Review of health benefit research and development relevant to the Australian seafood industry and members of the Australian Seafood CRC:

Project 1 of 3:
Health claims and other opportunities

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inspiring achievement

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Acronyms & Abbreviations

AD	Alzheimer's disease
ALA	alpha linolenic acid
CHD	coronary heart disease
COX	cyclo-oxygenase enzymes
CSIRO	Commonwealth Scientific and Industrial Research Organisation
CVD	cardiovascular disease
DAA	Dietitians Association of Australia
DEST	Department of Education, Science and Training
DHA	docosahexaenoic acid (C22:6)
DPA	docosapentaenoic acid (C22:5)
DPI	Department of Primary Industries
EPA	eicosapentaenoic acid (C20:5)
EAR	estimated average requirements
FDA	Food and Drug Administration (US)
FHC	Foods with Health Claims (Japan)
FNFC	Foods with nutrient function claims (Japan)
FOSHU	Foods for Specified Health Uses (Japan)
FSANZ	Food Standards Australia and New Zealand
g	gram
HbA1c	glycosylated haemoglobin
kJ	Energy measured in kilojoules
LC	long chain
LOX	lipoxygenase enzyme
LTB,C,D,E etc	leukotrienes
mcg/μg	microgram
mg	milligram
MHLW	Ministry of Health Labour and Welfare (Japan)
n-3 fatty acids	(same as) omega-3 fatty acids
NRV	nutrient reference values (includes EARS or estimated average requirements, and revised RDIs or Recommended Dietary Intakes)
NUTTAB2006	Reference nutrient database from FSANZ, containing mainly analytical data
PGI, E etc	prostaglandins
PUFA	Polyunsaturated fatty acids
RCTs	Randomised clinical trials
RDIs	Recommended dietary intakes
SFA	Saturated fatty acids
The Code	Australia New Zealand Food Standards Code
TXA	thromboxane
WCRF	World Cancer Research Fund

Executive Summary

Background and aims

The Australian Seafood CRC has requested 3 complementary projects be undertaken to review health benefit research and development relevant to the Australian seafood industry and members of the Australian Seafood CRC.

It is understood that these review projects will assist the Australian Seafood CRC identify research gaps and opportunities and ultimately provide the necessary background information and rationale for a potential supplementary bid to DEST for funding of a new program of health-related research. An overview of these reports will be used as the basis for discussion at the proposed Health Benefits of Seafood Workshop, Sydney, Dec 12th, 2007.

Aims

1. Document FSANZ requirements for health benefit claims in plain English
2. Detail the gaps in justification for product health benefit claims
3. Establish the CRC end-user priorities for R&D needed for justifying product health benefit claims
4. Contribute to literature review
    a. Focus on overview of mechanisms
5. Identify emerging gaps in research
6. Identify potential opportunities for collaboration with a range of partners
7. Identify potential alternative and collaborative funding

Approach and methodology

The FSANZ website and websites for the Japanese Ministry of Health, Labour, and Welfare and the US Food and Drug Administration were the major sources of information regarding health claims for Australia, Japan and the US. Japan and the US were included in this report as they are two key export markets for the Australian Seafood industry. This information was synthesised into flow charts and attempts were made to paraphrase the information into relatively plain English. Examples of seafoods, using specific seafoods of interest to the Seafood CRC were modelled through the proposed approaches for nutrition content and general level health claims. Specific examples were included on the flowcharts to try and increase relevance to the CRC participants.

Some confirmation of our understanding was sought from FSANZ but there has been limited input to date.

A brief review of the potential mechanisms of some of the observed health effects of fish and omega-3 fatty acids was undertaken, with most emphasis on the anti-inflammatory pathway as inflammation is a common underlying mechanistic pathway for many chronic diseases.

It is proposed that there be ongoing consultation with Seafood CRC participants to identify their priorities and interests in this overall area.

Key findings

Food regulations regarding nutrition content and health claims are likely to change within 12 months with the eventual introduction of a new Standard 1.2.7 to Part 1.2: Labelling and Other Information requirements. The final round of consultation for this standard occurred earlier this year and the comments are being consolidated into a Final Assessment Report due for completion around December 2007 with the view to it being presented to the Ministerial Council sometime in the first half of 2008 following review by the FSANZ Board.

This report has summarised the understanding of the authors of the health claim approach being proposed by FSANZ. However, this understanding cannot be based on the final proposal as this will not be available until around mid 2008. Once this approach is finalised, the findings from this report should be revisited.

1. Nutrition content claims

Some seafoods, depending on the species, appear likely to be able to make some nutrition content claims for being a 'source of' or 'a good source' of:

- omega-3 fatty acids (30mg or 60mg total EPA+DHA per serving),
- iodine (15 or 37.5μg per serving),
- selenium (7 or 17.5 μg per serving)
- protein (5 or 10g per serving)

or that they are

- low fat and low in saturated fat (<3g total and <1.5 g saturated and trans fatty acids).

The presence of other biologically active substances can also be claimed but without a statement saying they are a good source. These biologically active substances need to be present at a level of around 10% of the level necessary to see some form of health outcome.

Gaps/further information needed:

Comprehensive nutrient composition data are missing on the national food composition data base:

- iodine, selenium, vitamin E, vitamin D
- Levels of trans fatty acids in seafood.

There is little information on the content of non-nutrient biologically active substances that may be present in seafood:

- coenzyme Q10, other biologically active agents eg bioactive peptides

Some seafoods are not in the current data-base:

- abalone, sea cucumber, different species of commonly consumed fish.

2. General level health claims: the future

FSANZ has preapproved some nutrient function statements on which general level health claims can be based without the need for further substantiation.

General level health claims may be able to be made with respect to some seafood in the following areas:

- omega-3 fatty acids and heart health,
- DHA and brain development,
- iodine and thyroid hormones,
- protein and body tissues,
- vitamin D and calcium for bones
- selenium and antioxidant activity.

Gaps/further information needed:

Many of these nutrients have functions that extend beyond those listed above. There needs to be sufficient evidence that there is a 'probable' association between a food or a component of a food and a health outcome. This evidence can be provided by a systematic review of the literature or if an authoritative body has assessed the literature and provided a position statement. Science text books also acceptable source for generally accepted information source.

Potential opportunities to be explored further include

- protein and satiety, helping to maintain a healthy weight
- iodine and neurological development
- iodine and energy metabolism
- selenium and immune function
- omega-3 fatty acids/fish and mental health
- low saturated fatty acids and mental health
- omega-3 fatty acids/fish and bowel health

- omega-3 fatty acids and joint health
- omega-3 fatty acids and lung health.

Higher level health claims: the future

FSANZ has preapproved some higher level health claims.

A higher level health claim may be able to be made with respect to some seafoods being low in saturated fat leading to the lowering of LDL cholesterol.

Gaps/further information needed

The disease areas most widely researched that are relevant here are cardiovascular disease, cancer, and dementia.

- **Cardiovascular disease:** FSANZ recently reviewed the evidence for an omega-3 fatty acid and prevention of cardiovascular disease claim and stated that there was insufficient evidence to support such a claim, stating that more randomised clinical trials, more prevention trials (eg reduction of triglycerides and blood pressure risk factors) and additional trials in patients being treated for cardiovascular disease.
- **Colorectal cancer:** The World Cancer Research Fund recently reviewed the evidence into the role of diet and the prevention of cancer. They rated the evidence as 'limited but suggestive' of a protective role of fish in preventing colorectal cancer. No other cancers were reported to have an association with fish. Locally the Cancer Council in Australia came to a similar conclusion in 2006 and outlined the following gaps that needed to be filled before a more more conclusive association could be reached:

- - more comprehensive measures and reporting of intakes of omega-3 fatty acids
- - more prospective randomised controlled trials and cohort studies,
- - investigate the ratio of omega-3's to omega-6's in cancer, and
- - determine whether specific fatty acids are more or less associated with the risk of developing cancer.

- **Dementia:** Evidence is beginning to accumulate for some role in the prevention of dementia. Dementia has been identified as an emerging global disease burden as our populations age. The evidence is not yet convincing of a protective effect of fish or omega-3 fatty acids. Additional research is needed to provide high quality human evidence. Areas where there are gaps include the following:

- - What is the role of the long chain DPA?
- - RCTs are needed to determine if omega-3 fatty acids and fish can prevent cognitive impairment or reduce cognitive decline
- - The source, the dose and the exposure to omega-3 fatty acids need further exploration
- - Is there a role in slowing down the progression of Alzheimer's once it has been diagnosed?
- - Are there sub-populations of people who are at higher risk of developing Alzheimer's who may benefit most from increased consumption of omega-3 fatty acids or fish?

Iodine and prevention of goitre and cretinism. It has been known for quite some time that iodine is an essential nutrient and severe deficiency can cause goitre in adults and cretinism and mental retardation in children. The evidence is conclusive enough to recommend iodine supplementation in areas where iodine availability is low. As seafood is one of the richest sources of iodine in the diet (second after seaweed and not including iodised salt), this may present an opportunity to consider whether it may be worthwhile preparing a submission to FSANZ to pre-approve a high level health claim for iodine. The success of this will most likely depend on the current iodine status of the Australian population. In some ways it is analogous to the folate and prevention of neural tube defects health claim.

One of the important mechanisms for the observed widespread effect of seafoods on a range of health outcomes (such as coronary heart disease, cancer, arthritis, dementia) is the dampening of the inflammatory response by the 2 key bioactives in seafood, namely the long chain omega-3 fatty acids eicosapentaenoic (EPA) and docosahexaenoic acids (DHA). However there are other bioactives in fish worth exploring further.

Several research gaps were identified as part of this project and these have been outlined.

Potential collaborators or partners beyond the current CRC members and affiliates were identified and have been included in the body of this report, as are some early suggestions for alternative funding and funding models.

Recommendations: immediate

1. Consult more broadly with CRC participants to gain a better understanding of their R&D priorities needed for justifying product health benefit claims.
2. A comprehensive seafood composition analysis should be undertaken to ensure there are current and adequate data present in the national food composition data-base. This will be very important in order to obtain accurate information on Australian intakes and the availability of all of the key nutrients present in seafoods given that there is a national adult survey being planned for 2008/9 and several key nutrition education documents are about to be revised. Updated information is vital.
3. Evaluate the interest and feasibility of preparing information to support a claim that there is probable evidence of the following nutrients/fish being associated with a particular health outcome, in other words that there is already sufficient evidence suitable to make a general level health claim.

    - protein and satiety, helping to maintain a healthy weight
    - iodine and neurological development
    - iodine and energy metabolism
    - selenium and immune function
    - omega-3 fatty acids/fish and mental health
    - low saturated fatty acids and mental health
    - omega-3 fatty acids/fish and bowel health
    - omega-3 fatty acids and joint health
    - omega-3 fatty acids and lung health

    or for a high level health claim

    - iodine & prevention of deficiency leading to cretinism, goitre.
4. Evaluate the interest from the CRC participants and other potential collaborators in filling some of the research gaps in order to assist with the gathering of conclusive evidence that higher consumption of fish is associated with reducing the risk of developing cardiovascular disease, dementia, colorectal cancer and arthritis.

Recommendations: longer term

5. Keep a watching brief on changes in food code and status of the yet-to-be approved health claims. This should be part of the brief for ongoing environmental scanning for Health Benefits of Seafood Program Leader.
6. Integrate the 3 commissioned reports and the outcomes of the 12th December workshop to identify potential areas of research focus, collaborators and partners for a health benefits of seafood research program.

7. Establish a small strategic working party to further refine the research program by rigorously assessing the potential areas of research focus and opportunities identified.
8. Explore funding opportunities and different funding models, engage with potential funding partners, obtain agreement in principle.
9. Work with identified core health benefit research partners, collaborators, providers, stakeholders to finalise the proposed research program.
10. Finalise the budget and business plan for presentation to CRC Seafood Board.

Research gaps/opportunities

1. What is in our seafood? Do we have adequate data to inform ourselves of what we have and in preparation for future nutrition content claim, general level and high level health claims?
2. Interaction of potential contaminants (such as mercury) with other nutrients in seafood (such as selenium) and other nutrients in the diet (such as fibre).
3. Apparent fish and general level health claim opportunities (CHD & omega-3; thyroid and iodine, antioxidant activity and selenium, fish and mental health, protein and satiety, prevention of mental deficiencies); and high level health claim opportunity (low SFA and reduction of LDL cholesterol).
4. Do we really know what seafood Australians are eating? The tools to address usual fish consumption are inconsistent and often incomplete. There is a national nutritional survey of adults being planned for 2008/9, should a national fish intake tool be developed to be implemented in this survey, the first national survey since 1995?
5. What is the effect of different types of seafoods (bioavailabilities, balance of EPA and DHA etc) and different preparation methods on a range of health effects?
6. Do men need more? Gender effects of fish consumption have not been well explored.
7. Fish, Obesity and Diabetes. Fish is a good source of protein, and can be low in fat, and energy and is potentially high in satiety value. Omega-3 fatty acids can also impact on insulin sensitivity and reduce the pro-inflammatory effects.
8. Fish & Cardiovascular disease – despite years of research, it appears that there is not convincing evidence to support a high level health claim that omega-3 fatty acids could reduce the risk of coronary heart disease. There are still some gaps to be filled, especially for randomised controlled trials. The National Heart Foundation of Australia is currently reviewing evidence relating to fish consumption and cardiovascular disease in order to develop a position statement to be released in the near future.
9. Adopting modern molecular biology nutritional science to help us understand who will benefit most from increased fish consumption. The new science of nutrigenomics promises tailored diets and the potential to design more effective dietary interventions.
10. Fish as a source of selenium. Selenium is a well-recognised antioxidant, with a pre-approved nutrient function statement that theoretically can be utilised for a general level health claim. But there may be other functions of selenium that could form the basis of a nutrient function/general level health claim.
11. Fish as a source of iodine. Iodine intakes are declining and it has been suggested that the prevalence of deficiency may increase in Australia. Iodine is important for thyroid hormones and general energy metabolism. Deficiency can cause mental deficiency and goitre.
12. Fish as a source of bioactives & functional foods. Whilst there are some known bioactive nutrients and non-nutrients in fish, there is the potential for additional discovery programs to identify novel bioactives. These could be used as novel ingredients for new functional food development.
13. Fish and colorectal cancer prevention. The most recent World Cancer Research Fund report just released in November 2007 has stated that there is limited but suggestive evidence of a decreased risk of colorectal cancer with increased fish consumption. This report should be reviewed to see what gaps were identified.
14. Fish and dementia. There are currently no high quality double-blinded randomised controlled trials to investigate preventing or slowing cognitive decline.
15. Information on dose-responses with respect to fish consumption and (potential) health outcomes needs further elaboration.
16. What are other primary food categories doing? Reviewing what others in the same market space are doing can inform approaches for the seafood industry.

Overview of Project

The Australian Seafood CRC has requested 3 complementary projects be undertaken to review health benefit research and development relevant to the Australian seafood industry and members of the Australian Seafood CRC.

It is understood that these review projects will assist the Australian Seafood CRC identify research gaps and opportunities and ultimately provide the necessary background information and rationale for a potential supplementary bid to DEST for funding of a new program of health-related research. An overview of these reports will be used as the basis for discussion at the proposed Health Benefits of Seafood Workshop, Sydney, Dec 12th, 2007. The outcomes of this workshop, along with the information from the 3 reports, will thus provide information for the development of a research program with respect to health and seafood for the Australian Seafood CRC to consider as the basis of the additional bid.

This report focuses mainly on the current and future developments of health claims and highlights some apparent research opportunities and gaps for the Australian Seafood CRC members that arose from these considerations and through the undertaking of this project.

Additional information is provided on proposed mechanisms of the commonly reported health benefits of seafood consumption, which is supplementary information to the literature review being undertaken in Project 2.

Ideas for additional collaborative and funding partners and models are also included.

Limited consultation with the Australian Seafood CRC members was undertaken due to time constraints and delays in making contact with Food Standards Australia and New Zealand (FSANZ). However, it is proposed that this can continue, in collaboration with the CEO of the CRC, over the next 2-3 weeks after submitting this report.

Aims & objectives

1. Document FSANZ requirements for health benefit claims in plain English
2. Detail the gaps for product health claims
3. Establish the CRC end-user priorities for R&D in relation to health claims
4. Contribute to literature review
5. Focus on overview of mechanisms
6. Identify emerging gaps in research
7. Identify potential opportunities for collaboration with a range of partners
8. Identify potential alternative and collaborative funding

Introduction

Seafood in general is a good source of protein with low saturated fat content. It is high in long chain omega-3 fatty acids (Eicosapentaenoic acid, EPA and Docosahexaenoic acid, DHA) and some micronutrients in particular selenium and iodine.

Seafood has long been associated with improving health, in particular in reducing the risk of developing cardiovascular disease, and in facilitating infant brain & visual development. Whilst there is a considerable amount of literature referring to the consumption of seafood and its health benefits, the greatest body of literature has focussed on the impact of fish oils.

The most actively researched bioactive components of fish oils are the long chain omega-3 fatty acids, EPA and DHA. Fish oil supplements provide a standardised method of delivery these bioactives.

Seafood on the other hand can vary quite markedly in composition from species to species, between seasons, stages of their lifecycle and as a result of different feeding regimens if the fish are being farmed.

Nutrients in seafoods

There are many nutrients in seafoods that are worth considering in the context of health benefits and would theoretically provide additional advantages over the more purified fish oil supplements.

Seafood, depending on the species, has the potential to contain significant quantities of not just

- Omega-3 fatty acids EPA & DHA and
- Other long chain omega-3 fatty acids such as docosapentaenoic acid (DPA).

But may also be a source of

- Protein
- Vitamin E and preformed vitamin A (retinol) in fatty fish
- Iodine
- Selenium
- Vitamin D
- Zinc

As well as being

- Low in saturated fat
- Low in or free of *trans* fatty acids
- Low in cholesterol (not for some crustaceans).

Table 1 provides some nutrient composition information of selected seafoods and other comparable foods per 100g. All of the seafoods contain more long-chain omega-3 fatty acids (EPA (20:5), DHA(22:6)) per 100g than the other comparable foods. Alpha-linolenic acid (ALA 18:3)) is a shorter chain omega-3 fatty acid that is thought to be less bioactive than the other longer chain fatty acids. Most of the seafoods listed are lower than comparable foods in total and saturated fats apart from the fattier fish. Levels of cholesterol are comparable to the other protein sources apart from lobster and prawns which have higher levels.

There are limited data on the iodine content but some seafoods such as oysters and lobster have relatively high iodine levels. Most of the seafoods listed have relatively higher levels of selenium, especially canned tuna, oysters and prawns. Oysters appeared to be high in zinc and retinol or vitamin A. There are limited data available on the vitamin E content but it would be expected that levels of vitamin E would be higher in the fattier fish that have higher levels of the highly polyunsaturated omega-3 fatty acids.

Data on vitamin D are limited. Margarines and other edible oil spreads appear to be the major source of dietary vitamin D according to NUTTAB2006 information. Some seafoods may also provide significant amounts of vitamin D (especially herrings).

Potential protective non-nutrients

Additional compounds in seafood may exert a protective effect or health benefit, including but not limited to:

- Peptides/bioactives from bioprocessing eg sardine peptides used in Japan in functional foods to lower blood pressure

- Furan fatty acids (antioxidant activity through free radical scavenging)
- Bioactives in more exotic species eg sea cucumber extracts have been associated with reducing the risk of cancer, or cholesterol lowering agent in green lipped mussels
- Bioactives in waste material. An already commercialised example of this approach is the extraction of chitin and chitosans which are polymers that have molecular weights of approx 1000 kDa and contain >5000 acetylglucosamine and glucosamine units. Chitin is found in shells of crustaceans such as prawns. It has been linked with anti-tumour activity, cholesterol lowering, antimicrobial action, wound healing, blood pressure lowering and antiobesogenic properties.
- Bioactives that may be unique to particular species that are not yet identified.

Non-protective non-nutrients

- Potential contaminants such as methyl mercury, dioxin, polychlorinated biphenyls. Mercury exposure may increase the risk of neurological toxicity and heart disease and the other 2 potential contaminants may increase the risk of cancer.

The introduction of Standard 1.2.7 Nutrition, Health and Related Claims of the Code

The proposed Standard 1.2.7 is designed to regulate nutrition content claims, health claims, dietary information and cause-related marketing statements, whether appearing on food labels or in advertisement. The following types of material are examples of what would be considered labelling or advertising:

- Leaflets beside displays of food products
- Panels or posters displayed in shops
- Shelf wobblers and
- All forms of advertising, including through media such as print, radio, television and Internet

This standard will apply to food for retail sale where the food is not intended for further processing, packaging or labelling but does not apply to:

- Trade marks registered in Australia or New Zealand before or after the commencement of this Standard
- Endorsements made by an endorsing organisation
- Packaged meals provided to clients of a delivered meal organisation
- Food provided to patients in hospitals and similar institutions, when the food is not in a 'package'. This will allow hospitals to continue to label meals as 'low sodium', 'diabetic', etc.
- Government health promotional campaigns or public health materials published by community based organisations

Approach & Methodology

The FSANZ website and the websites for the Japanese Ministry of Health, Labour, and Welfare and the US FDA were the major source of information regarding health claims for Australia, Japan and the US respectively. Japan and the US were included in this report as they are two key export markets for the Australian Seafood industry. This information was synthesised into flow charts and attempts were made to paraphrase the information into relatively plain English. Examples of seafoods, using specific seafoods of interest to the Seafood CRC were modelled through the proposed approaches for nutrition content and general level health claims. Specific examples were included on the flowcharts to try and increase relevance to the CRC participants.

Some confirmation of our understanding was sought from FSANZ but there has been limited input to date. A list of questions was sent to FSANZ and we are still waiting a written response. It is understood that FSANZ is not able to provide specific advice.

Given the time constraints, and with agreement with the Seafood CRC, review of the potential mechanisms of some of the observed health effects of fish and omega-3 fatty acids was limited and restricted to a somewhat high level.

It is proposed that there be ongoing consultation with Seafood CRC participants to identify their priorities and interests in this overall area. This can occur through making arrangements with the CEO of Australian Seafood CRC and through the proposed workshop December 12th, Sydney.

Table 1: Nutrients in Selected Seafoods and Other Comparable Foods in 100g of food *(based on NUTTAB 2006 data that are publicly available)*

Food (per 100g)	Energy (kJ)	Protein (g)	Total Fat (g)	SFA (g)	EPA (mg)	DHA (mg)	ALA (g)	Chol-esterol (mg)	Iodine (mcg)	Sele-nium (mcg)	Zinc (mg)	Retinol Eq (mcg)	Vit E (mg)
Fish													
Tuna, yellowfin, fresh raw	435	23.4	1.0	0.2	39	190	0.01	45	n/a	37.0	0.5	18	0.5
Tuna, canned in brine, drained	497	23.8	2.5	0.8	70	475	0.00	51	10.9	78.6	1.0	19	n/a
Salmon, Atlantic, Fillet, raw	845	20.7	13.3	3.7	505	812	0.11	65	n/a	22.0	0.3	19	n/a
Salmon, Atlantic, steamed or poached	994	24.4	15.7	4.4	595	955	0.13	77	n/a	25.9	0.4	19	n/a
Prawn, King, Raw or Green	371	20.5	0.6	0.2	66	46	0.00	149	29.9	52.9	1.5	1	2.3
Oyster	303	12.0	2.4	0.8	264	256	0.05	80	162.0	69.4	47.9	24	0.9
Whiting, King George, Raw, Flesh only	372	20.3	0.7	0.2	46	46	0.00	98	9.7	53.5	0.8	0	0.5
Barramundi, Aquacultured, Fillet, Raw	385	19.4	1.5	0.4	55	107	0.01	n/a	n/a	32.5	0.3	n/a	n/a
Lobster, Purchased Steamed or Boiled	407	22.0	0.9	0.2	105	62	0.00	116	67.0	25.0	3.4	4	0.4
Beef													
Beef, Fillet, Raw, Lean	608	22.0	6.3	2.4	36	8	0.06	58	0.3	10.0	3.7	2	0.9
Beef, Sirloin Steak, Grilled, Lean	676	30.4	4.3	1.5	25	7	0.03	70	n/a	10.0	7.7	2	0.7
Beef, Topside Roast, Raw, Untrimmed	681	21.3	8.6	3.5	36	10	0.05	37	0.3	10.0	2.8	6	0.0
Pork													
Pork, Forequarter Chop, Raw, Separable Lean	476	19.5	3.9	1.4	0	14	0.02	62	n/a	12.0	3.0	0	0.0
Pork, Minced, Raw	672	19.1	9.4	3.6	0	26	0.09	60	1.1	20.0	2.1	0	0.2
Ham Steak, Grilled	680	19.4	7.8	2.9	7	14	0.06	47	n/a	n/a	2.5	14	n/a
Poultry													
Chicken, Breast, Lean, Baked	637	29.0	3.9	1.2	0	7	0.03	84	0.0	26.1	0.8	7	0.2
Turkey Hindquarter, Baked, Lean, Fat and Skin	911	25.6	12.9	4.4	0	0	0.14	90	n/a	18.4	4.0	36	0.2
Duck, Raw, Lean	506	17.8	5.5	1.7	0	5	0.03	110	n/a	25.0	2.0	18	0.4
Other													
Egg, Chicken, Whole, Hard-Boiled	587	13.0	9.7	3.0	0	65	0.02	384	21.6	27.1	1.1	132	2.5
Walnut, Baking or Eating Styles, Unroasted	2904	14.4	69.2	4.4	0	0	6.28	0	n/a	2.0	2.5	4	2.6

n/a = data not available

Nutrition and Health Claims

Overview of current Australian situation with respect to nutrition content, general level health claims and high level health claims

Current situation

Food Standards Australia and New Zealand (FSANZ) is the agency responsible for the development and maintenance of the joint **Australia New Zealand Food Standards Code** (the Code) which covers all foods produced and imported into Australia and New Zealand.

Claims made on or about foods could potentially refer to the nutrient content of foods or to claims that foods can have a health benefit, either of a general nature or refer to specific diseases.

Some nutrition content claims are currently permitted and are regulated by the *Code* and the voluntary **Code of Practice on Nutrient Claims in food labels and in advertisements** administered by the Australian Food and Grocery Council (e.g. 'This food is low in salt'). **Currently in Australia, health claims are prohibited** by Standard 1.1A.2 of the *Code*, with the **exception of the link between increased maternal folate consumption and a reduced risk of foetal neural tube defects.**

In addition, all information on food labels must comply with the *Trade Practices Act 1974* and must not be misleading or deceptive.

A summary of the key Code documents, current and proposed are listed in Appendix 1.

Changes are proposed

Changes in relation to the use of nutrition and health claims are expected if the proposed new Standard 1.2.7 Nutrition, Health and Related Claims of the *Australia New Zealand Food Standards Code* is approved. Below is a summary of the background and some aspects of the proposed Standard based on information from the Draft Assessment Report and the Preliminary Final Assessment Report P293 Nutrition, Health and Related Claims published by FSANZ (available at www.foodstandards.gov.au). This summary reflects the current understanding of the Standard but not of its final version as the Standard is yet to be finalised and approved and may be subjected to further amendments.

In December 2003, the Australia New Zealand Food Regulation Ministerial Council (Ministerial Council) agreed to a new Policy Guideline for the regulation of Nutrition, Health and Related Claims. FSANZ initiated the process of developing a new standard under the guidance of this policy and published the first of the three consultation documents, the Initial Assessment Report, in August 2004. After three rounds of consultations (following the release of the Initial Assessment Report, the Draft Assessment Report and the Preliminary Final Assessment Report in 2004, 2005 and 2007 respectively), a Final Assessment Report will be presented to the FSANZ Board for approval in December 2007. If this Final Assessment Report is accepted by the FSANZ Board and the Ministerial Council with no further review needed, it is anticipated that the new Standard 1.2.7 will be gazetted in mid-2008 and automatically become law in Australia and New Zealand. The new Standard will be enforced by state and territory government agencies and by the Australian Quarantine and Inspection Service (AQIS) for imported foods. There will be a 24 month transition period for standard implementation and for stock in trade.

Under the proposed new Standard, a wider range of claims about foods and their nutritional or health benefits will be permitted provided these claims can be **scientifically substantiated**. This new regulation will assist consumers in making informed food choices and achieving better health outcomes and at the same time protect consumers from misleading or deceptive claims. It will also provide new marketing opportunities for industry and justify the cost of developing new food products.

There will be three categories of claims:

- nutrition content claims,
- general level health claims and
- high level health claims.

Some foods will be ineligible to make any claims

Certain categories of foods (ineligible foods) are prohibited from making nutrition content claims or health claims.

These include

- food that contains more than 1.15% alcohol by volume,
- infant formula and
- kava.

(Note that for foods containing more than 1.15% of alcohol, nutrient content claims can be made regarding total alcohol, energy and carbohydrate contents)

Nutrition content claims

Proposed nutrition content claims are statements regarding the amount (could be the presence or absence) of a nutrient, energy or a biologically active substance in a food.

- Foods must satisfy **qualifying criteria**, where the nutrient referred to in the claim must be at a defined level as set out in the Standard.
- Other content claims other than those specified in the Standard can be made providing that they are not misleading
- Manufacturers or producers must have proof that the nutrient contained in food is the amount upon which the claim is made.
- Examples: *'this food is high in calcium'* or *'this food is low in fat'* or *'reduced fat'.*

Proposed general level health claims

Proposed general level health claims are statements describing a relationship between the consumption of a food or constituent and a general health effect; and the claim does not directly or indirectly refer to a serious disease or a biomarker of a serious disease.

Manufacturers or producers can base the general level health claim on the pre-approved nutrient function statements prepared by FSANZ, otherwise must hold scientific evidence to substantiate any other general level health claims, reaching a 'probable' level of evidence.

Foods must meet the qualifying criteria of the corresponding nutrition content claims

- For risk decreasing nutrients e.g. omega-3 fatty acid, the food has to be at least considered as a source of the nutrient
- For risk increasing nutrients e.g. saturated fatty acids, the food has to fit the criteria of being 'low' in that nutrient
- For other biologically active substance, the food must contain, per serving, at least 10% of the amount of the biologically active substance deemed to exert the health benefit. [Biological active substance is defined as a substance, other than a nutrient, with which health effects are associated e.g. Co-enzymes, phytoestrogens]
- Pass disqualifying scoring criteria based on the food's **nutrient profile** to prevent inappropriate foods from carrying health claims, except when the claim is made in relation to infant foods, gluten, lactose, a vitamin or mineral. A summary of the nutrient profiling scoring system is provided in Appendix 2.
- Comply to wording conditions which include stating the property of the food and its health effect, that the consumption of food and its health effect needs to be considered in the context of a varied and healthy diet, and if appropriate, the population group to which the associated health effect relates
- Examples:
  'calcium is good for strong bones and teeth, when consumed as part of a healthy diet containing a variety of foods, this food is high in calcium' or
  '*yoghurt high in X and Y may reduce your risk or stomach upset, when consumed as part of a healthy diet with a variety of foods'*

High level health claims

Proposed high level health claims are statements describing a relationship between the consumption of a food or constituent and a particular health effect; and the claim directly or indirectly refers to a serious disease or a biomarker of a serious disease.

A food can make a high level health claim only when the claim is listed in the Standard and the food can meet all the applicable specified criteria and conditions. FSANZ has pre-approval a list of high level health claim for inclusion in the Standard 1.2.7 which may be used as basis of the claim. Other proposed high level health claims not already listed will need to be scientifically substantiated reaching a level of 'convincing' evidence (see section below), pre-approved by FSANZ on a case-by-case basis, before incorporation into the Standard. As with general level health claims, any food carrying a high level health claim has to meet

- Qualifying criteria based on the amount of claimed nutrient source in the food. The required amount necessary to be provided per serving of food will ultimately be determined by FSANZ and included in the published Tables to the Standard
- Pass disqualifying scoring criteria based on the food's nutrient profile and
- Comply with wording conditions
- Examples:
  'This food is high in calcium. Diets high in calcium from a variety of foods may increase bone mineral density, which has particular importance for women' and
  'This food is low in sodium. A healthy varied diet including foods low in sodium may assist in reducing blood pressure'

Claims in relation to vitamins and minerals

The proposed criteria and conditions for nutrition content claims in relation to vitamins and minerals are currently being treated a little differently to other nutrients or food components.

Vitamin and mineral nutrition content claims will generally remain the same as listed in Standard 1.3.2 of the Code (but will eventually be moved to Standard 1.2.7 when enacted) until FSANZ review the Standard with consideration to the recently revised Nutrients Reference Values (NRVs) at a later stage. Foods must be classified as claimable foods to be able to make a claim around vitamins and minerals.

The only change that will be implemented for now is that the claim will be based on a per serving of food rather than the current reference quantity.

Claimable food

Fish, together with fruit, vegetables, grains, legumes, meat, milk, eggs, nuts and seeds are considered as primary foods, and are eligible to be classified as claimable foods in the Code. Most fish/seafood products would fall into the category of a claimable food.

Claimable food by definition means a food which consists of at least 90% by weight of (a) primary foods or foods listed in Standard 1.3.2 or (b) a mixture of primary foods and/or water and/or foods listed in Standard 1.3.2 excluding butter, cream and cream products, edible oils, edible oil spreads and margarine.

Substantiating Nutrition, Health and Related Claims on Foods

The level of substantiation requested by FSANZ varies according to the level of proposed claim.

High level health claims

There will be **eight pre-approved diet-disease relationships** where FSANZ has judged that there is sufficient scientific evidence to support these associations between foods/nutrients and disease. Therefore a high level health claim may be made without further substantiation (See Appendix 3), provided foods wanting to make these claims meet certain criteria (see Table 2). Of these current pre-approved diet-disease links/claims, the proposed claims about **low intakes of saturated fat and reduced LDL cholesterol** are likely to be most relevant to seafood products.

The substantiation process of a diet-disease relationship for a proposed high level health claim can be undertaken in one of two ways.

- The substantiation can be based on a comprehensive and rigorous review and involve identifying, categorising, assessing and interpreting all available evidence; and evaluating the totality of the evidence across all the studies.
- Alternatively, substantiation can be based on an authoritative review. In this case, several pivotal studies cited in the review and any other evidence that emerge after the publication of the review will need to be critically appraised so as to confirm the conclusion.

In either case, it is likely that a **'convincing'** level of evidence has to be reached before a high level health claim can be supported.

Pre-market approval by FSANZ of a high level health claim will be required.

Appendix 4 summarises the 2 substantiation approaches for high level health claims and Appendix 5 provides definitions for the different levels of evidence.

General level health claims

There will be a **pre-approved list of nutrient function statements** which can form the basis for general level health claim without further substantiation (see Appendix 6).

The substantiation of a general level health claim can also be based on authoritative, generally-accepted information sources, (e.g. national diet policy such as the Australia and New Zealand Dietary Guidelines) or follow a similar process required for substantiating high level health claim (see Appendix 4). In any case, it is likely that a **'probable'** level of evidence has to be reached before a general level health claim can be supported.

Pre-market approval of general level health claim will not be required but manufacturers must hold and produce the relevant evidence when requested by authorities.

Nutrition content claim

The only substantiation required is to be able to demonstrate the level of the nutrient that is the subject of a claim.

The preferred method of determining nutrient level is by laboratory analysis.

Food composition tables and other tools such as Nutrition Panel Calculator should only be used with caution. Manufacturers must hold and produce the relevant evidence when requested by authorities.

Summary: Australia

Table 2 summarises the key factors to be considered for a nutrition content, a general level health and a high level health claim.

Table 2 Requirements for making proposed nutrition content claim, general level and high level health claims

Category	Is not an ineligible food[1]	Met qualifying criteria[2] for nutrition content claim	Nutrition content substantiated[3]	Met nutrient profile scoring criteria[4]	Health effect substantiated [5]	Pre-market approval by FSANZ
Nutrition content claim	✓	✓	✓			
General level health claim	✓	✓	✓	✓	✓	
High level health claim	✓	✓	✓	✓	✓	✓

[1] An ineligible food is food that contains more than 1.15% alcohol by volume, an infant formula product or kava, (Note that for foods containing more than 1.15% of alcohol, nutrient content claims can be made regarding total alcohol, energy and carbohydrate contents)
[2] Table to Clause 11 of Standard 1.2.7 provides conditions for specific nutrition content claims that may be made
[3] The level of the component in food needs to be demonstrated, preferably by laboratory analysis or by using food composition tables or tools such as the Nutrition Panel Calculator
[4] 'Baseline' points allocated for increasing amount of energy, saturated fat, sodium and total sugars are offset by 'modifying' points allocated for increasing percentage of the product that is fruit/vegetables/nuts/pulses and the amount of fibre and protein. Under the current proposal, this criteria do not have to be met if a general level health claim is made in relation to a vitamin or a mineral, gluten, lactose or infant foods
[5] Scientific evidence rated as 'probable' is generally required to support a general level health claim; Scientific evidence rated as 'convincing' is generally required to support a high level health claim

Key export markets: Japan and US

There are various approaches in the regulation of health claims in different countries of the world. Some countries have no regulations specific to health claims. Some countries will allow nutrient function claims but will not allow any claims made in reference to a disease while some will allow both.

Health Claims are permitted in both Japan and the US and therefore provides opportunities for promoting the health benefits of seafoods to these countries. Details of the regulatory systems are listed in Appendix 6.

What does this mean for Australian seafood?

Using the most recent Australian reference nutrient composition database prepared by FSANZ, NUTTAB2006, we have prepared a summary table of the nutrient composition of Australian seafoods, focusing on some key nutrients (such as protein, long chain omega-3 fatty acids, saturated fat, selenium and iodine). NUTTAB2006 is based mainly on available analytical data for Australian foods.

Table 3 below lists the nutrient composition of some Australian seafoods.

Seafood in general is a good source of protein with low saturated fat content. It is high in long chain omega-3 fatty acids (Eicosapentaenoic acid, EPA and Docosahexaenoic acid, DHA) and some micronutrients in particular selenium and iodine.

This table highlights that there appear to be analytical data lacking for some seafoods.

Definition of fish in the Code

In the Code, the term 'fish' encompasses what is generally referred to as 'seafood' and is defined as any of the cold-blooded aquatic vertebrates and aquatic invertebrates, including shellfish, but does not include amphibians and reptiles.

Some claims appear likely

Some nutrition content claims, general level and high level health claims may be able to be made based on the current information available. However, the final version of the Code is not yet available and this statement and the following proposed claims would need to be checked once the final version is made available.

The following sections on omega-3 fatty acids, selenium, iodine, protein and vitamin E review what claims could potentially be made for seafood using pre-approved nutrient function statement for general level health claim and pre-approved high level health claims. However, there may be opportunities for additional

(1) nutrient function claims/general level health claims e.g. protein and satiety for weight loss or maintenance; omega-3 and mental health; iodine and mental development
(2) high level health claims (if sufficient convincing evidence available). The concurrent review being undertaken will help to inform this potential opportunities, e.g. omega-3 and inflammatory disease such as arthritis

Table 3: Protein, Long chain omega-3 fatty acids (LC n-3), Selenium (Se) and Iodinecontents in some common seafoods *(based on NUTTAB2006)*

	Serve size (g)*	Protein/ 100g	Protein/ serve	LC n-3 mg/100g	LC n-3 mg/serve	Se mcg/100g	Se mcg/ serve	Iodine mcg/100g	Iodine mcg/serve
Prawn king (large size), purchased cooked	160	23.7	37.9	149	238	46.8	74.9	25.1	40.2
Prawn, garlic, king, home prepared	188	20.4	38.4	110	207	n/a	n/a	n/a	n/a
Prawn king (large size), raw	190	20.5	39.0	112	213	52.9	100.5	29.9	56.8
Tuna, yellowfin, fresh, raw	158	23.4	37.0	229	362	37.0	58.5	n/a	n/a
Tuna, canned in brine, drained	61	23.8	14.5	545	332	78.6	47.9	10.9	6.6
Tuna, Canned in Vegetable Oil, drained	61	23.6	14.4	351	214	96.6	58.9	10.4	6.3
Atlantic Salmon Fillet, raw	158	20.7	32.7	1317	2081	22.0	34.8	n/a	n/a
Atlantic Salmon, steamed or poached	109	24.4	26.6	1550	1690	25.9	28.2	n/a	n/a
Australian Salmon, Canned in Brine, drained	61	20.5	12.5	2303	1405	n/a	n/a	n/a	n/a
Red Salmon, Canned in Water, No Added Salt, drained	61	21.9	13.4	2031	1239	n/a	n/a	n/a	n/a
Oyster, raw	85	12.0	10.2	520	442	69.4	59.0	162.0	137.7
Oyster, smoked, canned in oil, drained	61	17.4	10.6	1368	834	n/a	n/a	n/a	n/a
Whiting, King George, raw	158	20.3	32.1	92	145	53.5	84.5	9.7	15.3
Whiting, King George, Fried in Peanut Oil	114	23.0	26.2	140	160	n/a	n/a	n/a	n/a
Scallop, boiled in unsalted water	54	22.2	12.0	498	269	25.0	13.5	n/a	n/a
Lobster, purchased, steamed or boiled	54	22.0	11.9	167	90	25.0	13.5	67.0	36.2
Calamari or squid, poached	54	20.9	11.3	486	262	n/a	n/a	n/a	n/a
Barramundi aquacultural fillet, steamed or poached	114	22.8	26.0	190	217	38.2	43.5	n/a	n/a
Fish finger, frozen, uncooked	92	10.1	9.3	142	131	n/a	n/a	n/a	n/a
Anchovy, canned in oil, drained	61	25.4	15.5	753	459	n/a	n/a	30.0	18.3

n/a = data not available

* Serve sizes are based on suggestion from FoodWorks Professional 2007, a nutrition software for analysing dietary intakes, meal plans and recipes

Potential nutrition or health claims

Omega-3 fatty acids

Higher consumption of omega-3 fatty acids have been associated with a range of health benefits including

- reduction in the risk of cardiovascular disease,
- reduction in blood pressure,
- promotion of mental development and visual acuity, (DHA is a structural membrane lipid, important in particular for nerve tissue and the retina)
- anti-inflammatory action (eg reduction in symptoms of arthritis) and
- some evidence for a potentially protective action against the risk of developing colorectal cancer and Alzheimer's disease.

Nutrition content claims

A nutrition content claim for seafoods being **a source** of omega-3 fatty acids may be made provided

- the supplier of the food has records that substantiate the claim; and
- the food contains no less than **30mg total EPA and DHA per serving** (or 200mg alpha-linolenic acid (ALA) per serving)
- if saturated fatty acids is added, the food contains as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and trans fatty acids or no more saturated fatty acids and trans fatty acids than 5 g per 100g; and
- the nutrition information panel indicates the source and amount of omega-3 fatty acids and other information as stipulated by the Code.

In addition, a nutrition content claim for seafood being **a good source** of omega-3 fatty acids may be made if the food contains no less than **60mg total EPA and DHA per serving**. Most seafoods appear to provide this amount of long chain omega-3 fatty acids using the serving sizes listed in Table 3.

As omega-3 fatty acids are naturally present in seafood, the claim must refer to the food and not the brand of food.

Potential general level health claims

As stated previously, if FSANZ has pre-approved a nutrient function statement relevant to a nutrient contained in seafood, these can be used as the basis for a general level health claim, provided the other criteria are met as summarised in Table 2.

There is an existing nutrient function statement that refers to the omega-3 fatty acid **DHA and normal development of the brain, eyes and nerves** that has been pre-approved by FSANZ.

There is an existing nutrient function statement that has been pre-approved by FSANZ in relation to DHA, one of the omega-3 fatty acids present in seafood, which states that 'DHA, an omega-3 fatty acid, supports the normal development of the brain, eyes and nerves'.

FSANZ has already commissioned a review on the relationship between long chain omega-3 fatty acids consumption and the potential reduction in the risk of **cardiovasular disease** (Howe et al). FSANZ considered

FSANZ considers the evidence as 'probable' that omega-3 fatty acids reduce the risk of cardiovascular disease, sufficiently strong to make a general level health claim but not a high level health claim.

the evidence provided in this review as '**probable'** but not 'convincing' and therefore whilst they assessed that there was not strong enough evidence to support a high level health claim, FSANZ deemed that there was sufficient evidence to support a general level health claim for the relationship between long chain omega-3 fatty acids and cardiac health.

Comment from FSANZ was that there would not be a pre-approved general level health claim or prescribed wording for the omega-3 fatty acids and CHD.

Appendix 8 provides two theoretical flow charts outlining the steps that seafoods appear likely to be required to follow to determine if they can make a health claim with respect to heart health and omega-3 fatty acids. The first flow chart uses raw prawns as a specific example, demonstrating that prawns may theoretically be able to make a general level health claim linking omega-3 fatty acids and heart health (using an assumed serve size 190g for prawns) whereas smoked canned oysters appeared unable to do so because smoked canned oysters did not have the appropriate nutrient profile.

Selenium

Selenium is considered as a mineral under the Code.

Selenium has variety of functions but arguably the most well documented action/function is its ability to help prevent oxidative damage caused by free radicals. The current NRV was based on this action of selenium (level needed to saturate key antioxidant enzyme glutathione peroxidise). Selenium is also important for normal thyroid functioning (active thyroxine), energy metabolism, regeneration of vitamin C, potential role in muscle maintenance, fertility, potential protection against prostate cancer, and in establishing acquired immunity by providing defence against bacterial and viral infections. There is also an interrelationship with the regeneration of vitamin E. Selenium from animal sources is more actively absorbed (selenium methionine) than plant sources of selenium (selenium cysteine). The margin between adequate and toxic intakes is relatively narrow.

Nutrient content claims

A nutrition content claim for seafoods being **a source** of selenium may be made provided

- the supplier of the food has records that substantiate the claim; and
- a serve of the food contains at least **7µg of selenium** (10% of the RDI).

In addition, a nutrition content claim for good source of selenium may be made if the food contains no less than **17.5µg of selenium** per serving (25% of the RDI). Most seafoods (but not all) appear to provide this amount of selenium using the serving sizes listed in Table 3.

Potential general level health claim

There is an existing nutrient function statement that has been pre-approved by FSANZ that links selenium to an anti-oxidant effect, protecting damage against free radicals. This can be used as the basis for a general health claim, provided the other criteria are met as summarised in Table 2.The food which is the subject of the claim must contain at least **7 µg of selenium per serving**. It is not yet clear whether the upper limit needs to be taken into consideration.

There is an existing nutrient function statement that has been pre-approved by FSANZ in relation to selenium which states that *'Selenium is necessary for cell protection from some type of damage caused by free radical change'.*

Appendix 9 provides a theoretical flow chart outlining some likely steps for seafood producers to follow if they were wanting to make a general level health claim for selenium in the future. Prawns were used as a specific example and using an assumed serving size of 190g and NUTTAB2006 information on the levels of selenium available (approx 53µg/100g), prawns may theoretically be able to make a general level health claim around selenium.

Iodine

Iodine is considered as a mineral under the Code. Iodine is an integral component of thyroid hormones required for normal growth, development of the central nervous system, regulation of cell processes, energy production and oxygen consumption.

Foods of marine origin are the major food sources of iodine.

Iodine intakes and potential deficiency in Australia is becoming of increasing interest with some reports of increasing prevalence of deficiency and declining intakes. Iodine deficiency is the world's leading cause of mental retardation in children.

Suggested reasons for decline in intakes in Australia include:

- decreased consumption of iodised salt
- change in practice within dairy industry- now using chlorine-containing sanitizers instead of iodine-containing sanitizers
- a possible reduction of iodine levels in Australian soils

Seafood is the richest source of iodine, e.g. clams, lobsters, oysters, sardines and other saltwater fish, seaweed. The amount of iodine from animal source is determined by the iodides available in the diet of the animal and the amount of iodine from plant source is determined by the soil in which they grow.

However, utilisation of iodine once it has been absorbed from seafoods for example will depend on what other food-derived bioactives are present. Compounds present in brassica vegetables (cabbage, broccoli, brussel sprouts) and other vegetables (sweet potato) can interfere with iodine metabolism.

Iodine deficiency disorders range from severe iodine deficiency which can cause neurological cretinism or mental deficiency, congenital abnormalities and increased mortality in infants to less severe deficiency disorders that can lead to goitre and hypothyroidism, and impaired mental and physical development.

Nutrient content claims

A nutrition content claim for seafoods being a source of iodine in may be made provided

- the supplier of the food has records that substantiate the claim; and
- a serve of the food contains at least **15µg of iodine** (10% of the Recommended Dietary Intake).

In addition, a nutrition content claim for seafood being a **good source** of iodine may be made if the food contains no less than **37.5µg** of iodine per serving (25% of the Recommended Dietary Intake). It appears that there are limited data available for the iodine content of Australian seafoods.

Potential general level health claim

There is an existing nutrient function statement that has been pre-approved by FSANZ that links iodine to the production of thyroid hormones and this can be used as the basis of a general level health claim provided the other criteria are met as summarised in Table 2**.** The food which is the subject of the claim must contain at least **15 µg of iodine per serving.**

There is an existing nutrient function statement that has been pre-approved by FSANZ in relation to iodine which states that *'Iodine is necessary for normal production of thyroid hormones'.*

Appendix 10 provides 2 flow charts outlining steps for consideration for seafood and a general level health claim related to iodine. Using an assumed serving size of 190g for prawns and 61 g for canned tuna, prawns appear to theoretically able to carry a general level health claim based on iodine whereas canned tuna could not because it did not have sufficient iodine per serve.

Protein

Protein is important for overall health and development. Increasing interest in protein in recent years as being a significant contributor to satiety and hence may play an important role in weight management and weight loss.

Nutrient content claims

A nutrition content claim for seafoods being a **source of protein** may be made provided

- the supplier of the food has records that substantiate the claim; and
- a serve of the food contains **at least 5g protein per serving**.

Most seafoods will qualify for this statement. Furthermore the protein provided by seafoods will be of high quality containing all essential amino acids.

In addition, a nutrition content claim for seafood being a **good source** of protein may be made if the food contains no less than **10g** of protein per serving.

There is an existing nutrient function statement that has been pre-approved by FSANZ in relation to protein which states that *'protein helps to build and repair body tissues'*

Potential general level health claim

There is an existing nutrient function statement that has been pre-approved by FSANZ that could be used as the basis for a general level health claim. The food which is the subject of the claim must contain at least **5g of protein per serving** to be considered as a **source** of protein or **10g per serving** to be considered as a **good source**.

Low in fat & saturated fat

A diet high in fat, in particular animal fat, may provide high levels of saturated fat and cholesterol and increase the risk for cardiovascular disease. Less emphasis is placed on the impact of dietary cholesterol today compared to earlier years. Fat is a concentration form of energy. Consuming food that are lower in fat as in the case of seafoods may assist with weight control.

Nutrient content claims

A nutrition content claim for seafoods being **low in fat and saturated fat** may be made provided

- the supplier of the food has records that substantiate the claim; and
- a serve of the food contains **less than 3g of total fat and 1.5 g of saturated & trans fat per 100g**.

Many seafoods are lower in total and saturated fat than some more frequently consumed animal protein foods. Fatty fish may not fit these criteria. Therefore by substituting seafood for other animal protein foods it may be possible to decrease the overall intake of total fat, and saturated fat without compromising the protein intake. No information on trans fats were available on NUTTAB2006.

Potential high level health claim

There is a proposed pre-approved diet disease relationship that relates low intakes of saturated fat and lowering of LDL cholesterol levels that has been assessed by FSANZ as having sufficient evidence such that it does not need further substantiation. The food which is the subject of the claim must contain **less than 3g of total fat and 1.5g of saturated & trans fat per 100g.**

There is an existing pre-approved diet-disease relationship deemed by FSANZ as being sufficiently substantiated that relates low intakes of saturated fats and lowering of LDL cholesterol levels. This provides an opportunity for some seafoods to make a high level health claim linking seafood to a key biomarker of heart disease, LDL cholesterol

Vitamin E in fatty fish

Vitamin E is found in the fats of fish. The primary role of vitamin E is to protect polyunsaturated fatty acids from oxidation ie it acts as an antioxidant, mainly in the lipid phase in cell membranes. Alpha-tocopherol is the most biologically active form.

Nutrient content claims

A nutrition content claim for seafoods being a source of vitamin E in may be made provided

- the supplier of the food has records that substantiate the claim; and
- a serve of the food contains at least **1 µg vitamin E α-tocopherol equivalents** (10% of the Recommended Dietary Intake).

Depending on the serve size, some seafoods may be able to make the claim that they are a source of vitamin E. More information is needed on vitamin E contents in Australian seafoods.

In addition, a nutrition content claim for seafood being a **good source** of vitamin E may be made if the food contains no less than **2.5µg** of vitamin E per serving (25% of the Recommended Dietary Intake). It appears that there are limited data available for the vitamin E content of Australian seafoods. From what is available, no seafoods appear eligible to make this good source nutrition content claim.

Potential general level health claim

There is an existing nutrient function statement in relation to vitamin E which states that 'vitamin E is necessary for cell protection from the damage caused by free radicals' that has been pre-approved by FSANZ and could be used as the basis for a general level health claim. The food which is the subject of the claim must contain at least **1 µg vitamin E α-tocopherol equivalents per serving.**

Not all seafoods may qualify as a source of vitamin E so opportunities for seafoods to make a general level health claim with respect to vitamin E may be more limited than other nutrients previously considered. This will need further examination once there is more compositional data available.

There is an existing nutrient function statement that has been pre-approved by FSANZ in relation to vitamin E which states that *'vitamin E is necessary for cell protection from the damage caused by free radicals (such as oxidation of polyunsaturated fatty acids in red blood cell membranes.).*

Opportunities for seafoods to make a general level health claim around vitamin E may be limited.

Other biologically active substances in fish

These include

- Coenzyme Q10: a fat soluble antioxidant. Higher amounts in red flesh (and hearts) of fish. Fatty fish are likely to be the second richest source of coenzyme Q10 after red meat. Fish by-products may potentially be good sources.
- Chitin from shells
- Potentially bioactive peptides from fish protein
- Squalene
- taurine

Some potential general level health claims worth considering further.
Given that FSANZ has stated that evidence for a general level health claim can be supported by statements from authoritative bodies, text books, or other health claims assessed by overseas governments, the following general level health claims may be worth considering. The potential nutrient and the health effect are listed with some of the sources of authoritative or comprehensive reviews undertaken listed as the secondary dot point.

- **Protein and satiety**
  - CSIRO
- **Iodine and neurological function**
  - UK Joint Health Claims Initiative 2003
- **Iodine and energy metabolism**
  - UK Joint Health Claims Initiative 2003
- **Selenium and immune function**
  - UK Joint Health Claims Initiative 2003
- **Omega-3 fatty acids/fish and mental health**
  - Alzheimer's Australia Update Sheet Nov 2006: include fish in the diet, implying 1-2 oily fish/week, include omega-3 fatty acids
  - Connor 2007: n-3 fatty acids reduced decline in cognition
  - Logan 2004, Torpy 2006: Increased fish consumption – better mental health, less depression
- **Low saturated fat and mental health**
  - Alzheimer's Australia Position Statement 2005 supports
- **Omega-3 fatty acids/fish and bowel health**
  - World Cancer Research Fund 2007: Possible decreased risk colorectal cancer
- **Omega-3 fatty acids and joint health**
  - Arthritis Australia, Nutrition Australia
- **Omega-3 fatty acids and lung health**
  - National Asthma Council Foundation 2005; Asthma and Diet in Early Childhood. Fish can supply omega-3 fatty acids to help protect against inflammation of airways

Some potential higher level health claims worth considering

- **Low total fat and cancer prevention**
  - Approved health claim in US
- **Iodine and the prevention of cretinism, goitre**
  - Long standing evidence of this association

Mechanisms to supplement literature review

Inflammation: a common pathway for many diseases (Calder 2002)

Inflammation appears to play a role in several chronic diseases such coronary heart disease, cancer, arthritis and potentially Alzheimer's disease. Thus one of the potential pathways by which n-3 fatty acids may exert its pleiotropic health benefits may be through its effect on the inflammatory pathway.

Omega-3 fatty acids exert anti-inflammatory effects by:

- Suppressing the production of n-6 arachidonic acid (AA)-derived eicosanoids
    - Eicosanoids are a group of hormone like substances that include thromboxane (TX), prostaglandins (PG) and leukotrienes (LT)
    - EPA competes with AA for incorporation into the membrane phospholipids and therefore less substrate available for synthesis of eicosanoids from AA
    - Inhibits AA release from phospholipids by phospholipase A2
    - Competitively inhibits the oxygenation of AA by the cyclo-oxygenase enzymes (COX, especially COX2 isoform). It appears that DHA not EPA is the primary agent for reducing COX2 expression
- Elevating the production of the less biologically potent EPA-derived eisosanoids via the COX and 5-lipoxygenase (LOX) pathways, thereby dampening the inflammatory response
- Suppressing production of pro-inflammatory cytokines (such as tumour necrosis factor α, IL-1 and IL-6 which act as inflammatory agents)
- Modulating adhesion molecule expression to decrease binding of cell surface
- Down regulating inflammatory gene expression (eg via inhibition of COX-2 dampening the inflammatory response or by interaction with peroxisome proliferators-activated receptors, PPAR-γ, augmenting its known anti-inflammatory effect)

Overview of other mechanisms

Cardiovascular Disease and omega-3 fatty acids (Hooper et al 2007)

Many cardiovascular disease risk factors are favourably influenced by omega-3 fatty acids intake. Omega-3 fatty acids can

- lower blood pressure,
- alter lipid profile especially reduced serum triglyceride concentration,
- have anti-arrhythmic effects including reduction in heart rate,
- improved vascular endothelial function,
- increase plaque stability,
- increase paraoxonase levels (an enzyme associated with high-density lipoprotein which may protect against the oxidation of low-density lipoprotein) and
- improved insulin sensitivity

Dementia: Proposed mechanisms of potential protection (Lim et al 2007)

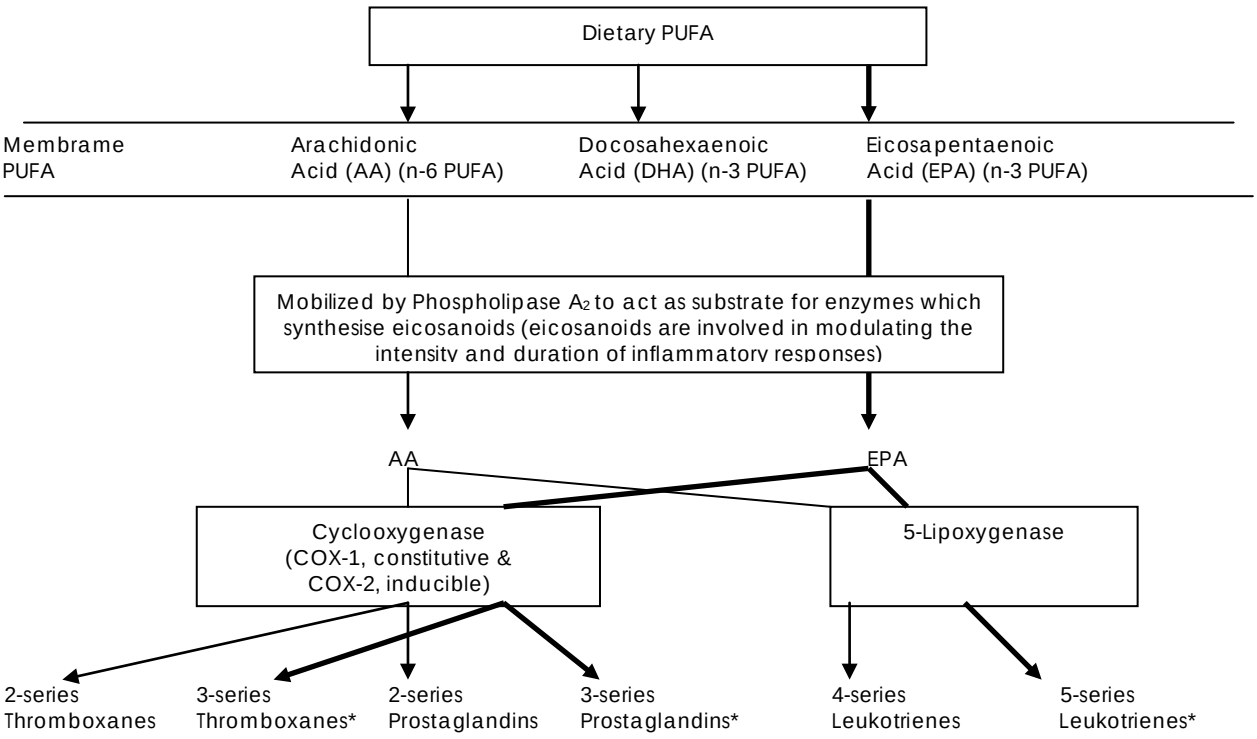
Omega-3 fatty acids may protect against dementia (Alzheimer's disease (AD) and vascular dementia) by reducing

- cardiovascular disease risk and non-haemorrhagic stroke risk due to antithrombotic, anti-arrhythmic, anti-inflammatory and anti-atherogenic effects, lowering of serum triglycerides and blood pressure and improving endothelial function
- dampening the inflammatory component of the dementia disease process (see diagram above)
- reducing the production of the β-amyloid protein, plaques of which are deposited in the brain and are the primary pathology associated with AD
- DHA, by being incorporated into membranes, may maintain membrane integrity and neuronal function
- DPA is also a longer chain omega-3 fatty acid (22:5) and higher intakes of DPA have been shown in animal models to slow the expression of AD and improve cognitive performance. This potential effect has not yet been evaluated in humans.

Cancer prevention and potential mechanisms

- Inhibition of eicosanoid production from the n-6 fatty acid precursors (such as AA) which leads to
    - Suppression of neoplastic transformation
    - Cell growth inhibition
    - Enhanced apoptosis
    - Anti-angiogenesis
    - Dampening of inflammatory response
- Alteration of oestrogen metabolism which leads to reduced oestrogen stimulated cell growth.

Figure 1: Schematic for anti-inflammatory action of omega-3 fatty acids



e.g. TXA_2
- Produced primarily by platelets
- Promotes platelet aggregation
- Vasoconstriction
- Mobilizes intracellular calcium
- Contraction of smooth muscle

(Champe et al 2005)

e.g. PGI_2
- Produced primarily by endothelium of vessels
- Vasodilation
- Inhibits platelet aggregation

PGE_2
- Produced by most tissues, especially kidney
- Vasodilation
- Relaxes smooth muscle
- Used to induce labour

$PGF_{2\alpha}$
- Produced by most tissues
- Vasoconstriction
- Contraction of smooth muscle
- Stimulates uterine contraction

(Champe et al 2005)

Produced in leukocytes, platelets, mast cells, and heart and lung vascular tissues

e.g. LTB_4
- Increased chemotaxis of leukocytes
- Release of lysosomal enzymes
- Adhesion of white blood cells

$LTC_4 \rightarrow LTD_4 \rightarrow LTE_4$
- Contraction of smooth muscle
- Bronchoconstriction
- Vasoconstriction
- Increased vascular permeability
- Components of slow-reacting substance of anaphylaxis (SRS-A)

(Champe et al 2005)

* less biologically potent than the analogues synthesized from AA, except PGI_3,

n-3 PUFA exerts anti-inflammatory effects by:
- Suppressing the production of AA-derived eicosanoids
  - EPA Competes with AA for incorporation into the membrane phospholipids and therefore less substrate available for synthesis of eicosanoids from AA
  - Inhibits AA release from phospholipids by phospholipase A2
  - Competitively inhibits the oxygenation of AA by COX
- Elevating the production of the less biologically potent EPA-derived eisosanoids via the COX and 5-lipoxygenase pathways
- Suppressing production of pro-inflammatory cytokines
- Modulating adhesion molecule expression to decrease binding of cell surface
- Down regulating inflammatory gene expression

n-3 PUFA is said to have cardio-protective effect by being able to lower blood pressure, alter lipid profile especially reduced serum triglyceride concentration, have anti-arrhythmic effects including reduction in heart rate, improved vascular endothelial function, increase plaque stability, increase paraoxonase levels and improved insulin sensitivity

Research Gaps identified

What is in our seafood?

1. What is missing?
    a. Comprehensive national analyses
    b. Not all seafoods are listed in NUTTAB2006 eg abalone
    c. Not all nutrients are listed in NUTTAB2006 eg selenium and iodine contents are not listed for some seafoods eg calamari
    d. What are the current levels of potential contaminants, especially for the higher order predatory species (mercury, dioxin, polychlorinated biphenyls)
    e. How recent is the omega-3 fatty acid data?
    f. Is DPA worth measuring specifically/investigating further (DPA may be converted to EPA or be active in its own right)
    g. What are the commonly consumed serving sizes of seafood in Australia today?
    h. Limited vitamin D data

    Why is it important?

    i. Need knowledge of own product
    j. Basis of any nutrition panel, or nutrition content claim in the future
    k. National Adult Survey likely to be underway 2009, proposal for Cancer Council ongoing school survey is being considered, Core food Groups and Dietary Guidelines being revised. Good composition and common serve size data will ensure quality of data coming out with the dietary analyses
    l. Note that WA has developed/validated a fish-focussed food frequency questionnaire – useful tool to use in state and national surveys to get specific information on different types of fish
    m. Undertake cost-benefit analysis
2. Interaction of potential contaminants (such as mercury) with other nutrients in seafood (such as selenium) and other nutrients in the diet (such as fibre)

Gaps for nutrition and health claims

3. Comprehensive composition data are central for making nutrition content and health claims
4. Are there any other nutrient function claims/general level health claims or high level health claims worth considering for a submission to FSANZ? This would require a systematic review of the evidence or building on a review that is pre-existing
    a. Eg prevention of iodine deficiency/mental function/prevention of cretinism
    b. Omega-3 fatty acids and inflammation
    c. Fish and mental health
    d. Protein and satiety

5. Is there enough evidence to prepare a systematic review for a nutrient for consideration for any other health claims? The current literature review being undertaken in the concurrent Project 2 should assist with a critical analysis and opportunity identification.
6. Does the upper limit for selenium need to be considered?

Intakes/preparation

7. Do we have sufficient economic analyses – impact of increasing fish consumption, fish production, risk-benefit (mercury vs health benefits)
8. Results may be inconsistent due to limited standardisation of tools to estimate fish intake – investigate usage of fish food frequency questionnaire developed in Western Australia. Some studies do not report on details of fish type or portion sizes.
9. Do not fully understand fish preparation effects – (Mozaffarian et al 2006, Myint et al 2006) – impact on bioavailability etc. Some suggestion that n-3 fatty acids obtained from cooked fish fillets are more efficiently absorbed than from uncooked sources. Mooney et al (2002) have done some investigations into the effects of processing and environment on the oil composition of some seafood species
10. Fish meals vs supplements
    a. Absorption of n-3s from a fish meal is likely to be more gradual than from concentrated fish oil where the oil tends to be taken as a bolus, causing a sudden increase in fatty acids.
    b. The more gradual dietary intake may be more beneficial in chronic heart disease (Burr 2005). DART2 trial revealed that fish oil capsules actually increased risk of cardiac and sudden death.

Gender effects?

11. Are there any gender effects? Very few intervention studies have been undertaken in women. Results from the EPIC study suggest that men may need to eat more fish than women to obtain the same blood concentrations. Potentially due to differences in body size & plasma volume, or due to differences in oestrogen or percentage of body fat? Very few studies have investigated the sex differences. EPIC study suggests that women get greater benefit than men for the same amount of fish consumed – the equivalent of an extra half a serve of fish. This is important to understand given the dietary recommendations to eat more fish.

Obesity and diabetes

12. Furthermore obesity is increasing along with a concomitant increase in mainly type 2 diabetes, metabolic sequelae of insulin resistance – hypertension and elevated plasma triglycerides. There is some evidence to suggest that higher consumption of fish in an obese population may reduce the risk of developing type 2 diabetes, independent of any weight loss. Insulin sensitivity has been positively associated with the proportion of LC PUFA present in cell membranes. The EPIC study found that eating oily fish as part of healthy lifestyle was associated with lower HbA1C albeit in women only. Some earlier studies suggested that higher intakes of n-3 fatty acids actually worsened glycaemic control but these findings have not been confirmed by more recent meta-analyses.

Cardiovascular disease: FSANZ analysis/review

13. Gaps identified by FSANZ upon consideration of Howe et al commissioned review looking at omega-3 fatty acids and CVD risk
    a. Insufficient randomised controlled trials (RCTs) that show reduced CVD risk

b. There is not enough evidence from primary prevention trials

c. Observational studies have not considered/adjusted for other lifestyle effects (gender, fish preparation)

d. Proposed anti-arrhythmic effects have not translated to reduced CVD events – need another large well designed RCT to determine if omega-3 fatty acids reduce sudden death in patients being treated for CHD

e. While there is convincing evidence that supplemental omega-3 fatty acids in doses of around 1g per day, modestly reduces blood pressure and triglycerides, there is still not enough evidence to show reduction in CVD risk in well designed RCTs

f. There is uncertainty as to what extent food (seafood) can lower triglycerides

Adopting modern molecular biology nutritional science

Nutrigenomics: offers the opportunity to understand the molecular basis of the health benefits of seafood in a systematic manner. This newer science offers the promise of a tailored approach which may be a prudent approach given concerns are sometimes expressed regarding sustainability of fish stocks across the globe. Nutrigenomics may eventually assist with defining key sub-groups of the population to whom the seafood health benefit message should be targeted.

a) Differences in individual's genetic makeup may cause some key nutrients to be metabolised differently and/or at different rates amongst different people or groups of people such that some may need more or less of a particular nutrient. Well-being may therefore be compromised if there is insufficient nutrient available

b) Alternatively, understanding how the bioactives in fish interact at the molecular level by affecting gene expression and therefore ultimately protein expression and metabolite production will further define those individuals most likely to benefit from increased consumption of seafoods. This may be worth exploring further in those with particular polymorphisms for coronary heart disease as biomarkers for this disease are well established. Trials that measure success by measuring changes in an established biomarker that correlates to a reduction in risk tend to be shorter, cheaper research options compared to waiting until trial participants are diagnosed with heart disease. Other diseases such as colorectal cancer and Alzheimer's are also worth exploring in this nutrigenomic context but biomarkers for these diseases are less established/accepted in the scientific community. Where biomarkers are not well established, longer term trials are needed, generally until the disease manifests itself. Such trials are therefore long and expensive.

Fish as a source of selenium

Undertake a more systematic analysis of the selenium content of Australian seafood. What other roles of selenium might be worth exploring further eg role of selenium in reducing role of infections?

Fish as a source of iodine

Undertake more systematic analysis of iodine content of Australian seafood.

Fish as a source of bioactives & functional foods

Bioprocessing of fish, fish by-products or waste could identify pre-existing bioactives that provide a health benefit to value-add to the seafood industry but could also produce novel bioactives through systematic bioprocessing that could generate potentially commercialisable intellectual property as ingredients for functional food development.

Fish and cancer prevention

Given the recent findings from the World Cancer Research Fund that deemed that there was limited but suggestive evidence that consumption of fish decreased the risk of colorectal cancer, it would seem prudent to gather information on the gaps in the evidence as identified by the reviewers once the whole document becomes readily available, later in 2007.

The Cancer Council Australia has also recently reviewed the evidence of the role of omega-3 fatty acids and fish in cancer prevention (Cancer Council Australia 2006). They identified the following research needs

- Prospective RCT and cohort studies
- Able to comprehensively measure and report omega-3 fatty acids in the diet from all sources
- Able to classify the omega-3 fatty acid group into individual fatty acids in order to investigate the association between specific fatty acids and risk of cancer
- Able to investigate the association between the omega-3 to omega-6 ratio and cancer risk
- Develop consistency in the way data is collected, measured and reported and classification for levels of evidence when reviewing the literature
- (Observational) studies should be conducted in populations with sufficient variation in intake of fish and individual fatty acids

Fish and dementia

A recent Cochrane review (Lim et al 2007) concluded that there was a growing body of evidence from biological, observational and epidemiological studies that suggested a protective effect of omega-3s against dementia in cognitively intact elderly aged 60 years and over. There were no RCTs available to include in the review but the authors noted that 2 RCTs were due to be completed in 2008.

Research opportunities identified in this recent review

- Determine if the potential protective effect of the long chain omega-3 fatty acid DPA against developing dementia can be replicated in humans
- What are the levels of DPA in fish?
- Need double-blinded RCTs to determine if omega-3 fatty acids can prevent cognitive impairment (or reduce decline)
- What are the effects of omega-3's on sub-populations in relation to prevention of dementia such as for those at more or less risk of developing dementia. Specifically, is there a differential benefit of increased consumption of omega-3 rich diets for those at higher risk (eg those carrying the apo-E4 polymorphism who have a higher risk of developing Alzheimer's) compared to those at lower risk of developing Alzheimer's.
- What is the effect of the source, the dose and exposure duration of omega 3 on potential dementia prevention
- Is there a place for omega-3's in secondary prevention – ie slowing down the progression of the disease that has been diagnosed at an early or mild stage. In the past this was not possible as the definitive diagnosis of Alzheimer's was only possible at post-mortem. However earlier diagnosis will soon be possible due to the outcomes of research that is focusing on identifying reliable early stage biomarkers and with the advent of more modern brain imaging techniques.

- At what age should those at increased risk, commence some preventative intervention such as a seafood-rich diet containing plenty of omega-3 fatty acids.

Chronic diseases in general

Dose-response relationships between omega-3 fatty acids (and hence amount of fish to be consumed) and prevention of chronic disease/promotion of well-being have not been adequately determined.

What are other primary food categories doing?

Additional opportunities may be identified for seafood if we examine the approaches that other primary food categories are adopting with respect to marketing and delivery of health messages

- Dairy – mixture of nutrients (calcium, B-vitamins), milk-protein derived peptides with bioactivity (such as reducing blood pressure, assisting with dental health and uptake of calcium into teeth, conjugated linoleic acids, components in colostrum (eg immune function and physical performance or peptides such as clostrinin that may play a protective role in Alzheimer's disease)
- Red meat – iron as one of key nutrients that is more readily absorbed from animal sources in the haem form compared to plant sources
- Soy – phyto-oestrogens
- Cereals – fibre as key ingredient but other more cereal-specific phytochemicals such lignans, resistant starch for bowel health
- Fruit and vegetables – antioxidants and phytochemicals

So it would be important to define what is currently a unique value-proposition for seafood – look at scientific literature for evidence, identify gaps. This is currently underway in Project 2. Leads can also be found by reviewing traditional medicine approaches. For example

- Is there a seafood colostrum equivalent? Fish roe likely to be unique
- Are seafood proteins likely to yield novel bioactive peptides once subjected to processing?
- Is there a unique compound or group of compounds only found in fish?
    - Long chain omega-3 fatty acids are an example but the fish oil supplement industry is a strong competitor.
    - Seafood is purportedly the best source of iodine (after seaweed which is not widely consumed in Australia)

Potential additional collaborators/funding bodies

Some selection criteria developed for choosing suitable collaborators

- Available capacity (at appropriate time and with appropriate scope)
- Relevant capability
- Expressed interest in the priority areas/research gaps
- Access to funding
- Track record or proven ability to be able to adapt to health benefits of seafood research
- Good understanding of the importance of health and a demonstrated readiness to work within a multidisciplinary team
- Freedom to publish findings (ie no commercial interests that would impede dissemination of findings)
- Cognisant of the needs of the seafood industry

List of potential collaborators/ research partners

Government Organisation

Federal

- Commonwealth Department of Agriculture, Forestry and Fisheries. *What are their priorities?*
- FSANZ – *food regulations and food composition team, ongoing analysis of Australian food composition data*
- Federal Department of Health & Ageing, Nutrition Section. *Funding the next adult nutrient and food intake survey. How to ensure that the seafood industry gets good information on seafood consumption in Australia. In addition, the Core Food Groups and the Dietary Guidelines are being reviewed over the next 1-2 years. Good seafood nutrient composition data would be relevant for both of these activities*
- NHMRC - *funding*
- Australian Research Council - *funding*

State and Territory

- State & Territory Departments of Health
- State Departments of Primary Industries
    - WA Department of Fisheries
    - South Australian Research and Development Institute (SARDI)
    - NSW Department of Primary Industries
    - Tasmania Department of Primary Industries and Water
    - Victoria Department of Primary Industries. Note the Food for Life initiative in Victoria
    - Northern Territory Department of Primary Industry, Fisheries & Mines
    - Queensland Department of Primary Industries and Fisheries

Non-government organisations

- Alzheimers Australia
- Neurosciences Australia (looking at diet & Alzheimers, cognitively impaired)
- Asthma foundation
- Cancer Council Australia
- Diabetes Australia
- Nutrition Australia
- International Life Sciences Institute (ILSI)
- Other health groups similar to Southern Adelaide Health Services

Professional Organisations (including consultations only)

- DAA (consultation)
- Nutrition Society (consultation)
- Environmental organisations – contaminations, cost-benefit ratios
- National Heart Foundation of Australia
- Cancer Councils
- Arthritis Australia
- Gut Foundation
- Australian Crohn's and Colitis Association

International Organisations

- World Health Organisation (cost-benefit ratio)

Research organisations

- CSIRO
  - Food Science Australia
  - Human Nutrition
  - Preventative Health National Research Flagship
  - Food Futures National Research Flagship
- International Diabetes Institute
- National Ageing Research Institute (NARI)
- National Institutes of Health (US)
- National Cancer Institute (US)
- Dementia CRC

Industry

- Australian Food and Grocery Council
- Simplot
- Nestle
- SeaLord (NZ)

Some different funding models for further consideration

1. Coinvestment with State Government Departments for a specific research program

- SA Strategic Health Research Program – one of the priorities for 2008 is bioactives in foods and prevention of cancer. This would appear to be an appropriate funding body to link into given that the CRC is headquartered in SA and that the WCRF's most recent review states that upon reviewing the totality of the evidence, the evidence was rated as suggestive of a decreased risk of developing colorectal cancer with increased fish consumption. However, expressions of interest have already been called for the 2008 round of funding.
- WA Department of Health has expressed interest in investing in the health arena.

2. Establish a centre of excellence (could be virtual) around a particular research expertise or research focus eg bioactive discovery

3. Applications to traditional research funding bodies for a large program grant eg to fund a large RCT

4. Coinvestment from FSANZ and industry to undertake a national analysis of nutrient and potential contaminants present in Australian seafoods

5. Collaboration established with bodies undertaking large national surveys to ensure there is an appropriate intake instrument utilised to gain an accurate understanding of seafood consumption.
    a. National adult nutrition survey
    b. Cancer Council schoolchildren survey
    c. Australian Imaging and Biomarker and Lifestyle survey (Alzehimers)
    d. Beyond Blue
6. Collaborate with Fisheries Research & Development Corporation: Investigate what health related projects FRDC currently funds and discuss agreed mutual priorities for health related research that are seen as a high priority by both the FRDC and the Australian Seafood CRC
7. Approach a CSIRO National Research Fund for a large Flagship Collaboration Program ($1-3m over 3 years). May fit with either the Food Futures Flagship or the Preventative Health Research Flagship.
8. Work with Cancer Councils, National Heart Foundation to get some agreed research priority areas where projects could be co-funded by both the CRC and the other funding body. The National Heart Foundation is currently reviewing evidence relating to fish consumption and cardiovascular disease with the view of releasing a position statement in the near future.
9. Explore sources of international funding.
    a. Approach WHO or other global funding bodies to undertake a comprehensive risk benefit analysis
10. The International Council for the Control of Iodine Deficiency Disorders (ICCIDD)?

Key recommendations

Recommendations: immediate

1. Consult more broadly with CRC participants to gain a better understanding of their R&D priorities needed for justifying product health benefit claims.
2. A comprehensive seafood composition analysis should be undertaken to ensure there are current and adequate data present in the national food composition data-base. This will be very important in order to obtain accurate information on Australian intakes and the availability of all of the key nutrients present in seafoods given that there is a national adult survey being planned for 2008/9 and several key nutrition education documents are about to be revised. Updated information is vital.
3. Evaluate the interest and feasibility of preparing information to support a claim that there is probable evidence of the following nutrients/fish being associated with a particular health outcome, in other words that there is already sufficient evidence suitable to make a general level health claim.
    - protein and satiety, helping to maintain a healthy weight
    - iodine and neurological development
    - iodine and energy metabolism
    - selenium and immune function
    - omega-3 fatty acids/fish and mental health
    - low saturated fatty acids and mental health
    - omega-3 fatty acids/fish and bowel health
    - omega-3 fatty acids and joint health
    - omega-3 fatty acids and lung health

    or for a high level health claim

    - iodine & prevention of deficiency leading to cretinism, goitre.
4. Evaluate the interest from the CRC participants and other potential collaborators in filling some of the research gaps in order to assist with the gathering of conclusive evidence that higher consumption of fish is associated with reducing the risk of developing cardiovascular disease, dementia, colorectal cancer and arthritis.

Recommendations: longer term

5. Keep a watching brief on changes in food code and status of the yet-to-be approved health claims. This should be part of the brief for ongoing environmental scanning for Health Benefits of Seafood Program Leader.
6. Integrate the 3 commissioned reports and the outcomes of the 12th December workshop to identify potential areas of research focus, collaborators and partners for a health benefits of seafood research program.
7. Establish a small strategic working party to further refine the research program by rigorously assessing the potential areas of research focus and opportunities identified.
8. Explore funding opportunities and different funding models, engage with potential funding partners, obtain agreement in principle.
9. Work with identified core health benefit research partners, collaborators, providers, stakeholders to finalise the proposed research program.
10. Finalise the budget and business plan for presentation to CRC Seafood Board.

References

Australian Government Department of Health and Ageing, NH&MRC Nutrient reference values for Australia and New Zealand Including Recommended Dietary Intakes. Commonwealth of Australia 2006

Burr ML, Dunstan FDJ & George CH 2005, 'Is Fish Oil Good or Bad for Heart Disease? Two Trials with Apparently Conflicting Results', *The Journal of Membrane Biology*, Vol. 206, pp.155-163.

Calder PC 2002, 'Dietary modification of inflammation with lipids', *Proceedings of the Nutrition Society*, Vol.61, pp.345-358

Cancer Council Australia. Health Professional Summary. Omega-3 fatty acids, fish and cancer prevention. 2006

Champe PC, Harvey RA & Ferrier Dr 2005, *Lippincott's Illustrated Reviews: Biochemistry*, 3rd edition, Lippincott Williams & Wilkins, Philadelphia, USA.

Connor & Connor 2007. The importance of fish and DHA in Alzheimer's disease. Am J Clin Nutr 85:929-930.

FSANZ website at www.foodstands.gov.au

Hooper L et al. Omega 3 fatty acids for prevention and treatment of cardiovascular disease. Cochrane Database of Systematic Reviews 2004, Issue 4. Art, No.:CD003177. DOI:10.1002/14651858.CD003177.pub2.

Howe P, Mori T & Buckley J 2006, 'The relationship between omega-3 fatty acid intake and risk of cardiovascular disease', viewed online 3 Oct 2007, http://www.foodstandards.gov.au

Japanese Ministry of Health, Labour, and Welfare viewed online 2 Nov 2007 < http://www.mhlw.go.jp/english/topics/foodsafety/fhc/index.html>

Joint Health Claims Initiative, Final Technical Report, Part 1 & 2. A report by the Joint Health Claims Initiative to the Food Standards Agency. 2003 JHCI/76/03

Lim et al. Omega 3 fatty acid for the prevention of dementia. Cochrane Database of systematic reviews 2006. Issue 1. Art No CD005379. DOI 10.1002/14651858.CD005379.pub2

Logan AC, 2004 Omega-3 fatty acids and major depression. A primer for the mental health professional. BioMed Central Online 3(25):1-8.

Mooney BD, Nichols PD & Elliott NG 2002, *Seafood The Good Food II*, CSIRO Marine Research, and Fisheries Research & Development Corporation (FRDC), Australia.

Mozaffarian D, Gottdiener JS, Siscovick DS 2006, 'Intake of tuna or other boiled or baked fish versus fried fish and cardiac structure, function and hemodynamics', *American Journal of Cardiology*, Vol. 92, no.2, pp.216-222.

Myint PK et al 2006, 'Habitual fish consumption and risk of incident stroke: the European Prospective Investigation into Cancer (EPIC) – Norfolk prospective population study', *Public Health Nutrition*, Vol. 9, no. 7, pp.882-888.

NUTTAB2006 online version available at www.foodstandards.gov.au

Massaro et al Omega-3 fatty acids, Inflammation and Angiogenesis: Nutrigenomic effects as an explanation for the anti-atherogenic and anti-inflammatory effects of fish and fish oils. J Nutrigenet Nutrigenomics 2008;1:4-23

Ohama, H, Ikeda, H, Moriyama H 2006, 'Health foods and foods with health claim in Japan', *Toxicology*, Vol. 221, pp.95-111.

Torpy JM, 2006. Eating fish: Health benefits and risks. JAMA 296(15):1926-1927

U.S. Food and Drug Administration/Center for Food Safety and Applied Nutrition viewed online 2 Nov 2007 <http://www.cfsan.fda.gov/~dms/lab-hlth.html>

World Cancer Research Fund/American Institute for Cancer Research, Food, Nutrition, Physical Activity, and the Prevention of Cancer: a Global Perspective. Washington DC: AICR, 2007.

World Health Organization 2003, *Diet, nutrition and the prevention of chronic diseases*, Report of a Joint WHO/FAO Expert Consultation, WHO Technical Report Series No. 916, WHO, Geneva.

Appendices

Appendix 1: Food Standard codes: current and proposed

Standards that will be affected by the introduction of Standard 1.2.7 Nutrition, Health and Related Claims

Existing Regulation	Proposed Regulation
Part 1.1- Preliminary	**Part 1.1- Preliminary**
Standard 1.1.1 – Preliminary Provisions – Application, interpretation and General Prohibitions	**Standard 1.1.1** – Preliminary Provisions – Application, interpretation and General Prohibitions
Many definitions used in the Code are contained in this standard	With added definitions (either new or moved from other Standards)
Part 1.1A Transitional Standards	**Part 1.1A Transitional Standards**
Standard 1.1A.2 – Transitional Standard for Health Claims	**Standard 1.1A.2** repealed 2 years after gazettal of Standard 1.2.7
Part 1.2 – Labelling and Other Information Requirements	**Part 1.2 – Labelling and Other Information Requirements**
Standard 1.2.7 (reserved)	**Standard 1.2.7** Nutrition, Health and related claims
Standard 1.2.8 – Nutrition Information Requirements	**Standard 1.2.8** – Nutrition Information Requirements
This Standard sets out nutrition information requirements in relation to food and the manner in which information is provided. It regulates the use of nutrition claims in relation to: • Polyunsaturated and monounsaturated fatty acid content • Lactose • Gluten content • Salt, sodium or potassium content • Omega fatty acid content • Low joule	Conditions for nutrition claims will be moved to Standard 1.2.7
Part 1.3 – Substances Added to Food	**Part 1.3 – Substances Added to Food**
Standard 1.3.1 – Food Additives	**Standard 1.3.1** – Food Additives
This Standard regulates the use of food additives in the production and processing of food.	This Standard will be amended by deleting the reference made to Standard 1.2.8 in the Editorial Note after clause 4
Standard 1.3.2 – Vitamins and Minerals	**Standard 1.3.2** – Vitamins and Minerals
This Standard regulates the addition of vitamins and minerals to foods, and the claims which can be made about the vitamin and mineral content of foods.	Claims in relation to the vitamin and mineral content of food will be moved to Standard 1.2.7. Labelling of foods with respect to vitamin or mineral content will be moved to Standard 1.2.8. This Standard will now mainly deal with permission to add vitamins and minerals to foods.

Part 2.6 – Non-alcoholic Beverages

- **Standard 2.6.2** – Non-Alcoholic Beverages and Brewed Soft Drinks

Part 2.9 – Special Purpose Foods

- **Standard 2.9.2** – Foods For Infants
- **Standard 2.9.3** – Formulated Meal Replacements and Formulated Supplementary Foods
- **Standard 2.9.4** – Formulated Supplementary Sports Foods

Part 2.10 – Standards for Other Food

- **Standard 2.10.2** Salt and Salt Products

Basically no change, except requiring amendment when referring to the relevant Standards

Appendix 2 Overview of proposed nutrient profiling model

Proposed Nutrient Profiling Model in Preliminary Final Assessment Report Proposal P293 Nutrition, Health and Related Claims, Attachment 1, draft Standard 1.2.7, with reference to seafoods

In order to carry a health claim, a food product must meet the scoring criteria set out below (except when the general level health claim is made in relation to gluten, lactose, infant foods, a vitamin or mineral) in addition to other qualifying criteria and conditions. This will help safeguard inappropriate foods from carrying health claims.

Food will be classified into three categories and will need to satisfy different scoring criteria (See Table 5):

Category 1 – Beverages (excluding milk)
Category 2 – Foods other than those included in category 1 or 3 **[Seafood will be classified as a Category 2 food]**
Category 3 – Edible oils and spreads; margarine; butter; and cheese with calcium content>320mg/100g

Category 1 and 2 foods are awarded points based on their Energy, Saturated fatty acids, Total sugars, Sodium, Fruit and Vegetable, Protein, and Fibre contents.

Final Score **(Table 5)**	=	Sum of all points scored for each of the 4 columns in **(Table 1)**	-	Points for Fruit and Vegetable **(Table 2)**	-	Points for Protein **(Table 3)**	-	Points for Fibre **(Table 4)**

Final Score of a food = Baseline Points – V Points – P Points – F Points
Refer to Table 5 to determine if a food meets scoring criteria for a health claim

Table 1. Baseline points for category 1 and category 2 food products (Baseline points for Category 3 food products is not shown here as it is not related to seafoods)

Points	Average energy content [1] (kJ) per 100 g/100 mL	Saturated fatty acids (g) per 100 g/100 mL	Total sugars (g) per 100 g/100 mL	Sodium (mg) per 100 g/100 mL
0	≤335	≤1	≤4.5	≤90
1	>335	>1	>4.5	>90
2	>670	>2	>9	>180
3	>1005	>3	>13.5	>270
4	>1340	>4	>18	>360
5	>1675	>5	>22.5	>450
6	>2010	>6	>27	>540
7	>2345	>7	>31	>630
8	>2680	>8	>36	>720
9	>3015	>9	>40	>810
10	>3350	>10	>45	>900

Table 2. Fruit and Vegetable Points (V Points)

	Column 1	Column 2
Points	% concentrated fruit, vegetable, and legumes	% fruit, vegetables, nuts and legumes
0	<25	≤40
1	≥25	>40
2	≥43	>60
5	≥67	>80

Table 3. Protein Points (P Points)

Points	Protein (g) per 100 g or mL
0	≤1.6
1	>1.6
2	>3.2
3	>4.8
4	>6.4
5	>8.0

Note: If a food product scores ≥11 baseline points, then it cannot score any Protein Points unless it can score 5 Fruit and Vegetable Points

Table 4. Fibre Points (F Points)

Points	Dietary fibre (g) per 100 g or mL
0	≤0.9
1	>0.9
2	>1.9
3	>2.8
4	>3.7
5	>4.7

Table 5. Scoring criteria for food categories

Food product	Final score	Meets scoring criteria to make a health claim
Category 1	< 1	Yes
Category 2	< 4	Yes
Category 3	< 28	Yes

Example 1: Prawn, King (Large Size)

Nutrient contents (per 100g, raw): (NUTTAB 2006)

Energy	371 kJ
Saturated Fatty Acid	0.2g
Total Sugars	0.0g
Sodium	350mg
Protein	20.5g

Step 1. Calculate baseline points

Total baseline points
= (points for average energy content) + (points for saturated fatty acids) + (points for total sugars) + (points for sodium)
= 1 + 0 + 0 + 3
= 4

Step 2. Calculate Fruit and Vegetable Points (V Points)

V Point = 0 for prawn

Step 3. Calculate Protein Points (P Points)

[If a food product scores ≥11 baseline points, then it cannot score any Protein Points unless it can score 5 Fruit and Vegetable Points]
P Point = 5

Step 4. Calculate Fibre Points (F Points)

F Point = 0 for prawn

Step 5. Calculate Final Score

Final Score = baseline points – (V Points) – (P Points) – (F Points)
= 4 – 0 – 5 – 0
= -1

Food Product	Final Score	Meets scoring criteria to make a health claim
Category 2 food	Final Score < 4	Yes, prawn meets scoring criteria

Example 2: Australian Salmon, Canned in Brine, drained

Nutrient contents (per 100g): (NUTTAB 2006)

Energy	680 kJ
Saturated Fatty Acid	3.2g
Total Sugars	0.0g
Sodium	526mg
Protein	20.5g

Step 1. Calculate baseline points

Total baseline points
= (points for average energy content) + (points for saturated fatty acids) + (points for total sugars) + (points for sodium)
= 2 + 3 + 0 + 5
= 10

Step 2. Calculate Fruit and Vegetable Points (V Points)

V Point = 0 for Australian Salmon, Canned in Brine, drained

Step 3. Calculate Protein Points (P Points)

[If a food product scores ≥11 baseline points, then it cannot score any Protein Points unless it can score 5 Fruit and Vegetable Points]
P Point = 5

Step 4. Calculate Fibre Points (F Points)

F Point = 0 for Australian Salmon, Canned in Brine, drained

Step 5. Calculate Final Score

Final Score = baseline points – (V Points) – (P Points) – (F Points)
= 10 – 0 – 5 – 0
= 5

Food Product	Final Score	Meets scoring criteria to make a health claim
Category 2 food	Final Score > 4	No, Australian Salmon, Canned in Brine, drained does not meet scoring criteria

Table 6. Final Scores for some common seafoods (calculated based on nutrient composition obtained from NUTTAB 2006)

Food Product	Energy kJ/100g	SFA g/100g	Total Sugars g/100g	Sodium mg/ 100g	Protein g/100g	Final score	Meets scoring criteria?
Prawn king (large size), purchased cooked	436	0.2	0.0	552	23.7	2	**Yes**
Prawn, garlic, king, home prepared	1110	3.3	0.3	569	20.4	12	No
Prawn king (large size), raw	371	0.2	0.0	350	20.5	-1	**Yes**
Tuna, yellowfin, fresh, raw	435	0.2	0.0	37	23.4	-4	**Yes**
Tuna, canned in brine, drained	497	0.8	0.0	327	23.8	-1	**Yes**
Tuna, Canned in Vegetable Oil, drained	889	2.1	0.0	425	23.6	3	**Yes**
Atlantic Salmon Fillet, raw	845	3.7	0.0	42	20.7	0	**Yes**
Atlantic Salmon, steamed or poached	994	4.4	0.0	42	24.4	1	**Yes**
Australian Salmon, Canned in Brine, drained	680	3.2	0.0	526	20.5	5	No
Red Salmon, Canned in Water, No Added Salt, drained	816	3.3	0.0	110	21.9	1	**Yes**
Oyster, raw	303	0.8	0.0	310	12.0	-2	**Yes**
Oyster, smoked, canned in oil, drained	739	3.4	0.0	391	17.4	4	No
Whiting, King George, raw	372	0.2	0.0	72	20.3	-4	**Yes**
Whiting, King George, Fried in Peanut Oil	638	1.3	0.1	70	23.0	-3	**Yes**
Scallop, boiled in unsalted water	433	0.3	0.0	155	22.2	-3	**Yes**
Lobster, purchased, steamed or boiled	407	0.2	0.0	306	22.0	-1	**Yes**
Calamari or squid, poached	410	0.5	0.0	355	20.9	-1	**Yes**
Barramundi aquacultural fillet, steamed or poached	453	0.4	0.0	n/a	22.8	n/a	n/a
Fish finger, frozen, uncooked	838	3.1	0.0	259	10.1	2	**Yes**
Anchovy, canned in oil, drained	762	2.0	0.0	5480	25.4	13	No

n/a = data not available

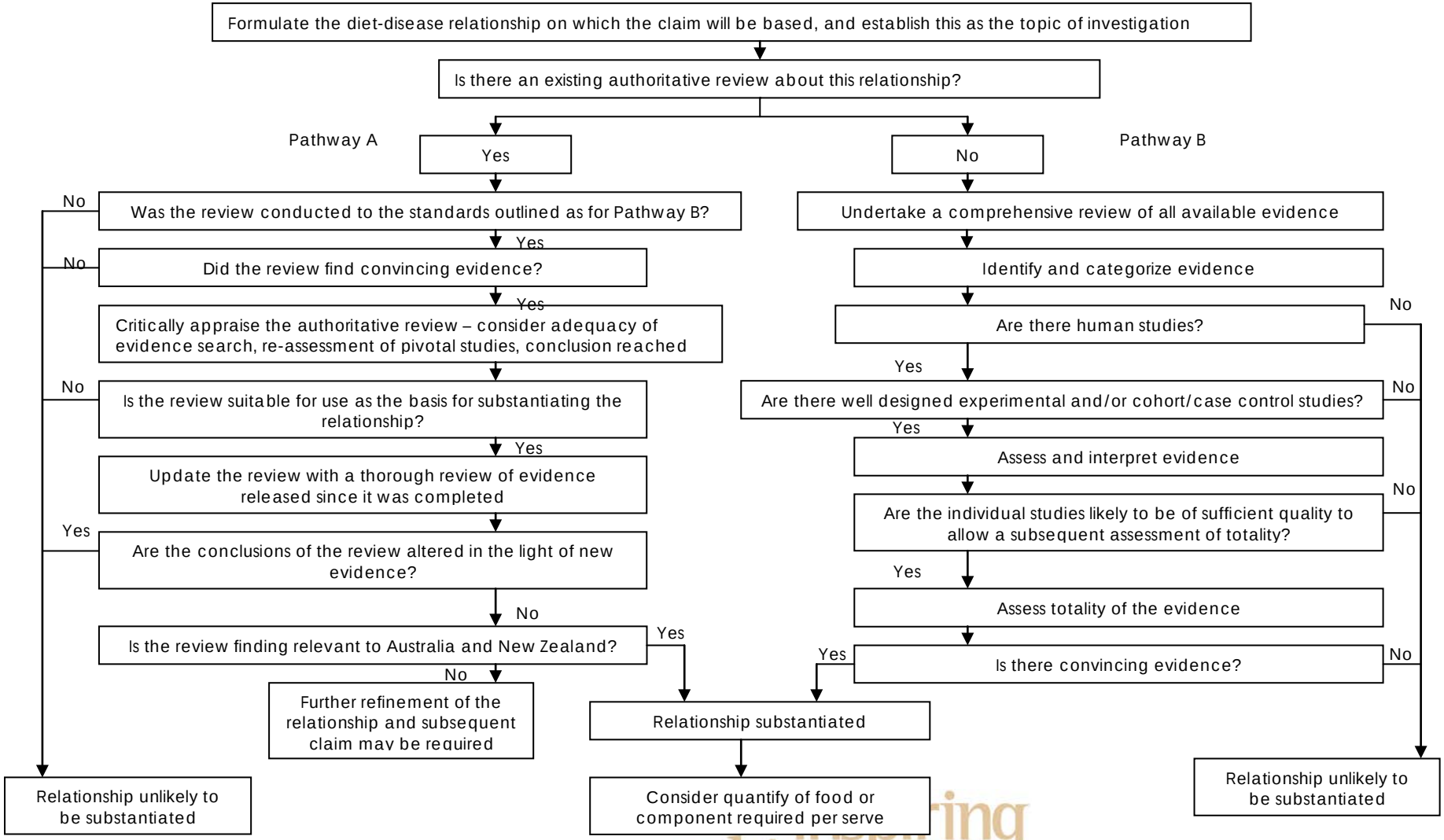
Appendix 3: Proposed pre-approved high level health claims as of November 2007

The following diet-disease relationships have been substantiated by expert review and FSANZ will pre-approve high level health claims based on these relationships:

- Dietary intake of calcium, vitamin D status and risk of developing osteoporosis, particularly in the 65 year and over age group
- Increased dietary intake of calcium and enhanced bone mineral density
- Reduction in dietary intake of sodium and reduction in blood pressure
- Folic acid and neural tube defects
- Saturated fatty acids and LDL cholesterol levels
- Saturated and trans fatty acids and LDL cholesterol levels
- Diet rich in vegetables and fruit and reduced risk of coronary heart disease
- Increased intake of vegetables and fruit and reduced risk of coronary heart disease.

Other high level health claims not listed above will require pre-market assessment and approval and will be considered by FSANZ on a case-by-case basis.

Appendix 4: Substantiation approaches for high level health claims



Substantiating a General level health claim

Substantiation can be based on

FSANZ Pre-approved nutrient function statements → No further substantiation required

OR

Authoritative, generally-accepted information sources:

- National diet policy publications such as the Australian and New Zealand National Dietary Guidelines and review of Nutrient Reference Values
- Position papers and scientific reviews conducted by peak medical, nutrition, scientific or public health non-government authoritative organizations
- Reviews conducted by internationally recognized scientific bodies such as reports of the Cochrane Collaboration and the World Health Organisation
- Authoritative, current, science texts presently used in university dietetics courses
- Reports of health claims assessed by overseas governments

OR

All available scientific evidence of appropriate quality (using a process similar to substantiating a high level health claim):

- Comprehensive review of all available evidence or
- Based on an existing authoritative reviews but need to ensure no new evidence has emerged since its publication which will affect the conclusion
- Also need to determine the amount of food of food component required to achieve the health effect

- Position papers and reviews are all conducted in accordance with processes generally drawn on for scientific research
- Scientific evidence rated as 'probable' is generally required to support a general level health claim.
- Must demonstrate relevance to the Australia and New Zealand population and environment if information is drawn from overseas documents or sources

Appendix 5 Classification of strength of evidence (based on World Health Organization 2003)

Evidence is rated as **convincing** when there are consistent associations between the diet, food or component and the health effect, with little or no evidence to the contrary. Studies providing the evidence should be conducted in humans and be of acceptable quality, preferably including both observational and experimental design. The mechanism of the effect can be established and is supportive of a causal relationship.

Evidence is rated as **probable** when the associations between the diet, food or component and the health effect is not so consistent and therefore cannot support a more definite judgement. Studies providing the evidence should be conducted in human and of acceptable quality, preferably including both observational and experimental design. Mechanistic and laboratory evidence are usually supportive and the relationship is biologically plausible.

Evidence is rated as **possible** when the number of appropriate studies available is limited. The studies generally indicate a relationship exists and is biologically plausible but may or may not be supported by mechanistic or laboratory evidence. More higher quality studies are required.

Evidence is rated as **insufficient** when the limited studies available are not of appropriate quality to substantiate a relationship. More higher quality studies are required.

Appendix 6: Proposed pre-approved nutrient function claims/statements

Most relevant to seafood

- Protein
- Vitamin E
- Vitamin D
- Selenium
- Iodine
- Zinc
- DHA

Table 1: Pre-approved statements for recognised vitamins and minerals.

Pre-approved statements for vitamins and minerals are based on the UK Joint Health Claims Initiative (JHCI) list of well-established statements.

Nutrient	Model statement from JHCI
Vitamin D	Vitamin D is necessary for the normal absorption and utilisation of calcium and phosphorus
Vitamin E	Vitamin E is necessary for cell protection from the damage caused by free radicals (such as oxidation of polyunsaturated fatty acids in red blood cell membranes)
Vitamin K	Vitamin K is necessary for normal coagulation (blood clotting)
Thiamin	Thiamine is necessary for the normal metabolism of carbohydrates
Riboflavin	Riboflavin contributes to the normal release of energy from food
Niacin	Niacin is necessary for the normal release of energy from food
Pantothenic acid	Pantothenic acid is necessary for the normal metabolism of fat
Vitamin B_6	Vitamin B_6 is necessary for the normal metabolism of protein
Folate	Folate is necessary for normal blood formation
Vitamin B_{12}	Vitamin B_{12} contributes to normal blood formation
Biotin	Biotin contributes to normal fat metabolism and energy production
Vitamin C	Vitamin C is necessary for normal structure and function of connective tissue (such as that required for normal gums, skin, healing processes, bone and cartilage)
Calcium	Calcium is necessary for normal structure of bones and teeth
Magnesium	Magnesium is necessary for normal energy metabolism
Iron	Iron contributes to normal blood formation
Copper	Copper is necessary for the normal function of the immune system
Iodine	Iodine is necessary for normal production of thyroid hormones
Zinc	Zinc contributes to the normal structure of skin and normal wound healing
Manganese	Manganese contributes to normal bone function
Phosphorus	Phosphorus is necessary for the normal structure of bone and teeth
Selenium	Selenium is necessary for cell protection from some types of damage caused by free radical damage

Table 2: Pre-approved statements for nutrients other than vitamins and minerals

Claims for protein and omega-3 polyunsaturated fatty acids are derived from the Canadian Food Inspection Agency (CFIA) system. The dietary fibre statement is based on background information in the Dietary Guidelines.

Nutrient	CFIA claim	Other claim (derived from the Australian Dietary Guidelines)
Protein	*"helps build and repair body tissues"*	
Docosahexaenoic acid (DHA)	*"DHA, an omega-3 fatty acid, supports the normal development of the brain, eyes and nerves"*	
Dietary fibre		*"contributes to regular laxation"*

Appendix 7: Information health claims in Japan &US

Health Claims in Japan[1,2]

In 2001, The Ministry of Health, Labour, and Welfare (MHLW) implemented a new system which allow foods including nutritional supplements to make claims in relation to certain nutritional or health functions. Foods that comply with specifications and standards are referred to as Foods with Health Claims (FHC). Figure 1 demonstrates where Foods with Health Claims (FHC) are positioned with respect to medicine and other foods. FHC can be further categorized into two groups:

1. Foods with Nutrient Function Claims (FNFC) and
2. Foods for Specified Health Uses (FOSHU)

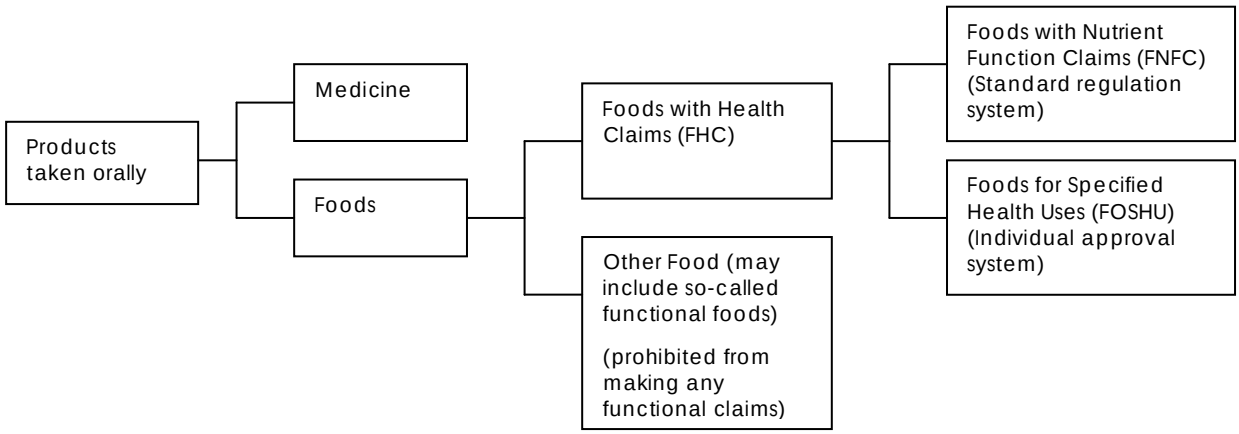


Figure 1. Positioning of Foods with Health Claims (FHC) with respect to medicine and other foods

1. Foods with Nutrient Function Claims (FNFC)

FNFC refer to all food that is labeled with the nutrient function claims specified by the MHLW. Currently, standards and specifications for nutritional function have been established for 17 ingredients (12 vitamins and 5 minerals). These foods may be freely manufactured and distributed without any permission from or notification to the national government, provided that it meets the established standards and specifications. In addition to the nutrient function claims, warning indications must also be displayed (Table 1). Eight other vitamins and minerals were considered by MHLW for standardization but did not receive approval. These were Vitamin K, phosphorus and potassium (no deficiency in Japan); iodine, manganese, selenium, chromium and molybdenum (data not available for the calculation of nutritional parameters based on the national nutritional survey).

[1] Japanese Ministry of Health, Labour, and Welfare viewed online 2 Nov 2007 < http://www.mhlw.go.jp/english/topics/foodsafety/fhc/index.html>

[2] Ohama, H, Ikeda, H, Moriyama H 2006, 'Health foods and foods with health claim in Japan', *Toxicology*, Vol. 221, pp.95-111.

Table 1. Standards and Specifications for nutrient function claims in Japan

Nutritional Ingredient	Specified Range of advisable daily intake	Function Claims	Warning Indication
Niacin	3.3 – 60mg	Helps to maintain skin and mucosa health	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the advisable daily intake.
Pantothenic acid	1.65 – 30mg	Helps to maintain skin and mucosa health	
Biotin	14 – 500mcg	Helps to maintain skin and mucosa health	
Vitamin A	135 – 600mcg	Helps to maintain vision in the dark, and helps to maintain skin and mucosa healthy	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the advisable daily intake. Women within the third months of pregnancy or women considering to be pregnant should be careful of over consumption
Vitamin B1	0.30 – 25mg	Helps to produce energy from carbohydrate and to maintain skin and mucosa healthy	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the advisable daily intake.
Vitamin B2	0.33 – 12mg	Helps to maintain skin and mucosa health	
Vitamin B6	0.3 – 25mg	Helps to produce energy from protein and to maintain skin and mucosa healthy	
Vitamin B12	0.60 – 60mcg	Aids in red blood cell formation	
Vitamin C	24 – 1000mg	Helps to maintain skin and mucosa healthy and has anti-oxidizing effect	
Vitamin D	1.5 – 5.0mcg	Promotes the absorption of calcium in gut intestine and aids in the growth of bone	
Vitamin E	2.4 – 150mg	Helps to protect fat in the body from being oxidized and to maintain cell health	
Folic acid	60 – 200mcg	Aids in red blood cell formation and contributes to the normal growth of the fetus	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with advisable daily intake. This product helps normal development of fetus, but increased intake of this product will not result in better development of fetus.
Zinc	2.1 – 25mg	Necessary nutrient to maintain normal taste and helps to maintain healthy skin and mucous membranes. It is involved in the metabolism of protein and nucleic acids and is helpful in maintaining health	Increased intake of this product will not result in curing diseases nor promoting health. Too much intake of zinc might inhibit absorption of copper. Please comply with the advisable daily intake. Infants and young children should avoid use of this product.
Calcium	210 – 600mg	Necessary in the development of bone and teeth	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the advisable daily intake.
Iron	2.25 – 10mg	Necessary in red blood cell formation	
Copper	0.18 – 6mg	Helps to form red blood cells and helps proper function of many body enzymes and bone formation	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the advisable daily intake. Infants and young children should avoid use of this product.
Magnesium	75 – 300mg	Necessary in the development of bone and teeth, maintain proper blood circulation, and helps proper function of many body enzymes and energy	Increased intake of this product will not result in curing diseases nor promoting health. Increased intake might cause diarrhoea. Please comply with the advisable daily intake. Infants and young children should avoid use of this product.

2. Foods for Specified Health Uses (FOSHU)

FOSHU refer to foods containing ingredient with functions for health or reduction of disease risk*; and officially approved to claim its physiological effects on the human body.
[*Currently the only two approved Reduction of Disease Risk Claims relate to Calcium and Osteoporosis; and Folic Acid and Neural Tube Defect]

Requirements of FOSHU approval:

- Effectiveness on the human body is clearly proven by human studies, elucidating the mechanism of activity and establishing the dosage level
- Absence of any safety issues
- Use of nutritionally appropriate ingredients
- Guarantee of compatibility with product specification by the time of consumption
- Established quality control methods

In addition to the 'existing' FOSHU, two other types of FOSHU were introduced in 2005 to facilitate applicants for FOSHU approvals.

- Qualified FOSHU – food with health function which is not substantiated on scientific evidence that meets the level of FOSHU, or the food with certain effectiveness but without established mechanism of the effective element for the function
- Standardized FOSHU – standards and specifications are established for foods with sufficient FOSHU approvals and accumulation of scientific evidence

Health claims are categorized into different groups as listed in Table 2.

Table 2. Examples of Specified Health Uses and Principals ingredients

Specified Health Uses	**Principal Ingredients (ingredients exhibiting health functions)**
Foods to modify gastrointestinal conditions	Oligosaccharides, lactose, bifidobacteria, lactic acid bacteria, dietary fibre, ingestible dextrin, polydextrol, guar gum, psyllium seed coat, etc.
Foods related to blood cholesterol and/or triacylglycerol level	Chitosan, soybean protein, degraded sodium alginate, plant sterol/stanol (esters), middle chain fatty acid, DHA, EPA, psyllium seed husk, etc.
Foods related to blood sugar levels	Indigestible dextrin, wheat albumin, guava tea polyphenol, L-arabinose, etc.
Foods related to blood pressure	Lactotripeptide, caesin dodecaneptide, tochu leaf glycoside (geniposidic acid), sardine peptide, etc.
Foods related to dental hygiene	Palatinose, maltitol, erythritol, etc.
Cholesterol plus gastrointestinal conditions, triacyglycerol plus cholesterol	Degraded sodium alginate, dietary fibre from psyllium seed husk, etc.
Foods related to mineral absorption	Calcium citrated malate, caesin phosphopeptide, haem iron, etc.
Foods related to osteogenesis	Soybean isoflavone, MBP (Milk basic protein), etc.

Under the Health Promotion Law, any claims of efficacy and function made on functional foods must be relevant and based on scientific ground and must not be misleading or deceptive.

Labelling system for Nutrient

Labelling is voluntary for all foods except foods with nutrition claims.

Nutrients covered in the Nutrition Labeling Standards are protein, fat, carbohydrate, sodium, zinc, potassium, calcium, chromium, selenium, iron, copper, sodium, magnesium, manganese, iodine, phosphorus, niacin, pantothetic acid, biotin, vitamin A, vitamin B1, vitamin B2, vitamin B6, vitamin B12, vitamin C, vitamin D, vitamin E, vitamin K and folic acid.

Energy value, the amount of protein, fat, carbohydrate, and sodium are mandatory and must be declared together with the amount of any other nutrient, in particular the nutrient that is the subject of the claim.

Provisions are made for nutrient content claims which allow the display of statements such as 'high/low in XX', 'zero', 'source of', 'enhanced/reduced' as set out in the Standard.

Health Claims in U.S.[3]

There are three categories of claims that can be used on food and dietary supplements:

- Health claims
- Nutrient content claims
- Structure/function claims

Health claims describe a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of a disease or health-related condition. Health claims are limited to claims about disease risk reduction and cannot be claims about the cure, mitigation, treatment or prevention of disease. Health claims may be authorized in one of three ways:

1. The Nutrition Labeling and Education Act (NLEA) authorized health claims, provide for health claims used on labels that characterize a relationship between a food, a food component, dietary ingredient, or dietary supplement and risk of a disease, provided the claims meet certain criteria. The U.S. Food and Drug Administration (FDA) authorizes these types of health claims based on an extensive review of the scientific literature using the significant scientific agreement standard to determine that the nutrient/disease relationship is well established.

   Approved Health Claims that may be relevant to seafoods:
   - Dietary Fat and Cancer [Model Claim, Statement: Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers]

2. Health claims based on authoritative standards
   The Food and Drug Administration Modernization Act of 1997 (FDAMA) allows certain health claims to be made as a result of a successful notification to FDA of a health claim based on an 'authoritative statement' from a scientific body of the US Government or the National Academy of Sciences. Currently this method for health claims cannot be used for dietary supplements.

   Example of Health Claim based on an Authoritative Statement of a Scientific Body:
   Saturated Fat, Cholesterol, and Trans Fat and Reduced Risk of Heart Disease

3. Qualified health claims
   The Consumer Health Information for Better Nutrition Initiative provides for the use of qualified health claims when there is emerging evidence for a relationship between a food, food component, or dietary supplement and reduced risk of a disease or health-related condition. In this case, the evidence is not well enough established to meet the significant scientific agreement standard required for FDA to issue an authorizing regulation. In such case, FDA will issue a letter of enforcement discretion.

   Qualified Health Claims that may be relevant to seafoods:
   - Selenium and Certain Cancers
   - Antioxidant Vitamins and Risk of Certain Cancers
   - Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease

All foods carrying health claims must also meet the following general requirements:

- Food meets certain criteria depending on the specific claim e.g. Claims related to Coronary Heart Disease will generally require the food bearing such claim to meet the

[3] U.S. Food and Drug Administration/Center for Food Safety and Applied Nutrition at http://www.cfsan.fda.gov/~dms/lab-hlth.html

'low fat', 'low saturated fat' and the 'low cholesterol' criteria as set out in the Code of Federal Regulations
- Food must not exceed any of the disqualifying nutrient levels for total fat, saturated fat, cholesterol, or sodium
- A conventional food, prior to any nutrient addition, must contain at least 10% of the Daily Value for vitamin A, vitamin C, iron, calcium, protein, or dietary fibre
- Enables the public to comprehend the information provided and to understand the relative significance of such information in the context of the total daily diet
- If the claim is about the effects of consuming the substance at decreased dietary levels, the level of the substance in the food is sufficiently low to justify the claim. If the claim is about effects of consuming the substance at other than decreased dietary levels, the level of the substance must be sufficiently high and in an appropriate form to justify the claim
- The label does not represent or purport that the food is for infants and toddlers less than 2 years of age

Nutrient content claims

NLEA permits the use of label claims that characterize the level of a nutrient in a food made in accordance the FDA's authorizing regulations. Nutrient content claims describe the level of a nutrient of dietary substance in the product, using terms such as 'free', 'high' and 'low', or they compare the level of a nutrient in a food to that of another food, using terms such as 'more', 'reduced', and 'lite'. FDA exercises its oversight in determining which nutrient content claims may be used on a label or in labeling for a food by two means: (1) FDA issues a regulation authorizing a nutrient content claim or (2) A firm submit a notification for a claim based on an authoritative statement.

Structure/Function claims

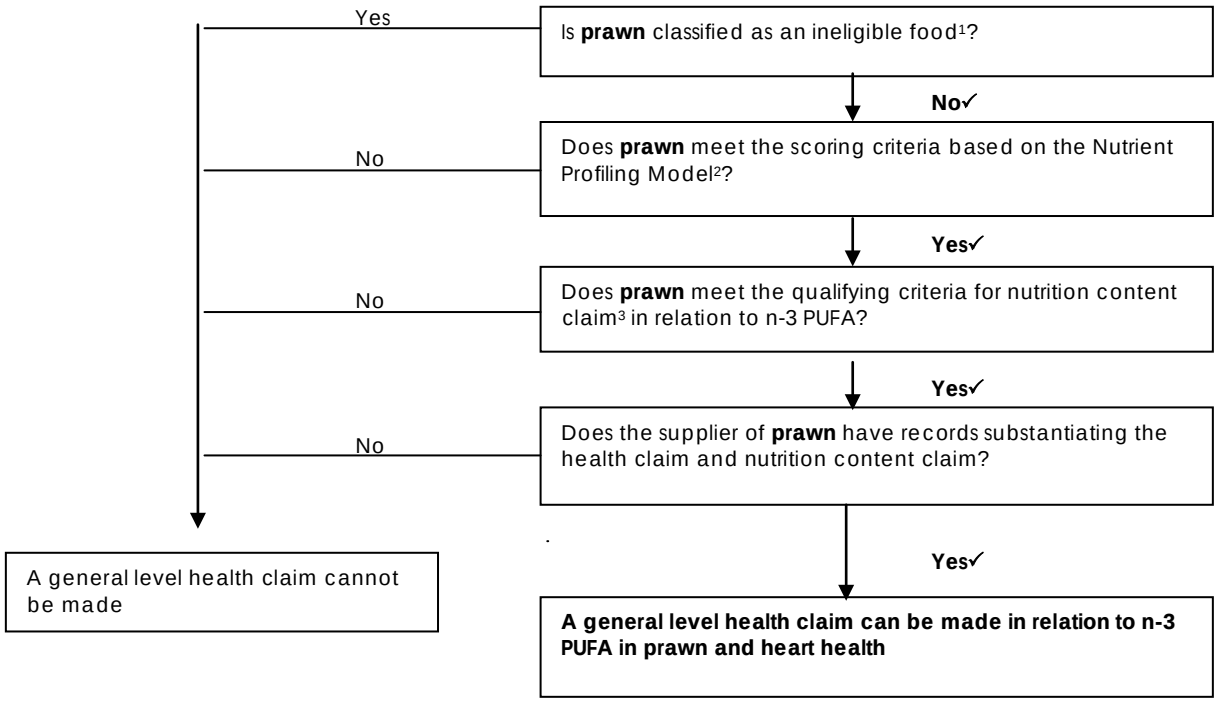
These are statements that describe the effect a dietary supplement may have on the structure or function of the body. For example, 'calcium builds strong bones'. Structure/function claims may also describe a benefit related to a nutrient deficiency disease (like Vitamin C and scurvy) as long as the statement also tells how widespread such a disease is in the US. The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims. No pre-approval by FDA is necessary, but manufacturer of the dietary supplement must submit a notification within 30 days of first marketing the product. The claim must also include a mandatory disclaimer statement.

Dietary guidance statements

Dietary guidance statements usually focus on general dietary patterns, practices and recommendations that promote health. Typically 'dietary guidance' statements make reference to a category of foods and not a specific substance. E.g. 'Carrots are good for you health'. Dietary guidance statements can be made without FDA review or authorization before use but the statements must be truthful and non-misleading.

[Dietary guidance statements and structure/function claims are not considered health claim and are not subject to FDA review and authorization]

Appendix 8: Theoretical flow charts for assessing prawns, canned oysters, n-3 fatty acids & general level health claim
Example: Prawn, king, raw 1 serving = 190 g



[1] An ineligible food is:
- Food that contains more than 1.15% alcohol by volume
- An infant formula product
- Kava

[2] Nutrient Profiling Model:
Final score for prawn
= Baseline point (1+0+0+3)–V Point (0)–P Point (5)–F Point (0)
= -1
Meets scoring criteria when final score is <4

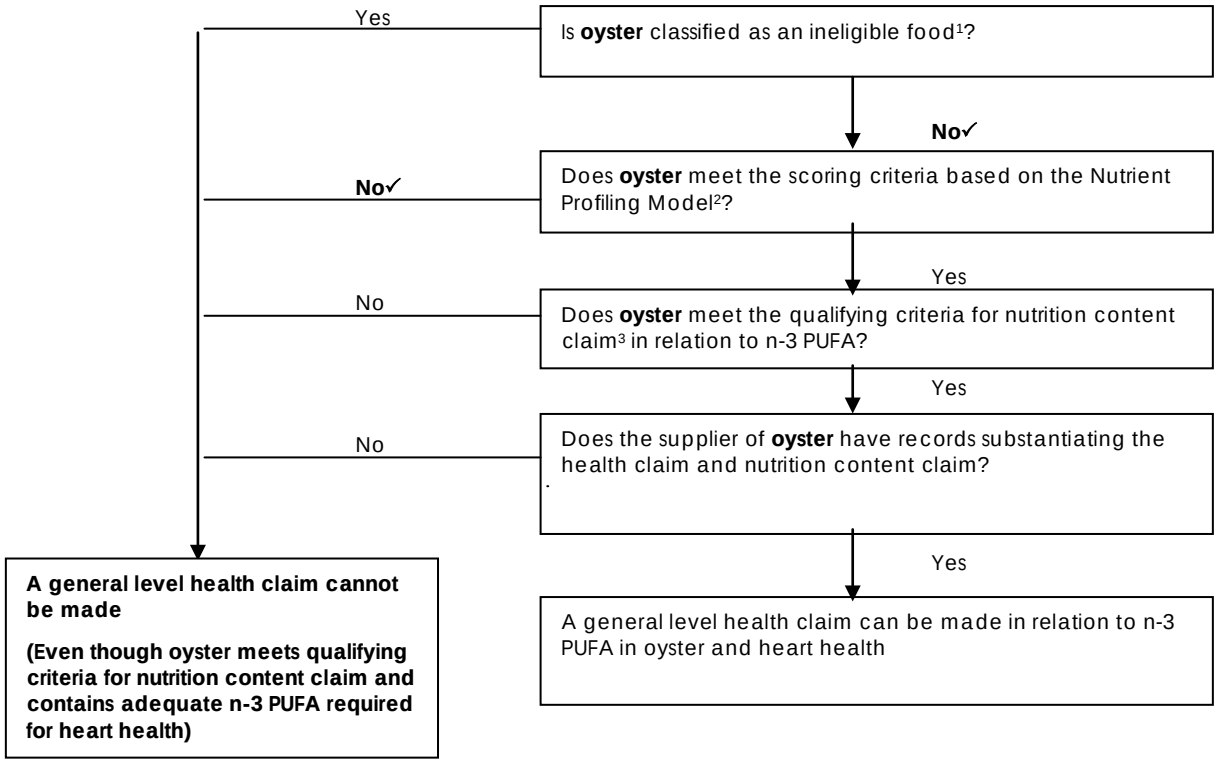
[3] Qualifying criteria for nutrition content claim in relation to n-3 PUFA:
- Food as per serving contains no less than 30mg total eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA); and

100g of prawn contains 112mg of total EPA and DHA
Per 190g serving contains 213mg of total EPA and DHA

Nutrient composition 100g of Prawn, king, raw (NUTTAB 2006):

Energy 371 kJ	Protein 20.5g
Saturated Fat 0.2g	EPA 66mg
Total Sugars 0.0g	DHA 46mg
Sodium 350mg	Trans Fatty Acids n/a

Example: Oyster (Smoked, Canned in Oil, Drained) 1 serving = 61 g



[1] An ineligible food is:
- Food that contains more than 1.15% alcohol by volume
- An infant formula product
- Kava

[2] Nutrient Profiling Model:
Final score for oyster, smoked, canned in oil, drained
= Baseline point (2+3+0+4)–V Point (0)–P Point (5)–F Point (0)
= 4
Meets scoring criteria when final score is <4

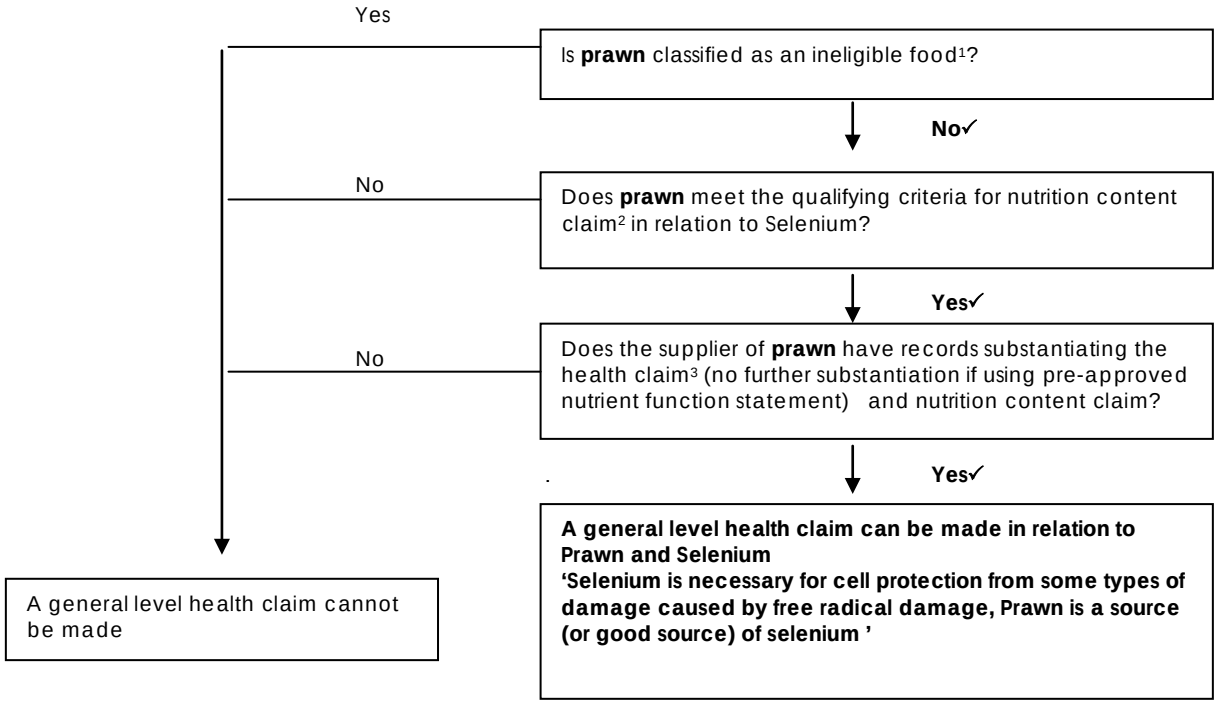
[3] Qualifying criteria for nutrition content claim in relation to n-3 PUFA:
- Food as per serving contains no less than 30mg total eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA); and
  100g of oyster contains 1368mg of total EPA and DHA
  Per 61g serving contains 834mg of total EPA and DHA✓
- Other than for fish or fish products with no added saturated fatty acids, the total of saturated fatty acids and trans fatty acids in the food is no more than 28% of its total fatty acids content or the amount of saturated fatty acids and trans fatty acids in the food is no more than 5g per 100g of the food
  Saturated fatty acids + Trans fatty acid in oyster = 3.4g / 100g✓

Nutrient composition of 100g Oyster, Smoked, Canned in Oil, Drained (NUTTAB 2006):

Energy 739kJ	Protein 17.4g
Saturated Fat 3.4g	EPA 901mg
Total Sugars 0.0g	DHA 467mg
Sodium 391mg	Trans Fatty Acids n/a

Appendix 9: Theoretical flow charts for assessing prawns, selenium & general level health claim

Example: Prawn, king, raw 1 serving = 190 g



[1] An ineligible food is:
- Food that contains more than 1.15% alcohol by volume
- An infant formula product
- Kava

[2] Qualifying criteria for nutrition content claim in relation to Selenium:
- Selenium is listed in Column 1 of the Schedule to Standard 1.1.1
- Prawn is a claimable food (Contains at least 90% by weight of primary food)
- One serving of prawn contains 100.5mcg of Selenium (≥10% of RDI)

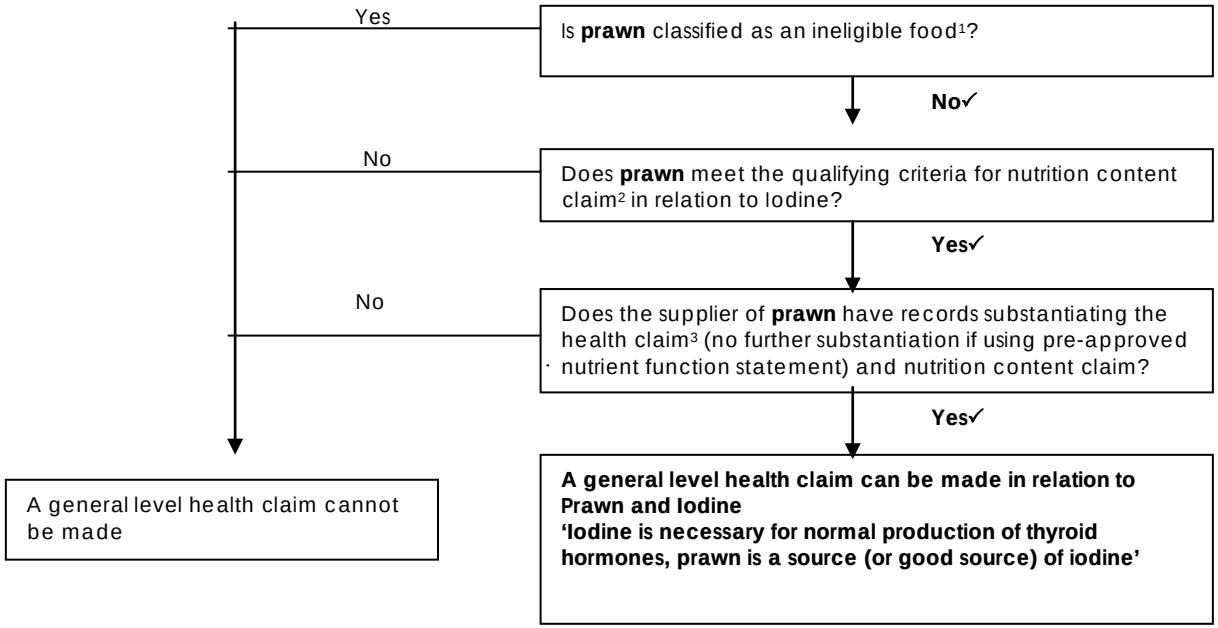
RDI = 70mcg

[3] FSANZ has prepared a list of nutrient function statements that can be used without further substantiation of a diet-health relationship 'Selenium is necessary for cell protection from some types of damage caused by free radical damage'

Nutrient composition 100g of Prawn, king, raw (NUTTAB 2006):

Energy 371 kJ	Protein 20.5g
Saturated Fat 0.2g	Selenium 52.9mcg
Total Sugars 0.0g	Sodium 350mg

Appendix 10: Theoretical flow charts for assessing prawns, tuna, iodine& general level health claim
Example: Prawn, king, raw 1 serving = 190 g



[1] An ineligible food is:
- Food that contains more than 1.15% alcohol by volume
- An infant formula product
- Kava

[2] Qualifying criteria for nutrition content claim in relation to Iodine:
- Iodine is listed in Column 1 of the Schedule to Standard 1.1.1
- Prawn is a claimable food (Contains at least 90% by weight of primary food)
- One serving of prawn contains 56.8mcg of Iodine (≥10% of RDI)

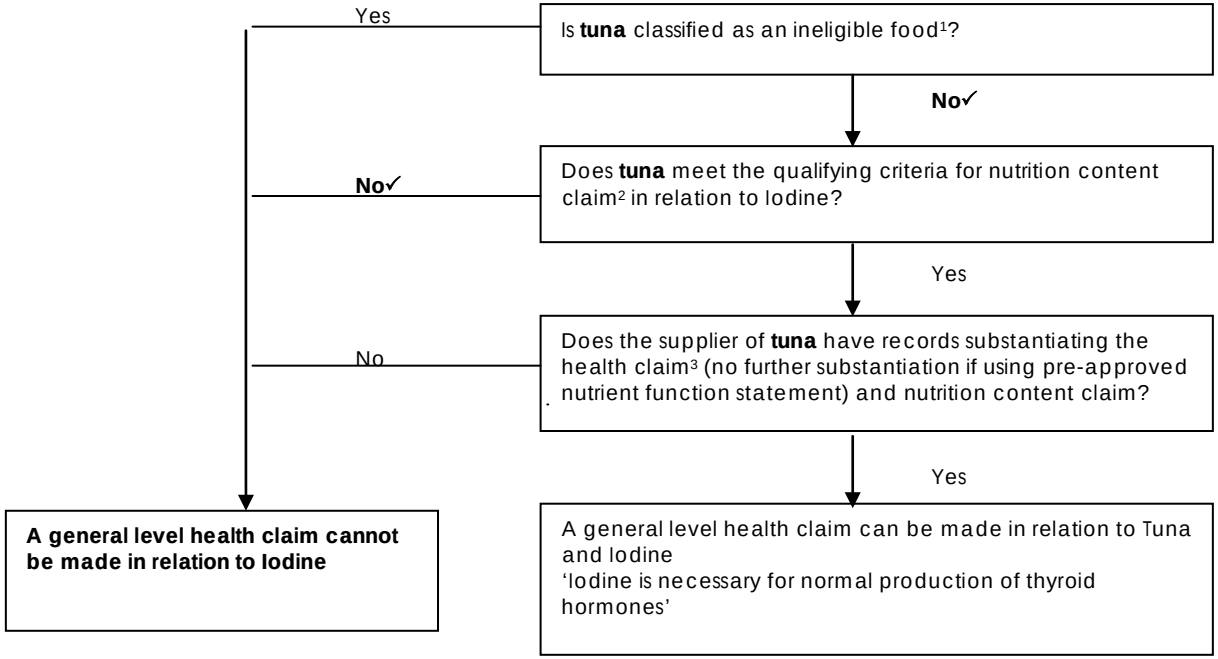
RDI of Iodine = 150mcg

[3] FSANZ has prepared a list of nutrient function statements that can be used without further substantiation of a diet-health relationship 'Iodine is necessary for normal production of thyroid hormones'

Nutrient composition 100g of Prawn, king, raw (NUTTAB 2006):

Energy 371 kJ	Protein 20.5g
Saturated Fat 0.2g	Iodine 29.9mcg
Total Sugars 0.0g	Sodium 350mg

Example: Tuna, canned in brine, drained 1 serving = 61 g



[1] An ineligible food is:
- Food that contains more than 1.15% alcohol by volume
- An infant formula product
- Kava

[2] Qualifying criteria for nutrition content claim in relation to Iodine:
- Iodine is listed in Column 1 of the Schedule to Standard 1.1.1✓
- Tuna is a claimable food (Contains at 90% by weight of primary food) ✓
- One serving of tuna contains 6.6mcg of Iodine (<10% of RDI)×

RDI of Iodine = 150mcg

[3]FSANZ has prepared a list of nutrient function statements that can be used without further substantiation of a diet-health relationship 'Iodine is necessary for normal production of thyroid hormones'

Nutrient composition 100g of Tuna, canned in brine, drained (NUTTAB 2006):

Energy 497kJ	Protein 23.8g
Saturated Fat 0.8g	Iodine 10.9mcg
Total Sugars 0.0g	Sodium 327mg