet chemical residues, especially antibiotics, in aquaculture • believes that the standard should apply to known/identified food safety hazards within the entire seafood industry (whole of chain) • believes that a sufficient definition for seafood would include: fish, crustaceans, molluscs and other marine invertebrates • believes that aquatic plants, reptiles and mammals should not be included in the standard unless significant risks to public health are identified e.g. the risk assessment should consider heavy metals in aquatic plants (such as arsenic in seaweed sold in health stores) • believes that if the risk mitigation processes that are proposed do not fit readily within the overall Standard then it may be more appropriate to develop a separate Standard • believes that the Standard should regulate seafood production (aquaculture) to the point of retail sale, if hazards are identified that require additional process controls for the retail sector

	• believes that food safety standards 3.1.1, 3.2.2 and 3.2.3 should continue to apply to all 'food businesses' and the PP&P Standard should only add requirements where there are specific risks identified and public health benefits are greater than the cost of implementation, and that the Standard should reference other parts of the Code where appropriate • believes that in general the government should not be imposing food safety regulations to the harvesting, handling and processing of seafood on board fishing vessels, given the public health risk for these activities is low • recognises that there may be specific risks identified that may require mandated controls e.g. cooking prawns of boats • suggests that a voluntary code of practice for good handling and hygiene, and vessel design, may also be useful • will support provision of technical data for incorporation into the FSANZ scientific risk assessment process • believe that industry may support mandating of hygiene standards for some sectors, to minimise the current low level of risk; • and note that it there is broad government and industry support for these sectors around Australia - SA would support including them in the Standard, provided industry is prepared to meet the regulatory costs attributable to industry • in general, supports industry developing and implementing voluntary industry standards e.g. the SSA Standard; • however, do not support currently using the SSA Standard as a voluntary basis for a national mandatory PP&P Standard for seafood, for the following reasons: o it mandates food safety programs for the whole seafood chain, which is not believed to be in line with the principle of minimum effective regulation and may not demonstrate a positive cost-benefit ratio (based on public health savings versus the cost of implementation) o would not accept SSA, a non-government body, developing and maintaining the guideline documents that would form the basis for regulatory application of a Standard o believes there are definitions and principles in the SSA Standards that appear to be in conflict with the Food Act, with which all regulatory instruments should comply • believes that in general, for specific hazards identified as a significant risk there should be mandated control processes in addition to existing controls specified in the FSC • recommends the following food management systems o mandating the principles underlying ASQAP for all bivalve molluscs collected for human consumption o food safety programs mandated for bivalve mollusc production, harvesting, processing and distribution o food safety programs mandated for control of *Listeria* in cold smoked salmon, as a high risk operation o mandated controls for retail outlets to minimise the risk of rudderfish 'poisoning' e.g. mandating correct identification of fish and/or warning signs o development of a voluntary code for all harvesters and catchers of seafood as, in general, most sectors are low risk • believes that compliance with food safety programs should be by third party auditors, approved by government, paid for by the industry, with reporting protocols to the regulators:

	o this audit system would be flexible enough to allow for government and contracted audit services, and validation systems should be part of the whole system • believes that compliance with mandated hygiene requirements in the catching and harvesting sectors should occur through government inspection, and that there should be an option for sectors to demonstrate compliance with hygiene requirements by voluntary adoption of food safety programs with accredited third party auditors • believes there are significant additional costs for successful implementation of food safety programs, and that these programs should not be implemented unless there is strong industry and government leadership supported by appropriate resources • believes that imposition on industry sectors should not occur unless there are strong public health reasons or there is strong industry support (and agreed to by government) • supports mechanisms that allow recognition of industry systems that demonstrate compliance with the Standard • notes that currently the PP&P Standard for seafood would be given legal effect via the SA Food Act • notes the SA is considering development of primary industry legislation to cover the pre-harvest part of the seafood chain, in which case the part of the Standard applicable to the pre-harvest sector would be applied under this legislation and the remainder under the Food Act • believes that implementation time frames for food safety systems will vary according to the food safety system required and the starting point of the industry sector o notes that an industry with a low level of preparedness would need over two years for implementation • believes that audit frequency should be necessary such as to provide confidence that the system is under control - in general there would initially be more frequent audits that would reduce to an agreed level, with more frequent audits if there is evidence that the system is not under control, and that regulators would determine the frequency of audit, based on reports from auditors and other agencies • supports the use of supporting guidelines for an outcome based Standard, and suggests that it would aid national consistency to have them developed nationally wherever possible
Seafood Services Australia / Ted Loveday (SSA)	• detailed comment is provided on the position of the ASS in relation to the various issues raised in the Issues Paper throughout the submission • believes that the proposed PP&PS for seafood should rely on relevant provisions in the Code to ensure that chemical and biological hazards associated with seafood are adequately expressed • the provisions in the Code relating to chemical and biological hazards associated with seafood, within the agreed definition of seafood, should be checked for accuracy and reviewed consistent with normal FSANZ processes • believes that the scope of the proposed PP&PS for seafood should cover the entire seafood industry • the proposed PP&PS and the ASS should have consistent definitions, and an agreed process for considering proposals to change definitions should be developed • believes that the PP&PS for seafood should also recognise the status of the Australian Fish Names list and reference it in the standard

	• notes that the PP&PS for seafood should not consider policy and regulatory issues other than food safety e.g. native fishing rights are considered in other fora
	• notes that the ASS has worked in consultation with government and industry to establish agreed definitions for inclusion in the ASS, that there have been many comparative studies of definitions used internationally and nationally, and that SSA has established the Fish Names Committee to act as a forum for initial debate on definitions to be considered for the ASS
	• notes that the underlying policy principle for the ASS is for jurisdictional issues not to be embedded in the Standard, rather, the Standard is outcome focused, takes a 'water to waiter' approach and in based on management of risk
	• believes that, similar to the ASS, the PP&PS for seafood should not allow jurisdictional issues to compromise integrity and focus
	• believes that with respect to regulation of harvesting, handling and processing of seafood onboard fishing vessels, the PP&PS for seafood should consider the approach taken by the ASS
	  o the ASS is not prescriptive about how a seafood business should achieve the required seafood safety and suitability outcomes, thereby providing flexibility
	• believes that the Issues Paper does not properly consider risk analysis in context or have regard to the significant amount of data already available to seafood businesses to assist them in implementing a HACCP based standard, rather, it appears to place undue emphasis on a sub-set of risk assessment more appropriate to the establishment of food product standards
	• believes that under a risk management system (consistent with Chapter 3 of the Code), the analysis required to relate production processes to hazards identified should be undertaken after the standard is established and should not impede the development of a uniform national standard
	• comments that the ASS is the industry preferred food safety standard, development of which has involved significant time and effort of industry members while utilising input from Commonwealth government agencies as well as state and territory regulatory bodies
	• notes that the ASS will continue to be developed and implemented by SSA Ltd as a voluntary food safety standard for seafood businesses
	• it is expected that the process will run concurrently with any PP&PS for seafood, such that a seafood business demonstrating compliance with the ASS will achieve recognition as complying with any nationally mandatory PP&PS for seafood
	• believes that all existing standards applying to seafood should be considered as part of the process of developing a national mandatory PP&PS for seafood, such as the NSW Food Production (Seafood Safety Scheme) Regulation 2001, and any international standards
	• suggests that when considering the suitability of any particular standard as a model it is important that the SDC consider an approach with maximum flexibility without compromising the achievement of food safety outcomes; an overly prescriptive standard may impose unnecessary costs on individual seafood businesses
	• considers that the Regulatory Impact Statement (RIS) prepared by FSANZ in support of the adoption of Chapter 3 of the CODE is relevant to consideration of the benefits/risks of possible risk management approaches
	  o the RIS asserts that HACCP-based food safety programs, in combination with good hygienic practices and education of food handlers, are seen as pivotal to reducing the incidence of food-borne illness

	• comments that Ministerial Council has established that risk management in relation to PP&P standards is to be consistent with Chapter 3 of the Code i.e.: HACCP based, and uses a model requiring businesses to implement HACCP based food safety programs based upon their risk classification (with high risk business to being required to implement first), and indicates that ASS has taken this approach in regard to fishing, farming, harvesting and processing businesses • notes that SSA will continue to help industry sectors to develop codes and guides based on industry demand and available resources • comments in relation to the costs and benefits of the food management systems, that consumer confidence that seafood is 'safe', 'clean' and 'green' is vital to the well-being of the seafood industry, the tens of thousands of jobs it supports, and regional coastal communities around Australia, and notes that ASS reflects the industry's commitment to providing seafood for human consumption that is produced in accordance with internationally recognised standards and which meets and where possible exceeds the requirements of domestic and international customers and food safety authorities • believes that agreement on national standards for seafood safety and suitability would facilitate establishment of a national and compatible certification framework that enables seafood businesses to demonstrate compliance with regulatory requirements in all relevant jurisdictions, through a single audit • suggests that the PP&PS for seafood must include provisions that automatically recognise export registered establishments as complying with the standard, inclusive of those establishments registered for export by AQIS or under AQIS approved arrangements such as state or third party certification • note that SSA is working with the Joint Accreditation System Australia and New Zealand (JAS-ANZ) and participating in the intergovernmental process for developing a national framework for food safety auditing, to help develop an accreditation and certification system that enjoys the confidence of the public, seafood consumers, the industry and government • believes that codes of practice or guides to best management practice need to be developed, in conjunction with industry, and that risk assessments that identify hazards and CCPs that will apply to all businesses in particular industry sectors need to be undertaken – these initiatives will avoid unnecessary duplication of efforts at the business level • note that several codes of practice and guides already exist as a consequence of projects such as the Australian Seafood Industry QA Program (ASIQAP), Australian Prawn Promotion Association's code of practice for wild caught prawns, etc • states that SSA will continue to help industry sectors develop GMP guidelines and other resources based on industry priorities, demand and availability of resources, and has a number of guidelines currently available, which are currently being reviews to ensure consistency with the ASS and the PP&PS for seafood, and to incorporate outcomes from industry case studies that are piloting the adoption of the ASS
Australian Government Department of Agriculture, Fisheries & Forestry (DAFF)	• supports access to safe food products • supports outcomes based regulations, based in science • recognises the Australian Seafood Standard (ASS), and the consultative process through which it was developed, as well as its broad industry acceptance • recommends the ASS should at least be a starting point from which to

	develop the Seafood Standard • suggests FSANZ clarify the intent of the statement 'Primary Production and Processing Standards shall apply in Australia only' - will the Seafood Standard will apply in Australia but not New Zealand, or in Australia but in no other country? • believes general provisions for microbiological criteria should be included, similar to those in Chapters 1 and 2 of the Code for food chemicals, i.e.: no residues are allowed unless there is a specific permission • reminds FSANZ that enforceability at the border must be considered, and sees competing requirements if FSANZ is to move away from such general provisions and criteria as are currently required • suggests the Standard should address the hazard ciguatera, perhaps through ancillary risk management programs such as size limits, or prohibitions on the sale of some species, or avoidance of harvesting hot spots etc • public health issues surrounding consumption of escolar and other oilfish species that contain indigestible wax ester oils should be considered • recognises parasites, including nematodes, cestodes, trematodes as significant potential hazards in raw, cold-smoked and undercooked fish and fish products • suggests the Standard should address bacterial pathogens currently absent from the Code, such as V*ibrio parahaemolyticus*, *V. vulnificus*, Y*ersinia enterocolitica*, *Clostridium botulinum* (type E in particular), *Salmonella* spp., *Staphylococcus aureu***s** (except in the cases of raw and cooled crustacea with respect to the latter two microbes) • suggests that the Australian Shellfish Quality Assurance Program (ASQAP) be cited within the Standard • other aquaculture situations, including farming of crustaceans and finfish, may require consideration with respect to animal health concerns, as viruses can replicate in these intensive farming situations • suggest that 'seafood sold in Australia' may be better worded 'For sale in Australia' or 'intended for sale in Australia' • advise that the term 'cold-blooded' is technically incorrect for seafood, and the term 'shellfish' is ambiguous • suggests a definition for 'seafood' or for 'fish' – 'aquatic vertebrates and aquatic invertebrates, including finfish, molluscs and crustacea, but excluding aquatic mammals' • advise that the regulation of crocodiles is already addresses under the Australian Standard For The Hygienic Production of Crocodile Meat for Human Consumption • consider that there is little need for regulatory control of aquatic plants in a food safety context • suggest that if crocodiles and aquatic plants are to be considered under the Standard, risk profiling should be conducted for these products • advise that Australia does not currently commercially harvest mammals, hence their inclusion in the Standard would not be appropriate • suggests that the Standard should consider pre-harvest conditions such as growing and feeding in relation to aquaculture • believes the Standard should reference other appropriate standards in the Code, in relation to standards for retail sale • recognises that feedstuffs are covered by current state regulations, sees development of the Standard as an opportunity to include feedstuff issues, or to call up and reference feedstuffs

	• regulation of harvesting, handling and processing of seafood onboard fishing vessels should be determined according to the extent to which specific onboard practices might introduce new hazards or compromise the safety of the final product (as determined by risk analysis) • supports FSANZ's current approach to scientific risk assessment • indicates that AQIS provides data associated with analysis of imported food to FSANZ on a regular basis • indicates that the Export Control (Processed Food) Orders should be considered as a base for the Standard • indicates also that the Codex Code of Practice for Fish and Fishery Products has useful elements that could be considered • suggests that AQIS may have useful information to contribute regarding compliance, as has regulated the export sector for approximately 15 years • suggests that industry compliance with export legislation should be deemed to comply with the food safety management options • consideration should be given to Commonwealth recognition of equivalent enforcement systems; enforcement of the national Standard should be consistent across all jurisdictions • the framework for judging the ability of a system to deliver the same level of food safety should be adapted from the CCFICS Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems • notes that the Export Control (Processed Food) Orders rewards high level compliance with reduced audit system, as does the Imported Food Inspection System, where good compliance history reduces the rate of inspection • notes that comprehensive guidelines are useful as support for regulations – both for compliance and for interpretation • suggests that the level of prescription contained in the Standard will affect whether guidelines are needed • DAFF is more than happy to provide assistance to the SDC or FSANZ on any matter pertaining to the experience gained during the evolution of the Export Fish Program, with regard to the strengths and weaknesses in the current system, industry compliance and enforcement issues
Coles Supermarkets (Coles)	• strongly feels that the Standard should not apply to retail • notes that the primary control over seafood safety at retail relates to temperature control, and existing standards in the Code are adequate and well enforced • notes also that any significant hazards after delivery of stock is accepted are already identified and appropriately addressed through hazard analysis • notes that if the Standard apply to retail, it would add another layer of enforcement and auditing fees for supermarkets, which they believe to be unreasonable when they believe the risk is being adequately managed • is concerned about duplication of activity if a separate enforcement agency is introduced for seafood, which is a small segment of the supermarket product range • believes that the need for specific expertise in the enforcement agency is restricted to the primary production sector of the seafood industry • believes that businesses selling ready-to-eat seafood should remain under the current arrangements • strongly believes that the Standard should cover activities on board fishing vessels, through requiring implementation of HACCP based food safety systems

	• considers the ASS a sound basis for the Standard • supports the requirement of HACCP based food safety programs (Std 3.2.2) for all seafood businesses, rather than just those demonstrating the highest risks • recommends that a Code of Practice or guidelines incorporating generic templates be developed, in conjunction with industry • believes businesses should also have the option of developing their own food safety programs and having them independently approved • believes the Standard should recognise other similar existing schemes and auditing bodies, to allow compliance to be achieved through a single audit • believes FSANZ has consistently underestimated costs to industry associated with implementation of HACCP based food safety programs • nonetheless believes that the benefits, in terms of food safety, outweigh the costs • notes benefits such as increased consumer confidence, fewer resources required to investigate complaints, lower likelihood of litigation etc • suggests a minimum of 2 years compliance period upon introduction of the Standard • notes a general concern that not all States and Territories may chose to adopt the FSANZ Standard; leading to national inconsistencies • believes the normal FSANZ review process should apply to any future amendments to the Standard • believes identification and nomenclature is an important issue not sufficiently addressed in P265 • suggests that the Australian Fish Names list (SSA) should be recognised/referred to by the Standard, and believes this would help prevent deceptive conduct associated with the naming and sale of seafood, as well as providing a means of consumer education

Abbreviations used:

ASQAP- Australian Shellfish Quality Assurance Program
GMP – Good Management Practice
PP&P – Primary Production and Processing
PP&PS – Primary Production and Processing Standard
MRL – Maximum Residue Limit
TASQAP – Tasmanian Shellfish Quality Assurance Program

Attachment 5

Summary of Public Submissions by Issue

Are there any chemical or biological hazards either further to, or currently included in Chapters 1 and 2 of the Code, that need to be addressed in the proposed seafood standard, or that should be additionally included in the current chapters of the Code?	
- Need to revisit MRLs in seafood.	Qld Health, SFQ
- Should not be duplication of existing legislation.	Qld Health
- Reference / rely on / review chemical and biological hazard standards from other Chapters.	TFIC, SASC, SSA
- Address these in an easily updated dynamic interpretive guideline.	TFIC
- Should specify the species that the histamine standard applies to.	TSGA
- Metabisulphites may cause serious health problems – 4-hexylresorcinol is a safe approved alternative.	Kanins
- Mercury in predatory fish should be resolved through advisory guidelines.	Simplot
- Attention needs to be given to allergen issues not covered by Code.	Simplot
- Non-micro risks such as fish bones must be addressed.	Simplot
- Need appropriate process controls for histamine, ciguatera, Vibrio in prawns, agvet chemicals in aquaculture (esp. antibiotics), and micro, biotoxin and heavy metal contamination in shellfish	PIRSA
Escolar, often sold as rudderfish, may need to be addressed.	SA DHS
- general micro criteria should be included, similar to for food chemicals, i.e.: no residues are allowed unless there is a specific permission	DAFF
What should be the scope of the proposed seafood Standard?	
- Should cover the entire seafood industry.	SSA
- Should have consistency between definitions in the PP&PS and the SSA / ASIC standard, and an agreed process to change these.	SSA
- Outcomes based, not prescriptive.	NTSC, Simplot
- Outcomes focussed and based on food safety risk.	SFM, SSA,

	MFMAA, AIEH SA, DAFF
- Refer to, but not duplicate, other Chapters.	NTSC, SA DHS, PIRSA
- Review Code as it does not allow health claims for omega 3 oil content.	Springs
- All foods should come under the standard not just foods for human consumption.	Springs
- Must apply equally to local and imported produce.	TFIC
- Should apply to all seafood produced or traded in Australia, including imports and exports.	SFM, MFMAA
- Should not consider policy and regulatory issues other than food safety, and should not consider jurisdictional issues.	SSA
- Recognise and reference Australian Fish Names List.	NTSC, SSA
- Don't incorporate fish names.	Sontari
- Exclude quality attributes and production methodologies.	Sontari
- If the onus is on the supplier to source safe product, don't need to heavily regulate primary production.	NT Govt
- Only regulate where significant risks and the benefits outweigh the costs.	SASC
- Standard should allow for voluntary codes of practice for GHP.	SASC
- Should simply apply Chapter 3 to primary production and processing, thus removing the need for a specific seafood standard.	TSGA
- Difficult to legislate marketing names, but if done then should include Tasmanian Atlantic salmon and ocean trout.	TSGA
- Self regulation is preferable to government regulation – use the SSA guidelines on GMP and specific industry codes of practice.	TSGA
- Where regulation is deemed necessary it must be targeted at addressing the specific food safety problem and not have general application.	TSGA
- Follow Codex Draft Code of Practice, except where too vague.	Simplot
- EU or FDA regulations and micro criteria acceptable for export / import.	Simplot
- Deceptive or misleading conduct best left to Trade Practices legislation.	Simplot
- Reference to cold chain compliance through supply chain recommended.	Simplot
- Should not extend labelling obligations beyond those in the Code.	Simplot

- Seafood industry should only have to comply with standards 3.1.1, 3.2.2 and 3.2.3.	AFFS
- Standards 3.1.1, 3.2.2 and 3.2.3 should continue to apply, with other requirements added where risk and cost-benefit indicates	PIRSA
- Need to differentiate between low inherent risks and higher risks through external impacts, and manage pollution of waterways.	SASMPA
- Will inevitably cross over into quality aspects – not undesirable.	SFQ
- Residue accumulation as a consequence of prior land use in aquaculture requires attention	SFQ
- Food safety risks should be managed according to the degree of risk.	SFQ
- Avoid prescriptiveness – deal with actual not hypothetical risks.	SASMPA
- Must have regard to existing market- and export-driven HACCP-based QA systems.	SASMPA
- A full HACCP plan warranted for activities and products that carry a high food safety risk.	SFM, MFMAA
- Food safety should be managed using a preventative approach based on through-chain risk management, with standards implemented in consultation and partnership with industry.	NSWFIC
Is the current definition of seafood in the Code adequate in terms of defining the commodities that the standard needs to cover?	
- Should be revisited to provide clarity.	Simplot
- Definition appears satisfactory.	SA DHS
- The Seafood Definition used by Codex would appear to be suitable.	SASMPA
- Should include fish, crustacea, molluscs and other marine invertebrates.	PIRSA
- Definition should not include crocodile or seaweed.	SFM, MFMAA
Should the proposed standard include aquatic plants, reptiles and mammals (which has implications for native fishing rights)?	
- No.	**SADHS, SFM, MFMAA, SIMPLOT**
- No, unless significant public health risks identified.	

- Include aquatic plants, exclude crocodile and mammalian meat. - Include these, but define the point at which they become seafood subject to the provisions of the standard. - Include aquatic plants, as some States already include these in legislation. - Questions whether the current crocodile meat standard is adequate. - Food safety still relevant to native rights, but low risk best addressed through risk communication	PIRSA TFIC Sontari Qld Health, SFQ Qld Health, SFQ SFQ
Should the standard regulate seafood production (aquaculture) from the point of harvest up to the back dock of retail establishments, or through to the point of retail sale? - Entire chain from harvest to retail, inclusive. - Aquaculture should be covered from production inputs to point of sale. - Aquaculture should be covered from harvest to point of sale. - Up to but not including point of retail sale. - From harvest up to point at which the Code currently applies. - Should only apply to seafood production. - Apply to whole chain, but focus on where the major risks and problems lie, in the lack of knowledge of cold-chain management and seafood handling in the food service and retail sectors - Reference other standards in the Code in relation to retail	 NTSC, TSGA, Sontari, Qld Health, SFM, MFMAA, Springs, PIRSA **SFQ** **SIMPLOT** **TFIC** SA DHS AIEH SA SASMPA DAFF

Should businesses selling ready to eat seafood remain covered under the current arrangements, or should these businesses be covered by the Primary Production and Processing Standard for seafood?	
- Leave them under the current arrangements.	SA DHS, AIEH SA, Springs
- Incorporate in primary production and processing standards.	Qld Health
- Should remain covered by the PP&PS by reference to Chapter 3	Simplot
- Need to consider sushi and sashimi specialty shops.	SASMPA
To what extent should the standard regulate harvesting, handling and processing of seafood onboard fishing vessels?	
- An outcomes based approach is recommended - Vessels may not need a full Codex HACCP system where risks are low.	Simplot, SSA SFM,
- Should include food safety plans / programs (FSPs) in line with the industry preferred standard	MFMAA Qld Health
- Should address in same manner as for food processing establishments.	
- The risks are low, so a standard should not apply.	Springs, Simplot SASC, PIRSA, SASMPA
- Specific risks may need mandated controls e.g. cooking prawns on boats.	PIRSA
- Voluntary code of practice for GHP and vessel design may be useful.	PIRSA
- No need to have a FSP if only producing live catch.	TFIC
- Limited space on vessels may preclude on-board inspectors, so vessel skippers should obtain accredited food safety training.	TFIC
- Need an awareness program to reinforce the basics of food safety on-board.	TFIC
- One option is to have a receival standard with regulation / enforcement beginning at dock, to encourage compliance.	TFIC
- Need to apply GHP unless processing on-board, then need a FSP.	AFFS
May need to address by a code of practice, as a standard will be difficult to enforce on-board.	SA DHS

Comment is sought on the scientific risk assessment process which forms the basis of the FSANZ regulatory measures.	
- Risk assessment process is supported.	SA DHS, Simplot, DAFF
- Risk assessment process needs to be appropriate for the level of risk.	TFIC
- Should rely on work already undertaken by authorities and the seafood industry.	SFM, MFMAA
- Assessment required of special techniques , the use of antibiotics, hormones and GM.	Simplot
- A scientific risk assessment is needed for each link in the chain.	NSWSIC
- The FSANZ risk assessment process does not properly consider risk analysis in context, ignores data already available to aid businesses implement HACCP, and places undue emphasis on risk assessment more appropriate to the establishment of food product standards.	SSA
- The analysis to relate production processes to hazards should occur after the standard is established	SSA
Technical data is sought from industry and relevant agencies for incorporation into the scientific risk analysis process.	
- The reported data for the relative amounts of local and imported seafood consumed in Australia is wrong – correct ratio is given.	Sontari
- Need more data on chemical / pesticide residues in aquaculture.	Qld Health
- Industry should be encouraged to fill the few remaining gaps in Australian risk assessment data	SFQ
- Can supply data from food microbiological surveys, if required.	SA DHS
- Supports provision of technical data for incorporation into the scientific risk assessment process	
- Prepared to assist with provision of technical data for incorporation into the scientific risk assessment process.	SFM, MFMAA
- Won't supply data if confidentiality can't be assured.	TSGA

Comment is sought on the suitability and/or any deficiencies of the industry-preferred standard proposed under the SSA/ASIC Application, if it were to be considered as a basis for a national mandatory Primary Production and Processing Standard for seafood.	
- Supports industry developing and implementing voluntary standards.	PIRSA
- Don't use it as basis of seafood standard (reasons given).	PIRSA
- Use the SSA / ASIC standard as an interpretive guideline.	TFIC
- Needs to be modified if to be used as a guideline.	SASC
- Some parts would be useful as a guideline document.	SA DHS
- Use it as a basis for the seafood standard.	NTSC, SFM, MFMAA, DAFF
- Use it as a basis, but it has some anomalies.	Qld Health, SA DHS, SFQ
- Sections 9 and 10 should apply to trawlers and premises used for live fish.	AFFS
- A wider view is required.	Sontari
Comment is sought on the suitability of any existing government standards, such as the NSW Food Production (Seafood Safety Scheme) Regulation 2001, and any international standards, as a model on which to base a national mandatory Primary Production and Processing Standard for seafood.	
- All existing Australian and international standards should be considered as part of the process of developing the PP&PS for seafood.	SSA
- Work undertaken by SafeFood NSW and issues raised in the NSW 'Section 73' review should be taken into account in developing the standard.	SFM, MFMAA
- There is anecdotal evidence of complexity and cost in the NSW and VIC schemes.	TSGA
- NSW scheme is deficient for several reasons.	Sontari
- NSW seafood safety manual should be the standard.	AFFS
- Current legislation covering imports is working.	Sontari
- The NSW scheme is a regulation, not a standard, but some of the oyster management parts would be useful as a guideline.	Qld Health
- Incorporate into interpretive guidelines as appropriate.	TFIC

- Utilise industry codes of practice *etc.* where mandatory measures would be ineffective.	TFIC
Comment is sought on the range of options available to manage food safety risks in the seafood sector and their appropriateness, including the costs and benefits of such approaches. - Should mandate ASQAP principles for all bivalve molluscs. - should cite ASQAP - FSPs for bivalve mollusc production and handling and for control of *Listeria* in cold smoked salmon - Since seafood is mainly low risk, only need to apply minimum regulatory controls where necessary. - Management focus and costs should be directed towards those segments presenting the greatest risk. - HACCP must be the basis for food safety management.	 SASC, PIRSA DAFF PIRSA SA DHS NSWSIC SASMPA
Stakeholders are invited to provide their views on issues relating to food safety management systems and whether options further to those raised in this paper should be considered in managing the potential public health and safety risks associated with seafood. - the Ministerial Council has established that risk management in relation to PP&PS is to be consistent with Chapter 3, HACCP based and implemented according to risk classification. - The solution, whether HACCP or GMP, should be appropriate to the level of risk. - Develop voluntary code for harvesters, as low risk. - Only need effective risk communication and targeted industry education. - FSPs should only apply where the risk is high. - Non-regulatory guidelines and codes of practice could be effective where risks are low. - FSPs should not be implemented unless there is strong industry and government leadership and it is supported by appropriate resources.	 SSA NTSC, SASC, Qld Health PIRSA Qld Health Qld Health SFM, MFMAA SA DHS, PIRSA

Information on the costs and benefits of the food safety management systems is sought. - The RIS in support of Chapter 3 of the Code is relevant. - Additional costs of implementation of FSPs are significant - Consumer confidence that seafood is safe is vital to the industry. - Information on the costs of compliance with, and administration of, the AQIS export certification program are presented.	 SSA PIRSA SSA SECC
Comment is sought on issues relevant to compliance by the industry with respect to the food safety management options outlined in this paper. - Compliance with FSPs by 3rd party audit, approved by govt, paid by industry, reporting to regulators. - Compliance measures and costs need to be commensurate with risks. - There needs to be consistency between jurisdictions. - Complexity of compliance and difficulties with enforcement argue against regulation. - Will there be a national accreditation mark? - Will there be consideration for good compliance history? - Multiple audits are very undesirable.	 PIRSA SA DHS SASMPA TSGA NT Govt NT Govt NT Govt, SASMPA, SASC, SFM, MFMAA
Comment is sought on food safety management options from an enforcement perspective. Specific issues that have been identified are listed below, but comment need not be confined to these issues: **- the costs of meeting current requirements and costs or difficulties in meeting the range of food safety management options that are mentioned in this paper;** **- THIS IS NO TIME FOR A CASH GRAB VIA LICENSING FEES.** - Information on the costs of compliance with, and administration of, the AQIS export certification program are presented.	 TFIC SECC

- ways that industry could comply with the food safety management options, for example by compliance with current industry or legislative requirements;	
- A business complying with the SSA / ASIC standard should be recognised as complying with the PP&PS standard.	SSA
- Need to recognise export establishments as complying with the standard.	NTSC, SECC, SASC SASMPA
- Industry would not support duplication of export and Australian domestic standards for seafood	
- other methods of cost effective compliance;	
Need education and training supported by a significant increase in government contributions.	NSWSIC
- how a Primary Production and Processing Standard for seafood would fit with any existing standards and State and Territory regulations governing primary products;	
- additional matters at State/Territory level that the States and Territory governments may have to consider in order to ensure compliance and enforcement with any national standard;	
- Local government enforces Chapter 3, Health Chapters 1 and 2.	AIEH SA
- Seafood production best regulated by Primary Industry, processing by Human Services and local authorities.	Unley
- Production should be regulated by Primary Industry, processing and retail sale by Health.	
- how equivalence between existing requirements and any new standards could be established;	
- the timeframes that industry may need to comply with the food safety management options;	
- Timeframes will vary according to the requirements of food safety systems and the readiness of the industry sector (over two years in some	PIRSA Simplot

sectors).	TFIC
- Need 3 year compliance and 2 year stock in trade timeframes	
- Timeframes should be set in close consultation with industry.	
- the role of incentive based compliance schemes, such as reduced frequency of audits;	SASC, PIRSA
- An initial high audit frequency should be reduced, unless there is evidence that the system is not under control.	Qld Health, SFQ
- This is a real opportunity to incorporate incentive-based compliance.	
- the need for comprehensive guidelines for those sectors of the seafood industry affected by a Primary Production and Processing Standard for seafood, including the role of industry and regulatory agencies in the development of any guidelines	Simplot PIRSA, SSA
- Guideline a vital support to any legislation.	SSA
- Supports nationally developed guidelines.	
- Many guides and codes of practice exist and SSA is helping industry develop GMP guidelines	Qld Health, SFQ
- Will need guidelines, but not all industry codes of practice will be acceptable – issues of adequacy and equivalence will need national review.	
- Other Comments	SECC
- State regulators are unlikely to have the capacity to implement and police a single standard that would also replace the AQIS requirements	Simplot
- Concerns with harmonisation with international standards.	SECC, SSA
- Need mutual recognition of audits between AQIS and jurisdictions.	SFM, SSA, MFMAA
- Need mutual recognition of audits and acceptance of third party audits. Past audit performance and risk profile need to be taken into account	NT Gov
- How will producers / processors who are also retailers be regulated?	SASMPA
- State regulators will require a major re-education to be able to police the standard.	Simplot
- Need to strengthen HACCP awareness and training.	Simplot
- Auditing should be in realm of market forces.	Simplot
- Number of skilled auditors for seafood in Australia is low.	NSWSIC

- Need a national approach aimed at eliminating inconsistencies between jurisdictions. SSA is working with FAS-ANZ on a national framework for food safety auditing, accreditation and certification.	SSA

Attachment 6

Australia New Zealand Food Standards Code requirements for seafood

Code	NAME	AREA OF APPLICATION
1.1	**Preliminary**	
1.1.1	Preliminary Provisions	Application, interpretation, and general provisions
1.1A	**Transitional Standards**	
1.1A.2	Health Claims	Specifies that health claims are not permitted, except where prescribed (none are prescribed for seafood).
1.1A.3	Country of Origin Labelling Requirements	Clauses 1,2 and 3 detail the country of origin labelling requirements for packaged and unpackaged seafood.
1.2	**Labelling and Other Information Requirements**	
1.2.1	Application of Labelling and Other Information Requirements	Sets out labelling requirements for food (including seafood) for retail sale and not for retail sale.
1.2.2	Food Identification Requirements	Specifies three types of information that must be included on a food label to identify the food in question – name of food, lot identification, name and address of supplier.
1.2.3	Mandatory Warning and Advisory Statements and Declarations	Sets out mandatory advisory statements and declarations that must be made in relation to certain substances. In relation to seafood, clause 4 sets a requirement that the presence of fish and fish products be declared.
Code	**NAME**	**AREA OF APPLICATION**
1.2.4	Labelling of Ingredients	Specifies requirements for labelling and naming of ingredients/compound ingredients
1.2.5	Date Marking of Packaged Food	Prescribes a date marking system for packaged food and the form in which these foods must be date marked. Applies to packaged seafood.
1.2.6	Directions for Use and Storage	Requires either direction for use and/or directions for storage of food, to be included on the label, where, for reasons of health and safety, the consumer should be informed of specific use or storage requirements.
1.2.8	Nutrition Information Requirements	Sets out nutrition information requirements in relation to food required to be labelled under the Code and for food exempt from these labelling requirements. Prescribes when nutritional information must be provided, and manner in which such information is provided. Note that where food is fish that comprises a single ingredient or category of ingredient, it is not required to carry a nutrition information panel.
1.2.9	Legibility Requirements	Sets out general and specific legibility requirements for labelling of packaged foods.
1.2.10	Characterising Ingredients and Components of Food	Specifies requirements for the declaration of the percentage of characterising ingredients and components of certain food products which are required to be declared. Includes methods for determining the proportion of characterising ingredient/s. Applies to packaged seafood.
1.3	**Substances Added to Food**	
1.3.1	Food Additives	Defines food additives and regulates their use in production and processing of food. Food additives not specified in this standard are not permitted to be added to foods.
1.3.3	Processing Aids	Regulates the use of processing aides in food manufacture, prohibiting their use in food unless there is a specific permission within this standard. Application may be relevant to processed seafood products.
1.3.4	Identity and Purity	Ensures that substances added to food in accordance with this Code meet appropriate specifications for identity and purity of food additives, processing aids, vitamins and minerals and other added nutrients. These are generally used by the international community. They may apply to imported seafoods.
1.4	**Contaminants and Residues**	
1.4.1	Contaminants and Natural Toxicants	Sets out the maximum levels (MLs) of specified metal and non-metal contaminants and natural toxicants in nominated foods. Those relevant to seafood include: arsenic (inorganic), cadmium, lead, mercury, tin, acrylonitrile, amnesic shellfish poisons, diarrhetic shellfish poisons, neurotoxic shellfish poisons, paralytic shellfish poisons, PCBs and vinyl chloride.

1.4.2	Maximum Residue Limits (Australia only)	Lists the maximum permissible limits for agricultural and chemical residues present in food *e.g.* benzocaine, cyhalothrin, cypermethrin, isoeugenol, oxolinic acid, oxytetracycline, phosphine, trifluralin, aldrin and dieldrin, BHC, chlordane, DDT, HCB, heptachlor, lindane.
1.4.3	Articles and Materials in Contact with Food	Provides permission for articles and materials to be in contact with food in accordance with the conditions set out in this standard. Standard 1.4.1 sets out the MLs for a number of metal and non-metal contaminants and natural toxicants that may be present in food as a result of contact with the articles and materials regulated in this standard.
1.5	**Food Requiring Pre-Market Clearance**	
1.5.1	Novel Foods	Regulates the sale of novel foods and novel ingredients. Lists the four novel foods that are currently permitted for use in foods, and the condition of use of these: HAD-rich dried marine micro-algae, DHA-rich oil derived from marine micro-algae, phytosterol esters, tall oil phytosterols. It is possible these may be ingredients added during production of fish product.
1.5.2	Food Produced Using Gene Technology	Regulates sale of food produced using gene technology, other than additives and processing aids. Prohibits sale and use of these foods unless they included under Division 1. Currently seafoods produced using gene technology are not permitted.
1.6	**Microbiological and Processing Requirements**	
1.6.1	Microbiological Limits for Food	Lists the maximum permissible levels of food-borne microorganisms that pose a risk to human health in nominated foods, or classes of foods. Includes mandatory sampling plans. Microorganisms relevant to seafood include - *Listeria monocytogenes*, coagulase-positive staphylococci, *Salmonella*, *Escherichia coli*.
2.2	**Food Product Standards – Meat, Eggs and Fish**	
2.2.3	Fish and Fish Products	Defines the term ‘fish’ and provides a compositional standard specific to histamine in fish and fish products. Also requires provision of certain cooking instructions for raw fish that has been joined using a binding system without the application of heat.
3	**Food Safety Standards (Australia only)**	
3.1.1	Interpretation/ Application	Apply to the other food safety standards set out in Chapter 3 of the Code.
3.2.2	Food Safety Practices and General Requirements	Sets out specific requirements for food businesses and food handlers that will ensure food does not become unsafe or unsuitable. Applies to establishments involved in processing and/or sale of seafood.
3.2.3	Food Premises and Equipment	Sets out requirements for food premises and equipment that will facilitate compliance by food businesses with the food safety requirements of Standard 3.2.2. Applies to establishments involved in processing and/or sale of seafood.

Attachment 7

Available Codes of Practice for the Safe Production of Seafood

Sumner, J. (1997). ISO Best Practice Manual: Catching and Handling of Live Reef Fish Aboard the Vessel and Storage and Delivery of Live Reef Fish. Australian Seafood Industry QA Project.

Sumner, J. (1997). ISO Best Practice Manual: Catching and Handling of Mullet. Australian Seafood Industry QA Project.

Sumner, J. (1997). ISO Best Practice Manual: Catching and Handling of Spanner Crabs and Spanner Crabs Processing and Delivery. Australian Seafood Industry QA Project.

Sumner, J. (1997). ISO Best Practice Manual: Catching and Handling of Wild-Caught Prawns and On-Shore Processing of Wild-Caught Prawns. Australian Seafood Industry QA Project.

Sumner, J. (1997). ISO Best Practice Manual: Harvest, Processing and Transport of Farmed Prawns and Harvest, Processing and Transport of Live Prawns. Australian Seafood Industry QA Project.

Sumner, J. (1999). The Australian Cold Chain Food Safety Programs 1999. Australian Food and Grocery council, Australian Supermarket Institute and Refrigerated Warehouse and Transport Association of Australia.

Sumner, J. (1999). The Australian Cold Chain Guidelines 1999. Australian Food and Grocery Council, Australian Supermarket Institute and Refrigerated Warehouse and Transport Association of Australia.

Australian Institute of Environmental Health (1993). National Code for the Construction and Fitout of Food Premises. AIEH; Deakin West.

Department of Primary Industries, Queensland (1999). Queensland Australia Aquaculture Information Series: Code of Practice Post Harvest Handling of Farmed Barramundi.

Department of Primary Industries, Queensland (1999). Queensland Australia Aquaculture Information Series: Code of Practice Post Harvest Handling of Farmed Black Tiger Prawns.

Jusseit, H and Robinson, E. (2003). Industry Code of Practice for Responsible Fishing. Eastern Tuna and Billfish Fishery. Mooloolaba, QLD.

New South Wales Silver Perch Growers Association (1998). Part 1: Quality Assurance. Part 2: Code of Practice.

SeaQual (1999). SeaQual Food Safety Guidelines for Seafood Harvesting[1].

SeaQual (1999). SeaQual Food Safety Guidelines for Seafood Processing[1].

SeaQual (1999). SeaQual Food Safety Guidelines for Seafood Retailing[1].

SeaQual (1999). From Catch to Distribution of Seafood. Food Safety System Guidelines[1].

SeaQual (2000). SeaQual Food Safety Guidelines for Seafood Aquaculture[1].

Seafood Services Australia (2003). Australian Seafood Standard - Version 9. Seafood Services Australia Ltd. http://www.seafoodservices.net/

Sydney Fish Market (2000). Seafood Handling Guidelines.

WA Seafood Quality Management Initiative (1999). Handbook for on Board Handling of Fresh Fish.

Warren, R. (1996). A Guide to the Safe Handling and Inspection of Seafood. Queensland Health; Queensland.

1 *Now Seafood Services Australia Ltd.*

Attachment 8

The Imported Food Inspection Scheme and Seafood Testing

The Imported Food Inspection Scheme (IFIS) is the subject of a memorandum of understanding (MOU) between Food Standards Australia New Zealand (FSANZ) and the Australian Quarantine and Inspection Service (AQIS). FSANZ is responsible for developing risk assessment policies and undertaking risk assessments when required to recommend on the appropriate risk categorisation of selected foods.

1. Categories of Inspection

Using scientific risk assessment, food is placed into one of three inspection categories that determine the frequency of inspection:

- *Risk,*
- *Active surveillance* and*,*
- *Random surveillance*.

Foods in the *risk* and *surveillance* categories are determined and routinely reviewed by FSANZ. Upon advice from FSANZ, the Minister of Agriculture, Fisheries and Forestry may make an order specifying a food/test combination within the inspection categories.

All foods in the *risk* category are inspected and tested, whereas all foods in the *surveillance* category referred to IFP are inspected, but not all are tested.

Risk categorised food is food that has the potential to pose a high risk to public health. At the point of entry, the Australian Customs Service (ACS) refers 100 percent of *risk* categorised foods, electronically, to AQIS for inspection status.

A performance-based approach applies. Food products from foreign producers with a consistent history of compliance are inspected less frequently than products from new suppliers or those with a history of failure against Australian standards. The three inspection rates are defined in the Imported Food Control Regulations, and any failure results in immediate intensification of the inspection regime. *Risk* categorised food remains subject to AQIS control pending the analytical results. The performance-based inspection levels are as follows:

- The first five shipments of a particular food first arriving from a particular producer are inspected; after five consecutively cleared shipments, inspection intensity drops to the next level;
- One in four shipments is then inspected (the other three are automatically released); after 20 cleared inspections and, if importation follows a steady pattern, inspection intensity drops to the next level;
- One in 20 shipments is then inspected (the other 19 are automatically released).

Active surveillance category 10 percent of shipments of designated *active surveillance* foods, from every supplying country, are inspected. These products are released upon sampling. The test results of *active surveillance* foods are analysed by FSANZ to determine the appropriate category classification for the foods.

Random surveillance category 5 percent of all consignments of foods not included in the *risk* or *active* categories are inspected. These products are released upon sampling. Neither AQIS nor the importer has the ability to predict which shipment or which foods will be selected for inspection.

A holding order can be issued where an *active* or *random surveillance* food does not comply with the standards. A holding order against a foreign supplier effectively raises the inspection category of the food to '*risk*' status. This means that all future shipments of that food from the offending supplier are automatically detained and held until compliance with Australia's requirements is confirmed. After five clear inspections, the food reverts to its prior category.

2. Imported Seafood Testing

There are currently tests applied to imported seafood on the *random surveillance* category and the *risk* list.

3. Current random category requirements

Product Group	Tariff Group	Food to be inspected	IFIS Testing Requirements	Limits
Fish -fish fillets and other fish meat	0302 0303 0304	All fish - fish fillets and other fish meat - fresh chilled or frozen and <u>not on the risk</u> list. All farmed fish	Histamine and metals (mercury only)	Refer to Code
Fish dried, smoked, in brine and fish meal	0305	All fish and fish meal - dried, smoked, salted, or in brine whether or not cooked Farmed fish products Ready-to-eat products	Histamine and metals (mercury only) As for 'all' plus *Staphylococcus enterotoxin*	Refer to Code nd
Crustaceans (raw)	0306	All crustaceans (raw) - chilled, frozen, dried or salted All farmed crustacea – Live crustaceans –	Metals (mercury only) and sulphur dioxide PROHIBITED IMPORTS	Refer to FSC
Molluscs (including snails) – (raw).	0307 0307.6000	All Scallops, cuttlefish, octopus- (raw), chilled, frozen, salted or dried Terrestrial snails All unopened bivalve molluscs & live snails are >	Metals (mercury only) (Cooked) - SPC and *E. coli* PROHIBITED IMPORTS	Refer to FSC

Note: the following amendments will be made to the random surveillance category in the near future:

- an antibiotic screen will apply to all fresh farmed fish;
- the mercury test will be deleted for 'all fish and fish meal';
- sea urchins are to be tested for *L. monocytogenes* (*L. mono*/25g n=5, c=0, m=0);
- jellyfish are to be tested for *L. monocytogenes* (*L. mono*/25g n=5, c=1, m=0, M=100).

Current *risk* list requirements

FOOD	RISK	ANALYSES	LIMITS
Crustaceans - (cooked & chilled) including cooked peeled prawns Excluding canned product that is commercially heat treated. [1]	H	*E. coli,* SPC *Salmonella* SET *Vibrio cholera* [2]	10/g 10^6/g nd nd nd
Crustaceans - (cooked & frozen) including cooked peeled prawns. Excluding canned product that is commercially heat treated. [1]	H	*E. coli* SPC *Salmonella* SET *Vibrio cholera* [2]	9/g 10^5/g nd nd nd
Fish of the following kinds whether <u>whole, filleted or further processed, whether dried or not.</u> All Shark (including Dogfish), *Rexea solandri* (Gemfish, Note; sometimes mistakenly referred to as NZ hake), and tuna. -------------------------- Canned tuna and tuna products -------------------------- Smoked vacuum packed fish and smoke flavoured vacuum packed fish	M M # H	Mercury Histamines ---------------------- Mercury and histamines ---------------------- *Listeria monocytogenes*	Refer FSC 200 mg/kg Refer FSC, 200 mg/kg nd

Marinara mix Chilled or frozen whether blanched or not. Excluding canned product that is commercially heat treated. [1]	H	*E. coli* SPC *Salmonella* Paralytic shellfish poison Domoic acid	See table 2 ' ' ' ' 0.8 mg/kg 20 mg/kg
Molluscs, ready for consumption, whether chilled or frozen. Bivalve molluscs, mussels, clams, cockles, scallops etc. Excluding canned product that is commercially heat treated. [1] -------------------- Mussels, Marinated mussels that are ready for consumption whether chilled or frozen. (excluding goods packed in metal cans, glass jars or glass bottles that have been commercially heat treated). [1]	H H	E. coli SPC Vibrio cholera Paralytic shellfish poison Domoic acid -------------------- As for Molluscs plus Listeria monocytogenes	See table 1 ' ' nd 0.8 mg/kg 20 mg/kg ---------- nd

[1] In this document 'canned product that is commercially heat treated' means:
Food that is enclosed in hermetically sealed containers such as:
- metal cans,
- retort pouches,
- plastic containers that have heat sealed lids or lids closed by a double seam *e*.g. as for metal cans), but excludes those with snap on plastic lids,
- glass jars with 'twist off' lids, but excludes those with screw top lids, and
- glass bottles with 'twist off' caps but excludes those with screw top caps,

where the food has been subject to commercial heat treatment (retorting) in the closed container or the food has been 'hot filled' into the containers before closing.

[2] *Vibrio cholerae*: if the presence of serotypes, 01, or 0139, or non 01, or non 0139 is confirmed in cooked crustacea whether chilled or frozen, the food must be deemed non compliant.

Table 1: Molluscs, other than scallops

Test	**n**	**c**	**m**	**M**
E coli	5	1	2.3	7
Standard Plate Count	5	1	10^5	5×10^5

Table 2: ***Marinara mix*** *(whether raw or cooked)*

Test	**n**	**c**	**m**	**M**
E coli	5	1	2.3	7
Standard Plate Count	5	2	10^5	10^6
Salmonella	Absent in 25g composite sample			

Abbreviations

M # = medium risk – Food may be released after initial inspection.

NOTE: The exception being where another test and hold risk test is applied *e.g.* if an aflatoxin test is applied to products containing peanuts or peanut products as an ingredient, such as with canned tuna in satay sauce, the food must be held pending the result of the aflatoxin analysis.

H = high risk - Food must be held pending results of analysis.
Nd = not detectable
SET = staphylococcal enterotoxin
SPC = Standard Plate Count

Note: the following amendments will soon be made to the *risk* list
- the mercury test will be deleted for canned tuna';
- the histamine test will be deleted for all Shark (including Dogfish), *Rexea solandri* (Gemfish; sometimes mistakenly referred to as NZ hake), and tuna.

Attachment 9

A risk ranking of seafood in Australia

MAY 2004

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Glossary

ANZFA	Australia New Zealand Food Authority
ASQAP	Australian Shellfish Quality Assurance Program
bw	bodyweight
cfu	colony forming units
Codex	Codex Alimentarius Commission
EHEC	Enterohaemorrhagic *Escherichia coli*
EIEC	Enteroinvasive *Escherichia coli*
EPEC	Enteropathogenic *Escherichia coli*
ETEC	Enterotoxigenic *Escherichia coli*
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FSANZ	Food Standards Australia New Zealand
g, ng, μg, mg, kg	gram, nanogram, microgram, milligram, kilogram
HACCP	Hazard analysis critical control point
IAEA	International Atomic Energy Agency
ICMSF	International Commission on Microbiological Specifications for Foods
JECFA	Joint FAO/WHO Expert Committee on Food Additives
l, ml	Litres, millilitres
MU	mouse units – the unit of measure described in *Recommended procedures for examination of seawater and shellfish*, Irwin N. (ed.) 4th Ed. 1970. American Public Health Association Inc.
nm	nanometre
ppt, ppm, ppb	parts per thousand, parts per million, parts per billion
PTDI	Provisional tolerable daily intake
PTWI	Provisional tolerable weekly intake
RNA	Ribonucleic acid
WHO	World Health Organization

Summary

This report qualitatively ranks the public health and safety risk posed by consumption of seafood in Australia. Overall the risks from seafood are usually well managed and are therefore considered relatively low. There are only a very small number of products that may present higher public health and safety risks.

The risk ranking compares the relative risks associated with the wide variety of seafood commodities available in Australia – domestically produced and imported. It takes into account the chemical and biological food safety hazards potentially present, and assigns each commodity or group of commodities to a broad relative risk category: low, medium or high.

The ranking brings together the available scientific and technical information on food safety hazards in seafood and identifies seafood commodities of higher priority for the development of risk management strategies. It provides a scientific basis for the development of a Primary Production and Processing Standard for seafood and informs other risk management approaches designed to protect consumers from seafood-borne illnesses.

Risk ranking method

Food Standards Australia New Zealand (FSANZ) estimated relative public health risks by considering the severity of any adverse health effect resulting from the presence of a particular hazard in a seafood commodity, together with the likelihood of that adverse health effect occurring.

Estimates of the severity of illness due to the presence of hazards in seafood followed an internationally accepted procedure that considers the duration of illness, likelihood of death and potential for ongoing adverse health effects.

Estimates of the likelihood of adverse health effects were based on:

- the link between the hazard and illness due to consumption of the particular seafood (epidemiological data)
- the prevalence and concentration or level of the hazard in seafood
- patterns of consumption of the specific seafood (frequency of consumption, amount eaten)
- the impact of existing regulatory and non-regulatory risk management systems
- data and information on the following factors related to the properties of the hazard and the effect of production, processing and handling, particularly in terms of how they might influence hazard levels at the point of consumption:
    1. the capacity for microbiological pathogens to survive or grow in the commodity
    2. any other relevant properties of the hazard (for example, toxigenic or infectious dose)
    3. the probable effect of production, processing and handling on the presence and level of the hazard
    4. the likely effect of consumer handling (including cooking and product shelf life) on hazard levels.

Using a ranking matrix, FSANZ combined the severity and likelihood estimates into a broad relative risk estimate for each hazard that might be found in a seafood commodity (for example, prawns) or group of similar commodities (for example, oysters and other bivalve molluscs). An overall relative risk ranking for each commodity (or group of commodities) was then obtained by determining the highest relative risk ranking estimated for the commodity.

Future reviews of the risk ranking

The risk ranking is based on the best current knowledge and data. Such rankings are dynamic, with their evolution reflecting increasing knowledge about the hazards and the consumer's exposure to them. For example, the introduction of new technologies, modified production practices and changes in management strategies may influence the need to review the rankings.

FSANZ will maintain a watching brief of the scientific literature and international activities, for example, Codex Alimentarius, which may impact on the risk ranking. Where significant data gaps impacting upon the risk ranking process are filled by the results of ongoing scientific studies and surveys of the prevalence and levels of food safety hazards in seafood in Australia, the robustness of the risk rankings can be better assessed and the rankings may be further refined.

Food safety hazards in seafood

Seafood can contain food safety hazards derived from several different sources. Some of these hazards occur naturally in the environment in which seafood lives and grows and are unavoidable contaminants of seafood when it is harvested. Others are a consequence of the impact of human activities on the environment.

In the pre-harvest phase of production, feed components, veterinary drugs and other chemicals employed in aquaculture production may also present a public health risk.
In addition to these, food hazards can be introduced into seafood, or caused to increase to potentially hazardous levels, through direct contamination by food handlers and contaminated utensils and equipment and by inadequate handling (for example, temperature abuse, cross-contamination, inadequate processing).

The extent to which any food safety hazard is likely to be present in seafood depends on a number of factors. These factors include the biology of the particular seafood species, its growing environment, and the conditions along its production and processing supply chain. Therefore, the broad biological classes of seafood species (bivalve and cephalopod molluscs, crustacea and finfish), and the public health risks posed by hazards associated with specific commodity groups within those classes, have been considered separately.

Summary of risk rankings

The relative risk rankings described in this report demonstrate the generally high level of safety of seafood products. Under current risk management practices – both voluntary and mandatory – public health risks are relatively low for the majority of seafood. A small number of commodities present a higher public health risk than other seafood.

The report concludes that the following seafood sectors are ranked in the higher relative risk category:

- oysters and other bivalve molluscs (except when the consumed product is only the adductor muscle, for example, roe-off scallops) harvested from growing environments likely to be exposed to faecal contamination and/or not under a shellfish safety management scheme
- ready-to-eat cold-smoked finfish (and other ready-to-eat cold-smoked seafood products), when eaten by population sub-groups susceptible to invasive Listeriosis.

Oysters and other bivalve molluscs

Oysters and other bivalve molluscs (except when the consumed product is only the adductor muscle, for example, roe-off scallops) harvested from growing environments vulnerable to faecal contamination and/or not under a shellfish safety management scheme present a relatively high risk to public health, mainly due to the likelihood of illness caused by contamination with hepatitis A virus and algal biotoxins (particularly amnesic shellfish poison and paralytic shellfish poison). These hazards are introduced in the pre-harvest phase of bivalve production.

This relatively high risk ranking is consistent with other studies based on recent epidemiological data that reflected a situation where inconsistent risk management systems were in place across Australia.

Food-borne illness due to oysters and other bivalve molluscs in Australia have resulted in a number of small outbreaks and sporadic cases due to *Vibrio* species and a few large outbreaks due to enteric viruses in oysters harvested from polluted and inadequately controlled waters.

While adoption of risk management strategies has improved the safety of bivalve shellfish in recent times, some risk remains. Although monitoring of harvest waters for indicators of sewage pollution (for example, faecal or total coliforms) helps to manage the risks due to enteric pathogens, bacterial and viral, it cannot predict levels of *Vibrio* species and enteric viruses in oysters. Oysters harvested from waters without a risk management system in place have a higher risk of contamination by algal toxins. Therefore, where oysters and bivalves are harvested from waters managed under a comprehensive shellfish safety scheme, such as the Australian Shellfish Quality Assurance Program (ASQAP), the risk is significantly reduced – notably, the likelihood of a food-borne illness is low.

The risk rankings for oysters and other bivalves were the same regardless of whether they were to be cooked or eaten raw, as the hazards leading to the risk rankings are not greatly affected by the light cooking normally applied to these products.

Ready-to-eat cold-smoked seafood

Ready-to-eat cold-smoked finfish (and other ready-to-eat cold-smoked seafood products) present a higher risk to public health relative to other seafoods due to the possibility of contamination with *Listeria monocytogenes* and the potentially severe illness it causes in at-risk population sub-groups such as pregnant women. *L. monocytogenes* is a ubiquitous organism often found in processing environments, and may also be present in fish at the time of harvest. Cold smoking is not a listericidal process.

Recognition of the risks by both regulators and the industry has resulted in a high level of management of *L. monocytogenes* in Australia and a lower risk of illness to the general population.

FSANZ has previously recognised the inherent risk to the general population due to *L. monocytogenes* in cold-smoked seafoods by including a microbiological limit standard for the organism in ‘ready-to-eat processed finfish, other than fully retorted finfish’ in the *Australia New Zealand Food Standards Code*. When the food safety risks are managed such that cold-smoked seafoods meet this regulatory requirement, the relative risk ranking for the general population is low, although the relative risk ranking for susceptible populations (for example, pregnant women, neonates, immunocompromised people and the elderly) is high. FSANZ is currently reviewing its dietary advice to these at-risk sub-groups in order to manage their food safety risks due to *L. monocytogenes* from all food sources.

If the food safety risks are not properly managed, such that cold-smoked seafoods do not meet the microbiological limit standard for *L. monocytogenes*, the relative risk ranking is high for at-risk sub-groups and medium for the general population. This takes account of the relatively long shelf life of the product and the high standards of hygiene and sanitation in processing and good temperature controls across the food supply chain, up to and including the consumer, that is needed to ensure the safety of the product.

Other seafood commodities

FSANZ ranked other seafood commodities as presenting a low or medium relative public health risk.

The vast majority of whole and filleted finfish was ranked in the low relative risk category. A few groups of fish species were ranked in the medium relative risk category:

- larger specimens of particular species of tropical and sub-tropical finfish from certain fishing areas, due to the potential for illness as a result of accumulation of ciguatoxins
- large, long living or predatory fish, such as swordfish, shark/flake and some tuna, which tend to accumulate higher levels of methylmercury than other fish species. The ranking applies to the at-risk sub-population (the foetus) when the mother consumes mainly those species.

A medium ranking was also assigned to the following commodity groups (due to the listed hazards):

- univalve molluscs (for example, abalone) and roe-off scallops (from algal biotoxins causing amnesic shellfish poisoning and paralytic shellfish poisoning)
- prawns (*V. cholerae* O1, *Salmonella* Typhi, arsenic)
- canned seafood (*Clostridium botulinum*)
- hot-smoked fish products (*C. botulinum*)
- some whole and filleted finfish (arsenic).

In most cases, hazards linked to these medium risk commodities are already regulated in the Code (for example, *Salmonella* in prawns, arsenic in finfish) or through longstanding and effective industry codes of practice (for example, *C. botulinum* in low-acid canned foods).

Of the seafood commodities ranked in the medium risk category, prawns and some finfish (whole or as fillets) have been linked to several outbreaks of food-borne illness in Australia in recent years. For prawns, the associated food safety hazards have been primarily microbiological hazards, while for finfish, ciguatoxin, histamine fish poisoning and escolar wax esters account for the great majority of the outbreaks.
The majority of seafood commodities presented a lower risk to the general population. For some of these commodities, limited consumption of the products was the main factor in leading to the conclusion that the likelihood of adverse health effects from associated hazards was very low. For others, the probable effects of downstream processing and consumer handling in reducing hazard levels were factors leading to a low likelihood of illness.

1. Scope and purpose

FSANZ has qualitatively ranked the relative public health and safety risks posed by chemical and microbiological hazards in seafood products eaten in Australia.

The output of this report is presented as a qualitative risk ranking, rather than as a risk assessment of commodity/hazard pairs. Risk ranking, a form of comparative risk assessment [1,2], enables differentiation of the relative level of risk posed by microbiological and chemical hazards present in the diverse range of seafood commodities in the Australian marketplace – for example, molluscs, crustacea and finfish.

Although not presented in the format of a formal risk assessment, the report is based on the elements of risk assessment defined by the Codex Alimentarius Commission: hazard identification; hazard characterisation; exposure assessment; and risk characterisation [3].

The analysis was, to some extent, constrained by the limited epidemiological data on seafood-borne illness and the scarcity of information of the prevalence and levels of hazards in seafood products in Australia. A quantitative exposure assessment was therefore not undertaken.

A qualitative assessment was made of the exposure of consumers to hazards in seafood products, drawing on available information on patterns of seafood consumption and the prevalence and levels of hazards in seafood. This assessment also took into account the likely influences of the conditions of production, processing, storage and use of seafood commodities along the entire seafood production and processing supply chain. No attempt was made to evaluate the efficacy of different risk management options.

Consistent with the needs of the risk managers, the output of this exercise is presented in the form of a three-tier relative risk ranking – low, medium and high. FSANZ will draw on the risk rankings and associated information presented in this report as a basis for developing suitable risk management options and strategies for seafood eaten in Australia. Commodities ranked as posing relatively high risks to public health and safety are identified as high priorities to be addressed in any risk management strategies that flow from consideration of the report by risk managers. Risk managers may also wish to consider whether specific risk management strategies need to be developed for commodities in the medium relative risk ranking category.

2. Introduction

This report draws on a number of risk assessments that have been undertaken on Australian seafood in recent times. For example, the former Australia New Zealand Food Authority (ANZFA) undertook risk assessments of contaminants and microbiological hazards associated with seafood as part of its review of the Code in 1999 [4–7]. These assessments informed the establishment of various standards applying to seafood, including those specifying microbiological limits and maximum levels of contaminants. More recently, risk assessments and risk profiling covering many seafood commodity/hazard combinations have been commissioned by Seafood Services Australia Ltd (SSA) and Safe Food Production New South Wales (SafeFood NSW) [8–10].

In addition, a number of international risk assessments of seafood have been conducted, focusing particularly on *Vibrio* species and *Listeria monocytogenes* [11–13]. These and other assessments [14–16] have sought to identify and assess the risk associated with specific commodity/hazard combinations.

The goal of this risk ranking document is to provide a broader comparative overview of risks associated with seafood in Australia, with the purpose of identifying higher-risk industry sectors and commodity groups.

In compiling this risk ranking document, a wide range of scientific literature and information from Australia and overseas (including the risk assessments mentioned above) was reviewed and evaluated. The evaluation identified key hazards and assessed where in the seafood production and processing supply chain these food safety hazards might be introduced, increased, reduced or eliminated. This latter information is presented in Appendix 1 as important background information for risk managers.

To the extent possible within the scope and purpose, the principles for conducting risk assessment outlined in *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* [3], as adopted at the 26th Session of the Codex Alimentarius Commission, were followed in the conduct of this risk ranking exercise.

The scope, purpose and form of output of this risk ranking are defined, and the extent to which the four steps of risk assessment have been incorporated is described, in Section 1. All available relevant quantitative and qualitative data have been taken into account, including information relating to through-chain factors impacting upon the relative level of risk. Constraints and uncertainties impacting on the process are described, along with the assumptions underpinning the comparative risk rankings. The risk rankings are presented in a format designed to help risk managers make informed decisions regarding strategies for risk minimisation.

Sources of hazards associated with seafood in Australia

Seafood can contain microbiological, chemical, and physical hazards derived from different sources. Some of these hazards occur naturally in the environment in which seafood lives and grows and are unavoidable contaminants of seafood when caught. Examples include:

- endogenous bacterial species (for example, vibrios, aeromonads) which may or may not be pathogenic to the host species

- biotoxins (typically of algal or bacterial origin, occasionally metabolised by the host to other toxic forms)
- helminthic parasites (where the seafood species is typically an intermediate host)
- heavy metals (for example, mercury, cadmium) and other naturally occurring chemicals (for example, dioxins).

Seafood may also contain food safety hazards as a consequence of the impact of human activities on the environment. Such environmental pollutants include:

- bacterial and viral pathogens derived from human sewage and animal faecal pollution of seafood growing and harvesting areas (for example, *Salmonella* spp., Noroviruses)
- industrial chemical pollutants (for example, heavy metals, polychlorinated biphenyls)
- agricultural chemical run-off (for example, pesticide residues).

Other potential sources of contamination of seafood in the pre-harvest phase include feed components, veterinary drugs and other chemicals employed in aquaculture production.

In the post-harvest phase, hazards can be introduced into seafood, or grow to potentially hazardous levels, through:

- direct contamination by food handlers and contaminated utensils and equipment
- inadequate handling (for example, temperature abuse, cross-contamination, inadequate processing)
- processing operations and the processing environment.
-

In addressing chemical hazards, the report distinguishes between:

- those contaminants which are present in food as a result of deliberate addition to seafood or use in seafood production or agriculture
- those which are present as natural contaminants.

The former, including agricultural chemicals, pesticides and veterinary drugs, are subject to pre-market safety assessment and their presence in food is regulated under the Code. These chemicals are not addressed in this report. However, food safety hazards which are natural environmental contaminants of seafood, such as certain heavy metals, and which are inherent or unintentional components of foods, are evaluated along the production and processing supply chain.

Physical hazards associated with seafood have not been specifically addressed in this risk ranking report. Such physical hazards include intrinsic hazards (for example, bones, shell fragments, pearls in oysters) and extrinsic hazards (for example, grit in shellfish, hooks, metal and glass inclusions). The intrinsic physical hazards are less likely to cause injury because of consumer awareness of the potential for the hazard to be present in seafood [17]. Extrinsic physical hazards are potentially introduced at all steps of the production and processing supply chain. Sources for such contaminants include raw materials, badly maintained facilities and equipment, improper production procedures, packaging materials and poor employee practices [18].

Physical hazards may cause traumatic injury to the mouth, tongue, teeth, gums, throat, stomach and intestines, as well as presenting a choking hazard, and would normally be addressed by adherence to Good Manufacturing Practices (GMP), a hazard analysis critical control point (HACCP) system and requirements relating to safe and suitable food in state and territory legislation.

Food-borne illness associated with Australian seafood

There have been a number of documented outbreaks of seafood-associated food-borne illness in Australia in recent years. Since 1987:

- outbreaks due to finfish have been caused by ciguatoxin, histamine (scombrotoxin) and wax esters (gempylotoxin)
- outbreaks due to crustacea have been caused by bacterial and viral pathogens, including *Salmonella* Typhi, *S.* Typhimurium PT 64, *Vibrio parahaemolyticus*, *V. cholerae* non-O1/ non-O139, hepatitis A virus and *Clostridium perfringens*
- outbreaks due to molluscs have been caused by Noroviruses, hepatitis A virus, *V. parahaemolyticus*, *V. vulnificus*, *S.* Mississippi, *Listeria monocytogenes* and diarrhoetic shellfish poison (Appendix 2; [19]).

However, these outbreak data represent only a small component of the total morbidity due to seafood consumption in Australia. Sporadic cases of food-borne illness are not included in these datasets (unless a death results), and a low level of reporting of food-borne illness is generally understood to be a major problem. While physicians are required to report some specific illnesses with food-borne aetiology, many food-borne illnesses are not notifiable. Furthermore, most people do not seek medical attention for various mild forms of gastroenteritis, and even quite severe illnesses are typically significantly under-reported [20].

In 2003, OzFoodNet conservatively estimated that the number of cases of food-borne illness in Australia in a typical year from all food sources is between 4 million and 6.9 million cases (mid point 5.4 million cases) [21]. However, in the same report, data is given for outbreaks of food-borne illness in Australia in 2002, indicating there were 92 documented outbreaks affecting only 1819 people. The extent of under-reporting of food-borne illness evident in these datasets highlights the danger of relying solely on outbreak data in evaluating the public health risks due to food safety hazards.

Approaches taken in this report

Grouping of seafood commodities

The extent to which a food safety hazard is likely to be present in seafood and to give rise to a public health and safety risk depends on a number of factors. These factors are related to the biology of the particular seafood species, its growing environment, and the specific activities along its production and processing supply chain. To simplify consideration of these factors, this report considers separately the broad classes of seafood species (bivalve and cephalopod molluscs, crustacea and finfish), and subsequently considers hazards associated with specific commodity groups within these classes. For molluscs and crustacea, these groups are defined broadly in terms of species, genus or family (for example, bivalves, abalone, prawns), whereas for finfish, the groups are based on the different post-harvest processing steps undertaken (for example, canning, smoking, fermenting).

In cases where these relatively broad commodity classes mask a wide range of relative risk across species or between different geographical areas, the impact of these factors on the rankings are discussed more fully in the summary and conclusions. Examples include methylmercury in larger, predatory and long-lived fish species and viral and algal toxin contamination of oysters and other bivalves harvested from polluted and/or unmanaged waters.

Format of this report

The method by which relative risk rankings were estimated for each commodity group is explained in Section 3. This section describes how consideration of the severity of adverse health effects due to hazards present in food and estimates of the likelihood of those adverse health effects occurring in the Australian population due to consumption of seafood are combined into commodity/hazard relative risk rankings. The method by which these rankings are used to provide the overall relative risk ranking for each commodity group is explained.

The relative risk rankings for individual seafood commodity groups are contained in Section 4. The likelihood and severity of adverse health affects due to the hazards potentially associated with each seafood commodity are described, and the estimated risk rankings tabulated. An overall ranking for the commodity is then generated by consideration of the highest relative risk level pertaining to that commodity. Those commodities ranked as relatively high or medium risk are discussed further in Section 5, with attendant uncertainties described in Section 6. The overall conclusions are in Section 7.

In order to avoid unnecessary duplication of material and to simplify this report, various sets of relevant data have also been collated in separate appendixes.

Appendix 1 contains information relevant to the through-chain assessment of hazards in seafood commodities. It includes:

- a description of the production and processing supply chain for each sector/commodity
- a discussion of the points along that supply chain at which specific hazards might be introduced, increased, reduced or eliminated
- a description of the effects of processing and handling and the impacts of existing food safety regulations and voluntary risk management practices on levels of hazards.
-

This information is important in assessing the level of food safety risk in cases where epidemiological and hazard prevalence data are scarce, and as an aid to developing appropriate risk management strategies.

Australian epidemiological data on outbreaks of food-borne illness linked to consumption of seafood between January 1995 and June 2002 are at Appendix 2.

Information on the consumption by (non-infant) Australians of various classes of seafood is at Appendix 3.

Detailed notes on the properties of identified food-borne hazards and their association with seafood commodities relevant to this evaluation are provided at Appendix 4.

The information includes data, where available, on the prevalence and concentration of hazards in seafood and further discussion of epidemiological evidence of food-borne illness due to the presence of each hazard in seafood in Australia or overseas. Much of the information in Appendix 4 has been drawn from formal quantitative and qualitative assessments of the risks associated with consumption of various classes of seafood, or with exposure to certain hazards within the total diet.

Risk ranking method

The public health and safety risks posed by particular seafood sectors have been ranked in general agreement with the principles for risk characterisation as outlined by the Codex Alimentarius Commission.
Codex defines risk as:

> a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food [22]

and recommends that a risk characterisation should provide a:

> qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment [22].

In the case of microbiological hazards, Codex further suggests that such estimates may be validated by comparison with relevant epidemiological data [23]. However, it should be recognised that epidemiological data do not clearly reflect the 'severity' component of risk, except to the extent that the severity of illness impacts upon the relative level of reporting.

Alternative risk ranking methods

Many alternative measures are available for, or have been applied to, the task of ranking the public health and safety risks posed by food, including seafood. Several of these are discussed briefly, below. Further information on these approaches may be obtained by reference to the specific literature cited.

Ross and Sumner's risk ranger

Risk ranger is a semi-quantitative tool for risk profiling based on deterministic Microsoft Excel spreadsheet functions, designed to help risk managers prioritise hazards for more intensive risk assessment and to inform decisions about the value of investing resources in fully quantitative risk assessments [24,25]. It can also be used to explore the effect of different risk management strategies or the extent of changes needed to bring about a desired reduction in risk.

Users of risk ranger input selections from a prepared list of qualitative statements or provide quantitative data (for example, survey or epidemiological data) to describe the commodity/hazard of interest. Based on these inputs, the tool calculates estimates of the probability and severity of outcomes arising from the level and frequency of exposure. These estimates include:

- probability of illness per day per consumer of interest
- total predicted illnesses per annum in the population of interest

- comparative risk in the population of interest
- a risk ranking.

The risk ranking is a logarithmic scale of risk with outputs ranging from zero (absence of risk) to 100 (certainty of death from each serving of food). Rankings were attributed to broad risk categories of Low: <32; Medium: 32–48; and High: >48.

Ross and Sanderson's qualitative risk assessment tool

Ross and Sanderson developed a novel tool to rank the potential impact of food-borne disease from various seafood commodity/hazard combinations, as part of their consultancy report for SafeFood NSW [8]. The scheme takes into account three factors: the severity of the illness (including severity of symptoms, illness duration and likelihood of death, and mode of transmission); the probability of illness (including likelihood of exposure and population susceptibility); and the likely effect of processing and cooking on levels of the hazard.

Corlett and Pierson's hazard classification scheme

Corlett and Pierson developed a two-stage risk assessment tool for food businesses to use in development of HACCP food safety plans [26]. Firstly, the raw materials, ingredients or food, along with the process and the intended consumer, are ranked according to six criteria (Table 1). For every applicable characteristic, the food is assigned a '+'. The higher the number of pluses, the greater the degree of risk attending the particular food.

Table 1: Hazard classification of Corlett and Pierson

Hazard	Risk characteristics
A	Special class restricted for at-risk populations, for example, aged, immunocompromised, infants
B	Product contains sensitive ingredients
C	Process has no step which destroys sensitive organisms
D	Product is subject to re-contamination between processing and packaging
E	Potential for abuse by distributor or consumer which could render the product hazardous
F	Product is consumed without further process to kill micro-organisms

Risk ranking scheme of Huss et al.

Huss et al. developed a qualitative scheme for categorising risk from consuming different seafoods using six criteria (Table 2) [27]. Specific seafoods are ranked according to the number of the risk characteristics that apply. A food is considered *high risk* if four or more risk characteristics apply, and *low risk* if less than four apply.

Table 2: Huss et al. risk ranking scheme

Hazard	Risk characteristics
I	Epidemiological evidence exists to link the product with food-borne disease
II	The manufacturing process lacks a Critical Control Point (CCP) for at least one hazard associated with the product
III	The product has the potential to become recontaminated after processing
IV	There is potential for abusive handling during distribution or in consumer handling
V	There is potential for growth of pathogens in the product
VI	There is no terminal heat process during meal preparation

Center for Food Safety and Applied Nutrition/Food Safety and Inspection Service/Center for Disease Control listeria risk assessment

The United States Food and Drug Administration's Center for Food Safety and Applied Nutrition, in collaboration with the United States Department of Agriculture's Food Safety and Inspection Service and in consultation with the Department of Health and Human Services' Centers for Disease Control and Prevention, conducted a qualitative assessment of the relative risk to public health from food-borne *L. monocytogenes* in selected ready-to-eat foods [11].

The exercise involved individual semi-quantitative risk assessments being performed for each of 23 food categories considered. The results and models for each food category were obtained and then compared, to establish the relative risk among the food categories, including an evaluation of the uncertainty associated with the risk comparison.

Risk ranking model employed

While each risk ranking approach has its strengths and could be used as a tool for ranking relative risks due to seafood consumption in Australia, none met the requirement of providing a broad three-tier categorisation of seafood industry sectors which could be used in a through-chain assessment of risk. Specifically, a need was identified for a broad comparative method able to take into account a large number of hazards having widely different adverse health consequences. This report uses a method based on consideration of the elements of risk as defined by Codex: the likelihood (probability of occurrence) and severity of adverse health effects (illness).

In deriving estimates of the likelihood of illness due to the presence of a particular hazard in a seafood commodity, available data on seafood consumption and the prevalence and levels of hazards in seafood in Australia were taken into consideration. However, significant data gaps have militated against completion of a formal quantitative exposure assessment for each hazard/commodity pairing considered. In addition, specific characteristics of each hazard, factors along the supply chain that might influence the final risk at point of consumption, and recent epidemiological data were all taken into account. Estimates of the severity of adverse health effects were based on an accepted international scheme, which was adapted to take into account hazards not originally included in that scheme (for example, heavy metals, algal biotoxins, helminthic parasites).

A decision matrix was developed to provide broad qualitative rankings of public health and safety risks due to food safety hazards associated with seafood sectors or commodities. The matrix combines the estimates of severity and likelihood of adverse health effects to arrive at a relative risk ranking. The method used to estimate the severity and likelihood of adverse health effects and to combine these into risk rankings are described below.

Severity of adverse health effects

The estimate of the severity of adverse health effects caused by a food-borne agent is based on the ranking scheme for food-borne pathogens and toxins described by the International Commission on Microbiological Specifications for Foods (ICMSF) [28]. The ICMSF ranking scheme categorises hazards by the severity of the threat they pose to human health, taking into consideration the:

- likely duration of illness
- likelihood of death
- potential for ongoing adverse health effects.

The severity of adverse health effects caused by a hazard is ranked as moderate, serious or severe according to the following definitions:

- moderate severity applies when the hazard is likely to cause an illness of short duration with no ongoing adverse health effects (sequelae)
- a serious hazard would cause an illness of longer duration, with some chance of ongoing chronic and debilitating effects
- a severe hazard would cause illnesses with serious sequelae or significant mortality rates.

Under the ICMSF ranking, severe hazards are further divided into those applying to the general population and those applying to specific sub-populations, that is, susceptible individuals (for example, the very young and old, the immunocompromised, and pregnant women and their unborn children). This takes into account those situations where a hazard considered to be of moderate or serious severity to the general population may cause a severe illness in certain susceptible sub-populations. This is reflected in the severity rankings presented in Table 3.

The ICMSF severity ranking scheme was developed to apply principally to microbiological hazards. In this report, the ICMSF approach has been adapted to rank the severity of threat posed by all microbiological and natural contaminant hazards potentially associated with seafood eaten in Australia. Certain chemical contaminants and microbiological hazards not originally ranked by the ICMSF have been added to Table 3 (entries with asterisks) based on information available on the severity of adverse health effects associated with exposure to them. Justification for severity rankings is in the relevant sections of Appendix 4.

In determining the severity ranking for chemical contaminants, particularly heavy metals, it was noted that adverse health effects tend to become evident after prolonged exposure, and are typically chronic in nature. This is in contrast to the situation applying to most microbiological hazards, where a single exposure can lead to illness.

In determining the severity of the threat to human health, no consideration has been given to the likelihood of exposure to the hazard or the probability of occurrence of any illness caused by that hazard. These considerations are encapsulated in the estimate of likelihood of adverse effects, below.

Table 3: Ranking of food-borne hazards by severity of adverse health effects

Severity	Description	Food-borne hazards in seafood	
Moderate	Not usually life threatening; no sequelae; normally short duration; symptoms are self-limiting; can include severe discomfort.	*Staphylococcus aureus* enterotoxin	Histamine
		Enteropathogenic *Escherichia coli*	*Vibrio parahaemolyticus*
		Enterotoxigenic *E. coli*	Zinc*
		V. cholerae non-O1/non-O139	Wax esters*
		Norwalk-like viruses (noroviruses)	
Serious	Incapacitating but not life threatening; sequelae infrequent; moderate duration.	Non-typhoid *Salmonella* spp.	*Yersinia* spp.
		Non-dysenteric *Shigella* spp.	*Listeria monocytogenes*
		*Aeromonas hydrophila**	*V. vulnificus**
		Hepatitis A virus	Helminthic parasites*
		Algal biotoxins* (DSP, NSP)	Mercury*
		Ciguatoxin*	
Severe	Life-threatening or substantial chronic sequelae or long duration.	**General population**	
		S. Typhi *S.* Paratyphi	Cadmium*
		Shigella dysenteriae	*V. cholerae* O1/O139
		Enterohaemorrhagic *E. coli*	Aflatoxins
		Clostridium botulinum neurotoxin	Arsenic*
		Algal biotoxins* (ASP, PSP)	Lead*
		Cadmium*	
		Susceptible populations	
		L. monocytogenes	*V. vulnificus*
		Enteropathogenic *Escherichia coli* and Enterotoxigenic *E. coli*	Hepatitis A virus
		Mercury	

* Hazards not originally listed in the International Commission on Microbiological Specifications for Foods severity ranking table.

Key: ASP = amnesic shellfish poison; DSP = diarrhoetic shellfish poison; NSP = neurotoxic shellfish poison; PSP = paralytic shellfish poison.

See Appendix 4 for discussion of the different severity rankings amongst the algal biotoxins.

Likelihood of adverse health effects

The estimate of the likelihood of adverse health effects takes into consideration relevant available data and information on:

- the link between the hazard and illness due to consumption of the particular seafood (epidemiological data)
- the prevalence and concentration or level of the hazard in seafood
- patterns of consumption of the specific seafood (that is, frequency of consumption, amount eaten)
- the impact of existing regulatory and non-regulatory risk management systems
- data and information on the following factors related to the properties of the hazard and the effect of production, processing and handling, particularly in terms of how they might influence hazard levels at the point of consumption:
    - the capacity for microbiological pathogens to survive or grow in the commodity

- any other relevant properties of the hazard (for example, toxigenic or infectious dose)
- the probable effect of production, processing and handling on the presence and level of the hazard
- the likely effect of consumer handling (including cooking and product shelf life) on hazard levels.

Epidemiological data

Australian and overseas epidemiological evidence of food-borne illness resulting from consumption of a particular seafood commodity demonstrates observed risk, and is accorded the highest weighting in considering the likelihood of adverse health effects. Where available, Australian epidemiological data were considered to be of greater relevance than those from overseas. However, it is important to note the limitations of existing epidemiological data on seafood-borne illness in Australia.

The hazards listed as 'moderate' in Table 3 result in self-limiting illnesses of short duration and tend to be poorly reported in all epidemiological datasets. This is emphasised by United States data that shows even quite severe illnesses are significantly under-reported or are not traced back to a particular hazard and/or food source [20]. In cases where an epidemiological link is established, the strength of the linkage is expressed as an odds ratio. The strength of that ratio indicates the likelihood that the linkage is true. It is understood that there is a great deal of uncertainty with this form of data.

Prevalence and concentration data

Data from monitoring studies of hazards in seafood were used to demonstrate a clear link between particular hazards and certain seafood commodities. For some commodity/hazard combinations (for example, mercury in finfish, *L. monocytogenes* in cooked crustacea), there have been sufficient studies conducted to provide a clear picture of the extent of contamination in products available in Australia. For other combinations there is little Australian prevalence and concentration data to draw on.

Other information used to assess the likelihood of adverse health effects included data on the prevalence and level of hazards in imported seafood (for example, data from the Australian Quarantine and Inspection Service Imported Food Inspection Program testing regime) and a database of Australian food recalls maintained by FSANZ.

Information from these sources was taken as being indicative of the potential for the seafood commodity/hazard combination to cause adverse health effects. This type of data is treated cautiously, however, as food standards are conservatively set to protect public health and safety. Therefore, failures to meet regulatory limits may not necessarily indicate the presence of a hazard at a concentration likely to present an immediate risk to public health. However, while the presence of a hazard does not necessarily imply an immediate threat of illness in a consumer of that product, other factors may apply, leading to a public health and safety risk.

The use of such routine inspection data also has other limitations. Not all testing is random, and sample size is often quite low compared to the total food volume. The data therefore have the potential to be biased and can become insensitive for low incidence pathogens, introducing uncertainty which can affect the validity of conclusions based upon them.

Consumption data

Data on the level of consumption of specific seafood commodities in Australia were used to adjust the estimates of likelihood of adverse health effects, to take into account relative exposure to hazards in different seafood commodities in the general population. Consumption figures were derived from the results of the 1995 National Nutrition Survey of Australia, using FSANZ's dietary modelling computer program, DIAMOND. The National Nutrition Survey collected data from 13 858 respondents, using a 24-hour food recall method. Data on consumption of seafood commodities are presented as mean and 95th percentile consumption amounts along with the number and percentage of respondents who ate that seafood commodity in the survey period (Appendix 3). Some limited frequency of consumption data were also collected as part of the National Nutrition Survey, but only covered a few broad food categories and were of limited value to this assessment.

Food-borne illnesses due to microbial hazards are almost always related to single exposure episodes or consumption on a single day. As such, the 24-hour recall data provide critical insights into the reach of the likely exposure over age/gender groups, the extent of the exposure in terms of individuals exposed and the dose of the exposure in terms of the portion eaten. Here, the long-term intake is not an important factor, so absence of frequency of consumption data is not a major limitation to the ranking. In this case, only sample size is a limitation for obtaining precise estimates for relatively rare events.

A limitation of the National Nutrition Survey method is that it tends to over-estimate habitual food consumption amounts for high consumers. In particular, for foods that people tend to consume less than once a week (for example, molluscs and crustacea), consumption figures derived from a 24-hour recall may be higher for most consumers than if consumption amounts were averaged over a longer time frame that better reflects habitual consumption of these foods.

For metals and toxins, the likelihood estimates are based on the dietary modelling conducted by ANZFA for the review of the Code [4,5,7].

Statistics on production, import and export of seafood commodities, such as those available from the Australian Bureau of Statistics – the *Apparent Consumption of Foodstuffs* series – and the Australian Bureau of Agricultural and Resource Economics – the *Australian Fisheries Statistics* series – were also considered, where appropriate. These data sources provide useful information on the gross amount of seafood available for consumption each year in Australia, but do not contain any insight into the frequency, prevalence or levels of consumption of these commodities within the Australian population such as is provided by the National Nutrition Survey data.

Impact of existing regulatory and non-regulatory risk management systems

The likelihood estimates and resultant risk rankings take into account the effect of the regulatory and non-regulatory mechanisms currently in place to manage seafood safety risks. This approach recognises that the epidemiological data and information on the prevalence and concentration of hazards in seafood are gathered in an environment where those existing risk management mechanisms apply. It also allows some conclusions to be made about the effectiveness of those measures and may point to inadequacies or gaps in the current system.

It is also recognised that changes in management of public health risks associated with seafood have recently taken place, either in response to incremental advances in awareness of food safety issues or in reaction to failures in the previous management systems.

The impact of these changes may not be fully gauged by assessing the burden of food-borne illness. Epidemiological data are an historical record and may not accurately reflect recent changes in the regulatory environment. For example, the effectiveness of the partial, yet ongoing, implementation of a shellfish safety program in New South Wales can only be completely validated over a period of time.

Such ongoing changes in risk management systems introduce a further degree of uncertainty into the final relative risk rankings generated in this report. They also demonstrate the need for risk assessment to be an ongoing, dynamic process, responsive to changes in circumstance and the availability of data.

Properties of the hazard and the effect of production, processing and handling

Factors potentially affecting levels of hazards in seafood at the point of consumption were also considered. Production and processing methodologies, consumer food handling habits, product shelf life and the capacity for the seafood to support the survival or growth of pathogens were taken into account. In specific instances, consideration was given to the potential for cross-contamination of seafood commodities during processing and consumer handling, although data on the incidence of contamination is extremely limited.

Data limitations

In general, limited access to or availability of data presented considerable difficulties for assessing the likelihood of adverse health effects. Insufficient data on the prevalence and levels of microbiological hazards in seafood available for consumption in Australia prevented the undertaking of a quantitative exposure assessment, so the estimates of likelihood of adverse health effects are largely qualitative, and this impacts on the risk rankings derived from them.

A clear distinction is made, however, between those cases where limited data is available (leading to uncertainty in the conclusions) and those where the available data shows lack of, for example, a specific hazard in a specific commodity (evidence which will tend to reduce the ‘likelihood of illness’ rating in that case).

Table 4 indicates the way in which the various forms of data and information were used to rank the likelihood of adverse health effects caused by a hazard into categories of unlikely, likely and very likely. Due to the gaps in data and information being unevenly spread across hazard/commodity pairs, it was necessary to employ a degree of expert opinion/judgement in the likelihood of illness ratings, to bridge the gap between what is indicated by the data and what is plausible, given our knowledge of the hazard, the seafood commodity, its regulatory environment, and its production and processing supply chain up to the point of consumption.

Table 4: Ranking of food-borne hazards by likelihood of adverse health effects

Likelihood	Factors influencing estimation of likelihood of adverse health effects
Unlikely	• Little or no evidence that the hazard has caused food-borne illness in Australia of overseas • Limited consumption of the commodity by the general population, or consumption primarily by selected sub-populations, and/or • Limited or no data demonstrating presence of the hazard in seafood.
Likely	• Limited evidence that the hazard has caused food-borne illness in Australia or overseas • Eaten periodically • Availability of data demonstrating the presence of the hazard in seafood, and/or • Availability of evidence from other data sources, for example, Imported Foods Inspection Program, FSANZ recall database, environmental surveillance, etc.
Very likely	• Evidence that the hazard is associated with reported incidents of food-borne illness in Australia • Widely and/or frequently eaten by the general population • Availability of data demonstrating the presence of the hazard in Australian seafood, and/or • Availability of significant evidence from other data sources, for example, Imported Foods Inspection Program, FSANZ recall database.

Risk ranking matrix

Estimates of the severity of adverse effects caused by the hazards encountered in seafood, and the likelihood of those effects occurring in the general population – defined as the population of generally healthy adults, irrespective of whether or not they consume seafood – are brought together to provide a ranking of the relative risk associated with the particular hazard/commodity combination using the matrix presented in Table 5.

This approach is consistent with the Codex recommendation that a risk characterisation integrate all of the qualitative and quantitative information available into a soundly-based risk estimate, and mirrors the Codex definition of risk as being a function of the probability and the severity of an adverse health effect. Using the matrix, the relative risk assigned to each commodity or group of commodities is qualitatively ranked as high, medium or low. Each broad risk ranking category can arise from three possible combinations of severity and likelihood estimates, as seen in Table 5.

In some susceptible sub-populations (for example, the very young and old, the immunocompromised, and pregnant women and their unborn children), certain hazards may cause illness of greater severity, or illness may occur at a lower infectious or toxigenic dose, leading to a ranking different to that obtained for the general population. In such cases, the relative risk rankings have been explicitly identified for both general and susceptible populations, to guide subsequent development of risk management strategies. However, the overall relative risk ranking for each seafood commodity or group of commodities in this report is a 'general population' risk estimate.

Table 5: A likelihood/severity matrix for ranking food safety risks in seafood

		likelihood of illness		
		unlikely	likely	very likely
severity of illness	moderate	low	low	medium
	serious	low	medium	high
	severe	medium	high	high

4. Risk rankings

A number of food safety hazards are associated with seafood, and the risk to public health and safety posed by each differs according to the characteristics of the particular hazard and of the seafood commodity being considered, and the amount and manner in which it is eaten. A description of these food safety hazards, the evidence for their association with seafood, and evidence linking them with adverse health effects due to consumption of seafood is presented at Appendix 4. A discussion of the interaction of the hazards with the production and processing supply chains for seafood commodities, indicating where the hazards might be introduced or where their level in seafood might be affected, is at Appendix 1.

Information provided in the appendixes is brought together in this section to provide an estimate of the likelihood of an adverse health effect due to each hazard associated with each seafood commodity or group of commodities.

These likelihood estimates are combined with the severity ranking for each hazard (from Table 3) to provide an estimate of the relative public health risk due to each hazard associated with that commodity. An overall relative risk ranking (high, medium or low) is then determined for each seafood commodity or sector, based on the highest risk ranking level pertaining to that commodity.

Food safety risks due to molluscan shellfish

Oysters and other bivalves (excluding roe-off scallops)

The hazards potentially associated with oysters and other bivalves through the production and processing supply chain (Appendix 1) may be grouped as follows:

- Endogenous bacteria that are human pathogens (*Aeromonas hydrophila*, *V. parahaemolyticus*, *V. vulnificus*, *V. cholerae* O1/O139, non-O1/non-O139 *V. cholerae*).
- Pathogens introduced through pollution or post-harvest contamination (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigell*a spp., *Yersinia* spp., *L. monocytogenes*, hepatitis A virus, Noroviruses).
- Environmental chemical contaminants/toxicants (algal biotoxins, mercury, cadmium, arsenic, zinc).

The severity of illness due to these hazards (Table 3) ranges from moderate (for example, zinc, noroviruses), through serious (for example, *L. monocytogenes*, hepatitis A virus) to severe (for example, amnesic shellfish poison and paralytic shellfish poison algal biotoxins, *V. cholerae* O1/O139). Some of the hazards are considered severe only for certain susceptible populations (for example, *L. monocytogenes*, hepatitis A virus).

The likelihood of adverse health effects due to this broad range of hazards is diverse, ranging from unlikely through to very likely. Several large outbreaks of food-borne illness in Australia, attributed to oysters harvested from polluted waters that were not subject to the requirements of a comprehensive shellfish safety scheme such as the Australian Shellfish Quality Assurance Program (ASQAP), attest to the potential for significant adverse public health outcomes from the presence of these hazards in bivalve molluscs [19].

Oysters and other bivalves are considered a food group that is occasionally eaten by a significant proportion of the population (Appendix 3; [7,9]) and, on this basis, evidence of the potential for a hazard to be present at an infectious or toxigenic level at the point of consumption is taken as the main determinant of the likelihood of adverse health effects for the general population.

The likelihood of adverse health effects due to each of the hazards identified in Appendix 1 is discussed briefly below.

Likelihood of adverse health effects: Unlikely

Aeromonas hydrophila: Aeromonads are ubiquitous in most aquatic environments, and there is significant evidence to indicate that at least some strains can cause food-borne illness [29]. *A. hydrophila* has been implicated in food-borne illness due to oyster consumption in the United States and the United Kingdom [29], but there is no epidemiological or other data suggesting a significant likelihood of adverse effects occurring due to pathogenic strains in Australia.

***E. coli*, *S. aureus*, *Salmonella*, *Campylobacter*, *Shigella* and *Yersinia* species**: Pathogenic strains of these bacteria may be present in oysters due to pollution of growing waters or post-harvest contamination. Results from the testing of imported foods (Appendix 1) demonstrate limited contamination of imported molluscan shellfish by these hazards. However, contamination of locally produced bivalves is also considered plausible, and under the provisions of the ASQAP, harvest waters and shellfish meat are tested for faecal or total coliforms, and harvesting bans or a requirement for relaying or depuration are placed on the harvesting area when counts of these indicator organisms exceed specified levels [30]. The combination of ASQAP and adherence to Good Hygienic Practice by shellfish processors and food handlers will tend to reduce the likelihood of adverse health effects from these enteric pathogens.

Toxigenic *Vibrio cholerae* O1/O139: Toxigenic strains of *V. cholerae* O1 have been found in fresh water reaches of rivers in Australia but not estuarine or marine environments [31]. There are no epidemiological or concentration data suggesting a significant likelihood of adverse health effects from toxigenic *V. cholerae* O1 in Australia through consumption of oysters and other bivalves.

L. monocytogenes: There are limited data indicating the potential for listeriosis due to consumption of molluscan shellfish. The only Australian outbreak, in Tasmania in 1991, was linked to imported smoked mussels eaten beyond their use-by date [9,32]. There are limited concentration data demonstrating the potential for *L. monocytogenes* to be present in molluscan shellfish, with only a low level of failure reported from testing of imported foods and a low number of recalls coordinated by FSANZ in the period 1990–2003 (one for oysters, two for mussels).

Arsenic, cadmium, mercury, zinc and lead: ANZFA reviewed the public health risks due to heavy metal contamination in foods (including molluscan shellfish) in 1999 [5,7]. Data on concentrations of heavy metals in foods was used to provide a total-diet estimate of exposure. The results were as follows:

- For **arsenic**, dietary modelling indicated that high consumers of molluscs could receive up to 6 per cent of the provisional tolerable daily intake (PTDI) for inorganic arsenic from molluscs, based on an inorganic arsenic content of seafood of 6 per cent of the total arsenic content.
- For **mercury**, ANZFA concluded that molluscs contribute only 0.17 per cent to total dietary exposure to mercury [7], and that even high consumers were unlikely to approach the provisional tolerable weekly intake (PTWI).
- For **zinc**, ANZFA [7] estimated that high consumers of oysters would approach 38 per cent of the PTDI. However, ANZFA concluded that it was likely that dietary exposures were overestimated and that exposure to zinc at the mean and high dietary exposures posed only a relatively low risk to human health.
- For **lead**, ANZFA [7] estimated that molluscs contribute approximately 0.6 per cent to the total dietary exposure. However, as lead exposure occurs through many exposure routes, a maximum limit for lead in molluscs was established due to the serious nature of lead toxicity and consistent with an overall goal of reducing blood lead levels in the general population.
- For **cadmium**, FSANZ performed a recent dietary exposure assessment in 2000. Dietary exposure to cadmium was estimated to be 52 per cent of the PTDI (calculated as the PTWI divided by 7) at the median daily level of consumption of oysters, and 7.9 per cent of the PTDI at the median daily level of consumption of mussels. However, as oysters and mussels are only occasionally eaten foods, with 94 per cent of the population consuming them less than once per week, this level of exposure would not be expected to occur on a daily basis.

<u>Likelihood of adverse health effects: Likely</u>

***Vibrios* (excluding toxigenic *V. cholerae* O1/O139)**: *V. parahaemolyticus*, *V. vulnificus*, non-O1/non-O139 *V. cholerae* and non-toxigenic *V. cholerae* O1 are found in estuarine and marine environments in Australia and have been isolated from oysters [31,33,34]. These endogenous pathogens are not efficiently removed by depuration [33–35] and levels do not necessarily always correlate with counts of coliform indicator organisms [9,34]. Monitoring of water quality may not be adequate to control the food safety risks due to these pathogens, and post-harvest measures, such as suitable temperature control to prevent outgrowth, is necessary. Several studies have demonstrated the presence of vibrios in Australian molluscan shellfish and there have been a number of outbreaks and sporadic cases of food-borne illness documented (Appendix 2; [9,19]).

Algal biotoxins: Potentially toxic algae are found throughout Australian shellfish growing waters [4]. However, not all isolates of the causative organisms produce toxin, and concentrations of the toxins in shellfish will not necessarily always correlate with levels of algae in the water [4]. Algal biotoxins are not quickly removed by depuration or relaying. Monitoring of water quality may not entirely control the food safety risks due to these hazards. Levels of algal biotoxins are not affected by processing or consumer food handling practices.

There is some evidence of food-borne illness caused by algal biotoxins in molluscan shellfish in Australia, limited to two outbreaks of diarrhoeic shellfish poisoning due to consumption of pipis harvested from waters that were not subject to the requirements of a shellfish safety program, but a significant number of outbreaks occur worldwide [4].

There have been no failures in imported foods tested for domoic acid (amnesic shellfish poison) or paralytic shellfish poison since 1998, and only one FSANZ-coordinated food recall due to domoic acid in the period 1990–2003. Analytical data demonstrate the occasional presence of paralytic shellfish poison, amnesic shellfish poison and neurotoxic shellfish poison in Australian bivalve molluscs [4,16].

<u>Likelihood of adverse health effects: Very likely</u>

Enteric viruses: Noroviruses and hepatitis A virus have been implicated in several large outbreaks of food-borne illness due to bivalve mollusc consumption in Australia and worldwide. These viruses persist and remain viable in oysters for long periods of time, and are not efficiently removed by depuration [36,37]. Levels do not necessarily always correlate with counts of faecal indicator organisms, so monitoring of water quality may not entirely control the food safety risks due to these hazards. The infectious dose is presumed to be low [9]. Light cooking does not inactivate noroviruses [38,39], and hepatitis A virus has significant heat stability [40].

<u>Likelihood of adverse health effects for cooked product</u>

Oysters and other bivalves, when not eaten raw, are usually only lightly cooked or steamed before consumption. In this report, it has been assumed that this cooking would normally be sufficient to reduce bacterial hazards to low levels. However, enteric viruses are significantly more heat resistant than bacterial pathogens and infectious doses are assumed to be very low, hence it is considered unlikely that cooking will effectively reduce them to safe levels. Algal biotoxins are also very heat stable [41,42].

Relative risk ranking for oysters and other bivalves – conclusions

The severity and likelihood of adverse health effects due to specific hazards associated with oysters and other bivalves are combined in Table 6 to provide relative risk rankings for those hazards. It is concluded that the overall public health risk for this commodity group is relatively high for product harvested in polluted waters and/or waters not subject to a monitoring scheme such as ASQAP, based on the potential presence and adverse health effects of hepatitis A virus and algal biotoxins. The ranking is high due to those algal biotoxins with 'severe' adverse health effects (that is, amnesic shellfish poison and paralytic shellfish poison), while it is medium for those rated as having 'serious' adverse health effects (that is, diarrhoetic shellfish poison and neurotoxic shellfish poison – these are not included in Table 6). The relative risk ranking is not significantly reduced where these products are cooked prior to consumption.

When the implementation of shellfish safety management schemes, such as ASQAP, is taken into account, the relative risk ranking for oysters and other bivalves is reduced to medium.

The overall relative risk ranking for product eaten raw is also high for people who are susceptible to primary septicaemia from *V. vulnificus* infection (that is, people with liver dysfunction or high serum iron levels).

Abalone and roe-off scallops

The hazards potentially associated with abalone and roe-off scallops (that is, scallops when the product eaten is only the adductor muscle) through the production and processing supply chain (Appendix 1) may be grouped as follows:

- Endogenous bacteria that are human pathogens (*A. hydrophila*, *V. parahaemolyticus*, *V. vulnificus,* non-O1/non-O139 *V. cholerae*).
- Pathogens introduced through pollution or post-harvest contamination (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, hepatitis A virus, Noroviruses).
- Environmental chemical contaminants/toxicants (algal biotoxins, mercury).

The severity of illness caused by these hazards (Table 3) ranges from moderate (for example, *V. parahaemolyticus*, noroviruses), through serious (for example, *L. monocytogenes*, hepatitis A virus) to severe (for example, amnesic shellfish poison and paralytic shellfish poison). Some of the hazards are considered severe only for certain susceptible populations (for example, *L. monocytogenes*, hepatitis A virus).

Data from the National Nutrition Survey of 1995 indicate that abalone and scallops (combined) are eaten approximately half as often as oysters and other bivalves, and that serving portions are smaller (Appendix 3). These conclusions are reinforced by recent data on the production, import and export of these seafood commodities, which show that the combined volume of abalone and scallops available for domestic consumption is about half that of oysters, pipis and mussels combined [43]. However, the data do not allow an estimate of the relative consumption of roe-on and roe-off scallops. These data indicate that abalone and roe-off scallops are considered a food group that is occasionally eaten by a small proportion of the population. On this basis, evidence of the potential for a hazard to be present at an infectious or toxigenic level must be balanced by the relatively limited consumption in estimating the likelihood of adverse health effects. In addition, and in contrast to oysters, abalone and roe-off scallops are normally cooked, at least lightly, prior to consumption, which will reduce the likelihood of adverse health effects from bacterial pathogens.

Adverse health effects due to each of the hazards identified in Appendix 1 is considered unlikely, as discussed briefly below.

Table 6: Relative risk rankings for oysters and other bivalves (excluding roe-off scallops)

Commodity	Hazard	Severity	Likelihood of adverse health effects	Relative risk Ranking
Raw oysters	*A. hydrophila*	Serious	Unlikely	Low
	V. parahaemolyticus	Moderate	Likely	Low
	V. vulnificus[1]	Serious	Likely	Medium
	V. cholerae O1/O139	Severe	Unlikely	Medium
	Non-O1/non-O139 *V. cholerae*	Moderate	Likely	Low
	L. monocytogenes[2]	Serious	Unlikely	Low
	E. coli (non-EHEC)	Moderate	Unlikely	Low
	Staphylococcus aureus	Moderate	Unlikely	Low
	Salmonella (non-typhoid)	Serious	Unlikely	Low
	Campylobacter spp.	Serious	Unlikely	Low
	Shigella spp.	Serious	Unlikely	Low
	Yersinia spp.	Serious	Unlikely	Low
	Noroviruses[4]	Moderate	Very likely	Medium
	Noroviruses[5]	Moderate	Unlikely	Low
	Hepatitis A virus[4]	Serious	Very likely	High
	Hepatitis A virus[5]	Serious	Unlikely	Low
	Algal biotoxins (ASP, PSP)[4]	Severe	Likely	High
	Algal biotoxins (ASP, PSP)[5]	Severe	Unlikely	Medium
	Arsenic	Severe	Unlikely	Medium
	Cadmium	Severe	Unlikely	Medium
	Lead	Severe	Unlikely	Medium
	Mercury[3]	Serious	Unlikely	Low
	Zinc	Moderate	Unlikely	Low
Cooked oysters	*A. hydrophila*	Serious	Unlikely	Low
	V. parahaemolyticus	Moderate	Unlikely	Low
	V. vulnificus[1]	Serious	Unlikely	Low
	V. cholerae O1/O139	Severe	Unlikely	Medium
	Non-O1/non-O139 *V. cholerae*	Moderate	Unlikely	Low
	L. monocytogenes[2]	Serious	Unlikely	Low
	E. coli (non-EHEC)	Moderate	Unlikely	Low
	Staphylococcus aureus	Moderate	Unlikely	Low
	Salmonella (non-typhoid)	Serious	Unlikely	Low
	Campylobacter spp.	Serious	Unlikely	Low
	Shigella spp.	Serious	Unlikely	Low
	Yersinia spp.	Serious	Unlikely	Low
	Noroviruses[4]	Moderate	Very likely	Medium
	Noroviruses[5]	Moderate	Unlikely	Low
	Hepatitis A virus[4]	Serious	Very likely	High
	Hepatitis A virus[5]	Serious	Unlikely	Low
	Algal biotoxins (ASP, PSP)[4]	Severe	Likely	High
	Algal biotoxins (ASP, PSP)[5]	Severe	Unlikely	Medium
	Arsenic	Severe	Unlikely	Medium
	Cadmium	Severe	Unlikely	Medium
	Lead	Severe	Unlikely	Medium
	Mercury[3]	Serious	Unlikely	Low
	Zinc	Moderate	Unlikely	Low

1. For susceptible sub-populations (people with liver dysfunction or high serum iron levels) the severity ranking is 'severe', and the relative risk rankings are high and medium for raw and cooked products, respectively.
2. For susceptible sub-populations (the immunocompromised, pregnant women, the foetus) the relative risk ranking is 'medium' (severe x unlikely).
3. For susceptible sub-populations (the foetus) the relative risk ranking is 'medium' (severe x unlikely).
4 For product from waters that are subject to pollution and/or do not have an effective management system in place.
5. For product from pristine waters or from waters that are subject to pollution but where harvesting is controlled under an effective management system.
Key: ASP = amnesic shellfish poison; EHEC = enterohaemorrhagic *Escherichia coli*; PSP = paralytic shellfish poison.

Likelihood of adverse health effects: Unlikely

Aeromonas hydrophila: *A. hydrophila* has not been implicated in food-borne illness due to consumption of abalone or scallops [29], and there are no epidemiological or presence data suggesting a significant likelihood of adverse health effects from pathogenic strains in Australia. Levels in abalone and roe-off scallops at point of consumption are likely to be significantly reduced by cooking.

***E. coli, S. aureus, Salmonella*, *Campylobacter*, *Shigella* and *Yersinia* species**: Pathogenic strains of these bacteria may be present in abalone and scallops due to post-harvest contamination, but are unlikely to be introduced through pollution of growing waters. Results from the testing of imported foods (Appendix 1) demonstrate that there is little contamination of imported molluscan shellfish by these hazards. Good hygienic practice by shellfish processors and food handlers will tend to minimise the likelihood of adverse health effects from these hazards. Levels of these pathogens in abalone and roe-off scallops at point of consumption are likely to be significantly reduced by cooking.

L. monocytogenes: There are no data indicating the potential for food-borne listeriosis due to consumption of abalone and roe-off scallops. Levels in abalone and roe-off scallops at point of consumption are likely to be significantly reduced by cooking.

Mercury: ANZFA recently reviewed the public health risk due to mercury contamination in foods (including molluscan shellfish) [7]. At the time, ANZFA concluded that molluscs contribute only 0.17 per cent of the total dietary exposure to mercury.

Algal biotoxins: Potentially toxic algae are found throughout Australian shellfish growing waters [4]. However, not all isolates produce toxin, and the concentration of toxins in shellfish will not necessarily always correlate with levels of algae in the water [4]. There is no evidence of food-borne illness due to algal biotoxins in abalone and roe-off scallops in Australia. These toxins are preferentially concentrated in the viscera of molluscan shellfish.

It is widely believed that scallop and abalone adductor muscle do not accumulate high concentrations of toxins [4], although there is evidence of accumulation of paralytic shellfish poison in the epipodal fringe of the South African abalone *Haliotis midae* [44,45]. There have been no failures in imported abalone and scallops tested for domoic acid or paralytic shellfish poison since 1998, and no FSANZ-coordinated food recalls due to algal biotoxins in these commodities. Available data do, however, demonstrate the occasional presence of paralytic shellfish poison and amnesic shellfish poison in Australian scallops, and neurotoxic shellfish poison has been detected in other shellfish in Australia [4].

Enteric viruses: Noroviruses and hepatitis A virus are unlikely to be introduced through pollution of growing waters, and would only be present in abalone and scallops due to post-harvest contamination by a food handler. There are no data suggesting their presence in abalone and scallops in Australia, and no evidence linking food-borne illness in Australia to the consumption of abalone and scallops.

***Vibrios* (excluding toxigenic *V. cholerae* O1)**: Although *V. parahaemolyticus*, *V. vulnificus*, non-O1/non-O139 *V. cholerae* and non-toxigenic *V. cholerae* O1 are found in estuarine and marine environments in Australia and have been isolated from oysters [31], there is no epidemiological evidence linking them to abalone or scallops in this country. There are limited data [9] showing the presence of *V. parahaemolyticus* in scallops in Australia and none indicating the presence of vibrios in abalone.

Relative risk ranking for abalone and roe-off scallops – conclusions

Consideration of the severity of illness and the likelihood of adverse health effects are combined in Table 7, to provide rankings for hazards associated with abalone and roe-off scallops. It is concluded that the relative public health risk ranking for this sector is medium, mainly based on the potential presence and adverse health effects of algal biotoxins (particularly the more severe toxins, amnesic shellfish poison and paralytic shellfish poison).

For populations susceptible to more severe illnesses due to *V. vulnificus*, *L. monocytogenes*, hepatitis A virus or mercury, the relative risk ranking is medium.

Table 7: Relative risk ranking estimates for abalone and roe-off scallops

Commodity	Hazard	Severity	Likelihood of adverse health effects	Relative risk Ranking
Cooked	*A. hydrophila*	Serious	Unlikely	Low
	V. parahaemolyticus	Moderate	Unlikely	Low
	V. vulnificus[1]	Serious	Unlikely	Low
	Non-O1/non-O139 *V. cholerae*	Moderate	Unlikely	Low
	E. coli (non-EHEC)	Moderate	Unlikely	Low
	Staphylococcus aureus	Moderate	Unlikely	Low
	Salmonella (non-typhoid)	Serious	Unlikely	Low
	Shigella spp.	Serious	Unlikely	Low
	Yersinia spp.	Serious	Unlikely	Low
	L. monocytogenes[1]	Serious	Unlikely	Low
	Noroviruses	Moderate	Unlikely	Low
	Hepatitis A virus[1]	Serious	Unlikely	Low
	Algal biotoxins (ASP and PSP)	Severe	Unlikely	Medium
	Mercury[1]	Serious	Unlikely	Low

1. For susceptible sub-populations the relative risk rankings are medium (severe x unlikely).

Key: ASP = amnesic shellfish poison; EHEC = enterohaemorrhagic *Escherichia coli;* PSP = paralytic shellfish poison.

Food safety risks due to cephalopod molluscs

The hazards associated with cephalopod molluscs through the production and processing supply chain (Appendix 1) may be grouped as follows:

- Endogenous bacteria that are human pathogens (*A. hydrophila*, *V. parahaemolyticus*, *V. vulnificus,* non-toxigenic *V. cholerae* O1, helminthic parasites).
- Pathogens introduced through pollution or post-harvest contamination (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, hepatitis A virus, Noroviruses).
- Environmental chemical contaminants/toxicants (mercury, cadmium).

The severity of illness caused by these hazards (Table 3) ranges from moderate (for example, *V. parahaemolyticus*, noroviruses), through to serious (for example, *L. monocytogenes*, hepatitis A virus). Some of the hazards are considered severe only for certain susceptible populations (for example, *L. monocytogenes*, hepatitis A virus). However, the relative risk ranking estimates below are determined for the general population, unless otherwise specified.

Data from the National Nutrition Survey of 1995 indicate that squid, octopus and other cephalopods (combined) are eaten about 75 per cent as often as oysters and other bivalves, and that serving portions are of similar size (Appendix 3). Approximately 80 per cent is imported product [43]. Cephalopod molluscs are therefore considered a food group occasionally eaten by a small proportion of the population. On this basis, the limited size of the consuming population must be considered along with evidence of the potential for a hazard to be present at an infectious or toxigenic level in estimating the likelihood of adverse health effects for the general population. In addition, and in contrast to oysters, squid, octopus and cuttlefish are normally cooked, at least lightly, prior to consumption, which will reduce the likelihood of adverse health effects from bacterial hazards.

Adverse health effects due to each of the hazards identified in Appendix 1 is considered unlikely, as discussed briefly below.

<u>Likelihood of adverse health effects: Unlikely</u>

A. hydrophila: There are no epidemiological or concentration data suggesting a significant likelihood of adverse health effects from exposure to pathogenic strains of *A. hydrophila* in Australia. Levels in cephalopods at point of consumption are likely to be significantly reduced by cooking.

***E. coli*, *Salmonella*, *Campylobacter*, *Shigella* and *Yersinia* species**: Pathogenic strains of these bacteria may be present in cephalopods due to post-harvest contamination, but are unlikely to be introduced through pollution of the marine environment from which cephalopods are harvested. There are no epidemiological or concentration data suggesting a significant likelihood of adverse effects from pathogenic bacteria in cephalopods. Levels in cephalopods at point of consumption are likely to be significantly reduced by cooking.

L. monocytogenes: There are no data indicating food-borne listeriosis due to consumption of cephalopods. Levels at point of consumption are likely to be significantly reduced by cooking.

Mercury: At the time of the review of metal contaminants in food in 1999 [7], ANZFA concluded that molluscs contribute only 0.17 per cent to total dietary exposure to mercury.

Enteric viruses: Noroviruses and hepatitis A virus are unlikely to be introduced through pollution of growing waters, and would only be present in cephalopods due to post-harvest contamination by food handlers. There is no epidemiological or concentration data suggesting a significant likelihood of adverse health effects from enteric viruses in Australia through consumption of cephalopods.

***Vibrios* (excluding toxigenic *V. cholerae* O1)**: Although *V. parahaemolyticus*, *V. vulnificus* and non-toxigenic *V. cholerae* O1 are found in estuarine and marine environments in Australia, there are no data demonstrating their presence in cephalopods in Australia and no epidemiological data indicating food-borne illness from this source.

Helminthic parasites: There are no epidemiological or other data suggesting a significant likelihood of adverse health effects from helminthic parasites in cephalopods in Australia. Levels at point of consumption are likely to be significantly reduced by cooking.

Relative risk ranking for cephalopod molluscs – conclusions

Consideration of the severity of illness and the likelihood of adverse effects are combined in Table 8, to provide rankings for the various hazards associated with cephalopod molluscs. It is concluded that the relative public health risk ranking for this sector is low, based on limited consumption by the general population, low potential for presence of hazards, and the tendency for consumers to cook these products before consumption. For populations susceptible to severe illnesses due to *V. vulnificus*, *L. monocytogenes*, hepatitis A virus or mercury, the relative risk ranking is medium.

Table 8: Relative risk ranking estimates for cephalopod molluscs

Commodity	Hazard	Severity	Likelihood of adverse health effects	Relative risk Ranking
Cooked	*A. hydrophila*	Serious	Unlikely	Low
	V. parahaemolyticus	Moderate	Unlikely	Low
	V. vulnificus[1]	Serious	Unlikely	Low
	Non-toxigenic *V. cholerae* O1	Moderate	Unlikely	Low
	E. coli (non-EHEC)	Moderate	Unlikely	Low
	Staphylococcus aureus	Moderate	Unlikely	Low
	Salmonella (non-typhoid)	Serious	Unlikely	Low
	Campylobacter spp.	Serious	Unlikely	Low
	Shigella spp.	Serious	Unlikely	Low
	Yersinia spp.	Serious	Unlikely	Low
	L. monocytogenes[1]	Serious	Unlikely	Low
	Noroviruses	Moderate	Unlikely	Low
	Hepatitis A virus[1]	Serious	Unlikely	Low
	Mercury[1]	Serious	Unlikely	Low

1. For susceptible sub-populations the relative risk rankings are medium (severe x unlikely).
Key: EHEC = enterohaemorrhagic *Escherichia coli*.

Food safety risks due to crustacea

The hazards potentially associated with crustacea through the production and processing supply chain (Appendix 1) may be grouped as follows:

- Endogenous bacteria that are human pathogens (*A. hydrophila*, *L. monocytogenes*, *V. parahaemolyticus*, *V. vulnificus*, *V. cholerae* O1/O139, non-O1/non-O139 V. cholerae).
- Pathogens introduced through pollution or post-harvest contamination (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *V. cholerae* O1, hepatitis A virus, Noroviruses).
- Environmental chemical contaminants/toxicants (mercury, arsenic).

The environment from which crustacea are harvested influences the range of hazards. Wild-caught crustacea from clean waters are unlikely to contain pathogens of enteric origin, while farmed/estuarine crustacea may be exposed to contamination in the growing environment.

The severity of illness caused by these hazards (Table 3) ranges from moderate (for example, *V. parahaemolyticus*, noroviruses), through serious (for example, *L. monocytogenes*, hepatitis A virus) to severe (for example, *V. cholerae* O1/O139). Some of the hazards are considered severe only for certain susceptible populations (for example, *L. monocytogenes*, hepatitis A virus). However, the relative risk ranking estimates below are determined for the general population, unless otherwise specified.

Prawns – green

Consumption data indicate that prawns are a food group occasionally eaten by a significant proportion of the population (Appendix 3; [7,9]). On this basis, evidence of the potential for a hazard to be present at an infectious or toxigenic level in this commodity is taken as the main determinant of the likelihood of adverse health effects. Adverse health effects due to each of the hazards identified in Appendix 1 is considered unlikely, as discussed briefly below.

<u>Likelihood of adverse health effects: Unlikely</u>

A. hydrophila: *A. hydrophila* has been implicated in food-borne illness due to prawn consumption in the United Kingdom [29], but there are no epidemiological or concentration data suggesting a significant likelihood of adverse health effects from pathogenic strains in Australia. The usual practice of cooking green prawns just before eating should significantly reduce the bacterial load.

B ***E. coli*, *S. aureus*, *Salmonella*, *Campylobacter*, *Shigella* and *Yersinia* species**: Pathogenic strains of these bacteria may be present in prawns due to pollution of growing waters or post-harvest contamination. Results from testing of imported foods (Appendix 1) demonstrate there is some limited potential for contamination of imported prawns by these hazards. The usual practice of cooking green prawns just before eating should significantly reduce the bacterial load, but will not affect the concentration of staphylococcal enterotoxin, which is thermostable. However, significant time–temperature abuse is usually needed to allow proliferation of *S. aureus* to levels likely to produce sufficient enterotoxin to cause illness [46]. Furthermore, the organism is a poor competitor, and commensal bacteria would hinder its ability to grow and produce toxin.

***Vibrio cholerae* O1/O139**: Toxigenic strains of *V. cholerae* O1 have been found in fresh water reaches of rivers in Australia but not in estuarine or marine environments [31]. There are only limited epidemiological [31] and concentration data suggesting a significant likelihood of adverse health effects from toxigenic *V. cholerae* O1 in Australia through consumption of prawns. Results from testing imported foods (Appendix 1) show no failures due to *V. cholera* O1/O139 in any seafood commodities. The practice of cooking green prawns just before eating should significantly reduce bacterial levels.

***Vibrios* (excluding toxigenic *V. cholerae* O1)**: *V. parahaemolyticus*, *V. vulnificus* and non-O1/O139 *V. cholerae* are found in estuarine and marine environments in Australia. There are limited data suggesting a significant likelihood of adverse health effects from vibrios through consumption of prawns. *V. parahaemolyticus* has been isolated from prawns [31] and non-O1/non-O139 *V. cholerae* has been found in imported crustacea. The usual practice of cooking green prawns just before eating should significantly reduce the bacterial load.

L. monocytogenes: There are limited data indicating the potential for food-borne listeriosis due to consumption of prawns. One small outbreak of Listeria bacteraemia has been reported, due to shrimp consumption, in the United States [63]. There are only limited data demonstrating the potential for *L. monocytogenes* to be present in uncooked prawns in Australia. Imported crustacea are not tested for *L. monocytogenes* under the Imported Foods Inspection Program, and there were no recalls coordinated by FSANZ in the period 1990–2003 for *L. monocytogenes* in crustacea. The practice of cooking green prawns just before eating should significantly reduce levels of this pathogen.

Enteric viruses: There are limited data indicating the potential for adverse health effects caused by exposure to enteric viruses due to consumption of prawns. There has been one outbreak of hepatitis A due to prawn consumption in Australia since 1995 (Appendix 2). Light cooking does not inactivate noroviruses [38,39], and hepatitis A virus has significant heat stability [40], so cooking may not inactivate these hazards.

Inorganic arsenic and mercury: ANZFA reviewed the public health risks due to heavy metal contamination in foods (including crustacea) in 1999 [5,7]. Data on concentrations of heavy metals in foods were used to provide an estimate of total dietary exposure. The results were as follows:

- For **inorganic arsenic**, ANZFA determined that prawns contributed up to 52 per cent of the total dietary exposure, and high consumers of crustacea could receive up to 18 per cent of the PTDI for inorganic arsenic, assuming the inorganic arsenic content of seafood is 6 per cent of the total arsenic content.
- For **mercury**, ANZFA concluded that crustacea contribute only 0.34 per cent to total dietary exposure of mercury [7].

Prawns – cooked

Prawns are often cooked on board the trawler or upon landing. They may also be peeled and possibly deveined, either mechanically or by hand. The cooking process does not significantly alter the concentrations of chemical hazards but should eliminate microbial pathogens if sufficient time is allowed. However, the potential for post-cooking recontamination of a product that is sold as ready-to-eat seafood and thus may undergo no further cooking, and which has a shelf life of several days, must be considered.

Sources of potential contamination of cooked prawns include estuarine or marine water used to cool the prawns, the ice or brine used to chill them, and contamination by food handlers and equipment. Insufficient cooking time and post-process time–temperature abuse may lead to higher counts of microbial pathogens. Hazards of concern are vibrios, *L. monocytogenes* and enteric pathogens including viruses. A significant proportion of outbreaks linked to cooked crustacea have been attributed to enteric bacterial pathogens [47].

The likelihood of adverse health effects due to certain hazards in cooked prawns must, therefore, be considered greater than for green prawns, which will be cooked before consumption. However, there are only limited data to support such a conclusion. One survey of *L. monocytogenes* in cooked prawns [48] detected low counts in 3 per cent of cooked prawns at retail. The samples included peeled and whole, chilled and frozen, local and imported cooked prawns. These data were included in a FSANZ risk assessment which concluded there was a very low risk of contracting listeriosis from cooked prawns in Australia [49]. Epidemiological evidence (Appendix 2; [19]) does provide some support, with recent outbreaks of hepatitis A, *S.* Typhi, *S.* Typhimurium and two outbreaks of *V. parahaemolyticus* being attributed to cooked (imported) prawns (Appendix 2).

Given the limited data, adverse health effects due to these hazards are considered to be unlikely, with the exception of *V. parahaemolyticus*, for which adverse health effects are considered more likely – an assumption supported by the epidemiological evidence.

<u>Relative risk ranking for prawns – conclusions</u>

Consideration of the severity and likelihood of adverse health effects are combined in Table 9, to provide rankings for hazards associated with green and cooked prawns. It is concluded that the relative public health risk ranking for green prawns is medium, due to the potential for contamination with *Salmonella* and *Vibrio* species in intensive farming systems or as a consequence of human faecal contamination of estuarine harvest areas.

For cooked prawns, the potential for post-process recontamination by microbial hazards was considered not to significantly increase the overall risk, as the product has a short shelf life, providing insufficient opportunity for outgrowth of pathogens unless subjected to significant time–temperature abuse. Therefore, the overall ranking for cooked prawns is also medium.

For populations susceptible to severe illnesses due to *V. vulnificus*, *L. monocytogenes*, hepatitis A virus or through exposure to mercury, the relative risk ranking is medium.

Lobsters and crabs

The vast majority of lobsters and crabs eaten in Australia is locally produced [43]. Consumption data indicate that lobsters and crabs are occasionally eaten by a small proportion of the population (Appendix 3; [7,9]). On this basis, the limited size of the consuming population must be considered along with evidence of the potential for a hazard to be present at an infectious or toxigenic level in estimating the likelihood of adverse health effects for the general population. The likelihood of adverse health effects due to each hazard identified in Appendix 1 is discussed briefly below.

Live/raw product

Hazards associated with eating lobsters and crabs are similar to those for locally produced prawns [47], and a similar unlikely rating for adverse health effects from those hazards is estimated. However, unlike prawns, lobsters and crabs are not produced in intensive aquaculture facilities, and the risk from *V. cholerae* O1 and typhoid-causing *Salmonella* species is considered negligible for these species. There are no epidemiological data indicating an association between food-borne illness and consumption of crab or lobster in Australia, and no data demonstrating the presence of hazards in these seafoods. In the absence of such data, the likelihood of adverse health effects from food-borne hazards through eating crab and lobster is estimated to be low.

Table 9: Relative risk ranking estimates for prawns – green or cooked

Commodity	Hazard	Severity	Likelihood of adverse health effects	Relative risk Ranking
Green	*A. hydrophila*	Serious	Unlikely	Low
	V. parahaemolyticus	Moderate	Unlikely	Low
	V. vulnificus[1]	Serious	Unlikely	Low
	V. cholerae O1[2]	Severe	Unlikely	Medium
	Non-O1/non-O139 *V. cholerae*	Moderate	Unlikely	Low
	E. coli (non-EHEC)	Moderate	Unlikely	Low
	Staphylococcus aureus	Moderate	Unlikely	Low
	Salmonella (non-typhoid)	Serious	Unlikely	Low
	Salmonella (typhoid)[2]	Severe	Unlikely	Medium
	Campylobacter spp.	Serious	Unlikely	Low
	Shigella spp.	Serious	Unlikely	Low
	Yersinia spp.	Serious	Unlikely	Low
	L. monocytogenes[1]	Serious	Unlikely	Low
	Noroviruses	Moderate	Unlikely	Low
	Hepatitis A virus[1]	Serious	Unlikely	Low
	Mercury[1]	Serious	Unlikely	Low
	Arsenic	Severe	Unlikely	Medium
Cooked	*A. hydrophila*	Serious	Unlikely	Low
	V. parahaemolyticus	Moderate	Likely	Low
	V. vulnificus[1]	Serious	Unlikely	Low
	V. cholerae O1[2]	Severe	Unlikely	Medium
	Non-O1/non-O139 *V. cholerae*	Moderate	Unlikely	Low
	E. coli (non-EHEC)	Moderate	Unlikely	Low
	Staphylococcus aureus	Moderate	Unlikely	Low
	Salmonella (non-typhoid)	Serious	Unlikely	Low
	Salmonella (typhoid)[2]	Severe	Unlikely	Medium
	Campylobacter spp.	Serious	Unlikely	Low
	Shigella spp.	Serious	Unlikely	Low
	Yersinia spp.	Serious	Unlikely	Low
	L. monocytogenes[1]	Serious	Unlikely	Low
	Noroviruses	Moderate	Unlikely	Low

	Hepatitis A virus[1]	Serious	Unlikely	Low
	Mercury[1]	Serious	Unlikely	Low
	Arsenic	Severe	Unlikely	Medium

1. For susceptible sub-populations the relative risk rankings are medium (severe x unlikely).
2. Product from intensive cultivation or estuarine harvest areas subject to human faecal contamination.
Key: EHEC = enterohaemorrhagic *Escherichia coli*.

Cooked product

A large proportion of the catch is sold either live or raw chilled/frozen. However, crab (in particular) may also be sold cooked, with a similar potential for re-contamination as with cooked prawns. As with live/raw product, lack of relevant data leads to the conclusion that adverse health effects due to food-borne hazards from consumption of cooked crab or lobster as ready-to-eat seafood is unlikely.

Relative risk ranking for lobsters and crabs – conclusions

By comparison to the rankings for prawns, it is concluded that the relative public health risk ranking for live/raw crab and lobster is low (Table 10), based on the limited consumption, low potential for presence of hazards, and the tendency for these products to be cooked before consumption. For cooked crab and lobster, the increased potential for post-process recontamination with some microbiological hazards does not affect the overall ranking, which is low.

Table 10: Relative risk ranking estimates for lobsters and crabs

Commodity	Hazard	Severity	Likelihood of adverse health effects	Relative risk Ranking
Live/Raw	*A. hydrophila*	Serious	Unlikely	Low
	V. parahaemolyticus	Moderate	Unlikely	Low
	V. vulnificus[1]	Serious	Unlikely	Low
	Non-O1/non-O139 *V. cholerae*	Moderate	Unlikely	Low
	E. coli (non-EHEC)	Moderate	Unlikely	Low
	Staphylococcus aureus	Moderate	Unlikely	Low
	Salmonella (non-typhoid)	Serious	Unlikely	Low
	Campylobacter spp.	Serious	Unlikely	Low
	Shigella spp.	Serious	Unlikely	Low
	Yersinia spp.	Serious	Unlikely	Low
	L. monocytogenes[1]	Serious	Unlikely	Low
	Noroviruses	Moderate	Unlikely	Low
	Hepatitis A virus[1]	Serious	Unlikely	Low
	Mercury[1]	Serious	Unlikely	Low
Cooked	*A. hydrophila*	Serious	Unlikely	Low
	V. parahaemolyticus	Moderate	Likely	Low
	V. vulnificus[1]	Serious	Unlikely	Low
	Non-O1/non-O139 *V. cholerae*	Moderate	Unlikely	Low
	E. coli (non-EHEC)	Moderate	Unlikely	Low
	Staphylococcus aureus	Moderate	Unlikely	Low
	Salmonella (non-typhoid)	Serious	Unlikely	Low

	Campylobacter spp.	Serious	Unlikely	Low
	Shigella spp.	Serious	Unlikely	Low
	Yersinia spp.	Serious	Unlikely	Low
	L. monocytogenes[1]	Serious	Unlikely	Low
	Noroviruses	Moderate	Unlikely	Low
	Hepatitis A virus[1]	Serious	Unlikely	Low
	Mercury[1]	Serious	Unlikely	Low

1. For susceptible sub-populations the relative risk rankings are medium (severe x unlikely).

For populations susceptible to severe illnesses due to *V. vulnificus*, *L. monocytogenes*, hepatitis A virus, or mercury ingestion, the relative risk ranking is medium.

Other crustaceans – marron, yabbie, redclaw crayfish and scampi

These crustacean species are eaten only occasionally by a small proportion of the population in Australia (Appendix 3). These products are usually sold live, then cooked immediately before consumption. There are no data for presence of food safety hazards in these species. Epidemiological evidence of the association of hazards with these crustacea is limited to two recent outbreaks due to *S.* Typhimurium and non-O1/non-O139 *V. cholerae* in redclaw crayfish and one outbreak where scampi was implicated as the vehicle for *S.* Typhimurium (Appendix 2; [19]). In the latter case, the scampi was subject to time–temperature abuse and served with a raw egg mayonnaise, which is a more likely vehicle for the pathogen.

Relative risk ranking for marron, yabbie, redclaw crayfish and scampi – conclusions

Considering the limited data available, the limited consumption, and the usual practice of selling these species live or as raw/green chilled or frozen product for cooking just before eating, adverse health effects due to food-borne hazards is considered extremely unlikely, similar to that for lobsters and crabs, and the overall relative risk ranking is low.

Food safety risks due to finfish

The hazards potentially associated with finfish and finfish products through the production and processing supply chain (Appendix 1) may be grouped as follows:

- Endogenous bacteria that are human pathogens (*V. parahaemolyticus*, *L. monocytogenes*, *C. botulinum*, helminthic parasites).
- Pathogens introduced through pollution or post-harvest contamination (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, hepatitis A virus, Noroviruses).
- Environmental chemical contaminants/toxicants (ciguatoxin, histamine, mercury, arsenic).
- Naturally occurring substances (wax esters).

The severity of the illness caused by these hazards (Table 3) ranges from moderate (for example, *V. parahaemolyticus*, noroviruses), through serious (for example, *L. monocytogenes*, hepatitis A virus) to severe (for example, *C. botulinum*). Some of the hazards are considered severe only for certain susceptible populations (for example, *L. monocytogenes*, hepatitis A virus).

However, the relative risk estimates below are determined for the general population, unless otherwise specified.

Chilled/frozen whole fish and fillets (including fish for raw consumption)

Based on the available consumption data, chilled/frozen whole fish and fillets are considered a food group that is regularly eaten by a significant proportion of the population (Appendix 3; [7,9]). On this basis, evidence of the potential for a hazard to be present at an infectious or toxigenic level is taken as the main determinant of the likelihood of adverse health effects for the general population. The likelihood of adverse health effects due to each of the hazards identified in Appendix 1 is discussed briefly below and listed in Table 11.

Consumption of raw finfish products, such as sashimi and some sushi products, is considered to be rare and mainly limited to certain sub-populations in Australia. There was no reported consumption of these products in the 1995 National Nutrition Survey data. However, changes in national eating habits are leading to increasing availability and consumption [9]. While there may be need to specifically consider these products at some future time, they have not been separately ranked in this report.

<u>Likelihood of adverse health effects: Unlikely</u>

Microbiological hazards: Fish sold at retail as fillets or whole or gutted fish are typically thoroughly cooked before consumption, reducing the likelihood of exposure to indigenous or introduced microbiological pathogens, including helminthic parasites. *Vibrio* species, for example, are readily inactivated by cooking [47].

There are no epidemiological data indicating food-borne illness due to the presence of helminthic parasites in raw finfish products in Australia. *V. parahaemolyticus* is often associated with food-borne illness due to consumption of raw and minimally processed fish in Japan, but there is no epidemiological link in Australia. Additional hazards potentially present in raw finfish products are enteric pathogens (bacterial and viral) and *L. monocytogenes* due to contamination by food handlers and from the processing environment. One outbreak of food-borne illness due to sushi consumption (Appendix 2) was tentatively ascribed to viral contamination [19].

Inorganic arsenic: ANZFA recently reviewed the public health risks due to heavy metal contamination in foods [5,7]. Data on concentrations of heavy metals in foods were used to provide an estimate of total dietary exposure. For inorganic arsenic, fish contributed up to 14 per cent of the total dietary exposure, and high consumers could receive up to 4 per cent of the PTDI for inorganic arsenic, assuming the inorganic arsenic content of seafood is 6 per cent of the total arsenic content.

Mercury: At the time of the review of metal contaminants in food [7], ANZFA concluded that median level consumers of fish were unlikely to exceed the PTWI for mercury. However, frequent consumers of fish might exceed the PTWI if all their consumption was of predatory or long-lived fish species. FSANZ has reviewed its risk assessment of mercury due to the Joint FAO/WHO Expert Committee on Food Additives (JECFA's) recent lowering of the PTWI [61], and has issued an updated advisory statement concerning consumption of fish by pregnant women and those considering becoming pregnant.

For the susceptible sub-population (the foetus), the likelihood ranking for mercury is likely if a significant proportion of the mother's fish intake is from large, carnivorous or long-lived fish species (for example, shark, billfish, orange roughy).

Likelihood of adverse health effects: Likely

Wax esters: Several outbreaks of food-borne illness due to indigestible wax esters present in some fish species (particularly escolar and oilfish) have been reported in Australia in recent times (Appendix 2; [50–53]). It is likely that this usually fairly mild adverse reaction is significantly under-reported in the epidemiological datasets [50]. Instances of escolar food poisoning tend to be sporadic cases or outbreaks involving only a small number of people, as evidenced in reports of up to 88 cases (41 incidents) in South Australia in the period 1997–99 (Delroy, personal communication). Some of these cases involved misnaming of escolar as, for example, rudderfish or butterfish.

Histamine: Time–temperature abuse during transport, processing, storage or display will potentially allow formation of histamine. Scombroid species of fish, which have high levels of histidine, are more likely to accumulate high concentrations of histamine under conditions of temperature abuse, but many non-scombroid species have been involved in outbreaks of histamine fish poisoning. Data from testing of samples at retail (Appendix 4) and results from testing of imported fish products (Appendix 1) indicate a low concentration of histamine in whole fish and fillets available in Australia. However, epidemiological data (Appendix 2) show a significant number of outbreaks in commercial and restaurant settings, indicating potential problems in the cold chain (time–temperature abuse). Tuna, blue grenadier and mahi mahi have been identified as species involved in these outbreaks.

Ciguatoxin: Ciguatoxins are responsible for many outbreaks of food-borne illness due to fish consumption in Australia. In the period 1995 to June 2002, outbreaks were recorded in all states except South Australia and Tasmania. Queensland and New South Wales accounted for the great majority of the outbreaks, reflecting both the linkage of the disease with fish caught near tropical reefs in Queensland and the role of Sydney as a hub of marketing for seafood on the east coast. A number of fish species were involved, with coral trout, queenfish, Spanish mackerel and cod species predominant.

In contrast to histamine fish poisoning, ciguatera outbreaks have predominantly been in the private residence setting (Appendix 2). This partly reflects the role of recreational fishing around reefs as a risk factor, and may also indicate the effectiveness of voluntary restrictions on marketing of larger specimens of known ciguatoxic fish species. However, epidemiological data reported in the National Risk Validation Project final report [19] indicate that a significant proportion of the outbreaks due to fish eaten in private residences were caused by fish purchased at retail markets.

Canned fish products

Based on the available consumption data, canned fish products are considered a food group that is regularly eaten by a significant proportion of the population (Appendix 3; [7,9]). On this basis, evidence of the potential for a hazard to be present at an infectious or toxigenic level is taken as the main determinant of the likelihood of adverse health effects for the general population. The likelihood of adverse health effects due to each of the hazards identified in Appendix 1 is discussed briefly below and listed in Table 9.

Likelihood of adverse health effects: Unlikely

Microbiological hazard*s*: Low acid canned fish products undergo a sterilisation process designed to reduce levels of heat-resistant bacterial spores (especially those of *C. botulinum*) to negligible levels, providing that Good Manufacturing Practices and approved thermal processes are applied. This is a well-established practice for production of shelf-stable products. The likelihood of adverse health effects due to bacterial contaminants is thus negligible in a properly controlled canning process. Viral pathogens and helminthic parasites will also be destroyed.

Inorganic arsenic: The concentration of inorganic arsenic is not affected by the canning process, and its concentration in the final product will reflect the concentration in the raw materials. As described for chilled/frozen whole fish and fillets above, the likelihood of adverse health effects due to inorganic arsenic is considered low.

Mercury: Concentrations of methylmercury are unaffected by canning, although for tuna, different species are used for canning, so canned tuna typically has lower levels of mercury than tuna sold fresh. Other fish species associated with high mercury levels (for example, shark, orange roughy) are not normally canned. Concentrations in the final product will reflect concentrations in the raw materials. At the time of the review of metal contaminants in food [7], ANZFA concluded that median level consumers of fish were unlikely to exceed the PTWI for mercury. However, frequent consumers of fish might exceed the PTWI if all their consumption was of predatory or long-lived fish species. FSANZ has reviewed its risk assessment of mercury due to JECFA's recent lowering of the PTWI [61], and has issued an updated advisory statement concerning consumption of fish by pregnant women and those considering becoming pregnant.

Staphylococcal enterotoxin: The enterotoxin produced by *S. aureus* is extremely heat stable, and may survive the heat processes used to sterilise low-acid canned foods [54]. However, production of significant amounts of toxin needs high cell densities (that usually only occur in the late logarithmic or lag phases of growth), and would need significant contamination and time–temperature abuse of the fish prior to canning.

Histamine: Time–temperature abuse of fish intended for canning will potentially allow formation of histamine. Histamine (and other biogenic amines) is not destroyed in the canning process. Data from testing of samples at retail (Appendix 4) indicate only a low prevalence of histamine in canned fish. Results from testing of imported fish products (Appendix 1) show few failures for canned tuna (0.2%), but a higher rate (3%) of non-compliance in other canned fish (salmon, mackerel, sardines, anchovies etc.). Epidemiological data (Appendix 2) is inconclusive, but it must be assumed that the outbreaks of histamine fish poisoning reported in a commercial/restaurant setting are unlikely to be due to canned fish products.

Ready-to-eat cold-smoked fish products

Data from the 1995 National Nutrition Survey (Appendix 3) do not distinguish between hot- and cold-smoked finfish, although consumption of hot-smoked seafood is believed to be small relative to cold-smoked seafood (Walsh, personal communication). It has been estimated that some (25%) of Australians eat smoked seafoods a few times a year [9], although the distinction is not made between hot- and cold-smoked products.

Also, smoked cod is a cold-smoked product that remains raw and must be cooked before consumption, and is not included in the definition of cold-smoked fish for the purposes of this section. Approximately 3000 tonnes of cold-smoked salmon and trout are available for consumption in Australia annually (equivalent to 30 million 100 gram serves), compared to approximately 10 000 tonnes of smoked cod needing further cooking (Walsh, personal communication).
It has been assumed, for this report, that ready-to-eat cold-smoked fish products are occasionally eaten by a significant proportion of the population. On this basis, evidence of the potential for a hazard to be present at an infectious or toxigenic level is taken as the main determinant of the likelihood of adverse health effects for the general population. The likelihood of adverse health effects due to each hazard identified in Appendix 1 is discussed briefly below and listed in Table 10.

Likelihood of adverse health effects: Unlikely

C. botulinum: Spores and vegetative cells are likely to survive the cold-smoking process, but growth is unlikely except in the case of vacuum or modified atmosphere-packed products, as *C. botulinum* is an obligate anaerobe.

Even in the case of vacuum packed and modified atmosphere-packed products, salt concentrations (typically in the order of 5% or higher) are likely to inhibit growth and toxin production by non-proteolytic (Group II and III) types [9,55]. There have been no recorded cases of botulism in Australia in the period 1991–2003 [56].

V. parahaemolyticus: Although it is possible that *V. parahaemolyticus* could survive the conditions of salt, water activity and temperature typically encountered in cold-smoked fish, there are only limited data demonstrating its presence in cold-smoked seafood products in Australia and no epidemiological data indicating food-borne illness from this source.

Enteric pathogens: There are no data demonstrating the presence of enteric bacterial or viral pathogens in cold-smoked seafood products in Australia and no epidemiological data indicating food-borne illness from this source.

Helminthic parasites: Cold smoking does not inactivate anisakids in salmon [57]. Freezing pre- or post-processing will eliminate the larvae. There are, however, no data demonstrating the presence of helminthic parasites in cold-smoked fish products in Australia and no epidemiological data indicating food-borne illness from this source.

Histamine: Time–temperature abuse of fish intended for smoking will potentially allow formation of histamine. Histamine and other biogenic amines are not destroyed in the cold-smoking process. Available data indicate that levels of histamine in smoked fish at retail in Australia are low (Appendix 4). Epidemiological data (Appendix 2) do not identify any smoked seafood as vehicles for outbreaks of scombroid fish poisoning.

L. monocytogenes: Contamination of cold-smoked fish products by *L. monocytogenes* at levels representing a health risk to the general population is considered unlikely, after consideration of the data demonstrating its presence in cold-smoked seafood products, as indicated in Appendix 1, and by reference to the imported food testing and food recall data.

Listeriosis is primarily a sporadic disease in Australia, with 35–70 cases annually (in the period 1990–2002) from all food sources, primarily amongst susceptible population sub-groups (pregnant women and their foetuses, neonates, immunocompromised individuals and the elderly) [56]. It is often not possible to identify the food source responsible for cases of listeriosis, due primarily to its long incubation time. Worldwide, cold-smoked fish products figure prominently in seafood-related outbreaks of listeriosis (Appendix 4), but there is no known epidemiological association in Australia. There is no listericidal step in the processing of cold-smoked fish, and its control is conditional upon adherence to Good Manufacturing Practices and the inhibitory effects of salt, reduced water activity, low storage temperature, etc.

The likelihood rating is considered to be ‘likely’ where there is insufficient management of the risk through the food supply chain, and for susceptible sub-populations (due to the lower infectious dose). The likelihood rating rises to ‘very likely’ when both conditions apply simultaneously.

Hot-smoked fish products

Data from the 1995 National Nutrition Survey (Appendix 3) do not distinguish between hot- and cold-smoked finfish, although consumption of hot-smoked seafood is believed to be small relative to cold-smoked seafood (Walsh, personal communication).

It has been estimated that some (25%) of Australians eat smoked seafoods a few times a year [9], although the distinction is not made between hot- and cold-smoked products. It has been assumed, for this report, that hot-smoked fish products are occasionally eaten by a small proportion of the population. On this basis, when estimating the likelihood of adverse health effects, evidence of the potential for a hazard to be present at an infectious or toxigenic level must be balanced by the relatively limited consumption. The likelihood of adverse health effects due to each of the hazards identified in Appendix 1 is discussed briefly below and listed in Table 9.

<u>Likelihood of adverse health effects: Unlikely</u>

V. parahaemolyticus: Vibrios are relatively heat-sensitive, and will be destroyed by the hot-smoking process. There are no data demonstrating its presence in hot-smoked seafood products in Australia and no epidemiological data indicating food-borne illness from this source.

C. botulinum: Spores will survive the hot-smoking process, but growth is unlikely except in the case of vacuum- or modified-atmosphere-packed products, as *C. botulinum* is an obligate anaerobe. Even in the case of vacuum-packed and modified atmosphere-packed products, salt concentrations (typically in the order of 3.5% or higher) and processing to an internal temperature of greater than 63ºC for at least 30 minutes are likely to inhibit growth and toxin production by non-proteolytic (Group II and III) types [9,55,64]. Proper storage at temperatures under 5ºC inhibits outgrowth and toxin formation by *C. botulinum* in these products [64]. There have been no recorded cases of botulism in Australia in the period 1991–2003 [56].

Enteric pathogens: These bacterial and viral contaminants will be destroyed in the hot-smoking process. There are no data demonstrating the presence of enteric bacterial or viral pathogens in hot-smoked seafood products in Australia and no epidemiological data indicating food-borne illness from this source.

Helminthic parasites: Hot smoking will inactivate anisakids larvae. There are no data demonstrating the presence of helminthic parasites in hot-smoked fish products in Australia and no epidemiological data indicating food-borne illness from this source.

L. monocytogenes: Temperature encountered during hot-smoking will kill *L. monocytogenes*. There is some low potential for recontamination of hot-smoked fish products with *L. monocytogenes*, but the absence of relevant data showing presence of the hazard indicates this may not be a problem in Australia.

Histamine: Time–temperature abuse of fish intended for smoking will potentially allow formation of histamine. Histamine and other biogenic amines are not destroyed in the hot-smoking process. Available data indicate that levels of histamine in smoked fish at retail in Australia are low (Appendix 4). Epidemiological data (Appendix 2) do not identify any smoked seafood as vehicles for outbreaks of scombroid fish poisoning.

Marinated, pickled, brined, dried or fermented fish products

In general terms, consumption of these classes of seafood is mainly confined to certain ethnic sub-populations. The main hazards identified for these types of products are endogenous (for example, parasites, *C. botulinum*) or arise through mishandling and process contamination (for example, histamine, human enteric pathogens, *L. monocytogenes*) [47]. There is an absence of data indicating these hazards present a significant problem in Australia.

<u>Likelihood of adverse health effects: Unlikely</u>

Microbiological hazards: The limited consumption and lack of epidemiological evidence that these types of seafood have caused illness in Australia leads to an overall general conclusion that adverse effects from these hazards is unlikely. The combination of low pH and high salt will usually reduce the likelihood of growth and survival of enteric pathogens and parasites.

<u>Likelihood of adverse health effects: Likely</u>

Histamine: The potential for formation of histamine in these products, due to poor quality or time–temperature abuse of raw materials is considered to be significant. Data from testing of imported foods (Appendix 1) supports this contention.

Surimi

Although not explicitly identified in the data from the 1995 National Nutrition Survey, Surimi products (seafood extender and imitation crab sticks, scallops and calamari rings) are considered to be occasionally eaten by a small proportion of the population.

Likelihood of adverse health effects: Unlikely

L. monocytogenes **and** ***V. parahaemolyticus***: The minced washed fish matrix used in surimi production generally contains higher levels of bacteria than fish fillets, due to the extensive handling and processing involved [47]. However, further processing includes a steaming and/or heating step to set the proteinaceous gel in the formed product. Survival of bacterial pathogens will be minimal, and the attendant adverse health effects will be unlikely. There is potential for post-processing contamination, and the product, especially in the form of 'seafood extender', is a ready-to-eat processed finfish product to which the microbiological limits in Standard 1.6.1 of the Code apply.

Roe and caviar

Consumption data indicate limited consumption of roe and caviar by the general population. While the hazards due to caviar and roe consumption are generally similar to those for raw fish consumption, adverse health effects in the general population are considered unlikely.

Relative risk ranking for fish and fish products – conclusions

Consideration of the severity of adverse health effects and the likelihood of adverse health effects for each fish product type are combined in Table 11, to provide relative risk rankings for the various hazards associated with fish and fish products.

It is concluded that the relative public health risk for ready-to-eat cold-smoked fish is low for the general population when the product meets the microbiological limit for *L. monocytogenes* in Standard 1.6.1 of the Code. The ranking is medium when through-chain hygiene and sanitation is not adequately managed, and high for that sub-group of the population susceptible to invasive listeriosis.

Whole fish or fillets (whether chilled or frozen, for cooking), hot-smoked fish and canned fish are ranked as medium risk, although it is recognised that a maximum level standard exists in the Code to ensure protection of public health and safety from inorganic arsenic in fish, and that ciguatera is largely confined to certain fish species harvested from a limited geographical area (tropical and sub-tropical reefs).

Products such as fish preserved by traditional methods (marinating, pickling, brining, drying or fermenting), surimi, roe and caviar are ranked as low risk, primarily on the basis of the limited consumption of these products by the general population in Australia.

The overall relative risk rankings for whole fish or fillets (whether chilled or frozen, for cooking) and for canned fish are also estimated to be medium for the sub-population susceptible to chronic ongoing effects due to exposure to mercury (that is, the foetus).

Table 11: Relative risk ranking estimates for fish and fish products

Commodity	Hazard	Severity	Likelihood of adverse health effects	Relative risk ranking
Chilled/frozen whole fish and fillets* (including fish for raw consumption) *Where fish and fillets are cooked before eating, the risk from non-spore-forming bacteria is significantly reduced.	*V. parahaemolyticus*	Moderate	Unlikely	Low
	E. coli (non-EHEC)	Moderate	Unlikely	Low
	Staphylococcus aureus	Moderate	Unlikely	Low
	Salmonella (non-typhoid)	Serious	Unlikely	Low
	Campylobacter spp.	Serious	Unlikely	Low
	Shigella spp.	Serious	Unlikely	Low
	Yersinia spp.	Serious	Unlikely	Low
	L. monocytogenes[1]	Serious	Unlikely	Low
	Noroviruses	Moderate	Unlikely	Low
	Hepatitis A virus[1]	Serious	Unlikely	Low
	Helminthic parasites	Serious	Unlikely	Low
	Histamine	Moderate	Likely	Low
	Escolar wax esters[3]	Moderate	Likely	Low
	Ciguatoxin[2]	Serious	Unlikely	Low
	Ciguatoxin/Tropical species[2]	Serious	Likely	Medium
	Mercury[6]	Serious	Unlikely	Low
	Mercury[6]	Serious	Likely	Medium
	Arsenic[4]	Severe	Unlikely	Medium
Canned fish products	*C. botulinum*[7]	Severe	Unlikely	Medium
	V. parahaemolyticus	Moderate	Unlikely	Low
	E. coli (non-EHEC)	Moderate	Unlikely	Low
	Staphylococcus aureus	Moderate	Unlikely	Low
	Salmonella (non-typhoid)	Serious	Unlikely	Low
	Campylobacter spp.	Serious	Unlikely	Low
	Shigella spp.	Serious	Unlikely	Low
	Yersinia spp.	Serious	Unlikely	Low
	L. monocytogenes[1]	Serious	Unlikely	Low
	Noroviruses	Moderate	Unlikely	Low
	Hepatitis A virus[1]	Serious	Unlikely	Low
	Histamine	Moderate	Unlikely	Low
	Mercury[1]	Serious	Unlikely	Low
	Arsenic[4]	Severe	Unlikely	Medium
Commodity	**Hazard**	**Severity**	**Likelihood of adverse health effects**	**Relative risk ranking**
Cold-smoked fish products	*C. botulinum*[7]	Severe	Unlikely	Medium
	V. parahaemolyticus	Moderate	Unlikely	Low
	Helminthic parasites	Serious	Unlikely	Low
	E. coli (non-EHEC)	Moderate	Unlikely	Low
	Staphylococcus aureus	Moderate	Unlikely	Low
	Salmonella (non-typhoid)	Serious	Unlikely	Low
	Campylobacter spp.	Serious	Unlikely	Low
	Shigella spp.	Serious	Unlikely	Low
	Yersinia spp.	Serious	Unlikely	Low
	L. monocytogenes[8]	Serious	Unlikely	Low
	L. monocytogenes[8,10]	Severe	Likely	High
	L. monocytogenes[9]	Serious	Likely	Medium

Cold-smoked fish products (cont.)	*L. monocytogenes*[9,10]	Severe	Very likely	High
	Noroviruses	Moderate	Unlikely	Low
	Hepatitis A virus[1]	Serious	Unlikely	Low
	Histamine	Moderate	Unlikely	Low
	Mercury[1]	Serious	Unlikely	Low
Surimi	*V. parahaemolyticus*	Moderate	Unlikely	Low
	L. monocytogenes[1]	Serious	Unlikely	Low
Hot-smoked fish products	*V. parahaemolyticus*	Moderate	Unlikely	Low
	C. botulinum[7]	Severe	Unlikely	Medium
	Helminthic parasites	Serious	Unlikely	Low
	E. coli (non-EHEC)	Moderate	Unlikely	Low
	Staphylococcus aureus	Moderate	Unlikely	Low
	Salmonella (non-typhoid)	Serious	Unlikely	Low
	Campylobacter spp.	Serious	Unlikely	Low
	Shigella spp.	Serious	Unlikely	Low
	Yersinia spp.	Serious	Unlikely	Low
	L. monocytogenes[1]	Serious	Unlikely	Low
	Noroviruses	Moderate	Unlikely	Low
	Hepatitis A virus[1]	Serious	Unlikely	Low
	Histamine	Moderate	Unlikely	Low
	Mercury[1]	Serious	Unlikely	Low
Marinated, pickled, brined, dried or fermented fish products	Helminthic parasites	Serious	Unlikely	Low
	Histamine	Moderate	Likely	Low
	E. coli (non-EHEC)	Moderate	Unlikely	Low
	Staphylococcus aureus	Moderate	Unlikely	Low
	Salmonella (non-typhoid)	Serious	Unlikely	Low
	Campylobacter spp.	Serious	Unlikely	Low
	Shigella spp.	Serious	Unlikely	Low
	Yersinia spp.	Serious	Unlikely	Low
	L. monocytogenes[1]	Serious	Unlikely	Low
Commodity	**Hazard**	**Severity**	**Likelihood of adverse health effects**	**Relative risk ranking**
Roe and caviar	*V. parahaemolyticus*	Moderate	Unlikely	Low
	E. coli (non-EHEC)	Moderate	Unlikely	Low
	Staphylococcus aureus	Moderate	Unlikely	Low
	Salmonella (non-typhoid)	Serious	Unlikely	Low
	Campylobacter spp.	Serious	Unlikely	Low
	Shigella spp.	Serious	Unlikely	Low
	Yersinia spp.	Serious	Unlikely	Low
	L. monocytogenes[1]	Serious	Unlikely	Low
	Noroviruses	Moderate	Unlikely	Low
	Hepatitis A virus[1]	Serious	Unlikely	Low
	Histamine	Moderate	Unlikely	Low
	Ciguatoxin[2]	Serious	Unlikely	Low
	Escolar wax esters	Moderate	Unlikely	Low

1. For susceptible sub-populations the relative risk ranking is medium (severe x unlikely).
2. Ciguatoxin is mainly found in larger members of particular species of tropical and sub-tropical finfish from certain fishing areas.
3. Wax esters are only present in a few fish species (particularly escolar and oilfish).
4. Inorganic arsenic in fish is regulated in the Code, to ensure protection of public health and safety.
5. For susceptible sub-populations the relative risk ranking is high (severe x very likely). For the general population, the risk ranking is high (serious x very likely) when processing and product handling are not managed.
6. Mercury is a problem in large, long-living or predatory fish, such as swordfish, shark/flake and some tuna. These fish tend to accumulate higher levels of methylmercury than other species. The relative risk ranking is medium for the at-risk sub-population (the foetus) when the mother consumes mainly large, predatory or long-lived fish species.
7. Industry adherence to good manufacturing practice, good hygiene practice and appropriate product formulation (for example, pH, levels of salt, preservatives) control this hazard.
8. When correctly managed, the risk ranking is low for the general population, but high for at-risk sub-populations.
9. When not managed, that is, processing, product handling and storage not adequately controlled, the risk ranking is medium for the general population and high for at-risk populations.
10. *L. monocytogenes* is a severe hazard for at-risk populations.

Key: EHEC = enterohaemorrhagic *Escherichia coli*

5. Discussion of relative risk rankings

The relative risk rankings for those commodity/hazard pairings ranked as medium or high are summarised in Table 12. The factors impacting upon the rankings are discussed below, and a comparison is made with the findings of other relevant risk assessments or ranking exercises.

High relative risk rankings

Oysters and other bivalve molluscs – polluted and/or unmonitored waters

Oysters and other bivalve molluscs (except when the consumed product is only the adductor muscle, for example, roe-off scallops) harvested from growing environments likely to be exposed to faecal contamination and/or not under a shellfish safety management scheme were found to present a relatively high risk to public health. The risk is mainly due to the likelihood of illness caused by contamination with the hepatitis A virus and algal biotoxins (particularly amnesic shellfish poison and paralytic shellfish poison). These hazards are introduced in the pre-harvest phase of bivalve production.

The incidence of food-borne illness from eating oysters and other bivalve molluscs in Australia is characterised by a number of small outbreaks and sporadic cases due to *Vibrio* species and a few large outbreaks due to enteric viruses in oysters harvested from polluted and inadequately controlled waters. While adoption of risk management strategies has improved the safety of bivalve shellfish in Australia, residual risks remain. Monitoring of harvest waters for indicators of sewage pollution (for example, faecal or total coliforms) helps manage the risks from enteric pathogens, bacterial and viral, but cannot predict levels of *Vibrio* species in oysters. Monitoring for potentially toxic species of algae only partly reduces the risks due to algal biotoxins, as concentrations of toxin in oysters do not necessarily always correlate with levels of algae in the water.

Based on these considerations, for oysters and bivalves harvested from waters managed by a comprehensive shellfish safety scheme, such as the ASQAP, the relative risk ranking reduces to medium.

The risk ranking for cooked oysters and other bivalves is the same as the ranking for product to be eaten raw, as the hazards leading to the risk ranking are not greatly affected by the light cooking normally applied to these products.

Table 12: Summary of selected seafood commodities including current risk management*

Commodity	Hazard/environment or species	Severity	Likelihood	Relative risk ranking[1]	Current risk management
Raw oysters	*V. vulnificus*	Serious	Likely	Medium	ASQAP/Ch 3[2]
	V. cholerae O1/O139	Severe	Unlikely	Medium	ASQAP/Ch 3[2]
	Noroviruses/Uncontrolled[3]	Moderate	Very likely	Medium	
	Noroviruses/Managed[4]	Moderate	Unlikely	Low	ASQAP
	Hepatitis A virus/ Uncontrolled[3]	Serious	Very likely	High	
	Hepatitis A virus/Managed[4]	Serious	Unlikely	Low	ASQAP
	Algal biotoxins/Uncontrolled[3]	Severe	Likely	High	Ch 1
	Algal biotoxins/Managed[4]	Severe	Unlikely	Medium	ASQAP/Ch 1
	Arsenic, Cadmium, Lead	Severe	Unlikely	Medium	ASQAP/Ch 1
Commodity	**Hazard/environment or species**	**Severity**	**Likelihood**	**Relative risk ranking[1]**	**Current risk management**
Cooked oysters	*V. cholerae* O1	Severe	Unlikely	Medium	ASQAP/Ch 3[2]
	Noroviruses/Uncontrolled[3]	Moderate	Very likely	Medium	Ch 3[2]
	Noroviruses Managed[4]	Moderate	Unlikely	Low	ASQAP/Ch 3[2]
	Hepatitis A virus/ Uncontrolled[3]	Serious	Very likely	High	
	Hepatitis A virus/Managed[4]	Serious	Unlikely	Low	ASQAP
	Algal biotoxins//Uncontrolled[3]	Severe	Likely	High	Ch 1
	Algal biotoxins/Managed[4]	Severe	Unlikely	Medium	ASQAP/Ch 1
	Arsenic, Cadmium, Lead	Severe	Unlikely	Medium	ASQAP/Ch 1
Cooked abalone /roe-off scallops	Algal biotoxins	Severe	Unlikely	Medium	Ch 1
Green prawns	*V. cholerae* O1[5]	Severe	Unlikely	Medium	Ch 3[2]
	Salmonella Typhi[5]	Severe	Unlikely	Medium	Ch 1/Ch 3[2]
	Arsenic	Severe	Unlikely	Medium	Ch 1
Cooked prawns	*V. cholerae* O1[5]	Severe	Unlikely	Medium	Ch 3[2]
	Salmonella Typhi[5]	Severe	Unlikely	Medium	Ch1/Ch 3[2]
	Arsenic	Severe	Unlikely	Medium	Ch 1
Chilled/ frozen whole fin fish and fillets	Mercury, Ciguatoxin[6]	Serious	Unlikely	Low	Ch 1/Advisory Notes
	Ciguatoxin/Tropical[7]	Serious	Likely	Medium	Advisory Notes
	Mercury/Predatory species[8]	Serious	Likely	Medium	Ch 1/Advisory Notes
	Arsenic	Severe	Unlikely	Medium	Ch 1
Canned fish products	*C. botulinum*[4, 9]	Severe	Unlikely	Medium	GMP/GHP
	Arsenic	Severe	Unlikely	Medium	Ch 1

Cold-smoked fish products	*C. botulinum*[4, 9]	Severe	Unlikely	Medium	GMP/GHP
	L. monocytogenes	Serious	Unlikely	Low[10]	Ch 1/Ch 3[2]/Advisory
	L. monocytogenes	Severe	Likely	High[10, 12]	Ch 1/Ch 3[2]/Advisory
	L. monocytogenes	Serious	Likely	Medium[11]	
	L. monocytogenes	Severe	Very likely	High[11, 12]	
Hot-smoked fish products	*C. botulinum*[4, 9]	Severe	Unlikely	Medium	GMP/GHP

* Relative risk rankings are under constant review to identify emerging significant information.

1. Risk ranking reflects current practice for that commodity/seafood sector. The risk ranking is based on the severity of the hazard and an estimate of the likelihood of illness that takes into account various factors, including current risk management practices.
2. Chapter 3 provisions in the Code apply to the processing sector only.
3. 'Uncontrolled' describes a growing environment not under a shellfish safety management scheme and/or likely to be exposed to faecal contamination. Includes growing waters adjacent to urban areas and rural habitation. In contrast, a growing environment considered pristine is unlikely to be exposed to faecal contamination. Pristine environments would typically include growing waters remote from human habitation and even if uncontrolled, present similar risk to managed waters for enteric pathogens. Algal toxins remain a risk for pristine environments.
4. **Where a food safety hazard is controlled under a management system/program, the likelihood of illness is very low.**
5. For product from intensive farming systems or estuarine harvest areas subject to human faecal contamination.
6. Majority of finfish present a low risk to consumers (serious x unlikely) due to mercury or ciguatoxin.
7. Ciguatoxin may be found in larger specimens of particular species of tropical and sub-tropical finfish from certain fishing areas. It is predominantly a problem in the recreational fishing sector (Table 4.19).
8. Predatory species – mercury is a problem in large, long-living or predatory fish, such as swordfish, shark/flake and some tuna. These fish tend to accumulate higher levels of methylmercury than other species. The relative risk ranking is medium for the at-risk sub-population (the foetus) when the mother consumes mainly large, predatory or long-lived fish species.
9. Industry adherence to good manufacturing practice, good hygiene practice and appropriate product formulation (for example, pH, levels of salt, preservatives) control this hazard.
10. When correctly managed, the risk ranking is low for the general population (serious x unlikely), but high for at-risk sub populations.
11. When not managed, that is, processing, product handling and storage not adequately controlled, the risk ranking is medium for the general population and high for at-risk populations.
12. *L. monocytogenes* is a severe hazard for at risk populations.

Key: ASQAP = Australian Shellfish Quality Assurance Program; GMP = good manufacturing practices; GHP = good hygiene practices.

Findings of other risk assessments

This high relative risk ranking for oysters and other bivalves from polluted and/or unmanaged waters is consistent with the findings of other risk assessments and ranking exercises conducted in Australia on viruses and algal biotoxins in molluscs.

The National Risk Validation Project ranked producers, harvesters, processors and vendors of raw ready-to-eat seafood (including oysters and other bivalves) amongst the five highest risk food industry sectors for food-borne illness in Australia, based on recent epidemiological data [19].
Ross and Sanderson [8] found that consumption of raw shellfish carried a relatively high risk of viral infection compared to other seafoods, whilst recognising that the generally low level of reported illness suggested existing control strategies are effective. They also deduced that the risk of illness due to algal toxins was reduced from medium to low when shellfish were harvested under a quality assurance system. These findings are consistent with the estimates of the likelihood of adverse health effects derived in this report (Table 12).

Sumner [9] ranked the risks from viruses in shellfish from contaminated waters and from algal toxins from uncontrolled waters in an algal event as high (risk rankings of 67 and 72, respectively), with the rankings dropping to low (risk rankings of 31) when harvesting was from approved waters under a quality assurance management system. Again, these are broadly in line with the risk ranking derived in this report (noting that a ranking of 32 is considered 'medium risk' in the Sumner system).

ANZFA [4] concluded that the available data suggested the potential for significant health risk from consumption of shellfish contaminated with algal biotoxins. As a result of that analysis, new end-point maximum level standards were introduced for diarrhoetic and neurotoxic shellfish poisons in bivalve molluscs, and standards were maintained unchanged for amnesic and paralytic shellfish poisons in bivalve molluscs in the Code.

Cold-smoked ready-to-eat finfish

Ready-to-eat cold-smoked finfish (and other ready-to-eat cold-smoked seafood products) present a higher risk to public health relative to other seafoods due to the possibility of contamination with *Listeria monocytogenes* and the potentially severe illness it causes in at-risk population sub-groups such as pregnant women. *L. monocytogenes* is a ubiquitous organism often found in processing environments, and may also be present in fish at the time of harvest. Cold smoking is not a listericidal process.

Recognition of the risks by both regulators and the industry has resulted in a high level of management of *L. monocytogenes* in Australia and a lower risk of illness to the general population. FSANZ has previously recognised the inherent risk to the general population due to *L. monocytogenes* in cold-smoked seafoods by including a microbiological limit standard for the organism in 'ready-to-eat processed finfish, other than fully retorted finfish' in the Code. When the food safety risks are managed, such that cold-smoked seafoods meet this regulatory requirement, the relative risk ranking for the general population is low, although the relative risk ranking for susceptible populations (for example, pregnant women, neonates and the elderly) is high. FSANZ is currently reviewing its dietary advice to these at-risk sub-groups in order to manage their food safety risks due to *L. monocytogenes* from all food sources.

If the food safety risks are not properly managed, such that cold-smoked seafoods do not meet the microbiological limit standard for *L. monocytogenes*, the relative risk ranking is high for at-risk sub-groups and medium for the general population. This takes account of the relatively long shelf life of the product, the high standards of hygiene and sanitation in processing, and good temperature controls across the food supply chain, up to and including the consumer, that is needed to ensure the safety of the product.

Invasive listeriosis is mainly confined to susceptible sub-populations, such as pregnant woman and their unborn children, neonates, immunocompromised people and the elderly. In addition, there is general susceptibility to a milder gastrointestinal illness due to *L. monocytogenes*.

While cold-smoked seafoods have been linked to outbreaks of listeriosis overseas, there has been no such epidemiological linkage established in Australia. However, there are several factors that might lead to an underestimation of the linkage. Listeriosis is primarily a sporadic disease mainly affecting the susceptible sub-populations and, although it can infect healthy people, the low rate of infection in the general population probably means some outbreaks go undetected [58].

In addition, there are inherent difficulties in determining the food vehicle due to the potentially long incubation time (up to three months) of listeriosis.

Findings of other risk assessments

Several recent risk assessments and ranking exercises have considered the public health and safety risk of *L. monocytogenes* in cold-smoked seafoods. There are some apparent inconsistencies between the findings of these studies.

Ross and Sanderson qualitatively ranked the risk to New South Wales consumers of listeriosis from consumption of ready-to-eat smoked seafood products to be low, relative to other seafood/hazard combinations. However, application of their quantitative ranking tool led to a higher relative ranking, behind only viruses and algal biotoxins in molluscs, and *C. botulinum* in vacuum-packed seafoods [8]. This higher ranking reflects the greater influence of the severity of outcomes in the ranking tool compared to the qualitative risk ranking. They further estimated that the incidence of listeriosis in the susceptible sub-population in New South Wales would be, at most, a few cases per annum, depending on the degree of adherence to the microbiological limit standard in the Code.

Sumner ranked the public health risk from smoked seafood containing *L. monocytogenes* as medium (risk ranking 39 for the general population, 47 for the foetus – the extremely susceptible sub-population).

However, he concluded that the estimate of 14 cases per annum due to smoked seafood, as generated by the ranking tool, was not supported by the epidemiological data, and that several factors could account for a lower actual case rate [9]. The average annual reported incidence of listeriosis in Australia (from all food sources) in the period 1991–2002 (inclusive) was 59 cases [56].

The quantitative comparative risk ranking of *L. monocytogenes* in ready-to-eat foods conducted jointly in the United States by the Food and Drug Administration, United States Department of Agriculture and Centers for Disease Control and Prevention concluded that smoked seafoods had a relatively high risk ranking on a per-serving basis, but only a moderate relative risk ranking on a per-annum basis (estimated 1.3 cases per annum in the whole population) [11]. However, these rankings are for ‘likelihood of illness’ (specifically, invasive Listeriosis) in the total population, and do not take into account a severity factor because the comparisons were made between risks due to a single hazard (*L. monocytogenes*) in a large number of foods. The report also generated estimates of likelihood of illness in the perinatal and elderly susceptible populations.

FSANZ previously concluded that *L. monocytogenes* in ready-to-eat finfish (such as cold-smoked salmon) poses a significant public health risk, particularly for vulnerable subgroups, recognising that while the incidence of disease is low in the population, the impact (death) for the infected individual is severe [49]. The assessment led to maintenance of the microbiological limit standard for *L. monocytogenes* in smoked seafood.

Medium relative risk rankings

Many of the medium risk rankings reflect hazards that have severe adverse health effects, although the likelihood of illness from these hazards in the seafood commodity is rated as 'unlikely'. This is the case for abalone and roe-off scallops (amnesic shellfish poison and paralytic shellfish poison); prawns, whether green or cooked (arsenic, *V. cholerae* O1 and *S.* Typhi); canned seafood (arsenic and *C. botulinum*); hot-smoked fish products (*C. botulinum*); and whole or filleted finfish, chilled or frozen, for cooking (arsenic). The 'unlikely' ratings for the likelihood of adverse health effects reflect the effectiveness of existing risk management systems in place for those commodity/hazard combinations.

That many of the medium risk rankings are assigned to hazard/commodity pairs based on severe adverse health effects with unlikely occurrence reflects that the likelihood and severity ratings are not linear and that they are measured on different scales. That reflects the value judgement inherent in the ranking process, and allows inferences to be drawn as to which factors play a more important role in the final risk ranking assigned to each specific commodity group.

Abalone and roe-off scallops

Abalone and roe-off scallops were ranked in the medium risk category of seafood products due to the potential presence and adverse health effects of algal biotoxins (particularly the more severe toxins, amnesic shellfish poison and paralytic shellfish poison). These are hazards which might be introduced in the pre-harvest phase of primary production. Significantly lower levels of algal biotoxins accumulate in the adductor muscle of scallops and the muscular foot of the abalone [16,44], reducing the likelihood of adverse health effects compared to those molluscs where the viscera is also eaten (for example, oysters). Growth, harvesting and processing of abalone and roe-off scallops are not covered by the requirements of the ASQAP.

<u>Findings of other risk assessments</u>

Lehane, in reviewing the public health implications of paralytic shellfish poisons, reported that scallops generally do not pose a public health threat because the adductor muscle does not accumulate toxins [16]. For abalone, Lehane reports the findings of Pitcher et al. [44] that the muscular foot made a low contribution to the total toxin content of abalone harvested during algal bloom events on the west coast of South Africa.

ANZFA [4], Sumner [9] and Ross and Sanderson [8] did not consider the risks due to algal toxins in abalone and roe-off scallop separately from other molluscan shellfish. Sumner noted the low proportion of domestic abalone production available for local consumption, as around 90 per cent is exported, and reported findings that algal toxins had been detected in abalone in Victoria and overseas.

Prawns

Prawns were ranked in the medium relative risk category due to arsenic, *V. cholerae* O1 and *S.* Typhi. The medium ranking reflects the severe nature of the adverse health effects potentially caused by these hazards and the effectiveness of current risk management strategies in reducing the likelihood of adverse health effects rating to 'unlikely'.

The bacterial pathogens are hazards which might be present in the growing environment, particularly in aquaculture facilities stocked to high densities, or could be introduced through use of contaminated cooling water for prawns cooked on-board trawlers or at aquaculture sites. Arsenic is an unavoidable contaminant that may be present in the growing environment for prawns. The medium relative risk ranking for these hazards were not significantly affected by consideration of the form in which these crustacea are sold (raw or cooked).

Standard 1.4.1 – Contaminants and Natural Toxicants – of the Code contains a maximum level standard for arsenic in crustacea (2 mg/kg), set in response to the findings of the risk assessment ANZFA conducted as part of Proposal P157 – *Contaminants in Foods – Metals* [7]. The likelihood of illness due to arsenic in prawns meeting the requirements of Standard 1.4.1 is considered negligible.

Standard 1.6.1 – Microbiological Limits for Food – of the Code includes microbiological limits for *Salmonella* in both cooked and raw crustacea. In addition, the User Guide to Standard 1.6.1 [59] includes additional non-mandatory guideline criteria for *V. cholerae* in cooked and raw crustacea. (When guideline criteria levels are exceeded it generally indicates a failure in food production or hygiene procedures, and alerts the processor and regulator that action should be taken to identify and remedy the problem.)

<u>Findings of other risk assessments</u>

The ongoing FAO/WHO Risk assessment of *Vibrio* spp. in seafood [12] considered the public health risk due to choleragenic *Vibrio cholerae* O1 and O139 in warm-water shrimps. The qualitative risk assessment showed 'there was not a public health problem associated with the consumption of imported warm-water shrimp.'

The quantitative risk assessment is yet to be finalised.

Sumner [9] focused on the public health risk from consumption of ready-to-eat prawns from Asia, the primary source of prawns imported into Australia. The resultant rankings were medium (risk rankings of 37) due to:

- *V. cholerae* (for the very susceptible sub-population)
- *Salmonella* (for the general population).

Ross and Sanderson [8] focused their assessment on the risk due to *Vibrio* spp. in raw ready-to-eat shellfish, primarily oysters, but concluded generally that the incidence of severe disease from *V. cholerae* through consumption of bivalve molluscs or crustaceans was low.

The former ANZFA [6] initially proposed microbiological limit standards for *V. cholerae* in raw and cooked crustacea during its review of the Code. However, in response to public submissions and issues raised at a stakeholder forum, ANZFA amended or deleted some proposed microbiological limit standards. As part of these changes, the proposed standards for *V. cholerae* in crustacea were moved into the guideline document. The rationale for this decision was that:

> While crustacea obtained from countries where this pathogen [*V. cholerae*] is not endemic will not present a hazard to the consumer, product obtained from those areas where it is endemic could do so. This is supported by epidemiological evidence. However, testing cannot be carried out on product only from countries where *V. cholerae* is endemic. Testing of all imported product would be onerous and unnecessary [62].

Canned seafood

Canned finfish (and other low-acid canned seafood products) were ranked in the medium relative risk category due to an unlikely rating for severe adverse health effects due to spore survival, outgrowth and toxin formation by *C. botulinum*. The relative risk due to arsenic was also ranked medium in these products. The medium relative risk rankings primarily reflect the severe nature of the adverse health effects potentially caused by these hazards.

The risk from botulism in low-acid canned foods has been successfully managed for many years through industry adherence to HACCP principles, scientifically based thermal processes, training of retort operators and good hygienic practices, and there have been very few outbreaks attributed to canned seafood either in Australia or other countries over the past 50 years [60].

Standard 1.4.1 – Contaminants and Natural Toxicants – of the Code contains a maximum level standard for arsenic in fish (2 mg/kg), set in response to the findings of the risk assessment ANZFA conducted as part of Proposal P157 – Contaminants in Foods – Metal*s* [7]. The likelihood of illness due to arsenic in canned fish products meeting the requirements of Standard 1.4.1 is considered negligible.

<u>Findings of other risk assessments</u>

Sumner [9] ranked the risk of illness due to *C. botulinum* in canned fish as very low (risk ranking 22), based on the demonstrated effectiveness of control mechanisms in place for canning low-acid foods.

Ross and Sanderson [8] focused their assessment on the risk from C. botulinum in vacuum-packed ready-to-eat (generally smoked) seafood products, rather than canned seafoods.

FSANZ [6] concluded that the risk of botulism from canned fish was very low due to rigorous control of canning facilities worldwide, while noting that 'the severity of this disease means that the potential for it to occur must always be allowed for.'

Whole and filleted finfish

For whole and filleted finfish (chilled or frozen, including fish for raw consumption) the only hazard falling into the medium relative risk ranking category was arsenic. The ranking primarily reflects the severe nature of the adverse health effects potentially caused by arsenic.

<u>Findings of other risk assessments</u>

Ross and Sanderson [8] and Sumner [9] did not assess the risks due to arsenic in seafoods. ANZFA concluded [7] that the likelihood of illness due to arsenic in fish and fish products meeting the maximum level standard (2 mg/kg) was negligible.

Whole and filleted finfish – larger reef fish

Certain species of reef fish prone to accumulating ciguatoxin were ranked in the medium relative risk ranking category. The epidemiological evidence strongly indicates the risk is greatest in Queensland and New South Wales – the states consuming the greater proportion of potentially ciguatoxic fish and having fisheries located in proximity to tropical and sub-tropical reefs. However, the interstate trade in fish in Australia leads to the risk being 'exported' to other states where the local fish catch is not a source of ciguatera.

<u>Findings of other risk assessments</u>

Ross and Sanderson considered the risk to New South Wales consumers of ciguatera fish poisoning to be 'relatively low' [8]. Sumner [9] ranked the risk of ciguatera in the general population as medium (risk ranking 45), and as high (risk ranking 60) for recreational fishers and their families in known ciguatera 'hot spots' in Queensland and the Northern Territory. The different rankings reflect self-regulation by fish marketing bodies, for example, bans on certain known ciguatoxic species and size limits on others, and the perceived need for greater education of recreational fishers.

ANZFA has not previously published a risk assessment of ciguatoxin in fish.

Whole and filleted finfish – large, carnivorous and long-lived fish species

For the susceptible sub-population (the foetus), the risk of chronic effects caused by exposure to mercury from large, carnivorous or long-lived fish in the maternal diet was also ranked as medium.

Standard 1.4.1 – Contaminants and Natural Toxicants – of the Code contains a maximum level standard for mercury of 1 mg/kg which applies to several identified fish species (including shark and billfish) known to accumulate higher levels of mercury. FSANZ has recently reviewed its risk assessment for mercury, particularly in fish and fish products, and has revised its advice on the consumption of fish by women of childbearing age.

<u>Findings of other risk assessments</u>

Ross and Sanderson [8] concluded that people consuming above-average levels of fish, particularly of shark and billfish might be exposed to hazardous levels of mercury. Sumner [9] ranked the risk due to mercury in fish as low (risk ranking of 24). Neither explicitly assessed the risk for the foetus, although both indicated that education of pregnant women and consumers of large amounts of larger, predatory fish species was a necessary risk management strategy.

Hot-smoked fish products

Hot-smoked fish products were ranked in the medium relative risk category due to an 'unlikely' rating for severe adverse health effects from spore survival, outgrowth and toxin formation by *C. botulinum*. The medium relative risk ranking primarily reflects the severe nature of the adverse health effects potentially caused by this hazard.

Findings of other risk assessments

Ross and Sanderson [8] considered that the risk to New South Wales consumers from *C. botulinum* in vacuum-packed ready-to-eat fish products was ‘relatively low’, and would only result from gross temperature abuse. Sumner [9] ranked the risk as ‘negligible’ on the basis of the low levels of spores likely to be in products available in the Australian marketplace and the typical salt levels in these products.

FSANZ has not previously published a risk assessment of *C. botulinum* in hot-smoked fish products.

Low relative risk rankings

A significant number of seafood commodities were ranked as presenting a low relative risk to the general population. For some of these, limited consumption of the product was the main factor that led to the conclusion that adverse health effects from associated hazards was unlikely. For others, the probable effect of downstream processing and consumer handling on hazard levels was a factor in reducing that likelihood.

6. Uncertainty and variability

The relative risk rankings outlined in this document will inform FSANZ’s consideration of risk management options. Consequently, it is important to recognise and consider the areas of uncertainty and variability in the ranking. While the rankings are underpinned by available epidemiological data, hazard identification, risk characterisation and detailed evaluations of the seafood supply chain, they remain largely qualitative.

Uncertainties in the risk rankings primarily come from significant data gaps in the information used to derive the ‘likelihood of illness’ rating. The available surveillance and epidemiological data demonstrating the association between hazards, seafood commodities and food-borne illness are recognised as being limited. In addition, the gaps in data and information are unevenly spread across hazards and commodities, necessitating employment of a degree of expert opinion/judgement in the likelihood of illness ratings, to bridge the gap between what is indicated by the data and what is plausible given our knowledge of the hazard, the seafood commodity, its regulatory environment, and its production and processing supply chain up to the point of consumption. This has militated against completion of a formal quantitative exposure assessment for each hazard/commodity pairing considered. Qualitative estimates of the likelihood of illness due to the presence of a particular hazard in a seafood commodity were derived, based on available information.

The seafood consumption figures were derived using data from the 1995 National Nutrition Survey of Australia, which was based on selected consumers’ recollection of the food they had consumed over a designated 24-hour period. This tends to lead to an over-estimation of habitual food consumption amounts for high consumers and for foods that are only occasionally eaten. Other limitations of the National Nutrition Survey data are that smoked finfish was not identified as being hot- or cold-smoked, or as ready-to-eat or raw (for example, smoked cod); and scallops were not identified as being roe-off or not.

Further uncertainty in the risk rankings arises from the evolving regulatory and non-regulatory risk management environment for seafood in Australia. The impact of such changes on the safety of seafood can only be judged over the course of a number of years, when it might be reflected in the epidemiological, prevalence and concentration data used in generating the risk estimates.
Variability in the risk posed by seafood products can arise from a number of factors, including geographical factors contributing to the risk (for example, risk of ciguatera poisoning is relative to levels of consumption of larger reef fish; risk due to *Salmonella* in cooked prawns is influenced by the method of production – wild-catch versus aquaculture).

Application of international data to the Australian situation may also be a source of variability in risk estimates. For example, differences in the virulence of pathogens, the susceptibility of populations or the levels of hazards in seafood can all affect the overall level of food-borne illness arising from a particular product/hazard combination. However, international data was used in the analysis, particularly in cases where Australian data was lacking or where a significant amount of the seafood commodity was imported.

As significant data gaps are gradually filled by the results of ongoing research and scientific evaluation, the robustness of the risk rankings can be better assessed and the rankings may be further refined. As it stands, the rankings place seafood industry sectors into broad relative risk categories as a basis for considering appropriate risk management strategies.

7. Conclusions

The relative risk rankings described in this report demonstrate that, under current risk management practices – both voluntary and mandatory – in Australia, public health and safety risks are low for the majority of seafoods. A small number of industry sectors present a higher public health risk relative to other seafoods.

The report concludes that the following seafood sectors are ranked in the high relative risk category:

- oysters and other bivalve molluscs (except when the consumed product is only the adductor muscle, for example, roe-off scallops) harvested from growing environments likely to be exposed to faecal contamination and/or not under a shellfish safety management scheme
- ready-to-eat cold-smoked finfish (and other ready-to-eat cold-smoked seafood products) when eaten by population sub-groups susceptible to invasive Listeriosis.

Oysters and other bivalves have been the food vehicle in several large and small outbreaks of food-borne illness in Australia over the past 15 years. The food safety hazards involved have included enteric viruses, algal biotoxins and pathogenic bacteria. When harvested from waters managed by a comprehensive shellfish safety scheme, such as the ASQAP, oysters and other bivalves were ranked in the medium relative risk category.

Cold-smoked seafoods have been linked to outbreaks of listeriosis overseas, but there has been no such epidemiological linkage established in Australia. However, there are several factors that might lead to an underestimation of the linkage.

Listeriosis is primarily a sporadic disease affecting susceptible populations (the foetus, pregnant women, neonates, the elderly and the immunocompromised) and, although it can infect healthy people, the low rate of infection in the general population probably means some outbreaks go undetected [58].

The inherent difficulties in determining the food vehicle, due to the long incubation time of the disease, typically militate against identification of the actual food vector.

Of the seafood commodities ranked in the medium relative risk category, prawns and fish (whole or as fillets) have been linked to several outbreaks of food-borne illness in Australia in recent years. For prawns, the associated food safety hazards have been primarily microbiological hazards, while for fish, ciguatoxin, histamine fish poisoning and escolar wax esters account for the majority of outbreaks.

The conclusions of the risk ranking are subject to uncertainties introduced by significant data gaps and ongoing changes in the risk management environment applying to seafood in Australia. Gaps and uncertainties mean the conclusions must be understood to be based on the current state of knowledge and that they are subject to revision in the light of any new information/data that might become available in the future. So, as the data gaps are filled by the results of ongoing scientific studies and surveys of the prevalence and levels of food safety hazards in seafood in Australia, the rankings may need to be reconsidered and further refined.

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Appendix 1

Hazards along the seafood production and processing supply chain

The public health risks posed by the consumption of seafood in Australia are affected by the production and processing practices along the entire supply chain of each commodity type.

This appendix summarises, for each broad commodity sector, data indicating the potential presence of food safety hazards and the significant points along the supply chain where there is the possibility of the introduction, increase, reduction or elimination of such hazards. As well as assisting in the evaluation of public health risks due to seafood consumption, the information in this appendix may be useful for the risk manager, helping to define critical points at which risk management strategies may be applied to greatest effect.

Molluscan shellfish

Molluscan shellfish, specifically oysters, scallops and pipis, have been implicated in several outbreaks of food-borne illness in Australia in the period 1995 to June 2002 (outbreak data are at Appendix 2). The hazards involved have included viruses (noroviruses and hepatitis A), algal biotoxins (diarrhoeic shellfish poisons in pipis) and bacteria (*Salmonella* serovars).

The Imported Foods Inspection Scheme, coordinated by the Australian Quarantine and Inspection Service, tests a large number of samples of seafood entering Australia each year. In the period 1998 to June 2003 (inclusive), failures were recorded for imported molluscs tested for *E. coli*, the Standard Plate Count (as an indicator of hygienic food preparation and handling), *Salmonella*, *L. monocytogenes* and mercury. No failures were recorded in tests for domoic acid (causes amnesic shellfish poisoning), paralytic shellfish poison, staphylococcal enterotoxin, *V. parahaemolyticus*, cadmium or arsenic (Table 1.1).

Table 1.1: Significant imported foods testing failures for molluscs, 1998–2003*

Hazard	Failures per tests (%)	Comments
Mercury	3/302 (1.0%)	
Salmonella	1/218 (0.5%)	
V. cholerae	1/644 (0.2%)	Includes 1/97 (1.0%) in oysters
E. coli	15/623 (2.4%)	Includes 10/207 (4.8%) in oysters
L. monocytogenes	2/238 (0.8%)	
Standard plate count	21/605 (3.5%)	Includes shellfish and cephalopods

* No failures were recorded for imported molluscs tested for *V. parahaemolyticus*, Staphylococcal enterotoxin, algal biotoxins, cadmium, inorganic arsenic, total arsenic, organophosphates, organochlorines or PCBs.

In the period 1990–2003, FSANZ coordinated four food recalls for oysters (hepatitis A, *L. monocytogenes*, domoic acid and excess lead) and four for mussels (*E. coli*, can defects and two for *L. monocytogenes*).

Factors affecting the presence of these and other potential hazards along the production and processing supply chain for molluscan shellfish have been considered at the point of harvest, during processing and at subsequent points in the distribution chain.

The hazards are broadly summarised in Table 1.2 and discussed at greater length for the main product groups (oysters, scallops, other bivalves and abalone) below.

Table 1.2: Potential food safety hazards along the molluscan shellfish supply chain

Supply chain sector	Source of hazards	Examples of hazards
Pre-harvest	Bacterial, viral and chemical contamination by sewage and runoff	• Enteric pathogens (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, hepatitis A virus, noroviruses) • Agricultural chemical residues
	Exposure to environmental contaminants	• Endogenous bacteria that are human pathogens (*A. hydrophila*, *V. parahaemolyticus*, *V. vulnificus, V. cholerae* O1, non-O1/non-O139 *V. cholerae* • Chemical (algal biotoxins, mercury, cadmium, zinc)
Depuration and shucking	Contamination by shuckers	• Microbiological pathogens (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, hepatitis A virus, noroviruses)
	Opportunity for outgrowth	• Bacterial pathogens (E. coli, S. aureus, Salmonella spp., Campylobacter spp., Shigella spp., Yersinia spp., L. monocytogenes, A. hydrophila, V. parahaemolyticus, V. vulnificus, V. cholerae O1, non-O1/non-O139 V. cholerae)
	Reduction in level of hazards due to depuration	• Reduced levels of some bacterial pathogens (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*)
Transport, marketing, retailing and food service	Contamination by food handlers	• Microbiological pathogens (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, hepatitis A virus, noroviruses)
	Opportunity for outgrowth	• Bacterial pathogens (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, *A. hydrophila*, *V. parahaemolyticus*, *V. vulnificus, V. cholerae* O1, non-O1/non-O139 *V. cholerae*)

Effects of processing on levels of hazards in molluscan shellfish

<u>Oysters</u>

Pre-harvest: Oysters are filter feeders, extracting marine algae, bacteria and nutrients from the surrounding waters. Because of this, they are prone to contamination from the growing environment, and concentrate certain chemical hazards as well as support viability and/or growth of microbiological contaminants. In Australia, oysters are mainly grown on aquaculture leases in estuarine environments, often close to populated or tourist recreational areas.

Some pathogenic bacteria are endogenous to aquatic environments and can survive or grow in oysters, presenting a risk to health if ingested. These include *V. vulnificus*, pathogenic strains of *V. parahaemolyticus* and *V. cholerae*, and *Aeromonas hydrophila*. Typically, levels of these pathogens in the environment will be low, being subject to environmental conditions such as salinity and water temperature.

In Australia, *A. hydrophila*, *V. vulnificus* and pathogenic strains of *V. parahaemolyticus* are present in estuarine environments where oysters are grown commercially. However, only non-toxigenic strains of *V. cholerae* O1 have been isolated from estuarine environments and oysters [1].

Microbiological hazards may also be introduced into oyster growing waters through pollution from sewage and animal waste. These pathogens typically survive for only short periods of time in the marine environment, but maintain viability for much longer when ingested by oysters. Examples include pathogenic strains of *E. coli* and *Salmonella*, *Campylobacter*, *Yersinia* and *Shigella* species. These organisms can multiply quickly, particularly at higher temperatures, potentially rendering oysters unsafe for consumption.

Pathogenic viruses, particularly hepatitis A and the small round structured viruses (noroviruses of the caliciviridae family) may be introduced to oyster growing waters through sewage pollution and can survive for long periods in oysters. While viruses will not replicate in shellstock, they have low infectious doses, and thus present a risk to human health.

Oysters can also extract chemical contaminants from their growing waters, and bioaccumulate them to hazardous concentrations in their flesh. Industrial, agricultural and sewage pollution may introduce various hazardous chemical into waterways where oysters are grown, while natural sources of heavy metals may also be of concern.

Certain species of toxin-producing marine dinoflagellate and diatomic algae present a food safety risk from oyster consumption. The algae and toxins can potentially accumulate to high concentrations in oysters, particularly during periods of algal bloom (for example, red tides) when levels of the algae suddenly increase in response to environmental triggers. The combination of factors triggering bloom events is not fully understood, and toxin concentrations do not necessarily correlate with levels of the algae in the marine environment, making it difficult to predict the degree of food safety risk from these hazards.

Post-harvest: Processing of oysters before retail sale is usually minimal. When necessary, algae adhering to the shell are removed by tumbling, a process that can result in some damage to the oyster shells and potentially allow contamination of the meat. Oysters may be purified to some extent by relaying or depuration. These processes are reasonably efficient at reducing the load of enteric bacteria in oysters, but are significantly less effective at reducing the levels of viruses, endogenous marine pathogenic bacteria, chemicals and algal biotoxins.

The main processing of oysters involves shucking and packing in boxes for sale on the half shell or bottling in fresh water, depending on the grade. The shucking process does not kill pathogenic microorganisms or remove chemical contaminants, but introduces the potential for further contamination by enteric pathogens. In addition, the potential exists during shucking and transportation for temperature abuse, allowing multiplication of bacterial pathogens to levels that might pose a public health risk. Further handling in the distribution chain also carries with it the potential for contamination and temperature abuse.

Scallops

Pre-harvest: Wild-catch southern scallops are harvested by dredging or diving in coastal waters up to 120 metres deep. Saucer scallops are capable of swimming out of the way of dredges, and are primarily caught by trawling (often as by-catch of demersal otter prawn trawling) in shallower waters, up to 75 metres deep.

Scallops filter-feed on plankton and organic detritus from water and sediments in which they settle. As filter feeders, they are subject to the same potential for bioaccumulation of chemical and biological food safety hazards as oysters (see above). However, the growing environments of wild-caught scallops are less likely to be subjected to significant levels of contamination by human sewage pollution or agricultural run-off. Levels of enteric pathogens and agricultural chemical residues are likely to be low at point of harvest. Endogenous marine pathogens may still present a risk, particularly the *Vibrio* species and also *C. botulinum*, which is found in marine sediments.

Until recently, aquaculture of southern scallops in Australia was limited to rearing wild or hatchery spat to the stage at which they detach from their initial sessile state. Intermediate culture in midwater cages was usually followed by reseeding of the sea floor for grow out to commercial size. More recently, the use of lantern nets or more rigid nets suspended from longlines throughout the ~18 month grow out cycle has been successfully employed. Food safety risks arising from water quality issues in the aquaculture of scallops are obviously related to the choice of site. Shallower coastal sites are preferred, which are closer to land and subject to greater potential for contamination by sewage and agricultural run-offs. The potential for contamination by algal biotoxins would be similar for farmed and wild scallops.

Post-harvest: After catching, scallops are sorted and washed on board, and stored live in steel crates or hessian sacks at ambient temperature. The processing of scallops involves removing the gut and shell and retaining the adductor muscle (scallop meat) and the roe (where applicable). After landing, the crates or sacks are opened and the scallops are emptied into hoppers. A knife is inserted to open the shell and the meat and roe are cut out and placed into containers. The freshly shucked scallops are washed and drained before being chilled or frozen. The potential for contamination and temperature abuse during shucking, transport and downstream food handling is similar to that encountered with oysters. Consumption of saucer scallops is usually restricted to the adductor muscle tissue, which tends to accumulate lower levels of food safety hazards than the roe.

Other bivalves

Mussels are grown by longline open water aquaculture in Australia. They obtain all their nutrients from the growing environment, filter feeding on plankton and other organic matter, and do not need additional dietary supplementation. All of Australia's mussel production is consumed locally, along with a similar amount of imported mussels (mostly from New Zealand). After reaching marketable size (65–85 mm) the mussels are removed from the long lines and the shells cleaned of external fouling, usually in a washer–tumbler machine in which the mussels are rotated and rub against each other to dislodge small mussels, barnacles and other fouling organisms. The mussels are then cleaned, graded and bagged for sale, live, without further processing. Aside from the potential for shell damage, and consequent contamination of the flesh, the major source of food safety risk is in the quality of the growing waters.

The choice of site determines the potential for contamination by sewage and industrial and agricultural run-off, while the risk from hazardous algal blooms is similar in scope (and unpredictability) to that encountered for scallops. Mussels are usually shipped and sold live. Dead mussels tend to gape, providing a convenient indicator of quality. Good quality mussels have closed shells, minimising the risk of contamination by food handlers.

Small quantities of pipis (also known as Goolwa cockles) are commercially harvested in Australia, mainly in New South Wales and South Australia, with smaller commercial catches in Queensland and Victoria. They are harvested along the waterline, and are usually sold live in the shells, with no processing. The main hazards likely to be present are endogenous marine pathogens and algal biotoxins, with the potential for temperature abuse after harvest and during transport.

Abalone

Abalone are gastropod molluscs that feed on drift algae and seagrass leaves. They are found primarily on rocky reefs in waters up to 40 metres deep around the southern coasts of Australia. Although there is increasing interest and investment in aquaculture of abalone, the vast majority (>99%) of Australia's abalone production is wild-caught, usually by diving. The abalone are usually landed live and processed onshore except in South Australia, where a large proportion of the catch is shucked at sea. After shucking, the meat (adductor muscle) is cleaned and graded, before being bulk frozen, parboiled then frozen, or cooked in brine then canned. A small amount is frozen whole on the shell.

As only the adductor muscle is eaten, the potential for accumulation of microbiological hazards and chemical contaminants from the growing environment is similar to that encountered with saucer scallops, as many of these hazards are preferentially concentrated in the viscera, which is discarded. During post-harvest handling, shucking and transport, contamination with microbiological (for example, *S. aureus*) and chemical hazards and temperature abuse are possible. The microbiological hazards will be controlled to some extent by chilling/freezing and canning processes.

In aquaculture of abalone, the potential for contamination by agricultural run-off is greater than for wild-caught abalone, and antibiotic and anaesthetic residues are also a potential hazard, while the hazards potentially introduced during handling are similar to those for wild-caught abalone.

Cephalopod molluscs

Cephalopod molluscs have not been implicated as the vehicle in any outbreaks of food-borne illness in Australia during the period 1995 to June 2002 (Appendix 2 for outbreak data) and were not the subject of any FSANZ-coordinated food recalls in the period 1990–2003.

Under the Imported Foods Inspection Scheme testing regime, failures were recorded for imported squid products for high mercury concentrations (one failure, at 1.6 mg/kg, in 98 tests) and the standard plate count (two failures in 19 tests) in the period 1998 to June 2003 (inclusive). No failures were recorded for enteric pathogens, *Vibrio*s or shellfish toxins.

Factors affecting the presence of potential hazards along the production and processing supply chain for cephalopod molluscs have been considered at the point of harvest, during processing and at subsequent points in the distribution chain. The hazards are broadly summarised in Table 1.3 and discussed at greater length below.

Effects of processing on levels of hazards in cephalopod molluscs

Octopus, squid and other cephalopods eat a diet of crustacea, fish and other molluscs. The marine environments from which they are harvested are largely free of significant levels of pollution. Endogenous hazards which may be present at point of harvest are broadly similar to those associated with other molluscan species, although there is no evidence for the accumulation of algal biotoxins in the cephalopods. Conversely, squid is known to be an intermediate host for anisakid parasites [2]. Squid and octopus are usually landed live and sold as chilled or frozen product. Squid are imported in many forms, including whole dried; dried and shredded; dried shredded and smoked; canned; frozen hoods; and frozen rings. Octopus are imported dried, salted, smoked and marinated.

In Australia, processing of octopus is minimal, involving washing, brining to evert the octopus, removal of teeth and organs, and subsequent chilling or freezing. Squid, calamari and cuttlefish are similarly minimally processed. The internal organs, skeleton and the skin are removed, the product washed, and cleaned tubes and/or bodies are stored chilled or frozen. Post-harvest handling introduces the risk of contamination by pathogenic microorganisms, and handling and transport introduce the possibility for outgrowth of bacterial pathogens if temperature is not adequately controlled.

Table 1.3: Summary of potential hazards along the cephalopod mollusc supply chain

Supply chain sector	Source of hazards	Examples of hazards
Pre-harvest	Exposure to environmental contaminants	• Endogenous bacteria that are human pathogens (*A. hydrophila*, *V. parahaem-olyticus*, *V. vulnificus,* non-O1/non-O139 *V. cholerae*) • Helminthic parasites (anisakids) • Chemical (mercury, cadmium)
Washing, brining, skinning	Contamination by handlers	• Microbiological pathogens (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, hepatitis A virus, noroviruses)
	Opportunity for outgrowth	• Bacterial pathogens (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, *A. hydrophila*, *V. parahaemolyticus*, *V. vulnificus,* non-O1/non-O139 *V. cholerae*)
Transport, marketing, retailing and food service	Contamination by handlers	• Microbiological pathogens (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, hepatitis A virus, noroviruses)
	Opportunity for outgrowth	• Bacterial pathogens (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, *A. hydrophila*, *V. parahaemolyticus*, *V. vulnificus,* non-O1/non-O139 *V. cholerae*)

Crustacea

Crustacea, specifically prawns and crayfish, have been implicated in six outbreaks of food-borne illness in Australia in the period 1995 to June 2002 (Appendix 1). The hazards involved have included hepatitis A virus, *S. typhi*, *S. typhimurium*, *V. cholerae* and *C. perfringens*. In the case of the two outbreaks of perfringens food poisoning from consumption of curried prawns, the likely source of contamination is the spices used in the dish [3], as *C. perfringens* is not usually considered a seafood-associated pathogen.

The failures recorded for imported crustacea in Imported Foods Inspection Program testing data for the period January 1998 to June 2003 (inclusive) are listed in Table 1.4.

In the period 1990–2003, FSANZ coordinated three food recalls for crustacea (for unspecified microbiological contamination, *Salmonella* and excess sulphur dioxide).

Further evidence of a public health risk due to crustacea was found in the recent cooked prawns survey coordinated by FSANZ [4]. In this survey, 380 samples of chilled or frozen cooked prawn were tested for the Standard Plate Count and *Listeria monocytogenes*. The retail temperature of the chilled prawns was also determined. The survey covered peeled and unpeeled, imported and domestic prawns.

The contamination rate of *Listeria monocytogenes* in cooked prawns was low (3%) and the levels of those detected were also low (<50 cfu/g). The Standard Plate Counts ranged from negligible (<103 cfu/g) to high (>107 cfu/g), and the temperatures of cooked prawns varied from frozen to 12.8°C. However, there was no correlation between high Standard Plate Counts and high temperatures. Results from the survey were used in the semi qualitative risk assessment FSANZ conducted for '*Listeria monocytogenes* in cooked crustacea' [5].

Table 1.4: Significant imported foods testing failures for crustacea, 1998–2003*

Hazard	Failures/Tests (%)	Comments
Sulphur dioxide	3/161 (1.9%)	
Salmonella	11/1383 (0.8%)	
V. cholerae	21/1674 (1.3%)	All failures are non-O1/non-O139 strains
E. coli	13/1432 (0.9%)	8/134 (6.0%) in lobster/crawfish
Staphylococcal enterotoxin	6/1815 (0.3%)	
Standard plate count (SPC)	81/1509 (5.4%)	
Chloramphenicol	4/76 (5.3%)	Frozen farmed prawns
Antibiotics	7/118 (5.9%)	Prawns: streptomycin, oxytetracycline

* No failures were recorded for crustacean imports tested for coliforms, mercury, cadmium, inorganic arsenic, total arsenic, other metals and heavy metals, organophosphates, organochlorines or PCBs.

Effects of processing on levels of hazards in crustacea

Prawns

Prawns are produced through both wildcatch and aquaculture production methods. Prawns are bottom-feeding, opportunistic omnivores, and will consume a wide variety of foods depending on availability. They are subject to a range of hazards through their environment, both chemical and microbiological.

Further hazards can also be introduced during subsequent processing, handling, transport and storage stages (Table 1.5).

Wildcatch: A range of prawn species are commercially harvested as wildcatch in Australia, from both estuarine and marine environments. Catch is obtained from a wide range of locations, covering much of the Australian coastline. The primary method of catch is demersal otter trawling. Free-living prawns may encounter a range of hazards in their environment, both chemical and microbiological.

Significant chemical hazards originating from the environment include the metals arsenic and mercury. Both of these are recognised as human toxins, and their presence in crustacea is regulated under the Code. Cadmium has also been identified as a food safety hazard associated particularly with endeavour prawns (*Metapenaeus* spp.) harvested in certain geographical regions [6], but it was concluded that no maximum level standard was necessary in the Code.

Other chemical residues may be present in wild-catch crustacea due to industrial pollution and agricultural run-off. This will be a greater risk in estuarine prawns than those caught in open marine waters.

Table 1.5: Potential food safety hazards along the crustacean supply chain

Supply chain sector	Source of hazards	Examples of hazards
Pre-harvest	Bacterial, viral and chemical contamination by sewage and runoff	• Enteric pathogens (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, hepatitis A virus, noroviruses) • Agricultural and veterinary chemical residues
	Exposure to environmental contaminants	• Endogenous bacteria that are human pathogens (*A. hydrophila*, *V. parahaemolyticus*, *V. vulnificus, V. cholerae* O1, non-O1/non-O139 *V. cholerae* • Chemical (arsenic, mercury)
On-board cooking and cooling	Reduction in level of hazards due to cooking	• Reduced levels of bacterial pathogens (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*)
	Re-contamination	• Microbiological pathogens (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, hepatitis A virus, noroviruses) • Chemicals – sulphite
	Opportunity for outgrowth	• Bacterial pathogens (E. coli, S. aureus, Salmonella spp., Campylobacter spp., Shigella spp., Yersinia spp., L. monocytogenes, A. hydrophila, V. parahaemolyticus, V. vulnificus, V. cholerae O1, non-O1/non-O139 V. cholerae)
Transport, marketing, retailing and food service	Contamination by food handlers	• Microbiological pathogens (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, hepatitis A virus, noroviruses)
	Opportunity for outgrowth	• Bacterial pathogens (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, *A. hydrophila*, *V. parahaemolyticus*, *V. vulnificus, V. cholerae* O1, non-O1/non-O139 *V. cholerae*)

Prawns are also potentially exposed to a range of indigenous microbial contaminants from the water environment, including *A. hydrophila*, *V. parahaemolyticus*, *V. vulnificus*, *V. cholerae*, *Salmonella* spp. and *L. monocytogenes* [3,7]. *Vibrio*s are known to utilise the chitinous exoskeleton of crustacea as points of attachment and to metabolise it as a carbon/energy source [3,8]. *V. parahaemolyticus*, *V. vulnificus* and *V. cholerae* are considered part of the indigenous microflora of estuarine prawns [9].

V. cholerae O1 and O139 and *Salmonella* spp. derived from faecal contamination may become established as environmental contaminants in waters from which prawns are harvested and have the potential to contaminate free-living prawns prior to catch. Noroviruses and hepatitis A may also be present. Prawns inhabiting estuarine environments may be exposed to a greater number of potential sources of microbial or chemical contamination, due to their proximity to shore, land animals, human dwellings, and the introduction of chemical and faecal pollutants [3].

After harvest, prawns caught on commercial vessels can be processed in a variety of ways. While on board, they may be boxed as green (uncooked) product and chilled or frozen on board. In some operations, catch is cooked on board vessels, and subsequently stored in either brine or ice. Dipping of prawns in metabisulphite to inhibit formation of blackspot can present a risk to asthmatics due to formation of sulphur dioxide.

The processing of prawns on board vessels presents considerable potential for further contamination. Raw product may come into contact with chemical or microbial contaminants through contact with water, surfaces or containers. Pathogens of concern include *V. cholerae*, *V. parahaemolyticus*, *E. coli*, *Campylobacter*, *Shigella*, *Yersinia* and *Salmonella* spp. and *L. monocytogenes*. Human handling also introduces potential for contamination by enteric pathogens such as *Salmonella*, *S. aureus*, hepatitis A virus and noroviruses.

Prawns that undergo a cooking step are effectively rendered pathogen free, as any microorganisms present will be inactivated, assuming that the product is heated at sufficient temperature and time. However, cooking will not remove or inactivate chemical hazards already present in the product, such as arsenic, mercury and other chemical residues. Cross contamination between raw and processed crustaceans during processing, transport and storage, particularly on board vessels, is recognised as an area of particular concern [3,7], potentially reintroducing environmental microbial hazards. Cooling water and brine/ice used for storage of prawns are also recognised as potential sources of recontamination. Cooked crustacea may also be contaminated by food handlers, introducing enteric pathogens.

Use of low temperatures during transport and storage (of both raw and cooked product), as well as during processing, will reduce the opportunities for growth of most microbial contaminants if temperatures are rigorously maintained below 5°C. However, some pathogens are able to proliferate at temperatures close to this: *V. cholerae* will grow at 8°C, *V. parahaemolyticus* can grow at 5°C [1], and *L. monocytogenes* is able to grow at temperatures as low as –0.4°C [19,20,21].

Once frozen, no further microbial growth can occur, and many pathogens will decline in number with prolonged frozen storage [3]. However, survival rates in frozen crustacea are variable. Time/temperature abuse of thawed product can provide opportunity for growth of any bacterial pathogens that have survived freezing.

In some situations, periods of several days may elapse between cooking of prawns and consumption. This time delay provides potential opportunities for outgrowth and further contamination with microbial pathogens, particularly *L. monocytogenes*. Frequently, consumption of pre-cooked prawns does not include another cooking step, or only one of insufficient time and/or temperature to inactivate these microbial contaminants. Cooked crustacea such as prawns are frequently added to cold dishes which receive only warming, and which are then potentially subject to time/temperature abuse. This may allow bacterial growth and toxin production by contaminating *S. aureus*. Toxin production may also be enhanced if the seafood is part of a dish with a starch component [7]. This general pattern of processing and consumption represents an area of primary concern to the health and safety of the prawn-consuming public.

Aquaculture: Prawn production through aquaculture has been established for the last fifteen years along the eastern coastline of Australia and in the Northern Territory. Australian prawn farms are restricted to the coastal zone, virtually all drawing their intake water from tidal creeks and estuaries. In addition, much of Australia's import of prawns is produced in aquaculture ponds.
In Australia, prawn aquaculture is carried out in earthen ponds, close to tidal sources of seawater. The pond bottoms have a clay base for retaining seawater. Most farmers harvest, process and ship product direct to markets. Harvesting and post-harvest treatments are species specific. Currently Australia grows two species of prawns: the black tiger prawn (*Penaeus monodon*) and the Japanese king or kuruma prawn (*P. japonicus*). The black tiger prawn is mostly sold on local Brisbane, Sydney and Melbourne markets, either fresh, frozen or cooked. Typically, black tiger prawns are harvested en-masse with a drain harvest, and then chilled or cooked on site before being shipped to domestic markets. The kuruma prawn is grown exclusively for the live trade to Japan.

Like wild-caught prawns, prawns produced through aquaculture may be exposed to various hazards through their water environment. These potential hazards are largely the same as for wild-caught prawns inhabiting estuarine environments, as described above. In intensive aquaculture systems, *Vibrio* and *Salmonella* species are considered to be inherent contaminants of prawns [3,10].

Water retained in earthen ponds may be come into contact with chemical pollutants or residues from the surrounding soil, depending on previous land use in the local environment. Further, chemicals and feed components may also be added to pond water, to modify the prawns' environment. Typically, these may include antibiotics, to combat any pathogens present, and possibly other chemicals with properties that enhance stock growth and/or health. Residues from these chemicals are likely to remain present in the product at time of harvest. Use of such agricultural chemicals and veterinary medicines in the food supply chain is regulated through an agreement between FSANZ and APVMA.

All animals grown intensively, under artificially high densities and in contained waters, are prone to disease. Crustacean aquaculture is no exception, with bacterial, viral and parasitic diseases having the potential to affect all life history stages and production phases from hatchery to grow-out. Most bacterial and parasitic diseases are easily identified and treated with better hygiene and limited use of veterinary drugs. Good husbandry practices, including ensuring high water-quality standards, lower stocking densities and the screening of spawners and post-larvae will minimise the occurrence and spread of any viral diseases.

Few of these diseases will be of public health and safety concern, being more relevant to the issue of maximising farm production and outputs. However, the use of chemicals and veterinary drugs to control them may present a potential food safety hazard.

Prawns produced by aquaculture are subject to the same potential hazards during processing, transport and storage as described above for wild-caught prawns.

Lobsters

Lobster fisheries are found in most Australian states (New South Wales, Western Australia, Victoria, South Australia, Tasmania and Queensland), with fisheries for ornate rock lobsters also found in the Torres Strait. The produce is caught mainly using baited pots, though diving and hand spears are also used in some places. A few types of lobster, including Shovel Nosed and Bay Lobsters, are caught mainly as by-product of other fishing operations, such as demersal trawling or dredge netting.

Australian lobsters are both exported and sold on the domestic market. Most of the product is sold or exported live or as raw chilled/frozen tails.

Lobsters inhabit similar marine environments to prawns, and are potentially exposed to the same environmental hazards, both chemical and microbial. Raw and frozen product are also subject to similar processing and similar potential hazards. Endogenous bacteria that are human pathogens (for example, *Vibrio*s and *A. hydrophila*) and environmental contaminants (arsenic and mercury) are potential hazards. Post-harvest handling, processing, transport and storage potentially introduce and allow outgrowth of human enteric pathogens (*E. coli*, *S. aureus*, *Campylobacter*, *Shigella*, *Yersinia* and *Salmonella* spp., and noroviruses and hepatitis A virus) and *L. monocytogenes*. However, as lobster is generally sold either as live or raw frozen product, and is generally cooked thoroughly just before eating, concerns regarding microbiological contamination of cooked product prior to consumption are less relevant than for cooked prawns.

Crabs

Fisheries for two commercial crab species in Australia (Spanner and Blue Swimmer Crabs) are found in Queensland, New South Wales and Western Australia. These are caught in both estuarine and marine waters, using baited tangle nets, or in traps, hoop nets or drag nets. When moving as large aggregations, Spanner crabs are also occasionally caught as a by-product of dermesal otter trawling operations. Cadmium has been identified as a food safety hazard associated particularly with spanner crabs (*Ranina ranina*). Blue Swimmer Crabs can also be caught as a by-product of prawn trawling or of the rock lobster and finfish fisheries.

Wild-caught crabs are generally sold whole, though some are also sold cooked or as crab meat, on either local, interstate or export markets.

In addition to these wild-caught species, production of mud crabs through aquaculture is a developing industry in Australia, as well as south-east Asia. Produce from this new industry is typically snap frozen, though a live crab market is also developing. Product is sold on domestic markets, both locally and interstate, or is exported for sale.

Crabs inhabit similar estuarine and marine environments to prawns, and are potentially exposed to the same environmental hazards, both chemical and microbial. Raw and frozen product are also subject to similar processing and similar potential hazards. Endogenous bacteria that are human pathogens (for example, *Vibrio*s and *A. hydrophila*) and environmental contaminants (arsenic and mercury) are potential hazards. Post-harvest handling, processing, transport and storage potentially introduce and allow outgrowth of human enteric pathogens (*E. coli*, *Campylobacter*, *Shigella*, *Yersinia* and *Salmonella* spp., and noroviruses and hepatitis A virus) and *L. monocytogenes*. However, as crab is generally sold either as live or raw frozen product, and is generally cooked thoroughly just before eating, concerns regarding microbiological contamination of cooked product prior to consumption are less relevant than for cooked prawns.

<u>Other crustaceans – redclaw crayfish, marron, yabbie and scampi</u>

Redclaw crayfish, marron and yabbie are native species of crustaceans that are produced and consumed in Australia. Redclaw are native inhabitants of the rivers of north-western Queensland and the Northern Territory, marron inhabit the river systems of Western Australia, and yabbie are widely distributed throughout central and southern inland Australia. Commercial ventures for production of these species exist in various states, including New South Wales, Western Australia, Victoria and South Australia for marron and yabbie, and Queensland and the Northern Territory for redclaw.
Redclaw and marron are produced solely through aquaculture, where they are typically cultured in earthen based ponds. Yabbies are also grown in purpose built ponds, though the primary method of procuring this species is via trapping what are essentially wild yabbies from farm dams.
Feed sources for cultured product typically involve a combination of the natural foods found in ponds, and commercial feeds such as crayfish or marron pellets. The primary food source for yabbies is generally crop plants, such as clover, which are grown in the dams they inhabit, though supplementary feed may also be added, and is considered essential to obtain higher than natural yabbie production.

Harvesting of stock may take place using a number of methods. Marron ponds are generally drained to allow collection by hand. Redclaw may be collected from growth ponds in a similar manner, or harvested using bait traps, though the most popular and effective method is thought to be the application of a flow-trap. The primary method of harvesting yabbies from dams involves bait pots or traps, or collection after draining. Drop nets can also be used, however it is generally recognised that harvesting yabbies from dams by seine netting damages the animals and can result in bacterial infection from mud stirred up from the bottom [13].

After collection, the harvested animals undergo cleaning. Harvested stock are gill washed and held in purging tanks for a period between twenty-four and forty-eight hours to prevent mortality due to bacterial infections arising from bottom sediments trapped in the gill chamber, and also to allow purging of the hindgut. Produce are then held in a cool, moist atmosphere, and prior to transport are packed between layers of packaging, generally consisting of foam rubber, or wood shavings, in polystyrene boxes with cool packs or ice bottles. Stock can live for many days out of water, and can be shipped alive if transported in a cool, moist atmosphere.

Redclaw, marron and yabbie are sold primarily as live export product. Some product is retained for domestic consumption; however, there is little retail sale of the raw product. There are typically three steps in the domestic marketing chain: producer, wholesaler and restaurateur. Only a small portion of product undergoes processing, though some cooking and freezing does take place.

The hazards potentially encountered during aquaculture production of redclaw, marron and yabbie are the same as those described for farmed prawns. These include the various chemicals and microbes that may be present in, or added into, the contained water environment. As these three species are predominantly sold live, either on export markets or for domestic consumption through restaurants, minimal processing of the product takes place. Exposure to processing hazards is therefore minimal. However, appropriate conditions (a cool, moist atmosphere) must be maintained during transport and storage of live product to avoid mortality of stock. Dead stock may easily fall prey to contaminating microbes, and cross contamination to live stock packed in close proximity would then be possible.

Scampi are commercially fished in north-western waters of Australia, with some species spreading along the northern coast of Western Australia. They are a demersal species, generally inhabiting burrows, and are caught in demersal trawlers similar to those used for prawns. Scampi are graded, packed and frozen whole on board trawling vessels. They are sold on both the domestic and export markets. Volume of catch has varied in the past two decades between ca. 50–200 tonnes/annum [11,12].

Environmental and on-board processing hazards potentially encountered by scampi are similar to those described for wild-caught prawns from marine environments. Endogenous bacteria that are human pathogens (for example, *Vibrio*s and *A. hydrophila*) and environmental contaminants (arsenic and mercury) are potential hazards. Post-harvest handling, processing, transport and storage potentially introduce and allow outgrowth of human enteric pathogens (*E. coli*, *S. aureus*, *Campylobacter*, *Shigella*, *Yersinia* and *Salmonella* spp., and noroviruses and hepatitis A virus) and *L. monocytogenes*.

Finfish

For the purposes of this assessment, finfish includes bony, vertebrate fish and cartilaginous fish such as sharks and rays.

Finfish have been implicated in many outbreaks of food-borne illness in Australia in the period 1995 to June 2002 (Appendix 1). The hazards have mainly been ciguatoxin, histamine or escolar wax esters. Pathogens implicated include *Salmonella* spp., Norwalk-like virus and *C. perfringens* (in a reef and beef dish). In the case of the outbreak of perfringens food poisoning, the likely source of contamination is the beef, as *C. perfringens* is a common surface contaminant of beef carcasses at slaughter but is not usually considered a seafood-associated pathogen [3].

Many of the outbreaks of ciguatera that occur in Australia are a result of amateur anglers catching fish from affected reefs, but a significant proportion occur in private residences from consumption of fish (whole or fillets) purchased from commercial suppliers (Appendix 2). The outbreaks due to histamine (scombroid) fish poisoning were primarily consumed in a restaurant setting (Appendix 2), implying a failure in the cold chain. Similarly, escolar wax ester illness was mainly reported from a restaurant setting (Appendix 2).

For histamine and escolar wax esters, the mildness of the illness compared to ciguatera probably leads to significant under-reporting of cases that are due to consumption in the home setting.

The failures recorded for imported finfish in the Imported Foods Inspection Program testing data for the period January 1998 to June 2003 (inclusive) are listed in Table 1.6. Of note are the high degree of failure for *L. monocytogenes* and histamine in processed products.

Table 1.6: Significant imported foods testing failures for finfish, 1998–2003*

Hazard	Failures/Tests (%)		Comments
Mercury	44/3486	(1.3%)	14/625 (2.2%) dogfish and other shark – fresh, chilled, frozen, dried, salted'
L. monocytogenes	102/674	(15.1%)	99/591 (16.8%) fish – smoked, vacuum packed'
Histamine	90/5613	(1.6%)	43/1447 (3.0%) fish – prepared/preserved' (includes canned, not tuna) 4/1985 (0.2%) tuna – prepared or preserved (includes canned) 37/397 (9.3%) fish/other – dried/salted/brine'
E. coli	3/46	(6.5%)	
Coliforms	6/476	(1.3%)	
Standard plate count (SPC)	3/175	(1.7%)	

*No failures recorded for finfish imports tested for *V. cholerae*, staphylococcal enterotoxin, *Salmonella*, cadmium, inorganic arsenic, total arsenic, other metals and heavy metals, organophosphates, organochlorines or PCBs.

In the period 1990–2003, FSANZ coordinated several food recalls for finfish. These included 11 due to *L. monocytogenes* contamination of chilled smoked salmon and salmon dips, mousse, and pate, and four due to *L. monocytogenes* in trout. Hazards potentially associated with finfish along the production and processing supply chain are listed in Table 1.7.

Effects of processing on levels of hazards in finfish

Fish from salt and freshwater environments, whether farmed or free range, may be sold as whole fish, gutted fish or fillets, chilled or frozen, or may be further processed, for example, hot or cold smoked, salted, dried, pickled, in oil, fermented or canned. This wide variety of processing methods necessitates consideration of a multiplicity of possible effects on hazard levels in finfish in the post-harvest sector.

Table 1.7: Potential food safety hazards along the finfish supply chain

Supply chain sector	Source of hazards	Examples of hazards
Pre-harvest	Exposure to environmental contaminants	Endogenous bacteria that are human pathogens (*A. hydrophila*, *V. parahaemolyticus*, *V. vulnificus, V. cholerae* O1, non-O1/non-O139 *V. cholerae, C. botulinum*, helminthic parasites) Chemical (ciguatoxin, histamine, arsenic, mercury)
On-board	Contamination	Microbiological pathogens (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, hepatitis A virus, noroviruses) Chemicals – sulphite
	Opportunity for outgrowth	Bacterial pathogens (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, *A. hydrophila*, *V. parahaemolyticus*, *V. vulnificus, V. cholerae* O1, non-O1/non-O139 *V. cholerae*)
Transport, marketing, retailing and food service	Contamination by food handlers	Microbiological pathogens (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, hepatitis A virus, noroviruses)
	Opportunity for outgrowth	Bacterial pathogens (*E. coli*, *S. aureus*, *Salmonella* spp., *Campylobacter* spp., *Shigella* spp., *Yersinia* spp., *L. monocytogenes*, *A. hydrophila*, *V. parahaemolyticus*, *V. vulnificus, V. cholerae* O1, non-O1/non-O139 *V. cholerae*)

Capture/harvest, including farmed and wild caught

Finfish are caught by a variety of methods, including longlining, poling, netting and trawling.

At the point of harvest, hazards potentially present in finfish include metals (for example, arsenic, mercury) and indigenous pathogens (for example, *Vibrio*s, *C. botulinum*) from the marine or estuarine environment which are naturally present in live fish. Marine toxins such as ciguatoxin may be a hazard in tropical reef fish. Histamine is a hazard in certain species (mainly scombroid, but also some non-scombroid species) of fish, particularly if the fish are harvested from warmer waters, die before landing, or are subject to time/temperature abuse after landing. Both ciguatoxin and histamine are heat-stable.

A number of single cell and multicellular parasites, which may be associated with fish species harvested from particular locations, have been associated with illness in humans after ingestion of raw or undercooked product. The most important of these are nematode species resulting in the disease named anisakiasis, but other fish-borne parasites such as the tapeworm *Diphyllobothrium latum* [14] and *Gnathostoma* spp. may be a problem in some areas. For certain parasites, aquaculture may disrupt the lifecycle, by removing contact between fish and other intermediate of definitive hosts. However, aquaculture may also allow for the presence of parasites not normally found in, for example, marine environments. For aquaculture operations, chemical contaminants and *Salmonella*e may also represent a food safety hazard of concern at point of harvest.

On-board handling and transport

After harvest/capture, fish may be subject to processes of microbial spoilage and proteolytic hydrolysis. These processes will be more rapid if fish are not gutted or adequately chilled/frozen.

Gutting on board fishing vessels may introduce the possibility of cross-contamination with human/enteric pathogens. Microbial spoilage of fish may, depending on both the species of fish and the bacteria present, result in the production of histamine to hazardous levels. Once formed, histamine remains a hazard during further processing, as it is heat stable and may not necessarily be associated with 'off' flavours or smells in the fish product. Histamine development is accelerated by temperature abuse or lack of chill storage on board.

Further processing

Following harvest, bacterial growth is potentially rapid because of the high a_w, high pH and large amounts of non-protein nitrogenous compounds available. Many of the endogenous bacteria are psychrotrophic, that is, capable of growth at refrigerated temperatures, as well as remaining viable for long storage periods. Heat processing reduces these bacterial populations greatly. Traditional preservation techniques, apart from heat treatments such as pasteurisation or canning, are usually bacteriostatic rather than bacteriocidal in nature. Therefore mishandling or temperature abuse of lightly preserved fish may result in spoilage and growth of pathogens.

Parasites may remain viable if the fish is chilled after harvesting, but can be inactivated by appropriate freezing. They will not multiply in the killed fish. Processes such as marinating, pickling and brining will not eliminate parasites, although these processes may reduce parasite numbers. Brining in 30 per cent solution for at least 10 days would control the hazard associated with the tapeworm, *Diphyllobothrium* spp. and the roundworms, *Anisakis* spp. and *Pseudoterranova* spp. [22]. Parasites will be killed in processes where the internal temperature of the fish reaches 60°C for 1 minute.

In addition to anisakiasis from ingestion of Anisakidae-parasitised fish, allergic reactions after ingestion of safely cooked but parasitised fish have also been reported.

C. botulinum (type E non-proteolytic strains), which causes botulism, is commonly associated with the marine environment. In addition, other strains may be present in the processing environment, including processing water. As spores tend to be associated with the gut of the fish, evisceration will reduce the risk of exposure. While illness caused by *C. botulinum* strains associated with seafood in Australia does not appear to be common, the severity of botulism disease means that the potential for it to occur should be addressed.

A significant hazard of concern with ready-to-eat fish products is *Listeria monocytogenes*. While contamination of fish with *L. monocytogenes* at harvest is not usually significant, the potential for contamination to occur post-harvest and during processing is an important factor impacting on the safety of ready-to-eat products.

Where cooked fish has been implicated in food poisonings, the contamination has usually been as a result of poor hygiene during preparation, the addition of contaminated ingredients such as batters or post-cooking contamination.

Chilled/frozen whole fish and fillets: The food safety hazards present in fish for sale whole or as fillets are generally the same as present at catch/harvest (including ciguatoxin, parasites, metals and endogenous bacteria that are human pathogens), with the added possibility of contamination during gutting/filleting with endogenous bacteria that are human pathogens from the viscera, human enteric pathogens and viruses, and *L. monocytogenes*.

Whole fish and fillets will normally be stored, transported and displayed chilled or frozen. Histamine formation due to the action of endogenous spoilage bacteria in fish/fillets subject to time/temperature abuse is also a possible hazard [15]. In Japan, *V. parahaemolyticus* outbreaks associated with consumption of fish are not uncommon, but are usually due to consumption of raw or lightly cooked fish meals. Thorough cooking of fish will reduce or eliminate parasites, bacterial pathogens and viruses, but will have no effect on the concentrations of chemical contaminants (toxins and metals).

Canning: Sterilising and packaging techniques intended to extend shelf life and which produce anaerobic conditions (for example, cans, gas flushed pouches or packing in oil), can lead to toxin production if *C. botulinum* is present. However, bacterial growth does not occur at temperatures below 3.3°C, salt concentrations above 5 per cent and in marinades below pH 5.0. Various combinations of hurdles may be used to restrict microbial growth. Historically, the major concern would have been the risk of botulism from inadequately processed canned fish, in particular, salmon. However rigorous control of canning facilities worldwide has reduced this risk to very low.

Other hazards potentially present in canned fish include histamine, due to poor quality raw materials, and staphylococcal enterotoxin due to contamination. Both of these hazards may survive the canning process. Concentrations of metal contaminants will not be reduced by the canning process.

Smoking: There are two main forms of fish smoking. Hot smoking is a pasteurisation process. The product is cooked during the process, and parasites and bacterial contamination will be destroyed provided a uniform temperature is reached.

The FDA recommends that the internal temperature of the fish must be maintained at or above 63°C throughout the fish for at least 30 minutes during hot smoking [18]. During cold smoking, temperatures do not normally reach levels high enough for pathogen or parasite control.

The most significant hazard of concern with cold-smoked fish products is *L. monocytogenes*. While contamination of fish with *L. monocytogenes* at harvest is not usually significant, extensive contamination may occur post-harvest and during processing. The level of contamination varies between processing sites and may be high. Keeping a processing environment totally free of *L. monocytogenes* is difficult, but levels can be reduced significantly with appropriate management strategies [3].

L. monocytogenes present on cold-smoked fish may either be an endogenous environmental contaminant or be introduced by pre- or post-process contamination. Since cold smoking lacks a listericidal step, the product will retain a similar level of contamination. If subject to post-process contamination, hot smoked fish may allow *L. monocytogenes* to increase to high levels, due to the absence of competing micro-organisms [16].

Smoked fish is typically not heated prior to consumption, that is, it is ready-to-eat. Prolonged chilled storage may allow numbers of *L. monocytogenes* to increase to significant levels. While conditions in the processing environment have an impact on the initial levels of *L. monocytogenes* in the product, outgrowth can occur in the post-processing environment.

Cold-smoked fish may be held for considerable periods of time in the retail sector, and there is the potential for time/temperature abuse to occur. In delicatessens, this is exacerbated by the opportunity for further contamination.

Other hazards in smoked fish products include *V. parahaemolyticus*, *Salmonella* spp., *C. botulinum* and parasites. *V. parahaemolyticus* is a contaminant of raw fish from warmer waters. The level of contamination may increase through post-harvest cross-contamination and by time/temperature abuse. *Salmonella* may be associated with fish due to harvesting from faecally contaminated water bodies, for example, lakes and closed aquaculture systems, or from contamination during processing. *C. botulinum* spores are often found in the gut of fish, and are a potential hazard in product that is not eviscerated prior to smoking. Some packaging technologies for extended shelf-life may also increase the risk of botulism by maintaining a suitable anaerobic environment for growth of vegetative cells and production of toxin. Parasites will normally be killed by hot smoking, but cold-smoked products may contain viable larvae if other control measures are not employed.

Marinating, pickling, brining, drying or fermenting: A variety of processes including salting, fermenting and drying that are used traditionally to preserve fish may need specific storage conditions to ensure the safety of the product during the time between production and consumption.

Marinated fish products employ a combination of low pH and moderate salt concentrations to limit the potential for growth of bacterial pathogens. An example of such a product is the Southern American dish ‘ceviche’, which consists of diced raw fillets marinated in lime juice and spices such as chilli, pepper and mint. Such products may contain several food safety hazards, most notably helminthic parasites, *L. monocytogenes*, and processing contaminants (staphylococci, *Salmonella*e). Suitable control of both pH and salt concentration is necessary to manage these hazards. The parasites, especially anisakids, are acid tolerant and need high salt concentrations for effective control. Freezing prior to pickling will kill the larvae.

Dried fish products can be roughly categorised into fully-dried and partly dried products. The former have been dried until their moisture content is close to uniform and water activity is close to or below 0.75. The shelf life of these products usually ranges between one week and several months under correct packaging and storage conditions. Hazards associated with these products include: histamine fish poisoning (a common condition normally associated with consuming spoiled tuna, mackerel, bonito, or skipjack); microbial growth in caught fish; chemical and bacterial contamination during washing; bacterial contamination during salting; microbial growth during drying and storage.

Partly dried fish products, including Norwegian herring kippers, are typically marinated in concentrated brine solutions for up to two days, then dried, with or without smoking, for up to three days. The products usually have a refrigerated shelf life of up to a week. Hazards are similar to fully dried fish. However, the higher water activity (usually in the range 0.8-0.9) is more conducive to growth of spoilage organisms and some bacterial pathogens (for example, *S. aureus*, *L. monocytogenes*). Conversely, higher salt activity will help to inhibit such growth, and also decreases the viability of helminthic parasites.

Various fermented fish dishes are popular in Europe and Asia. Fish are fermented in salt solutions (with sugar and spices) for anywhere from two weeks to 12 months, with flavour and aroma development due to endogenous enzymic activity and lactic acid bacterial activity.

Products can range from those in which the fish retain their form, to pastes and liquid sauces. In Asian products, rice or cassava is added as a source of fermentable sugars. The fermentation usually results in a rapid drop in pH which, along with the added salt, helps to limit growth of spoilage organisms and pathogens, while allowing the lactic acid bacteria to grow. The food safety hazards presented by such products include parasites, histamine (from poor quality raw materials), *Vibrio*s and *C. botulinum* (in specific ethnic foods not expected to be available in Australia).

The United States Food and Drug Administration provides guidance to food businesses producing this broad variety of acidified, fermented, dried and salted products [17,18], aimed at reducing the potential for growth and/or toxin production by pathogens:

The Food and Drug Administration suggests that shelf-stable products must be:

- heated in the final container to destroy spores of *C. botulinum* types A, B, E, and F
- acidified to pH 4.6 or below
- dried to a water activity of 0.85 or below, or
- salted to contain 20 per cent salt or more

and that refrigerated products must be:

- dried sufficient to inhibit the growth of *C. botulinum* type E and non-proteolytic types B and F by drying; and then stored at or below 4.4°C to control the growth of *C. botulinum* type A, and proteolytic types B and F, and other pathogens that may be present in the finished product
- acidified, salted, or dried to control the level of acidity (pH), salt, moisture (water activity), or some combination of these barriers, in the finished product sufficiently to prevent the growth of *C. botulinum* type E and non-proteolytic types B and F by formulation (that is, pH 5 or below; salt 5 per cent or more; or water activity below 0.97); and then stored at or below 4.4°C to control the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product
- stored and distributed at 4.4°C or below.

Surimi: Seafood items that look like crab, scallops, etc. but are really mostly white fish fillets, are thought of by most people as some sort of modern high-tech imitation products. They go by such names as ‘sea legs’, imitation crab or imitation shrimp, etc. In reality, this process was developed in Japan several hundred years ago when the Japanese discovered that mincing fish flesh, washing it and then heating it, caused a natural gelling of the flesh. If this was then mixed with other ingredients and steamed, the resulting ‘fish cake’ (*kamaboko*) stayed together as though it were a natural product. As surimi is a minced product, bacterial contamination of the surface of fish, whether through endogenous microflora or contamination, is potentially spread throughout the product. Hazards of particular concern are enteric pathogens, *L. monocytogenes* and *V. parahaemolyticus*.

Sashimi and sushi: Sashimi is raw fish. Sushi is a rice based product which may contain sashimi. There are many varieties of sushi which do not contain any raw fish and these are not considered here.

Sashimi is typically made from tuna, although halibut, red snapper, yellowtail and mackerel are also common. Fish for sashimi is usually thinly sliced. Hazards of concern are parasites and *V. parahaemolyticus*. With sushi, the primary concern is related to sushi prepared in advance and then stored for some time without refrigeration. This allows for growth of pathogens as the rice is generally shaped by hand, and the sushi may contain egg, raw vegetables, and a wide variety of other growth media. The potential hazards include parasites and *Vibrio*s and contamination by *S. aureus*, *Salmonella*, noroviruses and hepatitis A virus, and *L. monocytogenes*.

Roe and caviar: Caviar comes in a variety of shapes and colours the most prolific source country is Russia, from Sturgeon spp. in the Caspian Sea. It may be fresh, pasteurised or pressed. Lumpfish and salmon roe have been long-standing cheaper substitutes for caviar. Sea urchin roe is also a delicacy in some Asian countries. Processing typically involves draining, salting, colouring and pressing into a solid mass. As a raw product, the hazards are similar to those for other raw fish products, including parasites and endogenous and introduced pathogens.

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Appendix 2

Epidemiological data

Table 2.1: Food-borne illness outbreaks due to seafood consumption, Australia, 1995–2000

Year	Month	State	Setting Pr	Setting Co	Pathname	Cases	Vehicle
1995	Dec	NSW	commercial manufactured food	community	Salmonella typhi	4	seafood – prawns cooked, 1 lab acquired
1995	Jan	NSW	commercial – restaurant	restaurant	scombroid	3	seafood – tuna
1995	Aug	WA	recreational fisherman		Ciguatera	4	coral trout
1996	Aug	Qld/ NSW	contaminated primary produce	community	Norwalk-like virus	97	seafood - oysters
1996	Feb	NSW	contaminated primary produce	private residence	ciguatera	2	fish - frozen rock cod
1996	Jul	NSW	private residence	private residence	Clostridium perfringens	33	seafood - prawns (curried)
1997	May-Jun	NSW	contaminated imported food	restaurant	hepatitis a	17	Seafood – prawns
1997	Dec	NSW	contaminated primary produce	community	dinophysis species	56	seafood – pipis
1997	Nov	Vic.	contaminated primary produce	restaurant	ciguatera	18	fish – 16.2 kg Maori Wrasse
1997	Jan	NSW	contaminated primary produce	private residence	ciguatera	8	Fish (unknown)
1997	Jul	NSW	contaminated primary produce	private residence	ciguatera	6	seafood – coral trout from Fiji
1997	Nov	NSW	contaminated primary produce	private residence	ciguatera	10	seafood – coral trout (Qld)
1997	Jan–Apr	All S&Ts	contaminated primary produce	community	hepatitis a	466*	seafood – oysters
1997	–	NT	contaminated primary produce		ciguatera	20	Fish – Coral Cod
1998	Oct	NT	contaminated primary produce	private residence	ciguatera	7	Fish – barracuda
1998	Nov	NSW	contaminated primary produce	private residence	ciguatera	3	seafood – cod
1998	Aug	NSW	contaminated primary produce	private residence	ciguatera	10	seafood – spotted cod
1998	Jun	Vic.	commercial – restaurant		scombroid	6	seafood – tuna
1998	Sep	Vic.	commercial – restaurant		scombroid	3	seafood – tuna
1998	Oct	Vic.	commercial – restaurant		unknown	9	seafood – cajun fish (RR 5.4)
1998	Dec	Vic.	private residence		ciguatera	5	seafood – reef cod

Year	Month	State	Setting Pr	Setting Co	Pathname	Cases	Vehicle
1998	Dec	Vic.	private residence		ciguatera	3	seafood – reef fish
1998	Dec	Vic.	commercial – restaurant		scombroid	9	seafood – Thai fish cakes (RR 14.3)
1998	Feb	NSW	pipis	community	dinophysis species	22	seafood – pipis
1999	Jan	NSW	private residence	private residence	scombroid	4	seafood – tuna
1999	Nov	NT	commercial – restaurant	restaurant	scombroid	5	seafood – Blue grenadier
1999	March	SA	restaurant	restaurant	wax ester	19	Fish – Escolar
1999	Aug	Qld	contaminated primary produce	private residence	ciguatera	8	Fish – ciguatera toxin/queenfish
1999	Sep	Qld	contaminated primary produce	private residence	ciguatera	2	seafood – ciguatera toxin
1999	Nov	Qld	commercial – restaurant	restaurant	Vibrio cholerae	10	seafood – red claw crayfish
1999	Dec	Qld	commercial – restaurant	restaurant	Norwalk-like virus	14	seafood – sauteed scallops
1999	Jun	NSW	commercial – catered		Clostridium perfringens	43	Shrimp – curried prawns
1999	Jan	Vic.	private residence		ciguatera	4	seafood – Spanish mackerel (35 kg)
1999	Jan	Vic.	commercial – reception centre		Salmonella bareilly	26	seafood – smoked salmon suspected
1999	Oct	Vic.	commercial – restaurant		scombroid	4	seafood – pasta with tuna and chilli
1999	Nov	Vic.	commercial – restaurant		wax ester	14	seafood – butterfish
1999	Dec	Vic.	non-commercial function		Salmonella typhimurium (PT 64)	12	seafood – cooked prawns/crayfish
2000	Sep	WA	commercial – restaurant	restaurant	unknown	27	seafood – sushi
2000	Apr	NSW	private residence		ciguatera	5	seafood – black trevally
2000	Aug	Qld	private residence		ciguatera	9	seafood – coronation trout
2000	Feb	Qld	private residence		ciguatera	33	seafood – queenfish
2000	Feb	Qld	private residence		ciguatera	4	seafood – queenfish
2000	Mar	Qld	private residence		ciguatera	6	seafood – black kingfish
2000	Nov	Qld	private residence		ciguatera	4	seafood – coral trout
2000	Sep	Qld	private residence		ciguatera	5	seafood – spotted mackerel
2000	Mar	Vic.	contaminated primary produce		Salmonella Mississippi	2	seafood – oysters
2000	Dec	Vic.	contaminated primary produce		Ciguatera	3	seafood – coral cod or coral trout

Data provided by Dr C Dalton (Hunter Public Health Unit).

* 1 death

Table 2.2: Food-borne illness outbreaks due to seafood consumption (Australia; January 2001 to June 2002)

State	Year	Setting	Agent responsible	No. affected	Evidence	Vehicles responsible
NSW	2001	restaurant	unknown	4	D	Seafood sauce
NSW	2001	restaurant	unknown	20	C	Fish 'Lepidocybium flavobruuneum'
Vic.	2001	community	*Salmonella* Mississippi	6	B	Suspected oysters
Vic.	2001	private residence	Ciguatera poisoning	11	B	Coral trout
Vic.	2001	restaurant	unknown	4	B	Escolar fish
Qld	2001	private residence	Ciguatera poisoning	14	D	Spanish mackerel
Qld	2001	private residence	Ciguatera poisoning	2	D	Spotted mackerel
Qld	2001	restaurant	Scombroid	4	D	Mahi mahi fillets
Qld	2001	private residence	Ciguatera poisoning	3	D	Barracuda fish
Qld	2001	private residence	Ciguatera poisoning	4	D	Coral trout
Qld	2001	private residence	Ciguatera poisoning	9	D	Spanish mackerel
Qld	2002	private residence	Ciguatera poisoning	2	D	Striped Perch
Qld	2002	private residence	Ciguatera poisoning	3	D	Grunter bream
Qld	2002	private residence	Ciguatera poisoning	2	D	Spanish mackerel
Qld	2002	restaurant	Clostridium perfringens	9	A	Reef & beef
WA	2002	restaurant	Norovirus	60	A	Seafood salad; ravioli; grilled chicken

A: statistical evidence from epidemiological investigation

B: compelling supportive evidence

C: laboratory evidence

D: no specific evidence.

Data provided by Janet Li (OzFoodNet 2003).

Appendix 3

Seafood consumption in Australia by gender and age

The following seafood consumption figures were derived using FSANZ's dietary modelling computer program, DIAMOND. Data from the 1995 National Nutrition Survey of Australia were used to obtain the consumption figures. The National Nutrition Survey used a 24-hour food recall method.

The National Nutrition Survey had 13 858 respondents aged from 2 years and above. The figures below were derived using the whole population 2+ years and sub groups of the population including males and females 2–4 years, 5–12 years, 13–64 years and 65+ years and females of child-bearing age (16–44 years). The figures include where respondents consumed seafood alone or as a part of a mixed food, such as in a marinara sauce.

Limitations of the dietary modelling

A limitation of estimating dietary exposure over a period of time associated with the dietary modelling is that only 24-hour dietary survey data were available, and these tend to over-estimate habitual food consumption amounts for high consumers.

Molluscs and crustacea are occasionally consumed foods that people tend to consume less than once a week. Therefore, consumption figures derived from a 24-hour recall may be higher for most consumers than if consumption amounts were averaged over a longer time frame that better reflects habitual consumption of these foods. Other limitations of the dietary modelling include:

- smoked finfish was not identified as being hot- or cold-smoked in the National Nutrition Survey
- scallops are not identified as being roe-off or not.

Molluscan shellfish

Table 3.1: Consumption of oysters and other bivalves (including clams and mussels) in Australia, by gender and age

Population group	No. of consumers	% of total respondents	Mean consumer intake (g/day)	95th percentile consumer intake (g/day)
All population (2+ years)	59	0.4	91	270
2–4 years male	–	–	–	–
2–4 years female	1	0.3	20	20
5–12 years male	1	0.1	56	56
5–12 years female	1	0.1	150	150
13–64 years male	25	0.5	98	283
13–64 years female	21	0.4	100	302
65+ years male	4	0.4	46	60
65+ years female	5	0.5	77	180
16–44 years female	11	0.3	118	180

Table 3.2: Consumption of abalone and scallops in Australia, by gender and age

Population group	No. of consumers	% of total respondents	Mean consumer intake (g/day)	95th percentile consumer intake (g/day)
All population (2+ years)	24	0.2	40	186
2–4 years male	–	–	–	–
2–4 years female	1	0.3	11	11
5–12 years male	1	0.1	71	71
5–12 years female	–	–	–	–
13–64 years male	4	0.1	34	95
13–64 years female	15	0.3	48	195
65+ years male	2	0.2	9	15
65+ years female	1	0.1	15	15
16–44 years female	11	0.3	42	160

Cephalopod molluscs

Table 3.3: Consumption of octopus, squid and cuttlefish in Australia, by gender and age

Population group	No. of consumers	% of total respondents	Mean consumer intake (g/day)	95th percentile consumer intake (g/day)
All population (2+ years)	47	0.3	96	242
2–4 years male	–	–	–	–
2–4 years female	2	0.7	30	40
5–12 years male	1	0.1	79	79
5–12 years female	2	0.2	40	40
13–64 years male	16	0.3	98	245
13–64 years female	24	0.5	98	274
65+ years male	2	0.2	97	120
65+ years female	1	0.1	237	237
16–44 years female	16	0.5	97	212

Crustacea

Table 3.4: Consumption of prawns in Australia, by gender and age

Population group	No. of consumers	% of total respondents	Mean consumer intake (g/day)	95th percentile consumer intake (g/day)
All population (2+ years)	184	1.3	75	248
2–4 years male	–	–	–	–
2–4 years female	3	0.4	42	72
5–12 years male	5	0.6	56	96
5–12 years female	83	1.6	60	198
13–64 years male	71	1.5	89	284
13–64 years female	83	1.6	60	198
65+ years male	11	1.2	103	250
65+ years female	11	1.0	89	250
16–44 years female	52	1.6	50	160

Table 3.5: Consumption of scampi in Australia, by gender and age

Population group	No. of consumers	% of total respondents	Mean consumer intake (g/day)	95th percentile consumer intake (g/day)
All population (2+ years)	1	0.0	118	118
2–4 years male	–	–	–	–
2–4 years female	–	–	–	–
5–12 years male	–	–	–	–
5–12 years female	–	–	–	–
13–64 years male	–	–	–	–
13–64 years female	1	0.0	118	118
65+ years male	–	–	–	–
65+ years female	–	–	–	–
16–44 years female	–	–	–	–

Table 3.6: Consumption of lobsters and bugs in Australia, by gender and age

Population group	No. of consumers	% of total respondents	Mean consumer intake (g/day)	95th percentile consumer intake (g/day)
All population (2+ years)	14	0.1	78	408
2–4 years male	–	–	–	–
2–4 years female	–	–	–	–
5–12 years male	–	–	–	–
5–12 years female	–	–	–	–
13–64 years male	8	0.2	94	408
13–64 years female	5	0.1	64	204
65+ years male	–	–	–	–
65+ years female	1	0.1	18	18
16–44 years female	2	0.1	140	204

Table 3.7: Consumption of crabs in Australia, by gender and age

Population group	No. of consumers	% of total respondents	Mean consumer intake (g/day)	95th percentile consumer intake (g/day)
All population (2+ years)	17	0.1	36	96
2–4 years male	–	–	–	–
2–4 years female	–	–	–	–
5–12 years male	1	0.1	63	63
5–12 years female	8	0.2	41	96
13–64 years male	6	0.1	27	48
13–64 years female	–	–	–	–
65+ years male	1	0.1	63	63
65+ years female	1	0.1	2.5	2.5
16–44 years female	5	0.2	44	96

Table 3.8: Consumption of crayfish, marron and yabbie in Australia, by gender and age

Population group	No. of consumers	% of total respondents	Mean consumer intake (g/day)	95th percentile consumer intake (g/day)
All population (2+ years)	7	0.1	100	191
2–4 years male	–	–	–	–
2–4 years female	1	0.3	51	51
5–12 years male	1	0.1	115	115
5–12 years female	–	–	–	–
13–64 years male	3	0.1	89	153
13–64 years female	2	0.0	135	191
65+ years male	–	–	–	–
65+ years female	–	–	–	–
16–44 years female	1	0.0	191	191

Fish and fish products

Table 3.9: Consumption of finfish (fillets/gutted/whole for cooking) in Australia, by gender and age

Population group	No. of consumers	% of total respondents	Mean consumer intake (g/day)	95th percentile consumer intake (g/day)
All population (2+ years)	657	4.7	127	314
2–4 years male	9	3.2	78	211
2–4 years female	12	4.0	46	101
5–12 years male	14	1.8	82	167
5–12 years female	30	4.1	72	169
13–64 years male	256	5.5	161	423
13–64 years female	238	4.6	114	288
65+ years male	50	5.5	113	253
65+ years female	48	4.5	103	283
16–44 years female	132	4.2	112	283

Table 3.10: Consumption of canned finfish in Australia, by gender and age

Population group	No. of consumers	% of total respondents	Mean consumer intake (g/day)	95th percentile consumer intake (g/day)
All population (2+ years)	538	3.9	72	185
2–4 years male	5	1.8	45	110
2–4 years female	5	1.7	31	70
5–12 years male	19	2.6	72	180
5–12 years female	9	1.2	49	158
13–64 years male	167	3.6	91	239
13–64 years female	224	4.4	67	154
65+ years male	51	5.7	64	122
65+ years female	58	5.5	59	113
16–44 years female	125	3.9	67	154

Table 3.11: Consumption of smoked finfish in Australia, by gender and age

Population group	No. of consumers	% of total respondents	Mean consumer intake (g/day)	95th percentile consumer intake (g/day)
All population (2+ years)	85	0.6	72	185
2–4 years male	–	–	–	–
2–4 years female	1	0.3	20	20
5–12 years male	–	–	–	–
5–12 years female	2	0.3	80	95
13–64 years male	29	0.6	133	435
13–64 years female	32	0.6	82	397
65+ years male	13	1.4	116	554
65+ years female	8	0.8	63	198
16–44 years female	15	0.5	67	385

Table 3.12: Consumption of fish roe in Australia, by gender and age

Population group	No. of consumers	% of total respondents	Mean consumer intake (g/day)	95th percentile consumer intake (g/day)
All population (2+ years)	6	0.0	16	28
2–4 years male	–	–	–	–
2–4 years female	–	–	–	–
5–12 years male	–	–	–	–
5–12 years female	–	–	–	–
13–64 years male	5	0.1	17	28
13–64 years female	1	0.0	14	14
65+ years male	–	–	–	–
65+ years female	–	–	–	–
16–44 years female	1	0.0	14	14

Appendix 4

Hazard identification/hazard characterisation

This Appendix provides a brief description of the hazards associated with seafood along with information on the nature, severity and duration of adverse health effects resulting from exposure to these hazards. The incidence of illness and hazard levels detected in various seafood are also described.
The information presented in this attachment has largely been extracted from the 'Seafood Food Safety Risk Assessment' conducted by M&S Food Consultants, who were commissioned by Seafood Services Australia in 2001 to undertake a national seafood risk assessment. Other data was derived from FSANZ's 'Shellfish Toxins in Food: Toxicological Review and Risk Assessment', 1999, which was prepared as part of Proposal P158 – review of the maximum permitted concentrations of non-metals in food.

Bacterial pathogens

The bacterial pathogens discussed here are *Vibrio* spp., *Staphylococcus aureus*, *Salmonella* species, *Listeria monocytogenes*, *Clostridium botulinum*, *Aeromonas hydrophila* and *Escherichia coli*.

Vibrio spp.

Vibrio species are ubiquitous in the aquatic environment, with a small number of species/strains able to cause human disease (Morris 2003). Vibrios are described as gram-negative, facultatively anaerobic, halophytic (salt-loving), motile curved rods with a single polar flagellum (ICMSF 1996).

<u>Vibrio cholerae</u>

Description: The temperature range for *V. cholerae* growth is 10–43°C, the minimum a_w for growth is as low as 0.97 and the pH range for growth is 5.0–9.6. *V. cholerae* can survive in foods for periods up to a month or more as long as the a_w is sufficiently high (ICMSF 1996). *V. cholerae* is sensitive to acid and dry conditions and so survival under these conditions is generally <12 hours at room temperature.

There are three main serological groupings of *V. cholerae*; namely O1, O139 and non-O1/non-O139. Toxigenic *V. cholerae* O1 and O139 are the causative agents of cholera, a food-borne illness with epidemic and pandemic potential. Non-O1/non-O139 *V. cholerae* do not carry the virulence factors necessary to cause epidemic cholera but have been implicated as causes of diarrhoeal disease, wound infections and, in susceptible populations, septicaemia (Morris 2003).

V. cholerae O1 is divided into two serotypes, Indaba and Ogawa, and two biotypes, classic and El Tor (Prescott et al. 1999). The classic biotype, such as the *V. cholerae* strain first isolated by Robert Koch in 1883, was more prevalent in cholera outbreaks before 1960, whereas the El Tor biotype has been more frequently seen since that time (Madigan et al. 1997).

Pathology of illness: Illness in humans is initiated by adherence of toxigenic O1 and O139 *V. cholerae* cells to the surface of the small intestine, where they are not invasive but produce cholera enterotoxin, choleragen. The action of the toxin on mucosal cells leads to hypersecretion of salts and water.

Loss of water can be as much as 1 L/h and can lead to collapse and death. Initial symptoms include mild diarrhoea, abdominal pain and anorexia and are rapidly followed by severe diarrhoea (classic rice water stools), with rapid loss of body fluids and salts. Without treatment cholera can be fatal, but in otherwise healthy and well-nourished patients, recovery occurs in 1–6 days. *V. cholerae* non-O1 and non-0139, cause milder symptoms (ICMSF 1996).

The incubation period ranges from several hours to 5 days and depends in part on the dose. Onset of illness can be sudden or there may be premonitory symptoms such as anorexia, abdominal discomfort and diarrhoea.

Stomach acidity has a protective effect. Individuals who are achlorhydric (low stomach acidity) because of medication (such as antacids) or other reasons, are more susceptible to infection. Individuals of blood group O are also more susceptible to infection, although the mechanism of this susceptibility is not known (Oliver & Kaper 1997). Individuals with cirrhosis of the liver are susceptible to non-O1 *V. cholerae* bacteraemia (Lin et al. 1996).

Infectious dose/dose response: When ingested with food (or after neutralisation of stomach acidity) the infectious dose of *V. cholerae* O1 and O139 in healthy adult volunteers is estimated to be 103 – 104 cells (Levine et al. 1981; Kothary & Babu 2001). Lower inocula correlated with a longer incubation period and diminished severity of symptoms. Attack rates at these doses were >60 per cent. Analysis of outbreaks suggests *V. cholerae* O1 and O139 may be infectious at doses as low as 102 to 103 CFU (M&S Food Consultants 2001). *V. cholerae* non-O1/non-O139 strains appear to have a much higher infectious dose of between 106 and 109 bacteria (Cash et al. 1974; Oliver & Kaper 1997; Kothary & Babu 2001).

Levels in seafood: Only *V. cholerae* non-O1/non-O139 and non-toxigenic *V. cholerae* O1 strains have been isolated from brackish and estuarine waters and oysters in Australia (Desmarchelier 1997; Eyles & Davey 1984; 1988).

Epidemiological data: Seven pandemics have been recorded worldwide since 1817 (Morris 2003). Cholera remains epidemic in many parts of Central and South America, Asia, and Africa (CDC 1995). In 2001, 58 countries officially reported a total of 184 311 cases and 2728 deaths to the World Health Organisation (WHO 2002). Cholera is generally transmitted via ingestion of faecally contaminated foods and waters (Centre for Disease Control 1995). Outbreaks of cholera have been associated with consumption of seafood including oysters, crabs and shrimp (Oliver & Kaper 1997). For example, a seafood-associated outbreak of cholera in Hong Kong was linked to contaminated seawater in fish tanks used for holding live crustacea (Kam et al. 1995).

The incidence of cholera in Australia is low, with an average of less than 4 reported cases per annum in the period 1991–2002 (inclusive) (Communicable Diseases Australia 2003). The majority of reported cases in Australian are generally acquired overseas (Kraa 1995). An outbreak occurred in Australia in 1999 due to consumption of crayfish contaminated with V. cholera non-O1/non-O139, resulting in 10 cases of illness (Appendix 2).

Vibrio parahaemolyticus

Description: *V. parahaemolyticus* is distributed worldwide in inshore marine waters and is mesophilic. The temperature range for growth is 5–43°C, the minimum a_w for growth is as low as 0.94 and the optimal NaCl concentration for growth is 3 per cent ($a_w = 0.980$). *V. parahaemolyticus* will grow in the pH range of 4.8–11 (ICMSF 1996).

Pathology of illness: Illness is caused when the ingested organism attaches itself to an individual's small intestine and secretes a toxin. *V. parahaemolyticus* causes gastroenteritis and symptoms include watery diarrhoea, abdominal cramps, nausea, vomiting, headache, fever and chills. Onset of illness is generally after 4–96 hours with a mean of 15 hours. Illness usually resolves in three days and mortality is normally very low. A more severe dysenteric form of illness that may need hospitalisation has been reported in India, United States (2 cases) and Bangladesh (Twedt 1989). Severe illness is rare and usually occurs in people with weakened immune systems or chronic liver disease. In these cases, infection can lead to septicaemia (Morris 2003).

Not all strains of the organisms are pathogenic. There appears to be a lack of correlation between pathogenicity and serotype of *V. parahaemolyticus* isolates. Virulence correlates with the ability to produce a thermostable direct haemolysin termed the Kanagawa Phenomenon haemolysin. Kanagawa Phenomenon negative strains appear to be non-pathogenic (Twedt 1989; Oliver & Kaper 1997). Kanagawa Phenomenon haemolysin is heat-stable and therefore remains active even after cooking (Twedt 1989).

Infectious dose/dose response: Human volunteer studies have established an infectious dose for KP-positive strains between 2×10^5 and 3×10^7 cfu (Takikawa 1958; Sanyal & Sen 1974). Diarrhoeal illness was not caused by ingestion of up to 2×10^{10} cfu of a KP-negative strain (Centre for Food Safety and Applied Nutrition 2001). However, the level of *V. parahaemolyticus* in oysters from beds implicated in the United States 1997 and 1998 outbreaks was less than 200/g, indicating that human illness can occur at lower levels than currently suspected (Morbidity and Mortality Weekly Reports 1999).

Levels in seafood: Studies have demonstrated a seasonal and geographical variation in the concentration of *V. parahaemolyticus* in marine waters, with higher numbers detected in samples collected during the warmer months (DePaola et al. 1990; Cook et al. 2002; Gooch et al. 2002). This is in contrast to many other bacterial pathogens (such as *Salmonella*, pathogenic *E. coli* and *Campylobacter*) where survival is inversely related to temperature (Obiri-Danso & Jones 1999). Therefore, concentrations of *Vibrio* spp. do not always correlate with traditional faecal indicator organism concentration.

Concentrations of *V. parahaemolyticus* have been observed to be >100 times higher in oysters compared with the surrounding coastal water (DePaolo et al. 1990). In a study in the United States, the concentration of *V. parahaemolyticus* in freshly harvested oysters was typically between 200 and 2000 CFU/g (Kaufman et al. 2003). The prevalence of *V. parahaemolyticus* is usually lower in crustacea and finfish than in oysters (Table 4.1).

Table 4.1: Incidence of *V. parahaemolyticus* in seafood

Country	(% positive, no. of samples)	Level reported	Reference
Australia	Marine fish at market (59%, 39/66)	Not reported	O'Connor 1979
	Wholesale unopened oysters (100%, 16/16)	0.4/g to 2.3 x 10^4/g	Eyles et al. 1985
	Retail refrigerated opened oysters (93%, 13/14)	4.3/g to >1.1. x 10^3/g	Eyles et al. 1985
	Pacific oysters (69–74%)	Not reported	Kraa & Bird 1992
	Pacific oysters	2.4 x 10^3/g	Bird & Kraa 1995
	Scallops, mussels, oysters and fish	25% (20/80) contained 4/g	Gorczyca et al. 1984
UK	Retail cooked prawns and shrimps (0/148)	None detected	Greenwood et al. 1985
	Ready-to-eat molluscs (24%, 64/2311)	58/64 'detected' 6/64 10^2-10^4/g	Little et al. 1997
India	Crustaceans (79.3%), fish (37.5%)	Not reported	Lall et al. 1979
	Fish (51.26%), shellfish (78.57%), oysters (100%)	Not reported	Sanjeev & Stephen 1993
	Fish and shrimps from coastal waters (60%)	Not reported	Qadri & Zuberi 1977
China	Clam (50%), shrimp (25%) and fish (15%)	Not reported	Shih et al. 1996
NZ	Pacific oysters (57%, 85/149)	<10/g (95%) to >10^4/g	Fletcher 1985
	Cockles (0%)	None detected	Nicholson et al. 1989
Brazil	Oysters (77%) Mussels (67–92%)	MPN <3-1200/100g MPN <3-24 000/100g	Matte et al. 1994
USA	Oysters (33%, 12/36)	MPN 3.6 to 23/g	Tepedino 1982
	Oysters (100% total *V. parahaemolyticus*; 22% pathogenic *V. parahaemolyticus*; n=156)	<10 – 1.2 × 10^4 cfu/g	DePaola et al. 2003

Source: M&S Food Consultants 2001.

Key: MPN = most probable number; cfu = colony forming units.

A study by Gooch et al. (2002) investigated the ability of *V. parahaemolyticus* to grow in oysters, post-harvest. After 24 hours storage at 26°C there was a 790-fold increase (2.9 log CFU/g) in concentration, demonstrating *V. parahaemolyticus* can multiply rapidly in unrefrigerated oysters. After 14 days of refrigeration, there was a six-fold decrease (0.8 log CFU/g) of *V. parahaemolyticus*.

Epidemiological data: There have been a number of large outbreaks of *V parahaemolyticus* gastroenteritis in Australia (Appendix 2). In 1990 an outbreak affecting more than 100 people, one of whom died, was linked to fresh, cooked prawns from Indonesia. In 1992 there were two outbreaks affecting more than 50 people linked to the same wholesale supplier of cooked prawns (Kraa 1995). One death due to *V. parahaemolyticus* gastroenteritis associated with consumption of oysters was reported in 1992 (Kraa 1995).

In the United States and Europe, most gastroenteritis-related outbreaks have been due to the consumption of raw molluscs (oysters and clams) or cooked crustaceans (shrimp, crab and lobsters). In Japan, South-East Asia, Africa and India, raw fish has been implicated.

Vibrio vulnificus

Description: The temperature range for *V. vulnificus* growth is 8–43°C, the minimum a_w for growth is as low as 0.96 and the optimal NaCl concentration for growth is 2.5 per cent (a_w = 0.983). The pH range for growth is 5–10 (ICMSF 1996).

Pathology of illness: Disease caused by *V. vulnificus* is characterised by a 24-hour incubation period, followed by signs of sepsis, including fever, chills and nausea (Potasman et al. 2002). Symptoms typical of gastroenteritis, abdominal pain, vomiting and diarrhoeal are less common. *V. vulnificus* is highly invasive and produces a number of virulence factors which may cause tissue damage (including lesions). Again, immunocompromised individuals and those suffering from chronic liver disease are particularly susceptible to *V. vulnificus* infection. *V. vulnificus* can also lead to infection by directly contaminating open wounds during swimming, shellfish cleaning and other marine activities (Centre for Disease Control 1993).

Infectious dose/dose response: The infectious dose is not known. It has been suggested that the infectious dose may be very low in susceptible individuals (Oliver & Kaper 1997) and analysis of oysters associated with *V. vulnificus* primary septicaemia indicates that ca. 10^3/g of oyster or higher were associated with infection (Jackson et al. 1997; Tamplin & Jackson 1997).

Levels in seafood: Levels reported in seafood range from 15 – 6 × 104/g (Table 4.2; Oliver 1989; Oliver & Kaper 1997). Although human illness has only been associated with consumption of oysters, *V. vulnificus* has been isolated in high numbers (>10^6 cfu/g) from intestinal contents of fish, shrimp and prawns, with low numbers being detected in muscle (DePaola et al. 1994; Hoi et al. 1998; Thampuran & Surendran 1998; Berry et al. 1994; Prasad & Rao 1994).

Numbers of *V. vulnificus* in seawater and seafood vary according to season (Ruple & Cook 1992; DePaola et al. 1994; Motes et al. 1998). In Chesapeake Bay, United States, *V. vulnificus* was not detected in any samples collected during February and March (water temperature <8˚C) but was found in 80 per cent of the water samples collected during May, July, September, and December (water temperature >8˚C), with concentrations ranging from $3.0 \times 10^1 – 2.1 \times 10^2$/mL. Isolation from oysters was demonstrable when water temperatures were 7.6˚C, with concentrations ranging from $1.0 \times 10^3 – 4.7 \times 10^4$/g (Wright et al. 1996). High *V. vulnificus* levels in oysters (>10^3/g) are also associated with intermediate salinities (5 to 25 ppt), with numbers generally being lower in oysters from water salinities above 28 ppt (Motes et al. 1998).

V. vulnificus has been isolated from Australian waters (Myatt and Davis 1989) and cases of wound sepsis have been reported (Maxwell et al. 1991). A 1990 survey in New South Wales found 40 per cent of oysters were contaminated with *V. vulnificus* (McAnulty 1990). However, there is little published data on the levels of *V. vulnificus* in Australian seafoods or seawater. As indicated in Table 4.2, *V. vulnificus* has been found at 'low levels' in oysters in Australia (Bird and Kraa 1995; Buckle 1995).

Table 4.2: Incidence of *V. vulnificus* in seafood

Country	(% positive, no. of samples)	Level reported	Reference
Australia	Sydney Rock oysters	'low numbers'	Buckle 1995
	Oysters	'low numbers'	Bird & Kraa 1995
Denmark	Mussels (41%, 7/17)	water (0.8-19/litre)	Hoi et al. 1998
Germany	Seafood (30%, 99/330)	not reported	Janssen 1996
India	Fish	15 - 9 × 10^2/g	Thampuran & Surendran 1998
Brazil	Oysters (12%) Mussels (8–17%)	MPN (<3 – 30/100g) MPN (<3 – 3/100g)	Matte et al. 1994
United States of America	Oysters (summer)	$1.0x10^3$ – $4.7x10^4$/g	Wright et al. 1996
	Oysters (summer)	1 × 10^3/g	DePaola et al. 1994
	Oysters (summer)	≥1 × 10^5/g	Ruple & Cook 1992
	Oysters	MPN 2 × 10^3/g; 10/g	Motes et al. 1998
	Oysters (summer and fall)	<0.3/g Jan–Mar; 10^3 – 10^4/g	DePaola et al., 1998

Source: M&S Food Consultants 2001.

Key: MPN = most probable number.

Epidemiological data: In the United States between 1988 and 1996, 422 *V. vulnificus* infections from 23 states were reported. Of these reported cases, 45 per cent were wound infections, 43 per cent were primary septicaemia infections, 5 per cent were gastroenteritis infections and 7 per cent of infections were undetermined. Of those with primary septicaemia, 96 per cent had consumed raw oysters. The fatality rate of individuals with primary septicaemia was 61 per cent with underlying liver disease associated with fatal outcome (Shapiro et al. 1998).

An outbreak of *V. vulnificus* infection associated with consumption of raw oysters was documented in 1992. All cases were aged 50–74, suffered from chronic liver disease and presented with primary septicaemia; there were 2 deaths (Kraa 1995). Between 1987–2001, five individual incidents of *V. vulnificus* infection associated with consumption of raw oysters were reported, leading to four deaths, of which were primarily individuals with chronic liver disease (Food Science Australia & Minter Ellison Consulting 2002).

Staphylococcus aureus

S. aureus is a gram-positive, non-spore forming spherical bacterium. *S. aureus* is ubiquitous and occurs on mucous membranes and skin of most warm-blooded animals, including all food animals. Up to 50 per cent of humans may carry this organism (FDA 2003).

The temperature range for growth is 7–48°C, the minimum a_w for growth is as low as 0.85 and the pH range for growth is 4–10. The temperature range for toxin production is 10–48°C, the pH range is 4.5–9.6 and toxin production occurs at an a_w as low as 0.87 (ICMSF 1996). Toxins are not always totally inactivated by heat treatments used during processing of foods.

Humans and animals are primary reservoirs for *S. aureus*. Staphylococcal food poisoning occurs when enterotoxigenic *S. aureus* is introduced into a food that will support growth of the organism, and that food is stored under conditions allowing the organism to grow and produce sufficient quantities of enterotoxin (Ash 1997).

Foods commonly associated with staphylococcal food poisoning are raw meat and poultry, dairy products, salads, cream-filled bakery products and processed meat (Stewart 2003).

Pathology of illness: *S. aureus* is an opportunistic pathogen that typically causes infection via open wounds. *S. aureus* forms a wide range of substances associated with infectivity and illness, including the heat stable enterotoxins that cause food poisoning (Ash 1997). Eleven antigenic types of staphylococcal enterotoxins are currently recognised, with types A and D being involved in most food poisoning outbreaks. The toxins are thought to stimulate neuroreceptors in the intestinal tract which trigger vomiting (Stewart 2003).

Symptoms generally appear around 3 hours after ingestion (range 1–6 hours) and are self-limiting (Ash 1997). Common symptoms are nausea, vomiting, retching, abdominal cramping, and prostration. In more severe cases, headache, muscle cramping and transient changes in blood pressure and pulse rate may occur. Recovery usually takes 1–3 days, but can take longer in severe cases (Ash 1997). All people are susceptible to staphylococcal food poisoning, however the intensity/severity may vary, depending of individual sensitivities. Death from staphylococcal food poisoning is very rare, although it has occurred amongst the elderly (Ash 1997).

Infectious dose/dose response: The amount of enterotoxin that must be ingested to cause illness is not known exactly, but it is generally believed to be in the range 0.1–1.0 µg/kg (ICMSF 1996). Toxin levels within this range are typically reached when *S. aureus* populations exceed 100 000/g (Ash 1997).

Epidemiological data: Staphylococcal food poisoning associated with seafood consumption has not been reported in Australia (1987–2001). However, a limited number of outbreaks have occurred in other countries such as Canada and the United Kingdom (Sweet et al. 1989; Panisello et al. 2000).

Salmonella species

Salmonella is a gram-negative rod-shaped, generally motile, non-spore forming bacterium. It is found worldwide and has widespread occurrence in animals, especially poultry and swine and raw seafoods. The temperature range for growth is 5.2–46.2°C (however, most serotypes fail to grow below 7°C), the pH range is approximately 3.8–9.5 and growth occurs at an a_w as low as 0.94 (ICMSF 1996).

Pathology of illness: Acute symptoms of salmonellosis include nausea, vomiting, abdominal cramps, mild diarrhoea, fever, and headache. Onset of symptoms occur 8–72 hours after ingestion and symptoms generally last 1–2 days (Jay et al. 1997). Symptoms may be prolonged depending on host factors, ingested dose and strain characteristics. Chronic consequences such as arthritic symptoms may follow 3–4 weeks after onset of acute symptoms (FDA 2003).

S. Typhi and *S.* Paratyphi are serotypes that cause serious enteric fever (typhoid fever) and are particularly well adapted to invasion and survival in humans (Jay et al. 1997). There are also many other non-typhoid *Salmonella* serovars that cause gastroenteritis in humans. Typhoid fever is quite common in developing countries, whereas non-typhoidal *Salmonella* gastroenteritis is among the leading causes of food-borne morbidity in developed countries.

Salmonella causes illness by invading regions of the intestine, leading to an inflammatory reaction. Invasive strains (for example, *S.* Typhi) invade individual cells which can lead to septicaemia. All age groups are susceptible to infection however symptoms may be more severe in the elderly, infants and immunocompromised (Jay et al. 1997).
Salmonellae are found worldwide and are considered to be zoonotic organisms. Several animal reservoirs have been identified and many foods, mostly of animal origin or those subject to sewage pollution, have been responsible for transmission of salmonellae to humans. Food, feeds and water are the primary vehicles, but salmonellae can also become established and multiply in the environment and equipment of food-processing plants. Infected food handlers may also spread infection through poor hygienic practices.

Infective dose/dose response: The infective dose is usually generally high at >10^5 cells, but can be lower when the food vehicle is a fatty or buffering substance allowing passage through the acidic environment of the stomach (Jay et al. 1997). As few as 15–20 cells may also cause illness depending upon age and health of host and strain differences (FDA 2003).

Levels in seafood: Farmed seafood, or seafood harvested from in-shore waters, estuaries or rivers may be contaminated with *Salmonella* spp. due to faecal pollution of surrounding waters. Fish caught in deep waters are more likely to be contaminated with *Salmonella* spp. after harvesting (Jay et al. 2003). The prevalence of salmonellae in shrimp has been reported at 8.1 per cent from a survey of 211 samples (Gecan et al. 1994).

Epidemiological data: In 2002, 7917 cases of salmonellosis were reported in Australia, which represented a rate of 40.3 cases per 100,000 population (OzFoodNet 2003). During 1995–2002, there were five reported outbreaks associated with consumption of contaminated seafood including oysters, cooked prawns and crayfish (Appendix 2; Food Science Australia & Minter Ellison Consulting 2002).

Outbreaks have also occurred internationally due to the consumption of contaminated seafood. For example, smoked fish (halibut) was implicated in 11 cases of salmonellosis with *S.* Paratyphi in Germany in 1991 (Kuhn et al. 1994), and 19 cases of salmonellosis was due to the consumption of cockles contaminated with *S.* Enteritidis in the United Kingdom (Greenwood et al. 1998).

Listeria monocytogenes

L. monocytogenes is a gram positive, non-spore forming rod that may be isolated from a variety of sources including soil, silage, sewage, food-processing environments, raw meats and the faeces of healthy humans and animals (FDA 2003). *L. monocytogenes* grows in the temperature range –0.4°C to 45°C, over a broad range of pH (4.6–9.2) and to an a_w as low as 0.90 (glycerol as humectant) or 0.92 (NaCl as humectant) (ICMSF 1996). An important factor in terms of food-borne transmission is that the organism survives well under frozen conditions and has the ability to grow at low temperatures.

Pathology of illness: There are two main clinical forms of infection with *L. monocytogenes*, namely listerial gastroenteritis, where usually only mild, flu-like symptoms are reported, and the classic invasive listeriosis, where the bacteria penetrate the gastrointestinal tract and invade normally sterile sites within the body (FDA 2003).

Invasive listeriosis can be very severe, and in some cases, life-threatening. Invasive listeriosis is an opportunistic infection and a relatively rare illness, with a wide range of symptoms including meningoencephalitis and septicaemia. Mild or asymptomatic infections in pregnant women may lead to infection of the foetus (Sutherland & Porritt 1997). The incubation period prior to individuals becoming symptomatic with listeriosis can be long (up to 3 months) but most commonly in the region of several days, and for the gastrointestinal form less than 24 hours (Sutherland & Porritt 1997).

It is estimated that approximately 2–6 per cent of the healthy population harbours *L monocytogenes* in their intestinal tract, which suggests that people are frequently exposed to *L. monocytogenes* (Rocourt & Bille 1997; Farber & Peterkin 1991). This may also suggest that most people have tolerance to infection by *L. monocytogenes*, and given the relatively low number of reported cases, exposure rarely leads to serious illness (FDA 2003; Marth 1988; Hitchins 1996). However, a number of high-risk groups for listeriosis have been identified, including pregnant women and their foetuses, neonates, elderly, and the immunocompromised (Sutherland & Porritt 1997).

Infectious dose/dose response: Epidemiological evidence from investigations where the vehicle of infection has been identified indicates that foods contaminated with less 100 cfu/g of *L. monocytogenes* are unlikely to cause illness in the general population. There is one study that suggests that the level of *L. monocytogenes* needed to cause illness in susceptible groups may be lower (Maijala et al. 2001).

Factors affecting the likelihood of illness developing in an individual consumer may include their immune status, the type of food consumed, the virulence and infectivity of the pathogen, the concentration of the pathogen in the food, and the number of repetitive challenges (National Advisory Committee on Microbiological Criteria for Foods 1991). Thus, even when an outbreak occurs not all people consuming the contaminated foods will develop an infection.

Levels in seafood: There are few data describing the prevalence of *L. monocytogenes* in Australian seafood of which a number are not ready-to-eat and will receive a heat treatment prior to consumption, therefore inactivating the organism (Table 4.3). Garland (1995) and Garland and Mellefont (1996) isolated *L. monocytogenes* from only 3/718 smoked salmon samples at a Tasmanian plant. These levels are much lower than those reported for smoked salmon in Europe (M&S Food Consultants 2001). By contrast, the prevalence established in a retail survey in New South Wales during 1993 (Arnold & Coble 1995) is much higher than those determined at the processing plant by Garland and Mellefont, pointing to temperature/time regimes favourable for the growth of the pathogen. Also of concern is the high prevalence of *L. monocytogenes* (29.5–60%) in processed smoked salmon products (Arnold & Coble 1995; Garland & Mellefont 1996).

Table 4.3: *L. monocytogenes* in Australian seafood

Product	No. (%) of positive samples	Levels	Reference
Smoked salmon fillets and slices	1/285 (0.4) 2/433 (0.4)	Present in 25g	Garland 1995 Garland & Mellefont 1996
Salmon pate	8/61 (29.5)	Present in 25g	Garland & Mellefont 1996
Smoked fish and mussel products at retail in Canberra	49 (4.1)	4 MPN/g, 460 MPN/g	Rockliff & Millard 1997
Retail survey in Victoria			Dunn, Son & Stone 1998
Marinara mix	13 (31)	Present in 25g	
Smoked fish	9 (10)	Present in 25g	
Seafood salad/cocktail	37 (3)	Present in 25g	
Flake	70 (1.5)	Present in 25g	
NSW retail survey			
Smoked salmon	10/56 (17.9)	<100 MPN/g	Arnold & Coble 1995
Other smoked fish	0/11	Not stated	
Salmon cheese	3/5 (60)	Not stated	
Salmon dip	10/21 (47.6)	Not stated	
Salmon mousse/pate	2/8 (25)	Not stated	
Cooked prawns	12/380	<50 cfu/g	Marro et al. 2003

Source: M&S Food Consultants 2001.

Key: MPN = most probable number; cfu = colony forming units.

Epidemiological data: The estimated incidence of listeriosis in European countries is four to eight cases per million of the general population per year. In France, the estimated incidence of listeriosis is sixteen cases per million (general population) per year (Bille 1990). The United States estimates that approximately 8.8 people per million (general population) become seriously ill with listeriosis each year, with a fatality rate of 20 per cent. Of all the food-borne pathogens, *L. monocytogenes* resulted in the highest hospitalisation rate in the United States (FDA 2003).

While the incidence rate is low compared to other food-borne illnesses, such as *Salmonella*, the mortality rate is much higher, ranging between 5 per cent and 33 per cent, and averaging 22 per cent (Rocourt & Brosch 1992). In general, the incidence of listeriosis appears to be decreasing in most countries.

The estimated incidence of invasive listeriosis in New Zealand is five cases per million (average number of cases 17 per annum) of the general population per year (Anon. 1996–2001). The fatality rate in New Zealand since 1995 is approximately 17 per cent.

The number of reported cases of invasive listeriosis in Australia from 1991 to 2002, inclusive, is approximately fifty seven cases per year (Communicable Diseases Australia 2003), which equates to an estimated incidence of invasive listeriosis in Australia of three cases per million of the general population per year (Sutherland & Porritt 1997). In Australia, the exact mortality rate is not known, although the data available would suggest a rate of approximately 23 per cent.

A risk assessment undertaken by the United States Food and Drug Administration (2001) looked at all documented outbreaks of listeriosis internationally, including those listed in Table 4.4, and ranked fish products third behind meat and dairy products in terms of responsibility for outbreaks for which the food linkage has been identified.

Table 4.4: Cases of food-borne listeriosis associated with seafood

Location (year)	No. cases	Food	CFU g^{-1}	Strain serovar
USA (1989)	2	Shrimp	Not known	4b
Italy (1989)	1	Fish	Not known	4b
Australia (1991)	3	Smoked mussels	1×10^7	Not known
New Zealand (1992)	2	Smoked mussels	Not known	1/2b
Canada (1996)	2	Imitation crab meat	2×10^9	1/2b
Sweden (1994/95)	6–9	'Gravad' smoked rainbow trout	>100–2.5×10^6	4b
Finland (1999–2000)	10	Vacuum packed cold-smoked trout	Not known	1/2a

Source: M&S Food Consultants 2001; after FAO 1999.

Clostridium botulinum

C. botulinum is an anaerobic, gram positive, spore-forming rod shaped bacterium that produces a potent neurotoxin. Seven types of *C. botulinum*, (types A-G) are recognised, grouped according to the antigenic specificities of their toxins. *C. botulinum* has also been classified phenotypically into Groups I-IV. This organism is ubiquitous and is found in almost all foods, whether of plant or animal origin. Spores of *C. botulinum*, although usually in low numbers, are widely distributed in soil, the sediments of lakes and coastal waters and in the intestinal tracts of fish and animals.

Both the spores and the toxins are tolerant of freezing. Toxin is destroyed rapidly at temperatures of 75–80°C. Group I (proteolytic) spores are the most heat-resistant of all *C. botulinum* spores and this led to the development of the botulinum cook or '12D process' for low-acid canned foods. Strains of Group I will not grow if the water phase NaCl concentration exceeds 10 per cent ($a_w = 0.935$) while strains of Group II will not grow if the concentration exceeds 5 per cent ($a_w = 0.97$) in the water phase. All strains of *C. botulinum* grow and produce toxin to about pH 5.2 under optimal conditions. Strains of Group II will not grow below pH 5.0, while strains of Group I will not grow below pH 4.6 (ICMSF 1996).

Pathology of illness: Illness caused by *C. botulinum* can be of three types: food-borne, infant and wound botulism (FDA 2003). Food-borne botulism is caused by ingestion of preformed toxin. The mortality rate depends on the type of *C. botulinum* toxin ingested. Infant botulism affects infants under the age of 12 months and results from the ingestion of spores that colonise the alimentary tract and produce toxin.

Botulinum neurotoxin causes muscle paralysis, beginning in the upper body and progressing downward, paralysing the chest muscles, eventually leading to asphyxiation and death. Even with treatment, 20–40 per cent of victims die (M&S Food Consultants 2001).

Onset of symptoms in food-borne botulism is usually 18–36 hours after ingestion of the food containing the toxin, although cases have varied from 4 hours to 8 days. Early signs of intoxication consist of marked lassitude, weakness and vertigo, usually followed by double vision and progressive difficulty in speaking and swallowing, difficulty in breathing, weakness of other muscles, abdominal distension, and constipation may also be common symptoms (FDA 2003). All people are believed to be susceptible to the food-borne intoxication.

For seafoods, botulism is most commonly associated with *C. botulinum* type E (Group II). *C. botulinum* type E is capable of growth and toxin production at refrigeration temperatures (≥ 3.3°C) but generally needs weeks of growth to produce sufficient amounts of toxin to cause food-borne illness (Lyon & Reddmann 2000). This is significantly greater than the shelf life generally observed for seafood. Botulism is a concern, however, when processes are used to extend the shelf life, such as canning and vacuum packing. If the *C. botulinum* spores survived treatment processes prior to packaging, they have the ability to proliferate and produce toxin, especially if the food is subjected to temperature abuse.

Infectious dose/dose response: A very small amount (a few nanograms) of botulinum toxin can cause illness (FDA 2003). As little as 0.1–1.0 µg of type A toxin has been found to cause death in humans (ICMSF 1996).

Levels in seafood: The aquatic environment is frequently contaminated with *C. botulinum* spores and therefore fish are often contaminated. A large number of surveys have been conducted, including those for seafoods at retail (Table 4.5). The incidence and level of contamination of prepared fish in Europe and Asia appears to be much lower than that in North America, but fish from Scandinavia and the Caspian Sea appear to be exceptions (Dodds 1993).

Only a limited amount of data are available on the prevalence of *C. botulinum* in Australia. *C. botulinum* types A, B and C have been isolated from soils and waterways and have caused illness in domestic animals (Szabo & Gibson 1997). *C. botulinum* type B was found in two marine muds from Tasmania (Szabo & Gibson 1997). In a study specifically designed to isolate *C. botulinum* type E, Christian (1971) found no evidence from 528 samples of soils, marine muds, fish intestines and potato washings from Tasmania, New South Wales and Queensland. Gibson et al. (1994) examined 368 samples from various Australian coastal marine, harbour and estuarine sediments and found no samples positive for the presence of the organism.

Table 4.5: Prevalence and level of contamination of seafood products with *C. botulinum* spores

Product	Origin	% positive	MPN/kg	Types identified
Haddock fillets	Atlantic Coast, N. America	24	170	E
Vacuum packed frozen flounder	Atlantic Coast, N. America	10	70	E
Frozen packaged fish	Canada	<1	–	A,B,E
Smoked fish (28 processors)	Pacific Northwest	5	9	E
Salmon	Alaska	1	–	E
	Washington	8	–	E
	Oregon	6	–	E
	Alaska	100	190	A
Vacuum packed fish	England	0	–	
	England	<1	–	E
	North Sea	0	–	
	Norwegian Sea	44	–	E
Smoked fish	Caspian Sea	0	<68	E
Fish	Indonesia	3	6	A,B,C,D,F
Fish and seafood	Osaka	8	3	C, D
	Viking Bank	42	63	E

Source: M&S Food Consultants 2001; after Dodds 1993.

Key: MPN = most probable number.

Epidemiological data: Botulism caused by consumption of commercial foods is rare, with most cases involving non-commercial foods (M&S Food Consultants 2001). Outbreaks are generally associated with improperly canned food (usually home canned) and semi-preserved seafoods including smoked, salted (particularly when uneviscerated) and fermented fish.

Outbreaks of botulism have been reported due to consumption of contaminated mussels in Portugal (Lecour et al. 1988); uneviscerated salted mullet fish (Faseikh) in Egypt, in April 1991 (Weber et al. 1993); hot-smoked Canadian whitefish in 1997 (Korkeala et al. 1998). Ten outbreaks of botulism associated with seafoods have occurred in the United States over the period 1988–98 (Bean et al. 1996; Olsen et al. 2000). Three deaths were reported in New York city from consumption of contaminated seafoods (Wallace et al. 1999); another two deaths reported from botulinum type E toxin associated with eating ‘kapchunka’, a salted ungutted whitefish dish (Badhey et al. 1986) and a further 8 cases occurred in New York and Israel involving the same food (Telzak et al. 1990).

In Canada 61 outbreaks occurred in the period 1971–84, most (113/122) cases involving native peoples eating raw, parboiled or ‘fermented’ meats from marine mammals. A similar pattern of illness occurs in Alaska. Fermented salmon eggs or fish were responsible for 23 per cent of these outbreaks (Hauschild & Gauvreau 1985).

In 1978 (United Kingdom) and 1982 (Belgium) there were two outbreaks of botulism from canned salmon. In the United Kingdom, two people died and two recovered (Murrell 1979) while in Belgium, one died and one recovered (Anon. 1982). There were also a number of outbreaks from smoked, vacuum-packed whitefish in United States in 1963; in all there were 25 cases of botulism and 10 deaths (Anon. 1963).

In New Zealand, there have been two cases of illness (one death) due to botulism type A involving home-bottled fermented mussels and watercress, a traditional Maori food Hauschild (1993).

There have been no reported cases of food-borne botulism in Australia since national notification commenced in 1991 (Blumer et al. 2003). From 1942–83 there were five reported outbreaks of botulism in Australia (Hauschild 1993), of which one (two cases) was linked to consumption of Australian canned tuna (Murrell 1979).

Aeromonas hydrophila

Aeromonas hydrophila is a gram-negative, facultatively anaerobic, non-spore forming rod-shaped bacterium that is present in all freshwater environments and in estuarine environments. It is also found in a wide range of foods, including seafood products and shellfish, raw foods of animal origin (for example, poultry, ground meat, raw milk), and raw vegetables (Kirov 2003). *Aeromonas* spp. are ubiquitous and occur worldwide, but are most frequently isolated from treated and untreated water and animals associated with water such as fish and shellfish. Many authors use the name of *A. hydrophila* as a general term to include *A. sobria* and *A. caviae* as well as the main species of *A. hydrophila* (ICMSF 1996). In this document, *A. hydrophila* refers to this species only, unless otherwise indicated.

These bacteria are psychrotrophic and grow rapidly at refrigeration temperatures. Temperature range for growth is 2–45°C with an optimum range between 28°C and 35°C (ICMSF 1996). Growth is optimal in the presence of 1–2 per cent NaCl (a_w = 0.991–0.986) and has been found to be inhibited completely at a NaCl concentration of 6.0 per cent (a_w = 0.96) or pH 5.5. (ICMSF 1996).

Pathology of illness: *Aeromonas* spp. causes a broad spectrum of infections in humans, often in immunocompromised patients, but has not been definitively implicated as a significant cause of food-borne illness. *A. hydrophila* may cause gastroenteritis in healthy individuals or septicaemia in individuals with impaired immune systems or various malignancies. Two distinct types of gastroenteritis have been associated with *A. hydrophila*: a cholera-like illness with a watery (rice water) diarrhoea and a dysenteric illness characterised by loose stools containing blood and mucus.

Symptoms associated with *Aeromonas*-related gastroenteritis include diarrhoea, abdominal pain, nausea, chills and headache, dysentery-like illness and colitis. Symptoms usually occur within 24–48 hours of exposure and generally last from one to 7 days (Kirov 2003). On rare occasions the dysentery-like syndrome is severe and may last for several weeks (FDA 2003). All people are believed to be susceptible to gastroenteritis, although it is most frequently observed in very young children. People with impaired immune systems or underlying malignancy are susceptible to the more severe infections (FDA 2003).

Illness caused by *A. hydrophila* is thought to be mediated partly by production of several cytotoxins. Other virulence factors thought to be associated with colonisation of the intestine have not been conclusively identified.

Infectious dose/dose response: The infectious does of this organism is unknown. However, it is likely that illness can result from a low dose, as scuba divers who have ingested small amounts of water have become ill, and *A. hydrophila* has been isolated from their stools (FDA 2003).

Levels in seafood: *Aeromonas* spp. are ubiquitous throughout the environment (particularly fresh and marine waters) and have been isolated from a variety of foods (Birkenhauer & Oliver 2002).

Epidemiological data: Most cases of illness attributed to *A. hydrophila* have been sporadic, rather than associated with large outbreaks. To date, the number of reported food associated outbreaks attributed to *Aeromonas* species is small (Table 4.6).

Table 4.6: Seafood food-borne illness associated with *Aeromonas* species

Location	No. of people involved	Suspect food	Reference
Russia	'mass' poisoning	Fish (pre-frozen)	Kalina 1997
United States of America	472	Oysters	Agbonlahor et al. 1982
United States of America	7	Oysters	Abeyta et al. 1986
United States of America	29	unknown (school lunch)	Kobayashi & Ohnaka 1989
Japan	4	Seafood (sashimi)	Kobayashi & Ohnaka 1989
Scotland	>20	Cooked prawns	Todd et al. 1989
England	3	Oysters	Todd et al. 1989
England	14	Cooked prawns	Todd et al. 1989
England	2	Cooked prawns	Todd et al. 1989
Switzerland	1	Shrimp cocktail	Altwegg et al. 1991
Norway	3	Raw fermented fish	Granum et al. 1998
France	10	Dried fish sauce	Hansman et al. 2000

Source: Kirov 2003.

Suspect foods have been principally seafood and oysters, or other foods consumed with little or cooking. In only one case, which was linked to ready to eat shrimp cocktail, has the isolate from the suspect food and diarrhoeal faeces been shown to be the same ribotyping (Kirov 2003). Most recently reported *Aeromonas*-associated outbreaks have occurred in Sweden, Norway and France (Granum et al. 1998; Hansman et al. 2000; Krovacek et al. 1995). They are however, still insufficiently documented to definitively established *Aeromonas* spp. as the causative agents.

Escherichia coli

E. coli are members of the family Enterobacteriaceae. The organisms are gram-negative, facultatively anaerobic rod shaped bacteria (Desmarchelier & Fegan 2003). There are currently four main types of pathogenic *E. coli* that have been associated with food-borne diseases: enteropathogenic *E. coli* (EPEC), enterotoxigenic *E. coli* (ETEC), enteroinvasive *E. coli* (EIEC) and enterohaemorrhagic *E. coli* (EHEC).

EPEC have been defined as 'diarrhoeagenic *E. coli* belonging to serogroups epidemiologically incriminated as pathogens but whose pathogenic mechanisms have not been proven to be related either to heat-labile enterotoxins or heat-stable enterotoxins or to *Shigella*-like invasiveness' (Edelman & Levine 1983).

EPEC cause characteristic attaching and effacing lesions in the intestine, similar to those produced by EHEC, but do not produce Shiga toxins. Attachment to the intestinal wall is mediated by a plasmid-encoded outer membrane protein called the EPEC Adherence Factor in type I EPEC. However, pathogenicity is not strictly correlated to the presence of the EPEC Adherence Factor, indicating that other virulence factor are involved (ICMSF 1996).

ETEC that survive passage through the stomach adhere to mucosal cells of the proximal small intestine and produce a heat-labile and/or a heat-stable toxin. The heat-labile are similar in structure and mode of action to cholera toxin (Desmarchelier & Fegan 2003).

EIEC cause a shigellosis-like illness by invading the epithelial cells of the distal ileum and colon. The bacteria multiply within the cytoplasm of the cells, causing cells destruction and ulceration. Pathogenicity is associated with a plasmid-encoded type III secretory apparatus and other plasmid-encoded virulence factors (Desmarchelier & Fegan 2003).

EHEC are a group of *E. coli* organisms producing Shiga toxins and a number of other virulence factors, particularly the adhesion molecule, intimin. The Shiga toxins are closely related or identical to the toxins produced by *Shigella dysenteriae*. Genes of the virulence factors other than Shiga toxins are located in the locus of enterocyte effacement. These virulent factors and Shiga toxins allow the organisms to attach tightly to intestinal epithelial cells, disrupting the cytoskeletal structure and signalling pathways and causing effacing lesions (Ismaili et al. 1998). Many synonyms are used to describe EHEC, including Shiga toxin-producing *E. coli*, Shiga-like toxin-producing *E. coli*, verotoxin-producing *E. coli*, verocytotoxin-producing *E. coli*, as well as *E. coli* O157 and *E. coli* O157:H7.

Pathology of illness: EPEC primarily causes illness in infants and young children in developing countries. Symptoms include watery diarrhoea, with fever, vomiting and abdominal pain. The diarrhoea is usually self-limiting and of short duration, but can become chronic (more than 14 days). EPEC is also recognised as a food- and water-borne pathogen in adults, where it causes severe watery diarrhoea (with mucus, but no blood) along with nausea, vomiting, abdominal cramps, fever, headache and chills. Duration of illness is typically less than three days (Doyle & Padhye 1989).

ETEC is another major cause of diarrhoea in infants and children in developing countries, as well as being recognised as the main cause of 'travellers' diarrhoea' (Doyle & Padhye 1989). Symptoms include watery diarrhoea, low-grade fever, abdominal cramps, malaise and nausea. In severe cases, the illness resembles cholera, with severe rice-water diarrhoea and associated dehydration. Duration of illness is from three to 21 days (Doyle & Padhye 1989).

EIEC cause a dysenteric illness similar to shigellosis. Along with profuse diarrhoea, symptoms include chills, fever, headache, muscle pain and abdominal cramps. Onset of symptoms is usually rapid (<24 hours), and may last several weeks (Doyle & Padhye 1989).

EHEC infection normally results in diarrhoea like symptoms. Haemorrhagic colitis, an acute illness caused by EHEC organisms, is characterised by severe abdominal pain and diarrhoea. This diarrhoea is initially watery but becomes grossly bloody. Symptoms such as vomiting and low-grade fever may be experienced. The illness is usually self-limiting and lasts for an average of 8 days. The duration of the excretion of EHEC is about one week or less in adults, but it can be longer in children (ICMSF 1996).

Complications resulting from EHEC infections vary. About 5 per cent of haemorrhagic colitis victims may develop Haemolytic Uraemic Syndrome (European Commission 2000). This involves the rupture of red blood cells (haemolysis), subsequent anaemia, low platelet count and kidney failure. The case-fatality rate of Haemolytic Uraemic Syndrome is 3–5 per cent (WHO 1996). *Shigella* toxins produced by EHEC attack the lining of the blood vessels throughout the body, predominantly affecting the kidney.

However, other organs such as the brain, pancreas, gut, liver and heart are also affected and may result in further complications such as thrombotic thrombocytopenic purpura.
Infectious dose/dose response: EPEC: It is thought that only a few EPEC cells are necessary to cause illness in children (FDA 2003). Volunteer studies in adults demonstrated that illness could be caused by ingesting 10^6–10^{10} cells with sodium bicarbonate to neutralise stomach acidity (Doyle & Padhye 1989).

ETEC: Volunteer studies have shown that 10^8–10^{10} cells of ETEC are necessary for illness in adults (DuPont et al. 1971), although the infective dose is probably less for infants (FDA 2003).

EIEC: Volunteer studies have shown that 10^8 EIEC cells are necessary to cause illness in adults, with the infectious dose reduced to 10^6 when ingested with sodium bicarbonate (DuPont et al. 1971). However, the United States FDA suggest that as few as 10 cells may be needed to cause illness in adults, based on the organisms similarity with *Shigella* (FDA 2003).

EHEC: Investigations of known outbreaks of food-borne illness due to *E. coli* O157:H7 and systematic studies aimed at quantifying the dose–response relationship suggest that as few as 1–700 EHEC organisms can cause illness. The United States FDA suggests that the infective dose is of the order of 10 cells (FDA 2003).

Incidence and outbreak data: EIEC stains have been isolated from diarrhoeal cases in both industrialised and less developed countries with low frequency (Nataro & Levine 1994). Outbreaks have occurred in hospitals, on a cruise ship, and from contaminated water (Desmarchelier & Fegan 2003). ETEC stains are a major cause of diarrhoea in infants and young children in developing countries, particularly in the tropics, and are a leading cause of travellers' diarrhoea (Doyle & Padhye 1989; Gross & Rowe 1985; Nataro & Levine 1994). EPEC stains have caused infantile diarrhoea in hospitals and nurseries in the United Kingdom and the United States (Nataro & Levine 1994; Robins-Brown 1987). In developing countries, EPEC stains are still responsible for a high incidence of sporadic infant diarrhoea.

Among different EHEC serotypes, *E. coli* O157:H7 is the single most important EHEC serotype that dominates the number of reported food-borne illnesses caused by EHEC. Mead et al. (1999) reported that *E. coli* O157:H7 caused approximately 73 000 cases of illness each year, and non-O157:H7 EHEC caused approximately 37 000 cases of illness in the United States. During 1999 to 2002, inclusive, Australia recorded 55 cases of HUS (Communicable Diseases Australia 2003).

Levels in seafood: The occurrence of strains of EPEC, ETEC and EIEC in foods is typically the result of human faecal contamination, due either to poor hygienic practices by food handlers or raw sewage contamination of waters used in the food production and processing (Desmarchelier & Fegan 2003).

There have been only isolated outbreaks of food-borne illness attributed to seafood containing EIEC and ETEC strains of *E. coli* (Doyle & Padhye 1989). ETEC have been detected in Brazilian seafood harvested from contaminated waters (Teophilo et al. 2002).

EHEC are normally isolated from meat, dairy and plant products (Desmarchelier & Fegan 2003). However, a low level of contamination was detected in one survey of retail fish and shellfish samples in the United States (Samadpour et al. 1994).

Viral pathogens

The viral pathogens discussed here are hepatitis A and noroviruses.

Hepatitis A

Hepatitis A virus is classified within the enterovirus group of the *Picornaviridae* family. Hepatitis A virus has a single molecule of ribonucleic acid (RNA) surrounded by a small (27 nm diameter), non-enveloped, protein capsid (FDA 2003).

Hepatitis A virus is distributed worldwide and is usually transmitted from person-to-person via the faecal-oral route. Hepatitis A virus is excreted in faeces of infected people and can infect susceptible individuals when they consume contaminated water or foods. Water, shellfish, and salads are the most frequent sources.

Pathology of illness: The incubation period for hepatitis A virus is generally 2–6 weeks, and with a sudden onset of symptoms including fever, headache, malaise, fatigue, anorexia and nausea, usually followed by vomiting and abdominal pain. When symptoms do occur, they are usually mild and recovery is complete in 1–2 weeks. Many infections do no result in clinical illness especially in children (Grohmann 1997). Less than 0.4 per cent of reported cases in the United States are fatal, usually occurring in the elderly (Sobsey et al. 1991; FDA 2003). Recovery is complete and gives lifelong immunity to further infection. Immunocomprised individuals are more susceptible to infection (Sobsey et al. 1991; FDA 2003).

The mechanisms by which illness is caused are not fully understood, but viral particles are thought to replicate in the gastrointestinal tract and then the liver where they cause cellular damage.

Infectious dose/dose response: The infectious dose is unknown (Bidawid et al. 2000) but is presumably similar to other RNA enteroviruses (10–100 particles; FDA 2003).

Levels in seafood: Several studies have demonstrated the presence of hepatitis A virus in bivalve molluscs grown in waters subject to human faecal pollution (Table 4.7). The prevalence of contamination is typically higher in shellfish taken from waters closed for harvest, but significant rates of contamination have been demonstrated in areas open for harvest.

Table 4.7: Reported incidence of hepatitis A virus in seafood

Food (% positive)	Viruses detected	Reference
Shellfish (21%)	hepatitis A virus	Apaire Marchais et al. 1995
Mussel and cockle (73%)	hepatitis A virus	Crance et al. 1995
Cockles and mussels (67%)	hepatitis A virus	Le Guyader et al. 1993
Cockles and mussels (14%)	hepatitis A virus	Le Guyader et al. 1994
Cockles (84%)	hepatitis A virus	Le Guyader et al. 1995

Source: M&S Food Consultants 2001.

Epidemiological data: Shellfish have been associated with food-borne viral infection throughout the world. In 1991 almost 300 000 people in Shanghai contracted hepatitis and nine died after consuming cockles contaminated with hepatitis A virus (Tang et al. 1991).

Hepatitis A virus has also been linked to shellfish-associated gastroenteritis in Australia (Table 4.8). The first reported case of hepatitis A virus from shellfish in Australia was attributed to under-cooked mussels from contaminated waters in Victoria. Seven out of the ten consumers who ate the mussels developed symptoms of hepatitis A (Locarnini & Gust 1978).

The largest outbreak of hepatitis A in Australia occurred during 1996–97 following consumption of oysters harvested from the Wallis Lake region, New South Wales, Australia (Communicable Disease Intelligence 1997) when 444 people were affected and one died.

Table 4.8: Recent outbreaks of hepatitis shellfish-associated food poisoning in Australia

Year	Seafood	Growing area	Cases (deaths)
1997	Oysters	Wallis lake, NSW	466 (1)
1997	Prawns	Imported product	17

Source: C Dalton, Hunter Public Health Unit, personal communication.

Noroviruses

Noroviruses (previously termed Norwalk and Norwalk-like viruses) are non-enveloped RNA viruses classified in the Caliciviridae family. The group is described collectively as small round structured viruses.

Pathology of illness: Noroviruses cause gastroenteritis in adults and children. The illness is relatively mild and symptoms include nausea, vomiting, diarrhoea, fever and abdominal pain with an incubation period of 1–4 days, usually followed by recovery without complications (Grohmann & Lee 2003). Onset occurs 24–48 hours after infection and the acute phase of the illness generally lasts between 1 and 2 days (ICMSF 1996). Norwalk virus causes illness by invading and damaging the gastrointestinal tract. Infection may not confer long-term immunity.

Human Norovirus may cause epidemic gastroenteritis amongst all age groups and may be the most significant cause of infectious intestinal illness. Attack rates for small round structured virus seafood-associated gastroenteritis in outbreaks are relatively high, with rates of 56 per cent to 89 per cent being reported (Kirkland et al. 1996; Linco & Grohmann 1980).

Infectious dose/dose response: The infectious dose is unknown but presumed to be low (FDA 2003).

Levels in seafood: Norovirus has been shown to accumulate in bivalve molluscs and is commonly isolated from oysters grown waters impacted by faecal contamination (Formiga-Cruz et al. 2002; LeGuyader et al. 2000). Of particular concern, a study by Schwab et al. (1998) demonstrated that depuration of oysters may result in only a limited reduction of Norovirus concentration (7% reduction following 48 h depuration, compared with 95% reduction of bacteria).

Epidemiological data: Norovirus is a major cause of food-borne disease worldwide and is commonly associated with the consumption of faecally contaminated shellfish. This was first evident in 1977, when an outbreak of gastroenteritis in the United Kingdom (> 2000 cases) was linked to oysters harvested from George's River, Sydney (Fleet et al. 2000).

The oysters had been opened and frozen on the half shell prior to being exported. During 1987–2001, at least 13 outbreaks of gastroenteritis associated with Norovirus contamination of oysters were recorded in Australia (Table 4.9; Food Science Australia & Minter Ellison Consulting 2002). A major contributing factor with these outbreaks was the consumption of raw oysters following heavy rainfall, resulting in increased faecal contamination of shellfish growing areas due to sewage pollution.

Table 4.9: Recent outbreaks of Norovirus virus associated with seafood consumption in Australia

Year	Product	Location	Cases
1992	Oysters	Northern Territory	18
1990	Oysters	New South Wales	461
1989	Oysters	Australia	>370
1996	Oysters	New South Wales	97
1999	Scallops	Queensland	14

Source: Adapted from Food Science Australia & Minter Ellison Consulting, 2002.

Parasites

Parasites are eukaryote organisms that generally belong to either of two major taxonomic groups: protozoa and helminths. Among parasites associated with fish and seafoods, most of those known to cause illness in humans are helminths (parasitic worms) and include nematodes (roundworms), cestodes (tapeworms) and trematodes (flat worms, or flukes). Over 50 species of helminths from fishes, crabs, snails and other molluscs are known to cause human illness. Those of most concern are:

- Nematodes – *Anisakis simplex*, *Pseudoterranova decipiens*, *Eustrongylides* spp. and *Gnathostoma* spp.
- Cestodes – Diphyllobothrium.
- Trematodes – *Clonorchis sinensis*, *Opisthorchis* spp., *Heterophyes* spp., *Metagonimus*, *Nanophyetes salminicola* and *Paragonimus*.

Of the protozoa, none have been implicated in food-borne illness due to seafood consumption in Australia and are not further considered in this report. One recent study has demonstrated the recovery of viable infective *Cryptosporidium parvum* oocysts from oysters (Fayer et al. 1998). The same study failed to detect *Giardia* cysts.

Nematodes (roundworms)

Anisakis simplex, *Pseudoterranova decipiens*, *Eustrongylides* and *Gnathostoma* are anisakid nematodes (roundworms) that have been implicated in human infections.

Pathology of illness: Anisakiasis is caused by ingestion of the larval stages of nematodes (Myjak et al. 1994). The illness is characterised by, nausea, vomiting and haematemesis. It is most frequently diagnosed when the affected individual feels a tingling or tickling sensation in the throat and coughs up or manually extracts a nematode. In more severe cases abdominal pain is accompanied by a nauseous feeling. Symptoms occur from as little as an hour to two weeks after consumption of raw or undercooked seafood (FDA 2003). It has also been reported that exposure to material from dead *A. simplex* may result in allergic reactions in some individuals, with symptoms ranging from mild, acute allergic retains to anaphylaxis and chronic, debilitating conditions (Audicana et al. 2002).

Once ingested, larval nematodes from fish or shellfish usually burrow into the wall of the digestive tract to the level of the muscularis mucosae and can occasionally penetrate the intestinal wall completely and are found in the body cavity. They produce a substance that attracts eosinophils and other host white blood cells to the area. The infiltrating host cells form a granuloma in the tissues surrounding the penetrated worm. In the digestive tract lumen the worm can detach and reattach to other sites on the wall. Anisakids rarely reach full maturity in humans and usually are eliminated spontaneously from the digestive tract lumen within three weeks of infection. Penetrated worms that die in the tissues are eventually removed by the host’s phagocytic cells (FDA 2003).

Infectious dose/dose response: Ingesting one nematode is believed to be sufficient to cause illness, and is the usual number removed from patients (FDA 2003).

Prevalence in seafood: *Anisakis simplex* has been isolated from many species of fish including: rockfish, herring, cod, halibut, mackerel, wild-caught salmon, yellowfin and skipjack tuna, and squid, from many regions of the world (FDA 2003; Hurst 1984). Reports from Japan include mussels, oysters, crawfish, lobster and prawns as sources of anisakid infections (Durborow 1999).

The rates of infection are often high with 10–90 per cent of samples carrying the parasite (Bouree et al. 1997). Multiple larvae in each fish are also commonly recorded. Table 4.10 lists the incidence and prevalence of *A. simplex* and other parasites in fish at retail sale around the world.

In Australia *A. simplex* has been isolated from flathead (*Platycephalus speculator*), mackerel (*Scomberomorus* spp.), mackerel tuna (*Euthynnus alleteratus*), striped trumpeter and farmed salmonids (Ross 2000; Humphrey 1995). It is not known, however, whether the strains isolated were pathogenic to humans.

Table 4.10: Incidence of *A. simplex* larvae in market fish

Market	Species	Infection rate (%)	No. of larvae per fish/fillet	Reference
Belgium	Pollock, whiting, catfish, ling, cod, saithe, redfish	4–83	7.8/kg fillet	Piccolo et al. 1999
Kuwait	83 species of fish	13		Sey & Petter 1997
Spain	Horse mackerel	39 26 (A. simplex)		Adroher et al. 1996
Korea	Anchovies Sea eel	7 58 (not all pathogenic)	1–2	Song et al. 1995 Chai et al. 1992
Paris	13 species including herring, redfish, hake	83–89		Huang 1988
Iran	Tuna Pike perch	75 20		Eslami & Mokhayer 1977
France	Saithe, whiting	'Frequent'		Chord-Auger et al. 1995
USA sashimi restaurants	Salmon, tuna, mackerel, rockfish	~10	max. 3	Adams et al. 1994
Italy	10 species	54 3/4 smoked fish	average > 6	Pacini et al. 1993
Taiwan	13 species	38	average = 14 max 80/fish	Chao 1985

Source: M&S Food Consultants 2001.

Epidemiological data: Helminthic parasites are sensitive to freezing and to relatively mild heating (that is, normal cooking temperatures). Consequently, those parasites associated with seafood are generally passed to humans by consumption of raw, minimally processed or inadequately cooked chilled products which are mostly associated with sociocultural and behavioural factors (Adams et al. 1997). Anisakiasis is a relatively common disease in Japan, largely because fish is often eaten raw, lightly cooked or pickled. Infection is also relatively common in northern Europe where cured fish, such as pickled herring, are part of the diet. In Japan the annual incidence of anisakiasis is greater than 1000 cases/annum (Deardorff & Overstreet 1991). In the United States, approximately 10 cases per year are reported but it is considered that many cases go unreported (FDA 2003).

Infections of *A. simplex* have been reported in New Zealand, however, there has been no documented case of food-borne anisakid infection in Australian (Goldsmid & Speare 1997).

Trematodes (flat worms, flukes)

Fish-borne flatworm (trematode) infections are a public health problem in about 20 countries, particularly in south-east Asia, where freshwater fish are intermediate hosts for *Clonorchis* and *Opistorchis* and freshwater crustaceans in the case of *Paragonimus*. In terms of human infection, the most important species are from the genera *Clonorchis* and *Opistorchis* (liver flukes), *Paragonimus* (lung flukes) and to a lesser extent *Heterophyes* and *Echinochasmus* (intestinal flukes). Human susceptibility to infection appears to be universal.

Pathology of illness: When eaten by the definitive host, the metacercariae (infective stage) of *C. sinensis* encyst in the duodenum, migrate into the bile duct and grow to adulthood. Symptoms may be slight or absent in light infections, the symptoms resulting from local irritation of the bile ducts by the flukes.

Loss of appetite, diarrhoea and abdominal pressure are early symptoms of infection, which may take up to 30 days to become apparent. Jaundice may result in enlargement and tenderness of the liver, and progressive ascites and oedema followed by cirrhosis, although this is rare. The organisms may live in human host for 25–30 years. Diarrhoea, epigastric pain, and anorexia are common manifestations of acute illness. Adult worms can produce localised tissue damage that may interfere with bile function, leading to secondary bacterial infection. It is usually a mild illness, and often asymptomatic, but is a significant risk factor for the development of carcinoma of the liver (Goldsmid & Speare 1997).

Levels in seafood: Reservoir hosts of *Clonorchis sinensis* are wild and domestic mammals. Metacercariae have also been found in crayfish. Metacercariae encyst in fish gills, fins, muscles or under the skin. Adult worms (1.2–2.4 cm long and 0.3–0.5 cm wide) reside in the bile duct. Pancreatitis and choleangiocarcinoma has also been reported (Shin et al. 1996).

Infection by *Paragonimus westermani* (human lung fluke) can occur through eating raw or improperly cooked freshwater crabs or crayfish. Important hosts include freshwater and brackish-water crabs of the genera *Eriocheir*, *Potamon*, and *Sundathelphusa* and the crayfish *Procambarus* (M&S Food Consultants 2001). Direct person to person transmission does not occur (Benenson 1995).

Hosts of the liver fluke include grass carp (*Ctenophargyndon idellus*) and silver carp (*Hypothalamicthys molitrix*), common aquaculture species in Asia (Durborow 1999).

Infective dose/dose response: No data are available on the infective dose for trematode infection. Infections with as many as 500–1000 worms have been reported (M&S Food Consultants 2001). Severity of symptoms is related to the intensity and duration of infection.

Incidence and outbreak data: Fish-borne trematode illness is highly endemic in south-east China but also in other parts of Asia. *Clonorchis sinensis* affects an estimated 7 000 000 people worldwide. It is the most common parasite in Hong Kong, where 30–60 per cent of the population are believed to be infected. Opisthorchiasis (*O. viverrini*) is a major cause of death in north-east Thailand and it is estimated that 7 million people are infected in that country. The infection is very common in Laos (Durborow 1999).

Cestodes (tape worms)

Cestodes are tapeworms with segmented bodies and a structure that allows them to attach to the intestinal wall of their hosts. *Diphyllobothrium latum* a broad tapeworm is the species of most concern. *D. latum* parasites are distributed worldwide. A similar species is found in the southern latitudes and is associated with seal hosts. Cases have been reported worldwide, including Australia. It is the largest human tapeworm, growing up to 10 metres (FDA 2003).

Fish are intermediate hosts and infective larvae have been found in trout, whitefish, pike and salmon. Cestode larvae found in fish range from a few millimetres to several centimetres in length and are white or grey in colour. *Diphyllobothrium* tapeworms primarily infect freshwater fish, but salmon and related fish can also carry the parasite. *Diphyllobothrium* tapeworms are usually found unencysted and coiled in musculature or encysted in viscera (M&S Food Consultants 2001).

Diphyllobothrium spp. have been reported to be present in Australian fish (Humphrey 1995) but there is little detail of the parasite species or species of fish affected.

Pathology of illness: Common symptoms are nausea, abdominal pain, diarrhoea and weakness, but infection may also cause pernicious anaemia and vitamin B12 deficiency if the worm attaches to the jejunum. *D. denderiticum* and *Ligula intestinalis* (tapeworms of fish eating birds) and *D. pacificum* (tapeworm of seals) have also been found in humans. The infection is usually mild, or even asymptomatic, and often of long duration. Massive infections may be associated with diarrhoea and obstruction of the intestinal tract, because the mature worm may be up to 10 metres long in the human host (FDA 2003; Goldsmid & Speare 1997).

People are universally susceptible to cestode infection, and there appears to be no induction of immunity (Benenson 1995). People of Scandinavian heritage may be genetically more susceptible to developing severe anaemia due to the tapeworm's great requirement for and absorption of Vitamin B12 (FDA 2003). Victims may harbour more than one worm and multiple worms can amplify the symptoms of infection (M&S Food Consultants 2001).

Epidemiological data: Infection is related to dietary and culinary practices. As with nematodes, human infections have been linked to consumption of raw or minimally processed fish. Freezing and cooking temperatures lethal for anisakids will kill the infective stage of *D. latum*.

Acanthocephala (spiny headed worms)

These burrowing worms are widespread in nature, infecting amphipod crustaceans, freshwater and marine fish, and other, non-aquatic, species. They are intestinal parasites, and may cause an inflammatory response at the site of proboscis attachment, although usually there are no clinical signs. Wild aquatic birds (such as ducks, swans and geese), dogs, pigs and monkeys are the definitive hosts. These worms are considered to pose little risk to humans because they are relatively scarce in the fish eaten by man, and because the worms are usually localised in the viscera of fish, and thus less likely to be eaten (M&S Food Consultants 2001).

Chemical contaminants

The chemical contaminants discussed here are algal biotoxins, histamines, ciguatoxins, escolar wax esters, arsenic, cadmium, lead, mercury and zinc.

Algal biotoxins

Algae form an important component of the plankton diet of shellfish such as mussels, oysters and scallops. Molluscan shellfish may accumulate toxins produced by toxic algae or other marine microorganisms, and these may present significant human health risks. Shellfish generally become toxic following a hazardous algal bloom where toxigenic species reach high levels in the water. Of the estimated 2000 living dinoflagellate species, about 30 species produce toxins that can cause human illness from shellfish or fish poisoning. When humans eat seafood contaminated by these toxins, they may suffer a variety of gastrointestinal and neurological illnesses. The most common syndromes are:

- paralytic shellfish poisoning
- diarrhoeic shellfish poisoning
- neurotoxic shellfish poisoning
- amnesic shellfish poisoning.

In addition to these classes of algal biotoxins, azaspiracids (AZAs) are recently identified cytotoxins which have been found in Northern European mussels (specifically in Ireland, United Kingdom and Norway), causing a diarrhoeic shellfish poisoning-like acute toxic response in a small number of outbreaks of food-borne illness. There is no evidence that AZAs are found in Australian or New Zealand shellfish, and although some risk might occur due to imports (for example, mussels from the United Kingdom), these toxins have not been explicitly considered in this report.

Paralytic shellfish poisons

Potentially toxic dinoflagellates responsible for paralytic shellfish poisoning in Australian waters include *Alexandrium (Gonyaulax) catenella* (Port Phillip Bay, South Australia, New South Wales), *Alexandrium minutum* (Port River, South Australia; Western Australia; Shoalhaven, New South Wales), *Alexandrium tamarense* (presumed toxic strains in Port Phillip Bay), *Gymnodinium catenatum* (Tasmania, Victoria, South Australia, New South Wales) and *Pyrodinium bahamense* var. *compressum* (potential for blooms in the Gulf of Carpentaria) (Hallegraeff 1991, Hallegraeff et al. 1991).

Bivalve molluscs are most at risk of accumulating toxic levels of paralytic shellfish poisons because of their ability to filter and accumulate particles suspended in the water column. Blue mussels, *Mytilus edulis*, can accumulate in excess of 20 000 µg saxitoxin/100 gram tissue (RaLonde 1996). There are about 20 toxins responsible for paralytic shellfish poisoning, all of which are derivatives of saxitoxin. Shellfish species from the same affected area may accumulate different concentrations of toxin.

Hazard identification and characterisation: Paralytic shellfish poisoning toxins block the sodium channels of excitable membranes of the nervous system and associated muscles, inhibiting action potentials and nerve transmission impulses (ANZFA 1999a).

Symptoms of poisoning usually occur within 30 minutes to 2 hours after ingestion of shellfish, depending on the amount of toxin consumed. A mild case can cause a tingling sensation or numbness around lips, gradually spreading to face and neck; prickly sensation in fingertips and toes; and headache, dizziness, nausea, vomiting, and diarrhoea. Extreme cases (high doses) can lead to paralysis of the diaphragm, respiratory failure, choking sensation and death (Hallegraeff 2003). Predominant manifestations include paraesthesia of the mouth and extremities, ataxia, dysphagia and muscle paralysis; gastrointestinal symptoms are less common. The prognosis is favourable for patients who survive beyond 12–18 hours. In unusual cases, because of the weak hypotensive action of the toxin, death may occur from cardiovascular collapse despite respiratory support (FDA 2003).

The extreme potency of the paralytic shellfish poisoning toxins has, in the past, resulted in an unusually high mortality rate. In a study of paralytic shellfish poisoning in Alaska between 1973 and 1992, 54 outbreaks involving 117 ill people were examined. Illness was not associated with the shellfish toxin concentration, method of food preparation, dose, race, sex, or age (Gessner & Middaugh 1995).

In humans 120–180 µg paralytic shellfish poisons can produce moderate symptoms, 400–1060 µg PSP can cause death, but 2000–10 000 µg is more likely to constitute a fatal dose (Hallegraeff 2003).

Incidence of human illness: Paralytic shellfish poisoning is caused by consumption of contaminated shellfish. Usually by consumption of mussels, clams, cockles and scallops or broth made from cooked shellfish that contain either concentrated saxitoxin, an alkaloid neurotoxin or related compounds (FDA 2003). Globally, paralytic shellfish poisons are responsible for some 2000 cases of human poisoning per year, with around 15 per cent mortality (Hallegraeff 2003).

Lehane (2000) has undertaken a comprehensive review of paralytic shellfish poisons which indicates that, while potentially lethal concentrations of paralytic shellfish poisons have been detected in shellfish, there have been no documented outbreaks in Australia. Table 4.11 lists the number and the annual rates of algal biotoxin-related illness in the United States and Australia for the years 1990–2000.

Table 4.11: Algal biotoxin related outbreaks of food-borne illness in Australia and the United States, 1990–2000

Country	Outbreaks	Cases	Cases/outbreak	Annual rate (per 100 000 population)
Australia	3	102	34	0.060
United States	9	125	14	0.005

Source: Extracted from M&S Food Consultants 2001; after Smith de Waal et al. 2000.

Concentrations in seafood: The results of monitoring for paralytic shellfish poisons in Port Phillip Bay and Western Port Bay in Victoria are shown in Table 4.12 (ANZFA 1999a).

Table 4.12: Paralytic shellfish poison results in mussels in Victoria

Year	No. of samples	No. of positive samples	Average concentration (all samples)(µg/100 g)	Highest concentration (µg/100g)
1987	11	0	0	0
1988	81	17	29.1	480
1989	88	3	2	66
1990	87	3	3.16	121
1991	34	5	15.4	185
1992	46	25	710.4	10009.6
1993	160	41	64.3	4127.7
1994	188	25	26.6	1286.8
1995	165	10	6.6	406.6
1996	161	0	0	0
1997	44	0	0	0

Extensive testing for PSP has also taken place in Tasmania in mussels, oysters and scallops. The results are shown in Table 4.13 (ANZFA 1999a).

Table 4.13: Paralytic shellfish poison results in Tasmania

Food	No. of samples	Average concentration (µg/100 g)	Range
Mussels	168	636	35–18429
Oysters	75	123	38–699
Scallops	6	60	56–83

Current regulations: A maximum level 0f 0.8 mg/kg for paralytic shellfish poisons (saxitoxin equivalent) has been established in Standard 1.4.1 – Contaminants and Natural Toxicants – of the Code.

Ranking of hazard: PSP is ranked as 'severe' in terms of adverse health effects (Section 3, Table 3) because of its potential to be life-threatening or cause chronic sequelae following acute exposure.

Diarrhetic shellfish poisons

Diarrhetic shellfish poisoning is caused by a group of high molecular weight polyethers, including okadaic acid, the dinophysis toxins and the pectenotoxins produced by the armoured dinoflagellate algae *Dinophysis fortii* and *D. acuminata*.

In this report, yessotoxins have also been considered as a subset of the diarrhoetic shellfish poisons, although this classification is under review due to apparent significant differences in structure and mode of action between yessotoxins and the 'true' DSPs, particularly okadaic acid and dinophysis toxins.

Potentially toxic diarrhoeic shellfish poisoning plankton dinoflagellates in Australian waters include the planktonic species *Dinophysis acuminata*, *D. caudata*, *D. fortii*, *D. hastata*, *D. mitra*, *D. rotundata*, *D. tripos* and the benthic dinoflagellates *Prorocentrum lima*, *P. elegans*, *P. hoffmannianum* and *P. concavum* (Morton & Tindall 1995). Dense blooms have occurred in Tasmanian and New Zealand waters, and can sometimes be completely non-toxic, but at other times shellfish can become toxic even when only sparse dinoflagellate populations are present (ANZFA 1999a).

Hazard identification and characterisation: No human fatalities have been reported due to diarrhoeic shellfish poisoning and patients usually recover within three days. Diarrhetic shellfish poisoning is generally a mild gastrointestinal disorder, that is, nausea, vomiting, diarrhoea, and abdominal pain accompanied by chills, headache, and fever. Onset of the disease, depending on the dose of toxin ingested, may be as little as 30 minutes to 2–3 hours, with symptoms of the illness lasting as long as 2–3 days (ANZFA 1999a). Recovery is complete with no after effects and the poisoning is generally not life threatening (FDA 2003). In extreme cases chronic exposure may promote tumour formation in the digestive system (Hallegraeff 2003).

The toxic dose may be as low as 80 µg (Council for Agricultural Science and Technology 1994).

Incidence of human illness: Diarrhoeic shellfish poisoning is usually caused by the consumption of contaminated mussels, oysters and scallops (FDA 2003).

Pipi shellfish poisoning events occurred in New South Wales (56 patients) in December 1997 and in 1998 (20 patients) circumstantially linked to lipid soluble toxins (Hallegraeff 2003).

Concentrations in seafood: Low concentrations of diarrhoeic shellfish poisoning toxins (generally <0.5 mg okadaic acid/gram) have been reported from New Zealand shellfish (Jasperse 1993).

Current regulations: A maximum level of 0.2 mg/kg for diarrhetic shellfish poisons (okadaic acid equivalent) has been established in Standard 1.4.1 – Contaminants and Natural Toxicants – of the Code.

Ranking of hazard: Diarrhoeic shellfish poison is ranked as 'serious' in terms of adverse health effects (Section 3, Table 3) because of its potential to cause incapacitating but not life-threatening illness following acute exposure.

<u>Amnesic shellfish poisons</u>

Amnesic shellfish poisoning is caused by domoic acid, produced by chain-forming diatoms. Toxigenic *Pseudo-nitzschia* blooms also occur in the waters of north-west United States, Japan, New Zealand, Spain and Portugal. In addition to bivalve shellfish, razor clams as well as the hepatopancreas and viscera of Dungeness crab have been found to be contaminated (Hallegraeff 2003).

To date, low concentrations of *P. multiseries* have been detected in New South Wales estuaries, but its toxicity has not yet been confirmed (Hallegraeff 1994). Blooms of *P. pseudodelicatissima* are common in Tasmanian and Victorian coastal waters, but all cultured strains as well as field samples have proved to be non-toxic (Hallegraeff 2003).

Hazard identification and characterisation: The causative compound, domoic acid, is an excitatory amino acid acting as a glutamate antagonist on the kainate receptors of the central nervous system (ANZFA 1999a).

A mild case of amnesic shellfish poisoning is characterised by gastrointestinal disorders (nausea, vomiting, diarrhoea, abdominal pain) and neurological problems (confusion, disorientation, memory loss, seizure, coma). The toxicosis is characterised by the onset of gastrointestinal symptoms within 24 hours, followed by neurological symptoms occurring within 48 hours (FDA 2003).

The toxicosis is particularly serious in elderly patients, and includes symptoms reminiscent of Alzheimer's disease. All fatalities to date have involved elderly patients (FDA 2003). The neurologic effects can persist for years (Benenson 1995). An extreme case is characterised by decreased reaction to deep pain; dizziness, hallucinations, and confusion; short-term memory loss; and seizures (Hallegraeff 2003).

While the general population is susceptible to this form of shellfish poisoning, the elderly are apparently predisposed to the severe neurological effects of the amnesic shellfish poisoning toxin.

A limited number of human mortalities have also been associated with amnesic shellfish poisoning in Canada, with immunodepressed patients being most at risk. Humans affected had consumed mussels containing 300–1200 µg/g of domoic acid (Hallegraeff 2003).

Incidence of human illness: Amnesic shellfish poisoning is usually caused by the consumption of contaminated mussels (FDA 2003). A serious outbreak of shellfish poisoning occurred in eastern Canada in 1987 from Blue Mussels where 22 individuals were hospitalised and three elderly died (FDA 2003).

Concentrations in seafood: To date the only positive detection of domoic acid in Australian shellfish refers to scallop viscera from Lakes Entrance, Victoria (August 1993) (one sample 26 µg/g; all others <20 µg/g) but the causative organism was not identified in that case (Sang et al. 1992; Arnott 1998).

Maximum concentrations of domoic acid detected in New Zealand mussels have been up to 187 µg/g (Marlborough Sounds, Dec. 1994) with scallop digestive glands containing up to 600 µg/g (Jasperse 1993; Rhodes et al. 1996).

Extensive routine monitoring has been conducted in Port Phillip Bay (Victoria) since 1987 and no domoic acid has been recorded in bay mussels and scallops. Domoic acid has been detected in scallops in Bass Strait with concentration ranging from 0.12–1.2 µg/g in the edible portion (ANZFA 1999a).

Current regulations: A maximum level 0f 20 mg/kg for amnesic shellfish poisons (domoic acid equivalent) has been established in Standard 1.4.1 – Contaminants and Natural Toxicants – of the Code.

Ranking of hazard: Amnesic shellfish poison is ranked as ‘severe’ in terms of adverse health effects (Section 3, Table 3) because of its potential to be life-threatening or cause chronic sequelae following acute exposure.

<u>Neurotoxic shellfish poisons</u>

Neurotoxic shellfish poisoning is the result of exposure to a group of polyethers called brevetoxins from the unarmoured dinoflagellate Gymnodinium breve. Similar dinoflagellates have also been identified in low concentrations in Victorian, South Australian and West Australian waters with recent evidence suggesting that raphidophyte blooms of Chattonella marina, and possibly the related genera Fibrocapsa and Heterosigma, can also produce brevetoxin-like compounds (Hallegraeff 1998).

Hazard identification and characterisation: Brevetoxins and their derivatives exert their toxic effect by specific binding to site-5 of voltage-sensitive sodium channels (ANZFA 1999a). The toxins implicated in neurological shellfish poisoning are considered to be primarily ichthyotoxins (fish killing toxins) (Hallegraeff 2003). In humans, the symptoms of a mild case of neurotoxic shellfish poison intoxication include chills, headache, diarrhoea; muscle weakness, muscle and joint pain; nausea and vomiting after a few minutes to 3–6 hours after ingestion (Hallegraeff 2003). Symptoms can last as long as 2–3 days (FDA 2003). An extreme case can cause paraesthesia; altered perception of hot and cold; difficulty in breathing, double vision, trouble in talking and swallowing. No human fatalities from brevetoxin poisoning have ever been reported (Hallegraeff 2003).

Recovery is complete with no after effects and is generally not life threatening.

Respiratory problems in humans occur at about 10^5–10^6 cells/litre, while fish mortality occurs at >10^6 cells/litre (Hallegraeff 2003). Toxin concentrations in shellfish during the 1993 New Zealand shellfish poisoning outbreak reached 592 MU/100 g (Hallegraeff 2003).

Incidence of human illness: Neurotoxic shellfish poisoning is usually associated with the consumption of contaminated shellfish (FDA 2003). Until recently all reports were endemic to the Gulf of Mexico and the east coast of Florida (Hallegraeff 2003). In 1993 a neurotoxic shellfish poisoning incident involving 180 people was reported in New Zealand. Concentrations of neurotoxic shellfish poisons reached 592 MU/100g (Trusewich et al. 1996).

Concentrations in seafood: In January 1994, mussels from Tamboon Inlet on the Gippsland coast of Victoria were found to contain 27.5 MU/100g in association with a *G. breve* type bloom (Arnott 1998). There is no other record of detection of neurotoxic shellfish poisons in Australia (ANZFA 1999a).

Current regulations: A maximum level of 200 MU/kg for neurotoxic shellfish poisons has been established in Standard 1.4.1 – Contaminants and Natural Toxicants – of the Code.

Ranking of hazard: Neurotoxic shellfish poison is ranked as 'serious' in terms of adverse health effects (Section 3, Table 3) because of its potential to cause incapacitating but not life-threatening illness following acute exposure.

Histamines

Scombroid poisoning (histamine poisoning) is associated with the ingestion of foods that contain high concentrations of histamine and possibly other vasoactive amines and compounds.

Histamine is a physiological amine involved in allergic reactions, and is the main toxin involved in histamine fish poisoning. Histamine production in fish is related to the histidine content of the fish, the presence of bacterial histidine decarboxylase, and environmental conditions. Bacterial decarboxylase enzymes acting on free histidine and other amino acids in the fish muscle form histamine and other biogenic amines (Lehane & Olley 1999).

Species in the scombroid group (tuna, mackerel, and sardines) have high histidine levels and are most frequently associated with scombroid poisoning. Non-scombroid species implicated in scombroid poisoning are Australian salmon (*Arripis trutta*), Yellowtail kingfish (*Seriola lalandi*), Mullet (*Mugil cephalus*), Oilfish (*Ruvettus pretiosus*) and Warehou (*Seriolella*), known in New Zealand as Kahawai (Fletcher et al. 1998; Lehane & Olley 1999).

Hazard identification and characterisation: Initial symptoms include tingling or burning sensation in the mouth, rash on the upper body and drop in blood pressure. Frequently, headaches and itching are encountered. The symptoms may progress to nausea, vomiting and diarrhoea that require hospitalisation, particularly in the case of elderly or impaired patients (FDA 2003).

The onset of intoxication is rapid, ranging from immediate to 30 minutes. The duration of the illness is usually three hours, but may last several days (FDA 2003).

Due to uncertainty about its aetiology it is difficult to determine the susceptible population for scombrotoxicosis. A wide range of histamine concentrations in implicated foods, particularly the increasing number of incidents associated with low histamine concentrations, suggests that some individuals are more susceptible to the toxin than others. Differences may be due to the activity of histamine-degrading enzymes in the stomach. Symptoms can be severe for the elderly (FDA 2003) and for those taking medications such as isoniazid, a potent histaminase inhibitor (Morinaga et al. 1997).

The toxic dose for histamine is not precisely known and scombroid poisoning has occurred at histamine concentrations as low as 50 mg/kg. However most incidents involve fish with histamine concentrations of 200 mg/kg and over (Fletcher et al. 1998).

Clifford and Walker (1992) suggest that neither histamine nor biogenic amines are responsible for scombrotoxicosis. Volunteers fed mackerel with 6000 mg/kg histamine reported only mild tingling around the mouth. Lehane and Olley (1999) speculate that urocanic acid may be the missing factor ('scombroid toxin') in histamine fish poisoning.

Incidence of human illness: Histamine fish poisoning is a food-borne chemical intoxication caused by the consumption of fish containing high concentrations of histamine and other biogenic amines.

There is little information on the incidence of scombroid poisoning in Australia, suggesting either that it is rare or that symptoms are not usually severe enough for victims to seek medical attention. Several incidents have been reported and are listed in Table 4.14.

Table 4.14: Histamine fish poisoning outbreaks in Australia and the United States, 1990–2000

Country	Outbreaks	Cases	Cases/outbreak	Annual rate (per 100 000 population)
Australia	10	28	3	0.0165
United States of America	103	680	7	0.0272

Source: Extracted from M&S Food Consultants, 2001; after Smith de Waal *et al*., 2000.

Several cases of histamine poisoning were recorded in New Zealand in the mid-1970s. Nineteen outbreaks were reported from 1990–93 all resulting from the consumption of smoked Warehou (Kahawai) and Mackerel (Mitchell 1993).

Scombroid poisoning results in around 10–15 outbreaks per year in the United States (Centre for Disease Control 1996). Between 40 and 50 scombroid poisoning incidents are reported in England and Wales each year affecting about 100 people.

The annual prevalence of scombrotoxicosis in the United States is approximately 0.03 cases/100 000 population (Table 4.15) and the United Kingdom incidence is approximately 0.07/100 000.

Table 4.15: Seafood-related outbreaks of histamine poisoning in Australia, 1990–2000

Date	Location	No. affected (deaths)	Species	Reference
1990	Adelaide	3	Australian Salmon	Smart 1992
1991	Adelaide	4	Australian Salmon	Smart 1992
1993	Brisbane	2	Tuna	Brown 1993
1999	NSW	4	Tuna	Voetsch 2000
1995	WA	>6	Pilchards	Ruello 1999
1997	Sydney	2	Marlin	Ruello 1999
1998	Sydney	>1	Yellow fin tuna	Ruello 1999
1999	Sydney	3	Yellow fin tuna	Ruello 1999
1999	Unknown	2	Yellow fin tuna	Ruello 1999
1999	Victoria	>1	Salmon rissoles	Ruello 1999

Source: Extracted from M&S Food Consultants 2001.

Concentrations in seafood: Fish that have been implicated in histamine poisoning include mackerel, tuna, saury, bonito, mahi-mahi, sardines, pilchards, anchovies, herring, marlin and bluefish, however some salmon species have also been implicated (Lehane & Olley 1999). Table 4.16 indicates concentrations of histamine found in a variety of seafood products. In New Zealand, Fletcher et al. (1998) found 8/107 retail samples of smoked fish in Auckland had >50 mg/kg.

Histamine concentrations of >1000 mg/kg were reported from 117/405 incidents of presumptive scombrotoxicosis in United Kingdom between 1987–96 and high concentrations have also been described in tuna steaks imported from Sri Lanka (>7000 mg/kg) and from canned tuna (245 and 3900 mg/kg) (Scoging 1998).

Random import sampling reveals a small percentage of samples exceed 100 mg/kg and, of those that do, most are rarely much greater than this concentration. Information from an Australian tuna cannery that each batch of frozen tuna bodies routinely did not exceed 100 mg/kg (Lehane & Olley 1999).

Current regulations: A maximum level of 200 mg/kg for histamine has been established in fish and fish products in Standard 2.2.3 – Fish and Fish Products – in the Ccode.
Ranking of hazard: Histamine is ranked as 'moderate' in terms of adverse health effects (Section 3, Table 3) because of its potential to be cause short-term self-limiting symptoms following acute exposure.

Table 4.16: Reported concentrations of histamine in seafood in Australasia

Country	Histamine concentrations	Reference
Australia retail chilled	10/11 (91%) not detected 1/11 (9%) <100 mg/kg	Rigg 1997
Smoked fish	13/13 (100%) not detected	
Dried fish	1/5 (20%) not detected 3/5 (60%) <100 mg/kg 1/5 (20%) 653 mg/kg 6/7 (85%) not detected	
Canned fish	1/7 (15%) <100 mg/kg	
Australia retail canned tuna	101/104 (98%) <50 mg/kg 3/104 (2%) in 50–100 mg/kg range	Warne 1987

Smoked fish New Zealand	98/107 (92%) not detected 6/107 (6%) in 50–200 mg/kg range 2/107 (2%) >200 mg/kg	Fletcher et al. 1998

Source: Extracted from M&S Food Consultants 2001.

Ciguatoxins

Ciguatoxins are known to originate from several dinoflagellate algae species (predominantly *Gambierdiscus toxicus*) that are common to ciguatera-endemic regions in tropical waters. The ciguatoxins are lipid-soluble toxins. These are relatively inert molecules, and remain toxic after cooking and exposure to mild acidic and basic conditions.

When herbivorous fish are eaten by carnivorous fish dinoflagellate toxin is converted to the more potent ciguatoxin (Durborow 1999). These toxins accumulate through the food chain, from small fish grazing on algae on coral reefs into the organs of larger top-order predators. Toxin is concentrated in the head, liver and viscera of fish (Ting et al. 1998), but concentrations are lower in the muscle, the part more usually eaten. The occurrence of toxic fish is sporadic and not all fish of a given species or from a given locality will be toxic (Benenson 1995). If fish cease ingesting the dinoflagellate the toxin will slowly be purged from the fish.

Pathology of illness: Initial signs of poisoning occur within six hours after consumption and include perioral numbness and tingling (paresthesia) which may spread to the extremities, nausea, vomiting, and diarrhoea. Neurological signs include intensified paresthesia, arthralgia, myalgia, headache, temperature sensory reversal and acute sensitivity to temperature extremes, vertigo, and muscular weakness to the point of prostration. Cardiovascular signs include arrhythmia, bradycardia or tachycardia, and reduced blood pressure (FDA 2003).

Ciguatera poisoning is usually self-limiting and signs of poisoning often subside within several days from onset. However, in severe cases the neurological symptoms persist from weeks to months and, in rare cases, for several years. There is a low incidence of death resulting from respiratory and cardiovascular failure (FDA 2003).

All humans are believed to be susceptible to ciguatera toxins. Populations in tropical/subtropical regions are most likely to be affected because of the relatively higher frequency of exposure to toxic fishes (FDA 2003). Repeated ciguatoxin exposures are associated with more severe illness (Glaziou & Martin 1993; Katz et al. 1993).

Infectious dose/dose response: Ciguatoxin-1 is the major toxin (on the basis of both quantity and total toxicity) present in fish (Murata et al. 1990; Lewis 1994), except for certain herbivorous species which accumulate mostly gambiertoxins and less polar ciguatoxins. Lehane (1999) estimated the minimum toxic dose to be ~50 ng in an adult of 50 kg weight (that is, ~1 ng/kg body weight), on the basis of outbreak data.

Mode of transmission: Ciguatera poisoning is caused by eating subtropical and tropical reef fish that have accumulated naturally occurring toxins produced by marine algae.

Incidence and outbreak data: Ciguatera poisoning gives rise to considerable morbidity in 25 000 to 50 000 people worldwide each year (Hahn & Capra 2003).

The epidemiological patterns of ciguatera differ markedly between Australia and the United States (Table 4.17). The annual reported rate of ciguatera poisoning in Australia between 1990–2000 is 0.3182 per 100 000 population compared to the United States which has an annual rate of 0.0131 per 100 000 population (M&S Food Consultants 2001).

Table 4.17: Seafood-borne outbreaks due to ciguatera poisoning in Australia and the United States, 1990–2000

Country	Outbreaks	Cases	Cases/outbreak
Australia	3	61	20
United States of America	75	328	4

Source: Extracted from M&S Food Consultants 2001; after Smith de Waal et al. 2000.

In Australia, ciguatera fish poisoning usually occurs as sporadic isolated cases (Fenner et al. 1997; Lucas et al. 1997), although at least two larger outbreaks (>30 cases) have been reported (Table 4.18; Hallegraeff 1998).

Table 4.18: Ciguatera poisoning related outbreaks of food poisoning in Australia 1990–2000

Date	Location	No. affected (deaths)	Reference
1991	Darwin	3	Merianos et al. 1991
1994	Sydney	43	Capra 1997
1995	Queensland	15	Harvey 1995
Annual	Queensland	48	Lehane & Lewis 2000

Source: Extracted from M&S Food Consultants 2001.

The incidence of ciguatera in Australia is skewed geographically, with Queensland bearing the major burden. A wide variety of fish species have been implicated in outbreaks in Queensland (Table 4.19).

Table 4.19: Cases of ciguatoxin illness in Queensland 1965–84

Scientific name (common name)	No. of cases	No. of outbreaks
Scomberomorus commerson (Spanish mackerel)	226	30
Scomberomorus spp (mackerels, species unknown)	161	62
Sphyraena jello (barracuda)	29	13
Plectropomus spp (coral trout)	27	18
Epinephelus fuscoguttatas (flowery cod & other epinephalids)	27	14
Lutjanus sebae (red emperor) and *Lutjanus bohar* (red bass)	16	9
Scomberoides commersonnianus (giant dart)	8	3
Lethrinus nebulosa (yellow sweetlip)	4	1
Seriola lalande (yellowtail kingfish and other seriolids)	6	1
Caranx sp (trevally, species unknown)	4	2
Cephalopholis miniatus (coral cod)	3	2
Chelinus trilobatus (maori wrasse)	3	3
Choerodon venustus (venus tusk fish)	2	1
Trachinotus sp (dart)	1	1

Paracesio pedlryi (southern fuselier)	1	1
Lates calcarifer (barramundi)	1	1
Other and unknown	14	16

Source: Extracted from M&S Food Consultants 2001; after Gillespie et al. 1986.

In Queensland, several thousand cases were notified to authorities over a 10-year period (Ting et al. 1998) with an estimated 1.8–2.5 per cent of the population in that state affected (Glaziou & Legrand 1994; Lehane 1999). The average incidence in Queensland during the period 1985–90 was 1.6 cases/100 000, although in coastal Queensland the annual prevalence was estimated at 33/100 000 (Capra & Cameron 1988).

Forty-one cases of ciguatera poisoning in New South Wales have been reported for the period 1996–98, although the list was not comprehensive (M&S Food Consultants 2001). Due to under-reporting of this often mild illness, these data represent the minimum prevalence in New South Wales. There have also been several large outbreaks in Sydney at restaurants. In 1987, 63 people became ill after eating Spanish Mackerel (*Scomberomorus commerson*) which had been caught in Hervey Bay, Queensland.

Concentrations in seafood: Mackerel and barracuda from mid to north-eastern Australian waters have been reported to be frequently ciguatoxic (Price & Tom 1999).

Escolar wax esters

Escolar or oilfish (*Lepidocybium flavobrunneum*, *Ruvettus pretiosus*) contain a strong purgative oil, sometimes called gempylotoxin, that may cause diarrhoea when consumed (FDA 2001). Both species are significant bycatches (of the order of 400 tonne/annum) from tuna longlines on the east and west coasts of Australia (Shadbolt et al. 2002).

Pathology of illness: The diarrhoea caused by eating the oil contained in the flesh and bones of these fish develops rapidly and is pronounced (Warrington 2001). Symptoms range from mild and rapid passage of oily yellow or orange droplets, to severe diarrhoea with nausea and vomiting (Shadbolt et al. 2002). In reports of up to 88 cases (41 incidents) in South Australia in the period 1997–99 (Delroy, personal communication), 25 per cent of cases reported stomach/abdominal pain or cramping. There is probably a significant under-reporting of illness associated with consumption of these fish as the symptoms can be mild and short-lived. The onset of symptoms occurs with a median of 2.5 hours and a range of 1 to 90 hours after consumption (Shadbolt et al. 2002).

Infectious dose/dose response: There are no data on the amount of wax ester likely to cause illness. The question of whether there is general susceptibility to diarrhoea from consumption of the wax esters has not been resolved, and is complicated by the oil content of oilfish species varying between individual fish and across the cross-section of individual fish fillets (Yohannes et al. 2002).

Levels in seafood: *Lepidocybium flavobrunneum* (escolar) and *Ruvettus pretiosus* (oilfish) contain approximately 20 per cent (by weight) of indigestible wax ester oil (Nichols et al. 2001).

Epidemiological data: There have been several outbreaks of wax ester diarrhoea recorded in Australia in recent years (Shadbolt et al. 2002; Gregory 2002; Givney 2002; Yohannes et al. 2002).

Ranking of hazard: Escolar wax esters are ranked as 'moderate' in terms of adverse health effects (Section 3, Table 3).

Arsenic

Arsenic is ubiquitous and occurs naturally in both organic and inorganic forms. People are exposed to arsenic through the environment (primarily via the skin and by inhalation), food and water ingestion and through some workplaces.

Inorganic arsenic is the toxic form of arsenic for humans. There is little information on the organic forms of arsenic in terms of their toxicological properties, but it appears that they are much less toxic than the inorganic forms. Limited studies indicate that people who consume large quantities of organic arsenic in fish do not show any ill effects. Drinking water contains largely the inorganic form of arsenic, whereas food contains more than 90 per cent of its arsenic in the organic form.

Regulation of arsenic in seafood: FSANZ set maximum levels for arsenic in foods during its review of the Ccode in 1999. Proposal P157 – Contaminants in Food – Metals assessed which foods contributed significantly to dietary exposure to arsenic and set levels accordingly (Table 4.20).

Table 4.20: Maximum levels for arsenic in seafood in the Code

Commodity	ML (mg/kg)
Crustacea	2
Fish	2
Molluscs	1

Hazard identification and characterisation: The most relevant toxicological data, other than industrial exposure, are derived from studies of human populations exposed to arsenic in drinking water. Skin lesions, including hyperkeratosis and pigmentation, are characteristic and the most sensitive indicators of long-term toxicity of inorganic arsenic. Chronic arsenic exposure is associated with a multiplicity of cancers.

The lowest observed effect level of 0.0029 mg/kg bw/day for inorganic arsenic is based on population studies done in Taiwan, where drinking water exposures for periods of 12 years to whole-of-life were associated with cancers (skin, liver, bladder, lung). This level is effectively a lowest observed effect level for arsenic intake, but has also been shown to be indicative of a 'threshold' value, below which increased incidence of skin cancer could not be associated with arsenic exposure. This level, rounded-off to 0.003 mg/kg bw/day was taken to be the provisional tolerable daily intake (PTDI) for inorganic arsenic for the purpose of a previous risk assessment on arsenic in food performed by FSANZ under the review of the Code.

Recent surveys on arsenic in seafood: Oysters, smoked fish fillets, seafood sticks and canned red salmon were examined for inorganic arsenic in the 1994 Australian Market Basket Survey. Inorganic arsenic was not detected in the smoked fish fillets, seafood sticks and canned red salmon but low concentrations, ranging from not detected to 0.34 mg/kg with an average of 0.0773 mg/kg, were detected in oysters (Marro 1996).

Inorganic arsenic was also examined in calamari, estuarine fish fillets, battered flake fillets and canned tuna in the 1996 Australian Market Basket Survey. All samples were below the Limit of Reporting (0.05 mg/kg) (Hardy 1998).

Fish fillets, mussels, canned crab and canned red salmon were analysed for inorganic and total arsenic in the 19th Australian Total Diet Survey (FSANZ 2001). All samples were below the Limit of Reporting (0.05 mg/kg) except for the mussels, in which levels of up to 0.56 mg/kg were detected, with a median level of 0.153 mg/kg.

Prawns, fish fillets and portions, and canned tuna were analysed for inorganic and total arsenic in the 20th Australian Total Diet Survey (FSANZ 2003). All samples were below the Limit of Reporting (0.05 mg/kg).

Dietary exposure to arsenic: The main seafoods contributing to inorganic arsenic dietary exposure (>5%) from food alone were prawns (52%) and marine fish (14%). Although other seafood such as crabs, mussels and oysters are significant sources of inorganic arsenic per kilogram of food, the relatively small consumption levels of these foods means they do not make a significant contribution to mean inorganic arsenic dietary exposure for the whole population (ANZFA 1999b).

Dietary exposure estimates for high consumers of single food commodity groups indicate that high fish consumers could receive up to 4 per cent of the PTDI for inorganic arsenic, and that high consumers of molluscs and crustacea could receive up to 6 per cent and 18 per cent of the PTDI for inorganic arsenic respectively, assuming that the inorganic content of seafood is 6 per cent of the total arsenic content and assuming that these consumers eat molluscs and crustacea every day over a lifetime (ANZFA 1999b).

Ranking of hazard: Arsenic is ranked as ‘severe’ in terms of adverse health effects (Section 3, Table 3) because of its potential to be life-threatening or cause ongoing illness following chronic exposure.

Cadmium

Cadmium is a metallic element that occurs naturally at low levels in the environment. In Australia and New Zealand, the major source of cadmium in foods is via the soil, with plants playing a central role in the transfer of cadmium from the environment to humans. In the case of seafood, the level of cadmium in the sediment is an important determinant for cadmium levels in the animal.

Regulation of cadmium in seafood: The Code currently lists a maximum limit of 2 mg/kg for cadmium in molluscs (excluding dredge/bluff oysters). There is no maximum limit for fish, crustacea or calamari.

Hazard identification and characterisation: The most sensitive toxicological concern from cadmium exposure is long-term kidney damage. The provisional tolerable weekly intake (PTWI) of 7 µg/kg bw is based on the most sensitive parameter for kidney damage, namely, an increase in the urinary excretion of low molecular weight protein as a result of reduced re-absorption in the renal tubules. Toxicity is manifested only after many years of slow accumulation of cadmium in the renal cortex and then only if a critical concentration is achieved.

However, the toxicological significance of this observed change with respect to kidney damage is still not established, as it is clear that the excretion of low molecular weight proteins normally increases with age. Food-borne cadmium is recognised as the major source of exposure for the majority of the population.

In June 2003, JECFA maintained the current PTWI based on an evaluation of new data submitted on cadmium in humans. The Committee reaffirmed its previous conclusions that an effect on the kidney (renal tubular dysfunction) is the critical health outcome with regard to cadmium toxicity.

Recent surveys on cadmium in seafood: Seafoods analysed in the 1992 Australian Market Basket Survey reported concentrations of cadmium in fish fillets from not detected to 0.04 mg/kg; prawns from not detected to 0.58 mg/kg and canned tuna from not detected to only trace amounts (Stenhouse 1994).

Seafoods analysed in the 1994 Australian Market Basket Survey reported concentrations for cadmium in smoked fish fillets ranging from a minimum of not detected to a maximum of 0.02 mg/kg; oysters ranging from a minimum of 0.16 mg/kg to a maximum 0.91 mg/kg; canned red salmon ranging from a minimum of not detected to only trace amounts; and seafood sticks ranging from a minimum of only trace amounts to 0.06 mg/kg (Marro 1996).

Seafoods analysed in the 1996 Australian Market Basket Survey reported concentrations of cadmium in canned tuna ranging from a minimum of 0.012 mg/kg to a maximum 0.07 mg/kg; for calamari rings concentrations ranged from a minimum of 0.022 mg/kg to a maximum of 0.143 mg/kg; for battered flake fillets concentrations ranged from a minimum of only trace amounts to a maximum of 0.06 mg/kg, and for estuarine fish cadmium was not detected (Hardy 1998).

Canned crab, fish fillets, mussels and canned red salmon were analysed for cadmium in the 19th Australian Total Diet Survey (FSANZ 2001). Levels detected (minimum, maximum, median; units mg/kg) were: canned crab (0.08, 0.39, 0.18); fish fillets (not detected, 0.02, 0.003); mussels (0.26, 0.93, 0.48); and canned red salmon (0.004, 0.006, 0.005).

Prawns, fish fillets and portions, and canned tuna were analysed for cadmium in the 20th Australian Total Diet Survey (FSANZ 2003). Levels detected (minimum, maximum, median; units mg/kg) were: prawns (0.011, 0.500, 0.078); fish fillets (not detected, 0.053, not detected); fish portions (not detected, 0.110, not detected); and canned tuna (0.011, 0.030, 0.018).

Dietary exposure to cadmium: A recent dietary exposure assessment was performed in 2000 by FSANZ (unpublished). The mean dietary exposure for the whole population was 13–16 per cent of the PTDI and for high consumers was 34–41 per cent. No high consumers of any single frequently consumed food exceed the PTDI. Fish, molluscs and crustaceans did not make a significant contribution (>5%) to the overall dietary cadmium exposure for Australian consumers (fish 1.4%; crustaceans 3.5; oysters 1.4%).

Dietary exposure to cadmium for the median consumer from oysters (occasionally consumed foods) was 52 per cent of PTDI and for mussels was 7.9 per cent for Australian consumers. High consumers of prawns represented 8.8 per cent of the PTDI.

Ranking of hazard: Cadmium is ranked as 'severe' in terms of adverse health effects (Section 3, Table 3) because of its potential to be life-threatening or cause ongoing illness following chronic exposure.

Lead

Lead is found widespread in the environment and also in food and drinks as metallic lead, inorganic ions and salts and organometallic compounds. Lead is not easily extracted from the soil by plants and its occurrence in plants is often due to air pollution, leading to contamination of the plant surface. The occurrence of lead in food and drinks is mainly due to many years of use of lead technology and in particular to the use of alkyl-lead compounds as petrol additives. Lead fulfils no essential functions in mammals, but has a number of adverse effects including neurotoxicity at exposure levels that may be reached fairly easily.

Exposure to lead can affect many different organ systems, the most sensitive being the nervous system of children. Humans are exposed to lead via multiple exposure pathways with a significant route via food where lead contaminated soil and dust find its way into the food and water supply.

Regulation of lead in seafood: FSANZ set maximum levels for lead in foods during its review of the Code in 1999. Proposal P157 – Contaminants in Food – Metals assessed which foods contributed significantly to dietary exposure to lead and set levels accordingly (Table 4.21).

Table 4.21: Maximum levels for lead in seafood in the Code

Commodity	ML (mg/kg)
Fish	0.5
Molluscs	2

Hazard identification and characterisation: Studies have shown excessive exposure to lead can affect many different organ systems, and biochemical and physiological processes in both animals and humans, the most sensitive being the nervous system. Lead exposure is cumulative in nature with long half-lives (up to 27 years in various bone compartments).

The available data suggests that the developing brain is more at risk from lead exposure compared to the mature brain. This has been supported by cross-sectional epidemiological studies. Differences between children and adults in several aspects contribute to the greater susceptibility of children to lead toxicity. These include the higher metabolic rates and rapid growth rates compared to adults; immaturity of organ systems (namely the nervous and immune systems); the higher energy requirements for children reflected in their dietary intakes (and hence the intake of contaminants per unit body weight); and the unique behavioural characteristics (for example, heightened hand-to-mouth activity), which may result in significant exposure to lead from non-food sources.

JECFA established a Provisional Tolerable Weekly Intake of 25 µg/kg bw (equivalent to a PTDI of 3.5 µg/kg bw/day) for all age groups (WHO 1987). In 1999, JECFA maintained this PTWI at its 53rd meeting and concluded that the results of a recent risk assessment suggest that concentrations of lead in food would have negligible effects on neurobehavioral development of infants and children (WHO 2000).

Recent surveys of lead in seafood: Fish fillets, prawns and canned tuna were examined for lead in the 1992 Australian Market Basket Survey. Concentrations of lead ranging 'not detected' to 0.2 mg/kg; were reported for fish fillets, 'not detected' to 'trace' level for prawns and 'not detected' to 0.1 mg/kg for canned tuna Stenhouse 1994).

Smoked fish fillets, oysters, canned red salmon and seafood sticks were examined for lead in the 1994 Australian Market Basket Survey. Concentrations of lead ranged from 'not detected' to 'trace' level for smoked fish fillets, canned red salmon, and seafood sticks; and 'trace' level to 0.61 mg/kg for oysters (Marro 1996).

Canned tuna, calamari rings, battered flake fillets and estuarine fish were examined for lead in the 1996 Australian Market Basket Survey. Concentrations of lead ranged from 'trace' level to 0.018 mg/kg in canned tuna; 'trace' level to of 0.89 mg/kg for calamari rings; 'not detected' to 0.082 mg/kg for battered flake fillets; and ' not detected' to a 'trace' level for estuarine fish (Hardy 1998).

Canned crab, fish fillets, mussels and canned red salmon were analysed for lead in the 19th Australian Total Diet Survey (FSANZ 2001). Levels detected (minimum, maximum, median; units mg/kg) were: canned crab (0.02, 0.04, 0.03); fish fillets (not detected, 0.007, not detected); mussels (0.05, 1.10, 0.11); and canned red salmon (not detected, 0.006, 0.005).

Prawns, fish fillets and portions, and canned tuna were analysed for lead in the 20th Australian Total Diet Survey (FSANZ 2003). Levels detected (minimum, maximum, median; units mg/kg) were: prawns (not detected, 0.05, not detected); and fish fillets (not detected, 0.02, not detected). There were no levels above the limit of reporting (0.01 mg/kg) for samples of fish portions and canned tuna.

Dietary exposure to lead: The mean total dietary exposure to lead for all respondents ranged from 2–6 per cent PTDI, and for high consumers, 6 per cent of the PTDI. For groups considered at risk from lead exposure (namely, 2-year-old children) total dietary exposure to lead was 5–17 per cent PTDI for mean consumers and 15–35 per cent for high consumers (ANZFA 1999b).

Ranking of hazard: Lead is ranked as 'severe' in terms of adverse health effects (Section 3, Table 3) because of its potential to be life-threatening or cause ongoing illness following chronic exposure.

Mercury

Mercury occurs naturally in the environment as elemental, inorganic and organic mercury. Methylmercury, a form of organic mercury, is the most hazardous form of mercury encountered in food. Fish and other seafood is the main source of exposure to methylmercury for most individuals.

Methylmercury is largely produced from the methylation of inorganic mercury by certain microorganisms present in marine and freshwater sediments. Once produced, methylmercury is rapidly taken up and concentrated by filter feeding organisms, upon which other fish feed. This process results in the steady accumulation of methylmercury in the aquatic food chain, with all fish containing small amounts of methylmercury in their muscle tissue. Those species at the top of the food chain (for example, predatory fish or marine mammals) tend to accumulate the largest amount of methylmercury.

Regulation of mercury in seafood: FSANZ set maximum levels for mercury in foods during its review of the Ccode in 1999. Proposal P157 (Contaminants in Food – Metals) assessed which foods contributed significantly to dietary exposure to mercury and set levels accordingly (Table 4.22). FSANZ is currently reviewing its risk assessment for mercury due to JECFA's recent lowering of the PTWI.

Table 4.22: Maximum limits for mercury in seafood commodities in the Code

Commodity	ML (mg/kg)
Crustacea	Mean level of 0.5
Fish (as specified in Schedule 4 to Standard 1.4.2) and fish products, excluding gemfish, billfish (including marlin), southern bluefin tuna, barramundi, ling, orange roughy, rays and all species of shark	Mean level of 0.5
Gemfish, billfish (including marlin), southern bluefin tuna, barramundi, ling, orange roughy, rays and all species of shark	Mean level of 1
Fish for which insufficient samples are available to analyse in accordance with clause (6)	1
Molluscs	Mean level of 0.5

Hazard identification and characterisation: Methylmercury is readily (>95%) absorbed from the gut following ingestion and is rapidly distributed via blood to the tissues, including the brain where it accumulates and is slowly demethylated to inorganic mercury. The major routes of excretion are through the bile and faeces, with lesser amounts in urine.

The toxic effects of methylmercury, particularly on the nervous system, are well documented and an extensive body of literature is available. Most of what is known about effects in humans has been derived from investigations of large-scale poisoning episodes in Japan and Iraq, although more recently attention has focused on effects following chronic low-dose exposures through fish consumption. The severity of the effects depends largely on the magnitude and duration of the dose, with effects in adults occurring at much higher levels of exposure than those linked to effects in children following in utero exposure. The developing nervous system is thus considered the most sensitive target for toxicity, with the critical exposure period being during in utero development when the foetus is undergoing very rapid neurological development.

In the adult, the first effect observed following exposure to high levels of methylmercury is typically paraesthesia (numbness and tingling in lips, fingers and toes), which frequently appears some months after the exposure first occurred. In severe cases, there is progression to loss of coordination, narrowing of the visual fields, hearing loss and speech impairment, paralysis and death. The lowest observed effect level or threshold dose for neurological effects in adults following short to medium-term exposure to methylmercury is 200 ppb blood mercury (equivalent to 50 ppm hair mercury or an estimated intake of 2.8 µg/kg bw/day) (WHO 1990). The applicability of this level to chronic low-level exposure (for example, from fish consumption) is uncertain.

In the infant, following in utero exposure through maternal fish consumption, the effects observed typically manifest as decreased scores on tests that measure neurocognitive and fine motor function. A level of maternal hair mercury estimated to be without appreciable adverse effects in the offspring of fish eating populations is 14 ppm (equivalent to 56 ppb blood mercury or an intake of 1.5 µg/kg bw/day) (JECFA 2003).

A PTWI for methylmercury of 3.3 µg/kg bw was established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1988 (WHO 1990). This level was considered protective of the general population, but not the developing foetus. In June 2003, JECFA established a lower level of 1.6 µg/kg bw, to take account of the most sensitive population subgroup (JECFA 2003).

Recent surveys of mercury in seafood: Although methylmercury is of primary interest, surveys of contaminants in food typically only measure total mercury. However, about 95 per cent of mercury in fish is in the organic form, principally as methylmercury (Bloom 1989; Swan 1998). Mercury concentrations in most commercially harvested oceanic fish in Australia are <0.5 mg/kg methyl mercury, but larger species, predators and long-lived species tend to accumulate much higher concentrations.

Over the past two decades there have been several surveys of Australian finfish (Table 4.23), all of which have found that most seafood contains low concentrations of mercury (New South Wales Health Commission 1978; Working Group on Mercury in Fish 1979; Western Australian Food Monitoring Program 1993; Bureau of Resource Sciences 1997a and 1997b; White 1999).

In a New South Wales survey, 3/26 shark samples and 3/8 swordfish samples exceeded the 1 mg/kg (White 1999). The maximum concentration of mercury found in shark and swordfish in this survey was 2.3 mg/kg and 1.65 mg/kg, respectively. Several other recent surveys have found fish with mercury concentrations above 1 mg/kg. The 1989–1993 New South Wales health survey found that nearly 3 per cent of 1095 fish samples, all shark and swordfish, exceeded 1 mg/kg.

Canned crab, fish fillets, mussels and canned red salmon were analysed for mercury in the 19th Australian Total Diet Survey (FSANZ 2001). Levels detected (minimum, maximum, median; units mg/kg) were: canned crab (0.03, 0.07, 0.04); fish fillets (0.04, 1.30, 0.18); mussels (0.009, 0.04, 0.02); and canned red salmon (0.03, 0.05, 0.03).

Prawns, fish fillets and portions, and canned tuna were analysed for zinc in the 20th Australian Total Diet Survey (FSANZ 2003). Levels detected (minimum, maximum, median; units mg/kg) were: prawns (0.01, 0.048, 0.016); fish fillets (0.005, 0.05, 0.016); fish portions (0.042, 3.50, 0.25); and canned tuna (0.13, 0.31, 0.16).

Dietary exposure to mercury: During its review of metal contaminants in foods, ANZFA concluded that there is potential for consumers to exceed the PTDI set for mercury, especially from eating marine fish, the main contributor to mercury dietary exposure (ANZFA 1999b).

Dietary modelling conducted as part of that risk assessment determined that the exposure to mercury for the general population from a range of foods is well below the PTDI, at up to 23 per cent for mean consumers and up to 89 per cent for 95th percentile consumers. For adults consuming fish at a median level (70 grams fish/day) every day, the PTDI for adult neurological effects is approached (96% PTDI) assuming all fish is predatory, but not if all fish is non-predatory (30% PTDI). However, for high consumers of fish (adults consuming fish alone at the 95th percentile level – 321 grams fish/day) the PTDI for adult neurological effects is exceeded regardless of whether all fish is predatory (438% PTDI) or non-predatory (137% PTDI).

As a result of that review, ANZFA developed an advisory statement for pregnant women informing them about the amounts and types of fish that are safe to consume during pregnancy, as the foetus is the most vulnerable to the effects from mercury.
However, several factors have led to FSANZ instigating a review of its mercury risk assessment, particularly with regard to fish consumption.

The lowering of the PTWI by JECFA and the availability of a significant amount of recent data on mercury levels in a far greater number of fish species are allowing a complete and thorough revision of the dietary modelling, and the outcomes of this work are expected to lead to a reconsideration of existing risk management options for mercury in foods.

Table 4.23: Mercury concentrations in predatory fish in Australia

	Mean mercury levels (mg/kg) – number of samples in parentheses			
	NSW Health Commission 1978	Working Group on Mercury in Fish 1979	WA Food Monitoring Program 1993	White 1999
Gemfish	–	0.68 (148)	–	–
Tuna, Skipjack	–	0.15 (20)	–	–
Tuna, Southern Bluefin	–	0.22 (219)	–	–
Tuna, Yellow Fin	–	0.38 (20)	–	–
Swordfish	1.98	–	–	0.98 (8)
Marlin, Black	–	7.27 (42)	–	0.57 (3)
Shark	–	–	–	–
Angel	–	0.36 (36)	–	–
Blacktip Whaler	–	1.48 (8)	0.41 (14)	–
Blue Pointer	–	1.93 (2)	0.83 (2)	–
Blue Whaler	–	0.41 (2)	–	–
Bronze Whaler	–	0.72 (159)	0.52 (33)	–
Carpet	–	1.02 (76)	0.69 (12)	–
Gummy	–	0.44 (507)	0.29 (4)	–
'Shark'	–	–	–	0.48 (26)

Source: Extracted from M&S Food Consultants 2001.

Ranking of hazard: Mercury, in the form of methylmercury, represents a severe hazard for the developing foetus, which may exhibit adverse effects of long duration at a much lower level of exposure than in the general population. For the general population, mercury is ranked as a serious hazard (Section 3, Table 3). The effects can be debilitating, with the possibility of on going chronic sequelae.

Zinc

Zinc is an essential element that is found in a wide variety of foods at relatively low levels. Diet is the main source of zinc for consumers. Additional sources of exposure may occur from drinking water stored in old galvanised containers and dietary supplements may also add to the daily zinc burden.

Regulation of zinc in seafood: There is no maximum limit for zinc in seafood specified in the Code. However, following a review, generally expected levels were established for specific seafood commodities in order to identify the minimum level of contamination that is reasonably achievable, and to provide a trigger for remedial action if a level is exceeded (Table 4.24).

Table 4.24: Guideline generally expected levels for zinc in seafood

Commodity	GELs median (mg/kg)	GELs 90th percentile (mg/kg)
Crustacea	25	40
Fish	5	15
Oysters	130	290

GELs = generally expected levels

Hazard identification and characterisation: Limited human toxicological data are available for determining the maximum tolerable intake for zinc. Vomiting and fever after acute exposures, and damage to kidneys and pancreas after sub-chronic and chronic exposures in animals have been observed at dietary levels above 1000 mg/day. Copper and iron deficiencies have been documented in animals and in humans exposed to chronically high intake of zinc.

Interaction with other nutrients especially copper, where its absorption and utilisation is influenced at a biochemical level has been observed at intakes as low as 60 mg/day, when zinc was taken as a supplement to the diet. Biochemical changes observed at 60 mg/day were interpreted as the first indicator that the copper-dependent processes were affected.

JECFA established a PTDI of 1 mg/kg bw in 1982. To ensure that very few individuals in a population have an intake of 60 mg/day or higher, a WHO/FAO/IAEA Expert Consultation (1996) recommended that the adult population mean intake should not exceed 45 mg/day, assuming a 20 per cent variation in intake. The PTDI for zinc, for the purposes of a previous risk assessment by FSANZ was set at 1 mg/kg bw, based on a 60 kg adult.

Recent surveys on zinc in seafood: Smoked fish fillets, oysters, canned red salmon and seafood sticks were examined for zinc in the 1994 Australian Market Basket Survey. Concentrations of zinc ranged from 3.7 mg/kg to 12 mg/kg for smoked fish fillets; 6.4 mg/kg to 14 mg/kg for canned red salmon; 1.7 mg/kg to 2.6 mg/kg for seafood sticks; and 120 mg/kg to 660 mg/kg for oysters (Marro 1996).

Canned crab, fish fillets, mussels and canned red salmon were analysed for zinc in the 19th Australian Total Diet Survey (FSANZ 2001). Levels detected (minimum, maximum, median; units mg/kg) were: canned crab (22.0, 49.0, 25.0); fish fillets (3.6, 11.0, 6.3); mussels (13.0, 63.0, 26.0); and canned red salmon (5.7, 9.9, 8.1).

Prawns, fish fillets and portions, and canned tuna were analysed for zinc in the 20th Australian Total Diet Survey (FSANZ 2003). Levels detected (minimum, maximum, median; units mg/kg) were: prawns (7.8, 17.0, 12.0); fish fillets (2.9, 5.4, 3.7); fish portions (3.4, 11.0, 5.0); and canned tuna (6.6, 12.0, 8.7).

Dietary exposure to zinc: The mean total dietary exposure to zinc for all respondents ranged from 19–20 per cent PTDI. The dietary exposure estimates for high consumers of single food commodity groups indicated that consumers of oysters might receive relatively high levels of zinc from this source compared to any other food. Oysters are considered a food that is ‘occasionally consumed’ and the median consumption level was taken to be a representative level of consumption for a high consumer. Total dietary exposure to zinc for high consumers of oysters, assuming mean exposure from all other foods, is estimated to be 38 per cent of the PTDI (ANZFA 1999b).

Ranking of hazard: Zinc is ranked as 'moderate' in terms of adverse health effects (Section 3, Table 3). Acute exposure to high levels has an emetic effect of short duration.

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Attachment 10

Draft variation to the *Australia New Zealand Food Standards Code*

To commence: 12 months from gazettal

Note on commencement: Subclause 1(2) of Standard 1.1.1 applies to these amendments to the Food Standards Code. The effect of this subclause is that a food is taken to comply with Standard 4.2.1 (below) for a period of 12 months after the commencement of the Standard, provided the food otherwise complied with the Food Standards Code. Effectively, this means that seafood producers have 2 years from the gazettal of Standard 4.2.1 before they are required to comply with the Standard.

[1] ***Standard 3.2.1*** *of the Australia New Zealand Food Standards Code is varied by -*

[1.1] *Inserting in clause 1 –*

bivalve molluscs means bivalve molluscs as defined in Standard 4.2.1 of this Code.

[1.2] *Omitting subclause 2(2), substituting -*

(2) This Standard applies to –

(a) all food businesses that are determined by the appropriate enforcement agency under the Act to be within a priority classification of food business from the commencement date for that priority classification of food business, unless expressly provided elsewhere in this Code; and

(b) the activities specified in the Table to this paragraph.

Table to paragraph 2(2)(b)

The handling of bivalve molluscs intended for sale and the sale, other than retail sale, of bivalve molluscs

Editorial note: The effect of paragraph 2(2)(b) is that a food business which handles bivalve molluscs for sale, or sells bivalve molluscs (other than at the point of retail sale) must implement a food safety program as set out in clause 3 of this Standard. A food business will comply with clause 3 if it implements - 1. A food safety management system as set out in Standard 3.2.1; or 2. A food safety management system set out in the Commonwealth Export Control Orders; or

3. A Hazard Analysis and Critical Control Point System (HACCP) for food safety management. 'HACCP' has a technical meaning commonly understood by the food production and manufacturing industry.

[2] ***The Australia New Zealand Food Standards Code*** *is varied by inserting after Standard 3.2.3 –*

STANDARD 4.2.1

PRIMARY PRODUCTION AND PROCESSING STANDARD FOR SEAFOOD (AUSTRALIA ONLY)

Purpose and commentary

This Standard sets out food safety requirements for the primary food production of seafood.

Standard 3.1.1 of this Code defines 'primary food production' as the growing, cultivation, picking, harvesting, collection and catching of food, and includes –

– the transporting or delivery of food on, from or between the place on which the food was grown, cultivated, picked, harvested collected or caught; and

– the packing, treating or storage of food at the place on which it was grown, cultivated, picked, harvested collected or caught.

Primary production of seafood in this Standard covers the same activities as those listed above for 'primary food production', but also includes the packing, treating (by depuration, cleaning or otherwise), sorting, grading or storage of seafood both on and off the place on which the seafood was grown, cultivated, picked, harvested, collected or caught.

This Standard, together with the Standards in Chapters 1, 2 and 3, establishes a 'whole of the food chain' standards system for seafood, from pre-harvesting production of the seafood through to retail sale.

Under this Standard, a seafood business that sells or supplies seafood for human consumption must adopt a risk based food safety management system commensurate with the associated risks of the business's operations.

The food safety standards in Chapter 3 generally apply to all food businesses in Australia, however, the definition of 'food business' does not include primary food production activities. A 'food business' is a business, enterprise or activity that involves the 'handling' of food, including seafood, intended for sale or the sale of food (see clause 1 of Standard 3.1.1). 'Handling' includes such activities as producing, extracting, processing, storing, transporting, delivering, treating, preserving, packing, cooking, serving and displaying of food (see clause 1 of Standard 3.1.1 for the full definition of handling).

This Standard applies to a 'seafood business' that covers the primary food production activities of the food chain for seafood. It also covers processing of seafood to the extent that Chapter 3 does not adequately or specifically address food safety requirements relating to seafood processing that may occur during the primary production phase (for example, depuration of shellfish in Division 3 of this Standard.)

In addition to the food safety requirements in this Code, a seafood business must also comply with other legislative requirements applicable to the primary production of seafood contained in relevant Commonwealth, State and Territory legislation, such as sustainability requirements and animal health and welfare requirements.

Table of Provisions

Clauses

Division 1 – Preliminary

1 Application

(1) This Standard applies to seafood businesses and seafood handlers in Australia but not in New Zealand.

Editorial note:

This Standard does not apply to persons who harvest or catch seafood for recreational, cultural or traditional purposes, provided the activity does not come within the definition of a 'seafood business' – that is, the seafood harvested or taken is not intended for sale.

(2) To avoid doubt, this Standard does not limit the effect of Chapter 3 of this Code, and to the extent of any inconsistency between Chapter 3 and Chapter 4 of this Code, Chapter 3 prevails.

2 Interpretation

(1) Unless the contrary intention appears, the definitions in Chapter 3 of this Code apply for the purposes of this Standard.

(2) In this Standard -

chilled seafood means seafood that is maintained at a temperature between -1°C and +5°C.

depuration means a process using a controlled environment to reduce the level of certain pathogenic organisms that may be present in live shellfish.

fishing vessel means a vessel used for harvesting or transporting of seafood.

frozen seafood means seafood that has been changed into a different state by the reduction in temperature and is –

(a) held at a temperature of -18°C or colder at the thermal centre of the seafood after thermal stabilisation; or

(b) held in accordance with temperature controls that ensure the safety and suitability of the seafood given the conditions under which it is to be handled; and

(c) not partially thawed.

harvesting means the capture or taking of seafood and includes the capture or taking of seafood from an enclosure or pond used in aquaculture.

inputs includes any feed, chemicals or other substances used in, or in connection with, the primary production of seafood.

live seafood premises means a premises used for the primary production of live seafood.

primary production of seafood means primary food production relating to seafood, including the packing, treating, sorting, grading or storage of seafood on or off the place on which it was grown, cultivated, picked, harvested, collected or caught.

Editorial note:

The term ‘primary food production’ is defined in Standard 3.1.1 as follows –

primary food production means the growing, cultivation, picking, harvesting, collection or catching of food, and includes the following:

(a) the transportation or delivery of food on, from or between the premises on which it was grown, cultivated, picked, harvested, collected or caught;
(b) the packing, treating (for example, washing) or storing of food on the premises on which it was grown, cultivated, picked, harvested, collected or caught; and
(c) any other food production activity that is regulated by or under an Act prescribed by the regulations for the purposes of this definition.

However, primary food production does not include:

(d) any process involving the substantial transformation of food (for example, manufacturing or canning), regardless of whether the process is carried out on the premises in which the food was grown, cultivated, picked, harvested, collected or caught; or
(e) the sale or service of food directly to the public; or
(f) any other food production activity prescribed by the regulations under the Act for the purposes of this definition.

seafood means all aquatic vertebrates and aquatic invertebrates intended for human consumption, but excludes amphibians, mammals, reptiles, and aquatic plants.

seafood business means a business, enterprise or activity that involves the primary production of seafood intended for sale.

Editorial note:

The definition of ‘seafood business’ establishes the scope of the Standard, just as ‘food business’ sets the scope for the Chapter 3 standards.

seafood handler means a person who engages in or supervises the primary production of seafood, for a seafood business.

seafood premises means any premises including land, vehicles, parts of structures, tents, stalls and other temporary structures, vessels, pontoons, and any other place declared by the relevant authority to be a premises under the Food Act, kept or used for the primary production of seafood (exclusively or otherwise), regardless of whether the premises are owned by the proprietor, including premises used principally as a private dwelling.

thermal centre of seafood means the last point in the seafood at which a change in the temperature occurs.

thawed means seafood that has been brought from a frozen state to a chilled state.

treating means depuration, or washing or otherwise cleaning.

Comment sought: In addition to general comment on the whole draft standard, particular comment is sought on the draft definitions in clause 2.

Division 2 – General seafood safety requirements

Subdivision 1 – Primary production controls

3 General seafood safety management

A seafood business must systematically examine all of its primary production operations to identify potential seafood safety hazards and implement controls that are commensurate with the food safety risk.

Editorial note: The 'controls' referred to in this clause should – a. Control hazards from air, soil, water, bait and feedstuffs, fertilizers (including natural fertilizers), pesticides, veterinary drugs and any other agent used in primary production of seafood; and b. Protect food sources from faecal and other contamination.

4 Requirement to prevent contamination

A seafood business must take all necessary steps to prevent the likelihood of seafood being contaminated.

5 Inputs and harvesting areas

(1) A seafood business must only use inputs that do not adversely affect the safety and suitability of the seafood.

(2) A seafood business must not harvest seafood in an area if it is known, or ought reasonably be known, that the seafood, if harvested in the area, may not be safe and suitable when sold for human consumption.

6 Seafood storage

(1) A seafood business must, when storing seafood, store the seafood in such a way that the conditions under which it is stored will not adversely affect the safety and suitability of the seafood.

(2) A seafood business must, when storing potentially hazardous seafood, other than live seafood –

(a) store it under temperature control; and
(b) if it is seafood intended to be stored in a particular state (for example, frozen or chilled), ensure the seafood remains in that particular state during storage.

(3) A seafood business must, when storing live seafood, store the seafood at a temperature that will not adversely affect the safety and suitability of the seafood.

(4) Where seafood is required to be stored under temperature control, the seafood business must have a means of monitoring the temperature of the seafood.

7 Seafood transportation

(1) A seafood business must, when transporting seafood, transport the seafood under conditions that will not adversely affect the safety and suitability of the seafood.

(2) A seafood business must, when transporting potentially hazardous seafood, other than live seafood –

(a) transport it under temperature control; and
(b) if it is seafood intended to be transported in a particular state (for example, frozen or chilled), ensure the seafood remains in that particular state during transport.

(3) A seafood business must, when transporting live seafood, transport the seafood at a temperature that will not adversely affect the safety and suitability of the seafood.

(4) Where seafood is required to be transported under temperature control, the seafood business must have a means of monitoring the temperature of the seafood.

Editorial note:

For clauses 6 and 7 -

The terms 'temperature control' and 'potentially hazardous' are defined in Standard 3.2.2, clause 1.

temperature control means maintaining food at a temperature of:

(a) 5°C, or below if this is necessary to minimise the growth of infectious or toxigenic micro-organisms in the food so that the microbiological safety of the food will not be adversely affected for the time the food is at that temperature; or
(b) 60°C or above; or
(c) another temperature — if the food business demonstrates that maintenance of the food at this temperature for the period of time for which it will be so maintained, will not adversely affect the microbiological safety of the food.

potentially hazardous food means food that has to be kept at certain temperatures to minimise the growth of any pathogenic micro-organisms that may be present in the food or to prevent the formation of toxins in the food.

8 Seafood packaging

A seafood business must, when packaging food –

(a) only use packaging material that is fit for its intended use; and
(b) only use packaging material that is not likely to cause contamination of the seafood; and
(c) ensure that there is no likelihood that the seafood may become contaminated during the packaging process.

9 Seafood for disposal

(1) A seafood business must ensure that seafood for disposal is held and kept separate until it is –

(a) destroyed or otherwise used or disposed of so that it cannot be used for human consumption; or
(b) returned to its supplier; or
(c) processed in a way that ensures its safety and suitability; or
(d) ascertained to be safe and suitable for sale.

(2) A seafood business must clearly identify any seafood that is held and kept separate in accordance with subclause (1) as returned seafood, recalled seafood, or seafood that is or may not be safe and suitable.

Editorial note:

'Seafood for disposal' has the same meaning as 'food for disposal' as defined in Standard 3.2.2, clause 11 – that is – the seafood is subject to a recall, or has been returned, or is not safe or suitable, or is reasonably suspected of not being safe or suitable.

10 Seafood receipt

(1) A seafood business must take all practicable measures to ensure it only accepts seafood that is protected from the likelihood of contamination.

(2) A seafood business must, when receiving potentially hazardous seafood other than live seafood, take all practical measures to ensure it only accepts potentially hazardous seafood that is at a temperature of –

(a) 5°C or below; or
(b) 60°C or above;

unless the seafood business transporting the seafood demonstrates that the temperature of the seafood, having regard to the time taken to transport the seafood, will not adversely affect the microbiological safety of the seafood.

(3) A seafood business must, when receiving potentially hazardous seafood other than live seafood, take all practical measures to ensure that the seafood which is intended to be received frozen, is frozen when it is accepted.

11 Seafood recall

A seafood business must –

(a) have in place a system to ensure the traceability and recall of unsafe or unsuitable seafood; and
(b) set out this system in a written document and make this document available to an authorised officer on request; and
(c) comply with this system when tracing or recalling unsafe or unsuitable seafood.

Subdivision 2 – Skills and knowledge

12 Skills and knowledge

A seafood business must ensure that seafood handlers have –

(a) skills in food safety and food hygiene; and
(b) knowledge of food safety and food hygiene matters;

commensurate with their work and the food safety risks.

Subdivision 3 – Health and hygiene requirements

13 Health and hygiene requirements

(1) A seafood handler at a seafood premises, including a fishing vessel and live seafood premises, must exercise personal hygiene and health practices that are commensurate with the food safety risks and that do not adversely affect the safety or suitability of the seafood.

(2) A seafood business must take all reasonable measures to ensure that seafood handlers at seafood premises, including a fishing vessel and live seafood premises, exercise personal hygiene and health practices that are commensurate with the food safety risks and that do not adversely affect the safety or suitability of the seafood.

Editorial note:

Clause 13 sets out general health and hygiene requirements for all seafood premises, including fishing vessels, sea cages and live seafood premises. A seafood business that engages in activities beyond primary production (for example, processing of seafood) must comply with the specific requirements in Division 4 of Standard 3.2.2.

Subdivision 4 – Seafood premises and equipment

14 Seafood premises and equipment

A seafood business must ensure that seafood premises, including a fishing vessel and live seafood premises, and equipment used in the primary production of seafood are –

(a) kept clean; and

(b) designed, constructed, maintained and operated in a way that will not adversely affect the safety and suitability of the seafood.

Editorial note:

Clause 14 sets out general cleaning, maintenance and design requirements for all seafood premises, including fishing vessels, sea cages and live seafood premises. A seafood business that engages in activities beyond primary production (for example, processing of seafood) must comply with the specific requirements in Standard 3.2.3.

Division 3 – Harvesting and other requirements for bivalve molluscs

15 Interpretation

In this Division –

area means a bivalve molluscs growing or harvesting area.

Manual means the Australian Shellfish Quality Assurance Program Operations Manual, Edition – January 2002, Version 2002-02, or an equivalent manual recognised by a State or Territory.

relaying means the transfer of bivalve molluscs from one area to another for the reduction of contaminants in the bivalve molluscs, by using the ambient environment as a treatment process.

bivalve molluscs means molluscan bivalves, including oysters, clams, scallops, pipis and mussels, intended for human consumption, either shucked or in the shell, fresh or frozen, whole or in part, or processed, but excludes spat, scallops and pearl oysters where the only part of the product consumed is the adductor muscle.

spat means juvenile bivalve molluscs not immediately intended for human consumption, which are taken for the purposes of ongrowing.

State Shellfish Control Authority (SSCA) means the State or Territory government agency or agencies having the legal authority to classify growing areas, control and relaying, harvesting, depuration and handling of bivalve molluscs and to seize bivalve molluscs that is contaminated or has been harvested from prohibited or closed harvesting areas, where these functions are performed according to the corresponding terms in clauses 16, 17 and 18 of this Standard, as set out in the Manual.

Drafting note:

FSANZ is investigating the legal implications of the definition, as set out above, of ‘State Shellfish Control Authority’.

16 Harvesting bivalve molluscs for human consumption

A seafood business may only harvest bivalve molluscs for sale for human consumption from an area that -

(a) has been classified by the SSCA as –

(i) approved; or
(ii) conditionally approved; or
(iii) approved as remote; or
(iv) offshore; and

(b) is subject to a Marine Bio-toxin Management Plan; and
(c) has an open status.

17 Harvesting bivalve molluscs for depuration or relaying

A seafood business may only harvest bivalve molluscs for depuration or relaying from an area that –

(a) has been classified by the SSCA as –

(i) approved; or
(ii) conditionally approved; or
(iii) approved as remote; or
(iv) restricted; or
(v) conditionally restricted; and

(b) is subject to a Marine Bio-toxin Management Plan; and
(c) has an open status for the purposes of depuration or relaying.

18 Wet storage of bivalve molluscs

Subject to clauses 16 and 17, water used for the post harvest temporary wet storage of bivalve molluscs for sale for human consumption must be -

(a) sourced from an area that satisfies the conditions specified in clause 16, and continue to satisfy those conditions during the course of the wet storage; or

(b) effectively disinfected during the course of the wet storage.

19 Co-mingling of bivalve molluscs

For the purposes of clause 11 of this Standard, each lot of bivalve molluscs harvested must be separated in a manner that prevents co-mingling of lots.

Editorial note:

'Lot' is defined in Standards 1.1.1 as follows –

lot means a quantity of food which is prepared or packed under essentially the same conditions usually –

(a) from a particular preparation or packing unit; and
(b) during a particular time ordinarily not exceeding 24 hours.

20 Specific seafood safety management systems

Where a seafood business engages in any of the activities listed in the Table to this clause, the seafood business must implement a documented seafood safety management system that effectively controls the risk to the safety and suitability of the seafood.

Table to clause 20

Primary production of bivalve molluscs

Editorial note:

Clause 20 may be satisfied by implementing –

A food safety management system as set out in Standard 3.2.1; or

A food safety management system set out in the Commonwealth Export Control Orders; or

A Hazard Analysis and Critical Control Point System (HACCP) for food safety management. 'HACCP' has a technical meaning commonly understood by the food production and manufacturing industry.

Editorial note:

The terms 'approved', 'conditionally approved', 'approved remote', 'restricted', 'conditionally restricted', 'offshore', 'open status', 'Marine Bio-toxin Management Plan' and 'disinfected' have a technical meaning commonly understood by the Australian shellfish industry. The commonly understood meaning of these terms is contained in the *Australian Shellfish Quality Assurance Program Operations Manual* (the Manual).

The Australian shellfish industry recognises, and the SSCA adopts the Manual for the purposes of ensuring the safe growing, harvesting, depuration, relaying and wet storage of bivalve molluscs. The Manual is maintained, reviewed and updated by the Australian Shellfish Quality Assurance Advisory Committee.

Attachment 11

Abbreviations and Acronyms

ABS	Australian Bureau of Statistics
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQA	Approved Quality Assurance
AQIS	Australian Quarantine and Inspection Service
ASP	Amnesic Shellfish Poisoning
ASQAP	Australian Shellfish Quality Assurance Program
ASQAAC	Australian Shellfish Quality Assurance Advisory Committee
Authority	Food Standards Australia New Zealand
Board	Food Standards Australia New Zealand Board
C. botulinum	*Clostridium botulinum*
C. perfringens	*Clostridium perfringens*
CEO	Chief Executive Officer
COAG	Council of Australian Governments
Code	*Australia New Zealand Food Standards Code*
Codex	Codex Alimentarius Commission
DA	Draft Assessment
DAFF	Australian Government Department of Agriculture, Fisheries and Forestry
DAR	Draft Assessment Report
FAO	Food and Agriculture Organization
FPA	Food Processing Accreditation
FRSC	Food Regulation Standing Committee
FSANZ	Food Standards Australia New Zealand
GHP	Good Hygiene Practices
GMP	Good Manufacturing Practice
GVP	gross value of production (in dollars)
HACCP	Hazard Analysis Critical Control Point
ISC	Implementation Sub-Committee
L. monocytogenes	*Listeria monocytogenes*
Ministerial Council	Australia and New Zealand Food Regulation Ministerial Council
MRL	maximum residue limits

NRVP	National Risk Validation Project
NSP	Neurotoxic Shellfish Poisoning
PPP	Primary Production and Processing
S. mississippi	*Salmonella mississippi*
S. typhi	*Salmonella typhi*
S. typhimurium PT64	*Salmonella typhimurium* PT64
Safefood NSW	Safe Food Production NSW
SDC	Standard Development Committee
SPS	Seafood and Phytosanitary
SSA	Seafood Services Australia Ltd
SSCA	State Shellfish Control Authority
V. cholerae	*Vibrio cholerae*
V. parahaemolyticus	*Vibrio parahaemolyticus*
V. vulnificus	*Vibrio vulnificus*
WTO	World Trade Organization