7-04
11 August 2004

INITIAL ASSESSMENT REPORT

PROPOSAL P293

NUTRITION, HEALTH AND RELATED CLAIMS

DEADLINE FOR RECEIPT OF PUBLIC SUBMISSIONS by FSANZ in relation to this matter:
13 October 2004
(See 'Invitation for Public Submissions' for details)

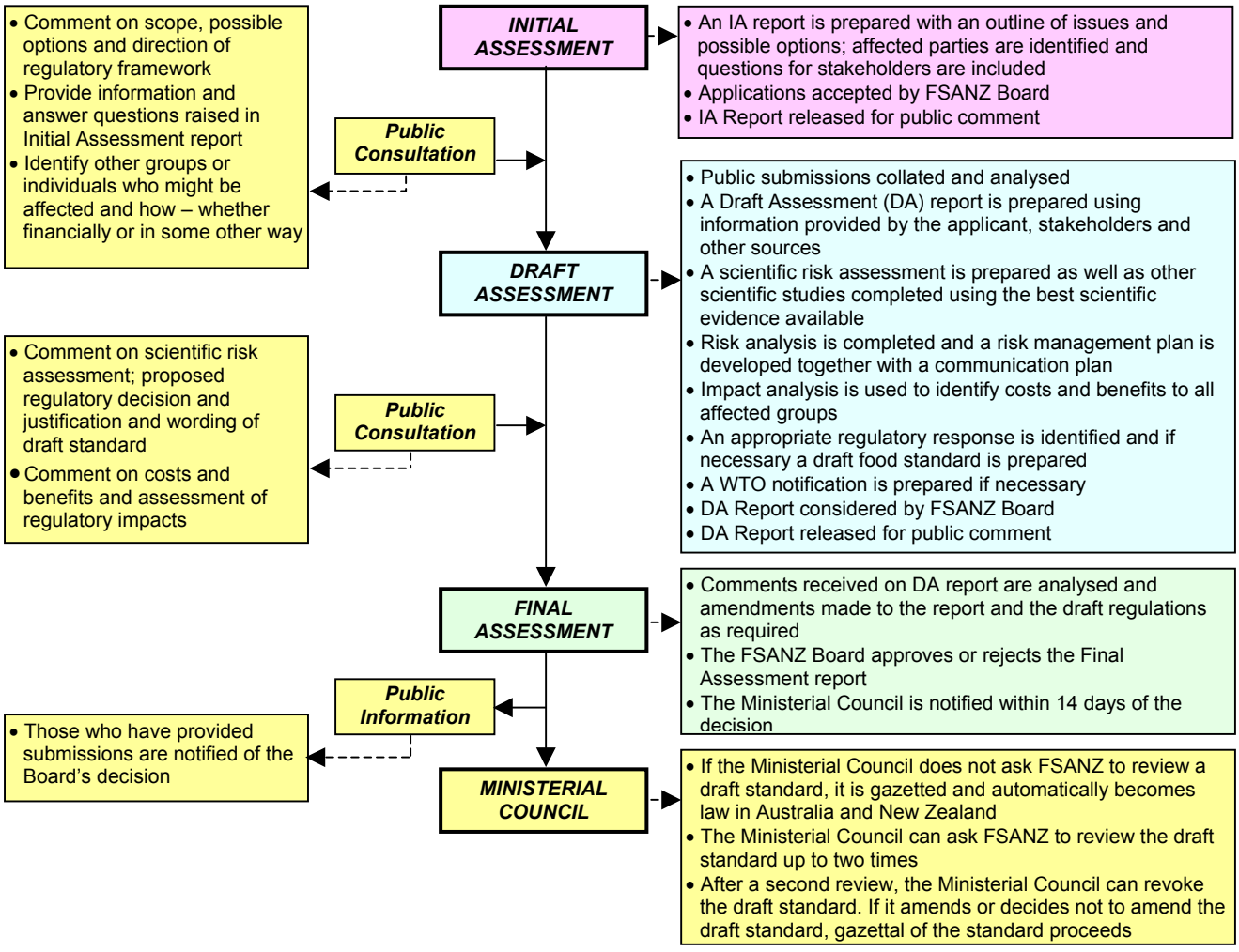
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

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

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

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



Invitation for public submissions

FSANZ has prepared an Initial Assessment Report of Proposal P293, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report based on regulation impact principles and the draft variation to the Code for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment Proposal. Submissions should, where possible, address the questions posed in this report, as well as the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

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

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

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

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

Submissions should be received by FSANZ **by 13 October 2004**.

Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

SUBMITTER RESPONSE BOOKLET – NEW INITIATIVE

To assist submitters in responding to the questions raised in the Initial Assessment Report (IAR), FSANZ has prepared a web based Submitter Response Booklet that includes the questions set out in the IAR and some additional questions in relation to the Regulatory Options.

The Submitter Response Booklet can be used as a submission in its own right or can be used in conjunction with a written submission and may be sent to FSANZ by email at slo@foodstandards.gov.au or by post.

The Booklet, including information on how to use it can be found at the FSANZ website at www.foodstandards.gov.au

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Glossary

claim criteria	FSANZ considers that 'claim criteria' are specific requirements regarding the food or its composition that must be met before a claim can be made. This would also include criteria around the eligibility of a food. Claim criteria apply once a claim is considered to be an eligible claim (see subsection 5.7.2).
claim prerequisites	Claim prerequisites are preconditions that must be met before a claim can be considered an eligible nutrition, health and related claim. Claim prerequisites apply to all claims irrespective of whether they are general level claims or high level claims. An example of a claim prerequisite is that all claims must be scientifically substantiated (see subsection 5.7.1).
claims classification framework	A framework outlining the categories of claims (general level claims and high level claims) and examples of each. The framework is based on the FSANZ interpretation of the Claims Classification Framework in the Policy Guideline (see subsection 5.3).
condition	FSANZ considers that a 'condition' is an additional mandatory statement, required to clarify the context of the claim, in order to protect public health and safety and/or prevent misleading and deceptive conduct (see subsection 5.7.3).
content claim	For the purposes of this Initial Assessment Report, a content claim is a type of general level claim. It is a quantitative statement generally about the level a nutrient in a food, for example 'this food is low in fat'. Within the context of Proposal P293, FSANZ is yet to determine whether this type of claim should also include a reference to biologically active substances. Consequently, FSANZ is yet to determine whether such a claim should more correctly be referred to as a 'nutrient content claim' or a 'nutrition content claim' (see subsection 5.5.1).
CoPoNC	Code of Practice on Nutrient Claims in Food Labels and Advertisements
FSANZ claims descriptors	A list of descriptions developed by FSANZ to give effect to the FSANZ Conceptual Framework discussed in the Initial Assessment Report. These terms may or may not need to be defined in the Standard for nutrition, health and related claims (see subsections 5.4 and 5.5).
FSANZ conceptual framework	Consists of three inter-related elements: the Claims Classification Framework, the FSANZ Claim Descriptors and the FSANZ Regulatory Model The Conceptual Framework proposes a system for categorising nutrition, health and related claims and how they might be regulated (see subsection 5.2).
FSANZ regulatory model	Is a model developed by FSANZ that identifies how claims can be regulated in relation to claim prerequisites, claim criteria and conditions according to their position in the Claims Classification Framework (see subsection 5.7).
general level claim	Is a type of nutrition, health and related claim which does not reference a biomarker or a serious disease or condition (see subsection 5.4.2).

guideline	In relation to the FSANZ Regulatory Model and the preliminary Impact Analysis, a Guideline is a form of quasi-regulation.[1] A Guideline is an alternative to a food standard. It is not legally binding and is not legally enforceable (see subsections 7.1, 7.2, 7.8 and section 10).
health claim	In relation to the FSANZ Conceptual Framework, a health claim is a claim, other than a therapeutic claim, that describes or indicates the relationship between the consumption of a food, a category of food or one of its constituents and health. FSANZ considers that a health claim may be a type of general level claim (but does not include a content claim) or a high level claim (see subsection 5.5.2).
high level claim	Is a type of nutrition, health and related claim which references a biomarker or a serious disease or condition (see subsection 5.4.3).
interpretive userguide	See 'userguide'
nutrition content claim	In the context of Proposal P234, an earlier ANZFA review of criteria and conditions for claims, a nutrition content claim is a type of claim which refers to the presence or absence of energy, nutrients or biologically active substances in a food.
nutrition, health and related claims	In the context of Proposal P293, this is a collective term for any claim which makes reference to nutrients, nutrition or diet and health.
SAG	Scientific Advisory Group
SDAC	Standards Development Advisory Committee
substantiation	Is the process of deciding whether a body of scientific evidence supports a claimed relationship between a diet, food or a component in a food and a health outcome (see Attachment 4).
substantiation framework	Establishes the principles and procedures for the scientific substantiation of nutrition, health and related claims (see section 6 and Attachment 4).
TEG	Technical Expert Group
userguide	In relation to the FSANZ Regulatory Model and the preliminary Impact Analysis, a userguide is an interpretive document that provides guidance on matters set out in a food standard. May also be referred to as an 'interpretive userguide' (see subsections 7.1, 7.2, 7.8 and section 10).

[1] 'A wide range of rules or arrangements by which governments influence businesses to comply, but which do not form part of explicit government regulation', Office of Regulation Review 1998, *A Guide to Regulation*.

Executive summary

Policy Guideline

In December 2003, the Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council) agreed to a Policy Guideline on Nutrition, Health and Related Claims (the Policy Guideline). The Policy Guideline provides the policy principles to underpin the regulation of nutrition, health and related claims including the elements of a regulatory system. It aims to ensure that the health and safety of the public is protected, while allowing for food industry innovation and trade. It does this by incorporating a number of elements designed to ensure claims made on food or in advertising are true, scientifically substantiated and not misleading.

The Policy Guideline includes:

- the policy principles that should underpin any regulation of nutrition, health and related claims for foods as well as the features of any regulatory system that is developed;
- the prerequisites with which any health claims must comply;
- the criteria for the classification of health claims;
- an outline of the recommended regulatory system; and
- the broad requirements for substantiation of any claims made under the proposed regulatory framework.

The Policy Guideline describes nutrition, health and related claims as 'all claims referring to nutrient content, nutrient function, enhanced function, reduction of disease risk or maintenance of normal health'. It outlines a claims classification framework, which distinguishes between two broad categories of claim: general level claims and high level claims. The classification of a claim is based on the degree to which the potential health benefits arising from the use of nutrition, health and related claims are balanced against the potential risks of an adverse outcome arising from the misinterpretation of the claim or an inappropriate use of the claim. The Policy Guideline states that the level of the claim, as determined by the Claims Classification Framework, will determine the degree to which the claim is regulated.

Proposal P293

This new Proposal for Nutrition, Health and Related Claims (Proposal P293) is the vehicle by which FSANZ will, having regard to the Policy Guideline, develop a Standard for regulating nutrition, health and related claims and an appropriate management system to support enforcement of the Standard. The overall aim of the Proposal is to enable the responsible use of scientifically valid nutrition, health and related claims.

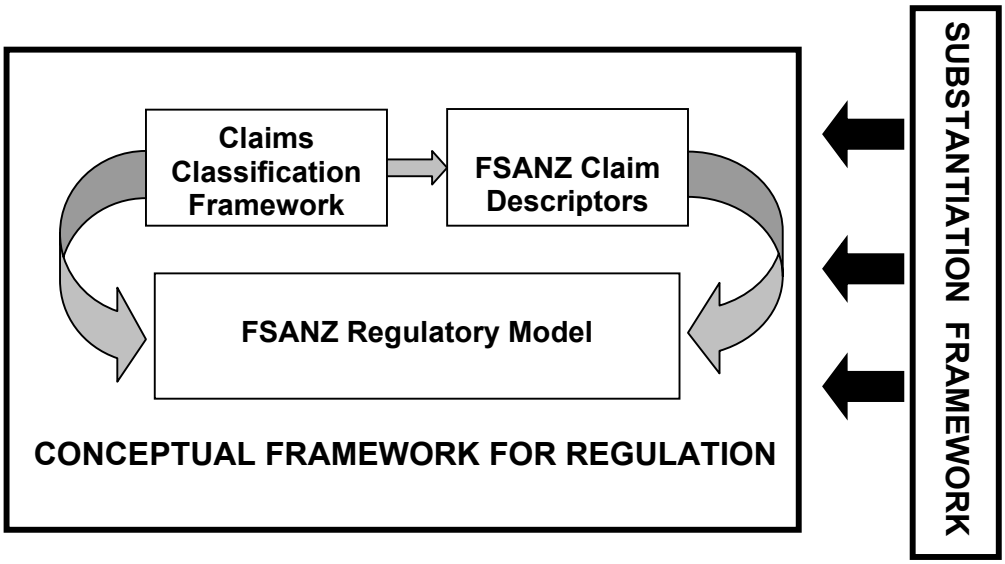
FSANZ Conceptual Framework

FSANZ has developed a Conceptual Framework to facilitate development of the Standard for nutrition, health and related claims (the Standard). It is based on the principle that regulatory intervention is warranted where there are greater risks to public health and safety and/or a greater potential for consumers to be misled. While there may be potential health benefits arising from use of nutrition, health and related claims, in the circumstances where these benefits are off-set by an increased risk to the consumer, the level of regulation to which the claim is subject should increase to mitigate the risk.

The purpose of the FSANZ Conceptual Framework is to establish, in regulatory terms, the parameters by which to define the scope, structure and elements of the Standard for nutrition, health and related claims. The FSANZ Conceptual Framework consists of three interrelated elements:

- Claims Classification Framework
- FSANZ Claim Descriptors
- FSANZ Regulatory Model for Nutrition, Health and Related Claims (the FSANZ Regulatory Model).

Below is a diagrammatic representation of the FSANZ Conceptual Framework.



The Substantiation Framework underpins the FSANZ Conceptual Framework by establishing principles and procedures to ensure that any claim describing a relationship between diet and health, is scientifically valid and is not misleading.

The Claims Classification Framework identifies the categories of claims that make up the continuum of nutrition, health and related claims. The FSANZ Claim Descriptors provide the detail around individual claim types.

The FSANZ Regulatory Model draws together the concepts in the Claims Classification Framework and the FSANZ Claim Descriptors in order to describe the means by which the different categories of claims could be regulated.

The development of the FSANZ Regulatory Model takes into account the need to set parameters to delineate between core regulatory requirements that apply to all claims irrespective of their classification and specific requirements which correlate to where the claim is situated in the Claims Classification Framework.

It is proposed that the parameters take the form of:

- claim prerequisites
- claim criteria

- conditions.[2]

Substantiation

Under the new Standard all nutrition, health and related claims on foods sold or supplied in Australia and New Zealand will be required to be substantiated by scientific evidence, to ensure claims are soundly based and do not mislead consumers.

Regardless of the level of claim, a set of principles will apply to the substantiation of claims. These are:

- a systematic and structured approach should be used to ensure all relevant evidence is considered and the conclusions are justified;
- the evidence must be of a suitable quality before it is considered;
- the evidence should demonstrate a causal relationship between consumption of the food, a nutrient, energy or a biologically active substance in the food and the claimed outcome;
- the evidence should substantiate the claimed health outcome for the intended population group; and
- the required intake of the diet, food or food component should be achievable in the context of the total diet of the intended population group.

FSANZ will evaluate high level claims on a claim-by-claim basis. General level claims will be substantiated by manufacturers or suppliers.

FSANZ has developed a detailed framework for substantiation. The Framework sets out the process by which FSANZ will identify, categorise and interpret studies and evaluate the totality of the evidence and determine eligibility criteria for high level claims. It also outlines the process manufacturers or suppliers will be required to follow to substantiate general level claims. For both high level claims and general level claims, the Framework provides guidance on the minimum requirements for substantiation.

Criteria and conditions for making nutrition content claims

The FSANZ Board rejected the draft variations for Proposal P234 (Criteria and Conditions for making Nutrition Content Claims) in July 2004 on the basis that they had been considered prior to December 2003 and did not have regard to the Policy Guideline. New criteria and conditions for content claims have therefore been developed in this proposal in the context of the Policy Guideline. However, relevant issues raised in submissions to Proposal P234 have been taken into consideration, as has the advice from the Technical Expert Group on General Level Claims.

Compliance and enforcement

The Policy Guideline notes that the Implementation Sub-Committee (comprising representatives from the Australian, New Zealand and each State and Territory governments) will undertake a watchdog role in relation to implementation of the nutrition, health and related claims system. This role includes receiving complaints and referring such complaints to the relevant jurisdictions for analysis and enforcement.

[2] See Glossary in relation to claim prerequisites, claim criteria and conditions.

Regulatory options

Option 1: Status Quo

Under this option, there would be:

- retention of the prohibition on health claims under Standard 1.1A.2;
- retention of the Code of Practice on Nutrient Claims in Food Labels and Advertisements (CoPoNC); and
- retention of specific nutrition content claims in Standard 1.2.8 and a small number of related claims in certain commodity standards, such as those which regulate electrolyte drinks and formulated supplementary sports foods.

Option 2: Development of a New Standard and Guideline(s)[3] for Nutrition, Health and Related Claims (with criteria and conditions for general level claims in a Guideline; high level claims in a Standard)

Under Option 2, FSANZ would develop a new Standard, which would allow food manufacturers to make nutrition, health and related claims on food products providing they meet specific conditions and are fully substantiated.

In relation to high level claims:

- a list of pre-approved claims, including criteria and conditions regarding the application of the claim, would be included in the Standard; and
- additional interpretive userguides would be developed to facilitate understanding of the requirements in the Standard, including the process for seeking pre-approval of high level claims and review mechanisms.

In relation to general level claims:

- only claim prerequisites would be included in the Standard; and
- criteria and conditions (other than those already specified in the Code) would be included in a Guideline.

Option 3: Development of a New Standard for Nutrition, Health and Related Claims (with criteria and conditions for both general level claims and high level claims in the Standard)

Under Option 3, FSANZ would develop a new Standard, which would allow food manufacturers to make nutrition, health and related claims on food products providing they meet specific conditions and are fully substantiated.

In relation to high level claims, Option 3 is the same as for Option 2.

In relation to general level claims:

- all criteria and conditions would be included in the Standard; and
- additional interpretive userguides would be developed to facilitate understanding of the requirements in the Standard and application of the substantiation framework.

[3] A Guideline is an alternative to a food standard. It is not legally enforceable and is not legally binding.

Consultation

This Initial Assessment Report raises a number of questions in relation to issues and the regulatory options outlined in the report. FSANZ encourages your feedback on these questions and the regulatory options.

The Standard and associated management system to support enforcement will be developed in accordance with the requirements of the FSANZ Act having regard to the Policy Guideline. The progress and direction of Proposal P293 will be guided by information received through the consultation process. Advice will be sought from the Standards Development Advisory Committee (SDAC), the Scientific Advisory Group and through targeted and public consultation. Public submissions are now invited in response to the matters raised in this Initial Assessment Report.

1. Introduction

Food Standards Australia New Zealand (FSANZ) and its predecessor the Australia New Zealand Food Authority (ANZFA) has been considering the development of a regulatory framework for health and related claims and nutrition and related claims for some time. Some of this work goes back as far as 1996 when the former ANZFA developed a concept paper specifically on health and related claims.

During this time several developments have impacted on FSANZ's ability to finalise work in this area. Significant among these has been the separation of responsibility for developing food policy (now vested with the Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council)) and for developing food standards (the responsibility of FSANZ).

Consistent with the new regulatory arrangements, the matter of nutrition, health and related claims was referred, by the former Australia New Zealand Food Standards Council (ANZFSC), to the Food Regulation Standing Committee for policy advice in July 2001. In December 2003, the Ministerial Council (which replaced ANZFSC) agreed to a Policy Guideline on Nutrition, Health and Related Claims, with the exception of biomarker maintenance claims. In May 2004, the Ministerial Council agreed that biomarker maintenance claims are to be treated in the same way as biomarker enhancement claims, that is, subject to pre-market assessment and approval by FSANZ. The Policy Guideline provides the policy principles to underpin regulation of nutrition, health and related claims, including the elements of a regulatory system. A revised Policy Guideline can be found at Attachment 1.

This new Proposal for Nutrition, Health and Related Claims, Proposal P293, is the vehicle by which FSANZ will, having regard to the Ministerial Council's Policy Guideline, develop a Standard for regulating nutrition, health and related claims and an appropriate management system to support enforcement of the Standard.

1.1 Current provisions in Australia and New Zealand regarding nutrition, health and related claims

Currently, regulation of nutrition, health and related claims in Australia and New Zealand is managed in a number of ways.

A small number of nutrition claims, including claims in relation to sodium, energy, gluten, lactose and certain claims in relation to fat, are regulated in Division 3 in Standard 1.2.8 (Attachment 2A) in the Australia New Zealand Food Standards Code (the Code). Vitamin and mineral claims, including claims that a food is a 'good source' of a vitamin or mineral, are regulated in Standard 1.3.2 in the Code. The Code applies to food produced in and imported into Australia and New Zealand. There is also a small number of related claims, including claims in relation to electrolyte drinks and formulated supplementary sports food, permitted in certain commodity standards in the Code.

The majority of nutrition claims, such as 'high fibre', 'reduced fat' and 'no added sugar' in Australia, are managed through the Code of Practice on Nutrient Claims in Food Labels and in Advertisements (CoPoNC). CoPoNC does not apply to foods imported into Australia and is not recognised in New Zealand.

In New Zealand, the majority of nutrition claims are managed by reference to the general provisions in the *New Zealand Fair Trading Act 1986*, which require that any representations in the course of trade and commerce regarding food must not be false or misleading.

In Australia and New Zealand, health claims (except for the permitted pilot health claim regarding maternal folate consumption and a reduced risk of fetal neural tube defects, such as spina bifida) are prohibited by Standard 1.1A.2 (Attachment 2B) in the Code on food labels or in advertising.

In summary, Standard 1.1A.2 prohibits on food labels or in advertising:

- slimming claims or references that a food has intrinsic weight-reducing properties;
- claims for therapeutic or prophylactic action;
- use of the word 'health' or words of similar import;
- any word, statement, claim (whether express or implied) or design which directly or by implication might be interpreted as medical advice; and
- a name or reference to a serious disease.

1.2 Policy Guideline

The Policy Guideline, agreed to by the Ministerial Council in December 2003 aims to ensure the health and safety of the public is protected, while allowing for food industry innovation and trade. It does this by incorporating a number of elements designed to ensure that claims made on food or in advertising are true, scientifically substantiated and not misleading.

The Policy Guideline includes:

- the policy principles that should underpin any regulation of nutrition, health and related claims for foods as well as the features of any regulatory system that is developed;
- the prerequisites with which any health claim must comply;
- the criteria for the classification of health claims;
- an outline of the recommended regulatory system; and
- the broad requirements for the substantiation of any claims made under the proposed regulatory framework.

1.2.1 Principles to guide the development of regulation for nutrition, health and related claims

The policy principles outlined in the Policy Guideline provide that any intervention by government should:

1. give priority to protecting and improving the health of the population;

2. enable the responsible use of scientifically valid nutrient, health and related claims;

3. support government, community and industry initiatives that promote healthy food choices by the population;

4. be consistent with and complement Australian and New Zealand national policies and legislation including those relating to nutrition and health promotion, fair trading, industry growth and international trade and innovation;

5. be cost effective overall, not more trade restrictive than necessary and comply with Australia's and New Zealand's obligations under the WTO Agreements;

6. contain a process of substantiation which aligns levels of scientific evidence with the level of claims along the theoretical continuum of claims, and at minimum costs to the community;

7. draw on the best elements of international regulatory systems for nutrient, health and related claims and be responsive to future trends and developments;

8. provide for collaborative action among enforcement agencies, industry and consumers to optimise educational resources; and

9. allow for effective monitoring and appropriate enforcement.

The Policy Guideline also lists the following as desirable features of any regulatory system for health, nutrition and related claims. The system should:

10. favour pre-market approval rather than post-market reaction;

11. enable better engagement of sectors other than government in providing nutritional advice and information;

12. promote a partnership between consumers, governments and industry in the delivery and responsible use of nutrition, health and related claims which protects consumers from false and misleading information that may result in distorted diets which harm health and increase health inequalities; and

13. allow for all transition issues to be clearly identified and steps taken to justify and to minimise costs of change and transition.

2. Regulatory problem

The Council of Australian Governments has determined that all intergovernmental standard-setting bodies and Ministerial Councils shall incorporate principles of good regulatory practice in their decision making.

These principles are documented in the 1997 Council of Australian Governments publication, *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies*. In essence, all standard setting bodies and Ministerial Councils are required to identify the need for regulation and quantify the potential benefits and costs of regulation and to present such analysis in a regulatory impact statement.

In relation to the current proposal, the Ministerial Council has provided detailed guidance to FSANZ on developing a new food standard. FSANZ is required to abide by the Council of Australian Governments principles of good regulatory practice when making a decision to adopt a new food standard. FSANZ is required to demonstrate the need for regulation and, in preparing the regulatory impact statement for public consultation, must ensure these issues are addressed.

In addressing the need for new regulation, consideration will be given to the size and nature of the risk to public health and safety, in comparison with the limitations of the current regulatory arrangements.

2.1 Potential risks to public health and safety

The need for regulation around the types of nutrition content and health claims that food manufacturers may wish to use to promote their products follows from a consideration of the potential risk to public health and safety. Claims that are made without reference to a public health framework have the potential to mislead and confuse consumers, encouraging consumer choices that may have adverse health impacts.

A large number of nutrition content claims in Australia are regulated in a voluntary Code of Practice (CoPoNC). The majority of manufacturers abide by the criteria in CoPoNC; therefore the nutrition claims on most products have a sound basis and help consumers make informed choices. However, some manufacturers do not comply with CoPoNC and, as it is a voluntary Code, government enforcement agencies are unable to address products with non-compliant claims. This disadvantages those businesses that do comply with CoPoNC and make claims in accordance with the criteria.

For consumers, non-compliant content claims may result in provision of poor quality and unreliable information, ill-informed decision making and, as a consequence, potential adverse health impacts. For example, a claim of '90% fat-free', which is not permitted under CoPoNC, could mislead consumers into believing the product is a low fat food.

The current regulatory arrangements illustrate that a voluntary Code of Practice is not as effective as a Standard in addressing non-compliance. This is largely because a Code of Practice does not have universal application (it only applies to signatories to the Code) and it is not legally enforceable. For example, the current CoPoNC does not apply in New Zealand or to any Australian food business that is not a signatory.

Question:

1. To what extent does the level of compliance and non-compliance with the CoPoNC impose costs on industry and consumers? How significant are these costs?

Claims relating to nutrition and health also involve other risks. Research shows that consumers will focus on the claim and tend not to read other relevant information on the product label. For example a product that correctly claims to be 'salt reduced' may give consumers the impression that it is healthy, however, consumers may not be evaluating the total nutritional profile of the food in making their choice.

Consumers choosing a number of products on the basis of their claimed nutrition and health value, may be at risk of believing that a diet comprised of such products has to be healthy and good for them. These consumers are at risk of losing a whole-of-diet perspective on their food purchases. A further risk is the possibility of claims having the effect of shifting consumption patterns from foods such as fruit and vegetables to less healthy alternatives such as processed foods which may contain nutrition or health claims. Such a shift in consumption patterns could have major adverse health consequences.

Question:

2. What are the likely impacts on consumption patterns arising from a permission to make claims relating to nutrition and health? If there is a consequential risk to public health and safety, how significant do you consider this risk to be? Please provide any evidence you have to support your response to the extent of these risks.

2.2 Limitations of the current arrangements

The current regulatory arrangements limit the opportunities that would otherwise exist for product development and placement while also limiting the benefits that might otherwise be achieved for consumers and industry. For example, consumers value nutrition and health and, potentially, could make better-informed food choices and achieve better health outcomes, if a broader range of nutrition and health claims were permitted on food labels. There are also marketing advantages to industry of making nutrition, health and related claims.

Questions:

3. Would consumers in general (or specific consumer groups) benefit from a broader range of nutrition, health and related claims? If so, which claims?
4. What opportunities could industry take up in terms of product development and placement? Provide examples or data to show how significant the opportunities are to industry at present.

3. Objective

3.1 FSANZ's objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

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

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

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

- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

3.2 Overall objectives

The overall aim of this Proposal is to enable the responsible use of scientifically valid nutrient, health and related claims for food products. In developing a framework to satisfy this broad objective, FSANZ will:

- give priority to protecting and improving the health of the population and preventing misleading and deceptive conduct;
- support government, community and industry initiatives that promote healthy food choices by the population;
- develop a cost effective food regulatory measure;
- develop a food regulatory measure that contains a process of substantiation which aligns levels of scientific evidence with the level of claims along the theoretical continuum for claims; and
- take account of other detailed guidelines issued by the Ministerial Council.

4. Background

4.1 Changes in the regulatory environment

New arrangements for the food regulatory system were implemented in mid 2002. These changes were brought about by the signing of a new intergovernmental Food Regulation Agreement, changes to the Australia New Zealand Joint Food Standards Treaty and amendments to the *Australia New Zealand Food Authority Act 1991*. Along with a name change from ANZFA to FSANZ, one of the principal changes to the food regulatory system is separation of the development of policy guidelines that apply to foods and the setting of food standards.

Previously, the ANZFA Board made recommendations on food standards to the ANZFSC having regard to the broader policies and objectives of the Australia and New Zealand governments. Under the new system the Ministerial Council decides on policy guidelines based on advice from the Food Regulation Standing Committee, which comprises senior government officials from the Commonwealth, New Zealand and the Australian States and Territories.

The separation of policy from regulation allows FSANZ to focus on the primary role of developing food standards. FSANZ must have regard to relevant Ministerial policy guidelines when it develops or reviews food standards.

4.2 Previous consideration on nutrition, health and related claims

In July 2001, the former ANZFA (now FSANZ) made a recommendation to the then ANZFSC regarding regulation of health claims (Proposal P153 – Review of Health and Related Claims). The recommendation to ANZFSC included a draft standard for health claims and a recommendation that a Code of Practice (to be overseen by a Code of Practice Management Committee) be developed to help implement and enforce the proposed standard for health claims.

In anticipation of a decision by ANZFSC, ANZFA started preparatory work on a Proposal (Proposal P250 – Development of a Co-regulatory System for Health and Related Claims) to develop a Code of Practice to support the proposed standard for health claims.

Around the same time (May 2001), ANZFA began a review of Nutrient Content and Related Claims (Proposal P234). The review was to consider the most appropriate regulatory mechanism for managing nutrition content and other related claims and to review the criteria that should apply to making such claims.

At the July 2001 meeting of the ANZFSC, Ministers decided to refer health and related claims, under the new food regulatory arrangements, to Food Regulation Standing Committee for policy advice and to include nutrition content claims in the scope of the policy framework. In response to the decision, ANZFA changed the scope of Proposal P234 with the objective to only review the criteria and conditions for nutrition content and related claims. In addition, ANZFA recognised that the scope of Proposal P250, which had initially been specific to health claims, should be broadened to address development of a Code of Practice for management of nutrition, health and related claims. However, because the outcomes of the policy development process were likely to have a significant impact on the proposed regulatory approaches in both Proposal P250 and Proposal P234, ANZFA suspended work on both proposals in 2002.

In the case of Proposal P250, despite the Initial Assessment Report being finalised and agreed to by the ANZFA Board, stakeholder consultation on the report was delayed in anticipation of the finalisation of the policy advice. However for P234, a Draft Assessment Report had been released in March 2002 for public consultation.

In December 2003, the Ministerial Council agreed to the Policy Guideline. In view of the need to consider criteria for nutrition content and related claims in the context of criteria for other health and related claims and the need to have regard to the Policy Guideline, the FSANZ Board has prepared this proposal (Proposal P293) to consider nutrition, health and related claims. Consequently, the FSANZ Board in July 2004 rejected Proposal P234 and abandoned Proposal P250.

Proposal P293 allows FSANZ to undertake a two-stage consultation process, maximising stakeholder input on the new options while allowing issues that were raised in Proposal P234 and Proposal P250 to be taken into account.

5. Conceptual Framework for the Regulation of Nutrition, Health and Related Claims

5.1 Background

The Policy Guideline describes nutrition, health and related claims as 'all claims referring to nutrient content, nutrient function, enhanced function, reduction of disease risk or maintenance of normal health'.[4]

[4] These terms are referred to in the Glossary of the Policy Guideline.

Claims on food labels or in advertising can communicate simple or complex nutrition and health messages. A nutrition content claim is a relatively simple nutrition message that conveys information about the amount of a nutrition related component (that is, a nutrient, energy or a biologically active substance) in a food. Consumers can generally rely on their knowledge and experience, in conjunction with other information on the food label, such as the Nutrition Information Panel, to interpret these messages appropriately.

If consumers are aware of the nutritional factors influencing their health they can better manage those factors to select an appropriate diet. When consumers can manage these factors based on their knowledge and experience there is less risk of an adverse health outcome and less need for regulatory intervention.

A health claim that describes a relationship between consumption of a food and a reduced risk of disease, such as cancer, is a health message that is more complex to interpret and to apply in the total diet context. While there is a potential health benefit in following the advice of the claim (in this case, the benefit of a reduced risk of disease), there is also the potential for the consumer to interpret the health message inappropriately, which may result in adverse outcomes. Such outcomes may include:

- over consumption of a food carrying a claim as consumers may perceive that increased consumption results in increased health benefits, for example, a consumer may consume more than the recommended serving of a food containing phytosterols in order to increase the potential health benefit arising from eating food containing phytosterols, which may result in an excess energy intake;

- consumers may consider a food healthier where it carries a claim in relation to a specific food component, regardless of the amount of other components in the food not mentioned in the claim. For example, a consumer may perceive that a product which carries the claim ‘This food is low in saturated fat which may reduce the risk of developing heart disease’ is a healthy food choice even if it has a high sugar content and is low in fibre;

- consumers relying on consumption of foods carrying health claims and excluding foods not carrying claims as they may believe foods with claims are a better choice. For example, fruits and vegetables not carrying a claim may be replaced in the diet by processed foods containing a small amount of fruits and/or vegetables, which carry a claim. While the food carrying the claim may not be an inappropriate food choice, the replacement of fruits and/or vegetables which have the potential to yield broader benefits may ultimately lead to an unbalanced or distorted diet; and

- consumers exclusively following the advice of a claim on food and failing to seek or follow advice from a health professional.

Claims on food labels or in advertising that reference a biomarker or a serious disease are likely to be highly complex health messages. Such claims need to be more highly regulated to mitigate the potential risk associated with consumers not being provided with complete information, resulting in consumers misinterpreting these complex health messages.

In summary, the more complex the relationship between diet and health described in a claim:

- the more complex the message is to interpret;
- the greater the potential for consumer confusion and misunderstanding;
- the greater the potential for an adverse health outcome;
- the greater the need for guidance about the role or use of that food in the total diet context; and
- the greater the need for regulatory intervention.

5.2 FSANZ Conceptual Framework

FSANZ has developed a Conceptual Framework to facilitate development of the Standard for nutrition, health and related claims. It is based on the principle that regulatory intervention is warranted where there are greater risks to public health and safety and/or a greater potential for consumers to be misled. While there may be potential health benefits arising from the use of nutrition, health and related claims, in the circumstances where these benefits are off-set by an increased risk to the consumer, the level of regulation to which the claim is subject should increase to mitigate the risk. This concept is described in the Policy Guideline in relation to the categorisation of a claim where it is proposed that claims offering a higher 'degree of promise'[5] to the consumer should be more highly regulated.

The objective of the FSANZ Conceptual Framework is to establish, in regulatory terms, the parameters by which to define the scope, structure and elements of the Standard for nutrition, health and related claims. The FSANZ Conceptual Framework consists of three interrelated elements: the Claims Classification Framework,[6] the FSANZ Claim Descriptors, and the FSANZ Regulatory Model for Nutrition, Health and Related Claims.

The Substantiation Framework underpins the FSANZ Conceptual Framework by establishing principles and procedures to ensure any claim describing a relationship between diet and health is scientifically valid and is not misleading. See section 6 regarding the Substantiation Framework.

The Claims Classification Framework identifies the categories of claims that make up the continuum of nutrition, health and related claims. The FSANZ Claim Descriptors provide the detail around individual claim types.

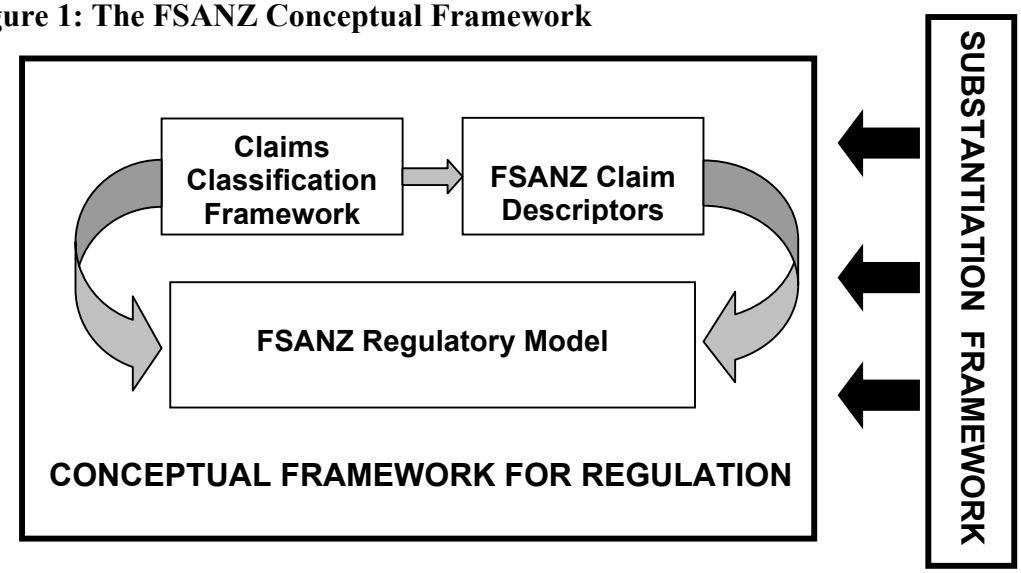
The FSANZ Regulatory Model for Nutrition, Health and Related Claims (FSANZ Regulatory Model) draws together the concepts in the Claims Classification Framework and the FSANZ Claim Descriptors in order to describe the means by which the different categories of claims could be regulated.

Each of the elements making up the FSANZ Conceptual Framework is discussed in more detail in the following sections. Figure 1 shows a diagrammatic representation of the Conceptual Framework for Regulation and the interrelationship between the Conceptual Framework and the Substantiation Framework.

[5] The Policy Guideline states that 'the categorisation of the claim is based on the degree of promise to the consumer of the claim. That is, the potential benefit to the consumer in consuming that food in preference to other foods and, commensurately, the degree of risk to the consumer (and public health) in following the advice of the claim.'

[6] This is the terminology used in the Policy Guideline.

Figure 1: The FSANZ Conceptual Framework



5.3 Claims Classification Framework

The Policy Guideline outlines a claims classification framework, which distinguishes between two broad categories of claims: general level claims and high level claims. As referred to earlier, the classification of a claim is based on the degree to which the potential health benefits arising from the use of nutrition, health and related claims are balanced against the potential risks of an adverse outcome arising from the misinterpretation of the claim or an inappropriate use of the claim. The Policy Guideline states that the level of the claim, as determined by the Claims Classification Framework, will determine the degree to which the claim is regulated.

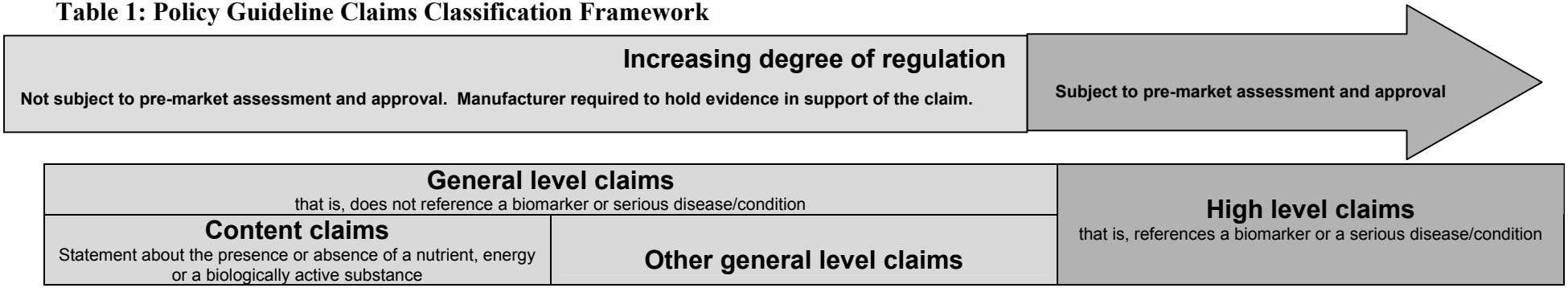
Table 1 outlines FSANZ's interpretation of the Claims Classification Framework, based on the two broad categories of claims: general level claims and high level claims. In addition, using examples provided in the Policy Guideline, FSANZ has identified several sub-categories of claims which fall into one or the other of the two broad categories of claim on the basis of whether or not they refer to a biomarker or a serious disease or condition.

The Claims Classification Framework needs to be interpreted in the context of the FSANZ Claim Descriptors. For further information regarding the FSANZ Claim Descriptors see subsection 5.4.

FSANZ discussed the Conceptual Framework with members of the Technical Expert Group (TEG) on 1 June 2004, and the Standard Development Advisory Committee (SDAC) on 8 June 2004. The comments from the TEG and SDAC are reflected in the following discussion of the FSANZ Conceptual Framework.

NB. The examples of claims provided in this Initial Assessment Report are for illustrative purposes only. They are not intended to represent how claims should be expressed according to any future regulatory framework for nutrition, health and related claims.

Table 1: Policy Guideline Claims Classification Framework



Examples	Examples	Examples
Absolute content claim Describe or indicate the presence or absence of a component in the food (nutrient, energy or biologically active substance). For example, 'this food is high in calcium' (Page 4 of Policy Guideline) **Comparative content claim** Describe or indicate the presence of a component in a food in comparison to other similar foods For example, ' reduced fat'	**Function claim** See the maintenance of good health or normal functions of the body. For example 'calcium is good for strong bones and teeth' (Page 4 of Policy Guideline) See specific benefits for performance and wellbeing in relation to foods. For example 'gives you energy' (Page 5 of Policy Guideline) NB. Depending on the wording of a performance and wellbeing claim it could be placed in either the function or enhanced function sub-category **Enhanced function claim** Describes how a diet, food or component can modify a function or body structure beyond its role in the normal development and maintenance functions of the human body For example 'exercise and a diet high in calcium and calcium containing foods like this product may help give you stronger bones' **Risk reduction (ref to non-serious disease) claim** See the potential for a food or component to assist in reducing the risk of or helping to control a non-serious disease or condition. For example, 'yoghurt high in acidophilus as part of a healthy diet may reduce your risk of stomach upsets' (Page 5 of Policy Guideline) **Whole of diet claims (based on the Australian Dietary Guidelines and the New Zealand Food and Nutrition Guidelines).** For example, 'a healthy, balanced diet that includes dietary fibre from a number of sources is one that can help reduce your risk of constipation' (Page 5 of Policy Guideline) NB. The example provided in the Policy Guideline for a whole-of-diet claim places it in this classification because the claimed benefit references a non-serious disease/condition. However it could be classified as any other GLC depending on the claimed benefit with which it is coupled.	**Biomarker maintenance claim** For example, 'this food is high in Omega-6 fatty acids which may help to maintain normal blood cholesterol' **Biomarker enhancement claim** For example, 'This food is high in Omega-6 fatty acids which may help to reduce blood cholesterol levels' **Risk reduction (ref aserious disease) claim** See the potential for a food or component to assist in: • controlling, reducing the risk of, or improving, a serious disease or condition; or • are whole of diet claims (based on the Australian Dietary Guideline or the New Zealand Food and Nutrition Guidelines) which refer to a biomarker or a serious disease or condition For example, 'this food is high in Omega-6 fatty acids, which as part of a diet low in saturated fat and high in soluble fibre may reduce the risk of developing heart disease' For example, ' a healthy diet that may lower your risk of certain kinds of cancer is one that is low in fats and includes fibre from a number of sources including a variety of fruits and vegetables, and wholegrain and bran cereals' (Page 6 of Policy Guideline)

5.4 FSANZ claim descriptors

During the policy development process a glossary of terms was developed.[7] The terms defined in the glossary are terms generally referred to in the Policy Guideline. These definitions, while potentially having a broader application, are generally specific to the context of the Policy Guideline.

The FSANZ claim descriptors is a list of terms referred to in the Claims Classification Framework with accompanying working definitions or descriptions. These definitions are based on definitions in the Policy Guideline and on definitions currently in use in Australia, New Zealand and internationally. These working definitions are for discussion purposes and to facilitate a common understanding of the types of claims captured in the Claims Classification Framework and the FSANZ Conceptual Framework.

During the standard development process, FSANZ will consult on definitions for inclusion in the Substantiation Framework and the Standard for nutrition, health and related claims. It is likely that FSANZ will need to develop regulatory definitions for the following terms: general level claim, high level claim, therapeutic claim, serious disease, non-serious disease, and biomarker.

FSANZ has posed a number of questions in relation to the claim descriptors. FSANZ specifically seeks your input on those aspects of the working definitions and descriptors identified in square brackets [ ]. Responses from stakeholders to questions in this section of the Report will help FSANZ finalise the FSANZ Conceptual Framework and identify those terms that will need to be defined for regulatory purposes.

5.4.1 Claim

Term	**Current definition Standard 1.1.1 in the Code**
claim	claim means any statement, representation, information, design, words or reference in relation to food which is not mandatory in this Code.

5.4.1.1 Background

The distinguishing features of a claim are that it:

- is a statement, representation, information, design, words or reference;
- relates to a food; and
- is a voluntary statement, as opposed to a mandatory statements that is required by the Code.

The term is used in a range of standards throughout the Code; Standard 1.2.8 (clauses 14–17); Standard 1.3.2 (clauses 4–9); Standard 2.9.1 (clauses 28 and 30); Standard 2.9.2 (clauses 6 and 8); and Standard 2.9.3 (clauses 3, 5 and 7). Generally, use of a particular type of claim, in relation to a food, triggers additional labelling requirements.

[7] See page 12 of the Nutrition, Health and Related Claims Policy Guideline.

The definition of a 'claim' is very broad, encompassing any voluntary representations made in relation to a food. This covers words or other artwork on food labels, or conveyed through other mediums such as advertisements.[8] It covers verbal representations in relation to food. It also covers representations in relation to food that are not nutrition or health related, for example, claims in relation to the processing of a food, for example, 'organic' foods.

This term is a fundamental component of different types of claims. It provides a basic threshold for the sub-categories of claims in the Claims Classification Framework. For example, in order for something to constitute a high level claim, it must first meet the criteria for being a claim.

FSANZ considers that the current definition of 'claim' in the Code is sufficient to provide a basis for defining other sub-categories of claims. The current definition of claim, which makes reference to 'representation' and 'words or reference in relation to a food' captures implied claims. However, to avoid doubt, the definition may be amended to expressly refer to implied claims. It should therefore not be necessary for subsequent definitions to make reference to 'states, suggests or implies' or 'describes explicitly or implicitly'. However, for the purposes of clarity, the working definitions in this section include this concept in square brackets.

5.4.2 General level claim

Term	**Proposed FSANZ working definition**
general level claim	is a claim which does not reference a biomarker or a serious disease or condition and [includes] [content] claims, function claims, enhanced function claims and risk reduction claims that reference a non-serious disease or non-serious condition.

5.4.2.1 Background

The Policy Guideline recommends a Claims Classification Framework that consists of two broad categories of claims: general level claims, and high level claims.

The Policy Guideline[9] indicates that the Standard for nutrition, health and related claims will include a definition for 'general level claim' and 'high level claim'.

'General level claim' is a broad category of claim. Examples of general level claims include content claims,[10] function claims, enhanced function claims and risk reduction claims that reference a non-serious disease or condition.

The distinguishing features[11] of a general level claim are that:

[8] Advertising is defined in the Model Food Act as 'any words, whether written or spoken, or any pictorial representation or design, or any other representation by any means at all, used or apparently used to promote, directly or indirectly, the sale food'.
[9] See page 6 of the Nutrition, Health and Related Claims Policy Guideline.
[10] Further discussion on content claims is set out in subsection 5.5.1 including whether these claims should more correctly be referred to as 'nutrient content claims or 'nutrition content claims'.
[11] See page 4 of the Nutrition, Health and Related Claims Policy Guideline.

- it does not reference a biomarker or a serious disease or condition[12]; and
- it is not subject to pre-market approval. That is, the manufacturer can make an assessment of the evidence relevant to the claim prior to the claim going to market. The manufacturer will hold evidence relevant to the claim and produce the evidence at the request of the enforcement agency.

In accordance with the Policy Guideline, it will be a requirement of the Standard for general level claims (other than content claims) to be made in the context of the appropriate total diet.

5.4.2.2 Rationale

The FSANZ working definition of 'general level claim' lists the sub-categories of the claim type in order to identify which claims will not be subject to pre-market assessment and approval by FSANZ. There is likely to be a need to define 'general level claim' in the Standard for nutrition, health and related claims.

Question:

5. Do you think the working definition of a 'general level claim' captures all the possible types of claims which would not reference a biomarker or a serious disease or condition? See subsection 5.4.5 for the proposed working definition of a serious disease.

5.4.3 High level claim

Term	Proposed FSANZ Working Definition
high level claim	is a claim which references a biomarker or a serious disease or condition and [includes] biomarker maintenance claims, biomarker enhancement claims and risk reduction claims which reference a serious disease or condition.

5.4.3.1 Background

The distinguishing features of a high level claim are that it:

- references a biomarker or a serious disease or condition[13]; and
- is subject to pre-market assessment and approval by FSANZ. A manufacturer is prohibited from making a high level claim unless permission for use of that claim is specified in the Standard for nutrition, health and related claims.

Examples of high level claims include biomarker claims (such as biomarker maintenance claims and biomarker enhancement claims); risk reduction claims which reference a serious disease or condition; and whole-of-diet claims[14] which refer to a biomarker or a serious disease or condition.

[12] FSANZ has proposed a definition for serious disease which is inclusive of disorders, conditions or defects. See subsection 5.4.5.
[13] As above.
[14] See page 6 of the Nutrition, Health and Related Claims Policy Guideline.

In accordance with the Policy Guideline, it will be a requirement of the Standard for high level claims to be made in the context of the appropriate total diet.

5.4.3.2 Rationale

The FSANZ working definition of 'high level claim' identifies the distinguishing features of a high level claim and lists sub-categories of claims in order to clarify which claims are subject to pre-market assessment and approval by FSANZ.

There is likely to be a need to define 'high level claim' in the Standard for nutrition, health and related claims in order to clarify which group of claims are prohibited unless pre-approved by FSANZ.

Question:

6. Do you think the working definition of a 'high level claim' captures all the possible types of claims which would reference a biomarker or a serious disease or condition? See subsection 5.4.5 for the proposed working definition of a serious disease.

5.4.4 Therapeutic claim

Term	Proposed FSANZ working definition
therapeutic claim	is a claim [outside the context of the total diet] which refers to the prevention, treatment, alleviation or cure of a disease, ailment, defect or injury.
For example, 'This food is high in iron for the treatment and prevention of anaemia.'	

5.4.4.1 Background

The Policy Guideline notes that therapeutic claims on foods are not to be permitted under the nutrition, health and related claims framework, except where expressly permitted in the Code. The Policy Guideline defines a therapeutic claim as a claim outside the context of the total diet that links a specific food or food component with:

- the prevention, diagnosis, or cure of a disease, ailment, defect or injury; or
- influencing, inhibiting or modifying a physiological process.

The Policy Guideline further states that:

- therapeutic claims may only be made for goods, which are regulated by the Therapeutic Goods Administration (TGA); and
- a statement about dosage is an implied therapeutic claim and is therefore not permitted on foods.[15]

[15] See page 15 of the Nutrition, Health and Related Claims Policy Guideline.

The *Therapeutic Goods Act 1989*[16] very generally defines therapeutic use as including use in, or in connection with 'preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury' or with 'influencing, inhibiting or modifying a physiological process'. The regulation of therapeutic goods and therapeutic claims is discussed in more detail in subsection 8.1.

5.4.4.2 Rationale

FSANZ has proposed a working definition, which reflects the advice of the Policy Guideline in relation to therapeutic claims being claims made outside the context of the total diet. This concept was supported by the SDAC at their face-to-face meeting on 8 June 2004.

In contrast to the definition proposed in the Policy Guideline, FSANZ has proposed to limit therapeutic claims to claims which refer to the 'prevention, treatment, alleviation or cure of a disease, ailment, defect or injury' as otherwise the definition of a therapeutic claim would capture functional claims which may be expressed as 'influencing, inhibiting or modifying a physiological process'.

Furthermore, an interpretation of the proposed FSANZ working definition is that the inclusion of the words 'outside the context of the total diet' would permit claims that are made in the context of the appropriate total diet which refer to the prevention, treatment, alleviation or cure of a disease, ailment, defect or injury.

There is also an issue concerning how the definition for therapeutic claim fits with other definitions, particularly for high level claims. The former uses the terms 'disease,

ailment, defect or injury' whereas the latter uses 'serious disease or condition' and 'biomarker'. This change in terminology may have the potential to cause confusion.

Once a regulatory framework for nutrition, health and related claims is implemented, identification of a therapeutic claim may be challenging. Care will have to be given to ensure a high level claim, that references a biomarker, or a serious disease or condition, is not presented as an implied therapeutic claim, even if the claim is made in the context of the total diet. A high level health claim, however, would be prohibited unless pre-approved by FSANZ.

SDAC also sought clarification on whether a high level risk reduction claim that used either the phrase 'may prevent' or 'helps reduce' resulted in the claim being considered a therapeutic claim. FSANZ considers this an issue that needs to be explored in consumer research.

Questions:

7. Are there any circumstances not adequately captured by the proposed wording of FSANZ's working definition of 'therapeutic claim'?
8. Should the definition of a therapeutic claim explicitly include claims that can be interpreted as medical advice or is this already implied in the definition? Or should such claims be treated separately?

[16] See Attachment 3.

9.	Does the terminology of 'disease, ailment, defect or injury' in the definition of a therapeutic claim, in contrast to the high level claim definition which centres on disease, conditions or biomarkers, cause any specific problems?

5.4.5 Serious disease

A key decision point, when determining the classification of a claim, is whether or not the claim makes reference to a serious disease. Therefore it is important to define 'serious disease'[17].

FSANZ considers it may be useful to broaden the definition outside the strict medical definition of disease to include disorders, conditions or defects,[18] so as to be explicit about the range of health outcomes encompassed by the definition. The inclusion of 'condition' in the proposed definition is not intended to imply inclusion of normal lifestages, such as childhood, pregnancy, etc.

The proposed definition for inclusion in the Standard is based on that used in the Therapeutic Goods Advertising Code.[19] FSANZ is aware that the definition of serious disease in the Therapeutic Goods Advertising Code is under review and therefore the definition proposed below may require further development to achieve consistency, as far as possible, between definitions used for foods and medicines.

Term	**Proposed FSANZ working definition**
serious disease, disorder, condition or defect	is one generally accepted as not being appropriate to be diagnosed or treated without consulting a suitably qualified health care professional, or one that is beyond the ability of the average person to evaluate accurately, or treat safely, without regular supervision by a suitably qualified health care professional

In addition, it is proposed to provide guidance, outside the Standard, on specific diseases, disorders or conditions that are considered to be serious. The following table, based on those used in the Therapeutic Goods Advertising Code [20] and the TGA Levels of Evidence document,[21] lists diseases, disorders or conditions that are serious.

[17] All references in this Report to 'serious disease or condition' are intended to encompass 'serious disease, disorder, condition or defect' as defined in subsection 5.4.5.

[18] Disease: any deviation from or interruption of the normal structure or function of any part, organ or system (or combination thereof) of the body that is manifested by a characteristic set of symptoms or signs (Dorlands, *Illustrated Medical Dictionary*, 28th edition, WB Saunders Company, Philadelphia, 1994).
Disorder: a derangement or abnormality of function (Dorlands 1994).
Condition: mode of being, state of health (*Macquarie Dictionary*, 3rd edition. The Macquarie Library Pty Ltd, Sydney, 1997).
Defect: an imperfection, failure or absence (Dorlands 1994).

[19] Therapeutic Goods Advertising Code Council 2003, *Therapeutic Goods Advertising Code*. Available at <http://www.tgacc.com.au/codeFull.cfm>.

[20] As above.

[21] Therapeutic Goods Administration 2001, *Guidelines for the levels and kinds of evidence to support indications and claims for non-registrable medicines, including complementary medicines and other listable medicines*, TGA, Canberra.

The inclusion of serious diseases such as neoplastic diseases (cancers) in this list of diseases requiring pre-approval is in contrast to the current prohibition within clause 5 of the Therapeutic Goods Advertising Code of inclusion of any reference to these diseases in the advertising of therapeutic goods.

Diseases, disorders, conditions or defects that are 'serious'	
Cardiovascular disease	Dental and periodontal disease
Diseases of joint, bone, collagen and rheumatic disease	Diseases of the eye or ear likely to lead to severe impairment, blindness or deafness
Diseases of the liver, biliary system or pancreas	Endocrine diseases and conditions including diabetes and prostatic disease
Gastrointestinal disease or disorders	Haematological disorders and diseases
Immunological diseases	Infectious diseases including sexually transmitted diseases
Insomnia, persistent	Mental diseases, ailments or defects, including substance abuse
Metabolic disorders	Musculoskeletal diseases
Neoplastic diseases (cancers)	Nervous system diseases
Renal diseases, diseases of the genito-urinary tract	Respiratory diseases
Skin diseases	

Questions:

10. Should a reference to 'disorders, conditions or defects' be included in the definition of serious disease?
11. Would it be useful to include a list of serious diseases/conditions in a guideline document? Do you have any suggestions about the proposed list of serious diseases/conditions?
12. Should claims in relation to cancer be permitted in food regulation?

5.4.6 Non-serious disease

For the purposes of assessing nutrition, health and related claims on foods, a non-serious disease, disorder, condition or defect is one generally accepted as being appropriate for treatment without consulting a suitably qualified health care professional or one that is within the ability of the average person to evaluate accurately, or treat safely, without regular supervision by a suitably qualified health care professional.

Questions:

13. Is there a need to define 'non-serious disease' in the Standard for nutrition, health and related claims?
14. Can you provide examples of what may constitute a non-serious disease or condition?

5.4.7 Biomarker

A second key decision point when determining the classification of a claim is whether or not the claim makes reference to a biomarker. Claims that make reference to a biomarker require pre-approval by FSANZ. The definition of a biomarker is also important in terms of the substantiation process, as a biomarker needs to be of appropriate validity before being used to demonstrate a relationship between intake of a diet, a food or food component and the claimed health outcome.

'Biomarker' is a commonly used contraction of the term 'biological marker'. While biomarkers are used in a range of medical and research circumstances (for example, as a measure of exposure to an agent), it is their use as surrogate outcome measures (or clinical endpoints) that is relevant in terms of classification of high level claims.

The definition of a biomarker proposed by FSANZ is broad in order to encompass most surrogate outcome measures of disease, disorders, conditions or defects, whether or not they are clearly linked to risk of a disease, disorder or condition.

Term	**Proposed FSANZ working definition**
biomarker	is a measurable biological parameter that predicts the risk of human disease, disorders, conditions or defects. The biomarker itself is not a measure of the disease, disorder or condition.

FSANZ proposes to establish some criteria about the validity of biomarkers as surrogate outcome measures, to guide applicants who are preparing to substantiate a claim. It is proposed that the following criteria be met before a biomarker is used in a claim or to substantiate a claim:

- the biomarker should be a physiological variable, preferably with a dynamic response to intervention;
- there should be a biological basis for believing the biomarker is on the causal pathway between exposure and the disease or health outcome;
- the biomarker should be highly predictive of the disease or health outcome; and
- the validity of the biomarker should have been rigorously evaluated.

The draft Substantiation Framework (Attachment 4) also provides some guidance on the use of biomarkers as measures of exposure in the substantiation of high level claims.

Questions:

15. Do you prefer the term 'biomarker' to that of 'surrogate outcome'?
16. What practical implications do you see from the proposed definition?
17. What practical implications do you see from the proposed criteria for use of biomarkers in substantiation?

5.5 Other related claim descriptors

The terms described in this section of the report are unlikely to be defined in the Standard for nutrition, health and related claims. However, as they are identified in the Claims Classification Framework and might be described or referred to in a Guideline and/or an interpretive user guide developed to support the Standard, FSANZ considers it necessary to establish a common understanding of these terms.

5.5.1 Content claim

Term	Related claim descriptor
content claim	is a general level claim which describes or indicates [explicitly or implicitly] the presence or absence of energy or a nutrient [or a biologically active substance] in a food.
For example, 'This food is reduced in fat' or 'This food is a good source of calcium'.	

In relation to the term content claim referenced in this section, FSANZ is yet to determine whether this type of claim should more correctly be referred to as a 'nutrition content claim' or a 'nutrient content claim'. Consequently, until this matter is resolved FSANZ proposes, in this report, to refer to these claims as content claims.

5.5.1.1 Background

Content claims have been appearing on food labels for some time. Content claims are relatively simple messages. There are many types of content claims, including a range of absolute claims and comparative claims.

Content claims might variously be referred to as 'nutrient content claims' or 'nutrition content claims'. A 'nutrient content claim' is generally a statement about the level of a nutrient in a food. A 'nutrition content claim' is not limited to 'nutrients' and might refer to other substances in food (such as biologically active substances) which have nutritional properties but which are not considered to be nutrients.

The United States, Canada and Codex refer to 'nutrient content claims'. In the European Union, the term 'nutrition content claims' is used.[22]

The FSANZ descriptor for a 'content claim' refers to the presence or absence of nutrients, energy [or other substances in food such as biologically active substances]. The reference to energy and to biologically active substances is consistent with the current definition of 'nutrition claim' in clause 1, Standard 1.2.8 (see Attachment 2B).

The definition of nutrition claim in the European Union proposal on nutrition and health claims covers 'other substances'.[23] 'Other substances' are separately defined as 'substances other than nutrients which have a nutritional or physiological effect'.

[22] See Attachment 3 for a summary of these definitions.
[23] Proposal for a Regulation of the European Parliament and of the Council on Nutrition and Health Claims made on foods, 2003/0165(COD).

If 'biologically active substances' are included in the definition of a 'content claim', they would be required to comply with the criteria and conditions set for content claims. However, if they are not included in the definition, they would fall outside the scope of the requirements for content claims in the Standard for nutrition, health and related claims. This would not prevent a quantity statement in relation to a biologically active substance in a food from being made. The regulation of such a statement would fall within the scope of the general provisions in food law and fair trading law in relation to misleading and deceptive conduct.

Question:

18. Should the descriptor for a 'content claim' refer to biologically active substances or other substances in addition to nutrients and energy? (See Attachment 6 for a further discussion of regulation of biologically active substances and other substances in food.)

As FSANZ is considering the need to regulate certain types of 'free claims' (for example, 'gluten free' and 'lactose free') in the Standard for nutrition, health and related claims, the working definition includes a reference to the 'absence of' as well as the 'presence of', nutrients, energy and [biologically active substances].

During the standard development process, FSANZ will determine whether content claims should more correctly be referred to as a 'nutrition content claim' or a 'nutrient content claim'. Once this issue is resolved, the relevant term will either be defined in the Standard for nutrition, health and related claims or described in a Guideline. If the term 'nutrient content claim' is decided upon, the Code may need to be amended for consistency with other definitions such as 'nutrition claim'.

As reflected in the Policy Guideline, a content claim is a type of general level claim.

5.5.2 Health claim

Term	**Related claim descriptor**
health claim	a claim, other than a therapeutic claim, that describes or indicates [explicitly or implicitly] that a relationship exists between the consumption of a food, a category of food or one of its constituents and health.

5.5.2.1 Background

Currently, the Code prohibits health and related claims. In this context 'health and related claims' includes therapeutic claims, slimming claims, claims which include the word 'health' and claims which reference a serious disease or physiological condition.[24]

FSANZ considers that it is necessary to clarify the definition of 'health claim', as the term is likely to be interpreted differently by stakeholders given the current requirements in the Code and how the term has been used previously.

[24] See Standard 1.1A.2 – Transitional Standards of the Code.

The FSANZ descriptor of 'health claim' is based on a definition of 'health claim' proposed by the European Union.[25]

In relation to the Claims Classification Framework, FSANZ considers that claims other than content claims are 'health claims'. That is, 'health claims' are claims that describe explicitly or implicitly a relationship between consumption of a food, a category of food, or a constituent of a food (such as a nutrient, energy or a biologically active substance) and health. A content claim, by contrast, is a statement about the amount of a nutrient, energy or [a biologically active substance] in the food. This concept is illustrated in the diagram of the Claims Classification Framework described below. It illustrates that a 'health claim' can be either a high level claim or a type of general level claim.

Claims Classification Framework

<table>
<tr><th colspan="2">General level claims</th><th rowspan="2">High level claims</th></tr>
<tr><th>Content claims</th><th>Other general level claims</th></tr>
<tr><td>Absolute claims
Comparative claims</td><td>Function claims
Enhanced function claims
Risk reduction claims
(ref. A non-serious disease or condition)</td><td>Biomarker maintenance claims
Biomarker enhancement claims
Risk reduction claims
(ref. A serious disease or condition)</td></tr>
<tr><td></td><td colspan="2">Health claim
describes a relationship between diet and health</td></tr>
</table>

There may not be a need to define the term 'health claim' in the Standard for nutrition, health and related claims. However, a definition of a 'health claim' has been described in this report in order to clarify the meaning of this concept within the broader Claims Classification Framework and to establish a common understanding of the term given the term has a number of different meanings in different contexts.

In accordance with the Policy Guideline, it will be a requirement of the Standard for all health claims to be made in the context of the appropriate total diet.

Question:

19. Do you agree that in accordance with the FSANZ Claims Classification Framework all claims other than content claims are health claims?

5.5.3 Function claims

Term	Related claim descriptor
function claim	a general level claim which describes [explicitly or implicitly] the biological role of a food or energy or a nutrient [or a biologically active substance] in [normal] growth, development, maintenance and other like functions of the body.
For example, 'Linoleic acid, one of the family of Omega-6 fatty acids is essential for healthy skin' or 'Calcium aids in the development of strong bones and teeth'.	

[25] Proposal for a Regulation of the European Parliament and of the Council on Nutrition and Health Claims made on foods, 2003/0165(COD).

enhanced function claim	a general level claim which describes [explicitly or implicitly] the biological role of a food or energy or a nutrient [or a biologically active substance] beyond [normal] growth, development, maintenance and other like functions of the body.
For example, 'A high fibre diet may help to improve bowel function'.	

5.5.3.1 Background

Function claims and enhanced function claims are a subcategory of general level claims.

The distinction between a function claim and an enhanced function claim is that the former describes the role of a food, a nutrient [or biologically active substance] in terms of normal growth and development while the latter describes the role beyond normal growth and development. Enhanced function claims are likely to use the words 'enhances, reduces or increases'.

There are various definitions internationally for function type claims. In the United States these claims are referred to as 'structure/function claims' and in Canada as 'biological role claims'. These definitions are summarised in Attachment 3. Definitions in international regulation do not appear to differentiate between a function related to normal growth and development and a function beyond normal growth and development.

FSANZ is considering whether the definition of a content claim should capture biologically active substances. While Canada permits a small number of quantitative declarations for biologically active substances such as lycopene, they do not permit health claims for biologically active substances.

Questions:

20. Should claims other than content claims (that is, health claims) be made in relation to biologically active substances?
21. Do you agree with the descriptors for a function claim and an enhanced function claim?

During the standard development process it will be necessary to determine whether specific definitions for the sub-categories of claims (in this case a function claim and an enhanced function claim) are required in the Standard. If there are no specific criteria and conditions linked to the various sub-categories of claims it is unlikely that they will need to be defined for regulatory purposes. However, they are discussed here in order to clarify what these terms mean in the context of the Claims Classification Framework.

5.5.4 Risk reduction claim in relation to a non-serious disease or condition

Term	Related claim descriptor
risk reduction claim in relation to a non-serious disease or condition	a general level claim which describes [explicitly or implicitly] the biological role of a food or energy or a nutrient [or a biologically active substance] in [significantly] reducing the risk of developing a non-serious disease or condition.
For example, 'This food is high in fibre which may reduce constipation'.	

5.5.4.1 Background

A risk reduction claim generally refers to the potential for a food, a nutrient or a substance in a food to assist in reducing the potential for diet-related illness or disease. Most international regulatory definitions of risk reduction claims are specific to reducing the risk of human disease.

The Policy Guideline[26] refers to a category of general level claim that references a 'non-serious disease or condition'. FSANZ is considering the need to develop a definition for 'non-serious disease or condition'. A general level claim, which refers to a non-serious disease or condition, will not be subject to pre-market assessment and approval.

The FSANZ Claim Descriptor is based on the definition of a 'reduction of disease risk claim' proposed by the European Union.[27] However, the descriptor makes reference to a non-serious disease or condition in order to differentiate between a high level claim, which references a serious disease or condition and a general level claim, which references a non-serious disease or condition.

The descriptor includes the term 'significantly' to clarify that any claimed risk reduction in relation to a non-serious disease or condition must be more than minor. This is intended to limit the potential for truthful but misleading risk reduction claims being made. It could be argued, however, that the substantiation requirements will prevent such claims being made because they could not be justified to the extent required by the substantiation framework.

Questions:

22. Should the descriptor for a risk reduction claim include the word 'significantly'?
23. Are there likely to be claims which reference a non-serious disease or condition which would not be expressed as 'risk reduction claims'? If so, is there a need to identify another sub-category of claim in the Claims Classification Framework?

During the standard development process it will be necessary to determine whether specific definitions for a sub-category of claim, in this case a risk reduction claim in relation to a non-serious disease or condition, is required in the Standard.

[26] See page 5 of the Nutrition, Health and Related Claims Policy Guideline.
[27] Proposal for a Regulation of the European Parliament and of the Council on Nutrition and Health Claims made on foods, 2003/0165(COD).

If there are no specific criteria and conditions linked to this sub-category of claim it is unlikely that it will need to be defined for regulatory purposes. However, a description is discussed here in order to clarify what the term means in the context of the Claims Classification Framework.

5.5.5 Biomarker claims

Term	**Related claim descriptor**
biomarker maintenance claim	is a high level claim which describes [explicitly or implicitly] the biological role of a food or energy or a nutrient [or a biologically active substance] in maintaining a normal level of a [recognised] biomarker.
For example, 'This food is low in saturated fat which, as part of a diet low in saturated fat, may help to maintain a healthy blood cholesterol level'.	
biomarker enhancement claim	is a high level claim which describes [explicitly or implicitly] the biological role of a food, energy or a nutrient [or a biologically active substance] in reducing or increasing the level of a [recognised] biomarker.
For example, 'This food is high in calcium which helps improve bone density when eaten as part of a varied diet high in calcium'.	

5.5.5.1 Background

Biomarker maintenance claims and biomarker enhancement claims are a sub-category of high level claims. In May 2004, the Ministerial Council agreed that biomarker maintenance claims are to be subject to pre-market assessment and approval by FSANZ.

The distinction between a biomarker maintenance claim and a biomarker enhancement claim is that the former describes the role of a food, a nutrient or a [biologically active substance] in relation to maintaining a biomarker at a normal level. The latter describes the role of a food, a nutrient or a [biologically active substance] in relation to reducing or increasing the level of a biomarker.

FSANZ has proposed a definition of 'biomarker' in subsection 5.4.7.

Question:

24. Should the descriptor for a biomarker maintenance claim and biomarker enhancement claim include the phrase 'recognised biomarker'?

During the standard development process it will be necessary to determine whether specific definitions for the sub-categories of claims (in this case a biomarker maintenance claim and a biomarker enhancement claim) are required in the Standard. If there are no specific criteria and conditions linked to the various sub-categories of claims it is unlikely that they will need to be defined for regulatory purposes. However, they are discussed here in order to clarify what these terms mean in the context of the Claims Classification Framework.

5.5.6 Risk reduction claim in relation to a serious disease or condition

Term	Related claim descriptor
risk reduction claim in relation to a serious disease or condition	is a high level claim which describes [explicitly or implicitly] the biological role of a food or energy or a nutrient [or a biologically active substance] in [significantly] reducing the risk of developing a serious disease or condition.
For example, 'A healthy diet that may lower the risk of certain cancers is one that is low in fats and includes fibre from a number of sources including a variety of fruits and vegetables, and wholegrain bran and cereals. This food is high in dietary fibre.'	

5.5.6.1 Background

A risk reduction claim generally refers to the potential of a food, a nutrient or a substance in a food to assist in reducing the potential for disease.

The Policy Guideline[28] refers to a category of high level claim that references a 'serious disease or condition'. FSANZ is developing a working definition for 'serious disease or condition' in order to identify what this category of claims is intended to refer to. As an example, cardiovascular disease, cancer and osteoporosis could be considered 'serious diseases or conditions'. A high level claim, which refers to a serious disease or condition is subject to pre-market assessment and approval by FSANZ.

It is also possible to construct a claim which refers to a serious disease or condition and which also makes reference to a biomarker. Such a claim might be expressed as: 'This food is high in Omega-6 fatty acids, which may help reduce blood cholesterol and reduce the risk of heart disease, when eaten as part of a varied diet low in saturated fat and high in fibre'.

The Policy Guideline notes that with a compound claim any part of the claim that falls within a higher claim category results in the totality of the claim falling into that category.[29] In the example cited above, either the reference to a biomarker or a serious disease require the claim to be assessed and pre-approved by FSANZ.

The FSANZ Claim Descriptor is based on the definition of a 'reduction of disease risk claim' proposed by the European Union.[30] It mirrors the FSANZ descriptor of a 'risk reduction claim in relation to a non-serious disease or condition'.

The descriptor includes the term 'significantly' to clarify that any claimed risk reduction must be more than minor. This is intended to limit the possibility of a truthful but potentially misleading risk reduction claim being made. However, it could be argued that the substantiation requirements will prevent such claims from being made because they could not be justified to the extent required by the substantiation framework.

[28] See page 5 of the Nutrition, Health and Related Claims Policy Guideline.
[29] See page 3 of the Nutrition, Health and Related Claims Policy Guideline.
[30] Proposal for a Regulation of the European Parliament and of the Council on Nutrition and Health Claims made on foods. 2003/0165(COD).

Questions:

25. Should the descriptor for a risk reduction claim in relation to a serious disease or condition include the word 'significantly'?

26. Are there likely to be claims that reference a serious disease or condition, which will not be expressed as 'risk reduction claims'?

During the standard development process it will be necessary to determine whether specific definitions for a sub-category of claim, in this case a risk reduction claim in relation to a serious disease or condition, is required in the Standard. If there are no specific criteria and conditions linked to this sub-category of claim it is unlikely that it will need to be defined for regulatory purposes. However, a description is discussed here in order to clarify what the term means in the context of the Claims Classification Framework.

5.6 Issues arising from the Claims Classification Framework

5.6.1 'Whole-of-diet' claims

The Policy Guideline[31] and Table 1 refer to two separate types of whole-of-diet claims based on the Australian Dietary Guidelines or the New Zealand Food and Nutrition Guidelines. One is a general level claim because it does not reference a biomarker or a serious disease or condition, and the other is a high level claim because it references a biomarker or a serious disease or condition.

Two examples of whole-of-diet claims included in the Policy Guideline are:

> A healthy balanced diet that includes dietary fibre from a number of sources is one that can help reduce the risk of constipation.
>
> A healthy diet that may lower the risk of certain kinds of cancer is one that is low in fats and includes fibre from a variety of sources including a variety of fruits and vegetables, and wholegrain and bran cereals.

As a consequence of the way in which these whole-of-diet claims are expressed in the Policy Guideline, FSANZ considers both these examples to be risk reduction claims. The first is a risk reduction claim which references a non-serious disease or condition (and is therefore considered a general level claim) and the second is a risk reduction claim which references a serious disease or condition (and is therefore considered a high level claim). FSANZ considers that these claims fulfil the requirement in the Policy Guideline for claims, other than content claims, to be made in the context of the appropriate total diet.[32] In which case, these examples of claims may not strictly be whole-of-diet claims.

FSANZ considers that there may be whole-of-diet claims that purely represent the Australian Dietary Guidelines or the New Zealand Food and Nutrition Guidelines. An example of such a claim is, 'The Australian Dietary Guidelines recommends a healthy diet containing at least five servings a day of vegetables'. One interpretation of this type of statement is that it may be dietary advice rather than an actual health claim.

[31] See pages 5 & 6 of the Nutrition, Health and Related Claims Policy Guideline.
[32] See page 2 of the Nutrition, Health and Related Claims Policy Guideline.

If such a statement was considered a health claim rather than dietary advice it is important to consider whether it is necessary to restrict the foods or categories of foods to which this type of claim can be made.

In relation to whole-of-diet claims, some members of SDAC expressed the following views:

- Whole-of-diet claims should only be allowed on 'appropriate' foods. That is, claims must be socially responsible and not be positioned on foods that have limited or insignificant nutritional value.
- It is not desirable that processed foods, including foods fortified with other substances, carry whole-of-diet claims which may make them appear more beneficial than fresh unprocessed foods such as fruits and vegetables.
- The classification of a whole-of-diet claim would depend on how the claim was expressed and whether it referenced a serious disease or biomarker.

Questions:

27. Do you think the examples of whole-of-diet claims provided in the Policy Guideline are claims made in the context of the appropriate total diet; and do you think the way the claimed benefit is expressed determines where the claim is positioned in the Claims Classification Framework?
28. Should whole of diet claims always be coupled with a claimed benefit (for example, those illustrated in the Policy Guideline are linked to a risk reduction claim), or should whole-of-diet claims purely represent either the Australian Dietary Guidelines or the New Zealand Food & Nutrition Guideline? If the latter, do you consider the claim to be dietary advice which would fall outside the scope of the regulatory framework for nutrition, health and related claims?

5.6.2 Performance and wellbeing claims

The Policy Guideline[33] also notes that claims must communicate a specific rather than a broad benefit. An interpretation of this principle is that a group of non-specific claims referred to as 'general wellbeing claims' and 'general performance claims' should not be permitted. These claims might be represented as: 'has a positive effect on wellbeing' or 'improves sport performance'.

The Policy Guideline[34] notes that claims that a food or a component of a food 'influences performance and wellbeing' must be made in the context of the total diet.

It therefore follows that claims that refer to performance or wellbeing, must convey a message about a specific benefit that may be gained by consuming the food and be made in the context of the total diet. Expanding on the examples provided above, performance and wellbeing claims could, more appropriately, be represented in the following way:

[33] See page 3 of the Nutrition, Health and Related Claims Policy Guideline.
[34] See the claim prerequisites on page 2 of the Nutrition, Health and Related Claims Policy Guideline.

this product is high in X which, when consumed as part of a balanced diet, may help improve immune function.

this product contains X which may extend the capacity to maintain a specific level of high-intensity intermittent exercise. This product should be consumed before starting exercise, as part of a balanced diet.

While the Policy Guideline references performance and wellbeing claims in tandem they will, from hereon, be treated as separate types of claims. Both TEG and SDAC considered they should be treated separately.

Performance claims and wellbeing claims can be positioned in either the high level claim or general level claim category according to whether or not the claim references a biomarker or a serious disease/condition.

With regard to performance claims, SDAC acknowledged that such claims could be made about whole-of-body, body systems or specific organ performance. It was recognised by TEG and SDAC that wellbeing claims are difficult to categorise as the meaning 'wellbeing' and other similar terms are subjective. An issue was raised as to whether performance claims and wellbeing claims should only be made in relation to a physiological function, as opposed to being made in relation to psychological wellbeing.

Question:

29. Given the general requirement that claims express a specific, rather than a broad, health benefit/outcome, do you think general wellbeing claims or general performance claims that do not reference a specific benefit should be prohibited?

5.6.3 Life stage claims

FSANZ is aware of the potential for claims to be expressed in the following ways:

'This product may relieve the symptoms of menopause'

'Enhances post-menopausal health'

'Foods rich in calcium are beneficial for pregnant and lactating women'.

FSANZ considers that these claims could be referred to as 'life stage claims'. The Policy Guideline does not specifically mention these types of claims and they are therefore not identified in the Claims Classification Framework by way of example.

FSANZ has proposed a definition for 'serious disease'[35] which includes disorders, conditions and defects. Although this definition includes a reference to 'condition' FSANZ does not intend that the definition of serious disease apply to normal lifestages, such as childhood or pregnancy. If normal lifestages, such as menopause and pregnancy, are not considered a serious disease or condition, any claim that references a normal lifestage will in effect be a general level claim.

[35] See section 5.4.5 in this Report.

Question:

30. Are there any unintended impacts of regulating claims that refer to normal lifestages as general level claims?

5.6.4 Slimming Claims

Standard 1.1A.2 – Transitional Standards of the Code currently prohibits foods bearing claims or statements that the food is a slimming food or has intrinsic weight reducing properties.

While making reference to a number of individual types of claims, the Policy Guideline is silent on 'slimming claims'. A possible example of a slimming claim is:

> This food contains X and can be consumed as part of a diet to assist in weight reduction.

Claims such as 'low in fat', 'reduced in fat', or 'low joule' are not considered slimming claims.

The type of claim outlined in the above example would be considered a general level claim if it is determined that the claim does not reference a serious disease or a biomarker. In such cases, the manufacturer would be responsible for making an assessment of the evidence supporting the claim and no pre-market approval would be required.

At TEG and SDAC, some members noted that, unless a food has intrinsic weight reducing properties, slimming claims should be prohibited as they are misleading. However, given the complexities around whether 'weight reduction' may be considered a biomarker, some SDAC members considered that it may be more appropriate to classify slimming claims as high level claims. Alternately, some SDAC members considered that 'slimming claims' should be regulated as general level claims.

SDAC sought clarification on how regulation of slimming claims would apply to foods for special medical purposes, for example, foods formulated for very low energy diets. FSANZ advised that any mandatory statements required by the Code would not be considered a health claim and would therefore fall outside the scope of the Standard for nutrition, health and related claims.

Question:

31. How do you think 'slimming claims' should be regulated? Please provide your rationale and supporting evidence.

5.6.5 Endorsements

The Policy Guideline[36] states that 'endorsement programs that state or imply a nutrition, health or related claim must comply with the principles and requirements of the relevant claim category'. Furthermore, a statement to explain why the endorsement program has been granted must accompany claims represented in the form of an endorsement.

[36] See page 3 of the Nutrition, Health and Related Claims Policy Guideline.

A claim in the form of an endorsement which refers explicitly or implicitly to a biomarker or a serious disease/condition would be considered a high level claim and would be prohibited unless pre-approved by FSANZ and specified in the Standard for nutrition, health and related claims.

Similarly, a claim in the form of an endorsement which does not refer explicitly or implicitly to a biomarker or serious disease/condition in accordance with the Claims Classification Framework would be considered a general level claim and would be permitted provided the claim complied with any criteria and conditions specified.

It would be the responsibility of individual endorsing organisations to maintain their own criteria for endorsing a product. If their endorsement represented a high level claim, it would be the endorsing organisation's responsibility to submit the claim to FSANZ's pre-market approval system.

If the endorsement represented a general level claim, a question arises as to who is responsible for the claim in terms of its substantiation and representation. More specifically, who would be responsible for holding the evidence to substantiate the claim – the manufacturer whose product is carrying the endorsement or the organisation that has endorsed the product? If the endorsing organisation were to be responsible, it may mean enforcement agencies would need to liaise with the endorsing organisation (as opposed to the manufacturer of the product) where issues in relation to compliance and enforcement need to be addressed.

Questions:

32. What are the impacts on industry, enforcement agencies and consumers in regulating endorsements as nutrition, health and related claims?

33. Who should be responsible for substantiating an endorsement that is considered a general level claim and hold the evidence to support the claim?

34. Can you provide examples of endorsements currently in the market place that may constitute a general level claim or a high level claim?

35. Can you provide any evidence that indicates how consumers interpret endorsement statements?

5.6.6 Cause-related marketing

Cause-related marketing is where a manufacturer donates a proportion of the money from the sale of a product to an organisation. Cause-related marketing provides an opportunity to develop supportive partnerships between industry and charitable organisations in order to raise funds and public awareness.

The Policy Guideline notes that marketing activities that promote charities or non-profit organisations that relate to a disease or health must have a disclaiming statement to ensure they are not interpreted as a nutrition, health and related claim.

Cause-related marketing if generally permitted, may have a range of positive effects but it may also have a number of unintended consequences. Consumers may infer that a relationship exists between the food carrying the marketing statement and the disease or physiological condition included in the name of the organisation. This may lead consumers to select foods on the basis of ill-founded assumptions. Manufacturers may rely on cause-related marketing statements to avoid the pre-approval process otherwise required for claims which reference a serious disease or condition.

Questions:

36. What are the impacts on consumers, public health professionals and industry of permitting cause-related marketing statements?
37. Is there any evidence to indicate how consumers interpret cause-related marketing statements?
38. What words could be used in a disclaiming statement to ensure cause-related marketing is not interpreted as a nutrition, health or related claim?

5.6.7 Implied claims

In developing the regulatory framework for nutrition, health and related claims, it is important to consider the concept of implied claims. One of the key elements in considering whether a claim suggests or implies something, is to consider to whom the claim might suggest or imply something. In this case the 'relevant class' would be that of reasonable people to whom a claim is directed.

This is consistent with trade practices law, where courts have generally held that the relevant class of persons for determining whether or not conduct has been misleading or deceptive, are reasonable members of the class towards whom the conduct in question is directed.

It may be necessary to undertake consumer research to determine what meaning consumers ascribe to the subject of a claim and as a consequence the perceived health benefit they associate with particular claims. Such consumer research would inform a determination as to when an implied claim constitutes a general level or high level claim.

Questions:

39. Are you able to provide any evidence that indicates how consumers may interpret various types of representations of claims?
40. Does FSANZ need to establish criteria to enable industry and enforcement agencies to determine whether the representation of a claim conveys a greater perceived health benefit to the consumer? If so, what might these criteria be?

5.7 FSANZ Regulatory Model

The Policy Guideline indicates that the Standard for nutrition, health and related claims in the Code will:

- set out high order principles of the health claims system including the requirement for all claims to be substantiated;

- define general and high level claims; and
- provide prescriptive detail relating to high level claims (pre-approvals).

The Policy Guideline[37] also states that the Code 'may set out qualifying and disqualifying criteria for certain types of claims (for example, nutrition content claims) and list categories of food that are ineligible to make claims (for example, alcohol and baby food).'

In relation to general level claims, the Policy Guideline notes that:

> A guideline document [will] provide the majority of detail surrounding general level claims.
>
> The level of the claim, as determined by the Claims Classification Framework, will determine to what degree the claim is regulated.
>
> The Standard should provide sufficient detail to enable enforcement action to be taken against all breaches, for all level of claims.

Development of the FSANZ Regulatory Model takes into account the need to set parameters to delineate between core regulatory requirements that apply to all claims irrespective of their classification and specific requirements which correlate to where the claim is situated in the Claims Classification Framework.

It is proposed that the parameters take the form of claim prerequisites, claim criteria and conditions. For the purposes of discussion, FSANZ provides the following explanation of these parameters.

5.7.1 Claim pre-requisites

Claims prerequisites are preconditions that must be met before a claim can be considered an eligible nutrition, health and related claim. Claims prerequisites apply to all claims irrespective of whether they are a general level claim or a high level claim. An example of a claim prerequisite is that all claims must be scientifically substantiated.

5.7.2 Claim criteria

The Policy Guideline[38] makes reference to 'eligibility criteria'. The Policy Guideline notes that before a food is permitted to carry a claim, all stipulated eligibility criteria for that food must be met.

FSANZ considers that 'claim criteria' are specific requirements regarding the food or its composition that must be met before a claim can be made. This would also include criteria around the eligibility of a food. Claims criteria apply once a claim is considered to be an eligible claim.

There are two types of 'claim criteria':

- **Qualifying criteria** are criteria relating to the nutritional component or food that is the subject of the claim and must be met before the claim can be made.

[37] See page 4 of the Nutrition, Health and Related Claims Policy Guideline.
[38] See the Glossary of Terms in the Policy Guideline for Nutrition, Health and Related Claims.

- **Disqualifying criteria** are criteria in relation to the composition of the food, other than qualifying criteria, that must be met before a claim can be made.

For example, in relation to a claim which includes a reference to 'high fibre' the qualifying criteria will directly relate to the amount of fibre present in the food while the disqualifying criteria might relate to other components in the food such as the amount of saturated fat, total fat, sodium, sugar or energy.

In relation to substantiation requirements, there must be enough of the food, nutrient, energy or [biologically active substance] in the food to achieve the claimed benefit when the food is consumed in quantities which can reasonably be expected to be consumed daily as part of an appropriate total diet. This is also articulated in the Policy Guideline.[39]

In addition to this underlying requirement, there are several factors that need to be considered for determining criteria for different types of claims. These include:

- whether the object of the claim is in relation to the presence or absence of a nutrient, energy or a biologically active substance (that is, a content claim) or whether the object of the claim is in relation to a relationship between the consumption of a food and health (that is, a health claim – either general level or high level);

- whether the health claim (either general level or high level) is expressed in relation to the whole food or a particular component (that is, nutrient, energy or biologically active substance) of the food. For example the claim 'Milk helps to build strong bones and teeth' is in relation to the whole food milk, while the claim 'this food is a good source of calcium which helps to build strong bones and teeth' on a dairy product such as yoghurt, is made in relation to the nutrient calcium;

- the nutritional profile of the food particularly in relation to saturated fat, sugar, salt and energy. For instance, criteria may be established which prevents some claims from being made on foods which are high in saturated fat, sugar, salt and/or energy; and

- the eligibility of certain categories of food such as alcohol and baby foods[40] to carry claims. For instance, criteria may be developed which prevent claims from being made on some categories of food.

5.7.3 Conditions

Unlike 'claims criteria' which apply specifically to the composition of the food, a condition applies specifically to the representation of the claim.

FSANZ considers that 'conditions' are additional mandatory statements, required to clarify the context of the claim, in order to protect public health and safety and/or prevent misleading and deceptive conduct.

[39] See page 3 of the Policy Guideline for Nutrition, Health and Related Claims.
[40] See page 4 of the Policy Guideline for Nutrition, Health and Related Claims.

For example, the Policy Guideline notes that claims that refer to the role of a food or a component of a food to manage, influence, inhibit or modify a physiological process may only be made in the context of the appropriate total diet. In relation to the current Claims Classification Framework, this would require all claims other than a content claim to be expressed in the context of the appropriate total diet. This would be a 'condition' for making such claims.

5.7.4 Setting criteria and conditions for claims

Table 2 illustrates how claims can be regulated, in relation to prerequisites, criteria and conditions according to their position in the Claims Classification Framework. Requirements articulated in the Policy Guideline and those that already exist in other regulatory regimes (that is, CoPoNC and the Code) have been included in Table 3 and identified as prerequisites, criteria or conditions. In addition, FSANZ has identified other requirements that may need to be established for certain types of claims during the Standard development process.

The arrows in Table 2 indicate where prerequisites, criteria and conditions may apply to more than one category of claim. This establishes a system whereby some of the requirements for some claims (that is, content claims which are the least regulated according to the rationale that the level of regulation increases as the perceived potential benefit and associated risks of the claim increases) set the minimum requirements for other claims further along the Claims Classification Framework. They are termed 'minimum requirements', as additional requirements may need to be developed according to the classification of the claim.

Table 2 – FSANZ Regulatory Model

	General Level Claims		High Level Claims
	Content Claims	**Other General Level Claims**	
	• **Absolute Claim** • **Comparison Claim**	• **Function** • **Enhanced Function** • **Risk Reduction Claim (ref. to non – serious disease or condition)**	• **Biomarker maintenance claims** • **Biomarker enhancement claim** • **Risk Reduction claim (ref to a serious disease or condition)**
Claim Prerequisites Preconditions that must be met before a claim can be considered an eligible nutrition, health and related claim	General prohibition on the use of therapeutic claims Claims have to be scientifically substantiated (refer to substantiation framework) The claim is socially responsible and does not promote irresponsible food consumption patterns Claims must not be personalised (that is, cannot use words such as 'you' and 'your' or words to that effect.)	This pre-requisite applies to all claims across the claims classification framework This pre-requisite applies to all claims across the claims classification framework This pre-requisite applies to all claims across the claims classification framework This pre-requisite applies to all claims across the claims classification framework	High Level Claims prohibited unless pre-market assessed and approved by FSANZ. (In standard development process FSANZ will pre-approve some high level claims.)
Claim Criteria Requirements regarding the food or its composition that must be met before a claim can be made	Criteria may need to be established regarding the eligibility of certain categories of foods for carrying claims (policy guideline specifies alcohol and baby food)	This criteria may apply to all claims across the claims classification framework	

	General Level Claims		High Level Claims
	Content Claims	**Other General Level Claims**	
	• **Absolute Claim** • **Comparison Claim**	• **Function** • **Enhanced Function** • **Risk Reduction Claim (ref. to non – serious disease or condition)**	• **Biomarker maintenance claims** • **Biomarker enhancement claim** • **Risk Reduction claim (ref to a serious disease or condition)**
Qualifying Criteria (QC) – is criteria relating to the nutritional component or food that is the subject of the claim and must be met before the claim can be made	Criteria associated with making Content Claims to be specified – most of these will be developed from CoPoNC and/or the Code and agreed to in P293. However these presently only relate to nutrients and energy, for example. 'this food is a rich source of calcium'	Certain content claims criteria will provide the minimum criteria for other general level claims that describe a relationship between a specific component of a food (that is, nutrient or energy) and a health benefit, for example, ' this food is a good source of calcium which helps to build strong bones and teeth'	The minimum criteria for other general level claims, which is based on certain content criteria, will need to be taken into account in pre-market assessment and approval of a high level claim that describes a relationship between a specific component of a food (that is, nutrient or energy) and a health benefit with reference to a biomarker or serious disease/condition, for example, 'this food is a rich source of calcium which may reduce the risk of developing osteoporosis'.
Disqualifying criteria (DC) - is criteria in relation to the composition of the food, other than qualifying criteria, that must be met before a claim can be made	May need to establish criteria for content claims in relation to a biologically active substances, for example, ' this food contains lycopene'. Criteria around the amount of the biologically active substance that must be present before a claim is made should be established.	If certain criteria established for content claims in relation to biologically active substances is developed they are likely to be the minimum criteria for other general level claims that describe a relationship between a biologically active substance and a health benefit, for example, 'this food contains lycopene which is an antioxidant that may help maintain a healthy immune system'	If the minimum criteria for other general level claims, which is based on certain content criteria is developed they will need to be taken into account in pre-market assessment and approval of a high level claim that describes a relationship between a biologically active substance and a health benefit with reference to a biomarker or serious disease/condition, for example, 'this food is a rich source of lycopene which is an antioxidant that may reduce the risk of developing certain types of cancer'
Claim Criteria Cont.		There is a need to determine how to establish criteria which will apply to other general level claims which describe a relationship between a whole food and a specific health benefit, for example, 'Milk helps to build strong bones and teeth'.	The criteria established for other general level claims in relation to whole foods, will need to be taken into account in the pre-market assessment and approval of a high level claim that describes a relationship between a whole food and a health benefit with reference to a biomarker or serious disease/condition, for example, 'Drinking milk as part of a balanced diet may help reduce the risk of developing osteoporosis'
Conditions Additional mandatory statements, which are required to clarify the context of the claim in order to protect public health and safety and prevent misleading	Currently there is a condition in the Code which requires an expanded nutrition information panel where claims are made in relation to nutrients other than the mandatory nutrients specific in the nutrition information panel.	This condition may apply to all claims across the claims classification framework	

	General Level Claims		High Level Claims
	Content Claims	**Other General Level Claims**	
	• **Absolute Claim** • **Comparison Claim**	• **Function** • **Enhanced Function** • **Risk Reduction Claim (ref. to non – serious disease or condition)**	• **Biomarker maintenance claims** • **Biomarker enhancement claim** • **Risk Reduction claim (ref to a serious disease or condition)**
and deceptive conduct.	Conditions in relation to how a Content Claim is to be expressed or additional statements that should accompany the content claim – most of these will be developed from CoPoNC or the Code and will be agreed to in P293, however presently these only relate to nutrients and energy	Certain content claims conditions will provide the minimum conditions for other general level claims that describe a relationship between a specific component of a food (that is, nutrient or energy) and a health benefit	The minimum conditions for other general level claims, will need to be taken into account in pre-market assessment and approval of a high level claim that describes a relationship between a specific component of a food (that is, nutrient or energy) and a health benefit with reference to a biomarker or serious disease/condition.
	There may be the need to establish conditions for content claims that reference a biologically active substance.	The conditions established for content claims in relation to biologically active substances are likely to be the minimum conditions for other general level claims that describe a relationship between a biologically active substance and a health benefit.	The minimum criteria for other general level claims, which is based on certain content criteria, will need to be taken into account in pre-market assessment and approval of a high level claim that describes a relationship between a biologically active substance and a health benefit with reference to a biomarker or serious disease/condition.
		There is a need to determine how to establish conditions in relation to how other general level claims which describe a relationship between a whole food and a specific health benefit are to be expressed or additional statements that should accompany the claim.	The conditions established for other general level claims in relation to whole foods, will need to be taken into account in the pre-market assessment and approval of a high level claim that describes a relationship between a whole food and a health benefit with reference to a biomarker or serious disease/condition
		The Policy Guideline indicates that there must be a statement to the effect of how the food is to be consumed to achieve the claimed benefit	This condition may apply to high level claims
		The Policy Guideline states that claims must be made in the context of the appropriate total diet	This condition may apply to high level claims
Conditions Cont.		The Policy Guideline indicates that where a claimed benefit does not relate to the total population, the sub group to which it relates must be specified	This condition may apply to high level claims

	General Level Claims		High Level Claims
	Content Claims	**Other General Level Claims**	
	• **Absolute Claim** • **Comparison Claim**	• **Function** • **Enhanced Function** • **Risk Reduction Claim (ref. to non – serious disease or condition)**	• **Biomarker maintenance claims** • **Biomarker enhancement claim** • **Risk Reduction claim (ref to a serious disease or condition)**
		The Policy Guideline states that where the claim is separated into sections (that is, split claim) the first part of the claim must direct the reader to further information provided elsewhere in the same communication medium	This condition may apply to high level claims → The Policy Guideline states that a claim that relates to the dietary management of a biomarker condition or disease that may require the supervision of a health care practitioner must have an advisory statement to that effect and must appear in close proximity to the claim in the same communication medium

Questions:

41. Can the criteria and conditions that apply to content claims establish the minimum criteria and conditions for other general level claims?
42. In addition, do these criteria and conditions need to be taken into account in pre-market assessment and approval of high level claims?
43. What factors need to be taken into account when establishing criteria which apply to general level claims that describe a relationship between a whole food and a specific health benefit? For instance, claims in relation to the whole food could only be made where that food is a primary food (that is, fruit, vegetables, grains, legumes, meat, milk, eggs, nuts, seeds and fish) otherwise the claim would need to specify the component within the food (that is, nutrient, energy or biologically active substance) that is linked to the claim benefit.

6. Substantiation

All nutrition, health and related claims on foods sold or supplied in New Zealand and Australia will be required to be substantiated by scientific evidence, to ensure claims are soundly based and do not mislead consumers.

Regardless of the level of claim, a set of principles will apply to the substantiation of claims. These principles are:

- a systematic and structured approach should be used to ensure all relevant evidence is considered and the conclusions are justified;
- the evidence must be of a suitable quality before it is considered;
- the evidence should demonstrate a causal relationship between consumption of the food, a nutrient, energy or a biologically active substance in the food and the claimed outcome;
- the evidence should substantiate the claimed health outcome for the intended population group; and
- the required intake of the diet, food or food component should be achievable in the context of the total diet of the intended population group.

The process for determining whether these principles are met will vary according to the type of claim, to allow evidential requirements to be tailored to the level of the claim while still ensuring claims are scientifically substantiated.

FSANZ will evaluate high level claims on a claim-by-claim basis. Key aspects of the requirements for substantiation of high level claims are:

- Human studies are required to substantiate claims and acceptable study types include well-designed, experimental and observational studies. Caution needs to be exercised when the available evidence is drawn solely from observational studies, even those with establish biological plausibility, in the absence of experimental human data.

- Evaluation of claims will be based on an assessment of the totality of the available evidence with consistent and convincing findings likely to be required across study types.

- Approval of a claim will also take into account the relevance and applicability of the evidence to Australians and New Zealanders.

- Qualifying criteria may be established in relation to the use of the claim to which all foods bearing that claim must comply.

General level claims will be substantiated by manufacturers or suppliers. Key aspects of the requirements for the substantiation of general level claims are:

- Substantiation must be based on authoritative, current and generally accepted information sources where such sources can be identified, or on a structured review of the totality of evidence as for high level claims.

- Verification of a health outcome is not required for content claims, or for those portions of claims that refer to the content of a component in the food.

- There must be evidence to demonstrate that the food contains the ingredient, nutrient or other component that is the subject of the claim, in the quantities required to achieve the outcome or attain the level stated in the claim.

A detailed substantiation framework document has been prepared (see Attachment 4). The document sets out the process FSANZ will use for high level claims to identify, categorise and interpret studies, to evaluate the level of totality and to determine eligibility criteria for a claim. It also outlines the process manufacturers or suppliers should follow to substantiate general level claims. For both high and general level claims, the document provides guidance on the minimum requirements for substantiation.

The substantiation framework has been developed drawing on similar frameworks developed in Canada and the United States. It has been reviewed and refined based on advice from the Scientific Advisory Group established for this purpose.

Questions:

44. Does the Substantiation Framework clearly establish the processes FSANZ will use to assess high level claims?
45. Have the different study types and evidence sources been described accurately and adequately for the purposes of the Substantiation Framework?
46. Do you agree with the proposed evidence requirements for substantiating high level claims?
47. Does the Substantiation Framework clearly establish the processes manufacturers should use to assess general level claims?
48. What practical issues do you envisage will arise when attempting to follow the Substantiation Framework to substantiate a general level claim?

49.	Are there authoritative evidence sources that could be included in the appropriate evidence sources for general level claims?
50.	Would you support FSANZ producing an indicative list of acceptable authoritative evidence sources?
51.	Do you support FSANZ developing a list of model general level claims and associated qualifying/disqualifying criteria, to help manufacturers/suppliers streamline the substantiation of claims? These model general level claims may be included in interpretive userguides.

7. Implementing the FSANZ Conceptual Framework for Nutrition, Health and Related Claims

In relation to the FSANZ Conceptual Framework there are at least two possible approaches to the way in which the parameters of the regulatory model (that is, claim prerequisites, criteria and conditions) can be applied. In essence, these two approaches define the way in which the contents of a Standard and Guideline(s) are formulated and provide a basis for possible regulatory options for nutrition, health and related claims (see section 9, Regulatory Options).

In simple terms, Standards are legally binding and legally enforceable. In this context, any parameters appearing in a Standard can be considered as fully regulated. Standards can be supported by 'interpretive userguides', which are designed to assist an understanding of the legal requirements in the Standard.

By contrast, Guidelines are alternatives to Standards and are not legally binding or legally enforceable. Although the parameters contained in a Guideline contribute to the overall regulatory framework, matters included in a Guideline are not considered to be fully regulated.

Issues that need to be considered in terms of whether parameters should be fully regulated relate to the protection of public health and safety and preventing misleading and deceptive conduct. Facilitating food innovation and trade also needs to be considered in this context. These issues are raised in section 10, Impact Analysis. Issues regarding enforcement and compliance in relation to Standards and Guidelines is discussed at subsection 7.8.

7.1 Approach One

Claim prerequisites, including the requirement for all claims to be scientifically substantiated, will be specified in the Standard.

7.1.1 Approach One specific to high level claims

- Consistent with the Policy Guideline all high level claims will be subject to pre-market assessment and approval by FSANZ. Unless specified in the Standard, high level claims will be prohibited.

- As part of the pre-market assessment and approval process, criteria and conditions regarding application of the claim will be determined and included in the Standard.

- An interpretive userguide to facilitate understanding of the requirements specified in the Standard for high level claims will be developed.

- An interpretive userguide for applicants providing guidance regarding the procedure for seeking pre-approval of high level claims, including review mechanisms as new scientific evidence becomes available, will be developed.

7.1.2 Approach One specific to general level claims

- The criteria for general level claims, other than certain claims specified in the Code (for example, gluten and lactose claims in Standard 1.2.8) would be set out in a Guideline.

- Conditions, other than those already specified in the Code (for example, the requirement for a Nutrition Information Panel to accompany a nutrition claim or any mandatory advisory statements that must be made in relation to a claim), will be set out in a Guideline.

- An interpretive userguide in relation to the application of the substantiation requirements of the Standard will be necessary to help manufacturers determine:

    - the process by which to collect, assess and hold evidence in support of general level claims (that is, whether the food or a component of food can achieve the claimed benefit); and
    - a suitable composition for a food to ensure that a general level claim is scientifically valid and not misleading or deceptive.

Table 3 is a diagrammatic representation of Approach One. The sections populated with crosses indicate those specific parameters that will be in the Standard (and supported by interpretive userguide(s)), whilst the unpopulated sections indicate those specific parameters that will be in a Guideline.

Table 3: Approach One for implementation

	Not subject to pre-market assessment and approval → Subject to pre-market assessment and approval		
	General Level		**High Level**
	Content	Other General Level Claims	
	Absolute Claim Comparison Claim	Function Claim Enhanced Function Claim Risk Reduction Claim (ref to non-serious disease)	Biomarker Claim Risk Reduction Claim (ref a serious disease)
Claim Prerequisites	**X**	**X**	**X**
Criteria			**X**
Conditions			**X**

7.2 Approach Two

Claim prerequisites, including the requirement for all claims to be scientifically substantiated, will be specified in the Standard.

7.2.1 Approach Two specific to high level claims

As described in Approach One.

7.2.2 Approach Two specific to general level claims

- The criteria for all general level claims will be specified in the Standard.
- The conditions for all general level claims will be specified in the Standard.
- An interpretive userguide to facilitate understanding of the requirements specified in the Standard for general level claims will be developed.
- A 'userguide' in relation to applying the substantiation framework will be necessary in order to help manufactures determine:
  - the process by which to collect, assess and hold evidence in support of general level claims (that is, whether the food or a component of food can achieve the claimed benefit); and
  - evidence in support of conclusions drawn about the food in relation to the provisions regarding criteria and conditions specified in the Standard.

Table 4 is a diagrammatic representation of Approach Two. The sections populated with crosses indicate those specific parameters that will be in the Standard. Unlike Approach One, all requirements will be in a Standard, complemented by various interpretive userguides.

Table 4: Approach Two for implementation

	Not subject to pre-market assessment and approval → Subject to pre-market assessment and approval		
	General Level		**High Level**
	Content	Other General Level Claims	
	Absolute Claim Comparison Claim	Function Claim Enhanced Function Claim Risk Reduction Claim(ref to non-serious disease)	Biomarker Claim Risk Reduction Claim (ref a serious disease)
Claim Prerequisites	X	X	X
Criteria	X	X	X
Conditions	X	X	X

7.3 International regulations

7.3.1 Canada and the United States

Table 5 is a diagrammatic representation of the Canadian and United States approach to the regulation of nutrition, health and related claims in comparison to the Claims Classification Framework proposed for Australian and New Zealand (that is, high level claims and general level claims) in accordance with the Policy Guideline. The sections populated with crosses indicate those specific parameters that are specified in Regulations and supported by interpretive userguide(s), whilst the unpopulated sections indicate those specific parameters that are not specified in Regulations or guidelines.

Table 5 indicates that the Canadian Food and Drug Regulations permit a number of nutrient content claims, comparative claims, biological role claims and diet related health claims. Criteria and conditions for such claims are specified in the Regulations.

The United States Code of Federal Regulations permit a number of nutrient content claims, comparison claims and risk reduction claims and provide the criteria and conditions for each. However, the United States recognises a category of claims they term structure/function claims that are largely unregulated. Such claims can be made on foods and manufacturers are not required to notify the Food and Drug Administration provided the claim does not create drug status or health claim status (that is, it is not a risk reduction claim).

The Canadian and United States approach for regulating nutrition, health and related claims in relation to the level of information specified in Regulations, other than the United States approach to structure/function claims, is similar to FSANZ's second approach for implementation outlined in subsection 7.2. FSANZ's second approach for implementation proposes that all claim prerequisites, criteria and conditions for general level claims be outlined in the Standard as well as all permitted high level claims and criteria and conditions for each.

Table 5: Canadian and United States approach to regulating nutrition, health and related claims

	General Level		**High Level**
	Content	Other General Level Claims	
Canada	**Nutrient Content Claim** Comparison Claim	**Biological Role Claim** – type of function claim	**Diet Related Health Claim** – type of risk reduction claim (prescribed wording)
Criteria/ conditions	**X**	**X** with detail provided in guidelines	**X**
	General Level		**High Level**
	Content	Other General Level Claims	
United States	**Nutrient Content Claim** Comparison Claim	**Structure/function Claim** – type of function claim (are unregulated)	**Risk Reduction Claim** (wording may be varied except for two claims that are prescribed)
Criteria/ conditions	**X**		**X**

The Canadian and United States system for regulating nutrition, health and related claims is described in more detail at Attachment 5.

7.3.2 European Union

The Commission of the European Communities has published a proposal for regulation of the European Parliament and of the Council on nutrition and health claims made on foods. The proposal provides a list of nutrition claims and their specific conditions of use. In addition the proposal considers comparative claims, scientifically substantiated enhanced function and risk reduction health claims. The proposal will not be considered by Parliament again until some time after 1 September 2004. The proposal is discussed in more detail at Attachment 5.

7.3.3 Codex Alimentarius

Currently, the Codex Alimentarius Guidelines for use on Nutrition Claims provides guidance on nutrient content claims, comparative claims and nutrient function claims. In addition to these Guidelines, Draft Guidelines for use of Nutrition and Health Claims are currently being considered and are at the final step of the procedure. The Draft Guidelines provide conditions for a number of nutrient content claims, provide guidance on comparative claims and health claims including nutrient function claims, other function claims and reduction of disease risk claims. Attachment 5 provides more detail on the Draft Guidelines.

7.4 Consultation on criteria and conditions for content claims

Attachment 6 outlines the proposed criteria and conditions for content claims.[41] In the attachment, FSANZ seeks comment from submitters on preferred criteria and conditions and on a number of questions to help develop the claims. *Please therefore note that Attachment 6 is not simply background information; rather it is an integral part of the Initial Assessment Report that will help determine the final outcome for content claims.*

In developing the criteria and conditions for content claims in the context of the Policy Guideline, FSANZ has taken into consideration any relevant issues raised in submissions to Proposal P234. The FSANZ Board rejected the draft variations for Proposal P234 (Criteria and Conditions for Making Nutrition Content Claims) in July 2004 on the basis that they did not have regard to the Policy Guideline as outlined in subsection 4.2. FSANZ also sought advice from the TEG on General Level Claims (see subsection 11.1.2), which was established during this Initial Assessment to advise on general level claims as well as the specific criteria and conditions for content claims. The group met on 1 June 2004. Their advice is included in Attachment 6.

7.5 Issues regarding high level claims

7.5.1 Preliminary advice on the priority list for pre-approved high level claims

Prioritisation of high level health claims is required for FSANZ to commence planning for the process of assessing such claims against the substantiation framework and enabling pre-approved claims to be incorporated into the draft Standard.

[41] Previous to this Proposal, these claims were referred to as 'nutrition content claims'. For consistency, given the discussion in section 5.5.1 in this Report, FSANZ proposes to refer to these claims as 'content claims'.

In addition to the formal process of consultation with stakeholders, FSANZ collaborated with the National Centre of Excellence in Functional Foods (NCEFF) to obtain preliminary advice on the high level health claims considered to be of high priority by public health and industry representatives. The two-stage targeted advisory process included an exploratory workshop for public health and industry stakeholders, followed by an electronic survey sent to a wider cross-section of stakeholders.

The exploratory workshop was held in Sydney on 26 May 2004. Invitations were sent to key public health and food industry groups in Australia and New Zealand identified from FSANZ and NCEFF contact lists. The 41 workshop participants were asked to rank a list of 30 diet–disease relationships that form the basis of existing approved claims from United States, Canada, United Kingdom, Sweden, Australia and New Zealand. Participants identified the factors they considered in ranking the health claims. The most important factors were consistently agreed quality of evidence for the claim and consistency with the dietary guidelines (see section 3 of Attachment 7).

The targeted electronic survey was distributed to people attending the workshop and additional potential contacts identified by workshop participants (241 altogether). Recipients were encouraged to forward the survey to interested colleagues. A total of 62 responses were received, including 15 from individuals who had attended the workshop. The email survey asked respondents to rank a modified list of 23 diet–disease relationships that form the basis of 30 health claims from other nations. Due to time constraints, NCEFF was not able to sample a broader range of stakeholders or provide more time for participants to consider the issues and provide their responses.

There was generally consistent agreement between the rankings obtained from the workshop and the electronic survey and between public health and food industry participants. The top 12 results of the survey ranking of high level claims are shown in Table 6, which is a summary of Tables 3 and 4 of Attachment 7.

Table 6: Top 12 results of ranking from preliminary advice on establishing priorities for high level health claims

Public health representative ranking	Food or food component	Disease or condition	Industry representative ranking
1	Fibre-containing grain products, fruits and vegetables	Cancer	4
2	Fruits and vegetables	Some cancers	12
3	Dietary saturated fat +/- cholesterol, trans fat	Coronary heart disease	2
4	Fruits, vegetables and grain products that contain fibre, particularly soluble fibre	Coronary heart disease	3
5	Calcium +/- vitamin D	Osteoporosis	1
6	Energy	Obesity	6
7	Saturated fat, dietary fatty acids	Blood cholesterol	8
8	Whole grain foods	Heart disease/ heart health	(15)
9	Folate	Neural tube defects	10

10	Whole grain foods	Heart disease and certain cancers	11
11	Sodium (salt) +/- potassium	High blood pressure and stroke	5
12	Omega-3 fatty acids	Factors affecting blood cholesterol, blood pressure and atherosclerosis	7
(13)	Dietary fat	Cancer	9

It is important to note that this activity does not preclude or replace any of the formal processes that FSANZ uses to obtain input from all stakeholders. The full report of this activity is included at Attachment 7 as a basis to assist *all* interested stakeholders to provide their views on which high level claims should be considered a priority to undergo assessment by the substantiation framework.

Questions:

A list of the 23 diet–disease relationships that form the basis of health claims approved in other countries is provided in Attachment 7. You are invited to use this list to provide your ranking of high level claims to FSANZ.

52. Which of the health claims approved overseas do you believe would have the most public health impact?
53. Which of the health claims approved overseas would industry wish to make?
54. What factors do you consider in prioritising the list of health claims in terms of scientific validation?
55. Are there any other health claims you believe should be considered for pre-market assessment?

7.5.2 Review of pre-approved high level claims

FSANZ believes it will be important to institute a review mechanism for pre-approved high level claims. Science is continually evolving and new evidence can result in major shifts in thinking. For example, large randomised control trials on the effect of specific micronutrients on cancer risk have not shown the protective effects that were previously hypothesised.

It is important to have a review process in place to ensure approved health claims are in line with current scientific evidence. If approved health claims are not reviewed there is a risk of a health claim statement no longer being agreed and therefore misleading consumers. This will affect consumer confidence in the health claims system. The frequency of review should be balanced with the need to provide industry with some certainty in the ability to use appropriate health claims on their products.

FSANZ needs to consider how the substantiation framework will address or manage emerging or contrary evidence once a high level claim has been approved. FSANZ is considering possible approaches for reviewing approved claims. These include:

- undertaking a regular rolling review, for example, every five to ten years, of all approved claims in order to consider new evidence; or

- maintaining a 'watching brief' and reviewing individual claims when relevant new and/or contrary evidence becomes available.

An application could also be made to change the Standard on a case-by-case basis. SDAC raised the need to review approved claims. They supported a regular review of approved claims and suggested that such a review could be linked to the Dietary Guidelines review.

Questions:

56. What do you consider would be an appropriate process to undertake a regular review of approved claims?

57. What risks would there be in maintaining a watching brief on new or contrary evidence as opposed to conducting a regular review?

7.5.3 Implications of the claim-by-claim approach to pre-market assessment

The Policy Guideline makes two references to a claim-by-claim approach. It states:

> It is suggested that only high level claims will be pre-approved, with approved claims being listed in the Standard. This could be done on a claim-by-claim (that is, not product-by-product) basis. … In general, approval of high level claims is to be 'claim-by-claim' and not 'product-by-product', although some products making high level claims may have undergone separate pre-market approval to ensure safety under other standards.

A claim-by-claim approach means that any pre-approved claim is available for use by the food industry generally, rather than only by an individual food manufacturer on their product(s). The main advantages of this approach are that it facilitates a broader use of scientifically validated approved high level claims, which may be seen as providing consumers with useful information with which to make informed choices. It minimises regulatory costs, in that FSANZ will only have to manage a single assessment process for a high level claim, rather than multiple assessment processes for the same claim by different manufacturers (as would be the case with a product-by-product approach). It also benefits smaller food manufacturers, who will be able to use approved high level claims, and will not in this respect be disadvantaged compared to large food manufacturers.

Question:

58. Given the claim-by-claim approach to pre-assessing claims, can you foresee any circumstance where a manufacturer can gain an exclusive right to a claim?

59. If so, does this present a problem in the context of the broader regulatory framework for nutrition, health and related claims?

7.6 Consumer research

The purpose of nutrition, health and related claims is to help consumers make healthy food choices. It is therefore relevant to examine the extent to which claims affect consumers' search for information and processing as well as their purchasing decisions.

This section provides a literature review of consumer research undertaken in this area, including consumers' interest in and use of health claims, the impact of health claims on information search and nutrition and health judgements, the interpretation of different levels of health claims, the link between nutrition content claims and health claims, and wording issues associated with claims.

7.6.1 Consumers' interest in and use of health claims on food packages

In 1995, six focus groups were conducted in the United States to determine whether and how authorised model health claim messages could be modified to better communicate health information to consumers.[42] The main finding was that consumers did not expect, want or see any need for food labels to carry generic health messages about diet–disease relationships as such information was obtained from other sources. Food labels were not considered to be an appropriate vehicle for nutrition education. Claims appear on the front of food packages and therefore tend to be associated with advertising. At that time only a quarter of consumers said they were using health claims to make food choices in a quantitative survey.[43] Similarly, health claims were being used on products in the United Kingdom when a qualitative test was conducted in 2002. Whilst participants stated that they were familiar with aspects of the claims, there was little interest in them. Few participants spontaneously mentioned claims when discussing the labelling elements they looked for on packages.[44] It is therefore likely that these findings will be replicated in Australia and New Zealand over the next few years.

The time lag between the appearance of information and familiarity and acceptance of information can be considerable, so the long-term situation may present different findings to the above. There has been a proliferation of health claims in the United States since the 1995 study, indicating that over time their use does impact on the sale of food and therefore on consumers' food choices. One study in particular has demonstrated that a new health claim positively affects the sales of a food product.[45]

7.6.2 Impact of health claims on consumers' information search and nutrition and health judgments

A large United States experimental study demonstrated that the presence of health claims and, to a lesser extent, nutrition content claims significantly increased the probability that consumers limited their search for labelling information to the front of the package and therefore tended to judge products on the basis of the claim rather than the claim plus the nutrition information panel.[46] Health claims appeared to have limited ability to communicate information about the products' health benefits as more than 20 per cent of the respondents did not record that a product had any health benefits even when the package carried an explicit health claim.

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[42] Levy, AS 1995, *Summary on health claims focus groups*, Food and Drug Administration, Centre for Food Safety and Applied Nutrition, Division of Market Studies, Washington, DC.
[43] Derby, B & Levy, A 1996, 'Consumer and market impacts of the Nutrition Labeling and Education Act', Paper presented at the Marketing and Public Policy Conference, 17 May, Rosslyn, VA.
[44] Food Standards Agency 2002, *Health claims on food packaging: consumer related qualitative research*, A report on behalf of Food Standards Agency prepared for COI Communications, London.
[45] Paul, GL, Ink, SL & Geiger, CJ 1999, 'The Quaker Oats health claim: a case study', *J. Nutraceuticals, Functional and Med Foods* 1(4): 5–32.
[46] Levy, A, Derby, B & Roe B 1997, *Consumer impacts of health claims: an experimental study*, Food and Drug Administration Centre for Food Safety and Applied Nutrition, Division of Market Studies, Washington, DC.

Respondents' perceptions about the health benefits of particular products appeared to be based mainly on their prior beliefs about the type of product rather than on specific information provided by the health claim. This in part explains why health claims were found to be most effective when they provided consumers with 'new' information. These results were also revealed in a United Kingdom qualitative study.[47]

One of the concerns with health claims is the possibility of a 'halo effect' (that is, consumers rating a product higher on other health attributes not mentioned in the claim). The United States experimental study found that the presence of a claim was associated with a halo effect. The Federal Trade Commission, which has responsibility for food advertising in the United States, examined the halo effect in more depth as part of a large-scale advertising copy test project in 1998.[48] Although the study applied to food advertisements, it should be noted that consumers process health claims on product labels in a similar manner to health claims in food advertisements.[49]

In the Federal Trade Commission study consumers were asked to examine food products that were both high in a beneficial nutrient (for example, calcium) and a risk-increasing nutrient (for example, saturated fat). A health claim was made about the beneficial nutrient, while a sequence of advertisements, which were designed to alert consumers to the presence of the risk associated nutrient, were shown. A clear, direct verbal disclosure (for example, a warning statement that 'diets high in saturated fat could increase the risk of heart disease' with an advisory statement that the advertised product was high in saturated fat) appeared to be more effective than quantitative disclosures (for example, declaring the amount of saturated fat per serving or milligrams) in conveying that a food may not be healthy in all respects.

Consumers did not, however, have enough information to make correct decisions about the healthiness of the food products tested. This therefore supports the notion that health claims should not be used for food that also contains substantial amounts of 'risk increasing' nutrients.

Another component of the Federal Trade Commission study tested the 'level of scientific certainty' via hypothetical health claims for both a food and a supplement product. The claims described health benefits that were based on strong, emerging science, but also involved situations where there was still some uncertainty about the nature or degree of benefit and some inconsistency in the research. The research tested two series of advertisements that disclosed, with varying levels of strength and detail, limitations in the degree of scientific support for the type of health benefit being advertised. The test confirmed that specific disclosures (such as explicit references to inconsistent study results or ongoing scientific debate) are necessary to alert consumers to limitations in scientific support. The report suggested that the wording of any disclosure had to be much stronger, the print size larger and the disclosure had to be an integral part of the advertisement compared to the disclosures in the copy test.

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[47] National Consumer Council 1997, *Messages on food: consumers' use and understanding of health claims on food packs*, National Consumer Council, London.

[48] Murphy, D, Hoppock, TH & Rusk, MK 1998, *Generic copy test of food health claims in advertising*, A joint staff report of the Bureaus of Economics and Consumer Protection, Federal Trade Commission, Washington, DC.

[49] Mazis, MB & Raymond, MA 1997, 'Consumer perceptions of health claims in advertisements and on food labels', *Journal of Consumer Affairs* 31:10–18.

In addition to the halo effect found in the United States experimental study, it was also found that for one of the three products tested, a 'magic bullet' effect occurred (that is, attributing inappropriate health benefits to the product).[50]

Several studies have examined the effect of various devices on communication effectiveness, such as shorter rather than longer claims, endorsements and split claims. There appears to be evidence to suggest that shorter claims are preferred and are more effective than longer claims.[51] The Food and Drug Administration's qualitative research found that consumers favoured shorter product-specific health messages and its experimental data found some small effects to show that shorter claims were better than longer ones.[52] The Quaker Oats Company also demonstrated that a shorter claim is not misleading and can communicate the disease relationship more effectively than a longer Food and Drug Administration claim.[53] Finally a qualitative study in the United Kingdom revealed that consumers found the longer, more complex claims confusing and therefore did not trust them.[54]

Although qualitative research in the United States and Canada both found support for endorsement from a reputable public health agency,[55] it was shown to have liabilities for one of the three products tested in the Food and Drug Administration's experimental study.[56] Specifically, adding an endorsement increased the negative impact of a low fat/heart disease health claim on a lasagna product. It may have been that because lasagna is not typically a low fat food, the endorsement reinforced the notion that the health claim was on the package for reasons other than providing truthful information.

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[50] Levy, A, Derby, B & Roe B 1997, *Consumer impacts of health claims: an experimental study*, Food and Drug Administration Centre for Food Safety and Applied Nutrition, Division of Market Studies, Washington, DC.

[51] Levy, AS 1995, *Summary on health claims focus groups*, Food and Drug Administration Centre for Food Safety and Applied Nutrition, Division of Market Studies, Washington, DC.
Levy, A, Derby, B & Roe B 1997, *Consumer impacts of health claims: an experimental study*, Food and Drug Administration Centre for Food Safety and Applied Nutrition, Division of Market Studies, Washington, DC.
National Consumer Council 1997, *Messages on food: consumers' use and understanding of health claims on food packs*, National Consumer Council, London.
Paul, GL, Ink, SL & Geiger, CJ 1999, 'The Quaker Oats health claim: a case study', *J. Nutraceuticals, Functional & Med Foods* 1(4): 5–32.

[52] Levy, AS 1995, *Summary on health claims focus groups*, Food and Drug Administration Centre for Food Safety and Applied Nutrition, Division of Market Studies, Washington, DC.
Levy, A, Derby, B & Roe B 1997, *Consumer impacts of health claims: an experimental study*, Food and Drug Administration Centre for Food Safety and Applied Nutrition, Division of Market Studies, Washington, DC.

[53] Paul, GL, Ink, SL & Geiger, CJ 1999, 'The Quaker Oats health claim: a case study', *J. Nutraceuticals, Functional & Med Foods* 1(4): 5–32.

[54] National Consumer Council 1997, *Messages on food: consumers' use and understanding of health claims on food packs*, National Consumer Council, London.

[55] Levy, AS 1995, *Summary on health claims focus groups*, Food and Drug Administration Centre for Food Safety and Applied Nutrition, Division of Market Studies, Washington, DC.
Health Canada 2000, *Health claims focus testing*, A report prepared by Goldfarb Consultants for Nutrition Evaluation Division, Food Directorate, Health Canada.

[56] Levy, A, Derby, B & Roe B 1997, *Consumer impacts of health claims: an experimental study*, Food and Drug Administration Centre for Food Safety and Applied Nutrition, Division of Market Studies, Washington, DC.

Opinion about split claims was mixed in Canada's qualitative study.[57] Some people believed it was necessary to have the whole claim in one part of the label in order to ensure the totality of information; others however, felt it would be too much information in one place and therefore splitting the claim would be more effective in making the crucial part easily discernible. Splitting messages between the front and back label made little difference in the Food and Drug Administration's experimental study.[58]

7.6.3 Consumers' interpretation of different levels of health claims

A United Kingdom qualitative consumer study in 2002 examined four levels of claims (functional, enhanced function, reduction of disease risk factor and reduction of disease risk claims), which were identified in a draft European Commission proposal for European Union legislation to control the use of health claims in food labelling.[59]

Respondents did not relate to health claims according to the levels identified by the European Commission. There was no consistent pattern applied to the grouping of claims because respondents evaluated them on the basis of their belief systems (that is, whether they were convinced by the claims), which relates to the impression or 'feeling' a claim makes on them, rather than on their objective understanding of the health benefit claimed. This meant participants either repeated or paraphrased the claims or tended to generalise (that is, one-size-fits-all health benefits) when trying to interpret them. Similar observations have also been made in Canada[60] and the United States.[61]

When participants in the United Kingdom study were presented with a list of claims (the European Union's four levels of claims) and asked to group them they were only able to do so in terms of contrasts (for example, claims suggested either 'maintenance' or a 'change'). Many dichotomies were expressed as:

- maintaining vs changing/altering/improving
- prevention/protection vs cure
- general health/body as a whole vs specific organ/part
- new and interesting vs known/familiar
- benefit now vs benefit in the future
- medicinal vs nutritional
- proven/substantiated vs unproven/unsubstantiated
- persuasive/convincing vs unbelievable/nonsensical
- positive vs negative
- definite vs nebulous

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[57] Health Canada 2000, *Health claims focus testing*, A report prepared by Goldfarb Consultants for Nutrition Evaluation Division, Food Directorate, Health Canada.
[58] Levy, A, Derby, B & Roe B 1997, *Consumer impacts of health claims: an experimental stud*y, Food and Drug Administration Centre for Food Safety and Applied Nutrition, Division of Market Studies, Washington, DC.
[59] Food Standards Agency 2002, *Health claims on food packaging: consumer related qualitative research*, A report on behalf of Food Standards Agency prepared for COI Communications, London.
[60] Health Canada 2000, *Health claims focus testing*, A report prepared by Goldfarb Consultants for Nutrition Evaluation Division, Food Directorate, Health Canada.
[61] Levy, A, Derby, B & Roe B 1997, *Consumer impacts of health claims: an experimental stud*y, Food and Drug Administration Centre for Food Safety and Applied Nutrition, Division of Market Studies, Washington, DC.

• wordy	vs	concise and clear
• marketing speak/hype	vs	informative/neutral
• specific group (e.g. kids, older women)	vs	everyone
• me	vs	not me (relevant condition)
• have bought or might buy	vs	would avoid

Such results overlap, to an extent, with the findings of an earlier study in the United Kingdom where consumers classified claims according to how well they understood them (that is, factual, explanatory, impenetrable, meaningless, spurious, unappealing or esoteric).[62]

The 2002 Food Standards Agency study concluded that 'the research suggests that a hierarchy of claims based on a purely scientific structure misses the point that the consumer's response is often of a non-scientific nature. They have other priorities and they look at claims in a wider and often 'fuzzy' context.[63]

While the United Kingdom has examined different levels of health claims in terms of a promised health outcome, the United States Food and Drug Administration's Centre for Food Safety and Applied Nutrition is currently investigating different levels of scientific support and the most effective wording to use in conveying these differences.[64] Methods being used include an experimental shopping centre intercept study (to determine whether health claims that do not meet the 'significant scientific agreement (SSA) standard of evidence' – level of scientific support are misleading to consumers and to evaluate options for generic disclaimers to correct for any misleading perceptions), focus groups (for examining the effectiveness of including graphics with health claims compared to health claims by themselves) and Internet panel experimental studies (to determine if claim and disclaimer language accurately communicates to a 'reasonable consumer' the level of scientific evidence behind the claim).

7.6.4 Link between nutrition content claims and health claims

A 1995 United States focus group study was undertaken when consumers were used to seeing predominantly nutrition content claims on packages. They saw content claims as implicitly referring to diet–disease relationships with which they were familiar.[65] The main reaction to different versions of health claims was to reduce them to 'reminders', which rendered them effectively the same as nutrition content claims. That these two types of claims may act as substitutes for one another when the nutrient and associated disease is well known, is also implied in a large follow-on experimental study in 1996, where the vast majority of respondents viewed both health and nutrition content claims as health information.[66]

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[62] National Consumer Council 1997, *Messages on food: consumers' use and understanding of health claims on food packs*, National Consumer Council, London.
[63] Food Standards Agency 2002, *Health claims on food packaging: consumer related qualitative research*, A report on behalf of Food Standards Agency prepared for COI Communications, London.
[64] Food and Drug Administration 2003, *Improving consumer understanding and product competition of health consequences of dietary choices*, Centre for Food Safety and Applied Nutrition. This report is at Attachment D of the Consumer studies research agenda of the Consumer Health Information for Better Nutrition Initiative, Task Force Final Report <http://www.cfsan.fda.gov/~dms/nuttf-d.html>.
[65] Levy, AS 1995, *Summary on health claims focus groups*, Food and Drug Administration Centre for Food Safety and Applied Nutrition, Division of Market Studies, Washington, DC.
[66] Levy, A, Derby, B & Roe B 1997, *Consumer impacts of health claims: an experimental study*, Food and Drug Administration Centre for Food Safety and Applied Nutrition, Division of Market Studies, Washington, DC.

Similarly, in the United Kingdom consumers make no distinction between nutrition content claims and some health claims.[67]

7.6.5 Wording issues

A number of studies have examined specific wording issues, such as 'may' and 'healthy diet'. The following is a summary of the results:

- 'May' was viewed in the United Kingdom with suspicion because it indicated a lack of confidence on the manufacturer's behalf and/or was perceived to act as a disclaimer for the manufacturer.[68] Participants in Canadian and American focus group studies were also concerned by the lack of certainty or weakness in a claim that used the word 'may'. They therefore wanted to see claims expressed more definitively or not at all.[69] In contrast to United Kingdom participants, the Canadian study participants viewed the ambiguity as being a disclaimer used by the government.

- 'Can' and 'helps' were considered to provide more certainty than 'may', but were also treated with caution in the United Kingdom.[70] In Canadian and American studies, 'help' was perceived as being positive, so a claim with 'help' was not considered to be cautionary, condescending or negative.[71]

- 'Risk' introduced the concept of uncertainty, even when the rest of the claim is definitive (that is, when the claim states that it 'reduces the risk' rather than 'may reduce the risk').[72]

- 'Risk' and 'risk factor' were seen as being the same thing by half the sample in a United Kingdom study.[73] Most of the other half, however, saw 'risk factor' as being more specific in that the product is addressing only one of a number of different factors contributing to the condition or disease.[74]

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[67] National Consumer Council 1997, *Messages on food: consumers' use and understanding of health claims on food packs*, National Consumer Council, London.
[68] Food Standards Agency 2002, *Health claims on food packaging: consumer related qualitative research*, A report on behalf of Food Standards Agency prepared for COI Communications, London.
[69] Health Canada 2000, *Health claims focus testing*, A report prepared by Goldfarb Consultants for Nutrition Evaluation Division, Food Directorate, Health Canada.
Levy, AS 1995, *Summary on health claims focus groups*, Food and Drug Administration Centre for Food Safety and Applied Nutrition, Division of Market Studies, Washington, DC.
[70] Food Standards Agency 2002, *Health claims on food packaging: consumer related qualitative research*, A report on behalf of Food Standards Agency prepared for COI Communications, London.
[71] Health Canada 2000, *Health claims focus testing*, A report prepared by Goldfarb Consultants for Nutrition Evaluation Division, Food Directorate, Health Canada.
Levy, AS 1995, *Summary on health claims focus groups*, Food and Drug Administration Centre for Food Safety and Applied Nutrition, Division of Market Studies, Washington, DC.
[72] Food Standards Agency 2002, *Health claims on food packaging: consumer related qualitative research*, A report on behalf of Food Standards Agency prepared for COI Communications, London.
[73] ibid.
[74] Food Standards Agency 2002, *Health claims on food packaging: consumer related qualitative research*, A report on behalf of Food Standards Agency prepared for COI Communications, London.

- 'As part of a healthy diet' was viewed by some participants in the United Kingdom as being fundamental to the claim but was irrelevant to others.[75] In Canada, participants did not pay much attention to 'healthy diet', although some people wondered to what degree a claim was void if people did not follow a healthy diet. Unlike 'healthy diet' the word 'diet' was seen by a few to indicate weight loss.[76]

- 'Moderation' was believed to be a vague term, as participants found it difficult to know what was a 'moderate' amount of a nutrient.[77]

- 'Rich in a variety' slightly reduced the credibility of a claim because the phrase was initially difficult to understand, as 'rich' does not specify a quantity and 'variety' does not indicate the extent that is required in order to achieve a claim's benefit.[78]

- 'Studies show' indicated some authoritative source in the United States study.[79]

- 'See back panel' was thought by many to make a claim more product specific and told the consumer to read the nutrition information on the back.[80] The phrase was viewed favourably because it addressed concerns about message credibility.

Additional information in a claim such as 'adequate intake of vitamin D is also necessary' on a calcium–strong bones and osteoporosis claim; or 'high blood pressure is a condition also associated with overweight, excessive alcohol consumption, inadequate intake of dietary potassium and physical inactivity' on a sodium–high blood pressure claim were not seen as being helpful. When the information was new, there was a tendency to dismiss it as it was not the focus of the claim and the claim's credibility was reduced. When the information referred to negative health practices such as being inactive, overweight or drinking excessive alcohol, the tendency was that people did not perceive themselves in this way and were turned-off by their reference.[81]

During the FSANZ standard development process, it will be necessary to conduct consumer research to address many of the issues raised in previous research. There are also other issues that FSANZ is interested in, such as how consumers view implied health claims and cause-related marketing claims. As discussed in section 8.4, consumer research will help FSANZ evaluate the effectiveness of the new Standard.

Questions:

60. Are you aware of any additional consumer research on nutrition, health and related claims?

[75] ibid.
[76] Health Canada 2000, *Health claims focus testing*, A report prepared by Goldfarb Consultants for Nutrition Evaluation Division, Food Directorate, Health Canada.
[77] ibid.
[78] ibid.
[79] Levy, AS 1995, *Summary on health claims focus groups*, Food and Drug Administration Centre for Food Safety and Applied Nutrition, Division of Market Studies, Washington, DC.
[80] ibid.
[81] Health Canada 2000, *Health claims focus testing*, A report prepared by Goldfarb Consultants for Nutrition Evaluation Division, Food Directorate, Health Canada.

7.7 Education

The elements of an education strategy will be important in ensuring effective implementation of the FSANZ Conceptual Framework.

For Approach One and Approach Two, as outlined in sections 7.1 and 7.2 respectively, the supporting interpretive userguide(s) that will be developed will provide a range of educational material for industry groups with respect to implementing the regulatory system for nutrition, health and related claims. However, if Approach One is adopted (where criteria and conditions for making general level claims are included in a Guideline rather than the Standard) it will be vital to include a comprehensive education package for both industry and other groups in order to ensure that claims in the market place are being presented in a consistent manner.

The Quantitative Consumer Labelling Research Report (2003)[82] indicated that consumers are aware of and use much of the label information available on food products. However, they may not interpret the information from each food label element appropriately in order to make their desired food choices. Regardless of the approach taken towards implementing the regulatory framework, an education strategy will be needed to help health professionals understand the implications of a new Standard for nutrition, health and related claims and to help consumers understand the nutrition and health related messages on food labels.

An overall education strategy for nutrition and health claims could consist of a variety of initiatives such as:

- information about claims on food as a result of the introduction of revised legislation around nutrition and health claims;
- information about the nutrition and health claims system as a whole – for example, how it operates, how claims are substantiated, and how a complaint can be made;
- information about approved claims – for example, the relationship between a food and/or component and a health outcome, sources of the component, the importance of dietary variety and links to food selection guides;
- linking the information on individual types of claims into broader, ongoing national public health nutrition strategies in Australia and New Zealand; and
- information about individual claims in relation to specific foods.

To implement such initiatives FSANZ, within its legislative responsibilities, could undertake the first and second initiatives: information about claims on food as a result of introducing revised legislation around nutrition and health claims; and information about the nutrition and health claims system as a whole.

It has been suggested that the third and fourth initiatives, will require a broader partnership approach involving a range of stakeholder groups including governments, non-government organisations and industry groups. It has also been suggested that it would be most appropriate for industry groups to undertake specific education activities, such as providing information about claims in relation to specific foods.

[82] Food Standards Australia New Zealand 2003, *Food Labelling Issues: Quantitative Research with Consumers*, Evaluation Report Series No.4.

Questions:

61. What do you consider to be the essential components of an education strategy for nutrition and health claims?
62. Who should be responsible for undertaking such education activities?
63. How can stakeholders work together to develop and implement an education strategy for industry, health professionals and consumers in relation to the proposed regulatory framework for nutrition health and related claims?

7.8 Compliance and enforcement

FSANZ notes that compliance and enforcement are separate but complementary concepts. 'Compliance', means measures taken to facilitate compliance with food standards, and to deter non-compliance. These may include measures such as development of interpretive userguides, fact sheets and other material to promote understanding of the requirements of the Code, and provision of services such as the FSANZ Industry Help Desk for more personalised support. By 'enforcement', we mean those activities undertaken by enforcement agencies, in response to possible industry non-compliance.

7.8.1 Implementation of the 'watchdog' function including the Advisory Panel

In December 2003, Ministers agreed that the Implementation Sub-Committee, which comprises representatives from the Australian, New Zealand and each State and Territory Government, would undertake a 'watchdog role' in relation to implementing the nutrition, health and related claims system. The watchdog role will include:

- helping FSANZ develop and maintain guideline documents intended to support implementation of the Standard;
- providing recommendations to Food Regulation Standing Committee about proposed amendments to the Standard or the guideline documents;
- receiving complaints and referral of such complaints to the relevant jurisdictions for analysis and enforcement;
- maintaining a record of complaints received and monitoring enforcement action taken by the jurisdictions in response to those complaints; and
- providing periodic reports to Food Regulation Standing Committee.

In addition, Ministers recommended establishment of an Advisory Panel to assist the jurisdictions determine adequacy of supporting evidence in relation to substantiation of general level claims. The Advisory Panel is to be a register of independent experts.

The Policy Guideline notes that claims referring to a biomarker are to be an enforcement priority during implementation of the Standard.

At the SDAC meeting, members supported the Implementation Sub-Committee watchdog developing a proactive approach to enforcement – that is, not only receiving complaints, but also monitoring claims being made in the marketplace.

While the Implementation Sub-Committee is responsible for establishing the watchdog role, including establishing the Advisory Panel and the procedures and processes with which enforcement matters will be dealt, FSANZ will work with the Implementation Sub-Committee on these issues during the Standard development process.

7.8.2 Compliance across the claims continuum

The Claims Classification Framework consists of two broad categories of claims: general level claims and high level claims. While all claims must be substantiated, there is a difference in the mechanism by which claims will be substantiated.

In relation to general level claims, the manufacturer will need to make an assessment of the evidence supporting the claim and to hold that evidence and produce the evidence at the request of the enforcement agencies. High level claims will be subject to pre-market assessment by FSANZ.

7.8.2.1 Compliance and enforcement of evidence in relation to general level claims

There are a number of issues arising from compliance with and enforcement of the requirements for general level claims, particularly in relation to determining the adequacy of supporting evidence relevant to substantiation of a claim. These issues include:

- how a manufacturer is to assess, compile and hold evidence;
- how an enforcement agency will request and assess evidence;
- who an enforcement agency can request evidence from;
- how an enforcement agency will request advice from the Advisory Panel; and
- what rights a manufacturer will have when the Advisory Panel makes a determination about the adequacy of the evidence held.

FSANZ will develop an interpretive userguide to support understanding of substantiation requirements specified in the Standard. This will include advice about how a manufacturer (or other person as appropriate) can assess and compile evidence in relation to a general level claim, in order to promote compliance. Other issues, particularly those relating to engagement of the Advisory Panel and use of advice from the Advisory Panel will be managed by the Implementation Sub-Committee. The Implementation Sub-Committee has established a Working Group to progress work in this area.

FSANZ is aware, however, that the requirements for general level claims, specifically in relation to the assessment of evidence, may present some challenges in relation to food imported into Australia or New Zealand. A requirement for a manufacturer to hold evidence and to provide that evidence at the request of the enforcement agency, as foreshadowed in the Policy Guideline, may give rise to practical and legal problems in relation to imported foods. That is, where the manufacturer is located in another country, there are clear compliance and enforcement issues associated with attempting to apply such requirements to a manufacturer, rather than to a party located within Australia and/or New Zealand (for example, the importer). Consistent with the approach taken elsewhere in the Code, it may be appropriate to extend the requirement to hold evidence to the supplier of the food (that is, the manufacturer, importer, packer or vendor) rather than limiting the requirement to the manufacturer.

FSANZ also notes that model food legislation contains provisions enabling authorised officers to request production of documents or records relating to the handling of food intended for sale or the sale of food. These provisions may provide enforcement agencies with powers to 'call on' evidence in support of general level claims, in the absence of such provision in the Standard.

Questions:

64. Would it be more appropriate for the 'manufacturer' or the 'supplier' to hold and produce evidence in relation to a general level claim?
65. What are the legal and/or practical difficulties for an enforcement agency when requesting and assessing evidence in relation to general level claims?
66. Under existing food legislation, are the current powers of enforcement agencies to 'call on' evidence in support of general level claims, adequate?

7.8.2.2. Enforcement of a standard vs a guideline

Enforcement issues arise from including information about managing general level claims in a Guideline, as opposed to a Standard. While a Guideline can be more readily amended than a Standard, it is not legally enforceable. This presents an enforcement challenge where a manufacturer may be acting inconsistently with a Guideline, though consistently with the Standard.

There are two possible approaches to implementing the FSANZ Conceptual Framework for Nutrition, Health and Related Claims – Approach One and Approach Two (see subsections 7.1. and 7.2 respectively). Under Approach One, certain criteria and conditions (such as the criteria for content claims) would be elaborated on in a Guideline (as distinct from an interpretive guide) while other criteria (such as certain criteria currently specified in the Code) would be included in the Standard.

The current experience with the CoPoNC in Australia illustrates that there are deficiencies in a regulatory system which relies on a Code of Practice to facilitate compliance. There is no mechanism for enforcement in response to breaches, due to the essentially voluntary nature of such a Code. There are likely to be similar issues arising from including certain criteria and conditions (such as the criteria for content claims) in a Guideline instead of a Standard.

Questions:

67. From the point of view of industry, consumers, public health professionals and enforcement agencies, what are the benefits of including certain criteria and conditions relating to general level claims in a Guideline instead of a Standard?
68. From the point of view of industry, consumers, public health professionals and enforcement agencies, what are the costs of including certain criteria and conditions relating to general level claims in a Guideline instead of a Standard?

7.8.3 Measures to promote compliance

Section 7 of the FSANZ Act sets out the FSANZ functions. Under s.7(1)(c) FSANZ can:

> develop guidelines to assist in the interpretation of the Code on its own initiative or in consultation with the States, the Territories and any other body or person that FSANZ considers appropriate.

In this context, Guidelines (that is, interpretive userguides) are intended to be interpretive in nature and are specific to those matters contained in the Code. Interpretive userguides are intended to facilitate industry compliance and enforcement agency understanding of Standards.

The Policy Guideline makes several references to development of 'guideline documents' to support implementation of the Standard. The following is a list of issues that could be addressed in interpretive userguides intended to support implementation and enforcement of the Standard for nutrition, health and related claims:

- The principles of substantiation as they apply across the claims continuum including how to compile and assess evidence.
- Instructions for applicants about the procedure for seeking pre-approval of high level claims including review mechanisms as new scientific evidence becomes available.
- The processes by which manufacturers should collect, assess and hold evidence in support of general level claims.
- Model claims and interpretive advice regarding the wording and representation of claims, particularly general level claims.
- The process for assessing compliance with the standard and the likely steps to be undertaken by the jurisdictions where the evidence held by manufacturers in support of general level claims might be considered inadequate.
- Education and communication strategies to support consumers' use of claims.

During the standards development process there will be a need to prioritise development of relevant interpretive userguides to meet stakeholders' implementation needs.

Interpretive userguides on general level claims and on the substantiation requirements for all levels of claims are likely to be the main priority for FSANZ during the Standards development process. Other interpretive userguides could be developed during the implementation and monitoring stage.

Question:

69. From the point of view of industry, consumers, public health professionals and enforcement agencies, which interpretive guides should be given priority during the Standard development process?

8. Other relevant issues

When developing a food Standard, FSANZ must have regard to a number of matters including other relevant legislation.

8.1 Therapeutic goods and foods

Currently, in Australia and New Zealand there are different regulatory requirements for the assessment, licensing and marketing of therapeutic products.

8.1.1 Therapeutic goods

8.1.1.1 Regulation of therapeutic goods in Australia

The *Therapeutic Goods Act 1989* and the Therapeutic Goods Regulations 1990 which are administered by the TGA, set out the specific requirements (including advertising and labelling), for inclusion of therapeutic goods on the Australian Register of Therapeutic Goods. Any product regarded as being a therapeutic good must be included in the Australian Register of Therapeutic Goods, with some exceptions. This applies equally to complementary, prescription and over-the-counter medicines.

The Therapeutic Goods Act provides that a therapeutic good is one, which 'is represented in any way to be for therapeutic use, or is likely to be taken to be for therapeutic use, (whether because of the way in which the good is presented or for any other reason).'[83] Therapeutic goods also include those represented as, or likely to be taken to be, goods for use as ingredients or components in therapeutic goods, and goods included in a class of goods whose sole or principal use is therapeutic.

Therapeutic goods do not include foods which have a tradition of use in Australia or New Zealand in the form in which they are presented, or goods for which there is a prescribed standard in the Code[84] or goods which are declared not to be therapeutic goods under section 7 of the Therapeutic Goods Act.

Therapeutic use is defined in the Therapeutic Goods Act as use in or in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or
- influencing, inhibiting or modifying a physiological process in persons or animals; or
- influencing, controlling or preventing conception in persons; or
- testing for pregnancy in persons; or
- the replacement or modification of parts of the anatomy in persons or animals.

Currently, under section 7 of the Therapeutic Goods Act a declaration may be made that a product is, or is not, a therapeutic good. This may only be done where the Secretary is satisfied that a particular good or class of goods is or is not a therapeutic good, either generally or when used, advertised or presented for supply in a particular way.

[83] *Therapeutic Goods Act 1989* s.3(1).
[84] There are also other categories of exemption from the definition of therapeutic good - see s. 3(1) for details.

The purpose of a section 7 declaration is to provide certainty to industry and regulatory bodies about the appropriate regulatory classification of a group of goods, in instances where uncertainty exists. It is not designed to shift products that otherwise would clearly not be regarded as therapeutic goods, into this category.

The Therapeutic Goods Advertising Code sets out principles and guidelines with which all advertisements about therapeutic goods directed to consumers must comply. The Code ensures socially responsible marketing and advertising of therapeutic goods. Only those products available without prescription may be advertised to the general public.

Complementary medicines

Complementary medicines include herbal medicines, vitamins, minerals and trace elements, other nutritional supplements, homoeopathic medicines and aromatherapy oils. A variety of claims can be made on complementary medicines providing such claims comply with the TGAC and are supported by appropriate levels of evidence. Such claims may include health maintenance claims, health enhancement claims, nutritional supplementation claims and risk reduction claims. Complementary medicines can be either listed or registered on the Australian Register of Therapeutic Goods, depending on their ingredients and the claims made, although the majority of complementary medicines are listed. Some complementary medicines, such as the majority of homoeopathic medicines, are exempt from inclusion in the Australian Register of Therapeutic Goods.

The 'listed' category is for those products containing ingredients assessed as low risk and that may be used only for minor, self-limiting conditions. Sponsors must hold appropriate evidence to support claims they have made about their products.

The 'registered' category is for those products containing higher risk substances or which carry more serious claims than allowed for the listed category. Claims relating to treatment, management, cure or prevention of a disease, disorder or condition (or claims in relation to a serious disease, disorder or condition) are permitted on registered products only. Complementary medicines that carry claims of this nature are required to be registered on the Australian Register of Therapeutic Goods. Certain vitamin and mineral supplements require registration. Registration applications undergo a scientific evaluation for quality, safety and efficacy.

8.1.1.2 Regulation of therapeutic products in New Zealand

Currently, in New Zealand therapeutic products are primarily regulated under the *Medicines Act 1981* and the Medicines Regulations 1984 administered by New Zealand Medicines and Medical Devices Safety Authority (Medsafe). Dietary supplements are regulated by the Dietary Supplement Regulations 1985, under the *Food Act 1981*, administered by the New Zealand Food Safety Authority.

Complementary medicines

Most complementary medicines in New Zealand are sold as dietary supplements. As such, no pre-market registration requirements and only minimal compositional and labelling requirements apply to such products.

Dietary supplements cannot be labelled or advertised with therapeutic claims, unless permitted under medicines legislation.[85]

8.1.1.2 Trans-Tasman therapeutic products agency

The New Zealand and Australian Governments have agreed to establish a trans-Tasman therapeutic products agency. From 1 July 2005 the joint agency will replace the Australian TGA and New Zealand's Medsafe.

The current legislation in Australia and New Zealand governing regulation of therapeutic goods will be repealed and replaced by new legislation that will cover regulation of therapeutic products in both countries.

The Joint Scheme will regulate a range of therapeutic products including medicines and medical devices. The key elements of the regulatory framework for therapeutic products are:

- pre-market assessment of product safety, quality and efficacy;
- licensing of manufacturers to assure product quality;
- post-market monitoring of product safety and quality; and
- surveillance to check for compliance.

These regulatory elements will be applied to all therapeutic products, regardless of whether the product is a prescription medicine, an over-the-counter medicine or a complementary medicine. However, the manner and extent of regulation will depend on the type of product and the level of risk associated with its use.

For prescription and over-the-counter medicines, the Joint Scheme will effectively consolidate and unify the, already similar, existing New Zealand and Australian regimes.

Complementary medicines

Most complementary medicines are expected to be classified as low-risk medicines. For low-risk medicines sponsors will be required to enter information into a web-based system, providing basic details about the product, declaring the products meet certain standards and certifying that they hold the necessary information or documentation to support their declaration. Products certified in this way will only be allowed to contain ingredients from a 'permitted ingredients list' and there will be restrictions on the therapeutic claims that can be made. This is very similar to the system currently in place for listed products in Australia. The Joint Scheme will introduce risk-based regulation of complementary medicines as therapeutic products for the first time in New Zealand.

Food-medicine regulatory interface

A number of foods contain ingredients and are presented in a manner that places them at the interface of regulations relating to foods and therapeutic goods.

[85] Reg. 11, Dietary Supplements Regulations 1985.

In particular, products that may potentially be regarded as novel foods or foods containing novel ingredients and 'dietary supplement' products imported into Australia under the Trans-Tasman Mutual Recognition Arrangement are most likely to raise questions as to whether they are foods or therapeutic goods. Under the Trans-Tasman Mutual Recognition Arrangement, food-type dietary supplement products can be legally imported from New Zealand into Australia without meeting the compositional and labelling requirements of the Code, provided they comply with the Dietary Supplements Regulations in New Zealand. The Trans-Tasman Mutual Recognition Arrangement does not apply to dietary supplements that would be considered complementary medicines in Australia. As a result, food such as non-caffeinated vitamin-fortified energy drinks that are not currently permitted by the Code, are entering Australia from and through New Zealand. Medicines most likely to sit at or near the food–medicine interface are complementary medicines.

In previous advice to the former ANZFA, the TGA indicated that the distinction between some food products and some therapeutics goods was becoming more challenging as innovations in manufacturing technologies and product development produced products which might traditionally have been considered to be foods but which are now presented as 'therapeutic goods'. In particular, foods that have been modified to serve a physiological role beyond the provision of simple nutrient requirements are most likely to sit close to the food–medicine interface. The TGA raised concerns that, as manufacturers make health related claims about more traditional foods, these foods will be positioned closer to the food–medicine interface.

The Policy Guideline states that, except where permitted by the Code, claims that a food or a component of a food or diet can prevent, diagnose, cure or alleviate a disease, condition, ailment, defect or injury in humans would be considered therapeutic claims and should not be permitted. Having regard to this, therapeutic claims are not proposed to be permitted under the FSANZ Conceptual Framework. The FSANZ claim descriptor for 'therapeutic claim' is discussed at subsection 5.4.4.

Question:

70. From the point of view of food and medicine enforcement agencies and food and medicine manufacturers, can the proposed FSANZ Conceptual Framework for the Regulation of Nutrition, Health and Related Claims ensure a clear boundary at the food–medicine interface for foods carrying health related claims?

Regulatory equality

The Australian medicine industry has raised concerns with FSANZ that regulation of nutrition, health and related claims for foods would place medicine manufacturers at a disadvantage relative to food manufacturers. The TGA previously advised ANZFA that, where similar claims are to be potentially permitted on both foods and therapeutic goods, similar approaches to risk management would be important. In particular, the TGA considers that the substantiation requirements for claims will need to lead to equality on both sides of the interface. The table at Attachment 8, compares the Australian regulatory system for complementary medicines and foods.

Question:

71. From the point of view of food and medicine enforcement agencies and food and medicine manufacturers, would the proposed FSANZ Conceptual Framework for the Regulation of Nutrition, Health and Related Claims and proposed Substantiation Framework promote equality between the regulation of foods and medicines?

8.2 Trade marks

A trade mark is a sign used, or intended to be used, to distinguish goods or services dealt with or provided in the course of trade by a person, from goods or services dealt with or provided by others. Registered trade marks are registered under and protected through use of the *Trade Marks Act 1995* (Cwth). Such trade marks are registered in relation to particular goods and/or services. The owner of the trade mark has the exclusive right to use the trade mark, and to authorise other people to use the trade mark, in relation to the goods and/or services in respect of which the trade mark is registered. One of the advantages of registration is that it is easier for the owner to obtain relief against infringement of his or her trade mark.

In addition to standard trade marks, there are other types of trade marks. A certification trade mark is a sign used to distinguish goods or services in respect or origin, material, mode of manufacture or some other characteristic, from goods or services not so certified. An example of a certification trade mark used in relation to food is the National Heart Foundation tick, which indicates that the food in question complies with requirements specified by the Foundation, designed to ensure that products upon which it appears are healthier choices within a particular food category.

A trade mark may potentially constitute a general or high level claim, or part of a claim. As part of its assessment of P293, FSANZ will be considering the appropriate way in which to address trade marks that constitute claims.

8.3 Fair trading legislation

Provisions designed to protect consumers from misleading or deceptive conduct are located in trade practices and fair trading legislation, as well as in food legislation. The former are of general application and so encompass conduct in relation to food; the latter specifically relate to food. In addition, one of FSANZ's objectives in developing food standards is the prevention of misleading or deceptive conduct.[86].

In the course of this proposal, FSANZ will seek to promote its objective of preventing misleading or deceptive conduct, and to ensure consistency between the regulation of nutrition, health and related claims, and fair trading provisions, and to remove areas of potential conflict. This may be achieved through a variety of means, including remaining silent on issues already adequately regulated by fair trading provisions, developing complementary provisions, or tailoring prescription to avoid any conflict or inconsistency. The approach that should be taken to regulating unqualified free claims is likely to be one of the key questions in this area.

[86] FSANZ Act s.10(1)(c).

Both the Australian Competition and Consumer Commission and the New Zealand Commerce Commission consider that the term 'free' means 'nil'. That is, where a food is labelled as being 'fat free', it should contain no fat whatsoever. This view is consistent with FSANZ consumer research, which found that consumers generally understood the term 'free' to mean the food contained none of the substance indicated.

However, the Codex Guidelines for Use of Nutrition Claims (CAC/GL 23–1997) provide conditions for free claims in relation to energy, fat, saturated fat, cholesterol, sugars and sodium, whereby the food can contain a small amount of the substance it is claimed to be 'free' of, rather than none at all. This is the approach that was adopted in CoPoNC.
It is interesting to note that the Codex Guidelines for Use of Nutrition Claims are expressly intended to supplement the Codex General Guidelines on Claims (CAC/GL 1–1979 (Rev. 1–1991)).[87] These general guidelines are based on the principle that:

> no food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.

However, the tolerance levels provided for free claims could be considered to be promoting a practice that is inconsistent with this principle, based upon consumers' understanding of what free claims signify.

This disjuncture between fair trading laws and CoPoNC in relation to unqualified free claims has created potential difficulties from an enforcement perspective, and has meant industry and consumers have been provided with conflicting advice and information.

The issue of unqualified free claims is further explored in Attachment 6.

Question:

72. With the exception of unqualified 'free' claims, are there any areas where the regulation of nutrition, health and related claims and fair trading provisions might be inconsistent or in conflict?

8.4 Monitoring and evaluation

FSANZ has identified evaluation of the use of nutrition, health and related claims and their impact on consumers and other stakeholders as a priority area of work for inclusion in the FSANZ 2004–08 Evaluation Strategy.[88] The SDAC also considered that evaluation issues were of particular importance. It would be cost-effective to work with the Implementation Sub-Committee Working Group to ensure this work is compatible with that of the watchdog role for the Implementation Sub-Committee and meets the needs of both.

[87] These aspects of Codex reside in Guidelines, rather than Standards. The Codex Alimentarius website states that these are 'provisions of an advisory nature ... to assist in achieving the purposes of the Codex Alimentarius', distinguishing them from internationally adopted food standards. However, the importance of Guidelines should not be underestimated – for the purposes of the Sanitary and Phytosanitary Measure and Technical Barrier to Trade agreements, Guidelines have the same function as Standards.
[88] Food Standards Australia New Zealand 2004, *FSANZ Evaluation Strategy 2004–08* [online]. Available at: <http://www.foodstandards.gov.au/_srcfiles/Evaluation%20strategy%20FINALv2.pdf>.

Planned FSANZ evaluation activities include an assessment of claims made on food labels and advertisements and changes in consumer attitudes and behaviour towards these claims. Several phases for data collection are suggested, the intention being to work with jurisdictions, where appropriate.

These data collections would provide information over time on the extent of use of claims, the type of claims used, their validity in terms of content of the substance claimed, as well as on consumers' attitudes, knowledge and behaviour towards claims. Once the new Standard is implemented, it will be possible to track changes in claims made and to assess the effectiveness of the measures put in place.

A key question for the evaluation would be to assess whether the new Standard has achieved the intended objectives of the Proposal and if not, why not. For example, has the new Standard clarified the use of claims, resulted in a reduction in the number of ambiguous claims in the market place and made enforcement easier?

8.4.1 Proposed evaluation research activities

It is proposed that the FSANZ evaluation research be divided into four phases:

Phase 1: Baseline data collection: cataloguing of claims and supporting nutrition information panel details used on food labels that have already been collected as part of the 2002–03 FSANZ label monitoring project, and those from a separate 2003 food type dietary supplement survey. The claims considered would include content and function claims (including vitamin and mineral claims), and folate/neural tube defects health claims that are permitted under the current regulations. Other claims that may also be of particular interest include claims made through endorsements and claims that might be considered to breach the spirit of the current regulations, including ambiguous claims in the market place at the time of these surveys.

The current FSANZ label collection has 2400 labels from a cross-sectional sample of food categories (1200 labels collected during July–December 2002 and 1200 labels collected during July–December 2003). The food type dietary supplement survey collected a smaller number of labels from specific food categories.

Phase 2: Baseline data collection for specific food categories: additional data collection of food labels from specific food categories likely to carry nutrition, health or related claims, particularly those where jurisdictions have identified food categories where claims tend to be made that may cause enforcement problems. As the Standard is likely to also apply to advertisements it may be worthwhile to extend the baseline data collection to include the use of claims in food advertising, particularly at the point of purchase of unpackaged foods, as in restaurants or food courts.

Jurisdictions would be involved in developing a survey framework where such food categories and advertisements are sampled and a record made of the types of claims being used. The sample would be such that it could be analysed at State and Territory or national level (Australia and New Zealand) if required. In this instance the feasibility of laboratory analysis of a subset of foods making claims on the labels or in advertising could be assessed, so the validity of such claims made on the labels or in food advertising could be measured in relation to the actual content of that substance in the food.

Question:

73. Can the jurisdictions provide enforcement data on food categories where the use of nutrition, health and related claims may be a problem?

74. Can the food industry provide data on the types of food categories currently carrying content or function claims, a folate/neural tube defect health claim or endorsements?

    Provision of detailed information in your answers will help FSANZ devise a sampling framework for label monitoring that is representative of foods currently in the market place carrying claims.

Phase 3: Baseline consumer research: baseline research on consumer attitudes and behaviour towards claims that will build on quantitative research completed in 2002[89]and preliminary qualitative research on consumers' use of nutrition claims and food type dietary supplements completed by FSANZ in 2003.[90]

Information will be required on consumers' knowledge, use and understanding of nutrition and health claims, the perceived clarity and trustworthiness of claims, and consumer expectations of products carrying claims. Information received from stakeholder submissions in response to this Initial Assessment Report and the subsequent Draft Assessment Report will be considered in the development of future consumer research. Preliminary qualitative research by FSANZ indicates that consumers do tend to verify content claims on different products, including those made on the food type dietary supplement, by checking the nutrition information panel. This issue that can be validated in a quantitative survey by assessing the connection consumers make between the claim on a food label and information given in the nutrition information panel.

Follow-up consumer surveys will be needed at least two years from the date of implementation of the nutrition, health and related claims Standard to evaluate its impact on consumers.

Phase 4: Ongoing monitoring: from the baseline research, an ongoing label monitoring project could be jointly developed by FSANZ and jurisdictions that tracks the information given on food labels and in advertising in general but with a specific component to assess the use of nutrition, health and related claims.

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[89] Food Standards Australia New Zealand 2003, Food Labelling Issues: Quantitative Research with Consumers. Evaluation Report Series No. 4, [online]. Available at: <http://www.foodstandards.gov.au/mediareleasespublications/publications/foodlabellingissuesquantitativeresearchconsumersjune2003/index.cfm>.

[90] Food Standards Australia New Zealand 2003, *Food Labelling Issues: Qualitative Consumer Study related to Food-Type Dietary Supplement Labelling*, Evaluation Report Series No. 6, [online]. Available at: <http://www.foodstandards.gov.au/mediareleasespublications/publications/consumerstudyrelatedtofoodtypedietarysupplementlabellingjuly2003/index.cfm> and Food Standards Australia New Zealand 2003, *Food Labelling Issues: Qualitative Consumer Study Related to Nutrition Content Claims on Food Labels*, Evaluation Report Series No. 5, [online]. Available at: <http://www.foodstandards.gov.au/mediareleasespublications/publications/consumerstudyrelatedtonutritioncontentclaimsjuly2003/index.cfm> [23 January 2004].

Findings from the baseline survey undertaken before new regulatory measures are implemented, may help jurisdictions identify key areas for surveillance after implementation of the new Standard. In this way, enforcement activities can be prioritised with scarce resources targeted to the main problem areas. The benchmark information will also be valuable to FSANZ to feed into development of the nutrition, health and related claims Standard. The final reports from each period of reporting could form the basis of the requirements for the Implementation Sub-Committee to report on the use of nutrition, health and related claims on a periodic basis to Food Regulation Standing Committee.

9. Regulatory options

There are three regulatory options from which to choose – maintain the status quo; develop a new Standard and Guidelines for nutrition, health and related claims; and develop a new Standard for nutrition, health and related claims.

9.1 Option 1: Maintain the status quo

Under this option:

- The prohibition on health claims under Standard 1.1A.2 would be retained except where approval has been granted in the Standard for a pilot health claim regarding maternal folate consumption and a reduced risk of foetal neural tube defects. This pilot claim will not be permitted after 13 February 2006 unless an extension is agreed to.
- CoPoNC would be retained.
- Specific nutrition content claims in Standard 1.2.8 and a small number of related claims in certain commodity standards, such as those which regulate electrolyte drinks and formulated supplementary sports foods, would be retained.

9.2 Option 2: Develop a new Standard and Guideline(s)[91] for nutrition, health and related claims

This option relates to 'Approach One' to implementation as described in subsection 7.1. FSANZ would develop a new Standard which would allow food manufacturers to make nutrition, health and related claims on food products providing they meet specific conditions and are fully substantiated.

In relation to high level claims:

- a list of pre-approved claims including criteria and conditions regarding the application of the claim would be included in the Standard; and
- additional interpretive userguides would be developed to facilitate understanding of the requirements in the Standard including the process for seeking pre-approval of high level claims and review mechanisms.

In relation to general level claims:

- claim prerequisites would be included in the Standard; and

[91] A Guideline is an alternative to a food standard. It is not legally binding and is not legally enforceable. Refer to the following footnote for further information.

- criteria and conditions (other than certain claims specified in the Code) would be included in a Guideline document. [92]

9.3 Option 3: Develop a new Standard for nutrition, health and related claims

This option relates to 'Approach Two' to implementation as described in subsection 7.2. FSANZ would develop a new Standard which would allow food manufacturers to make nutrition, health and related claims on food products providing they meet specific conditions and are fully substantiated.

In relation to high level claims:

- a list of pre-approved claims including criteria and conditions regarding the application of the claim would be included in the Standard; and
- additional interpretive userguides would be developed to facilitate understanding of the requirements in the Standard including the process for seeking pre-approval of high level claims and review mechanisms.

In relation to general level claims:

- all criteria and conditions would be included in the Standard; and
- additional interpretive userguides would be developed to facilitate understanding of the requirements in the Standard and application of the substantiation framework.

10. Impact analysis

FSANZ requires further information in order to present a complete impact analysis of the current arrangements and options to facilitate development of a Standard for nutrition, health and related claims. However, the following discussion has been drawn from information presented in the impact analysis for Proposal P234,[93] The Allen Consulting Group's cost benefit analysis on regulatory options for nutrient content and related claims[94] and from the impact analysis for Proposal P153.[95]

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[92] Food standards are, themselves, not legally enforceable. Standards acquire legal force through their incorporation by reference into State and Territory food legislation, into New Zealand food standards, and via the operation of the Commonwealth *Imported Food Control Act 1992*. Unlike food Standards, codes of practice and other documents (such as guidelines) developed and approved by FSANZ are not incorporated into food legislation. The FSANZ Act contains no relevant power to directly compel compliance with codes of practice and other documents, unlike some other legislative schemes which contain mechanisms by which such documents may be rendered mandatory. This issue cannot be addressed by incorporating a code of practice or guideline as amended from time to time into a Standard by reference. In the case of a guideline, this would have the effect of enabling a Standard to be changed via amendments to the guideline, rather than through the statutory process for amending a Standard, which would be inconsistent with the current provisions of the FSANZ Act. Accordingly, a guideline is not a legally enforceable document.

[93] Australia New Zealand Food Authority 2001, Issues Paper for Proposal P234 Review of Nutrient Content and Other Related Claims, available at <http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp234 reviewofnutrientcontent/index.cfm>.

[94] The Allen Consulting Group 2001, *Nutrient Content and Related Claims – Evaluating the Regulatory Options*.

[95] Australia New Zealand Food Authority 2001, Inquiry Report for Proposal P153, Review of Health and Related Claims, available at: <http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp153 healthandrelatedclaims/index.cfm>.

In order to progress the impact analysis for this Proposal (P293), FSANZ seeks further information from the general public, and particularly from consumers and health professionals, industry and government on the possible impacts. Where possible, please provide data in your response or give examples.

10.1 Consumers and the community

10.1.1 Regulatory Option 1 – Status quo

10.1.1.1 Costs

Certain aspects of the current prohibition are ambiguous. As a consequence, some statements on food labels and in advertising, such as those in relation to certain endorsements and implied claims, which are not in breach of the current prohibition may be seen as inconsistent with the intent of the prohibition.

Questions:

75. Are consumers currently being presented with consistent messages regarding the role of individual foods in improving or maintaining health?
76. If not, what is the extent of any inconsistency and what is the impact on consumers?
77. What is the impact of the general prohibition on health claims on the ability of consumers to make informed choices about foods?

Under the current arrangements it is possible that some consumers may be persuaded to purchase dietary supplements, on which health claims are permitted,[96] in preference to food products which are not permitted to carry such claims.

Questions:

78. Are consumers' choices being distorted towards purchasing dietary supplements in preference to food not carrying health claims? Is so, to what extent is this occurring?
79. What, if any, are the impacts on consumers of choosing to purchase dietary supplements over food?

The majority of content claims in Australia are regulated by the industry-led CoPoNC, while in New Zealand they are regulated under fair trading law. CoPoNC cannot impose legal obligations on industry and has no formal status in New Zealand. As a consequence, in Australia there are a number of content claims being made on food labels that do not comply with criteria specified in the CoPoNC.

A recent study found that the level of non-compliance with criteria specified in CoPoNC was 14.8 per cent while the level of non-compliance with the Code was 13.3 per cent.[97] Non-compliance with CoPoNC may lead to confusion or misinformation about food products.

[96] Therapeutic Claims are prohibited in relation to dietary supplements. However, it should be noted that the definition of therapeutic claims under the regulations may capture some, but not all, health claims – see Regulation 11 of the Dietary Supplements Regulations 1985 (NZ).

[97] Williams, P et al 2003, 'Nutrition and Related Claims used on Packaged Australian Foods – Implications for Regulation', *Asia Pacific Journal of Clinical Nutrition* 12(2): 138–150.

Additionally, CoPoNC has not been comprehensively reviewed since its inception in 1995[98] and hence consumers may not be provided with the most accurate and up-to-date information.

Question:

80. Are consumers in Australia confused or misled by current nutrition content claims? If so, to what extent is this occurring?

New Zealand fair trading legislation contains general provisions concerning false and misleading conduct that may be used to address issues with certain content claims. However, other than a small number of content claims regulated in the Code, there are no specific criteria for making other content claims in New Zealand.

Question:

81. Are consumers in New Zealand confused or misled by the absence of specified criteria for making content claims? If so, to what extent is this occurring?

10.1.1.2 Benefits

The current prohibition on health claims provides general protection for consumers against false and misleading claims.

Although CoPoNC in Australia is not legally binding, it does provide a framework for industry to make content claims and some guidance for consumers in decision making.

Question:

82. To what extent has the CoPoNC been effective in providing a framework to facilitate informed consumer choice?

In both Australia and New Zealand, there is an established mechanism by which consumers can seek redress against claims which are inconsistent with fair trading laws.

10.1.2 Regulatory Option 2 – Standard and Guideline

10.1.2.1 Costs

Industry may pass on some of the costs of making claims on food labels to consumers.

Question:

83. In what circumstances would consumers be prepared to pay higher prices for foods carrying claims?

[98] Whilst a limited review of CoPoNC was undertaken with subsequent recommendations made to the (then) ANZFA Board (February 1998), these recommendations were not supported because inadequate analysis had been carried out and were not clearly linked to the supporting policy principles of CoPoNC.

Consumers choosing a number of products on the basis of their claimed nutrition and health value, may be at risk of believing that a diet comprised of such products is healthy and good for them. These consumers are at risk of losing a whole-of-diet perspective on their food purchases.

Questions:

84. Under Option 2, is there a risk of consumers losing a whole of diet perspective when choosing food?

85. To what extent could this risk be addressed through education and the efforts of health professionals?

Similar to the status quo option, under Option 2 the criteria for making content and other general level claims would be included in a Guideline and would not be legally enforceable. Under Option 2, there would be permission for a greater range of claims. It would be possible for a manufacturer to comply with the requirements in the Standard and not necessarily comply with the recommended criteria in relation to content and other general level claims set out in the Guideline.

Question:

86. Under Option 2, what would be the impacts on consumers of including a greater range of claims in a Guideline, which is not legally enforceable?

10.1.2.2 Benefits

Under Option 2, health claims would be permitted and consumers should have an increased range of information upon which to base informed choices about individual foods and specific health benefits. Option 2 should facilitate development of functional type foods which should increase the variety of foods carrying health claims to consumers.

Question:

87. To what extent would consumers use additional information presented in health claims and in what circumstances would this be of benefit to them?

Although the criteria for making content and other general level claims would not be legally enforceable if set out in a Guideline, consumers should have a certain degree of assurance that there is a system to facilitate consistency in the representation of such claims. Consumers in New Zealand in addition to Australia would be able to refer to the criteria around content and other general level claims in the Guideline, which is not possible under Option 1.

10.1.3 Regulatory Option 3 - Standard

10.1.3.1 Costs

Industry may pass on some of the costs of making claims to consumers.

Question:

88. Under what circumstances would consumers be prepared to pay higher prices for foods carrying claims?

Consumers choosing a number of products on the basis of their claimed nutrition and health value, may be at risk of believing that a diet comprised of such products is healthy and good for them. These consumers are at risk of losing a whole-of-diet perspective on their food purchases.

Questions:

89. Under Option 3, is there a risk of consumers losing a whole of diet perspective when choosing food?

90. To what extent can this risk be addressed through education and the efforts of health professionals?

10.1.3.2 Benefits

Under Option 3, consumers would have access to an expanded choice of food products with health claims, and the benefits that have been identified under Option 2 would apply.

Given that both high level claims and general level claims would be regulated in the Standard, and therefore the requirements associated with such claims would be legally enforceable, consumers in both Australia and New Zealand may have greater assurance that all claims are reliable, substantiated and not misleading.

Question:

91. Does Option 3 provide greater benefits to consumers than Option 2 in relation to the reliability and validity of general level claims? If so, why?

10.2 Industry

10.2.1 Regulatory Option 1 – Status quo

10.2.1.1 Costs

Certain aspects of the current prohibition on health claims are ambiguous and hence some manufacturers make statements on some food labels and in advertising which are implied health claims. These are not technically in breach of the current prohibition though they may be seen as being inconsistent with the intent of the prohibition. This results in inconsistency in applying the Standard within industry, so that some manufacturers may gain a market advantage over those that do not make claims in accordance with their interpretation of the prohibition.

Question:

92. To what extent, if any, has your business been disadvantaged by the current ambiguities regarding the prohibition on health claims?

The current prohibition on health and related claims may also act as a disincentive for innovation in the food industry, as newly developed products are not able to be marketed using health claims.

Question:

93. To what extent does the current prohibition on health claims prevent real marketing opportunities for your products or limit innovation?

A further impact of the prohibition on health and related claims on the food industry is the requirement for some imported foods to be relabelled due to inconsistencies between domestic and international regulations regarding health claims. This does not apply, however, to food type dietary supplements imported into Australia from New Zealand. Under the Trans-Tasman Mutual Recognition Arrangement, products lawfully manufactured and labelled in New Zealand in accordance with the Dietary Supplements Regulations (other than products considered to be therapeutic goods) can be legally sold in Australia. While these regulations do not permit therapeutic claims to be made in relation to dietary supplements, some health claims may be made.

Question:

94. To what extent, if any, is the Australian food industry disadvantaged by being unable to make health claims on products that compete with imports?

As outlined above for the Australian food industry, CoPoNC provisions are not legally enforceable. This situation may lead to uncertainty and inequality for industry, as those manufacturers making claims that are not compliant with CoPoNC, may gain a market advantage over those that do comply.

Question:

95. In Australia, how effective is CoPoNC in providing guidance to industry on content claims and does the fact that it is not legally enforceable create compliance problems?

Under Option 1, New Zealand industry may be disadvantaged by not having a guideline, which provides criteria around the use and representation of content claims.

Question:

96. In New Zealand, are there any costs to industry from a general reliance on fair trading provisions to manage content claims? If so, please identify these costs.

10.2.1.2 Benefits

One of the benefits of CoPoNC for Australian industry is that it provides an established framework for making content claims in respect of food products.

Question:

97. How effective is the Code of Practice on Nutrient Claims in Food Labels and in Advertisements in providing guidance to industry in marketing current products and developing new products?

A further potential benefit of CoPoNC is that it provides greater flexibility in terms of amending the provisions relating to permitted content claims and criteria, although it is noted that no amendments have been made to CoPoNC since its inception in 1995.
Regulatory Option 2- Standard and Guideline

10.2.2.1 Costs

While under Option 2, industry in Australia and New Zealand would be permitted to make high level claims (which are not currently permitted) there would be costs to industry arising from this permission. Initially, industry would only be permitted to make claims that FSANZ has pre-approved during the standard development process. This may limit the ability of industry to harness new marketing opportunities. Furthermore, industry will bear the cost of seeking FSANZ pre-market assessment and approval of high level claims which are not pre-approved during the Standard development process, through costs associated with making application to amend the Code (although these costs may be passed on to consumers).

Question:

98. Can industry indicate the nature and extent of compliance costs that could be incurred under Option 2?

As the criteria for making general level claims would not be legally enforceable, there may be greater potential for non-compliance. Those manufacturers, including importers, that make claims yet choose not to comply with the provisions in the Guideline could potentially gain a market advantage over those that do comply.

Under Option 2, industry in Australia and New Zealand would be responsible for assessing and compiling evidence to substantiate general level claims (including content claims). This would require industry to establish systems for gathering, assessing, compiling and holding evidence. These costs do not apply under Option 1 and may ultimately be passed on to consumers.

Question:

99. Can industry indicate the probable cost of complying with the need to develop systems to compile and assess evidence to substantiate general level claims?

It is yet to be determined what involvement industry might have in maintaining a Guideline on content and other general level claims required under Option 2. However, there may be costs to industry in maintaining and/or administering such a Guideline and in educating industry members regarding the new requirements.

10.2.2.2 Benefits

The significant benefit under Option 2 for industry would be the ability to make high level claims and take advantage of marketing opportunities leading to potential increases in sales revenue arising from using such claims. This is currently not possible under Option 1, with the exception of those manufacturers in Australia and New Zealand making use of the permitted folate claim.

Another benefit of this option is that it could potentially have a positive impact on scientific research as industry may provide more funding for research because of the potential to make health claims.

Question:

100. What would be the impact on your business arising from a permission to use high level claims? In your response consider marketing opportunities and potential sales revenue.

The inclusion of criteria in a Guideline would provide specific guidance for industry when making content and other general level claims on their products and would consolidate all general level claims criteria into the one document. There are potential benefits for New Zealand industry which does not currently have criteria or guidance.

Additionally, it is expected that industry would have access to a wider range of claims than those currently available under CoPoNC and the Code. This may result in increased marketing opportunities leading to potential increases in sales revenue not fully realised under Option 1.

Question:

101. What would be the impact on your business arising from permission to use a greater range of general level claims? In your response, consider marketing opportunities and potential sales revenue.

10.2.3 Regulatory Option 3 - Standard

10.2.3.1 Costs

The compliance costs under Option 3 would be the same as under Option 2.

In terms of general level claims, full regulation would lead to reduced flexibility when seeking amendments to criteria and/or conditions, which may also lead to opportunity costs for industry. As a consequence, some new products may not be developed.

10.2.3.2 Benefits

The benefit to industry of being able to make high level health claims under this option is the same as under Option 2.

It is likely that the full regulation of general level claims would have specific benefits for the food industry. Inclusion of requirements for general level claims in the Standard would ensure the requirements are legally enforceable. Therefore, Option 3 may potentially provide a higher degree of industry compliance and would ensure regulatory coverage of all food manufacturers and importers of food in Australia and New Zealand.

Question:

102. To what extent, does Option 3 provide greater benefits to your business than Option 2 in relation to general level claims?

10.3 Government

10.3.1 Regulatory Option 1 – Status quo

10.3.1.1 Costs

There are administrative and resource costs for enforcement agencies associated with administering the requirements of Standard 1.1A.2, particularly in those areas where its requirements are ambiguous or incomplete.

10.3.1.2 Benefits

As CoPoNC is a self-regulatory scheme, there would be no costs to government in maintaining and administering the system. Additionally, retention of CoPoNC would be less resource intensive for enforcement agencies as industry is responsible for enforcing and managing complaints. However, where this does not occur, complaints are likely to be forwarded to the relevant enforcement agencies for action (although no legal action can be taken) and there are costs associated with responding to these and liaising with industry.

Question:

103. What are the impacts of the current regulatory arrangements on enforcement agencies? Please provide evidence of the level of resources involved.

10.3.2 Regulatory Option 2 – Standard and Guideline

10.3.2.1 Costs

Enforcement agencies in Australia and New Zealand would be responsible for enforcement of requirements in relation to all high level claims and the costs associated with establishing and ongoing administration of the Implementation Sub-Committee watchdog.

Enforcement agencies in Australia and New Zealand would be responsible for enforcement of general provisions in the Standard in relation to general level claims including assessment of evidence for substantiating claims. Part of this process may include seeking independent scientific advice from the Advisory Panel. These costs do not apply under Option 1.
As the Guideline would not be legally enforceable, Option 2 may not overcome the problems described in Option 1 with respect to lack of enforceability.

Under Option 2, additional general level claims would be permitted and hence additional resources would be needed to enforce the requirements of the standard in relation to substantiation.

10.3.2.2 Benefits

Under Option 2, enforcement agencies would not be needed to resolve ambiguities around the current health claims provisions in Standard 1.1A.2.

Including all criteria and conditions for content and other general level claims in one document (which would have uniform application in Australia and New Zealand) would address issues regarding lack of harmonisation that exists under the status quo option.

10.3.3 Regulatory Option 3 - Standard

10.3.3.1 Costs

There are likely to be greater costs to enforcement agencies associated with enforcing a wider range of high level claims and incorporating all general level claims in a new Standard.

Question:

104. To what extent would Options 2 and 3, that permit a wider range of claims, require additional resources to enforce?

10.3.3.2 Benefits

In relation to high level claims, enforcement agencies would not be required to resolve ambiguities around the current Standard.

Question:

105. Are there any additional benefits for government in proceeding with Option 3? If so, please identify.

10.4 Submitter's Preferred Regulatory Option

Question:

106. What is your preferred regulatory option and why?

11. Consultation

There is significant public interest in development of the Standard for Nutrition and Health Related Claims on the part of governments, consumers, public health professionals and industry. FSANZ is keen to hear the views of all stakeholders. In order to facilitate this we have developed a comprehensive consultation strategy. The foundation for this is the statutory two-stage public consultation as laid down in the FSANZ Act where interested parties are invited to make written submissions. FSANZ has built extensively on this strategy to provide a range of opportunities for stakeholders to provide further input in a range of fora. The aim of the strategy is to provide information and seek feedback on the Standard development work from as broad a range of stakeholders as is feasible.

11.1 Advisory Groups

FSANZ has convened several committees to provide advice on development of the Standard and associated documentation (see Figure 2). The membership of these Advisory Groups and their terms of reference are at Attachment 9.

11.1.1 Standard Development Advisory Committee

The Nutrition and Health Related Claims SDAC has been established under s. 43 of the FSANZ Act to advise FSANZ on development of the Standard and associated Guidelines. Membership is comprised of representatives from industry, consumer groups, governments and public health professionals.

11.1.2 Technical Expert Group

The Technical Expert Group on General Level Claims (TEG) has been convened to advise FSANZ on matters related to general level claims and the criteria and conditions for nutrition content claims. Members have a background in nutrition and/or dietetics.

11.1.3 Scientific Advisory Group

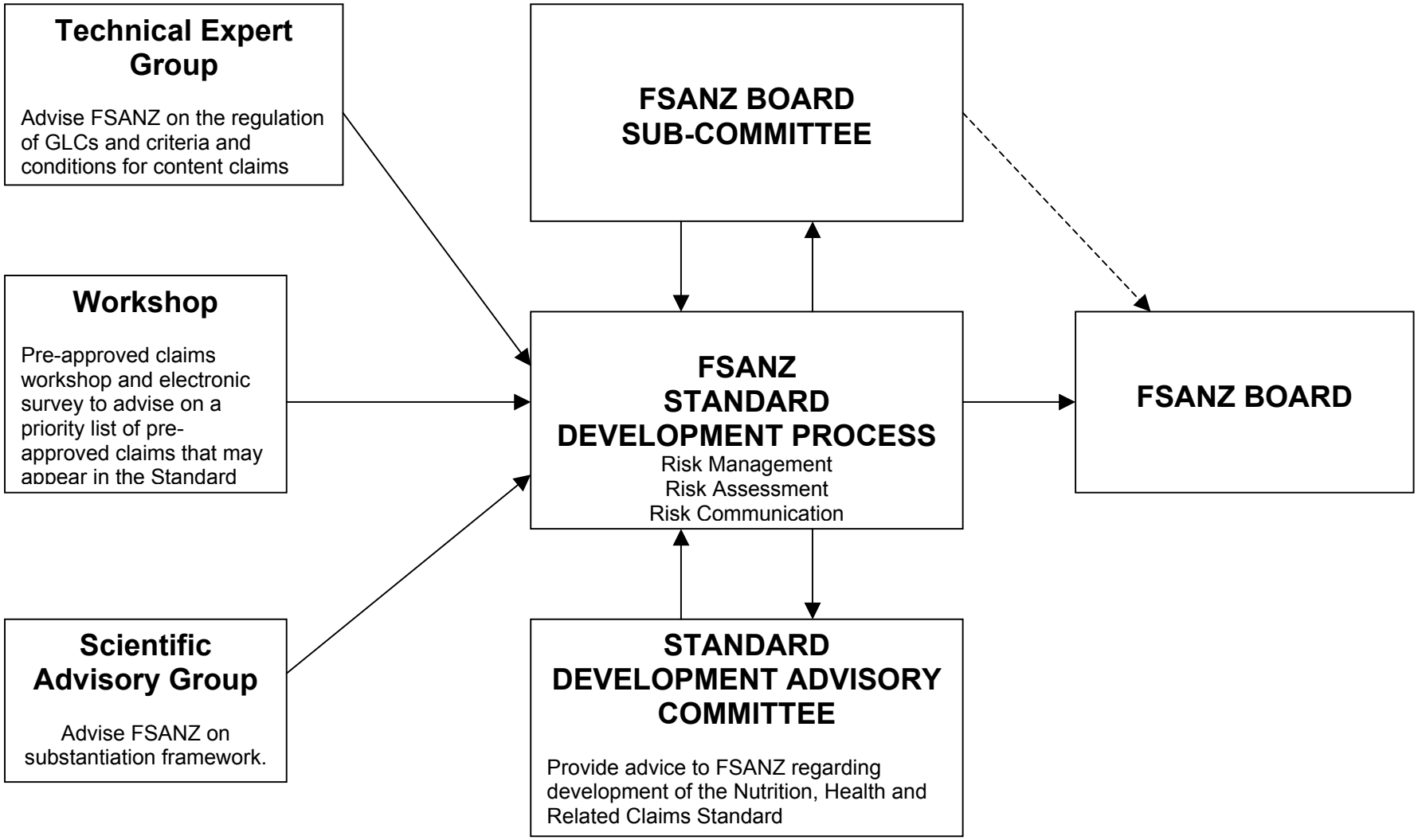
The Scientific Advisory Group has been established to provide advice to FSANZ on the Substantiation Framework for Nutrition, Health and Related Claims. Membership is comprised of experts from a range of relevant scientific disciplines including nutrition and epidemiology.

Establishment of the three FSANZ Advisory Groups described above is a major initiative in ensuring a range of views is canvassed during the standard development process. In addition, there will be a number of other strategies employed to enable stakeholder input.
At the recent SDAC meeting a number of ideas were put forward including:

- making public presentations in several cities in both Australia and New Zealand such as Sydney, Melbourne, Auckland and Wellington. For the second round of public consultation this list may be revised to include other capital cities such as Adelaide and Brisbane;
- conducting targeted meetings to discuss particular aspects of the Standard (these may be co-hosted by organisations such as the Public Health Association) with stakeholder groups such as public health, consumer groups, enforcement agencies and industry;
- providing presenters at forums or meetings such as New Zealand Institute of Food Science and Technology and the Nutrition Society Conference in Brisbane.

In addition, the SDAC made several suggestions that will be explored and incorporated as appropriate. These include: a number of upcoming events that may be suitable forums at which FSANZ representatives could speak; establishment of an interactive, moderated, web-based discussion group (such as that used previously by organisations like the World Health Organization); and, as part of the consultation–communication interface, proactively engaging specialist health journalists in the media.

Figure 2 : Nutrition, health and related claims advisory and technical groups and their role in advising FSANZ



11.2 World Trade Organization (WTO)

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

There are relevant international standards and amending the Code to allow nutrition, health and related claims is likely to have a significant effect on international trade as:

- there is currently a prohibition in Australia and New Zealand on health related claims;
- nutrition related claims in Australia are managed in an industry Code of Practice which does not apply to food imported into Australia; and
- there are different approaches internationally on how to regulate nutrition, health and related claims.

This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the World Trade Organization Technical Barrier to Trade or Sanitary and Phytosanitary Measure Agreements. This will enable other World Trade Organization member countries to comment on proposed changes to Standards where they may have a significant impact on them.

12. Transitional Issues

Currently, health claims are regulated by Standard 1.1A.2 Transitional Standard – Health Claims. Once a new nutrition, health and related claims Standard is gazetted, the following transitional arrangements would apply in respect of health claims, in the absence of any amendments in this area.

- If Standard 1.2.7 were gazetted on 1 February 2006, Standard 1.1A.2 will cease to have effect on 2 February 2008.
- From 1 February 2006 to 2 February 2008, food may comply with either Standard 1.1A.2 or Standard 1.2.7.
- From 2 February 2008 to 3 February 2009, food is taken to comply with Standard 1.2.7 if it was otherwise compliant with the Code.
- From 4 February 2009, food must comply with Standard 1.2.7.[99]

However, as Standard 1.2.7 is likely to apply not just to health claims, but also to other types of claims such as content claims, these transitional arrangements have an added level of complexity. For other types of claims, the default 12-month transition period under subclause 1(2) of Standard 1.1.1 would apply. That is:

- if Standard 1.2.7 were gazetted on 1 February 2006 then, in respect of claims other than health claims, a food is taken to comply with Standard 1.2.7 until 2 February 2007, if it was otherwise compliant with the Code before Standard 1.2.7 was gazetted.

[99] In accordance with the *Acts Interpretation Act 1901*, where periods of time are prescribed from a given day, these are reckoned exclusive of that day.

This means different transitional arrangements would apply to different parts of Standard 1.2.7. Clearly this has the potential to cause confusion and difficulties for industry, government and consumers. FSANZ suggests that an alternative, uniform transition period be set for Standard 1.2.7 as a whole. Given the subject matter of Standard 1.2.7 is the making of voluntary claims, in contrast to the mandatory labelling requirements set by other standards, FSANZ proposes that a uniform 12-month transitional period apply to Standard 1.2.7. That is:

- if Standard 1.2.7 were gazetted on 1 February 2006 then, in respect of all claim types covered by the Standard, a food is taken to comply with it until 2 February 2007, if it was otherwise compliant with the Code before Standard 1.2.7 was gazetted.

Question:

107. Are there any reasons why the proposed transitional arrangements should be shortened, lengthened or otherwise changed?

If this proposal results in changes to other Standards in the Code, FSANZ will need to consider what transitional arrangements should apply – particularly whether the 12-month default transitional period or another period will be appropriate. The nature of any changes will be crucial to such considerations.

In addition, the CoPoNC in Australia may be superseded by the nutrition, health and related claims Standard and other measures developed by FSANZ. If this is the case, to avoid confusion it would seem advisable that CoPoNC is updated or withdrawn, as appropriate, following commencement of Standard 1.2.7.

13. Conclusion

FSANZ has taken a number of steps during the Initial Assessment phase of this Proposal to facilitate development of the Standard for nutrition, health and related claims and other elements of the regulatory framework, having regard to the Ministerial Council's Policy Guideline on Nutrition, Health and Related Claims. Significant among these steps has been development of the Substantiation Framework and the FSANZ Conceptual Framework and consultation on the priority list for pre-approved high level claims. Development of these steps has been assisted by advice from several committees, which FSANZ has convened namely the Standards Development Advisory Committee, the Technical Expert Group on General Level Claims and the Scientific Advisory Group.

This paper discusses a range of issues in relation to nutrition, health and related claims. FSANZ seeks comment on these issues from all sectors of the community including consumers, industry, health professionals and government.

Submissions to this Initial Assessment will be used to further develop Proposal P293, including preparation of draft food regulatory measures, which will be circulated for a second round of public comment in the Draft Assessment Report. It is likely that the Draft Assessment Report will be available for comment in May 2005.

Information regarding how to make a submission to Proposal P293 is included in the section 'Invitation for Public Submissions' on page 3 of this report.

14. Review

The Policy Guideline states:

> A review of the health, nutrition and related claims system should be undertaken within two years of implementation of the Standard. The review should take particular note of the effectiveness of the 'watchdog' body and its ongoing role (if any), the Advisory Panel and overall compliance of industry.

Questions:

108. While the Policy Guideline points to an assessment of the effectiveness of the 'watchdog' body, what aspects of the system for regulating nutrition, health and related claims should be a priority for review within two years of implementing the Standard?

109. Noting that the focus of the review is on implementation, compliance and enforcement under the health, nutrition and related claims system, who should be involved in conducting such a review and how might this be undertaken?

ATTACHMENTS

1 The Australia New Zealand Food Regulation Ministerial Council Policy Guideline on Nutrition, Health and Related Claims

2A Standard 1.1A2, Transitional Standard - Health Claims

2B Standard 1.2.8, Nutrition Information Requirements

3 FSANZ Claims Descriptors Summary Table of Relevant Definitions

4 The Substantiation Framework for Nutrition, Health and Related Claims

5 International Regulations

6 Criteria and Conditions for Content Claims

7 National Centre of Excellence in Functional Foods Report

8 Therapeutics and Food – A Comparison of the Australian Regulatory System for Complementary Medicines and Foods

9 FSANZ Advisory Groups: Membership and Terms of Reference