FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

06/03
18 December 2002

ISSUES PAPER

(Initial Assessment – Prepare a Proposal
Under s.12AA of the *FSANZ Act 1991*)

PROPOSAL P265

DEVELOPMENT OF A PRIMARY PRODUCTION AND PROCESSING STANDARD FOR SEAFOOD

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
28 February 2003
(See 'Invitation for Public Submissions' for details)

FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

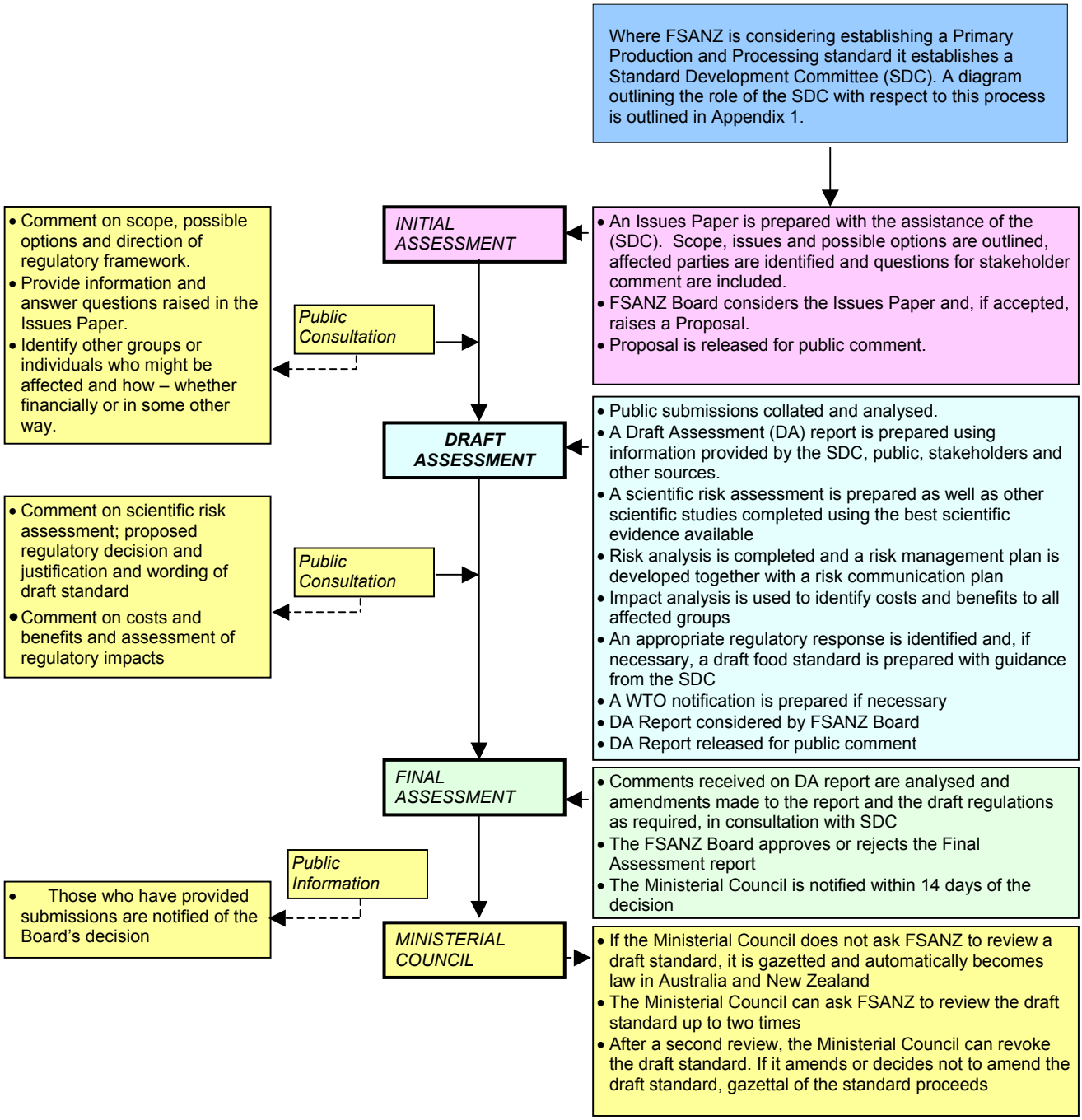
FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law 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 and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

In addition, FSANZ has recently assumed responsibility for the development of Primary Production and Processing Standards that will apply to Australia only. As a result of this new function, the Australia New Zealand Food Regulation Ministerial Council (Ministerial Council) has developed an Overarching Policy Guideline covering all primary production and processing standards to underpin the FSANZ standard development process. The FSANZ Board has subsequently established a Standard Development Committee (SDC) for seafood consisting of industry, government, research and consumer representatives to assist FSANZ in the development of the proposed standard. The role and the relationship of the SDC with respect to FSANZ and the standard setting process is outlined at Appendix 1.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia 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 *Food Standards 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

The Authority has prepared an Issues Paper for Proposal P265, which includes the identification and discussion of the key issues.

The Authority invites public comment on this Issues Paper for the purpose of preparing an amendment to the *Food Standards Code* for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the Draft Assessment/Final Assessment for this Proposal. Submissions should, where possible, address the objectives of the Authority as set out in section 10 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). Information providing details of potential costs and benefits of the proposed change to the *Australia New Zealand Food Standards 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 the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires the Authority 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 the Authority **by 28 February 2003**. Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions 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 Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports or issues papers are available for viewing and downloading from the FSANZ website or alternatively paper copies of reports can be requested from the Authority's 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

Food Standards Australia New Zealand's (FSANZ) role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. Under the new food regulatory arrangements and the new *Food Standards Australia New Zealand Act 1991,* FSANZ has assumed responsibility for the development of Primary Production and Processing Standards for food produced by the primary industry sector within Australia.

These standards are developed within the framework of the *Food Standards Australia New Zealand Act 1991.* The initial stage of the process is the preparation of a proposal, along with the release of an Issues Paper to generate public input to assist the Authority in developing the standard. This first round of public consultation is part of a process whereby FSANZ gathers information and evidence in order to allow it to undertake a thorough and rigorous scientific risk assessment and analysis of the regulatory impacts of any proposed standard. The process continues at a later stage with the Draft Assessment whereby the legal drafting of proposed standards is developed after all issues have been considered. The Draft Assessment report is also released for public comment prior to the FSANZ Board's deliberation at the Final Assessment stage.

Seafood, like all other food products, needs to be produced under conditions that result in a safe product. Regulatory measures need to place minimum requirements on the seafood industry while achieving optimal food safety outcomes with respect to protecting public health and safety. The Australian population consumes significant amounts of seafood, approximately 300,000 tonnes of seafood being consumed in the year 2000-2001. A significant proportion of seafood consumed by the Australian population is imported.

The development of the proposal must consider the broad range of products, food safety risks and management systems in place and harmonise, where possible, with international standards. This Issues Paper raises a number of issues for consideration, covering the scope of the proposal, the scientific process used, options for food safety management systems and compliance issues. These issues are summarised below.

For more detailed background and description of specific issues please refer to the sections of this paper as indicated. The paper may not cover all issues necessary for consideration in the development of the seafood standard and further issues may be identified during this public consultation.

All stakeholders are invited to participate in the standard development process by providing comment on the issues raised.

SUMMARY OF ISSUES RAISED FOR COMMENT IN THIS PAPER

- Are there any chemical or biological hazards either further to, or currently included in Chapters 1 and 2 of the *Food Standards Cod*e, that need to be addressed in the proposed seafood standard, or that should be additionally included in the current chapters of the *Food Standards Code*? (Section 4.2.2)

- What should be the scope of the proposed seafood standard? (Section 5)

- Is the current definition of seafood in the Food Standards Code adequate in terms of defining the commodities that the standard need to cover? (Section 5.1)

- Should the proposed standard include aquatic plants, reptiles and mammals (which has implications for native fishing rights)? (Section 5.1)

- 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? (Section 5.2)

- 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? (Section 5.2)

- To what extent should the standard regulate harvesting, handling and processing of seafood onboard fishing vessels? (Section 5.2)

- Comment is sought on the scientific risk assessment process (detailed in Section 6) which forms the basis of the FSANZ regulatory measures.

- Technical data is sought from industry and relevant agencies for incorporation into the scientific risk analysis process (Section 6)

- 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 (Section 7.2.3)

- 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.

- 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 (Section 7.2.4)

- 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. (Section 7)

- Information on the costs and benefits of the food safety management systems is sought. (Section 7)

- Comment is sought on issues relevant to compliance by the industry with respect to the food safety management options outlined in this paper. (Section 8)

- Comment is sought on food safety management options from an enforcement perspective (Section 8). 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;
    - ways that industry could comply with the food safety management options, for example by compliance with current industry or legislative requirements;
    - other methods of cost effective compliance;
    - 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;
    - 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;
    - the role of incentive based compliance schemes, such as reduced frequency of audits; and
    - 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

1. INTRODUCTION

1.2 Background

The Board of Food Standards Australia New Zealand (FSANZ) has raised a Proposal for the development of a nationally enforceable food safety primary production and processing standard for seafood. A Standards Development Committee (SDC), comprising stakeholder representatives from relevant government, industry and consumer groups, has been established by the Board to assist it in the process of developing the seafood standard. The role of the SDC, among other things, will be to report to the FSANZ Board with respect to the scope of the proposed standard. The SDC will also provide drafting instructions to FSANZ with respect to any proposed regulatory measure that results from the standard development process. Details of the membership of the SDC can be found at www.foodstandards.gov.au .

The seafood SDC has identified broad issues related to the proposed standard and FSANZ seeks, through the publication of this Proposal and Issues Paper, to generate public input into developing the standard.

This first round of public consultation is part of a process whereby FSANZ gathers information and evidence in order to allow it to undertake a thorough and rigorous scientific risk assessment and analysis of the regulatory impacts of any proposed standard.

2. THE SEAFOOD INDUSTRY

There are approximately 600 marine and freshwater seafood species harvested for domestic and export markets each year in Australian waters. (Fisheries Research and Development Corporation, www.frdc.com.au/industry/resources.html) Although Australia's coastal fishing zone is the third largest in the world, the nutrients and plankton produced in Australian ocean waters do not support high-tonnage finfish catches. Consequently, Australia's commercial catch represents only 0.2 percent of the world tonnage. Although Australia is ranked 52 in the world with respect to commercial tonnage, the per-capita production is among the highest in the world. In addition, aquaculture is playing an increasingly significant role with respect to overall fisheries production, with the gross value of this industry increasing by 9% in the year 2000-2001, contributing 23% to the value of Australia's edible gross fisheries production for that fiscal year.

Due to the low production capacity of Australia's fisheries, the growth of the Australian seafood industry depends on the supply of high quality seafood as well as continued market access. Food safety plays a vital role in maintaining consumer confidence in seafood products and in maintaining market access. Developing minimum cost effective regulation for food safety is therefore crucial for assuring Australian consumers and export markets of the safety of seafood.

2.1 Australian Seafood Industry by Value

The seafood industry contributes significantly to the Australian economy, employing some 19,000 people. Three quarters of these people are associated with wild catch production, the rest being employed in aquaculture. In addition, approximately 8,500 people are employed in seafood processing and wholesaling industries (ABARE, study 1998).

The gross value from fishery products (finfish, crustaceans and molluscs, including pearl production) during 2000-2001 was estimated at $2.48b (adjusted figure). This value covers wild catches from State fisheries of $1.31b, Commonwealth fisheries of $0.48b, and aquaculture production of $0.75b. A breakdown of the Australian commercial fishing industries in dollar terms on a State by State basis is shown in Table 1.

Table 1. Value of commercial fisheries production 2000-2001

	NSW	VIC	QLD	WA	SA	TAS	NT	Cwth
Value (million)	133	127	302	610	492	307	89	480
% of the share	5	5	12	24	19	12	4	19

Australia exported approximately $2.17b worth of fisheries products in 2000-2001. Of this figure, the value of edible seafood was $1.72b, approximately 69% of the value of fisheries products produced in Australia. The principal markets for exported Australian seafood are Hong Kong, Japan, Chinese Taipei and the United States.

Australia, imported $0.87b worth of seafood in the year 2000-2001 primarily from Thailand (28%) and New Zealand (18%). Imported seafood products in the past met the demand from those segments of the Australian market that the domestic production could not supply. However, ABARE statistics (Australian fisheries statistics, 2001) show that in recent years, imported seafood products are directly competing with domestic product in the Australian market.

2.2 Australian Seafood Industry by Volume

Australian fisheries produced 230,000 tonnes of seafood products in 2000-2001, consisting of 136,186 tonnes of finfish, 55,112 tonnes of crustaceans and 37,883 tonnes of molluscs. Approximately 72% (164,500 tonnes) of the domestically harvested seafood was consumed domestically. Australia also imported 144,409 tonnes of seafood in 2000-2001, representing approximately 47% of the seafood consumed domestically.

Australia exported 64,707 tonnes of domestically produced seafood in the year of 2000-2001, which was less than half of the volume of imported seafood.

A summary of Australian seafood production, export from and import into Australia is presented in Table 2.

Table 2. Value and volume of seafood produced domestically, exported and imported

	Domestic production*	Exported	Imported
Value ($billion)	2.48	1.72	0.87
Volume (tonnes)	230,000	64,707	144,409

* Domestic production includes both seafood and non-edible fisheries products.

These statistics demonstrate that Australia imports, on a volume basis, more than twice the amount of seafood than is exported. In value terms, the ratio is reversed with exports worth twice the value of imports.

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.

2.3 The Need for Regulation

The food safety risks to Australian consumers posed by the consumption of seafood are generally low, with the exception of some high risk categories such as raw ready to eat seafood products. This is due to factors related to the type of seafood, diversity in the preparation of seafood and consumer consumption patterns. For example, cooked fish fillets, in normal circumstances, pose little or no risk to consumers. However, raw ready to eat seafood, such as oysters, if contaminated by microbial pathogens or heavy metals through polluted water, would pose a high level of risk to consumers. Therefore, effective management options need to consider all of the possible factors likely to impact on consumers, ranging from the type of potential hazard (chemical, physical, microbiological or parasitic) to the harvesting, storage and preparation of seafood.

The failure to implement food safety management options can result in consumers being exposed to unacceptable health risks and industry being exposed to significant trade and economic loss. Furthermore, there is an increasing market driven expectation to implement food safety and quality systems within the seafood industry, with new systems and codes of practice continuing to emerge. This burgeoning number of multiple systems is presenting significant challenges to industry and can ultimately undermine the effectiveness of food safety and quality management initiatives.

The development of a seafood standard must consider the broad range of products, food safety risks and management systems in place and harmonise, where possible, with international standards.

3. REGULATORY FRAMEWORK

3.1 Recent Changes to Food Regulation in Australia

In order to implement the food regulatory reform objectives recommended in 1999 by the Council of Australian Governments (COAG) Senior Officials Working Group on Food Regulation, the COAG Food Regulation Agreement was signed in 2000. As a result of this agreement, the government has acted on recommendations in the Blair Review to centralise food standards development within a single agency (FSANZ), giving overall responsibility to a single Ministerial Council representing a whole of government approach. This, in turn, requires a continued commitment to a government / industry / consumer partnership to ensure that appropriate outcomes-based regulations, based on scientific risk assessment, are implemented efficiently and at least cost across the whole of the production and processing chain ("from production to consumption").

This change has created a clear responsibility for FSANZ to develop all domestic food standards, including those for primary production and processing. Enforcement, compliance and other service delivery functions continue to be the responsibility of the relevant State or Territory agencies. Under the terms of the agreement between the government of Australia and the government of New Zealand concerning a joint food standard system the primary production and processing standards will not apply in New Zealand.

The development of Primary Production and Processing Standards by FSANZ will ensure that all domestic food standards are integrated and that food regulatory decisions are considered through a whole of food supply chain approach. For the first time, a single national framework now exists for the development of all domestic food standards. This is consistent with international approaches to managing food safety, where it has been identified that in order to ensure safe food, responsibility must be taken at all points across the food supply chain.

Primary production and processing standards will be developed using the FSANZ methodologies of scientific risk analysis and widespread stakeholder consultation, having regard to policy advice from the Ministerial Council. A key component of the standard development process under the new national framework is the establishment of standards development committees. This ensures, among other things, that the interests of the primary sector are taken into account through appropriate industry representation on the SDC.

3.2 FSANZ Obligations when Developing Standards

When developing nationally enforceable standards FSANZ has statutory obligations with respect to section 10 of the FSANZ Act which establishes the following objectives in descending order of priority:

- 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.

The FSANZ Act also requires FSANZ to have regard to:

- the need for standards to be based on risk analysis, using the best available scientific evidence;
- the promotion of international consistency in setting food standards;
- the promotion of an internationally competitive and sustainable food industry;
- the promotion of fair-trading in food; and
- any written policy guidelines formulated by the Council and notified to the authority, such as the Overarching Policy Guideline on Primary Production and Processing Standards.

3.3 Ministerial Policy Guidelines

In addition to achieving the statutory objectives outlined above, FSANZ must take into account the Overarching Ministerial Policy Guideline on Primary Production and Processing Standards. This guideline outlines the Broad Policy Framework, High Order Principles, and Policy Guidance that must be taken into account by when developing primary production and processing standards. The Ministerial Policy Guideline also outlines the broad roles and responsibilities of the FSANZ Board and Standards Development Committees and requires FSANZ to have due regard to COAG's *Principles and Guidelines for National Standards Setting and Regulatory Action by Ministerial Councils and Standards Setting Bodies*.

The High Order Principles and Policy Guidelines are summarised below.

Primary Production and Processing Standards 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 *Food Standards 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 supply 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;
- provide for collaborative action among enforcement agencies to optimise the use of resources and effectiveness.

Primary Production and Processing Standards shall:

- apply in Australia only;
- be consistent with the Broad Policy Framework and High Order Principles;
- focus primarily on food safety matters and be complementary to, and not inconsistent with, Chapters 2 and 3 of the *Food Standards Code*;
- deal with specific commodity groups on a standard by standard basis while taking a consistent regulatory approach across the Standards;
- cover the supply chain for a particular commodity group to the extent determined by the Standards Development Committee (SDC) or as detailed in a commodity specific policy guideline.

As well as having regard to the Overarching Ministerial Policy Guideline on Primary Production and Processing Standards FSANZ must also conform to the Model for the Development of Primary Production and Processing Standards (the Model) and the FSANZ Primary Production and Processing Standards Protocol (the Protocol), which incorporate obligations under the *Food Standards Australia New Zealand Act 1991*, and other relevant Commonwealth policies.

These documents are available at www.foodstandards.gov.au .

3.4 Further Considerations

The above-mentioned guidance documents are designed to structure the standards setting process to achieve outcomes-based standards that are consistent in their regulatory approach, provide minimum effective regulation and promote consumer confidence in the food supply chain. The standards must also be consistent with Codex standards, save where, after consideration of the scientific evidence, the relevant standard does not sufficiently protect public health and safety in Australia.

The FSANZ statutory objectives for the setting of food standards clearly recognise that public health and safety has priority and that, to ensure this, food safety must be addressed across the entire food supply chain. The Primary Production and Processing Standards will be incorporated into a new Chapter 4 of the *Food Standards Code*. The emphasis will be on food safety, hygiene and handling using outcomes based, rather than prescriptive requirements and will be consistent with the Food Safety Standards contained in Chapter 3 of the Code.

FSANZ must also ensure that Primary Production and Processing Standards do not unnecessarily restrict trade and that they fulfil Australia's obligations to World Trade Organisation (WTO) agreements. FSANZ must also have regard to the regulatory impact of any standards it develops and ensure that the cost of the overall system is commensurate with the assessed level of risks and benefits.

4 REGULATORY PROBLEM

4.1 Regulatory Context

Some sectors of primary production and processing, such as meat and dairy, have been regulated at the State and Territory level for a number of years. More recently, some jurisdictions have also actively moved to regulate the seafood primary industry sector. SafeFood NSW, for example, implemented whole of supply chain regulation of its seafood industry in 2001. Other State and Territory governments have already expended significant time and resources in addressing seafood safety. However, with the exception of part of the shellfish sector, some sectors of the seafood industry either remain unregulated or are facing a fragmented regulatory approach through food safety schemes which, in some States, may not cross all sectors of the industry or be effectively enforced, or may differ from State to State. This is inconsistent with the COAG agreed principles on a national approach to food regulation in Australia to assure food safety and market access. It is within this context that FSANZ is undertaking the development of Primary Production and Processing Standards for all primary industry sectors, beginning with the seafood sector.

4.1.1 Existing regulation of the seafood industry

Compliance with the *Code* is required under State and Territory legislation and is enforced by State and Territory governments. It is also an offence under State and Territory legislation to sell for human consumption any food that is unsafe, damaged, deteriorated or perished.

Some aspects of seafood are covered by the general standards in Chapter 1 of the Code. These Standards generally apply to food sold or traded at retail and wholesale level in Australia, and include labelling and compositional standards. Chapter 1 of the Code also contains standards for contaminants, residues and microorganisms. These standards apply to seafood sold and imported into Australia and New Zealand. New Zealand regulates its own maximum residue limits for agricultural and veterinary chemicals in food.

Chapter 2 of the Code contains requirements affecting particular classes of foods, including a specific standard for fish and fish products. This standard is limited to defining the term 'fish' and providing a compositional standard specific to histamine in fish and fish products. The standard also requires cooking instructions for raw fish that has been joined using a specific binding system.

The Food Safety Standards in Chapter 3 of the Code provide for the safe and hygienic handling of food and the premises and equipment where the food is handled. They do not apply to the primary production of seafood except under certain circumstances such as where there is direct sale to the public or the seafood is processed. The Food Safety Standards apply in Australia only; New Zealand has its own food hygiene arrangements.

Chapter 3 of the Code also contains a 'Model' Food Safety Standard, namely Standard 3.2.1, which sets out the requirements for Hazard Analysis and Critical Control Point (HACCP)-based food safety programs. This Standard aims to take a risk-based and preventive approach to managing food safety. The Standard is currently voluntary unless mandated under specific State or Territory legislation. An initial approach to the development of the proposed seafood standard is to acknowledge existing standards in the Code relating to seafood and ensure that these are not duplicated in the seafood standard.

The seafood industry in New South Wales is regulated under the NSW Food Production (Seafood Safety Scheme) Regulation 2001. The Australian seafood industry, through an industry association, Seafood Services Australia Pty Ltd, has reached an advanced stage in developing an industry preferred seafood standard for voluntary implementation by the seafood industry. Development has been based on achieving a consultative approach between State, Territory and Commonwealth Governments, FSANZ (previously ANZFA) and the seafood industry.

A quality assurance scheme, Australian Shellfish Quality Assurance Program (ASQAP) has been in existence for export establishments for approximately twelve years and more recently has been applied to domestic producers. The ASQAP scheme was developed by the Australian Shellfish Sanitation Advisory Committee, which has government and industry representation and is administered by State governments.

4.1.2 Seafood imports

Imported seafood products are required by legislation to comply with the *Code.* Chapters 1 and 2 of the Code set useful prescriptive criteria relating to aspects of food labelling, composition, residual toxins and microbiological limits. These criteria are essential in terms of evaluating the level of safety of imported seafood in the absence of information on the efficacy of food safety management systems in other countries.

4.1.3 Seafood exports

Seafood businesses exporting seafood are required to comply with national legislation for export control and specifically with Export Control (Processed Foods) Orders administered by the Australian Quarantine and Inspection Service of Agriculture, Fisheries and Forestry – Australia. These Export Control Orders assist in fulfilling importing country requirements with respect to food safety and quality parameters for exported Australian seafood. They require companies that wish to export their products to be accredited under AQIS and to have in place a documented HACCP plan in order to assure an appropriate level of food safety.

4.2. Public Health and Safety Considerations

Seafood generally has a good food safety record. Many of the food safety risks associated with seafood are well known. Documented food borne illnesses caused through seafood consumption are outlined in Appendix 2. (Ross. T, Sanderson. K, December 2000, A Risk Assessment of Selected Seafoods in NSW - Final Report, SafeFood New South Wales).

4.2.1 Microbiological Risks associated with seafood

Historically, certain categories of seafood have been known to be high risk for causing food-borne illness. Recently, the National Food Safety Risk Validation Project (NFSRVP), being undertaken with funding from the Commonwealth Department of Health and Ageing (DoHA) and the NSW Department of Health, published its Final Report. It drew, in part, on data from OzFoodNet (a collaborative project of State and Territory health authorities, DoHA and FSANZ which aims to investigate and understand food-borne disease in Australia). The report concluded that the raw ready to eat seafood sector (covering producers, harvesters, processors and vendors) is among the top five high risk food sectors / industries associated with food-borne illness outbreaks (Final Report of the National Risk Validation Project, Food Science Australia & Minter Ellison Consulting, 2002). The annual cost to the Australian food industry, public and Government of food-borne illness due to recorded outbreaks is estimated to be $1.67 billion. When sporadic illness in taken into account, this figure is estimated to be in excess of $4.2 billion. Within this aggregate cost, the cost attributed to raw ready to eat seafood (*e.g.* oysters) was estimated to be $181 million.

The Australian epidemiological data presented in the NFSRVP report covered the period 1987-2001. It details 88 outbreaks of microbiological food-borne illness related to seafood consumption, involving more than 1800 cases including 8 deaths. Oysters (69 outbreaks, >1423 cases, including 7 deaths) and prawns (14 outbreaks, >264 cases, including 1 death) account for the vast majority of these. The microbiological agents responsible were primarily *Vibrio* spp. and Norwalk and Hepatitis A viruses.

During the same period, 51 outbreaks of chemical food poisoning (including some in a private residence setting as a result of consumption of the products of recreational fishing) involving over 497 cases (no deaths) were recorded, primarily involving ciguatoxin (36 outbreaks, 314 cases) and scombrotoxin (11 outbreaks, >52 cases).

A case study of the 1997 outbreak of Hepatitis A virus due to consumption of oysters from Wallis Lake, NSW, formed part of the NFSRVP report. This outbreak was caused by contamination of the waterway by human sewage after a period of unusually heavy rains, demonstrating the interdependence between the natural environment and the safety of food from the primary production and processing sector. On-going legal action by some of the 467 victims of the outbreak makes it difficult to draw final conclusions as to the total associated socio-economic costs. However, the direct cost to oyster producers and the wider seafood industry was estimated to be in the range $10-$30 million, as oyster sales fell by ~90% and seafood prices fell by up to 25% at the time of the outbreak.

Epidemiological data, recorded in the United States of America, has shown similar known risks in the seafood sector. Data from the Centre for Disease Control (CDC) for the period 1993-1997 demonstrates that shellfish and other fish were the vehicle of transmission in 1.7% and 5.1% of outbreaks of food-borne disease, respectively (Surveillance for Foodborne-Disease Outbreaks – United States, 1993-1997, Olsen *et al.*, 2000, Morbidity and Mortality Weekly Report 49, No. SS-1). The major hazards were viral (11/21 cases of known aetiology) in the case of shellfish, and chemical (ciguatoxin and scombrotoxin; 120/140 cases of known aetiology) in the case of other fish.

Risk assessments undertaken by FSANZ (then ANZFA) in the process of reviewing the microbiological limits for Volume 2 of the Code considered data on Australian and international food poisoning outbreaks due to seafood consumption (Proposal P178 Review of Microbiological Limits; Gazetted December 20, 2000). This process identified a number of microbiological hazards associated with the various sub-categories of seafood and recommended various risk management strategies, including implementation of quality assurance programs and microbiological standards.

4.2.2 Chemical risks associated with seafood

Several other Proposals were raised during the extensive review of the Code, as the process identified several public health and safety issues relating to chemical contaminants associated with seafood. As a result, Volume 2 of the Code has been updated to incorporate, among other things, biotoxins associated with shellfish poisoning, the inclusion of histamine levels associated with finfish, and the allowable level of mercury in crustacea, finfish and molluscs. (Proposals P158 Non metal Contaminants; P183 Fish; P157 Metal Contaminants; Gazetted December 2000).

Given that many issues associated with the food safety risks to human health from seafood have been thoroughly assessed by FSANZ and subsequently regulated, in particular through Chapters 1 and 2 of the Code, there is little requirement for the proposed seafood standard to readdress these areas.

Comment is, however, sought on whether there may be any other chemical or biological hazards that may need to be addressed in the proposed standard or in the current chapters of the Code.

A list of the current chemical and microbiological contaminants currently regulated through Volume 2 of the Code are outlined in Appendix 3.

5. SCOPE OF THE STANDARD

Industry, consumers and government are invited to provide comment on the scope of the proposed seafood standard.

The seafood standard will aim to achieve a through chain integrated approach to managing seafood safety from production (aquaculture) or harvest through to retail sale. As part of this process, the roles of industry and government for effective implementation of the standard need to be considered. The standard will apply to seafood sold in Australia and will harmonise, to the extent possible, with existing domestic and international Standards. The standard will focus on food safety and be consistent with the objectives for setting standards in the FSANZ Act and as outlined in the Ministerial guideline.

Quality attributes and production methodologies that do not relate to food safety are normally addressed through industry mechanisms such as industry guidelines and codes of practice and would not normally be found in a regulatory scheme.

Some initial issues for consideration involve the definition of seafood, the commodities the standard intends to cover, and the application of the standard across the seafood industry and along the supply chain.

These questions need to be considered in the context of the common Food Acts of the States and Territories, which require:

- that food for sale is both safe and suitable for human consumption; and
- the prevention of misleading and deceptive conduct in connection with the sale of food.

5.1 Definition of Seafood

At present the Code does not define 'seafood' as such. However, the Code defines 'fish' as:

- any cold blooded aquatic vertebrates and aquatic invertebrates including shellfish, but does not include amphibians and reptiles.

The Codex Alimentarius Draft Code of Practice for Fish and Fishery Products defines seafood separately in terms of fish and shellfish with the following definitions provided:

- Fish – any of the cold-blooded (ectothermic) aquatic vertebrates. Amphibians and aquatic reptiles[1] are not included.
- Shellfish – those species of aquatic molluscs and crustaceans that are commonly used for food.

[1] Currently, there exists an Australian Standard for the Hygienic Production of Crocodile Meat for Human Consumption, which is incorporated as part of the current meat standards.

Comment is invited as to whether the current definition in the Code is adequate in terms of defining the commodities that the standard will cover.

Under the current definition in the Code, seafood commodities that the standard could cover include:

- finfish
- crustaceans
- cephalopods (*e.g.* octopi, squid)
- oysters
- mussels and other molluscs (*e.g.* pipis, scallops, abalone)

Whether the standard should include aquatic plants, reptiles and mammals (which has implications for native fishing rights) are also issues which need to be considered.

5.2 Application of the Seafood Standard across the Food Supply Chain

The exact scope of the proposed standard can only be accurately determined by undertaking a thorough Risk Assessment of the nature and severity of the risks associated with the production and processing of all types of seafood sold for human consumption in Australia, where gaps are identified in current regulatory regimes. The standard may also be required to address identified risks associated with aquaculture, given the increasing significance of this industry within Australia.

The known risks associated with seafood are wide ranging and are closely related to the circumstances under which seafood is produced and consumed. For example, cooked finfish poses a much lower risk than raw ready to eat seafood as such products inherently undergo a bactericidal step prior to consumption. Processes associated with the harvest, aquaculture, transport, processing, packing and selling of seafood also poses risks that range from high to low.

Comments on the scope of the standard are invited.

Other issues for comment and consideration are:

- **Should the standard regulate seafood production (aquaculture) from point of harvest up to the back dock of retail establishments or through to the point of retail sale?**
- **Should businesses selling ready to eat seafood remain covered under the current arrangements i.e. should this matter be dealt with under Chapter 3 - Food Safety Standards or should these businesses be covered by the Primary Production and Processing Standard for seafood? and**
- **To what extent should the standard regulate harvesting, handling and processing of seafood onboard fishing vessels?**

6. PUBLIC HEALTH AND THE STANDARD DEVELOPMENT PROCESS

6.1 Public Health

The primary objective of the FSANZ Act is the protection of public health and safety. Any regulatory measures, which are developed by FSANZ are based on the outcomes of a scientific process (such as risk assessment) and a Regulatory Impact Statement (assessing the feasibility and practicality of the regulation), both of which inform the development of appropriate risk management options.

6.2 Risk Analysis Framework

FSANZ utilises the risk analysis framework to assist its regulatory decision-making. Risk analysis consists of three components: risk assessment, risk management and risk communication. Risk assessment is essentially a scientific process undertaken to characterise the risk posed by food borne hazards to public health and safety. Risk management is the process of weighing regulatory alternatives and, if required, selecting and implementing appropriate control measures. Risk communication is an interactive exchange of information concerning risk amongst assessors, managers, consumers and other interested parties and can include explaining risks, how to control risks, the scientific evidence underpinning risk assessment and education on managing risks.

6.2.1 Risk assessment process

The structure and process of risk assessment has been well established internationally by the Codex Alimentarius Commission and the FAO/WHO. Risk assessments undertaken by FSANZ are consistent with international protocols and essentially consist of four distinct steps: hazard identification, hazard characterisation, dietary exposure and risk characterisation. This process is further elaborated in the FSANZ document *Framework for the Assessment and Management of Health Risks in Relation to Food*.

The outcome of a risk assessment is to state the probability and severity of an adverse health effect due to the consumption of a food containing a particular biological, chemical or physical agent. In so doing, the risk assessment should identify where in the process, from production to consumption, controls over the particular hazard will have the greatest impact in minimising risk (i.e. where risk management will be most effective).

6.2.2 Will FSANZ be conducting risk assessments for seafood commodities?

Many studies have already been carried out both domestically and internationally, by industry and governments, investigating risks associated with the consumption of seafood. A list of Risk Assessments relating to Australian seafood are at Appendix 4.

FSANZ has legislative obligations to develop standards based on sound science through a risk assessment process.

FSANZ aims to identify the risk assessments and other technical evaluations, which have already been undertaken and review these against the through-chain approach to be addressed by this proposal and identify gaps for further scientific evaluation.

In this way, the undertaking of a full risk assessment process may be limited only to where significant gaps exist in existing scientific evaluations and where such a detailed assessment is considered necessary as a result of, for example, risk profiling.
This will provide an efficient and effective mechanism for identifying and assessing potential hazards in seafood.

Existing risk assessments and other scientific work will be evaluated by FSANZ in accordance with a number of considerations:

- The relevance of the data
- The quality of data
- The appropriateness of the methodology used
- The adequacy of the study design
- The appropriateness of statistical analysis
- Reproducibility of the data
- Concurrence with published literature

6.3 What is Risk Profiling?

Risk profiling is defined by the FAO/WHO[2] as "the process of describing a food safety problem and its context, in order to identify those elements of the hazard or risk relevant to various risk management decisions". A risk profile provides an initial evaluation of a food safety issue in relation to the scope of the public health concerns, the extent of pertinent scientific information and available control measures. Risk profiling is used as a tool to direct what further action should be taken, such as:

- whether a risk assessment is necessary;
- what priority should be given to the issue; and
- if any further action is required.

Risk profiling is a valuable tool in determining where in the food supply chain regulatory intervention should occur so that it has most impact in the food supply chain continuum with respect to protecting public health and safety, providing minimal cost to industry and government.

6.4 What Data will FSANZ Need During the Draft Assessment Phase of the Standard Development Process?

The use of data on the levels and extent of contamination of seafood with particular hazards, epidemiological studies linking adverse health outcomes to those hazards and dietary exposure to the hazard will be essential in determining the level of risk associated with specific seafood product/pathogen combinations and in designing appropriate regulatory responses to these risks. FSANZ intends to work closely with industry and relevant agencies to ensure that as much relevant data as possible can be incorporated into its scientific evaluations.

[2] *Risk Management and Food Safety: Report of a Joint FAO/WHO Consultation*, FAO/WHO Food and Nutrition Paper No. 65, 1997.

Stakeholders are invited to provide their views on the issues raised above relating to the risk assessment process and provide technical data for incorporation into the scientific risk analysis process.

7 OPTIONS FOR FOOD SAFETY MANAGEMENT SAFETY SYSTEMS

7.1 Options for Managing Food Safety

All food for human consumption produced in Australia is required by law to be safe and suitable. The proposed seafood standard will address gaps in the seafood supply chain where it has been identified, through scientific risk assessment, that current regulatory regimes do not adequately address the risks.

FSANZ is obliged under the COAG agreed principles for standards development to establish outcomes based (rather than prescriptive) food safety standards using a risk-based approach. This avoids unnecessary regulatory impost on industry, while still allowing business flexibility in terms of how to comply with the requirements of a regulatory standard.

In developing standards to protect public health and safety, FSANZ is required to pay due regard to the COAG Food Regulation and WTO agreements. These agreements require the development of standards based on sound science, the harmonisation of Australia's domestic and export food standards, the harmonisation of domestic standards with internationally recognised Codex Standards and a consistent regulatory approach across Australia. These measures assist in protecting public health and safety, facilitate trade and avoid unnecessary impost on food businesses. Where appropriate, and legally plausible, referencing or signposting existing domestic standards in the seafood standard, where they apply, could be considered, thereby avoiding duplication and providing a seamless transition in terms of regulating the seafood primary industry sector.

7.2 Regulatory and Non-Regulatory Approaches to Managing Food Safety

There are ranges of food safety management options that may be used to control food safety risks associated with seafood primary production and processing. The risk management options developed will depend on the outcomes of a scientific risk assessment process to be conducted by FSANZ, a cost benefit analysis of proposed risk management options and further public consultation mechanisms that will be undertaken.

There are likely to be a broad range of risks in the seafood sector, due to the diversity of the sector, and the approaches to managing these risks may vary accordingly.

Options for managing risks across the supply chain will be dependent on the level of risk posed and the most effective and appropriate intervention strategy. Risk management measures could take a variety of forms from regulatory to non- regulatory.

Approaches may utilise food safety management systems such as food safety programs based on HACCP principles for all sectors in the seafood industry through to non-mandatory Codes

of Practice and industry standards or a 'do nothing' option. Possible approaches are discussed below.

At present there are a variety of ways that industry and government manage risks associated with seafood production and consumption. These include complying with the current *Food Standards Code,* compliance with State based regulations that require food safety programs, AQIS export requirements which include food safety programs, and industry self regulation through voluntary compliance with codes of practice, industry preferred standards including food safety/quality assurance programs and guidelines. In some businesses, Good Manufacturing Practices (GMP), and Good Hygiene Practices (GHP) based on agreed industry best practice may be all that is necessary to control certain risks associated with seafood production and processing.

7.2.1 Food Safety Programs

Food safety programs, which proactively identify and manage a business' food safety risks, are not new for a significant portion of the seafood industry. The export sector has been complying with EU and AQIS Export (Processed Food) Orders for a number of years. This requires seafood processors to be accredited by AQIS in order to maintain market access. Accreditation involves, among other things, seafood producers to have in place a documented food safety program based on Codex principles of HACCP. Some businesses within the sector supplying the domestic market are required, either through State legislation or through commercial contracts, to have in place HACCP based food safety programs as a means of guaranteeing food safety and quality and to gain market access.

Food safety programs provide a risk-based approach to managing food safety. If food safety programs are an appropriate risk management option for the seafood sector, based on the scientific risk assessment, consideration may need to be given to the extent of their application in managing food safety across the seafood supply chain. The benefit of requiring such programs across the industry would be that the approach is tailored to the individual business and its food safety risks. Hence, if the risk is low, the food safety program will be minimal. It can, therefore, be argued that such programs are risk based and minimise the impost on food businesses.

However, several options may be explored with respect to the use of food safety programs for managing the risks associated with seafood businesses. These involve mandating the use of food safety programs for all seafood businesses or restricting their use to those businesses demonstrating the highest risks. Given the known risks associated with seafood production are wide ranging, the degree of risk will differ significantly between sectors within the industry and between individual operations.

As part of any decision to use food safety programs as the appropriate risk management option, consideration would need to be given to whether it is necessary to develop materials to support nationally consistent compliance and enforcement. The appropriate support/implementation roles at the national, state and industry level would need to be considered.

The Australia New Zealand Food Regulation Ministerial Council is considering the uptake of mandatory food safety programs based on the results of national studies commissioned by the Commonwealth Department of Health and Ageing over the last two years. These studies

included: a national project to identify high risk food businesses based on the outcome of known food-borne illness outbreaks and a detailed cost benefit assessment; a second study that analysed the broader cost and benefits of food safety programs; and a study on the incidence and causes of food-borne illness.

7.2.2 Other regulatory options

If food safety programs were recommended for high-risk areas of the seafood industry, other regulatory options, including existing regulation may be considered satisfactory for lower risk businesses. For example, standards similar to Food Safety Standards 3.2.2 and 3.2.3, tailored to the seafood sector, may suffice where risks are not identified as high.

Domestic retail and food service businesses that process and sell seafood are already regulated in terms of food safety under the *Australia New Zealand Food Standards Code.* Chapters 1 and 2 of the Code regulate labelling, additives, contaminants, pesticide residues, antibiotics, microbiological limits and heavy metals in food.

Chapter 3 of the Code contains the following mandatory Food Safety Standards:

- Standard 3.2.2 - Food Safety Practices and General Requirements
- Standard 3.2.3 - Food Premises and Equipment

The mandatory Food Safety Standards are primarily designed to mitigate the risks associated with the processing, handling, storage and transport of food with respect to microbiological, chemical and physical contamination and require food businesses to implement GMP and GHP within their operations so as to achieve the food safety objectives in the Standard.

When assessing other regulatory options with respect to managing food safety risks associated with the production and processing of seafood, it will be necessary to consider whether the current Chapter 3 Standards in the Code will provide appropriate food safety management options to address the risks associated with the primary production and processing of seafood. Where risks are identified as high, these existing food safety standards may not be considered adequate.

7.2.3 Develop a standard based on existing industry and government standards such as the SSA/ASIC Australian Seafood Standard

One possible regulatory option would be to develop a new mandatory Primary Production and Processing Standard for seafood based on the *Australian Seafood Standard* developed by Seafood Services Australia Ltd (SSA) and the Australian Seafood Industry Council (ASIC). This approach is set out in the Application submitted to FSANZ by these organizations in November 2002 seeking the development of an Australian primary production and processing standard for seafood.[3]

The seafood industry, through SSA and ASIC, has been actively developing a voluntary industry-preferred food safety standard based on existing regulations for a number of years.

[3] The Application to FSANZ and the proposed *Australian Seafood Standard* can be downloaded from www.seafoodservices.com.au

This process has involved significant time and effort from the industry, and has utilised the input of Commonwealth and State regulators. The standard has strong support from industry members represented by the SSA organization.

The proposed SSA/ASIC standard is based on seafood businesses implementing a food safety management system (FSMS) that is commensurate with the level of food safety and suitability risks associated with the business. The applicants have clarified that the intention of the industry standard is to require all seafood businesses to manage their food safety risks, through a tailored FSMS that addresses the particular risks associated with each business's operations. As the risks vary considerably across operations in the seafood industry, so may the systems to manage those risks. For example, some seafood businesses may be required to have in place a documented HACCP-based food safety plan covering each stage of the process for seafood produced or handled by the business, with monitoring, control and verification requirements built in to the system. However, it may be sufficient for seafood businesses with demonstrably low food safety risks to comply with less demanding food safety management requirements.

The SSA/ASIC also includes performance-based criteria are established in respect of:

- Seafood handling;
- Harvesting and production;
- Temperature controls;
- Processes to preserve or extend shelf life;
- Storage, display, transport and service of seafood;
- Health and hygiene requirements;
- Premises, equipment and fishing vessels; and
- Identification, traceability and recall.

Comment is sought on the suitability and/or any deficiencies of this industry-preferred standard, if it were to be considered as a basis for a national mandatory Primary Production and Processing Standard for seafood.

In addition, the NSW government has recently regulated the seafood industry in NSW through the SafeFood NSW Food Production (Seafood Safety Scheme) Regulation 2001. Other States and Territories are also actively moving to regulate their respective seafood sectors.

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.

7.2.4 Non-regulatory options

There are a range of non-regulatory options available to use where food safety risks are low or for those cases in which mandatory measures are not effective. These may range from voluntary industry or government Codes of Practice or other schemes to the 'do nothing option'.

Industry may also wish to consider the use of such guidelines and codes of practice as a means of addressing seafood quality / market parameters that will not be addressed in the national seafood safety standard.

Comment is sought from stakeholders 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.

7.3 Import Legislation

Under WTO agreements, imported seafood products are required to meet the same level of food safety as is required to be delivered by the standard for domestic seafood.

In Australia, the Imported Food Program is jointly run by the AQIS and FSANZ, with FSANZ advising on food risk assessment policy for the program and AQIS having operational responsibility for inspection and sampling. The legal basis for the inspection of imported food in Australia is the *Imported Food Control Act 1992*. The standards applied are those set down in the Code, which also apply to foods produced and processed in Australia.

Imported food is placed into one of three inspection categories, which determine the frequency with which food will be inspected. The categories are risk, active surveillance and random surveillance. All risk-categorised food is referred to AQIS for inspection. Currently most imported seafood products such as crustacea, shark, gemfish, tuna, smoked vacuum packed fish, mussels, molluscs and marinara mix are classified as high risk and are inspected through a performance based regime under the 'risk' category for inspection.

Chapter 3 of the Code applies in Australia only and is, therefore, although applicable, not enforceable at the border because individual countries regulate hygienic practices. It is possible for AQIS to establish certification systems with individual countries. However the process is costly and time consuming and undertaken in limited form.

While endpoint testing does have limitations, Codex does recognise the role of microbiological limits when other means of verifying the efficacy of HACCP based systems and good hygienic practices are not available.

Stakeholders are invited to provide their views on the issues raised above relating to food safety management systems and whether other options should be considered in managing the potential public health and safety risks associated with seafood. Any information on the costs and benefits of any of the options is welcomed, as these are issues that must be considered and developed at the next stage of public consultation.

8. COMPLIANCE WITH THE PROPOSED FOOD SAFETY MANAGEMENT OPTIONS

States and Territory premiers, as signatories to the *Food Regulation Agreement 2000*, have agreed to objectives to govern compliance and enforcement arrangements under the national food regulation system. These are:

- there will be compliance and enforcement arrangement for industry and governments that are cost effective; and

- the regulatory approach will be consistent across Australia through nationally agreed compliance and enforcement procedures.

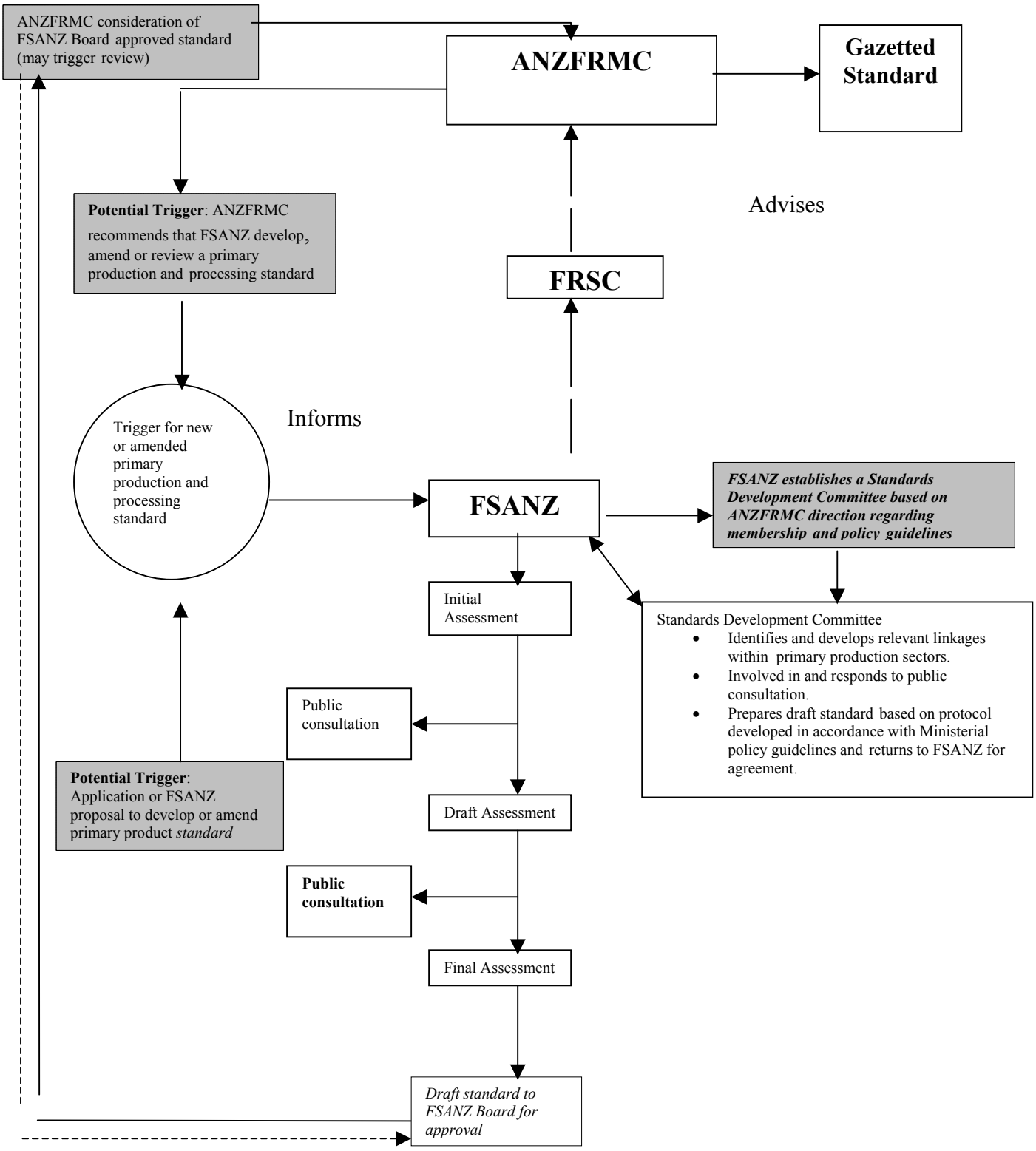
To assist in the development of regulatory measures that meet these objectives, comment is sought on issues relevant to compliance by the industry with the food safety management options listed earlier in the paper. Comment is also sought on the options from an enforcement perspective.

Comment is sought on:

- **the costs of meeting current requirements and costs or difficulties in meeting the range of food safety management options that are mentioned earlier in this paper;**
- **ways that industry could comply with the food safety management options, for example by compliance with current industry or legislative requirements;**
- **other methods of cost effective compliance;**
- **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;**
- **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;**
- **the role of incentive based compliance schemes, such as reduced frequency of audits; and**
- **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.**

Appendix 1

How primary production and processing standards are developed under FSANZ



Appendix 2

The following table outlines some of the known hazards associated with Australian seafood (A Risk Assessment of Selected Seafoods in NSW - Final Report December 2000, SafeFood New South Wales, Ross. T, Sanderson. K)

Known hazards associated with Seafood	
Hazard	**Commodity**
* Algal biotoxins	Shellfish
Viruses	Shellfish
Ciguatera toxin	Reef fish
* *Listeria monocytogenes*	Ready to eat seafood Products
Vibrio vulnificus	Raw oysters
* Histamine poisoning	Scromboid fish species
Vibrio cholerae	Cooked prawns
Vibrio parahaemolyticus	Cooked prawns
* Enteric pathogenic bacteria	Imported cooked shrimp and shellfish
* Mercury	Predaceous fish species
Parasites	Sushi/sashimi
Clostridium botulinum	Canned fish and vacuum packed ready to eat fish products

* Hazard currently regulated to some extent in the *Food Standards Code*

Appendix 3

Seafood hazards regulated under Volume 2 of the *Food Standards Code*

<table>
<tr><th>Type of Seafood</th><th colspan="2">Hazard Regulated under the Food Standards Code</th></tr>
<tr><td rowspan="2">Fish and fish products</td><td colspan="2">Chemical hazards only</td></tr>
<tr><td colspan="2">Histamine
Arsenic (inorganic),
Polychlorinated biphenyls
BHC
Chlordane
DDT
Heptachlor
Lindane
Oxolinic aid
Aldrin and Dieldrin (freshwater fish
HCB (freshwater and marine fish)
Isoeugenol (diadromous, freshwater and marine fish)</td></tr>
<tr><td rowspan="2">Ready-to-eat processed finfish (other than fully retorted finfish)</td><td>Chemical</td><td>Microbiological</td></tr>
<tr><td></td><td>Listeria monocytogenes</td></tr>
<tr><td>Crustacea</td><td>Arsenic (inorganic)
Mercury</td><td>Coagulase-positive staphylococci
Salmonella
Listeria monocytogenes (cooked crustacea only) – currently under review</td></tr>
<tr><td>Molluscs, including bivalve molluscs</td><td>Arsenic (inorganic)
Mercury
Lead
Cadmium (excluding dredge/bluff oysters and queen scallops)
Amnesic shellfish poisons (domoic acid equivalent)
Diarrhetic shellfish poisons (okadaic acid equivalent)
Neurotoxic shellfish poisons</td><td>Escherichia coli (other than scallops)
Listeria monocytogenes (applies to molluscs that have undergone processing other than depuration)</td></tr>
<tr><td>Canned seafood</td><td>Tin</td><td></td></tr>
<tr><td>Seaweed (edible kelp)</td><td>Arsenic (inorganic)</td><td></td></tr>
</table>

Appendix 4

Additional Information
Risk Assessments that relate to Australian Seafood

Title	Author/State/Country	Date
A Risk Assessment of Selected Sea foods in NSW *Summary available at:* *http://www.safefood.nsw.gov.au/pages/3.5.2.Seafood-RA-Summary1.htm*	Safe Food NSW	December 2000
Consultancy for Researching the Business Profile of the NSW Seafood Industry & Food Safety Hazards of Seafood in NSW *Summary available at:* *http://www.safefood.nsw.gov.au/pages/3.5.2.Seafood-RA-Summary1.htm*	Safe Food NSW	26 October 1999
Report on Seafood Sector Working Groups' Development of Model Food Safety Programs	Safe Food NSW	June 2000
Risk Assessment of Fish Cold Smoking and Marination Processes Used by Australian Businesses	Safe Food NSW	February 2002
Risk Prioritisation for the QLD Seafood Industry	Safe Food QLD	Companion work to Gap analysis in the QLD Seafood Industry June 2002
QLD Seafood Risk Characterisation – Discussion Paper	Safe Food QLD	September 2002
Food Safety System for the Victorian Seafood Industry *Available at:* *http://www.nre.vic.gov.au/web/root/domino/cm_da/nrecfaq.nsf/2fc3379bd0005bd64a2566cf00283d52/a4a87454fb7ecf38ca256bff0001fd4c/$FILE/seafood.pdf*	Seafood Safety Management Working Group	April 2002
National Seafood Risk Assessment CD ROM • SeaQual's Guide to Hazards and their control in the seafood industry • Assessment of Product: Pathogen Pairings • SeaQual's Guide to Risk Assessment • The Risk Ranger • SeaQual's Guide to HACCP and Quality Assurance	Seafood Services Australia	May 2001
Commissioned Survey of the food safety and Shelf Life of Western King Prawns caught in the Spencer Gulf and West Coast waters *(Not yet out)*	South Australian Research and Development Institute (SARDI)	To be Done in 2 stages April – June November – January 2002

National Residue Survey Report on levels of mercury in shark species	ANZFA – TAG Paper	88-01
NZ Proposed Bivalve Molluscan Shellfish Regulated Control Scheme	Ministry for Agriculture and Forestry (NZ) (Food Assurance Authority)	March 2002
Guideline for the changes to marine biotoxin management in relation to NSP	Ministry for Agriculture and Forestry (NZ) (Food Assurance Authority)	June 2002
Framework for the assessment and management of food related health risks	FSANZ	September 96
Crustacea and Other Seafoods – Risk Assessment	FSANZ – Sally Hasell	Done as Part of the Proposal to Review Micro Standards
Finfish Seafoods – Risk Assessment	FSANZ – Sally Hasell	Done as Part of the Proposal to Review Micro Standards
Shellfish – Risk Assessment	FSANZ – Sally Hasell	Done as Part of the Proposal to Review Micro Standards
Listeria Risk Assessment in Cold Smoked Fish and Cooked Prawns	FSANZ	2002
Risk Categorisation of Sushi	FSANZ – Sally Hasell	August 2002
Shellfish Toxins in Food A Toxicological Review and Risk Assessment *Available at*: *http://www.foodstandards.gov.au/_srcfiles/TR14.pdf*	FSANZ	November 2001
Antibiotic use in Aquaculture – Antimicrobial Drug Resistance *Hard copy held.*	AFFA- Aquatic Animal Health Office	January 2002
Risk Assessment in Food Safety and Policy Practice *Available at:* *http://www.affa.gov.au/content/publications.cfm?Category=Agriculture%20and%20Food%20Sciences&ObjectID=4826DC2D-C850-4D00-99F2AB3E0ED21258*	AFFA –Bureau of Rural Sciences	2001
Oysters - Independent Review of the Relationship between Healthy Oysters and Healthy Rivers, Draft Report Available at: http://www.hrc.nsw.gov.au/site/pubs_frame.html	Healthy Rivers Commission	October 2002
A Seafood Safety Risk Assessment	Food Science Australia Mr Paul Vanderlinde Dr Patricia Desmarchelier	2002