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)

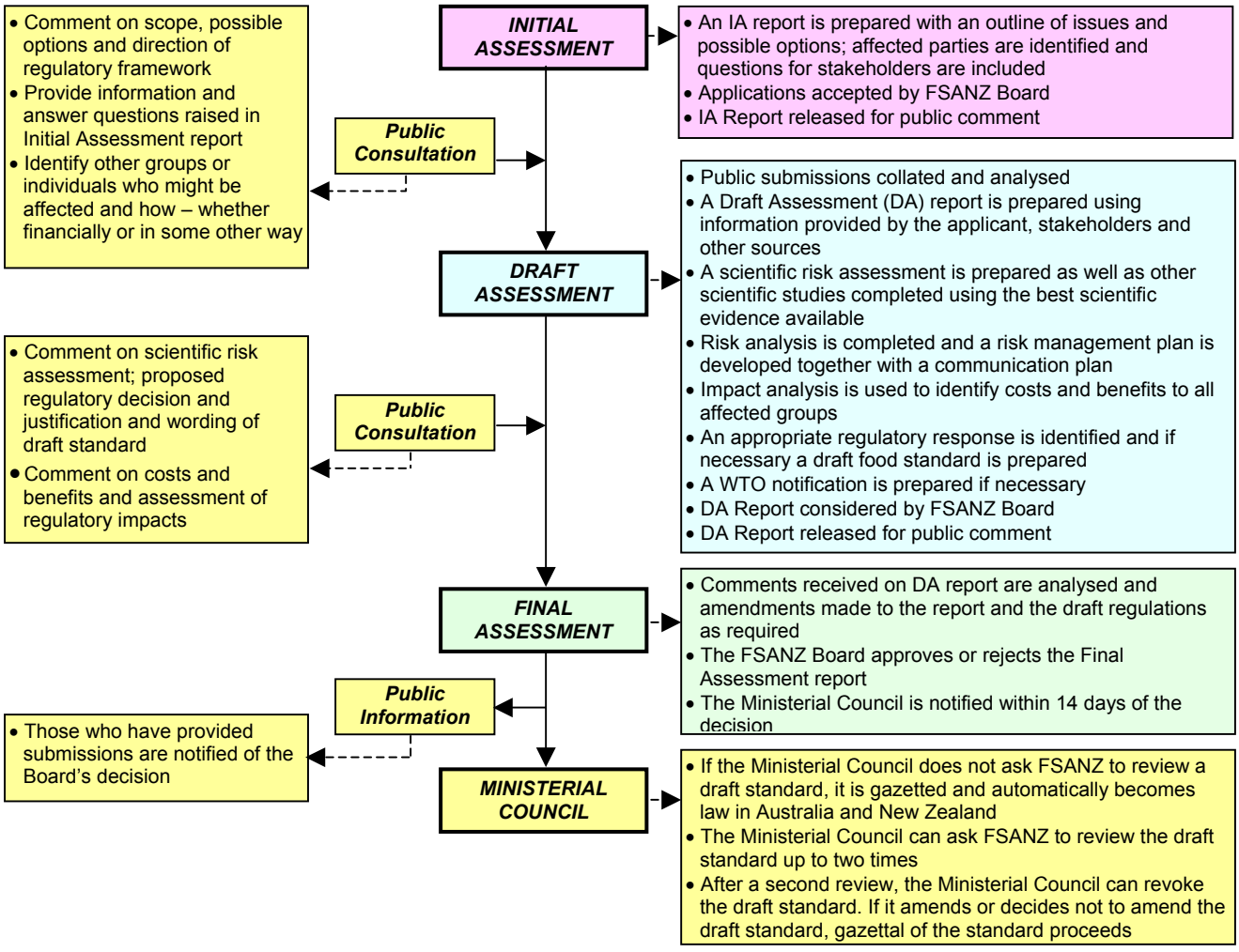
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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.

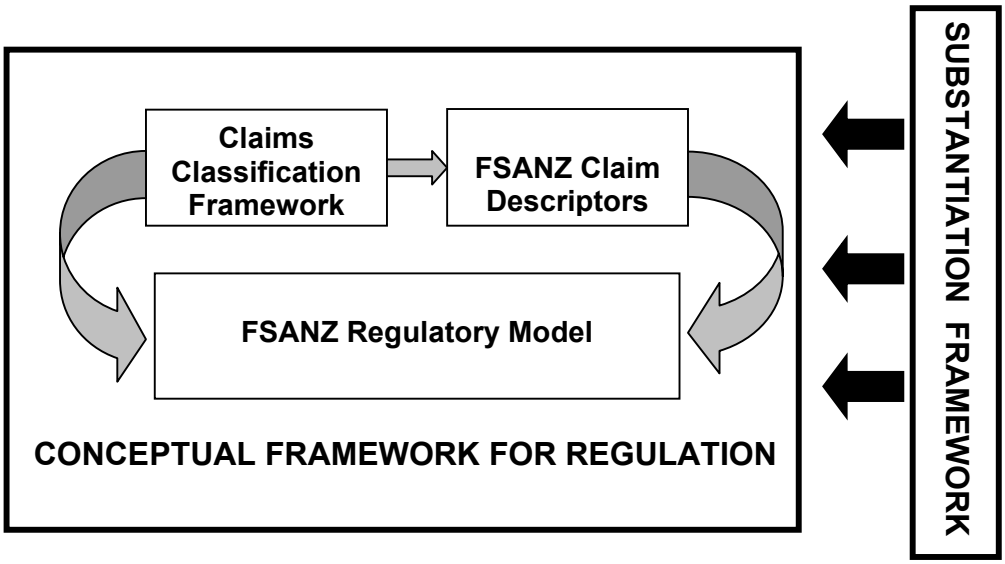
FSANZ Conceptual Framework

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.

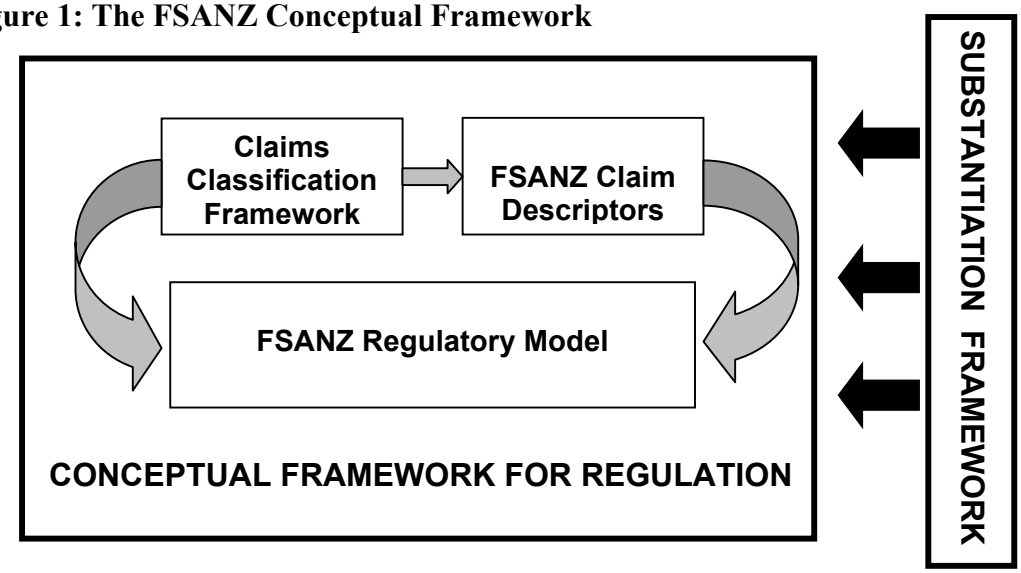
The FSANZ Regulatory Model for Nutrition, Health and Related Claims (FSANZ Regulatory Model) draws together the concepts in the Claims Classification Framework and the FSANZ Claim Descriptors in order to describe the means by which the different categories of claims could be regulated.

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.

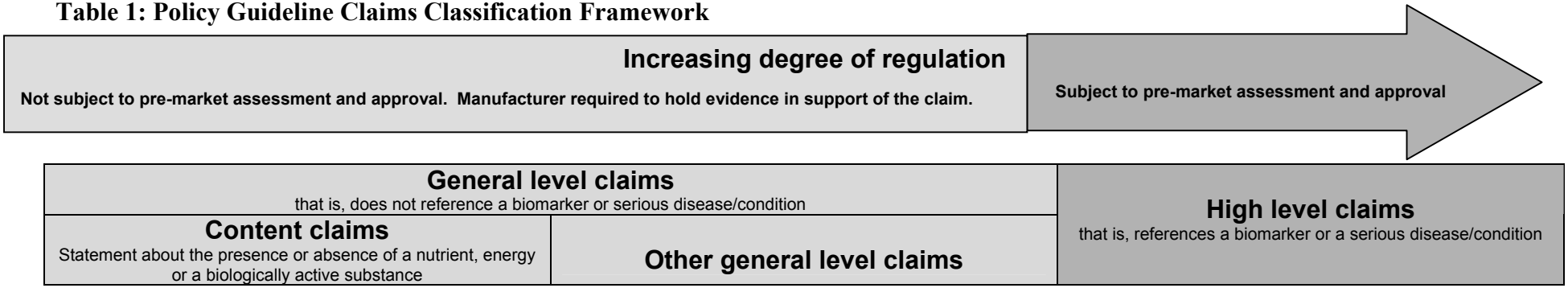
Table 1 outlines FSANZ's interpretation of the Claims Classification Framework, based on the two broad categories of claims: general level claims and high level claims. In addition, using examples provided in the Policy Guideline, FSANZ has identified several sub-categories of claims which fall into 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

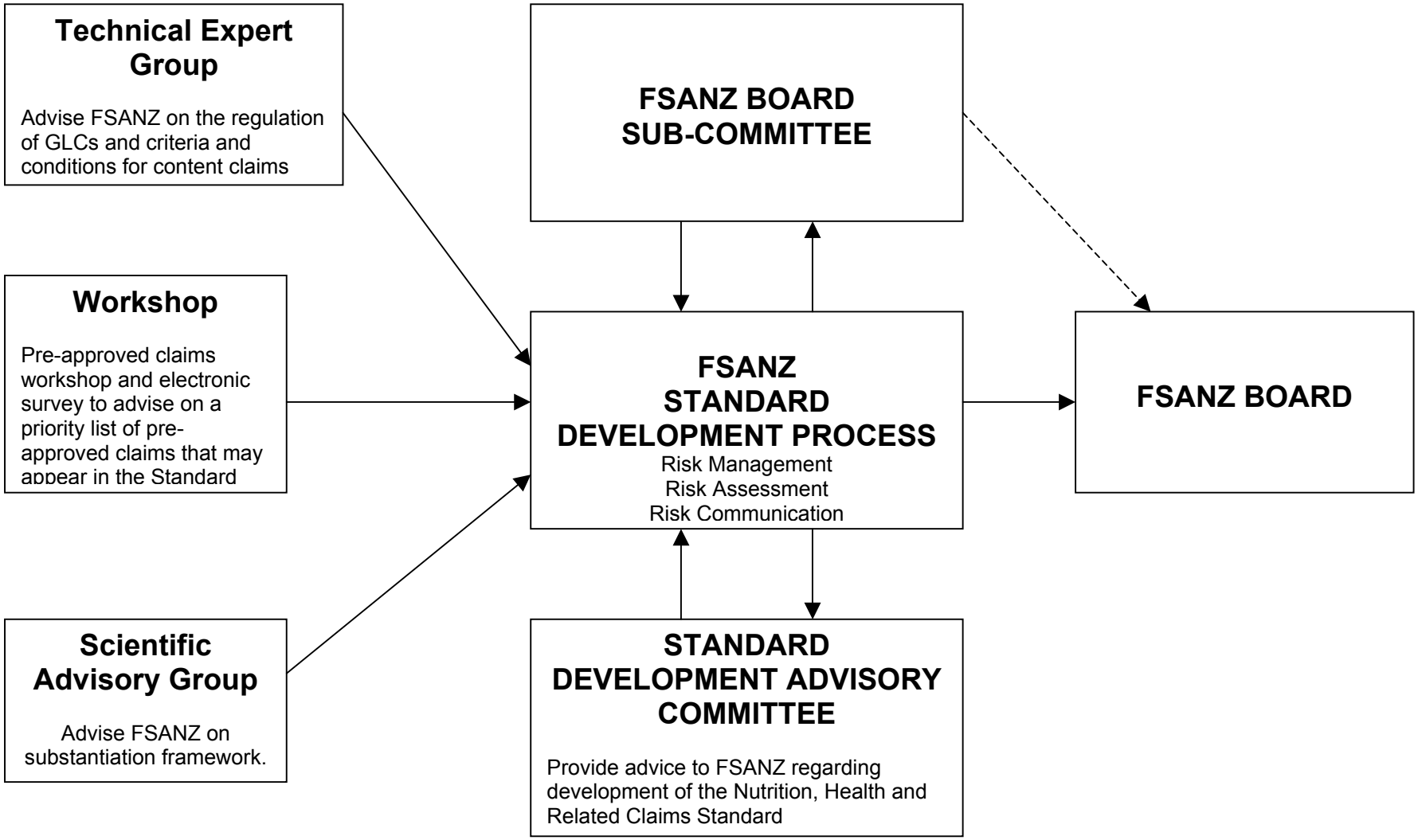
The Scientific Advisory Group has been established to provide advice to FSANZ on the Substantiation Framework for Nutrition, Health and Related Claims. Membership is comprised of experts from a range of relevant scientific disciplines including nutrition and epidemiology.

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

ATTACHMENT 1

AUSTRALIA AND NEW ZEALAND FOOD REGULATION MINISTERIAL COUNCIL POLICY GUIDELINE PROPOSAL ON NUTRITION, HEALTH AND RELATED CLAIMS

POLICY PRINCIPLES

The policy principles endorsed by Australian New Zealand Food Regulation Ministerial Council (ANZFRMC) for nutrition, health and related claims for food 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 following features of any regulatory system for health, nutrition and related claims are also considered desirable. 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.

CLAIM PRE-REQUISITES

Every health claim made must comply with the following, overarching policy principles, regardless of their claim classification level.

The overarching policy principles are:

1. Claims can be made providing. the food and/or component is safe for consumption in recommended quantities as part of the total diet;
   - all requirements contained in Food Standards in the Australia New Zealand Food Standards Code are met;
   - the claims have been scientifically substantiated;
   - there is enough of the specified component to achieve the claimed benefit when consumed as directed;
   - the eligibility criteria, including qualifying and/or disqualifying criteria (and any excluded categories of foods, such as alcohol and infant foods), are complied with;
   - the claim is socially responsible and does not promote irresponsible food consumption patterns.
2. Except where permitted by the Food Standards Code, claims that a food or 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 are not permitted (eg. eating this food protects you from getting 'Q' disease).
3. Claims that a food or component:
   - influences performance and wellbeing;
   - manages, influences, inhibits, or modifies a physiological process;
   - reduces the risk of a disease, condition, ailment, defect, or injury;

   may only be made in the context of the appropriate total diet (that must be described) *(eg. This food is high in 'S' that may help reduce your risk of 'G' disease. People with 'G' disease should eat a varied diet low in 'A' & 'B' and high in 'S', 'X' & 'Y'. Eg. This food contains 'X' which may improve 'Y' when eaten as part of a varied diet low in 'A' & 'B' and high in 'X' & 'C').*
4. Claims about a food or component can describe a health benefit for the population but must not:
   - imply or state a universal or guaranteed benefit for all individuals, except where permitted by the Australia New Zealand Food Standards Code;
   - imply or state a health benefit for the population if the claimed benefit applies only to a particular subgroup of the population, unless the population subgroup is stated;
   - lead a consumer to self-diagnose or self-manage a condition or disease that should be medically diagnosed and/or managed;
   - encourage over-consumption of single foods or ingredients;
   - state or imply that a healthy diet is reliant on the inclusion of a single food;
   - arouse unwarranted and/or unrealistic expectations of the benefit to the individual;
   - be alarmist. That is they cannot:

- contain language that could bring about fear or distress;
- lead the consumer to believe that they are suffering from a serious ailment or disease;
- lead the consumer to believe that harmful consequences may result if they do not consume the particular product.

5. A claimed benefit must be:

. achievable when the food is consumed in quantities which can reasonably be expected to be consumed daily as part of an appropriate total diet;

. derived from the food or component in question for which the claim is made and not from consuming the food with a combination of specific foods.

6. Claims must communicate a specific rather than a broad benefit. (Eg. improves recovery from exercise rather than improves sport performance)7. Claims that refer to: . a disease, condition, ailment, defect or injury should include a statement explaining how the claimed benefit is achieved. (Eg. high in 'Z', diets high in 'Z' do X which may reduce the risk of 'G' disease);

. the dietary management of a biomarker, condition or disease that may require the supervision of an appropriate health care practitioner, must have an advisory statement to the effect that a health care practitioner's advice is required.

8. Where advisory or warning statements in relation to the claim are required, they must appear in close proximity to the claim in the same communication medium8. Where the information about the claim is separated into sections (split claim) the first part of the claim must direct the reader to further information provided elsewhere in the same communication medium10. In 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 category11. Endorsement Programs that state or imply a nutrition, health, or related claim must comply with these principles and the requirements of the relevant category of claim. They will require a statement to explain why the endorsement has been granted (eg. meets nutrient criteria required by the endorsement program)12. Marketing activities that promote charities or non profit organisations (ie. cause-related marketing programs) that relate to disease or health must have a disclaiming statement to ensure they are not interpreted as a nutrition, health or related claim13. Communication to health professionals of a nutrition, health, or related claim about specific food products or food types (eg. milk, meat etc) must comply with these principles and the requirements of the relevant category of claim

CLAIMS CLASSIFICATION CRITERIA

The claims classification framework sets out criteria for two levels of claims: general and high.

The categorisation of a 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.

The level of a claim, as determined by the claims classification framework, will determine to what degree the claim is regulated, including the nature of the evidence required for substantiation. 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 (i.e. not product-by-product) basis. The standard could also include pre-approved 'generic' high level claims which refer to serious diseases or conditions, with consideration given to the Australian Dietary Guidelines or the New Zealand Food & Nutrition Guidelines. Flexibility in wording of claims should be considered, provided the overarching principles and claim pre-requisites are satisfied.

Consideration should be given during the FSANZ standard development process for including the criteria for making each level of claim and any parameters (eg. qualifying and disqualifying criteria, or exclusions for certain categories of food, such as alcohol and baby foods) should be specifically stated in the standard. These parameters will be particularly important to the monitoring and enforcement of nutrient content claims.

General level claims

General level claims are claims where the manufacturer has to make an assessment of the evidence supporting the claim prior to the product going to market, and to hold the evidence (to be produced at the request of enforcement agencies).

General level claims do not reference a serious disease. That is, references to non-serious diseases would be allowed in this category, as would claims that make no reference to a disease at all.

General Level claims are those which:

- describe or indicate the presence or absence of a component in that food (Nutrient Content Claims) *(eg. This food is high in calcium);* or
- refer to maintenance of good health or normal physiological processes (including normal growth and development, or maintenance or other like functions of the human body) (eg. helps keep you regular as part of a high fibre diet). This includes claims that describe the component and its function in the body (eg. Calcium is good for strong bones and teeth); or
- refer to specific benefits for performance and wellbeing in relation to foods (eg. gives you energy); or

. are whole of diet claims based on the Australian Dietary Guidelines or the New Zealand Food & Nutrition Guidelines which may refer to the relevant benefits as described in the associated Australian Dietary Guideline or New Zealand Food & Nutrition Guideline background papers but do not refer to a serious disease or condition (eg. A healthy, balanced diet that includes dietary fibre from a number of sources is one that can help reduce your risk of constipation); or

. describe how a diet, food or component can modify a function or body structure beyond its role in the normal growth, development and maintenance and other like functions of the human body but do not state or imply a serious disease *(eg. exercise and a diet high in calcium and calcium containing foods like product 'X' may help give you stronger bones)*; or. refer to the potential for a food or component to assist in reducing the risk of or helping to control a non-serious disease or condition (*eg. Yoghurt high in X and Y as part of a healthy diet may reduce your risk of stomach upsets*)

High level claims

High level claims are those claims which make reference to a serious disease, including.
claims that refer to the potential for a food or component to assist in controlling a serious disease or condition (i.e. those referring to risk reduction or a reduction or improvement in health);

Eg. this food is high in X, which as part of a diet low in saturated fat and high in soluble fibre may reduce your risk of heart disease.

. claims that refer to the potential for a food or component to assist in reducing the risk of, or improving a serious disease or condition;

Eg. This food is low in Y which may reduce your risk of having a stroke through Z.

. are whole of diet claims which refer to a serious disease or condition based on the Australian Dietary Guidelines or the New Zealand Food and Nutrition Guidelines which may refer to the relevant benefits as described in the associated Australian Dietary Guideline or New Zealand Food and Nutrition Guideline Background Papers;

Eg. 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.

. biomarker[1] maintenanceclaims;

Eg. This food is high in Y which may help maintain healthy cholesterol levels through Z.
biomarker enhancement claims; and

Eg. This food is low in Y which may reduce your blood pressure through Z.

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biomarker claims that make reference to a serious disease.

Eg. This food is rich in Y. In conjunction with Z, Y helps to maintain your healthy cholesterol levels and can reduce your risk of heart disease.

REGULATORY MODEL

It is recommended that the following arrangements apply to the regulation and monitoring of nutrition, health and related claims:

- the Australia New Zealand Food Standards Code would set out the high order principles of the health claims system, the definitions of general and high level claims, and provide prescriptive, individual detail for high level claims. The standard may also set out qualifying and disqualifying criteria for certain types of claims (eg. nutrient content claims) and categories of foods which may be excluded from making claims (eg. alcohol and baby foods)
- a guideline document would provide the majority of the detail surrounding general level claims. This guideline will be designed to assist industry in utilising the system correctly;
- a 'watchdog' body would serve as the public face of the health claims system, and undertake a number of key tasks.
- Jurisdictions would be responsible for receiving complaints in the usual way. Enforcement of the Health Claims Standard, including assessing possible breaches and undertaking prosecutions, would be the responsibility of the State/Territory and New Zealand enforcement agencies. Enforcement agencies would be responsible for coordinating action across jurisdictions, and informing the 'watchdog' body of complaints received and actions taken, and providing feedback on any perceived problems with the regulation of health claims.

The 'watchdog' would:

- assist FSANZ in the creation and maintenance of the guideline document (in consultation with stakeholders);
- provide recommendations to FRSC regarding proposed amendments to the Standard or the guideline document;
- receive complaints via a mailbox and refer any complaint to the relevant jurisdiction(s) for analysis and enforcement action;
- record complaints received (either directly by the watchdog or jurisdictions), and monitor enforcement actions undertaken by jurisdictions in response to those complaints; and
- provide periodic reports to FRSC.

A schematic representation of the proposed Regulatory Arrangements is provided at page 8 of this guideline.

The newly established Implementation Sub-Committee (ISC) will act as the Health Claims 'watchdog'. ISC consists of an official from the Australian, the New Zealand and each State and Territory Government. ISC will report to FRSC on enforcement and implementation issues and will also require a secretariat.

Consideration needs to be given as to whether these duties should be dealt with as a standing agenda item, or whether special, dedicated meetings should be convened to deal with Health Claims watchdog functions.

It is recommended that the "watchdog" function be funded by jurisdictions on a pro-rata to population basis, similar to the AHMAC model. This would be re-assessed in a review to be undertaken two years after implementation of the standard.

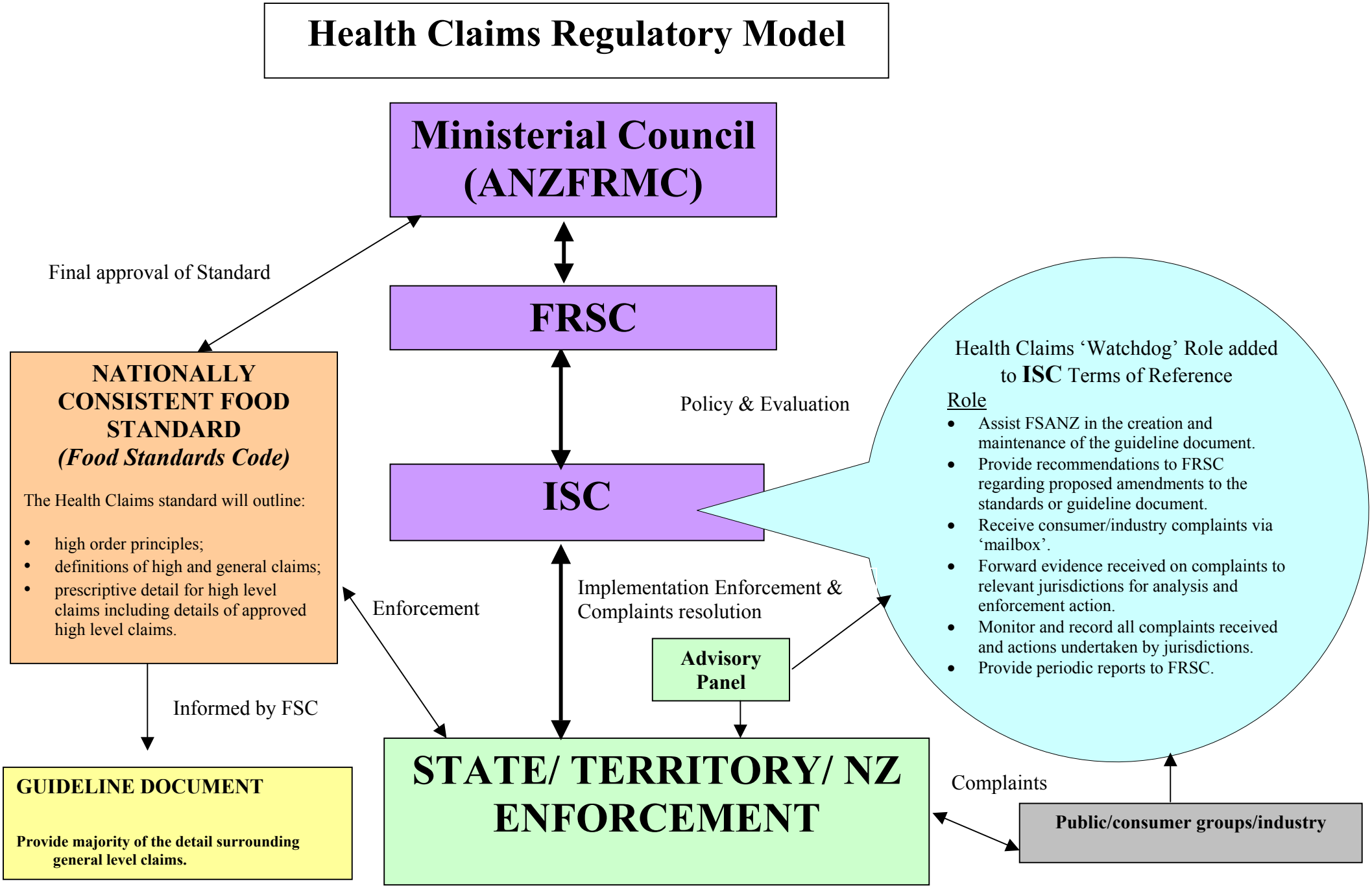
Advisory Panel

The proposed Advisory Panel is a register of independent experts set up under an administrative arrangement. The Advisory Panel would be available to jurisdictions on a cost-recovery basis.

Individual members from this panel would be available to assist enforcement agencies by providing their expert opinions on potential breaches, if requested. This could include advice on the adequacy of supporting evidence that food companies are holding to support their claims. The panel member would provide advice only, as opposed to an enforceable ruling, however they could be asked to assist in prosecution actions if required.

The Advisory Panel would also assist jurisdictions to build an enforcement capacity with regard to health claims during a fixed implementation period.

Health Claims Regulatory Model



SUBSTANTIATION REQUIREMENTS

It is recommended that consideration be given to the following requirements for the type of evidence to be held, and who is required to hold it, for each level of claim.

It is the responsibility of the food manufacturer to refer to the Standard and associated guidelines and make an assessment as to the classification of the claim they wish to use.

For simple nutrient content claims, the manufacturer needs to hold evidence that the product contains the relevant component(s) in the amount(s) being claimed, and to meet any qualifying or disqualifying criteria specified in the standard. For other general level claims, there are two alternative requirements: where the evidence is 'consistently agreed' or where there is 'weight of evidence'.

'Consistently agreed' evidence for a claim refers to the conclusion that there is a sufficient body of sound, relevant scientific evidence that shows consistency across different studies and among different researchers. This body of evidence permits the key determination of whether a change in the dietary intake of the substance will result in an outcome consistent with the claim being made. For 'consistently agreed' evidence the manufacturer is required to hold appropriate scientific evidence of why and where the claim is substantiated, as well as evidence that the product contains an adequate amount of the relevant component(s).

'Weight of evidence' applies when the accepted scientific evidence for the claim outweighs any opposing evidence. Manufacturers will be required to hold this evidence in the form of a dossier consisting of:

. copies of the relevant studies;

. an outline of all the evidence available and a summary evaluation of the totality of evidence;

. together with evidence that the product contains an adequate amount of the relevant component(s).

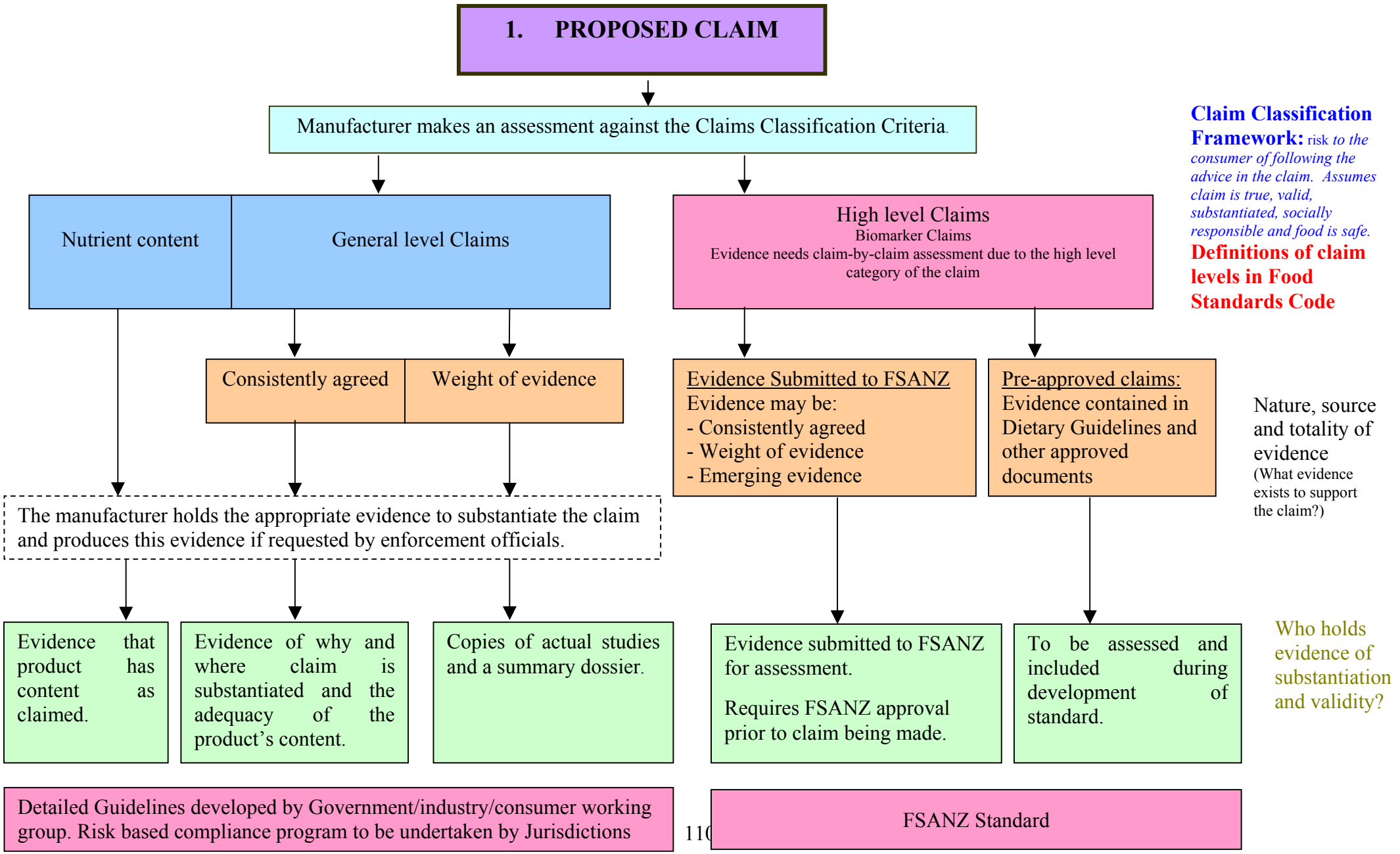
The basic substantiation requirements will be set out in the standard, to ensure that they are enforceable, with links to additional, detailed guidance. The detailed guidance on evidence requirements and maintaining appropriate dossiers will be provided in the guideline document that will be developed by FSANZ in conjunction with ISC and stakeholders. This guideline document will contain reference back to the standard, and will assist industry in complying with the requirements and due diligence. Manufacturers would have an obligation to ensure that the evidence used to make a claim has not changed, and, if further evidence comes to light, to reassess the validity of the health claim. Industry will be required to prepare their dossiers in advance of the claim being submitted to market and must produce this evidence on demand from enforcement agencies.

If a manufacturer wishes to make a high level claim, this will need to be one of the pre-approved claims, unless an application to add a new high level claim to the standard is made to FSANZ.

Pre-approved claims based on dietary guidelines and other approved documents will be assessed during the initial development of the standard so that they are available when it commences.

If a manufacturer wishes to make a **high level claim that has not already been approved**, an application will need to be made to FSANZ. Manufacturers will need to submit supporting evidence with their applications. This may include 'consistently agreed' evidence, 'weight of evidence', or emerging evidence. FSANZ will assess the evidence in accordance with usual statutory FSANZ processes. Approval by FSANZ, notification and acceptance by the Ministerial Council, and subsequent gazettal of variations to the standard will be required before any new high level claims can be made.

Substantiation Requirements Diagram



ADDITIONAL GUIDANCE

To ensure the system protects public health and safety, whilst assisting and encouraging industry the following recommendations are made in relation to additional work to be undertaken:

- **A communication strategy** to educate and inform the food industry about what is expected under the new framework, to reduce the risk of inappropriate claims. This will include a clear strategy for general level claims, as well as guidance on the forms of media captured in the framework (ie internet etc).
- **Compliance and enforcement** to be closely monitored, with claims referring to a biomarker being a particular priority. Jurisdictions will also need to make audits and enforcement a priority, particularly during the introductory period. The Advisory Panel would be available on a user pays basis to jurisdictions needing timely, expert advice. The watchdog body would report to Ministers on the use of biomarker claims and other enforcement issues within 6 months of commencement.
- Further work to be undertaken to provide guidance around the **definitions of 'disease', 'serious disease or condition'** and **'therapeutic claims'**, to include asymptomatic disease and resolve tensions between the TGA and PAG definitions. This will be done in conjunction with the development of the standard.
- Further work is also needed to consider whether **nutrient content claims** can be adequately controlled, monitored and enforced. Consideration should be given whether certain parameters (eg qualifying and disqualifying criteria) (or exclusions for certain categories of food eg. alcohol and infant food) should be specifically stated in the standard. This will be done in conjunction with the development of the standard.
- **Work on pre-approved claims** will be concurrent with the development of the standard. It is envisaged that pre-approved claims based on the National Health and Medical Research Council (NHMRC) Australian Dietary Guidelines or the New Zealand Dietary Guidelines will be considered for inclusion in the Health Claims Standard from its commencement. For the purposes of reviewing the evidence for health claims, FSANZ should look to the NHMRC's recent independent evaluation of nutritional and dietary evidence in developing national dietary guidelines.
- **The standard should not prescribe exact wording** for the pre-approved high level claims. Some flexibility in the wording of claims should be permitted provided there is compliance with the Overarching Principles. 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. Again, it is envisaged that the standard will not prescribe exact wording.
- **The standard should provide sufficient detail to enable enforcement action** to be taken against all breaches, for all levels of claims. However, only the 'high' level category is to include specific pre-approved claims, whilst still allowing for flexibility in wording.
- **The Nutrition, Health and Related Claims Policy Advisory Group should have continued involvement** as an external advisory group to FSANZ during the standard development process.
- Any costs associated with the 'watchdog' function should be funded on a pro-rata basis by jurisdictions. A model similar to the AHMAC model could be used. This will be re-assessed in the review of the system.

- **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.

GLOSSARY OF TERMS

It is recommended that consideration be given to the list of definitions for inclusion in the standard and any other guidelines.

Biomarker: any parameter from which the presence, absence or risk of a disease can be inferred by the level of the parameter (rather than being a measure of the disease itself.)

Claim: a stated or implied nutrition, health or related claim that can be communicated through all mediums including statements, symbols, vignettes, print or electronic media, or other forms of communication and or advertising.

Component: a component of a food includes a nutrient (including phytonutrient), non-nutrient or other ingredients.

Compound claim: a claim containing two or more clauses that can stand independently. The clauses are often linked by a conjunction such as 'and', 'by', 'but' etc.

Conditions or diseases that are medically managed: conditions and diseases in which a health care professional would be expected to prescribe and manage therapeutic treatment and monitor progress.

Dietary management of a disease: the selection of foods or food components to optimise the health of an individual with a specific disease or condition.**Disease:** an unhealthy condition characterised by clinically significant signs or symptoms.

Dosage: a measured quantity administered at any one time or at stated intervals. A statement about dose or dosage would be considered a therapeutic claim and is therefore not permitted on foods. However, a manufacturer is allowed to state the amount of a component in a serving of the food together with the amount required to beconsumed daily to achieve the desired effect. Specified serving sizes should reflect a realistic amount of the food that a person might normally consume. (e*g. a serve contains Xg of the component. Consume Y serves per day, which as part of the appropriate total diet provides the claimed benefit*).**Eligibility criteria:** before a food is permitted to carry a claim, all stipulated eligibility criteria for that food must be met. Eligibility criteria can include qualifying and disqualifying criteria, such as the requirement for the presence and/or absence of components in the food or entire food categories.

Endorsement program: in the commercial sense – an advertising testimonial: an instance of public endorsement of a product for advertising purposes.

Nutrition, health and related claims: include all claims referring to nutrient content, nutrient function, enhanced function, reduction of disease risk or maintenance of normal health.

Serious disease or condition: forms of diseases, conditions, ailments or defects which are generally accepted to be beyond the ability of the average consumer to evaluate accurately and to treat safely without regular supervision by a suitably qualified health care professional.

Socially responsible: meets ethical and moral standards and does not abuse the trust or exploit the lack of knowledge of the general public or contain language which could bring about fear or distress.

Therapeutic claim: a claim outside the context of the total diet that a specific food or food component will prevent, diagnose, cure or alleviate a disease, ailment, defect or injury; or influence, inhibit or modify a physiological process. Therapeutic claims on foods are not permitted under the Nutrition, Health and Related Claims framework, except where expressly permitted in the Food Standards Code. Therapeutic claims may only be made for goods which are regulated by the Therapeutic Goods Administration. A statement about dosage is an implied therapeutic claim and is therefore not permitted on foods.

Whole of diet claims: claims which communicate the appropriate total diet required to achieve the stated benefit.

Attachment 2A

STANDARD 1.1A.2

TRANSITIONAL STANDARD – HEALTH CLAIMS

Purpose

This Standard incorporates clause (19) of Standard A1 of the Australian *Food Standards Code*, and operates as a transitional alternative standard to Standard 1.2.7 for a period of two years from the commencement of Standard 1.2.7. During this time, food must comply with this Standard or Standard 1.2.7 of the Code. After the two-year transition period, Standard 1.2.7 will exclusively apply. 'Stock-in-trade' provisions contained in Standard 1.1.1 should also be referred to, along with Standard 1.2.8 and 1.3.2.

Clauses

(1A) For the matters regulated in this Standard, food must comply with this Standard or Standard 1.2.7, but not a combination of both.

(1B) Subject to clause (1C), this Standard ceases to have effect two years from the commencement of Standard 1.2.7.

(1C) Subclauses (3)(e), (f), (g), (h) and (i) cease to have effect on 13 February 2006.

(2) The label on or attached to a package containing or an advertisement for food shall not contain a claim or statement that the food is a slimming food or has intrinsic weight-reducing properties.

(3) (a) Save where otherwise expressly prescribed by this Code, any label on or attached to a package containing or any advertisement for food shall not include a claim for therapeutic or prophylactic action or a claim described by words of similar import.

(b) Any label on or attached to a package containing or an advertisement for a food shall not include the word 'health' or any word or words of similar import as a part of or in conjunction with the name of the food.

(c) Save where otherwise expressly prescribed by this Code, any label on or attached to a package containing or any advertisement for food shall not contain any word, statement, claim, express or implied, or design that directly or by implication could be interpreted as advice of a medical nature from any person.

(d) Save where otherwise expressly prescribed by this Code, the label on or attached to a package containing or any advertisement for food shall not contain the name of or a reference to any disease or physiological condition.

(e) Subject to subclauses (3)(f), (g) and (h), a food listed in column 1 of the Table to this subclause may have a health claim listed in column 3 of the Table made in respect of that food, provided that the food meets the relevant eligibility criteria in column 2 of the Table.

Table to subclause (3)(e)

Permitted Health Claims

Column 1	Column 2	Column 3
Food	**Eligibility Criteria** **Amounts specified are per each serving as specified in the nutrition information panel**	**Permitted Claim**
PRIMARY FOODS Eggs Eggs Fruit Avocado Grapefruit Orange Legumes McKenzie's Borlotti Beans McKenzie's Cannellini Beans McKenzie's Chick Peas McKenzie's Dried (Whole Green) Peas McKenzie's Green Split Peas McKenzie's Haricot Beans McKenzie's Italian Style Soup Mix McKenzie's Lima Beans McKenzie's Red Kidney Beans McKenzie's Red Split Lentils McKenzie's Soya Beans McKenzie's Whole Green Lentils McKenzie's Yellow Split Peas Mellow Yellow Red Kidney Beans Mellow Yellow Soya Beans Mellow Yellow Chick Peas Sanitarium Red Kidney Beans Nuts Peanuts Vegetables Beetroot Broccoli Brussels Sprouts Cabbage Cauliflower English Spinach Green beans Harvest FreshCuts Vegetable Medley	**Primary foods as defined in Standard 1.3.2** Contains at least 40 micrograms folate **Other foods** Contains at least 40 micrograms folate and not more than – (A) 14 g fat, of which no more than 5 g is saturated fat; (B) 500 mg sodium; and (C) 10 g in total of added sugars and honey.	A claim which states – (a) that increased maternal folate consumption in at least the month before and 3 months following conception may reduce the risk of fetal neural tube defects; and (b) the recommendation that women consume a minimum of 400 micrograms folate per day in at least the month before and at least the first 3 months following conception.

Table to subclause (3)(e)

Permitted Health Claims (continued)

Column 1	Column 2	Column 3
Food	**Eligibility Criteria** **Amounts specified are per each serving as specified in the nutrition information panel**	**Permitted Claim**
Leeks Lettuce Mushrooms Parsnip Sweet corn Watties Garden Peas Watties Baby Peas Watties Choice Cut Green Beans Watties Supersweet Corn Zucchini <u>PROCESSED FOODS</u> <u>Bread</u> Burgen Sunflower Barley and Sunflower Seed Load Burgen High Bake Heritage Rye Burgen High Bake Heritage White Burgen High Bake Heritage Granary Malt Burgen High Bake Heritage Soy and Linseed Burgen High Bake Heritage Wholemeal Burgen Mixed Grain Loaf Burgen Mixed Grain Fruit Loaf Burgen Oat Bran and Honey Loaf Burgen Traditional Rye Loaf Burgen Soy-Lin Loaf Pro-Rol Swiss Maid Tip Top English Muffins Tip Top Holsom's Wholemeal Tip Top Holsom's Wholemeal Toast Tip Top Holsom's Wholemeal with Wheatgerm Tip Top Holsom's Wholemeal with Wheatgerm Toast Tip Top Hyfibe White Tip Top Hyfibe White Muffins Tip Top Hyfibe White Thick Tip Top Multigrain Tip Top Multigrain 9 Grain Tip Top Multigrain 9 Grain Muffins Tip Top Multigrain 9 Grain Toast Tip Top Multigrain Muffins Tip Top Multigrain Toast Tip Top Pro-Rol Thick	**Primary foods as defined in Standard 1.3.2** Contains at least 40 micrograms folate **Other foods** Contains at least 40 micrograms folate and not more than – (A) 14 g fat, of which no more than 5 g is saturated fat; (B) 500 mg sodium; and (C) 10 g in total of added sugars and honey.	A claim which states – (a) that increased maternal folate consumption in at least the month before and 3 months following conception may reduce the risk of fetal neural tube defects; and (b) the recommendation that women consume a minimum of 400 micrograms folate per day in at least the month before and at least the first 3 months following conception.

Table to subclause (3)(e)

Permitted Health Claims (continued)

Column 1	Column 2	Column 3
Food	**Eligibility Criteria** **Amounts specified are per each serving as specified in the nutrition information panel**	**Permitted Claim**
Tip Top Sunblest Thick Tip Top Sunblest Sandwich Tip Top The White Stuff Tip Top The White Stuff Muffins Uncle Toby's Vitagold Bread Uncle Toby's Energy White Bread Uncle Toby's GrainsPlus Bread <u>Cereals</u> Goodman Fielder Nature's Gold Jackaroo Flour Kellogg's All Bran Kellogg's All Bran Fruit 'n Oats Kellogg's Bran Flakes Kellogg's Corn Flakes Kellogg's Golden Wheats Kellogg's Guardian Kellogg's Just Right Kellogg's Mini-Wheats Apricot Kellogg's Mini-Wheats Blackcurrent Kellogg's Mini-Wheats Strawberry Kellogg's Mini-Wheats Whole Wheat Kellogg's Special K Kellogg's Sultana Bran Lowan Flake Medley with Wild Berries Sanitarium Cornflakes* Sanitarium Fruity Bix – Apricot* Sanitarium Fruity Bix – Tropical* Sanitarium Fruity Bix – Wild Berry* Sanitarium Good Start* Sanitarium Light 'n Tasty Sanitarium Lite-Bix* Sanitarium Soy Tasty Sanitarium Weet-Bix Sanitarium Weet-Bix HiBran Soy & Linseed Sanitarium Weet-Bix plus Oat Bran Uncle Toby's Lite Start Breakfast Bars Uncle Toby's Lite Start Breakfast Cereal <u>Fruit/Vegetables</u> Golden Circle Kernel Corn Golden Circle Sliced & Baby Beetroot	**Primary foods as defined in Standard 1.3.2** Contains at least 40 micrograms folate **Other foods** Contains at least 40 micrograms folate and not more than – (A) 14 g fat, of which no more than 5 g is saturated fat; (B) 500 mg sodium; and (C) 10 g in total of added sugars and honey.	A claim which states – (a) that increased maternal folate consumption in at least the month before and 3 months following conception may reduce the risk of fetal neural tube defects; and (b) the recommendation that women consume a minimum of 400 micrograms folate per day in at least the month before and at least the first 3 months following conception.

Table to subclause (3)(e)

Permitted Health Claims (continued)

Column 1	Column 2	Column 3
Food	**Eligibility Criteria** **Amounts specified are per each serving as specified in the nutrition information panel**	**Permitted Claim**
<u>Juices</u> Berri Orange Juice (Long Life) – No Added Sugar Berri Orange Juice (Long Life) – Premium Berri Pure N' Fresh (Chilled Orange Juice) Citrus Tree Orange Juice Coles Apple Juice – No Added Sugar (Sourced from Berri Ltd)Coles Apple and Blackcurrant Juice - No Added Sugar (Sourced from Berri Ltd) Coles Orange Juice – No Added Sugar (Sourced from Berri Ltd) Coles Orange and Mango Juice – No Added Sugar (Sourced from Berri Ltd) Coles Viten Fernland Balance Orange Juice Golden Circle Cloudy Apple Juice Golden Circle Orange Juice Golden Circle Pineapple Juice Just Juice Apple Just Juice Orange McCoy Orange Juice Quelch Just Squeezed Orange Stefans Orange Juice <u>Soy Products</u> Soy Feast Soy & Corn Fritters <u>Extracts</u> Sanitarium Marmite Kraft Vegemite <u>Supplementary Foods</u> National Foods Edge *approved pending folate fortification	**Primary foods as defined in Standard 1.3.2** Contains at least 40 micrograms folate **Other foods** Contains at least 40 micrograms folate and not more than – (A) 14 g fat, of which no more than 5 g is saturated fat; (B) 500 mg sodium; and (C) 10 g in total of added sugars and honey.	A claim which states – (a) that increased maternal folate consumption in at least the month before and 3 months following conception may reduce the risk of fetal neural tube defects; and (b) the recommendation that women consume a minimum of 400 micrograms folate per day in at least the month before and at least the first 3 months following conception.

(f) A health claim must not be made in respect of the following foods -

(i) food standardised in Part 2.7 of this Code;
(ii) food standardised in Standards 2.9.1, 2.9.2 and 2.9.4 of this Code; and
(iii) soft cheeses and pâté; and

(iv) formulated meal replacements standardised in Standard 2.9.3.

(g) The label on or attached to a package of food, in respect of which a health claim set out in the Table has been made, must include -

(i) a nutrition information panel in accordance with Standard 1.2.8, which additionally includes the average quantity of folate in one serving of the food, beside the proportion of the RDI of folate contributed by one serving of the food;
(ii) an asterisk accompanying the word 'folate' in the nutrition information panel which refers to a footnote advising that the RDI of 200 micrograms referred to is for adults, whereas for women, at least one month before and during pregnancy, the recommended folate intake is 400 micrograms per day;
(iii) an accompanying statement that it is important to maintain a varied diet; and
(iv) a statement of particular storage, handling or cooking requirements, where the ability of a food to contain at least 40 micrograms folate per each serving depends on those requirements.

(h) Where a label, in respect of which a health claim set out in the Table has been made, is displayed on or in connection with a food which is displayed for retail sale other than in a package, the label must include -

(i) a nutrition information panel in accordance with Standard 1.2.8, which additionally includes the average quantity of folate in one serving of the food, beside the proportion of the RDI of folate contributed by one serving of the food; and
(ii) an asterisk accompanying the word 'folate' in the nutrition information panel which refers to a footnote advising that the RDI of 200 micrograms referred to is for adults, whereas for women, at least one month before and during pregnancy, the recommended folate intake is 400 micrograms per day.
(iii) an accompanying statement that it is important to maintain a varied diet; and
(iv) a statement of particular storage, handling or cooking requirements, where the ability of a food to contain at least 40 micrograms folate per each serving depends on those requirements.

(i) Where a health claim may be made in relation to a food in accordance with this Standard the same claim in relation to that food may be made in an advertisement, provided the advertisement includes a statement that it is important to maintain a varied diet.

Attachment 2B

STANDARD 1.2.8

NUTRITION INFORMATION REQUIREMENTS

Purpose

This Standard sets out nutrition information requirements in relation to food that is required to be labelled under this Code and for food exempt from these labelling requirements. This Standard prescribes when nutritional information must be provided, and the manner in which such information is provided.

This Standard does not apply to infant formula products where either Standard 2.9.1 – Infant Formula Products or Standard 1.1A.1 – Transitional Standard for Infant Formula Products otherwise provides. Standard 2.9.1 sets out specific nutrition labelling requirements that apply to infant formula products. Standard 1.3.2 (Vitamins and Minerals) sets out the labelling requirements for claims made about the vitamin and mineral content of foods.

Table of Provisions

Division 1 - Interpretation

Clauses

1 Definitions

In this Standard –

average energy content means the energy content of a food determined by multiplying the average amount of each food component per 100 grams of the food by the energy factor for that food component and summing the amounts calculated for each using the following formula -

Average energy (kJ/100 g) = $\sum W_i F_i$

Where -

$\mathbf{W_i}$ means the average weight of the food component (g/100 g food); and
$\mathbf{F_i}$ means the energy factor assigned to that food component (kJ/g).

biologically active substance means a substance, other than a nutrient, with which health effects are associated.

Editorial note:

Examples of biologically active substances are phytoestrogens.

carbohydrate means –

(a) 'carbohydrate by difference', calculated by subtracting from 100, the average quantity expressed as a percentage of water, protein, fat, dietary fibre, ash, alcohol, and if quantified or added to the food, any other unavailable carbohydrate and the substances listed in column 1 of Table 2 to subclause 2(2); or

(b) 'available carbohydrate', calculated by summing the average quantity of total available sugars and starch, and if quantified or added to the food, any available oligosaccharides, glycogen and maltodextrins.

dietary fibre means that fraction of the edible part of plants or their extracts, or synthetic analogues that -

(a) are resistant to the digestion and absorption in the small intestine, usually with complete or partial fermentation in the large intestine; and

(b) promote one or more of the following beneficial physiological effects -

(i) laxation;

(ii) reduction in blood cholesterol;
(iii) modulation of blood glucose;

and includes polysaccharides, oligosaccharides (degree of polymerisation > 2) and lignins.

fat means total fat.

gluten means the main protein in wheat, rye, oats, barley, triticale and spelt relevant to the medical conditions, Coeliac disease and dermatitis herpetiformis.

monounsaturated fatty acids means the total of cis-monounsaturated fatty acids and declared as monounsaturated fat.

nutrition claim means a representation that states, suggests or implies that a food has a nutritional property whether general or specific and whether expressed affirmatively or negatively, and includes a reference to -

(a) energy; or
(b) salt, sodium or potassium; or
(c) amino acids, carbohydrate, cholesterol, fat, fatty acids, fibre, protein, starch or sugars; or
(d) vitamins or minerals; or
(e) any other nutrient; or
(f) a biologically active substance;

but does not include -

(g) a reference in a statement of ingredients, a prescribed name, or any other prescribed information; or
(h) the provision of particulars relating to a nutrient or energy that is required by clause 5; or
(i) a reference in the commonly accepted name of a food; or
(j) a reference to a quantitative or qualitative declaration of certain nutrients, ingredients or energy in the label where that declaration is required otherwise by the Act or this Code; or
(k) a reference to a reduction in alcohol content.

Editorial note:

'Sweetened', 'salted' and 'calcium enriched' are examples of nutrition claims that are expressed affirmatively. Examples of nutrition claims that are expressed negatively are 'unsweetened', 'no added sugar' and 'low in fat'.

Examples of a reference in a commonly accepted name of a food are 'sweet corn', 'sweet potato' and 'sweetbread'.

A reference to a nutrient that is not required by clause 5 in a nutrition information panel is a nutrition claim and, depending upon the nutrient claimed, may trigger the need for particulars of further nutrients to be included in the panel.

polyunsaturated fatty acids means the total of polyunsaturated fatty acids with cis-cis-methylene interrupted double bonds acids and declared as polyunsaturated fat.

saturated fatty acids means the total of fatty acids containing no double bonds acids and declared as saturated fat.

sugars means monosaccharides and disaccharides.

trans fatty acids means the total of unsaturated fatty acids where one or more of the double bonds are in the trans configuration acids and declared as trans fat.

unit quantity means, in the case of a solid or semi-solid food, 100 grams or, in the case of a beverage or other liquid food, 100 millilitres.

2 Energy factors

(1) In this clause -

energy factor means the metabolisable energy (ME) of the food component calculated according to the following formula, expressed in kilojoules per gram of food component, rounded to the nearest whole number -

ME = GE – FE – UE – GaE – SE

Where –

ME means metabolisable energy
GE means gross energy (as measured by bomb calorimetry)
FE means energy lost in faeces
UE means energy lost in urine
GaE means the energy lost in gases produced by fermentation in the large intestine
SE means the energy content of waste products lost from surface areas

(2) Energy factors in relation to the food components listed in column 1 of Table 1 and column 1 of Table 2 to this subclause are specified in the corresponding entry in column 2 of Table 1 and Table 2.

Table 1 to subclause 2(2)

Column 1	Column 2
Food Component	**Energy factor (kJ/g)**
Alcohol	29
Carbohydrate (excluding unavailable carbohydrate)	17
Unavailable carbohydrate (including dietary fibre)	8
Fat	37
Protein	17

Table 2 to subclause 2(2)

Column 1	Column 2
Food Component	**Energy factor (kJ/g)**
Erythritol	1
Glycerol	18
Isomalt	11
Lactitol	11
Maltitol	16
Mannitol	9
Organic acids	13
Polydextrose	5
Sorbitol*	14
D-Tagatose	11
Xylitol	14

Editorial note:

Average energy content may also be expressed as Calories. The conversion factor is one Calorie for each 4.18 kilojoules.

* Energy factor for sorbitol taken as an average of calculated range determined with or without ingestion of other foods.

Division 2 – Nutrition information panels

3 Nutrition information requirements and exemptions

Subject to clause 4, the label on a package of food must include a nutrition information panel except where the food is -

(a) sold at fund-raising events; or
(b) an alcoholic beverage standardised in Part 2.7 of this Code; or
(c) a herb, a spice, a herbal infusion; or
(d) vinegar and related products as standardised in Standard 2.10.1; or
(e) salt and salt products as standardised in Standard 2.10.2; or
(f) tea, decaffeinated tea, decaffeinated instant or soluble tea, instant or soluble tea, coffee, decaffeinated coffee, decaffeinated instant or soluble coffee, instant or soluble coffee, as defined in Standard 1.1.2; or
(g) an additive for the purposes of Standard 1.3.1; or
(h) a processing aid as defined in Standard 1.3.3; or
(i) fruit, vegetables, meat, poultry, and fish that comprise a single ingredient or category of ingredients; or
(j) in a small package; or
(k) gelatine as defined in Standard 1.1.2; or
(l) water, or mineral or spring water as defined in Standard 2.6.2; or
(m) prepared filled rolls, sandwiches, bagels and similar products; or
(n) jam setting compound; or
(o) a kit which is intended to be used to produce an alcoholic beverage standardised in Part 2.7 of this Code; or
(p) kava as standardised in Standard 2.6.3.

4 Requirements for nutrition information panels where nutrition claims are made in relation to food

(1) Where a nutrition claim is made in relation to a food, a nutrition information panel must be included on the label on the package of the food.

(2) Subject to subclause (3), where a nutrition claim is made in relation to a food which is not required to bear a label pursuant to clause 2 of Standard 1.2.1, the information prescribed in clause 5, must be -

(a) declared in a nutrition information panel displayed on or in connection with the display of the food; or
(b) provided to the purchaser upon request.

(3) Where a nutrition claim is made in relation to a food in a small package, the label must include the information prescribed in clause 8.

5 Prescribed declarations in a nutrition information panel

(1) A nutrition information panel must include the following particulars -

(a) the number of servings of the food in the package; and
(b) the average quantity of the food in a serving expressed, in the case of a solid or semi-solid food, in grams or, in the case of a beverage or other liquid food, in millilitres; and
(c) the unit quantity of the food; and
(d) the average energy content, expressed in kilojoules or both in kilojoules and in calories (kilocalories), of a serving of the food and of the unit quantity of the food; and
(e) subject to clause 12, the average quantity, expressed in grams of, protein, fat, saturated fat, carbohydrate and sugars, in a serving of the food and in a unit quantity of the food; and
(f) the average quantity, expressed in milligrams or both milligrams and millimoles, of sodium in a serving of the food and in the unit quantity of the food; and
(g) the name and the average quantity of any other nutrient or biologically active substance in respect of which a nutrition claim is made, expressed in grams, milligrams or micrograms or other units as appropriate, that is in a serving of the food and in the unit quantity of the food;

set out, unless otherwise prescribed in this Code, in the following format –

NUTRITION INFORMATION		
Servings per package: (insert number of servings) Serving size: g (or mL or other units as appropriate)		
	Quantity per Serving	Quantity per 100g (or 100mL)
Energy	kJ (Cal)	kJ (Cal)
Protein	g	g
Fat, total	g	g
- saturated	g	g
Carbohydrate	g	g
sugars	g	g
Sodium	mg (mmol)	mg (mmol)
(insert any other nutrient or biologically active substance to be declared)	g, mg, µg (or other units as appropriate)	g, mg, µg (or other units as appropriate)

(2) A nutrition information panel must clearly indicate that –

(a) the average quantities set out in the panel are average quantities; and
(b) any minimum and maximum quantities set out in the panel are minimum and maximum quantities.

Editorial note:

'Average quantity' is determined in accordance with the definition set out in clause 2 of Standard 1.1.1. Average quantities may be indicated, for example, by inserting the word 'Average' or an abbreviation for average at the beginning of 'Quantity per Serving' and the 'Quantity per 100 g (or 100 mL)' columns, or including a note at the end of the panel stating that all specified values are averages.

No format is prescribed for the indication of minimum and maximum quantities. They may be indicated, for example, by inserting the bracketed abbreviations '(min)' and '(max)' immediately after the relevant quantities in the Quantity per Serving column and the Quantity per 100 g (or 100 ml) column.

Clause 12 explains when minimum and maximum quantities may be indicated.

(3) The word 'serving' may be replaced in the nutrition information panel by -

(a) the word 'slice', 'pack' or 'package'; or
(b) the words 'metric cup' or 'metric tablespoon' or other appropriate word or words expressing a unit or common measure.

(4) The nutrition information panel must include declarations of the trans, polyunsaturated and monounsaturated fatty acids in accordance with subclause (7), where a nutrition claim is made in respect of -

(a) cholesterol; or
(b) saturated, trans, polyunsaturated or monounsaturated fatty acids; or

(c) omega-3, omega-6 or omega-9 fatty acids.

(5) The nutrition information panel must include a declaration of the presence or absence of dietary fibre in accordance with subclause (7), where a nutrition claim is made in respect of -

(a) fibre; or
(b) any specifically named fibre; or
(c) sugars; or
(d) any other type of carbohydrate.

Editorial note:

Absence of dietary fibre must be declared as zero (0).

(6) The nutrition information panel must include declarations of unavailable carbohydrate where the unavailable carbohydrate has been subtracted in the calculation of 'carbohydrate by difference' as defined in clause 1.

(6A) The reference to 'unavailable carbohydrate' in subclause (6) does not include dietary fibre.

(6B) The nutrition information panel must include individual declarations of those substances listed in column 1 of Table 2 to subclause 2(2) where they are present, either singly or in combination, in the final food in an amount of no less than 5g/100g, and where –

(a) any of the substances listed in column 1 have been subtracted in the calculation of 'carbohydrate by difference' as defined in clause 1; or
(b) any of the substances listed in column 1 have been quantified or added to the food, if 'available carbohydrate' as defined in clause 1 is used.

(6C) The reference to 'substances listed in column 1 of Table 2 to subclause 2(2)' in subclause (6B) does not include organic acids.

(7) The information prescribed in subclause (4) and subclause (5), where required to be included in a nutrition information panel, must be set out in the following format -

NUTRITION INFORMATION		
Servings per package: (insert number of servings) Serving size: g (or mL or other units as appropriate)		
	Quantity per Serving	Quantity per 100g (or 100mL)
Energy	kJ (Cal)	kJ (Cal)
Protein, total	g	g
- *	g	g
Fat, total	g	g
- saturated	g	g
- **	g	g
- trans	g	g
- **	g	g
- polyunsaturated	g	g
- **	g	g
- monounsaturated	g	g
- **	g	g
Cholesterol	mg	mg
Carbohydrate	g	g
- sugars	g	g
- **	g	g
- *	g	g
- **	g	g
Dietary fibre, total	g	g
- **	g	g
Sodium	mg (mmol)	mg (mmol)
(insert any other nutrient or biologically active substance to be declared)	g, mg, μg (or other units as appropriate)	g, mg, μg (or other units as appropriate)

*a sub-group nutrient **a sub-sub-group nutrient

Editorial note:

This format sets out how sub-groups and sub-sub-groups of nutrients may be included. The word 'total' following 'protein' or 'dietary fibre' in the first column of the panel need only be included if it is immediately followed by the sub-group.

(8) The declaration of dietary fibre in a panel must be a declaration of dietary fibre determined in accordance with clause 18.

6 Expression of average energy content and quantities of nutrients and biologically active substances

(1) The average energy content, and average or minimum or maximum quantities of nutrients and biologically active substances must be expressed in the panel to not more than three significant figures.

(2) Where the average energy content of a serving or unit quantity of the food is less than 40 kJ, that average energy content may be expressed in the panel as 'LESS THAN 40 kJ'.

(3) Where the average quantity of protein, fat, classes of fatty acids, carbohydrate, sugars or dietary fibre in a serving or unit quantity of the food is less than 1 gram, that average quantity may be expressed in the panel as 'LESS THAN 1 g'.

(4) Where the average quantity of sodium or potassium in a serving of the food, the unit quantity of the food is less than 5 milligrams, that average quantity may be expressed in the panel as 'LESS THAN 5 mg'.

7 Percentage daily intake information

(1) Information relating to the percentage daily intake of nutrients set out in a nutrition information panel may be included in the panel.

(2) Where percentage daily intake information is included in a panel -

(a) the percentage daily intake of dietary fibre may be included in the panel; and

(b) the following matters must be included in the panel –

(i) the percentage daily intake of energy, fat, saturated fatty acids, carbohydrate, sugars, protein and sodium; and

(ii) the statement –

'*Percentage daily intakes are based on an average adult diet of 8700 kJ. Your daily intakes may be higher or lower depending upon your energy needs.'.

Editorial note:

The inclusion of '% Daily Intake' information is voluntary. An example of a recommended nutrition information panel for mandatory nutrients incorporating the optional '% Daily Intake' element is set out below.

EXAMPLE:

NUTRITION INFORMATION			
Servings per package: (insert number of servings) Serving size: g (or mL or other units as appropriate)			
	Quantity per Serving	% Daily Intake* (per Serving)	Quantity per 100g (or 100mL)
Energy	kJ (Cal)	%	kJ (Cal)
Protein	G	%	g
Fat, total - saturated	g g	% %	g g
Carbohydrate - sugars	g g	% %	g g
Sodium	mg (mmol)	%	mg (mmol)
(insert any other nutrient or biologically active substance to be declared)	g, mg, µg (or other units as appropriate)	%	g, mg, µg (or other units as appropriate)
* Percentage Daily Intakes are based on an average adult diet of 8700kJ. Your daily intakes may be higher or lower depending on your energy needs.			

(3) The percentage daily intakes of the food components listed in column 1 of the Table to this subclause, that are included in the panel, must be calculated using the corresponding reference value specified in column 2.

Table to subclause 7(3)

Column 1	Column 2
Food Component	**Reference Value**
Energy	8700 kJ
Protein	50 g
Fat	70 g
Saturated fatty acids	24 g
Carbohydrate	310 g
Sodium	2300 mg
Sugars	90 g
Dietary fibre (if included)	30 g

8 Food in small packages

(1) Subject to subclause (2), where a nutrition claim is made in relation to a food in a small package, the label on that package must include a declaration, expressed in accordance with clause 5 and subclause 13(5), of the –

(a) average quantity of the claimed nutrient or biologically active substance present per unit quantity of the food; and

(b) average quantity of energy, carbohydrate, sugars and dietary fibre present per unit quantity of the food where a nutrition claim is made in respect of -

(i) fibre; or
(ii) sugars; or
(iii) any other type of carbohydrate; and

(c) saturated fatty acids, trans fatty acids, polyunsaturated fatty acids and monounsaturated fatty acids content of the food where a nutrition claim is made in respect of -

(i) cholesterol; or
(ii) saturated fatty acids, trans fatty acids, polyunsaturated fatty acids or monounsaturated fatty acids; or
(iii) omega-3, omega-6 or omega-9 fatty acids; and

(d) average quantity of energy present per unit quantity of the food where a nutrition claim is made that the food is fat-free, sugar-free, low joule or any similar term.

(2) The information required to be declared in subclause (1) need not be set out in the prescribed panel format.

Editorial note:

Standard 1.2.1 defines 'small package' as a package with a surface area of less than 100 cm^2. Food in a small package is not required to have a nutrition information panel although the information that must be declared under clause 8 may be declared in a panel.

9 Food in dehydrated or concentrated form

Where a food in dehydrated or concentrated form is labelled with directions that indicate that the food should be reconstituted with water before consumption, the label on the package of that food must include the particulars set out in each column of the panel expressed as a proportion of the food as so reconstituted.

10 Food that must be drained before consumption

The label on a package of food with directions indicating that the food should be drained before consumption, must clearly indicate that the particulars set out in each column of the panel relate to the drained food.

11 Food to be prepared or consumed with other food

The label on a package of food intended to be prepared or consumed with at least one other food, may include an additional column at the right hand side of the panel specifying, in the same manner as set out in the panel, descriptions and quantities of the foods in question together with the average energy content of the food and the average quantities of nutrients and biologically active substances declared in the panel.

Division 3 – Conditions for making certain nutrition claims

12 Claims in relation to polyunsaturated or monounsaturated fatty acid content of foods

(1) A nutrition claim, subject to clause 13, must not be made in relation to the polyunsaturated fatty acid content or monounsaturated fatty acid content of a food unless -

(a) the total of saturated fatty acids and trans fatty acids comprises no more than 28 per cent of the total fatty acid content of the food; and
(b) the fatty acid in respect of which the nutrition claim is made comprises no less than 40 per cent of the total fatty acid content of the food.

(2) Where a claim is made in relation to the polyunsaturated fatty acid content or monounsaturated fatty acid content of foods for which there are compositional requirements specified in Standard 2.4.1 or Standard 2.4.2, the quantity of saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids and trans fatty acids may be set out in the panel as a minimum or maximum quantity in a serving of the food.

Editorial note:

Subclause 12(2) provides manufacturers of edible oils and edible oil spreads with the option of setting out the minimum and maximum fatty acid content of the types of fatty acids referred to in subclause 12(2) instead of their average quantity. Total fat must still be expressed as an average quantity in accordance with paragraph 5(1)(e).

13 Claims in relation to omega fatty acid content of foods

(1) Where a nutrition claim using the word 'omega' is made in relation to the omega fatty acid content of a food, the word 'omega' must be qualified by the type of omega fatty acid present and this qualification must appear immediately after the word 'omega'.

Editorial note:

For example, in the format 'Omega-3', 'Omega-6' or 'Omega-9'.

(2) Subject to subclause (3) and subclause (4), a claim must not be made in relation to the omega-3 fatty acid content of a food, other than fish or fish products that have no added saturated fatty acids, unless the –

(a) total of saturated fatty acids and trans fatty acids is no more than 28 per cent of the total fatty acid content of the food; or
(b) food contains no more than 5 g of saturated fatty acids and trans fatty acids per 100 g of the food.

(3) A nutrition claim must not be made in relation to the omega-3 fatty acid content of a food, unless the food satisfies the requirements of subclause (2) and contains no less than –

(a) 200 mg alpha-linolenic acid per serving; or
(b) 30 mg total eicosapentaenoic acid and docosahexaenoic acid per serving.

(4) A nutrition claim must not be made that a food is a 'good source' of omega-3 fatty acid or words of similar import, unless the food satisfies the requirements of subclause (2) and contains no less than 60 mg total eicosapentaenoic acid and docosahexaenoic acid per serving.

(5) Where a nutrition claim is made in accordance with subclause (3) or subclause (4), the declarations in the nutrition information panel must indicate the source of omega 3 fatty acids, namely, alpha-linolenic acid, docosahexaenoic acid and/or eicosapentaenoic acid.

(6) A nutrition claim must not be made in relation to the omega-6 or omega-9 fatty acid content of a food, unless the –

(a) total of saturated fatty acids and trans fatty acids content of the food is no more than 28 per cent of the total fatty acid content of the food; and
(b) fatty acid in respect of which the nutrition claim is made comprises no less than 40 per cent of the total fatty acid content of the food.

Editorial note:

The omega-3, omega-6 or omega-9 fatty acid content of a food that is the subject of such a claim should be set out in the nutrition information panel in the format immediately following subclause 5(6) as a sub-sub-group of polyunsaturated fatty acids or monounsaturated fatty acids, as the case may be.

14 Low joule claims in relation to food

(1) Subject to subclause (2), a claim to the effect that a food is a low joule food, must not be made unless the average energy content of the food is no more than -

(a) 80 kJ per 100 mL of beverages or other liquid foods; and
(b) 170 kJ per 100 g of solid or semi-solid foods.

(2) Where a food is to be prepared as directed on the label, the average energy content of the food must be calculated for the food as prepared.

Editorial note:

Low joule food claims are nutrition claims as they make reference to the energy content of a food.

The term describing the energy content of a food intrinsically low in energy must not precede the name of the food (e.g. ‘low joule’ [name of the food]), but should refer to the whole class of foods, and be in the following form –

‘[class of the food] is a low joule food’

15 Lactose claims in relation to food

(1) A claim to the effect that a food is low lactose must not be made unless the food contains no more than 0.3 g of lactose per 100 g of the food.

(2) A claim to the effect that a food is lactose free must not be made unless the food contains no detectable lactose.

(3) A claim to the effect that a food is lactose reduced must be accompanied by a declaration of the proportion by which the lactose content of the food has been reduced.

Editorial note:

Where a claim is made that a food is lactose reduced, the proportion of lactose in the food should be declared in words to the effect -

'[here state percentage] % lactose reduced'

(4) Where a claim is made in relation to the lactose content of a food, particulars of the lactose and galactose content of the food must be provided in accordance with subclause 5(1).

Editorial note:

The declaration of the lactose and galactose content of a food in the nutrition information panel should be in the following form:

Carbohydrate
- sugars
  - lactose
  - galactose

16 Claims in relation to gluten content of food

(1) Claims in relation to the gluten content of food are prohibited unless expressly permitted by this Code.

Editorial note:

This subclause does not prohibit the declaration of the presence of gluten, for example, in an ingredient list on the label on a food.

(2) A claim to the effect that a food is gluten free must not be made in relation to a food unless the food contains no -

(a) detectable gluten; and
(b) oats or malt.

(3) A claim to the effect that a food has a low gluten content, must not be made in relation to a food unless the food contains no –

(a) more than 20 mg gluten per 100 g of the food; and
(b) oats or malt.

Editorial note:

Subclauses (2) and (3) of this clause permit claims to the effect that a food is gluten free or has a low gluten content, providing certain specified conditions are met.

(4) A claim to the effect that a food contains gluten or is high in gluten may be made in relation to a food.

Editorial note:

Subclause 16(1) prohibits all claims about gluten unless expressly permitted. Subclauses 16(2), (3) and (4) provide those express permissions.

17 Claims in relation to salt, sodium or potassium content of food

(1) A claim to the effect that a food is low in sodium content must not be made unless the food contains no more than 120 mg of sodium per 100 g of the food.

(2) Where a nutrition claim is made in respect of the salt, sodium or potassium content of a food, or any two or all of them, then particulars, including particulars relating to both the sodium and potassium content of the food, must be provided in relation to the food in accordance with subclause 5(1).

Editorial note:

If the claim is made for a food naturally or intrinsically low in sodium, it should refer to the whole class of similar foods.

Division 4 – Miscellaneous

18 Methods of analysis to determine total dietary fibre and specifically named fibre content of food

(1) Subject to subclause (2), the methods set out in the Table to this subclause are the prescribed methods of analysis for the determination of total dietary fibre and any specifically named fibre content of food for the purposes of nutrition labelling in this standard.

Table to subclause 18(1)

Column 1	Column 2
Food Component	**Method of analysis**
Total dietary fibre	Section 985.29 of the AOAC, 17th Edition (2000), or Section 991.43 of the AOAC, 17th Edition (2000).
Inulin and fructooligosaccharide	Section 997.08 of the AOAC, 17th Edition (2000).
Inulin	Section 999.03 of the AOAC, 17th Edition (2000).
Polydextrose	Section 2000.11 of the AOAC, 17th Edition, 1st Revision (2002)

(2) The results obtained using the analytical methods outlined in column 2 of the Table to subclause 18(1) must be summed together after ensuring that there is no double counting of any specifically named fibre.

Editorial note:

For the purposes of subclause 18(2), where a manufacturer chooses to include a specifically named fibre in the declaration of dietary fibre, the manufacturer must first work out which food components in column 1 are present in the food and then use the appropriate methods of analysis in column 2, or in the case of total dietary fibre, choose which method of analysis to use. The results of the chosen methods of analysis are then added together. If any substance has been measured by more than one analysis, then allowance must then be made by discounting for double counting of that amount to arrive at the total figure.

For example, the dietary fibre content of a cereal bar with added inulin is calculated by adding the result of the analysis for total dietary fibre, using one of the two possible methods of analysis, to the result of the analysis for inulin, and subtracting from the total that part of the inulin content that was included in the result of the analysis for total dietary fibre.

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Attachment 3

FSANZ claims descriptors summary of relevant definitions (Australia, New Zealand and international)

Health claim or similar

Reference	Definition
Canada	**Diet-related health claim** is a statement that describes the characteristics of a diet that may reduce the risk of developing a diet-related disease or condition, such as osteoporosis or stroke, and the properties of a food that make it a suitable part of the diet. Source: Canadian Food Inspection Agency, 2003 Guide to Food Labelling and Advertising, Chapter 8, Diet-Related Health Claims <http://www.inspection.gc.ca/english/fssa/labeti/guide/ch8e.pdf>
United States	**Health claim** is any claim made on the label or in labelling of a food, including a dietary supplement, that expressly or by implication, including 'third party' references, written statement (for example, a brand name including a term such as 'heart'), symbols (for example, a heart symbol), or vignettes, characterises the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols or vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence of level of a substance in the food and a disease or health-related condition. Source: CFR Sec. 101.14(1)
European Union	**Health claim** means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health. (Proposed) Source: Proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on food. 2003/0165

Nutrition content claim or similar

Reference	Definition
Codex	**Nutrient content claim** is a nutrition claim that describes the level of a nutrient contained in a food. Source: CAC/GL 23-1997, Sec 2.1.1 **Comparative claim** is a claim that compares the nutrient levels and/or energy value of two or more foods. Source: CAC/GL 23-1997, Sec 2.1.2

Canada	**Nutrient content claim**: Any statement or expression which describes, directly or indirectly, the level of a nutrient in a food or group of foods. Source: Canadian Food Inspection Agency 2003 Guide to Food Labelling and Advertising, Chapter 7, Nutrient Content Claims <http://www.inspection.gc.ca/english/fssa/labeti/guide/ch7e.shtml#7.3> **Comparative claim** is a statement that compares, directly or indirectly, the nutritional properties of two or more foods. Source: Canadian Food Inspection Agency 2003 Guide to Food Labelling and Advertising, Chapter 7, Nutrient Content Claims <http://www.inspection.gc.ca/english/fssa/labeti/guide/ch7e.shtml#7.3>
United States	**Nutrient content claim**: A claim that expressly or implicitly characterises the level of a nutrient of the type required to be in nutrition labelling under Sec. 101.9 or under Sec. 101.36. An **expressed nutrient content claim** is any direct statement about the level (or range) of a nutrient in the food. An **implied nutrient content claim** is any claim that: (i) describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount; or (ii) suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient. Source: CFR Sec. 101.13(b), 101.13 (1), 101.13 (2)
European Union	**Nutrition claim** means any claim which states, suggests or implies that a food has particular nutrition properties due to: (a) the energy (calorific value) it • provides, • provides at a reduced or increased rate, or • does not provide, and/or (b) the nutrient or other substances it • contains, • contains in reduced or increased proportions, or • does not contain. (Proposed) **Other substance** means a substance other than a nutrient that has a nutritional or physiological effect. Source: Proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on food. 2003/0165
Proposal P153: Previous ANZFA Proposal on Health and Related Claims (Inquiry Report)	**Nutrition content claim** means a nutrition claim which describes or indicates the presence or absence of a component in that food. (Proposed)

Function claims or similar

Reference	Definition
Codex	A **nutrient function claim** is a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body. Source: CAC/GL 23-1997, Sec 2.1.3

Canada	A **biological role claim** is a claim that refers to the generally recognised nutritional function of energy or nutrients as an aid in maintaining the functions of the body, for the maintenance of good health, or for normal growth and development. Source: Canadian Food Inspection Agency 2003 Guide to Food Labelling and Advertising, Chapter 8, Diet-Related Health Claims <http://www.inspection.gc.ca/english/fssa/labeti/guide/ch8e.pdf>
United States	**Structure/function claims** describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterise the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, provided that such statements are not disease claims.
Proposal P153: Previous AZFA Proposal on Health and Related Claims (Inquiry Report)	A **nutrition function claim** is a claim about the specific beneficial effects of consuming a food or component in a food, in the context of the total diet, on the normal growth, development, maintenance or other like functions of the human body. (Proposed) An **enhanced function claim** is a claim about the specific beneficial effects of consuming a food or component in a food, in the context of the total diet, on the physiological, psychological or biological functions of the human body, beyond its role in the normal growth, development, maintenance and other like functions of the human body. (Proposed)

Risk reduction claims or similar

Reference	Definition
European Union	**Reduction of disease risk claim** means any health claim that states, suggests or implies that consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease. Source: Proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on food. 2003/0165

Therapeutic claim or similar

Reference	Definition
Proposal P153: Previous ANZFA Proposal on Health and Related Claims (Inquiry Report)	**Therapeutic action**: action relating to treating, curing or alleviating a disease, ailment, defect or injury. **Prophylactic action**: prevention of an abnormal physiological, psychological or biological state or disease, but does not include maintenance of normal physiological, psychological or biological function.
Therapeutic Goods Act 1989	**Therapeutic goods** means goods: (a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be: (i) for therapeutic use; or (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or (iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or (b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);

	and includes medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include: (c) goods declared not to be therapeutic goods under an order in force under section 7; or (d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or (e) goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a prescribed standard in the Australia New Zealand Food Standards Code as defined in subsection 3(1) of the Australia New Zealand Food Authority Act 1991; or (f) goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented. The Act defines therapeutic use as follows: Therapeutic use means use in or in connection with: (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or (b) influencing, inhibiting or modifying a physiological process in persons or animals; or (c) testing the susceptibility of persons or animals to a disease or ailment; or influencing, controlling or preventing conception in persons; or (d) testing for pregnancy in persons; or (e) the replacement or modification of parts of the anatomy in persons or animals.

SUBSTANTIATING NUTRITION, HEALTH AND RELATED CLAIMS ON FOODS

A draft framework

June 2004

Acknowledgement

The content of this paper has been developed drawing on a number of sources including the Australian National Health and Medical Research Council (1998, 1999, 2000), the Australian Therapeutic Goods Administration (2001), Health Canada (2000), Hennekens & Buring (1987), Khan et al. (2001), Mann & Truswell (1997), Mann (2002), Rychetnik & Frommer (2002), Truswell (2001a and 2001b, 2002), the United States Food and Drug Administration (1999), the World Cancer Research Fund (1997), and the World Health Organisation (2003), together with other sources identified in the bibliography. The framework has been prepared with input from a group of New Zealand and Australian scientists who are experts in assessing scientific evidence relating to public health and diet.

Contents

Summary

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

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

- A structured approach should be used to ensure that all relevant evidence is considered and the conclusions are justified.
- Evidence must be of a suitable quality.
- The evidence should demonstrate a causal relationship between consumption of the diet, food or food component and the claimed outcome.
- The evidence should be relevant to the intended population group for which the claim is intended.
- 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 that 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.
- 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 take into account the relevance and applicability of the evidence to Australians and New Zealanders.
- Qualifying and disqualifying criteria may be established in relation to use of the claim to which all foods bearing that claim must comply.

General level claims will be substantiated by manufacturers. Key aspects of the requirements for 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 and form required to achieve the outcome or attain the level stated in the claim.

- Foods carrying claims must comply with any qualifying and disqualifying criteria that may have been established in relation to the use of the claim.

Chapter 1 Introduction

This document sets out the approach that FSANZ will adopt when evaluating whether high level nutrition, health and related claims proposed for use on foods are substantiated by the available scientific evidence. It also provides guidance for manufacturers and suppliers wishing to substantiate general level nutrition, health and related claims. The purpose of setting principles and procedures for the scientific substantiation of a claim is to ensure the claim describes a demonstrated relationship between diet and health and is not misleading.

For simplicity, the document separates substantiation requirements for high level claims from those for general level claims.

Further refinement of the content of this document is likely as FSANZ undertakes the process of developing the Standard on nutrition, health and related claims.

1.1 General principles for considering evidence to substantiate health and related claims

Substantiation is the process of deciding whether the body of scientific evidence supports a claimed relationship between a diet, food or component (including a nutrient or other bioactive substance) and a health outcome. This decision is made on the basis of an assessment of all available scientific evidence of appropriate quality, on a claim-by-claim basis.

The evaluation process used in determining whether or not a proposed nutrition, health and related claim is substantiated must be rigorous, to determine with confidence that the evidence shows consistent associations that will stand the test of time. The general principles that apply to the substantiation of claims are:

- A 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.
- The evidence should demonstrate a causal relationship between consumption of the diet, food or food component and the claimed outcome.
- The evidence should be relevant to the intended population group for which the claim is intended.
- 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.

1.2 A 5-step process for evaluating whether a high level claim is substantiated

Taking into account the general principles (above), FSANZ will use a five-step process when evaluating scientific information related to substantiating high level claims. The five steps FSANZ will use are:

1. identifying and categorising evidence

2. grading the quality of the evidence
3. interpreting the evidence, study-by-study
4. evaluating the totality of the evidence across studies
5. determining qualifying criteria associated with the claim (if a claim is supported).

Substantiation of high level claims is detailed in Chapter 2 of this document. Because high level claims must be substantiated on a claim-by-claim basis, the detailed application of these steps may vary.

1.3 A streamlined process for evaluating general level claims

A streamlined substantiation approach is proposed for general level claims, based on the same general principles that apply to all claims but recognising that these claims will largely be based on consistently-agreed evidence of suitable quality that has previously been subject to critical review. The steps that should be used are:

1. identifying an appropriate authoritative, current and generally accepted source to provide substantiated information on the link between the diet, food or food component and a health outcome, and
2. determining whether the food subject to the claim contains the necessary level of the food or component in question and meets qualifying or disqualifying criteria that may have been established.

Where an appropriate authoritative evidence source is not able to be identified, the 5-step process outlined for high level claims should be followed.

Substantiation of general level claims, other than content claims, is detailed in Chapter 3 of this document; content claims are covered in Chapter 4.

1.4 Safety of foods carrying health and related claims

It is assumed in this document that, prior to submitting any application for a health claim, manufacturers or suppliers have satisfied themselves that the food or component that is the subject of the claim is safe for its intended purpose and meets all other requirements of the Australia New Zealand Food Standards Code (the Code).

The purpose of the substantiation process is not to assess the safety of foods carrying claims. Nevertheless, information on adverse effects associated with studies of the efficacy and effectiveness of diet, food or food components will not be ignored.

1.5 Reviewing approved claims

Despite health claims being based on a rigorous substantiation process, evidence relating to the relationship between diet and health emerges continually. It is anticipated, therefore, that approved claims may be subject to review to ensure they continue to reflect the best available evidence.

Chapter 2 Substantiating high level claims – a 5-step process

This chapter sets out the process FSANZ will use when determining whether or not a proposed high level claim is substantiated by evidence.

2.1 Identifying and categorising the evidence – step 1

Identifying all relevant studies, whether or not they support the proposed claim, is a critical first step in the substantiation process. It is not possible to later evaluate the totality of evidence in relation to a proposed claim unless the evidence is drawn from a systematic and thorough search of the scientific literature.

Substantiation of a high level claim requires evidence derived from studies of humans, to ensure a high degree of certainty that a proposed claim is relevant to Australians and New Zealanders. If the identification and categorisation process outlined in this step does not identify information from human studies, the claim cannot be substantiated.

Depending on the substance of the claim, evidence to substantiate it could be drawn from a variety of study types, including reports of original (or 'primary') human experimental and observational studies, animal studies and in vitro or in vivo studies examining biological mechanisms ('primary sources'), and from reports that analyse this primary evidence ('secondary sources'), such as systematic reviews, reports of evaluations of health claims that have been approved overseas, national diet policy documents and meta analyses. Unpublished studies may be included in the substantiation process and efforts should be made to ensure such studies are identified and assessed.

It is not possible to offer guidance on the number of studies and reports that need to be considered in evaluating a health claim. Each claim will be considered on a claim-by-claim basis and the amount of information available will vary with each case. However, it is highly unlikely a claim would be approved based on the findings of a single study or a very small number of studies.

A useful resource for those preparing to identify and categorise evidence is the Australian National Health and Medical Research Council's 1999 publication *How to review the evidence: systematic identification and review of the scientific literature*.

2.1.1 Searching scientific literature

Searching scientific literature can be a complex task and may require assistance from an experienced information manager. There is no fixed search strategy that can be applied in all cases as strategies need to be tailored to the particular issue under evaluation. Identifying studies will generally involve searching electronic databases (such as MEDLINE, EMBASE, FSTA, Science Citation Index and others). Several databases should be searched as different databases cover different publications and topics.

The task may also include manual searching, such as checking the bibliographies of review articles to identify important studies not identified through electronic searches, and scanning research registers and conference proceedings. It may be useful to consult one or more experts in the area who are familiar with the subject matter and may be able to identify any key evidence sources that have been missed in the literature search.

A clear and explicit outline of the search strategy used to gather evidence for a claim is essential to clearly identify the scope of the evidence considered in assessing the claim. The outline should include the strategy for searching electronic databases (such as the key search words or terms, the search limits, the time period searched and the databases searched) and the strategy used to select studies for detailed review.

The initial search will identify many studies that may not be useful for determining if a claim is substantiated. The search results therefore need to be reviewed to select those studies that will be subject to detailed evaluation. It is important to identify in advance the criteria that will be used to select studies for detailed evaluation, to avoid bias in study selection and to be satisfied that studies evaluated are relevant to the proposed claim. These criteria will depend on the particular claim being evaluated and should be explicitly stated. They should allow inclusion of studies where findings appear to support the claim, as well as studies where the findings appear to show no effect, an equivocal effect or refuting evidence. Once all potentially relevant studies have been identified, reports of all these studies should be obtained for detailed evaluation.

Some scientific journals publish letters or comments from researchers critiquing the findings of previously-published reports. Where this is the case, these critiques should accompany the report of the study and should be taken into account when assessing study quality. Attention should be paid to the potential for publication of the same study findings in more than one journal paper, or of the inclusion of previously published data in the results of a follow-up study. Where this occurs the results should not be recorded as entirely separate studies.

2.1.2 Categorising the evidence – primary sources

Primary evidence is evidence derived from individual, original studies of a particular diet, food or component and a health relationship. Categorising studies into broad types is a helpful first step as it provides an indication of the range of available evidence and its potential quality.

There are a number of types of studies that may be identified in the evidence search, not all of which will be suitable on their own for substantiating claims. In practice, evidence to support high level claims is likely to be derived from a number of the following categories:

- Experimental studies examining diet/food/component and health relationships in humans. Experimental studies include randomised and non-randomised, blinded and non-blinded clinical trials. These studies may include product-specific studies (for example, of the effect of consuming product X on cholesterol levels). If studies are unpublished, and therefore have not been subject to external peer review, very detailed reports of the studies should be available for review. These studies should have been conducted to the same ethical and quality standards as other experimental studies.

- Observational studies of humans, including cohort and case control studies.

- Supporting primary evidence including data from in vitro or in vivo studies involving chemical, cellular or animal models. Data from human biological experiments investigating plausible mechanisms of action of foods or components also fit in this category, as might some observational studies such as case series and cross-population studies. Supporting evidence is evidence that may add weight to an assessment but is not sufficient on its own to substantiate a claim.

2.1.3 Categorising the evidence – secondary sources

Secondary evidence sources are those that analyse and interpret the findings of a number of original studies for a specific purpose. Types of secondary evidence sources suitable to aid substantiation are:

- Systematic reviews, which are comprehensive analyses of all the available information relevant to a review question. Examples of such reviews are publications of the Cochrane Collaboration, which have traditionally focused on clinical trial data. The Cochrane Collaboration in Australia now has a health promotion and public health field that incorporates evidence in addition to clinical trial data; see <http://www.vichealth.vic.gov.au/cochrane/welcome/index.htm>. The International Agency for Research on Cancer also publishes systematic reviews; see <http://www.iarc.fr/> for details.

- Reports of evaluations of proposed health claims conducted by overseas governments or international agencies. These may include evaluations conducted with a comparable degree of rigour to that proposed by FSANZ for use in Australia and New Zealand.

- Publications such as the current Australian Dietary Guidelines (National Health and Medical Research Council 2003) or the New Zealand Food and Nutrition Guidelines (Ministry of Health 2003), reports of Australian and New Zealand government reviews into Recommended Dietary Intakes for nutrients and reports of the World Health Organization (for example, WHO 2003).

- Meta analyses, where data from different primary studies are integrated to achieve quantitative assessment of the overall evidence base.

2.1.3 Language and other requirements for applications

Applications for high level claims should include a summary report that presents a critical appraisal of the studies submitted as evidence and copies of all individual studies and reports that comprise the evidence. All studies submitted to FSANZ in support of a claim must be in English. Where studies in other languages are submitted, an English translation must also be provided. The full text of articles retrieved must be available for evaluation; abstracts or summaries of articles are rarely sufficient to allow detailed evaluation.

2.1.4 Example of the process of study identification and categorisation

Table 1 provides an example of a systematic process used to retrieve relevant evidence relating to a proposed health claim: 'Consumption of fruits and vegetables may be associated with a reduced risk of cancer'. The example covers the process from an initial thorough literature search, to selection of studies for detailed review based on pre-defined criteria, to initial categorisation into study type. It does not, at this stage, include assessment of study quality.

Table 1: Example of a search and categorisation strategy used to identify evidence to substantiate a claim that consumption of fruits and vegetables is associated with a reduced risk of cancer*

Databases searched	**Cancerlit, Medline, Medline Biol, Medline Psych, Medline Sociol, current titles**
Search key words (search words refined after other search words such as 'Diet' and 'Cancer' retrieved a very large number of references, many with little relevance)	'Fruit and vegetables' and 'Cancer prevention' 'Fruit' and 'Cancer prevention' or 'Vegetables' and 'Cancer prevention' 'Diet' and 'Cancer prevention' 'Diet' and 'Cancer risk reduction' 'Diet' and 'Behaviour change' and 'Cancer' 'Food Group and Cancer' As above for specific vegetables or fruits. Keywords were mapped to subject headings, for example 'Cancer prevention' was mapped to the subject heading 'Neoplasms' and then to the subheading: 'Prevention and Control'
Search key words not used	'Nutrients'/'Phytoestrogens'/'Antioxidants' and 'Cancer prevention' 'Diet' and 'Cancer treatment'
Search dates	1989 to present, because systematic reviews were identified early in the planning process that reviewed literature prior to 1989
Other information sources checked	International Agency for Research on Cancer Directory of Ongoing Research in Cancer Prevention <http://www-dep.iarc.fr/direct/projects.htm> Personal discussions with two New Zealand experts on this area
Total references retrieved from all sources	228 (number of papers retrieved would have been much greater if an earlier search date had been used)
Method of determining if references should be reviewed	Results from the search were printed by title and abstract Inclusion: if studies were directly related to the subject of the review, involved humans, if the intervention was not a component extracted from fruits and vegetables. Abstract scanned for relevance and abstracts provisionally classified as Experimental, Observational or Review Full text of relevant abstracts obtained
Number of references to be subject to further review	50 studies met the inclusion criteria
Category of studies retrieved	No experimental studies identified 46 observational studies identified (listed in attachment) 3 review articles identified (listed in attachment) 1 report of an assessment of a health claim conducted in an overseas country (listed in attachment)

* This table is provided as an example only and does not imply that alternative search and selection strategies may not be appropriate

2.2 Grading the quality of the evidence – step 2

Once all relevant evidence has been identified in step 1, the next step is to grade the quality of this evidence. It is important to grade the quality of evidence because, in the subsequent assessment of totality of the evidence, greater weight will be placed on higher quality studies.

Study quality is difficult to define and will be evaluated on a claim-by-claim basis by experts with experience in the critical appraisal of scientific information relevant to the claim in question. This section provides general information on the issues that may be considered when assessing quality of both primary and secondary evidence sources. Because high level claims will be assessed on a claim-by-claim basis, FSANZ may also consider issues that are not identified below, where appropriate.

In general, well-designed experimental studies such as blinded, randomised, placebo controlled clinical trials represent the highest study quality and are likely to be given the greatest weight in the subsequent assessment of the totality of the evidence, where such studies are available. In practice, there are likely to be many instances where high quality experimental studies are not available to assist in the evaluation of claims. Experimental studies of diet and disease are less common than experimental studies linking single foods or components to surrogate disease outcomes. Where experimental evidence is lacking it is possible that the quantity and quality of observational evidence may be sufficient to substantiate a health claim.

Assessment of the quality of primary evidence includes (but may not be limited to) assessment of the following elements:

- the completeness and appropriateness of the described methodology
- appropriate and accurate description and measurement of exposure to the diet, food or food component
- appropriate and accurate measurement of the health related outcome
- sample size
- study biases
- potential confounding variables
- inclusion of appropriate controls
- study duration, and
- appropriate statistical methods.

Each of these elements is discussed in more detail below.

A technique that can be used to manage assessment of large quantities of evidence is to identify, during step 2, those studies of greatest quality and relevance. Pivotal studies may be those considered to have, for example, the largest sample size, the most relevant subject, the best measurement techniques and the least bias. These 'pivotal' studies will carry the greatest weight in the later assessment of the totality of evidence.

A useful resource for those preparing to assess the quality of evidence is the Australian National Health and Medical Research Council's 2000 publication *How to use the evidence: assessment and application of scientific evidence*.

2.2.1 Complete and appropriate study methodology

The study design chosen should be the one most appropriate to the stated aims of the study and the particular relationship being studied. Whatever the study type, the report of that study should fully describe the aims of the study, the methodology used (including its limitations) and the results achieved. Assessment of study methodology should also identify where inadequate information was provided or where information gaps exist. Where unpublished studies, which have not been peer-reviewed, are used to substantiate a claim, it may be necessary to review all data (including individual 'raw' data points). These reports should indicate the names and affiliations of the principal researchers and note any possible conflicts of interest.

2.2.2 Appropriate and accurate description and measurement of the diet, food or food component

Experimental and observational studies require two key sets of measurements: measurement of the diet, food or component being studied; and measurement of the outcome being assessed. Inappropriate measurement techniques limit the conclusions that can be drawn from a study.

Assessment of the appropriateness of the description and measurement of the diet, food or component requires assessment of methods for describing and monitoring dietary patterns, appropriate measurement techniques for intakes of components (where relevant) and consideration of the bioavailability of food components (where relevant).

Identification and description of the diet, food or food component being measured

Studies should clearly identify the dietary pattern, the specific food consumed or the intake of a component that is the subject of the study. For example, if fruit and vegetable consumption is being measured the study should identify which specific fruits and vegetables are being studied and whether this includes processed fruits and vegetables such as potato crisps. Processing or cooking methods should be specified where this may be relevant. Where intake of a specific food component is being measured the study should define what particular chemical forms are included in this component. For example, a study of the effect of consuming vitamin E on a health outcome should describe the particular stereoisomers of alpha tocopherol that are measured and whether other tocopherols or tocotrienols are included in the study's definition of vitamin E.

Monitoring dietary patterns

Measurement of overall dietary patterns, or of consumption of a particular food, can be difficult to achieve in practice outside tightly-controlled experimental situations. Measurement can be more difficult in retrospective studies, such as case control studies, because these studies rely on participants recalling what they have eaten in the past.

All techniques for measuring dietary intake have significant limitations and may require a large sample size to enable valid conclusions to be drawn. Whatever method is used it is important that the limitations of the dietary collection method are taken into account. Dietary recording techniques used in studies should have been validated before use.

Some studies may have included measurement of one or more physiological markers of exposure to a particular component as an objective method for quantifying intake or validating other dietary measurement techniques. Where markers of intake or exposure are used, they should be specific to the dietary intervention being measured, measure responses across the range of intakes being studied, be measurable with precision and sufficient sensitivity and be applicable to the population group being studied.

In evaluating study quality, consideration should be given to whether the study participants adhered to the intervention throughout the trial. For example, if many participants were unable to maintain the intervention diet for the trial duration, the value of the study is lessened. Therefore for studies of dietary patterns or intakes of specific foods, dietary compliance may need to be measured at several different stages in the study. This is particularly important in longer-term studies where dietary patterns may change from those at the commencement of the study.

Measuring intakes of a food component

The study should measure intake of the food or component from all foods consumed and from non-food sources such as dietary supplements. For example, a study of the relationship between vitamin C intake and a health outcome would need to consider vitamin C intake from all foods consumed, both from naturally occurring vitamin C and from its use as a food additive. Intake of vitamin supplements containing vitamin C should also be recorded.

If laboratory determination of levels of a food component is required, measurements should be conducted at laboratories experienced, and preferably quality certified, in that particular method of analysis. Ideally, methods of analysis should be chosen that are well-accepted and have previously been validated and published. The method chosen should quantify the actual component that is being investigated. For example, components such as dietary fibre are not a single chemical entity and different analytical methods will be required depending on the chemical form of the fibre being studied.

Reliable measurement of the intake of a particular component is generally more difficult in an observational study because these studies do not involve a direct intervention with a controlled amount of the component. Quantification of intake is likely to be by indirect techniques such as the use of food composition tables.

If nutrient data are drawn from published food composition tables rather than analysis it is important that close consideration be given to selecting appropriate food matches, to the origin of the data (ideally Australian or New Zealand data should be used in Australian or New Zealand studies) and to the limitations of the data (for example, if values were determined using outdated methods of analysis or on foods no longer available). It should also be recognised that levels of components, such as nutrients, vary considerably within a single type of food, for example depending on factors such as processing and storage methods and innate biological variability.

Bioavailability of food components

Bioavailability of specific food components can be affected by factors such as:

- the chemical form in which the substance is consumed
- the individual's physiological need or nutritional status (for example, if body stores are lacking, more of the material may be absorbed from the diet)

- interactions between substances in the food, the meal or the total diet.

The form of a component used in experimental studies to substantiate a claim should be the same as the form present in the food for which a claim is proposed, so that equivalent bioavailability can be assumed. If this is not the case, it will be necessary to demonstrate that the two forms are of equivalent bioavailability.

2.2.3 Appropriate quantification of the health related outcome

The health outcome measured in a study must be relevant to the study hypothesis. The outcome measured may be a health or disease outcome (for example, measurement of the number of new cases of colorectal cancer) or a surrogate outcome (for example, measurement of numbers of adenomatous polyps as a biomarker for colorectal cancer).

Where the health outcome is assessment of a disease initiation or progression, consistent diagnostic and assessment criteria must be used and it may be necessary to train study assessors in applying these criteria.

Anthropometric measurements, such as of body mass or height, must be conducted using consistent techniques and equipment to overcome the considerable variation in these measurements that can result from different measurement techniques.

Where a biochemical parameter is the outcome being measured, analyses should be conducted in accredited laboratories with experience in the required method of analysis. Analytical methods must be sufficiently sensitive that small changes in levels can be accurately measured and reported.

All assessment techniques should have been validated before the study commenced.

Use of surrogate outcomes

Surrogate outcomes or endpoints are often used, particularly in experimental studies, because they may be easier to measure objectively and may develop in a shorter time than disease outcomes. These surrogate outcomes are commonly referred to as biomarkers.

Studies using surrogate outcomes are only useful in the substantiation process where there is a well accepted, predictive and dynamic relationship between the surrogate and a health outcome. Where studies of surrogate outcomes are used as evidence, the validity of that outcome should be demonstrated.

More information on the use of biomarkers in substantiating high level claims is in Appendix 1.

2.2.4 Sample size

Studies must include sufficient participants, in both the test and control groups, to be able to reach confident, statistically valid conclusions about the outcome, particularly where the magnitude of the outcome is likely to be small or the rate of occurrence of the outcome is expected to be low. Sample size calculators are available to aid assessment of the sample size needed to reach a conclusion at a given level of statistical significance; see for example, <www.sch.abs.gov.au>.

2.2.5 Sample and measurement bias

Avoiding bias in a study can be difficult and requires rigorous study design. Because it can be difficult to avoid bias, it is vital that any assessment of study quality considers the presence and extent of bias.

There are three major types of bias that need to be considered when evaluating primary evidence sources for health claims. These are:

- **Selection or allocation bias**. Issues that may be relevant to consider, depending on the particular study design, include the appropriateness of the randomisation technique used and the similarity of test and control groups in factors such as age, gender, socioeconomic status, ethnicity, exercise status, disease or risk factor progression. Whatever study design is used, study reports should fully describe the participant inclusion or exclusion criteria and should have collected detailed information on study participants at or prior to commencement of the study.

- **Performance and measurement bias**. Issues to consider, depending on the particular study design, include whether the test and control groups were reviewed at the same time intervals, using the same assessment procedures, whether they experienced similar confounding variables and the 'blinding' technique used (where appropriate). In studies of whole foods or diets it is rarely possible to conceal the intervention from participants or assessors. In retrospective studies, recall bias may be a particular issue as assessment is based on events that took place in the past.

- **Attrition or exclusion bias**. Study reports should identify the completion rate in both test and control groups and reasons for non-completion. Loss to follow-up is likely to be a greater issue in long-term studies.

2.2.6 Potential confounding variables

Confounders are factors associated with a disease, disorder or condition, or with an intervention, that prevent researchers from being able to unequivocally attribute an intervention to an outcome. Studies should attempt to control, as far as possible, potential confounders or to take them into account when analysing and interpreting the study results.

Common confounders in studies of diet and health include changes in body mass, exercise level, alcohol intake and smoking cessation. In addition, when one component of a food or diet is altered (for example, total fat content), the levels of other components are also likely to be altered (for example, protein and carbohydrate levels may change). It can therefore be difficult to separate the contribution of one dietary change from that of another.

2.2.7 Inclusion of appropriate controls

Controls are used in experimental or observational studies to take into account the effect of chance or other non-intervention factors on the study outcome. The most common control used in experimental studies is the placebo. However, when the intervention being studied is a food or dietary change, it is difficult to disguise this change with a placebo, because the sensory properties of the diet or food also change. In observational studies the control may be a matched group of participants who do not receive the food in question or who follow a different dietary pattern. Because of the difficulty in developing appropriate controls for food and/or diet studies, the results of these studies may have a greater degree of uncertainty than experimental studies of, say, a new medicine.

2.2.8 Study duration

Study duration should be sufficient to allow development of whatever health outcome is being measured to take place and therefore to enable conclusions to be drawn about the significance and sustainability of the measured outcome. If disease, rather than changes in the level of a biomarker, is the study outcome, studies will need to be of much longer duration.

In experimental studies, time should be allowed at the beginning of the study ('lead-in' period), and between any separate interventions in a crossover trial ('wash out' period), to allow biochemical parameters to stabilise.

The health status of participants in experimental studies should be followed up some time after the study finishes to monitor long-term health outcomes.

2.2.9 Statistical analysis

All experimental and observational studies should be subjected to rigorous statistical analysis. Without this it is rarely possible to conclude with confidence that a health outcome measured in a study has been affected by the study treatment. The statistical analysis should enable some judgement to be made about the magnitude of the outcome measured. Common ways in which the outcome is analysed include use of a P-value, confidence intervals, odds ratios, relative risk, attributable risk, number needed to treat, standardised mean difference or weighted mean difference. Definitions of these terms are provided in the glossary at the end of this paper.

Statistically significant results may be observed in a study that are of no clinical or health significance; the finding of statistical significance does not automatically imply that a health claim is appropriate.

2.2.10 Quality of systematic reviews

Systematic reviews selected to aid substantiation of a claim should be directly relevant to the subject of the proposed claim. If a review has been identified that is relevant, some specific aspects of the quality that should be considered include:

- The review should have a clearly stated aim.

- The review should be based on a comprehensive search for evidence that used clearly stated inclusion and exclusion criteria relating to the purpose of the evaluation. The search strategy should be fully described. The study selection criteria should not automatically exclude studies published in languages other than English, or unpublished studies.

- The reviewers should have assessed the effect of publication bias (such as many small studies that have a positive effect compared to only a few well-designed experimental studies that have a negative effect).

- The quality and validity of each cited study should have been reviewed. The use of more than one assessor may help to overcome assessment bias.

- The results should be presented clearly and effectively.

- Conclusions reached should be supported by the data and the analysis presented.

Systematic reviews of appropriate quality may help streamline the substantiation process. However, if they are used as evidence to substantiate a claim, the following steps should also be undertaken:

- Pivotal studies cited should be obtained and reviewed independently to determine the appropriateness of the conclusions reached in the review.

- All evidence that has emerged since publication of the report should be obtained and evaluated and the findings of the review re-assessed in light of any new evidence.

- The review should be supplemented by evidence to show the relevance and generalisability of the review to Australians and New Zealanders.

2.2.11 Quality of other secondary evidence sources

Meta analyses

Meta analyses should follow the same quality criteria as set out for systematic reviews. In addition, the following should be considered:

- Individual studies included in the analysis should have closely related outcomes and measurement techniques so it is reasonable to combine the results.

- Appropriate statistical techniques should have been used to analyse the results.

Reports of evaluations of proposed health claims conducted by overseas governments

Reports of the assessment of health claims on foods conducted by overseas governments may be suitable for use as part of the substantiation process where:

- The subject of the claim is consistent with that proposed for Australia and New Zealand.

- The assessment was conducted to the standards established by FSANZ.

- Pivotal studies cited in the review should be obtained and reviewed independently to enable a determination on the appropriateness of the conclusions reached in the review.
- The evaluation is supplemented with evidence that has become available since the time the overseas assessment was conducted.
- The evaluation is supplemented with consideration of the applicability of the findings to the Australian and New Zealand populations.

2.2.12 Summary of studies suitable for use in substantiating claims

Table 2 summarises the types of primary evidence that can be used to substantiate high level claims. This is an indicative categorisation as each claim will be assessed on a case-by-case basis.

Table 2: Indicative categorisation of primary evidence sources for the substantiation of high level claims

Required for substantiation	Desirable for substantiation as supporting information	Not suitable for substantiation
Experimental studies of humans, with satisfactory study design, particularly: • appropriate techniques to minimise bias with particular attention to randomisation and blinding • sufficient sample size and study duration • appropriate controls • adequate definition and measurement of the intervention and outcome • good control of potential confounders.	In vitro or in vivo studies involving chemical, cellular or animal models.	Experimental studies of humans where there are major flaws in study design or conduct.
	Data from human biological experiments investigating plausible mechanisms of action of foods or foods substances.	Observational studies of humans where there are major flaws in study design or conduct.
AND/OR		
Observational studies (cohort and/or case control) of humans, with satisfactory study design, particularly: • appropriate techniques to minimise bias with particular attention to measurement and attrition bias • appropriate control groups used • adequate definition and measurement of diet and/or food intake and the health outcome • good control of potential confounders.	Observational studies that are well designed and conducted, other than cohort and case control studies.	Any study that is not relevant to the proposed claim.

2.2.12 Example of the assessment of study quality

Table 3 provides an example of a template that can be used to facilitate assessment of the quality of primary evidence sources available to substantiate high level claims. A range of such templates can be used depending on the claim under evaluation. It is not essential to use such a template but practical experience suggests they are useful tools both for evaluators and for manufacturers submitting evidence, to identify weaknesses in the evidence base prior to submitting an application.

When a large number of studies are available for review, it can be helpful to group studies by study design, by the type of intervention and/or by the outcome being measured,

Please note that the study described in Table 3 is fictitious.

Table 3: Example of a template that can be used to evaluate the quality of available studies

Study	Study hypothesis, Study design	Quantification of intervention and outcome	Subjects, inclusion criteria, duration	Sample and measurement bias, inclusion of controls	Confounders	Statistical analysis	Quality rating (within category)
Zones et al 1998	Increased consumption of fruits and vegetables to 7 serves/day will result in beneficial changes in plasma lipid concentrations Experimental - randomised, controlled clinical trial. Not blinded.	Health outcome: plasma lipids measured with appropriate method in experienced lab. Diet measured with 2x4-day diet records (wks 0 and 4) and 1x24 hour recall (wk 6) – additional measurement at end of study would have helped. Did not fully define what was included as fruit and vegetable – were processed varieties included? Bioavailability not relevant.	n=85, 23 Caucasian males aged 19-69 years, 62 Caucasian females aged 18-63 years. Healthy. Inclusion if eat ≤ 3 serves fruit and vegetables per day. 8 week test, plus 2 week run-in Sample size adequate, longer duration would have assisted study weight.	Test and control groups did not differ significantly in key inclusion criteria and baseline lipid parameters. Further detail required on randomisation techniques. Measurements bias not apparent – same techniques applied to all participants. No differences in drop-out rates between test and control groups. Blinding not possible due to nature of intervention. Control is individuals maintaining ≤ 3 serves per day.	Changes in antioxidant intake. Changes in fat intake. Body mass change if energy intake not controlled.	Appropriate analysis undertaken – 95% CI determined.	Suitable for consideration. Not a pivotal study due identified deficiencies in design.

2.3 Interpreting the evidence study-by-study – step 3

Once studies have been identified, categorised and their quality assessed, as set out in steps 1 and 2, it is then necessary to consider the findings of the individual studies. Does the evidence in an individual study show a causal relationship between the diet, food or food component and a health outcome? If so, what is the specific relationship and under what circumstances does this relationship exist? Is the study relevant to the proposed claim and can its findings be generalised to the broader population?

2.3.1 Assessing causality

A causal relationship exists when it is shown, with reasonable certainty, that consumption of a diet, food or component alters the probability of developing a health outcome, independent of other factors. Different study designs vary in their ability to show a causal relationship, with experimental studies generally the most effective at establishing causality. Where only observational studies are available, causality has to be inferred through the strength of measured associations.

The assessment of causality, within an individual study, generally involves assessment of each of the following key areas:

- strength of association (for observational studies) or size of effect (for experimental studies)
- independence of association
- dose–response relationship
- temporal relationship.

As many as possible of the following should also be considered:

- reversal of effect
- specificity, and
- biological plausibility.

When examining a series of related studies, consistency of findings provides further weight for a causal relationship existing.

<u>Strength of association or size of effect</u>

A relationship is more likely to be causal if there is a large difference (for example, in the relative risk) between test and control groups. However, a smaller observed difference may indicate acceptable strength when it was derived from a study with a large number of participants.

Narrow confidence intervals and strong statistical significance lead to greater confidence in the study. In observational studies, the relative risk or odds ratio should be different from, and not overlap, one, as a ratio of one indicates no significant difference between test and control groups. Absolute risk should be reported as well as relative risk. The confidence interval should also be reported.

Independence of association

An association or relationship between a treatment and an outcome is independent of other factors when it cannot be explained by any alternative or confounding explanations. For example, in a study of the effect of increasing fruit consumption on low density lipoprotein cholesterol levels, is an observed decrease in low density lipoprotein cholesterol with increasing fruit consumption actually a result of a concurrent decrease in energy and/or fat intake? Multivariate statistical analysis techniques are often used to take into account the effect of key confounders.

Dose–response relationship

While in theory the magnitude of an observed response is related to the dose of the food or component administered, these relationships are not always observed in studies of foods or diets, for example because there is a threshold above or below which no detectable change takes place or because there is a limit to the amount of food people can consume. However, it should be possible to determine from a study the minimum intake of a food or component that is needed to achieve the reported health outcome.

Temporal relationship

If a causal relationship exists, the desired outcome should not occur until after the intervention takes place; in other words, the intervention is required to achieve the outcome. If the outcome occurs before exposure to the intervention, it is not possible to conclude that the intervention was responsible. In retrospective observational studies, it can be difficult to determine whether or not the appropriate temporal relationship exists.

Reversal of effect

If a food or food component has a beneficial effect, this effect should be removed when the food or food component is removed from the diet, after an appropriate time period.

Specificity

If a relationship between an intervention and an outcome is specific, only the intervention should cause the outcome and the intervention should not cause another outcome. Specificity may be very difficult to determine in studies of diets and foods.

Biological plausibility

Evidence for a causal relationship is strengthened if there is a known or postulated biological mechanism to explain the relationship. Similarly, if the mechanism does explain the outcome, the effect of the intervention is likely to also be seen in related endpoints. Lack of knowledge of a biological mechanism to explain an outcome does not prevent a claim being substantiated.

2.3.2 Specific relationship and circumstances of its existence

If, after reviewing a study, a causal relationship appears to exist between the intervention and the health outcome, it is important to clearly define exactly what this specific relationship is and the circumstances under which it occurs. This assists in later steps when establishing qualifying criteria for a claim.

When defining the specific intervention, issues to be considered include identifying the specific dietary pattern that was followed, the foods or food components that were associated with the outcome, the required intake and/or frequency of intake and, in the case of components, the specific chemical form and food matrix in which it was administered.

When defining the specific outcome, issues to be considered include identifying the outcome that was measured (for example, low density lipoprotein cholesterol levels) and the magnitude of the outcome.

For each study evaluated, the affected population group should be clearly defined. Factors to be considered here may include the age, gender, race, socioeconomic status, geographic location, family history, dietary patterns, health status and motivation of the population studied.

Any additional dietary factors associated with the outcome should also be identified. For example, the intervention may have only been studied in association with a specific dietary pattern such as a diet containing no more than 30% of energy from fat, or may have been associated with a specific food matrix (such as supplemental calcium administered only in milk-based drinks).

Identify adverse effects

Adverse effects associated with an intervention in an experimental study should be identified. These may include adverse health outcomes, changes in key biomarkers that may predict adverse health outcomes, or undesirable changes in dietary patterns as a result of the intervention.

2.3.3 General applicability and relevance of study findings

Once a specific causal relationship has been defined, consideration must be given to whether this relationship is likely to be reproduced in a 'real-life' situation, where peoples' diets are complex and variable and there are a multitude of influences on health and nutrition.

Where the available evidence is based on a particular population subgroup (for example, males over 45 years, or those with elevated low density lipoprotein cholesterol levels) it is not acceptable to extrapolate this evidence to apply to other population groups. If the effect of the food or component only occurs in a specific subgroup of the population, consideration will be given, during assessment, of the totality of the evidence (step 4) as to whether a health claim on food products would be useful to this subgroup. This will take into account factors such as gender, ethnicity, physiological status and age.

Similarly, if the study related to a food or dietary pattern that is unusual in New Zealand or Australia, the study findings are unlikely to be broadly applicable in the context of the total diet in Australia and New Zealand. For example, the evidence may demonstrate that a particular intake of a component or food is required to achieve the claimed outcome. Consideration of the dietary patterns of Australians and New Zealanders may show that it is unlikely that such an intake could be achieved in practice. In considering applicability to dietary patterns, FSANZ will take account of information on the most recent national nutrition surveys held in New Zealand and Australia, or from company-specific market research.

2.3.4 Example of an interpretation of study findings

Table 4 provides an example of a template used to interpret and summarise the findings of a fictitious study. Summaries such as this aid in the subsequent assessment of the totality of evidence but are not mandatory.

Table 4. Example of an interpretation of the findings of a study submitted in support of a high level claim

<table>
<tr><th rowspan="2">Study</th><th rowspan="2">Results</th><th colspan="3">Causal relationship?</th><th rowspan="2">Relationship identified

Negative effects identified</th><th rowspan="2">Context of the relationship

Overall conclusion</th></tr>
<tr><th>Strength, statistical significance</th><th>Dose response, temporal relationship</th><th>Specificity, confounders, reversal of effect, plausibility</th></tr>
<tr><td>Zones et al 1998

Experimental study</td><td>
<table>
<tr><th>Intake</th><th>Baseline control</th><th>Baseline test</th><th>Wk 4 control</th><th>Wk 4 test</th><th>Adjusted difference* (95% CI)</th></tr>
<tr><td>Fruit (g)</td><td>37 ± 51</td><td>93 ± 118</td><td>55 ± 84</td><td>256 ± 132</td><td>177 (124-225)</td></tr>
<tr><td>Vegetables (g)</td><td>196 ± 87</td><td>228 ± 127</td><td>218 ± 104</td><td>332 ± 149</td><td>104 (45-160)</td></tr>
<tr><td>Fibre (g)</td><td>17</td><td>19</td><td>19</td><td>25</td><td>6.2 (2.1-9.0)</td></tr>
</table>
* Between treatment and control groups at week 4 adjusted for age, sex, baseline value

Plasma lipid concentration (mmol/L) (mean±SD)
<table>
<tr><th>Lipid</th><th>B'line cntrol</th><th>B'line test</th><th>Wk 8 cntrol</th><th>Wk 8 test</th><th>Adj diff (95% CI)</th></tr>
<tr><td>LDL</td><td>3.17 ± 0.85</td><td>2.95 ± 0.91</td><td>2.97 ± 0.92</td><td>2.82 ± 0.85</td><td>0.02 (-0.29 - 0.25)</td></tr>
<tr><td>HDL</td><td>1.27 ± 0.38</td><td>1.18 ± 0.38</td><td>1.35 ± 0.40</td><td>1.23 ± 0.41</td><td>-0.08 (-.15-.001)</td></tr>
</table>
</td><td>No statistically significant relationship found.</td><td>No relationship found.</td><td>Not applicable</td><td>No relationship identified between consumption of an extra 4 serves of fruit and vegetables per day for 8 weeks, and plasma lipid levels in healthy adult males and females.

No adverse effects noted. Foods omitted to accommodate additional fruit and vegetable were snack-type foods. However total energy intake increased by 500 kJ per day.</td><td>Healthy adult individuals, males and females, free living, omnivores, Western diet – study applicable to general adult population in Australia & NZ.

Conclusion:
Does not support proposed health claim</td></tr>
</table>

2.4 Evaluating the totality of the evidence – step 4

A single study can never be considered definitive in understanding a particular diet–health relationship. Understanding a relationship involves consideration of all relevant information – the evaluation of 'totality' and assessing the consistency of findings across a range of studies. The concept of totality recognises that scientific evidence is built on the collective strength of different approaches, and allows for weaknesses in certain studies to be complemented by strengths in others.

Evaluation of the totality of evidence refers to evaluation of all available data of suitable quality relevant to the claim, including evidence that supports the claim as well as equivocal evidence and evidence of no effect and/or opposing effects. Evaluation of totality does not mean it will be necessary to consider every relevant paper ever published. In many cases the existence of a high quality systematic review or overseas government evaluation of a health claim may help streamline the review of primary evidence if combined with an assessment of the primary pivotal studies, as outlined in section 2.2.10.

2.4.1 Factors that will be considered when assessing totality

Key matters that will be considered in assessing totality include, but are not limited to:

- The range and type of studies available will be assessed to determine whether there is any evidence of appropriate quality.
- Greater weight will generally placed on higher quality studies.
- Areas where there is lack of evidence across studies will be identified and the impact of these deficiencies will be taken into account.
- The overall relationship (if any) between the type and amount of diet, food or component and the health outcome will be determined.
- Where possible, the dose–response relationship or required intake of a food or component will be determined.
- Dietary patterns or other lifestyle patterns associated with the health outcome will be determined.
- An assessment will be made of whether the claimed beneficial effect is of a nature or size that would have population health significance.
- Whether there is a biologically plausible mechanism to explain the claimed effect.
- Consistency of findings across study types will be evaluated.
- The relevant characteristics of the populations studied will be determined and compared to the target group to whom the claim is directed assessed.
- The likely sustainability of the claimed beneficial effect in the target population under experimental and every-day circumstances will be assessed.

- Whether the required dietary pattern or food or component intake could be achieved in practice, as part of an appropriate total diet, and the potential impact of this consumption pattern on the health of New Zealanders and Australians generally.

- Any adverse effects identified.

- The degree of confidence that new evidence is most unlikely to challenge the claim.

As previously stated, evaluation of totality will be undertaken on a claim-by-claim basis and therefore factors not identified above may be taken into account.

2.4.2 Classifying the likelihood that the proposed claim is substantiated

Once the overall relationship has been determined, the likelihood of this relationship being true will then be assessed. The following classification scheme (which is based on the classification of the World Health Organization (2003)) will be used:

- **Convincing evidence** – shows consistent associations between the diet, food or component and the health outcome, with little or no evidence to the contrary. There should be a substantial number of human studies of acceptable quality, preferably including both observational and experimental studies and preferably conducted in different population groups. Any dose–response relationships should be supportive of a causal relationship and the relationship should be biologically plausible. Supporting evidence sources should be consistent with the findings of primary human evidence.

- **Probable evidence** – there should be a number of acceptable human studies, preferably including observational and experimental studies. These studies show associations that are either not so consistent, with a number of studies not supporting the association, or the evidence base is insufficient to make a more definite judgement (for example, there are a limited number of studies or the studies are of limited duration, small sample size or with incomplete follow-up). Some of the evidence may have only recently emerged and still be subject to ongoing research. Mechanistic and laboratory evidence are usually supportive and the relationship should be biologically plausible.

- **Possible evidence** – studies generally indicate a relationship exists, but the studies may be limited in number, quality (for example, only supporting evidence sources may be available) or consistency or may reflect predominantly emerging evidence. There may or may not be supportive mechanistic or laboratory evidence and the relationship should be biologically plausible. More higher quality studies are required to support the tentative relationship.

- **Insufficient evidence** – there are only a few studies, which while generally consistent are not of appropriate quality to substantiate a relationship. More well-designed research is needed.

*While all high level claims will be assessed on a claim-by-claim basis, approval of such claims is likely to require **convincing** scientific evidence so as to offer reasonable certainty that the claim is unlikely to be contradicted in the future by new evidence.*

2.5 Determining qualifying criteria and assessing whether the food meets these criteria – step 5

2.5.1 Determination of qualifying criteria

After FSANZ has assessed the totality of the evidence to support a health claim, it will consider what criteria must be met before a food is eligible to carry that claim. These qualifying criteria may include specific compositional requirements (including a minimum level of a component that must be able to be delivered). FSZNZ may restrict the claim to certain types of foods, and it may establish particular information that must be included with the claim, or may relate to other matters.

For example, the evidence may have demonstrated that the health outcome is associated with a specific population group, a minimum concentration of the component in a food, a minimum amount of a food or component consumed per day, a specific associated dietary pattern, a specific food matrix or a particular chemical form of a substance. In these circumstances, the qualifying criteria would reflect these findings.

2.5.2 Assessing whether a food meets the qualifying criteria

In assessing whether foods are likely to meet qualifying criteria for use of a claim, FSANZ may consider one or more of the following issues. If FSANZ approves a claim, it is the manufacturer's responsibility to ensure any food they manufacture that carries this claim meets all qualifying criteria.

If one or more of the criteria relate to a particular level of a component in a food, there should be evidence to show that the food in question reliably contains that component in the required quantities. In the case of a component occurring naturally in that food (for example, a nutrient or other bioactive substance), natural variation in levels of that substance, and the effects of processing and storage on the stability of the substance, will be considered. In certain circumstances it may be necessary to examine evidence assessing bioequivalence of different forms of the component, if a health outcome is dependent on the bioavailability of a component or on a specific food matrix.

If the claim relates to a food rather than a specific component of the food (for example, oat bran that may be added as an ingredient to another food such as a breakfast cereal), information on the processing steps that control levels of ingredients may be considered.

2.5.3 Consumer perceptions about the claim

Information presented in a high level claim must not only be substantiated by scientific evidence, but must also take into account how consumers receive and use label information. FSANZ may therefore take into account research about how consumers interpret a proposed claim or classes of claims and about the associated information (if any) they may also need to interpret a claim.

Chapter 3 General level claims

General level claims are claims that do not reference a biomarker or a serious disease. They include claims referring to the function of nutrients in the body. Many of these functions are well documented and widely accepted and have, essentially, been substantiated in a process analogous to the process FSANZ will use for evaluating high level claims. Given this, and also that general level claims do not reference serious diseases, it is appropriate to simplify the substantiation process for these claims where the claimed relationship is well-established (or consistently agreed). The simplified process adheres to general substantiation principles but presents a streamlined process of evidence collection based on use of authoritative, generally-accepted information sources under some circumstances.

General level claims include content claims. Content claims are considered separately in Chapter 4 of this document as the requirements for these claims have been further streamlined.

3.1 Identifying an appropriate authoritative evidence source – step 1

If a manufacturer wishes to make a general level claim, an appropriate, authoritative evidence source must be available to substantiate this claim. Authoritative evidence sources that may be appropriate for substantiating general level claims include:

- information in Australian and New Zealand national dietary guidelines and reviews of recommended dietary intakes, or other relevant national, diet-related policy documents released by authoritative bodies
- information in authoritative, current science texts of a standard suitable for use in university courses in dietetics
- information from reports of health claims assessed by overseas governments.

The appropriateness of these evidence sources relies on there being no equally strong, equivocal or opposing evidence relevant to the claim in question.

Each of these evidence sources is described in detail below.

Where no authoritative evidence source can be identified to support the proposed claim, manufacturers should follow a substantiation process consistent with the requirements for substantiation of high level claims.

3.1.1 Australian and New Zealand diet-related policy documents

In Australia, the National Health and Medical Research Council has published detailed position papers in support of the most recent dietary guidelines. These documents can be accessed at <www.nhmrc.gov.au/publications/nhome.htm>. The New Zealand Ministry of Health publishes comparable documents and other food-related policy statements, including food and nutrition guidelines, that can be accessed at <http://www.moh.govt.nz/moh.nsf/wpg_Index/Publications-Index>.

The most recent versions of national dietary guidelines and other policy documents should be consulted when substantiating a general level claim, to ensure the claim is based on current evidence. In some cases it may be appropriate to undertake a search of the scientific literature published since the documents were released to be satisfied that no major new evidence has emerged that would modify the conclusions reached in these documents. Information on searching scientific literature is provided in section 2.1.1.

When interpreting information contained in dietary guidelines, it is important to bear in mind that the guidelines apply to the total diet and not to a single food within a diet. Where the dietary guidelines documents indicate that evidence for a relationship is weak, this suggests that the relationship is not substantiated to a consistently agreed level.

3.1.2 Information in current authoritative texts

Characteristics of texts that may be suitable for substantiating general level claims include:

- the texts are of a standard suitable for use in teaching university level dietetics courses
- they are the most recent edition, preferably released within the previous five years
- they draw on primary evidence (for example, articles in scientific journals) and do not simply repeat previously published text without independent verification
- they contain a detailed bibliography
- they are prepared by authors who are recognised experts in the field or by a range of authors under the direction of an experienced scientist or appropriate editorial committee.

A search of the scientific literature published since the texts were released should be carried out to ensure no major new evidence has emerged that would modify the conclusions reached in these documents. Information on searching scientific literature is provided in section 2.1.1.

Authoritative texts cannot be taken to provide evidence to substantiate a general level claim when these texts indicate that a particular relationship between a diet, food or component and a health or physiological outcome is uncertain, is yet to be confirmed, is based only on animal studies or is speculative.

3.1.3 Reports of health claims evaluated by overseas governments

Reports of the assessment of health claims on foods conducted by overseas governments may be suitable for use as part of the substantiation process for general level claims where:

- the subject of the proposed claim is consistent with that proposed for Australia and New Zealand
- the assessment was conducted to the standards established by FSANZ for high level claims
- the evaluation is supplemented with evidence that has become available since the time the overseas assessment was conducted

- consideration is given to the applicability of the findings to the Australian and New Zealand populations.

3.1.4 Evidence gathered through a structured review of the totality of all available evidence

If no authoritative evidence source is available to substantiate a general level claim, an assessment of the totality of available evidence, as required for substantiation of a high level claim, can be undertaken. Chapter 2 provides guidance on how to do this. It is suggested that manufacturers or suppliers who wish to follow this substantiation approach seek advice or assistance from a suitably qualified expert.

3.1.5 Unacceptable evidence sources for general level claims

Evidence from studies of nutrients or other bioactive substances consumed in the form of medicines or dietary supplements may not be appropriate for substantiating a claim for that nutrient or bioactive substance consumed as part of a food, due to differences in bioavailability and dose.

Information obtained from newspapers, magazines, non-peer reviewed newsletters and many Internet sites are not suitable for use in substantiating claims.

3.2 Determining if the proposed claim is consistent with the available evidence – step 2

3.2.1 Determining the amount and type of food or food component that is required

The substantiation process in step 1 should identify the amount of a food or component that needs to be consumed in order to achieve the claimed health outcome.

If evidence is obtained from an authoritative source, information should be available in that source to indicate the required daily intake of the food or component. For example, dietary guideline documents will contain information on the recommended number of serves of different classes of foods.

Where a review of the totality of evidence has been undertaken, this review should have identified the required daily intake of a food or component. If the evidence indicates that a specific amount of a component is required to achieve the claimed health outcome, a food that carries that claim should contribute a significant proportion of the total daily intake required in a reasonable serve of the food. Consideration may need to be given as to whether there are any other significant sources of that component in the diet of New Zealanders and Australians.

3.2.2 Qualifying and disqualifying criteria for nutrition function claims

In the case of nutrition function claims, qualifying and disqualifying criteria are likely to be established. These criteria may include a minimum content of a nutrient the food should contain before making a claim relating to that nutrient.

3.2.3 Determining whether the food contains sufficient of the food or component in question

After determining that a proposed claim is substantiated and the amount of the food or component that must be consumed to achieve the outcome, it is then necessary to determine if the food that is proposed to carry the claim can supply these amounts. Can the required amount of food realistically be consumed? Does the food that is to be supplied contain the required amount of a food or component?

Consideration must be given to the likelihood that the required quantity of a food or food component can realistically be achieved from existing dietary habits among New Zealanders and Australians. Information on current dietary patterns may be obtained from the most recent national nutrition surveys held in New Zealand and Australia, or from company-specific market research. Serving sizes used to determine whether the food contains sufficient of another food or of a component to achieve the desired outcome should be realistic and should not be misleading to consumers.

Determining whether the product supplied contains sufficient of a food or component may involve assessing manufacturing techniques and/or conducting laboratory analyses of the product.

Where the proposed claim requires a particular level of a food ingredient in a multi-ingredient food (for example, oat bran that may be added as an ingredient to another food such as a breakfast cereal), the processing steps that control levels of ingredients should be assessed to be confident that the required ingredient level is attained and that the processing undertaken does not damage or destroy the health-related properties of that ingredient.

Where the proposed claim requires a particular level of a component, there should be evidence to show that the food in question reliably contains that component in the required quantities. This evidence should preferably be derived from laboratory studies of the level of that component in the specific food, stored under usual conditions of storage, with samples selected based on a statistically-valid sampling plan.

In the case of a food component occurring naturally in that food (for example, a nutrient or other bioactive substance), natural variation in levels of that substance, and the effects of processing and storage on the stability of the substance, should be considered.

Where the health outcome is associated only with a specific chemical form of a component (for example, a specific calcium salt) it will be necessary to ensure this is the form that is present in the food proposed to carry the claim. Alternatively, there should be evidence to demonstrate that the form used in the food in question is bioequivalent to that used in evidence.

Chapter 4 of this document provides some additional information on determining whether a food contains sufficient content of a component to support a general level claim relating to that component.

3.2.3 Information a manufacturer or supplier should hold to demonstrate substantiation

Where evidence to substantiate a claim is consistently agreed evidence, such as that derived from one of the authoritative sources outlined in section 3.1, the manufacturer or supplier should hold:

- a copy of the relevant section of the authoritative evidence source(s), plus, if necessary, any additional material released since the authoritative source was published
- evidence to demonstrate that the product contains the required amount of the food or food component

Where evidence to substantiate a claim is 'weight of evidence', such as that derived from a systematic review of the totality of evidence, the manufacturer should hold:

- copies of all studies cited in the substantiation process
- a summary evaluation of the totality of the evidence
- evidence to demonstrate that the product contains the required amount of the food or food component.

Chapter 4 Content claims

Content claims are specific types of general level claims for which further streamlining of the substantiation requirements is appropriate. They include nutrition content claims (for example, 'this food is a source of calcium') and claims about the content of other biologically active substances. Because these claims do not make reference to any health outcome or role of a component, it is not necessary to identify an evidence base to support these relationships. The only substantiation requirements are determination of the level of the component in the food.

4.1 Determining the level of a component present in the food

Foods carrying content claims should, on average, contain the component that is the subject of the claim, at the levels referred to in the claim.

To determine whether a food does indeed contain the stated component content, it is preferable to undertake laboratory analysis to measure the component content in a range of batches manufactured or grown at different times, with the analysis conducted using appropriate and recognised methods of analysis. Samples for analysis should be selected using a structured and validated sampling plan. Laboratories undertaking these analyses should be experienced in that analysis and follow appropriate laboratory quality control procedures.

While food composition tables and tools such as the Nutrition Panel Calculator (available at <www.foodstandards.gov.au>) can be used to determine the level of a nutrient in a food, it is recommended that they are only used with caution when substantiating specific content claims, particularly claims that relate to a multi-ingredient food.

The content should be determined on the form of the food in which it is intended to be consumed. For packaged foods, this will generally be the form suggested in the directions for use included in the label. When determining the nutrient content per serve of a food, nominated serving sizes should be realistic and should not be misleading to consumers.

4.2 Determining whether the food contains component levels required before a claim can be made

Once the level of the nutrient in question has been determined, it is necessary to compare this to any levels stipulated in the Code or related materials. It is anticipated that qualifying and disqualifying criteria associated with specific content claims will be developed, at least for content claims that refer to nutrient levels.

Appendix 1: Biomarkers in the substantiation of nutrition, health and related claims

What is a biomarker?

For the purposes of substantiating claims on foods, biomarkers (or biological markers) are surrogate outcome (or clinical endpoint) measures. The following is a working definition of a biomarker, which will form the basis for a regulatory definition:

> A biomarker is a measurable, biological parameter that predicts the risk of human disease, disorders, conditions or defects. The biomarker is not a measure of the disease, disorder or condition itself.

Within the context of this document, the term biomarker does not refer to markers of exposure to a component or markers of intake of a food.

Why are biomarkers relevant to nutrition, health and related claims?

Biomarkers have two key roles in relation to claims:

- they may be the outcome measures used in human studies of the effect of a diet, food or component and health outcomes
- they may form the subject of a claim (for example, 'Diets low in saturated fats may help maintain healthy cholesterol levels').

What criteria should a biomarker meet?

When biomarkers are used to help substantiate a claim, the following criteria should be met:

- The biomarker should be a physiological variable, preferably with a dynamic response to intervention.
- There should be a biological basis for believing that 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.
- The validity of the biomarker should have been rigorously evaluated.

The criteria that apply to biomarkers used in substantiation of a claim can also be applied to biomarkers proposed for use as the subject of claims. In other words, a biomarker should have scientific credibility before it is used in the wording of a claim. In addition, biomarkers proposed as the subject of a claim should be ones that are meaningful to, and do not mislead, consumers. It may be necessary to determine, through consumer research, that consumers apply an appropriate meaning to a biomarker before it is used in a claim.

What biomarkers are acceptable for use in claims?

The following biomarkers are likely to be acceptable for use in substantiating high level claims, without the need to submit detailed information validating use of that biomarker:

Biomarker	Related health/disease outcome
Serum low density lipoprotein cholesterol levels	Cardiovascular disease
Bone mineral density	Osteoporosis
Blood pressure	Hypertension/cardiovascular disease/stroke
Intestinal polyps	Colorectal cancer
Fasting blood glucose	Diabetes

Where it is proposed to use other biomarkers to substantiate a claim, evidence should be submitted to FSANZ (in the case of a high level claim) to demonstrate that the biomarker meets the above criteria.

In future, it is likely that validated genetic markers of disease risk will meet these criteria.

Where can I find more information on biomarkers?

Useful resources on the use of biomarkers in health claims include papers by Health Canada (2000) and Roberts (2002). Information on the use of genetic biomarkers in cancer risk can be found on the International Agency for Research on Cancer website at <http://www.iarc.fr/>.

Glossary

absolute risk reduction	The difference between the rate of a health outcome in the treatment group compared to the control group (National Health and Medical Research Council 1999)
bias	A systematic deviation of a measurement from the 'true' value leading to either an over- or under-estimation of the treatment effect. Bias can originate from many different sources, such as allocation of patients, measurement, interpretation, publication and review of data (National Health and Medical Research Council 2000).
bioavailability	The ability of a food component such as a nutrient to be readily absorbed, distributed and utilised in the body (Elwood 1992).
biological plausibility	The observed association has a known or postulated biological mechanism by which the exposure might reasonably alter the risk of developing the disease (Hennekens 1987).
[biomarker]	[A measurable, biological parameter that predicts the risk of human disease, disorders, conditions or defects. The biomarker is not a measure of the disease, disorder or condition itself.]
blinding (or masking)	The process used in epidemiological studies and clinical trials in which the observers and the subjects have no knowledge as to which treatments subjects are assigned. It is undertaken in order to minimise bias occurring in patient response and outcome measurement. In single-blind studies only the subjects are blind to their allocations, whilst in double-blind studies both observers and subjects are ignorant of the treatment allocations (National Health and Medical Research Council 2000).
case-control study	Patients with a certain outcome or disease and an appropriate group of controls without the outcome or disease are selected (usually with careful consideration of appropriate choice of controls, matching etc) and information is obtained on whether the subjects have been exposed to the factor under investigation (National Health and Medical Research Council 2000).
case series	The intervention has been used in a series of patients (may or may not be consecutive series) and the results reported. There is no separate control group for comparison (National Health and Medical Research Council 2000).
clinical significance	The quality of a study's outcome that convinces physicians to modify or maintain their current practice of medicine. The assessment of significance is usually based on the size of the effect observed, the quality of the study on which it is based and the probability that the effect is a true one (Therapeutic Goods Administration 2001).
cohort study	Participants are classified on the basis of the presence or absence of exposure to a particular factor and followed for a specified period of time to determine the development of disease in each exposure group (*American Journal of Clinical Nutrition*: 69 1999)

comparative study	A study including a comparison or control group (National Health and Medical Research Council 2000).
component	A chemical or biological substance contained in, or extracted from, a food. It may include a nutrient or other biologically active substance.
concurrent controls	Controls receive the alternative intervention and undergo assessment concurrently with the group receiving treatment. Allocation to the intervention or control is not random (National Health and Medical Research Council 2000).
confidence interval	An interval within which the true value is expected to lie with a given degree of certainty (usually 95%) (National Health and Medical Research Council 1999).
control	In experimental or observational studies, a person or group that does not receive the intervention under evaluation. Instead, that person or group receives a placebo or no intervention. In a case-control study, the control is the person in the comparison group without the disease or outcome of interest (Therapeutic Goods Administration 2001).
correlational study (or ecological study)	Where the rate of disease is compared across different populations (United States Food and Drug Administration 1999). An example of this would be a study of cancer rates in different states (Last 1995).
crossover trial	A research design where subjects receive a number of treatments in sequence. Generally this means each trial participant receives both the intervention and the control, with or without a 'washout' period between treatments.
cross-sectional study (or prevalence study)	Where both exposure and outcomes are measured at the same time (National Health and Medical Research Council 2000).
dose–response	A gradient of response associated with the degree of exposure (Hennekens 1987).
ecological study (or cross population study)	A study in which those analysed are populations or groups rather than individuals.
epidemiology	Study of the distribution and determinants of health-related states or events in specified populations.
[general level claim]	[General level claims on foods do not reference a biomarker or a serious disease. They may describe or indicate the presence or absence of a component in that food, refer to maintenance of good health or normal physiological processes, refer to specific benefits for performance and wellbeing in relation to foods, be whole of diet claims based on dietary guidelines, describe how a diet, food or component modifies a function or body structure beyond its role in normal growth or refer to the potential for a food or component to assist in reducing the risk of or helping to control a non-serious disease or condition.]

[high level claim]	[These are claims that make reference to a serious disease including claims that refer to the potential for a food or component to assist in controlling a serious disease or condition, claims that refer to the potential for a food or component to assist in reducing the risk of or improving a serious disease or condition, or are whole of diet claims which refer to a serious disease or condition and are based on dietary guidelines.]
level of evidence	Study designs are often grouped into a hierarchy according to their validity, or degree to which they are not susceptible to bias. The hierarchy indicates which studies should be given most weight in an evaluation (National Health and Medical Research Council 2000).
meta-analysis	Results from several studies, identified in a systematic review, are combined and summarised quantitatively (National Health and Medical Research Council 2000).
non-randomised cross-over design	Patients are measured before and after introduction or withdrawal of the intervention and order of introduction and withdrawal is not randomised (National Health and Medical Research Council 2000).
number needed to treat	The number of patients who need to be treated to prevent one undesirable outcome (Khan et al. 2001).
odds ratio	The ratio of the odds of an event in an intervention group to the odds of an event in a control group. An odds ratio less than one indicates that the intervention reduced the odds of that outcome. 'Odds' is the ratio of the number of people in a group with an event to the number without an event. In a sample of 100 people, if 20 people experienced an event and 80 did not, the odds ratio would be 20/80, or 0.25 (Khan et al 2001).
observational studies (or epidemiological studies)	Are usually undertaken by investigators who are not involved in the clinical care of the patients being studied and who are not using the treatment under investigation in this group of patients (National Health and Medical Research Council 2000).
p-value	Probability that the observed results of a study could have occurred by chance (Khan et al 2001).
placebo	An inactive substance or treatment that supposedly has no treatment value, that is given to trial participants as a control against which to compare the effects of the test food and/or food component.
pre-test post-test study	A study design where a group is studied before and after an intervention and serves as its own control. Interpretation of the result is problematic as it is difficult to separate the effect of the intervention from the effect of other factors (National Health and Medical Research Council 2000).
randomised controlled trial	An experimental comparison study in which participants are allocated to treatment/intervention or control/placebo groups using a random mechanism. Participants have an equal chance of being allocated to an intervention or control group and therefore allocation bias is eliminated (National Health and Medical Research Council 2000).

randomised cross-over trial	Patients are measured before and after exposure to different treatments (or placebo) which are administered in a random order (and usually blinded) (National Health and Medical Research Council 2000).
relative risk (risk ratio)	The ratio of the proportions in the intervention group and in the control group who experience the health outcome (Khan et al. 2001).
risk difference (attributable risk)	The difference in the proportion of a sample with the outcome, between the treatment and control groups. If the risk difference is negative, this suggests the treatment reduces the risk (National Health and Medical Research Council 1999).
serious disease	For the purposes of assessing nutrition, health and related claims on foods, a 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 (Therapeutic Goods Advertising Code 2003).
statistical significance	The probability that an event or difference is real or occurred by chance alone. It does not indicated whether the difference is small or large, or of clinical significance. The level of statistical significance depends on the number of participants studied or observations made, and on the magnitude of the difference observed.
surrogate outcome or endpoint	See biomarker

[Square brackets] indicate that the wording of the definition is subject to change.

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Attachment 5

International regulations

Canada

Content Claims

Nutrient content claims

The Canadian Food and Drug Regulations provide a number of nutrient content claims about the content of energy, protein, fat including total fat, saturated fatty acids, trans fatty acids, omega-3 and omega-6 polyunsaturated fatty acids, cholesterol, sodium, potassium, sugar, fibre and vitamin and mineral in foods. 'Light' and 'lean' claims can also be made. Only the wording permitted in the Regulations may be used. The Regulations also prescribe the compositional criteria for each claim and any related additional labelling requirements.

Examples of the types of nutrient content claims permitted in Canada include: 'low in X', 'source of X', 'excellent source of X', 'no added X'. Canada permits 'free' claims, including: 'free of energy', 'free of fat' and '100% fat fee'. 'Free' claims are permitted in foods that have a trace amount of the respective nutrient. In addition, Canada permits the use of the words 'diet' or 'dietetic' only where the food is for special dietary use and where specific criteria is met.

Comparative claims

The Canadian Food Inspection Agency Guide to Food Labelling and Advertising describes comparative claims as those that compare the nutritional properties of two or more foods. Examples of comparative claims include 'more X', 'reduced in X', that is, '3 grams more fibre than 1 slice of Brand X bread'. Only those comparative claims listed in the Regulations may be used. The Regulations set out conditions for foods where various comparative claims are made. In general comparative claims must:

- involve similar foods, or foods of the same food group depending on the type of claim
- clearly identify the foods being compared and the differences between them
- be based on differences which are both nutritionally and analytically significant.

Health Claims

In Canada the term 'health claim' is generally used to mean claims in relation to food that associate consumption of the food with the reduced risk of the disease. However, given the proposed FSANZ Claims Classification Framework uses the term 'health claim' to apply to a broader spectrum of claims including function claims, the Canadian classification of biological role claim is being discussed in this section.

Biological role claim

Canada allows certain biological role claims. Biological role claims are claims that refer to the generally recognised nutritional function of energy or nutrients as an aid in maintaining the functions of the body, for maintenance of good health, or for normal growth and development. Biological claims can only be made in respect of the energy value or nutrients in a food. The Regulations permit the following biological role claims for all nutrients and energy:

- 'Energy (or name of the nutrient) is a factor in the maintenance of good health.'
- 'Energy (or name of the nutrient) is a factor in the normal growth and development.'

The Regulations specify nutrients in which the above biological role claims can be made without a quantitative statement. Where the above biological role claims are made in relation to nutrients not specified in the Regulations, for example essential fatty acids such as linolenic acid, a quantitative statement of the nutrient in grams per serving must appear on the label.

Nutrients are not defined in the Regulations. However, a substance is considered a nutrient if it is recognised as such by the Institute of Medicine of the National Academies. Biological role claims may not be made for other components of food, such as lycopene, lutein, anthocyanins, although, a quantitative statement is permitted for these other components, for example, '14 mg of lycopene per 50 g serving'.

In addition, to the two general claims listed above, Table 1 lists acceptable specific biological role claims for nutrients. This table is provided in the Canadian Food Inspection Agency Guide to Food Labelling and Advertising. These examples of biological role claims have been scientifically recognised in maintaining good health and normal growth and development and are considered to be acceptable by Health Canada and the Canadian Food Inspection Agency. Other biological role claims for nutrients may also be acceptable and will be evaluated by Health Canada and Canadian Food Inspection Agency on a case-by-case basis.

Table 1: Acceptable biological role claims for nutrients

Nutrient	Claim
Protein	helps build and repair body tissues helps build antibodies
Fat	supplies energy aids in the absorption of fat-soluble vitamins
Carbohydrate	supplies energy assists in the utilisation of fats
Vitamin A	aids normal bone and tooth development aids in the development and maintenance of night vision aids in maintaining the health of the skin and membranes
Vitamin D	factor in the formation and maintenance of bones and teeth enhances calcium and phosphorus absorption and utilisation
Vitamin E	protects the fat in body tissues from oxidation
Vitamin C	factor in the development and maintenance of bones, cartilage, teeth and gums
Thiamine (Vitamin B1)	releases energy from carbohydrate aids normal growth
Riboflavin (Vitamin B2)	factor in energy metabolism and tissue formation
Niacin	aids in normal growth and development factor in energy metabolism and tissue formation
Vitamin B6	factor in energy metabolism and tissue formation
Folate	aids in red blood cell formation
Vitamin B12	aids in red blood cell formation
Pantothenic Acid	factor in energy metabolism and tissue formation
Calcium	aids in the formation and maintenance of bones and teeth
Phosphorus	factor in the formation and maintenance of bones and teeth
Magnesium	factor in energy metabolism, tissue formation and bone development
Iron	factor in red blood cell formation
Zinc	factor in energy metabolism and tissue formation
Iodine	factor in the normal function of the thyroid gland

Where a biological role claim is made, the food must meet the compositional criteria that apply to certain biological role claims and any additional labelling requirements, such as specific requirements for the inclusion of nutrients in the nutrition facts table.

Diet related health claim

Canada regulates certain diet related health claims on foods where sound scientific evidence has established a relationship between certain elements of healthy diets and reduction of risk of certain disease.

A diet related health claim is a statement that describes the characteristics of a diet that may reduce the risk of developing a diet related disease or condition, such as osteoporosis or stroke, and the properties of a food that make it a suitable part of the diet.

The regulations permit five diet related health claims which deal with the following relationships:

- a diet low in sodium and high in potassium, and the reduction of risk of hypertension
- a diet adequate in calcium and vitamin D, and the reduction of risk of osteoporosis
- a diet low in saturated fat and trans fat, and the reduction of risk of heart disease
- a diet rich in vegetables and fruits, and the reduction of risk of some types of cancer
- minimal fermentable carbohydrates in gum, hard candy or breath-freshening products, and the reduction of risk of dental caries.

The Regulations prescribe a number of alternative statements for each permitted diet related health claim. For example, the Regulations prescribe two statements in relation to diet related health claims with respect to saturated and trans fats. The prescribed statements are as follows:

- a healthy diet low in saturated and trans fats may reduce the risk of heart disease. (naming the food) is free of saturated and trans fats or
- a healthy diet low in saturated and trans fats may reduce the risk of heart disease. (naming the food) is low in saturated and trans fats.

Manufacturers must use the exact wording and must meet the compositional criteria specified for the food to qualify for each claim and any related additional labelling requirements, such as specific requirements for the inclusion of nutrients in the nutrition facts table.

The following general criteria must be met for all risk reduction health claims:

- The claim must be expressed in English and French.
- The claim must follow exact wording as prescribed.
- The claim must be displayed in one place, with words in equal prominence and have no part highlighted.
- Foods in which claims are made should fall into one of the four food groups of Canada's Food Guide to Healthy Eating (grain products, vegetables and fruit, milk products, meat and alternatives).
- Foods in which claims are made should be consistent with Nutrition Recommendations for Canadians.

Risk reduction health claims are not permitted on the following foods:

- Foods intended for children less than 2 years old.
- Foods represented for use in very low energy diets.

- Foods and beverages that are not part of any food group from Canada's Good Guide to Healthy Eating, unless excepted on a claim-by-claim basis (includes foods that are mostly fats and oils: mostly sugar; high fat and/or high salt snack foods, beverages such as water, tea, coffee, alcohol and soft drinks; herbs, spices and condiments).

United States

Content Claims

Nutrient content claims

There are a number of nutrient content claims specified in the Code of Federal Regulations administered by the United States Food and Drug Administration, including claims regarding the energy, protein, total fat, saturated fatty acids, cholesterol, fibre, potassium, sugar and sodium content of a food. Examples of the types of nutrient content claims permitted in the United States include: 'low in X', 'high X', 'good source X', 'contains X' and 'provides X'. 'High' and 'good source' claims can only be made for nutrients with an established 'Daily Value'. 'Good source' claims can only be made where the food contains at least 10% of the Daily Value for that nutrient and 'high' claims may be made when a food contains at least 20% of the Daily Value. Where there is no established Daily Value for a nutrient, such as omega-3 fatty acids, 'contains' and 'provides' claims can only be made where the claim is accompanied by a quantitative statement which specifies the amount of the nutrient per serving, that is, 'x grams omega 3 fatty acids'. In addition, a quantitative claim on its own can be made for nutrients without an established Daily Value.

'Free' claims such as 'calorie free', 'fat free', 'saturated fat free', 'cholesterol free' and 'sugar free' are permitted in foods that have a trace amount of the respective nutrient. In addition, 'light', 'lean', 'healthy' and 'modified' claims can also be made. Only the wording permitted in the Regulations may be used. The Regulations also prescribe the compositional criteria for each claim and any related additional labelling requirements that vary depending on the claim. Nutrient claims that are not prescribed in the Regulations are prohibited. However, there is a system in place whereby a firm may submit a notification for a nutrient content claim based on an authoritative statement by a United States government scientific body for consideration.

Where a nutrient content claim is made and the food contains either fat, saturated fat, cholesterol or sodium in excess of prescribed levels (13 g, 4 g, 60 mg and 480 mg respectively), a disclosure statement is required to draw the consumer's attention to that nutrient or nutrients, for example, 'see nutrition information for sodium content'.

With a few exceptions nutrient content claims are not permitted on foods intended specifically for infants and children less than 2 years of age. In addition, implied claims about a food or ingredient that suggest the nutrient or ingredient is absent or present in certain amounts, or implied claims about a food that suggest it may be useful in maintaining healthy dietary practices and which are made with an explicit claim (for example, 'health, contains 3 grams of fat') are prohibited unless specifically provided for in the Regulations.

Comparative claims

In the United States only those comparative (or relative) claims listed in the Regulations may be used, for example 'reduced X'. The Regulations set out conditions for foods where various comparative claims are made. In addition to these conditions, all comparative claims must:

- declare the percent or fraction of change and the identity of the reference food in immediate proximity to the most prominent claim
- declare on the information panel, the quantitative comparison of the amount of the nutrient in the product per labelled serving with that in the reference food.

Health claims

In the United States, the term 'health claim' is generally used to mean claims in relation to food that associate consumption of the food with the reduced risk of the disease. Health claims are those that characterise the relationship of a food to a disease or health-related condition. The United States system recognises a category of claim, they term 'structure/function claims' that have historically appeared on the labels of conventional foods, dietary supplements and drugs.

Structure/function claims

In relation to food, structure/function claims describe the role of a nutrient and its effect on normal structure or function in humans, for example, 'calcium builds strong bones.' In addition, they may describe the means by which a nutrient acts to maintain such structure or function, for example, 'fibre maintains bowel regularity', or 'antioxidants maintain cell integrity', or they may describe general wellbeing from consumption of a nutrient. A food may claim to have an impact on the structure or function of the human body provided the claim does not represent that the food will cure, mitigate, treat, or prevent disease (which would create drug status) and provided further that the claim would not be regarded as a health claim under the United States system, that is, a risk reduction health claim. The Food and Drug Administration does not require conventional food manufacturers to notify them about their structure/function claims and disclaimers are not required for conventional foods, as they are for dietary supplements.

Risk reduction claims

The United States regulates 12 scientifically substantiated risk reduction claims. The food must meet compositional requirements set out in the Regulations. The wording of these claims may be varied providing all claim requirements are met. The risk reduction health claims permitted deal with the following relationships:

- calcium and osteoporosis
- sodium and hypertension
- dietary fat and cancer
- dietary saturated fat and cholesterol and risk of coronary heart disease
- fibre containing grain products, fruits and vegetables and cancer
- fruits, vegetables and grain products that contain fibre, particularly soluble fibre and risk of coronary heart disease
- fruits and vegetables and cancer
- folate and neural tube defects
- dietary sugar and alcohol and dental caries
- soluble fibre from certain foods and risk of coronary heart disease
- soy protein and risk of coronary heart disease

- plant sterol/stanol esters and risk of coronary heart disease

The following two claims are authorised based on authoritative statements by federal scientific bodies through provisions of the Food and Drug Administration Modernization Act 1997. The Food and Drug Administration dictates the required wording for these claims.

- Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol may reduce the risk of heart disease and some cancers.
- Diets containing foods that are a good source of potassium and that are low in sodium may reduce the risk of high blood pressure and stroke.

Only the above claims are permitted although, there is a system in place whereby a firm may submit a health claim based on an authoritative statement by a United States government scientific body for consideration.

The following general criteria must be met for all risk reduction health claims:

- The claim must have all information in one place.
- The claim must only have information on the value that intake or reduced intake, as part of a total dietary pattern, may have on a disease or a health-related condition.
- The claim must enable the public to understand the information provided and the significance of information in the context of a total daily diet.
- The claim must be complete, truthful and not misleading.
- Foods in which claims are made must contain 10% or more of the Daily Value (without fortification) for one of six nutrients (vitamin A, vitamin C, iron, calcium, protein or fibre).
- The claim must use the terms ‘may’ or ‘might’ to express the relationship between substance and disease.
- The claim must not quantify any degree of risk reduction.
- The claim must indicate that disease depends on many factors.
- Foods in which claims are made must contain less than the specified levels of four disqualifying nutrients (fat, saturated fat, cholesterol, sodium).

In addition, risk reduction health claims are not permitted on foods intended for infants less than 2 years old.

Where a health symbol is used, such as a heart symbol, it is considered to be a health claim and the same requirements apply as to written health claims. In order for a health symbol to be used, the health claim must first be permitted, the food must meet the above criteria and in addition to the symbol the label must include all the required health claim information.

European Union

In the European Union, there are currently detailed rules on labelling and nutrition labelling of foods. In relation to claims, there is a general provision that claims should not mislead the consumer. Furthermore, the label, presentation and advertisement of a food cannot attribute to the food prevention, treatment and curing properties. In relation to health, nutrition and related claims, these general principles are open to different interpretations.

The absence of specific provisions at the European level, have resulted in proliferation of a number of different types of claims appearing on labels of foods. Consequently, some European Union Member States adopted legislation and other measures to regulate the use of such claims. This has resulted in different approaches to managing regulation of health, nutrition and related claims. Regulations relating to health claims vary from permissive systems operating under self-regulation to total prohibitions. Sweden and the United Kingdom are two countries that operate self-regulatory or co-regulatory systems for management of risk reduction health claims.

As a result of these inconsistencies, harmonisation of the rules on claims at the European Union level has been advocated. The Commission of the European Communities has published a Proposal for a regulation of the European Parliament and of the Council on nutrition and health claims made on foods (2003/0165). The Proposal is currently delayed and will not be considered again by Parliament until some time after 1 September 2004.

Content claims

Nutrition claims

The Proposal provides a list of nutrition claims and their specific conditions of use. The list was composed taking into account existing provisions of some Member states, the Codex Alimentarius guidelines and some community provisions. The list includes a number of nutrition claims in relation to energy, protein, total fat, saturated fatty acids, sodium, sugar, fibre and vitamin and/or minerals. Examples of the types of nutrition claims include 'low X', 'very low X', 'high X', 'source of X', 'high source of X'. The Proposal allows for free claims such as 'fat free', 'saturated fat free', 'sugars free' and 'sodium free', where there is trace amount of the respective nutrient. The Proposal also allows for 'light' claims.

Comparative claims

For comparative claims, such as 'increased' or 'reduced', the Proposal considers it necessary that the products being compared are clearly identified to the consumer and comparisons are made between foods of the same category. The difference in the quantity of a nutrient and/or energy value should be stated and the comparison should relate to the same quantity of food.

Health claims

The Proposal provides for scientifically substantiated enhanced function and risk reduction health claims under an approach whereby any food that satisfies criteria required for approved claims, may make the claim. The claim must be well understood by the average consumer and the scientific evidence must be well established and generally accepted. Upon receipt of an application, the European Food Safety Authority will assess the evidence and will take into account the wording of the claim to ensure claims are truthful, clear and reliable. An exception to this process is made for health claims which describe the role of a nutrient or other substance in growth, development and normal physiological functions of the body and are based on long-established and non-controversial science. A list of permitted claims will be drawn up for this type of claim.

The Proposal states that health claims will only be permitted if the following information is included on the label:

- a statement indicating the importance of a balanced diet and a healthy lifestyle

- the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect
- a statement addressed to people who should avoid using the food, where appropriate
- a warning not to exceed quantities of the product that may represent a risk to health, where appropriate.

It is proposed that there will be a prohibition on implied health claims which relate to slimming or weight control; make psychological or behavioural references, for example 'reduce stress'; reference doctors or their associations; and vague claims relating to 'wellbeing'. In addition, it is envisaged that nutrition and health claims will not be allowed on alcoholic beverages.

Codex Alimentarius

Currently, the Codex Alimentarius (Codex) Guidelines for use of Nutrition Claims provide guidance on nutrient content claims, comparative claims and nutrient function claims. In addition to these Guidelines, Codex has developed Draft Guidelines for use of Nutrition and Health Claims which supplement the current Guidelines by providing guidance on the use of health claims as well as nutrition claims.

The Draft Guidelines propose two broad categories of claims: nutrition claims and health claims. Health claims include nutrient function claims, other function claims and reduction of disease risk claims. It is proposed that nutrition and health claims not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.

The Draft Guidelines are currently at the final step (step 9) of the procedure. At this step, the draft standard will be submitted through the Secretariat to the Commission together with any written proposals received from Members and interested international organisations with a view to adopting the Codex standard.

Content claims

Nutrient content claims

Conditions for a number of nutrient content claims are set out in the Draft Guidelines, including 'low' and 'free' content claims for the following nutrients: energy, fat, saturated fat, cholesterol, sugars, sodium. Additionally, conditions are provided for the following claims: very low sodium, source of protein, high protein, source of vitamins and minerals and high vitamins and minerals. The recommended wording of these claims is: 'a low (name of nutrient) food' and 'a (name of nutrient)-free food'. 'Free' claims are permitted in foods that have a trace amount of the respective nutrient. 'Light' claims are also permitted.

In addition, Codex is currently developing a table of conditions for nutrient content claims in relation to dietary fibre which is at step 6 of the procedure. The draft table sets conditions for source of dietary fibre and high dietary fibre claims.

Comparative claims

The Draft Guidelines recommend that comparative claims should be permitted providing the foods being compared are different versions of the same food or similar foods. The foods being compared should be clearly identified and a statement of the amount of difference in the energy value or nutrient content should be provided. The comparison should be based on a relative difference of at least 25% in the energy value or nutrient content, except for micronutrients where a 10% difference in the Nutrient Reference Value set out in Codex Guidelines on Nutrition Labelling, would be acceptable.

Health claims

A health claim is defined in the Draft Guidelines to be any representation that states, suggests or implies that a relationship exists between a food or a constituent of that food and health. Health claims include nutrient function clams, other function claims and reduction of disease risk claims.

Nutrient function claims

A nutrient function claim is defined as a claim that describes the physiological role of a nutrient in growth, development and normal functions of the body. For example, 'Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development). Food X is a source of/high in nutrient A'.

Codex recommends that nutrient function claims should only be permitted where claims are made in relation to essential nutrients for which a Nutrient Reference Value has been established in the Codex Guidelines on Nutrition Labelling or those nutrients which are mentioned in officially recognised dietary guidelines of the national authority having jurisdiction.

Other function claims

Other function claims are defined as claims with specific beneficial effects of the consumption of foods or their constituents in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health. For example, 'Substance A (naming the effect of substance A on improving or modifying a physiological function or biological activity associated with health). Food Y contains X grams of substance A.

Reduction of disease risk claims

Reduction of disease risk claims are defined as claims which relate to consumption of a food or food constituent in the context of the total diet, to the reduced risk of developing a disease or health-related condition. Risk reduction means significantly altering a major risk factor(s) for a disease or health related condition. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as a prevention claim. An example of a reduction of disease risk claim is, 'A healthy diet low in nutrient or substance A may reduce the risk of disease D. Food X is low in nutrient or substance A'.

Codex propose that all health claims consist of two components:

- information on the physiological role of the nutrient or on an accepted diet-health relationship, followed by
- information on the composition of the product relevant to the physiological role of the nutrient or the accepted diet-health relationship (unless the relationship is based on whole foods where research does not link to specific constituents of a food).

The Draft Guidelines recommend that health claims should be permitted provided the following conditions are met:

- Health claims must be based on current relevant scientific substantiation. Any health claim must be acceptable to the competent authorities of the country where the product is sold. Only health claims that support national health policy and goals should be allowed.
- The claim must be truthful and not misleading.
- The claimed benefit should arise from the consumption of a reasonable quantity of the food or food constituent in the context of a health diet.
- Health claims should have a clear regulatory framework for qualifying and/or disqualifying conditions for eligibility to use the specific claim, including the ability of competent national authorities to prohibit claims made for foods that contain nutrients or constituents in amounts that increase the risk of disease or an adverse health related condition. Health claims should not be made that encourage or condone excessive consumption of the food or disparages good healthy practice.
- Where the claimed effect is attributed to a constituent of a food, there must be a validated method to quantify the food constituent.

In addition, to the above conditions it is recommended that if a claimed benefit is in relation to a constituent of a food for which a Nutrient Reference Value is established, the food should be:

- 'a source of' or 'high' in the constituent in cases where increased consumption is recommended, or
- 'low in', 'reduced in' or 'free of' the constituent where reduced consumption is recommended.

(Where applicable, the conditions for nutrient content claims and comparative claims will be used to determine the levels for 'high', 'low', 'reduced' and 'free'.)

The Draft Guidelines recommend that food bearing health claims should have the following on the label:

- information on the target group, if appropriate
- information on how to use the food to obtain the claimed benefit and other lifestyle factors or other dietary sources, where appropriate
- advice to vulnerable groups on how to use the food and advice to groups who need to avoid the group, if appropriate
- maximum safe intake of the food or constituent where necessary
- information on how the food or food constituent fits within the context of the total diet

- a statement of the importance of maintaining a healthy diet.

Codex propose that claims which relate to dietary guidelines or ‘healthy diets’ should be permitted providing certain conditions outlined in the Guidelines are met.

Attachment 6

Criteria and conditions for content claims

CONTENTS

1. Background to content claims

The proposed working definition for a content claim is 'a general level claim which describes or indicates [explicitly or implicitly] the presence or absence of energy or of a nutrient [or biologically active substance] in a food'. Examples of such claims include 'source of omega-3 fatty acids', 'high in fibre', 'reduced in sodium' and 'light/lite'.

1.1 Placement of content claims

As stated in subsection 1.1 of the Initial Assessment Report, content claims are managed in a number of ways. The definition for 'nutrition claim' and generic provisions for a small number of content claims are regulated in Standard 1.2.8 of the Code. Generic provisions for vitamins and minerals are provided in Standard 1.3.2. There are also provisions for some commodity standards such as those prescribed in the Code – Part 2.9 Special Purpose Foods. The majority of content claims in Australia are managed through the Code of Practice on Nutrient Claims in Food Labels and in Advertisements (CoPoNC). CoPoNC is not legally enforceable in Australia or New Zealand. In New Zealand, the majority of content claims are regulated under the New Zealand *Fair Trading Act 1986*.

The Technical Expert Group (TEG) agreed that generic provisions for making content claims as provided in CoPoNC and Standard 1.2.8 of the Code should be placed in one Standard in the Code. Because the claims in Standard 1.3.2 are also generic, they queried whether they should be placed in the same Standard as the other generic claims.

Question:

1. What is the best approach for the placement of generic content claims? Please provide a rationale to support your preferred approach.

2. General conditions for content claims

2.1 Eligibility of food

The Policy Guideline states, 'consideration should be given during the FSANZ standard development process for including the criteria for making each level of claim and any parameters (for example, qualifying and disqualifying criteria, or exclusions for certain categories of food, such as alcohol and baby foods) should be specifically stated in the standard. These parameters will be particularly important to the monitoring and enforcement of nutrient content claims.'

The Codex Draft Guidelines for the Use of Nutrition and Health Claims, says nutrition and health claims will not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or in national legislation.

In Australia and New Zealand, specific labelling requirements for foods for infants, including vitamin and mineral claims, are regulated under Standard 2.9.2 – Foods for Infants, in the Code. Standard 2.9.1 regulates infant formula products and includes a list of prohibited representations (Clause 20). There are no standards regarding claims for products directed to 'young children'.

The definition of 'nutrition claim' in the Code does not include any reference to a reduction in alcohol content (Standard 1.2.8 Clause 1). Alcohol labelling is generally regulated under Standard 2.7.1 – Labelling of Alcoholic Beverages and Food Containing Alcohol. Clause 4 is of relevance to content claims as it covers the representation of low alcohol products.

The TEG did not believe that any foods should be prohibited from making content claims, other than those standards already specified in the Code.

Question:

2. Should any foods be prohibited from making content claims, other than those standards already stipulated in the Code? Please provide evidence and a cohesive rationale to support your answer.

2.2 Methods of analysis

Nutrition, health and related claims are voluntary and are used by manufacturers not only to help consumers make healthy, informed food choices, but to also create a marketing advantage over competitors. The ability of a manufacturer to make a general level claim or a high level claim may depend on whether a product meets the criteria for certain content claims. Consideration therefore needs to be given to whether the present system for determining the levels of nutrients, energy and biologically active substances will be adequate in the new context of permitting certain health claims.

The issue of prescribed analytical methods for measuring food components was raised during P234 (Criteria and conditions for making nutrition content claims). A number of food industry and public health submitters to P234 Draft Assessment asked that analytical methods be specified for measuring food components, most especially for fat, gluten and lactose, in order to create equality for food manufacturers and to avoid the potential to mislead consumers.

FSANZ has not generally favoured prescribing acceptable laboratory methods for nutrient analysis because methods are subject to continual improvement. To generally prescribe methods would impose a considerable burden on the regulator, enforcement agencies and the industry to remain up-to-date, which is not commensurate with the risk to consumers. FSANZ expects that laboratory analyses would be appropriate for the food matrix and conducted according to the most up-to-date methods. The choice of an inappropriate method could also be construed as deceptive and contrary to other legislation. Currently claims and nutrient declarations can be based on generally available data, which could be derived from a number of different methods of analysis. Specifying appropriate methods would severely curtail the use of such data, unless the data were exempt from application of prescriptive methods, such as the mandatory nutrition information panel, which then renders the original objective of the prescriptive approach ineffective.

The TEG did not believe that individual analytical methods should be prescribed for content claims. However they did favour consideration of an approach that stipulates that only NATA accredited laboratories are used.

Question:

3. Do you think there should be provisions that stipulate analytical methods for content claims? If yes, what is the appropriate approach or what are the appropriate methods?

2.3 Synonyms

Widespread use of synonyms (or alternative terminology) may result in claims being misleading and not understood because of the belief that there are differences among the terms. FSANZ therefore proposes to include a list of alternative terms for each type of content claim. Synonyms that are currently being used or are permitted in overseas countries are:

- Free: 'zero', 'no', 'without', 'free of'
- Low: 'little', 'few' (for calories/joules), 'contains a small amount of', 'low source of'
- Reduced: 'less', 'lower', 'fewer'
- Increased: 'more', 'more than', 'higher'
- No added: 'without added', 'no – added'
- Source: 'contains', 'with', 'supplies', 'giving', '√'
- High: 'good source', 'rich'
- Very high: 'excellent source of'

Question:

4. Are the above synonyms similar in meaning to the above types of content claims? Should the list be considered 'exhaustive' and therefore stipulated in a Standard in the Code or 'illustrative' and therefore provided in a guideline document as examples for manufacturers to use?

2.4 Conditions regarding food for consumption

Australia's CoPoNC provides conditions under which content claims may be made. These stipulate that the conditions apply to the food in the form in which it is intended to be consumed. Thus, if the claim depends for its accuracy on the method of preparation by the consumer, the label must include information that allows the consumer to prepare the food in such a way that the prepared product meets the claim. Also when directions are given for mixing the food with other ingredients, such that the final product does not comply with the claim made for the food, the label must draw attention to the fact that the final product will not meet the claim.

Question:

5. Do you agree with CoPoNC's conditions regarding food for consumption? If not, please provide a rationale for why they are not appropriate.

2.5 Foods naturally or intrinsically high or low in a nutrient

Under CoPoNC, claims made in respect of nutrients which occur at a naturally or intrinsically high or low level in a food must be expressed in terms that make it clear the claim refers to the whole class of similar foods and not only to the particular brand of food on which the claim appears (for example, 'Bread – a low fat food' is permissible but 'low fat bread' is not as the latter may imply that the particular bread is low in fat compared with other breads. The New Zealand Food Regulations 1984 (NZFR) provided specific provisions for claims in respect of foods intrinsically high or low in a particular nutrient or in energy (Regulation 13B). The approach is similar to CoPoNC in that such claims can only be made in respect of a class of food and not specified brands of food. The NZFR are now repealed but have been included in the discussion for historical purposes.

Question:

6. Do you agree with CoPoNC and NZFR conditions for foods naturally or intrinsically high or low in a nutrient? If not, please explain why you think they are not appropriate.

2.6 Normal counterpart or reference foods

'Normal counterpart' or 'reference foods', against which a food may be compared in making a content claim, is defined under CoPoNC as falling into one of three categories:

- The 'weighted average' food of that type based on an industry norm for the particular type of food; this category is not appropriate where the composition of 'normal' foods of that type on the market varies over a wide range.
- The 'regular' product which has been produced for a significant period by the manufacturer making the claim.
- A food of the type in question whose composition is determined by reference to published food composition tables.

Under CoPoNC the reference food must be of the same type as the food with which the comparison is made (except in the case of comparative claims between different foods), or as near to the same type as possible. When the basis for selecting the reference food may not be obvious to the consumer, the comparison statement must include an explanation of the choice of the particular reference food.

The NZFR (now repealed) used the term 'normal counterpart' but there is no definition for what this means.

Question:

7. Do you agree with CoPoNC requirements for 'normal counterpart' or 'reference foods'? If not, please explain why you think they are not appropriate.

3. Specific content claims and preferred criteria

Appendix 1 provides a table of international comparison of content and related claims.

3.1 Comparative claims

Comparative claims are those claims that compare a food with a similar food or class of foods. Examples of comparative claims are those using the terms 'reduced', 'increased', or 'less than'.

3.1.1 International comparison of comparative claims

A minimum percentage reduction of 25% for 'reduced' claims is the approach taken by Codex, CoPoNC, Canada, the United States and the United Kingdom (in terms of the Food Standards Agency (FSA) guidelines) for energy or nutrient content, except for micronutrients (note that Standard 1.3.2 sub-clause 4(b) of the Code prohibits the comparison of the vitamin or mineral content of food, except where specifically permitted). The European Union proposal is for 30%, while NZFR was 33%. The repeal of the NZFR in December 2002 may, however, have resulted in many manufacturers using a relative difference of 25%.

CoPoNC requires, and the NZFR required, that a statement accompany comparative claims on the label, which compares the food with a reference food. Codex's provisions are slightly more specific in that a statement of the amount of difference (in percent, fraction or absolute amount) to an identified comparable food is required in close proximity to the claim.

Finally, CoPoNC only permits comparative claims between foods of the same food group or foods that may substitute for one another in the diet. For example, comparative claims might be made between foods such as beef and chicken, potatoes and rice or orange juice and apple juice, but are not encouraged between foods such as milk and fruit juice or fruit and nuts.

3.1.2 Energy as an additional criterion

The increasing prevalence of overweight and obesity in the Australian and New Zealand population is a serious public health concern. Some submitters to P234 Draft Assessment sought disqualifying criteria for 'reduced' claims that relate to fat and sugars, such that a reduction in energy should also occur when compared with a reference food. This was seen as a strategy for dealing with the problem of overweight and obesity at a population level, because of the belief that the food industry adds back sugars when removing fat from foods, such that there is little difference in energy content of the food.

A recent study, however, demonstrated that foods carrying 'reduced fat' claims were significantly lower in energy density than full fat equivalents (La Fontaine 2004). The mean energy density for the 63 'reduced fat' foods examined was 7.7 ± 5.5 kJ per g compared to 10.2 ± 6.5 kJ per g for 63 full fat equivalent foods and 5.1 ± 1.6 kJ per g. Assuming similar serve sizes were used in the study, this translates to a mean 24.5% reduction in energy. The standard deviation is however large, indicating that there is considerable variability amongst products. In particular, certain brands of potato chips, peanut butter and chocolate cookies were identified as having less change in energy density than predicted. The authors noted there did not seem to be any distinguishing characteristics of products that were either higher or lower in energy density than predicted. In their conclusion they stated,

food regulations in relation to 'reduced fat' claims need to be tightened to include energy density criteria and to ensure that the marketing of 'reduced fat' products does not imply that the products are 'guilt-free' or that they will promote weight loss.

The La Fontaine study (2004) was not available when the TEG met. At that time they did not support disqualifying criteria for energy but considered a disclosure statement, such as 'See nutrition information panel for energy content' to be appropriate.

3.1.3 FSANZ's consumer research

FSANZ's qualitative consumer research on content claims (FSANZ 2003b, p. 32) revealed there was a high level of scepticism around comparative claims and a great deal of confusion as to how they related to terms such as 'low', 'lite', 'diet' and 'high' as well as how they related to public health recommendations. This confirms the results of a previous quantitative study, which found that only 11% of respondents identified a 'reduced in salt' claim as containing more salt than a similar food with a 'low salt' claim (FSANZ 2003a). Because of dissatisfaction with the degree of ambiguity around 'reduced' claims, participants suggested that the percentage reduction should be stated (that is, '% reduced' or 'reduced from X% to Y%'). Consumers had fewer concerns with 'increased' claims because they assumed product alterations related to 'positive' rather than 'negative' nutrients. They were also less concerned with 'less than' claims because these were quantified (for example, 'less than 5 g of sugar').

3.1.4 FSANZ's preferred criteria for comparative claims

Claim	**Preferred criteria (and conditions)**
'reduced', 'increased' 'less than'	With the exception of micronutrients, the comparison should be based on a relative difference of at least 25% in the energy value or relevant nutrient content. The identity of the reference food and the percent, fraction or amount of difference in energy value or nutrient content should be indicated adjacent to the comparative claim. Comparative claims should only be made between foods of the same food group or foods that may substitute for one another in the diet.

Questions:

8. Should these comparative claims be permitted? Briefly explain.
9. If permitted, do you agree with FSANZ's preferred criteria?
10. Should there be an additional criterion that relates to energy when 'reduced' and 'less than' claims are made in relation to total fat and sugar? If so, what criteria should apply and what evidence supports such an approach?

3.2 'Free' claims

'Free' claims include those claims which are claimed to be 'free' of a specific nutrient, for example 'fat free', 'sugar free', 'cholesterol free', 'salt free'. It does not include qualified free claims; for example, '99% fat free'.

3.2.1 International comparison of 'free' claims

CoPoNC, United States, Canada, Codex, the United Kingdom (in terms of FSA guidelines) and the European Union proposal permit small tolerances for 'free' claims in relation to fat, sugar and salt. CoPoNC, Canada, United States and Codex also permit insignificant amounts for 'cholesterol free' and 'calorie free' with the exception that CoPoNC has no provision for 'calorie free'. This approach is based on using 'free' as a descriptor of physiologically insignificant components. Sometimes it is based on the level of the nutrient that is at or near the reliable limit of detection for the nutrient in food, while at other times it is the technically unavoidable residual level of the nutrient left after processing (for example, 'sugar free'). 'Gluten free' and 'lactose free' claims in Standard 1.2.8 are slightly different to other content claims in that they are defined by a 'no detectable' provision, rather than by a stated amount, because of their relevance to public health and safety.

3.2.2 Inconsistencies with fair trading laws

The Australian *Trade Practices Act 1974* and the New Zealand *Fair Trading Act 1986* prohibit conduct which is false, misleading or deceptive and apply to the supply of food in trade and commerce. The Australian Competition and Consumer Commission and the New Zealand Commerce Commission, which administer the respective Acts, both interpret 'free' claims as meaning that none of the substance should be present in the food, irrespective of food regulations and codes of practice. This therefore creates potential inconsistency between fair trading legislation and CoPoNC. In resolving the situation, FSANZ must give priority to preventing misleading or deceptive conduct, thereby aligning with fair trading laws.

3.2.3 FSANZ's consumer research

FSANZ's consumer research (FSANZ 2003b, p. 39) revealed favourable attitudes towards 'free' claims – they were viewed as definitive and non-comparable claims. Some regarded them as a quick and easy tool to use, while others used the nutrition information panel to verify the claim and to look for nutrient trade-offs. Unprompted reactions were that 'free' means 'nil' and, upon discussion, all groups unanimously confirmed that 'free' should mean 'zero' because that is the common meaning and it was unacceptable to have 'nutritional insignificance' for some claims (for example, fat and sugar) but not for others (for example, gluten and lactose).

3.2.4 ACCC and NZCC preferred approach

FSANZ has met with the Australian Competition and Consumer Commission and the New Zealand Commerce Commission on several occasions in relation to the issue of 'free' claims. The purpose of the most recent meeting on 10 May 2004 was to develop a preferred approach for use of the term 'free' as it relates to content claims. The agreed position was to not stipulate criteria for 'free'; that is, to remain silent in respect of unqualified 'free' claims. Claims will therefore be regulated through fair trading laws, and manufacturers will be able to use 'free' claims provided they are consistent with these requirements. There is a precedent for this in the labelling of genetically modified foods and 'free' claims, where the Code is silent on the use of such claims.

3.2.5 FSANZ's preferred criteria for 'free'

Claim	Preferred criteria (and conditions)
'Free'	No provisions.

Questions:

11. Should 'free' claims be permitted? Briefly explain.

12. If permitted, do you agree with FSANZ's preferred criteria?

3.3 Energy

3.3.1 Policy context

Recommendations for energy intake for groups or individuals must take into account all the factors contributing to balance between intake and expenditure (Truswell et al. 1990). Recommendations for intakes of energy are difficult because of the wide range of requirements, even in individuals with the same age, sex, weight, height and general pattern of activity (Truswell et al. 1990).

In the Dietary Guidelines for Australians (National Health and Medical Research Council 2003) there are no specific guidelines for energy, although they are indirectly related to several guidelines. They include:

> Consume only moderate amounts of sugars and foods containing added sugars;
>
> Limit saturated fat and moderate total fat intake
>
> Prevent weight gain: be physically active and eat according to your energy needs.

The New Zealand guideline for energy is to 'Maintain a healthy body weight by eating well and by daily physical activity' (Ministry of Health 2003).

3.3.1.1 Evidence of increasing obesity

Overweight and obesity is an epidemic that is increasing worldwide as a result of sedentary lifestyles, high fat and energy dense diets. The 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey indicate that obesity is an increasing problem for all age groups and priority groups such as Indigenous people. For example, 27% of Maori men and 28% of Maori women are obese, compared to 13% and 17% of other New Zealand men and women respectively. Within the Australian Aboriginal and Torres Strait Islander population, some 25% of men and 27% of women are obese compared with the national prevalence of around 18%. It has been suggested that an excess consumption of sugar and fat contributes to an energy dense diet that may lead to energy imbalance and obesity.

Studies in animals and humans have indicated that both fat and energy intake are strongly and positively associated with excess body weight. While a consensus is developing among experts that fat consumption at least has an association with excess weight gain, the mechanism is less clear.

Most randomised controlled diets do not show a relationship between intake of carbohydrates and weight reduction. However, it is important to stress that excess energy in any form will promote accumulation of excess body fat, and high carbohydrate diets are only suitable for individuals in accordance with energy needs.

While reduced or low energy foods (diet and low joule) are not recommended for children and some individuals, the increasing incidence of obesity through sedentary lifestyles and energy dense diets suggests they may have an important role in protecting public health. This is particularly pertinent when we take into consideration that fat, sugar and energy are important in energy balance and may be related to obesity.

3.3.2 Low calorie, low joule, low energy

These claims were revised as a part of the review of food Standards in Australia and New Zealand in the development of the Code. 'Low joule' claims and claims to the same effect are prescribed in the Code. The criteria are based on 'per 100 g' and are consistent with criteria in Codex, the United Kingdom, the European Union proposal and the NZFR. United States and Canadian criteria use reference amounts as the basis of their conditions, although Canada has additional criteria per labelled serving which is consistent with the criteria for solids in Codex and the Code. The United Kingdom has exceptions for intense sweeteners and products that consist of a mixture of an intense sweetener and other substances that, when compared on a weight-for-weight basis, is significantly sweeter than sucrose.

There was general support for the claim and criteria from submitters to P234 Draft Assessment Report. The issue of whether calorie claims should be removed or not was raised. In response, the TEG considered it worthwhile prescribing, given that manufacturers are using the term. Under P234, there was also a request for increased energy levels for products like jams and confectionary that are consumed in small amounts, as provided by United States and Canadian provisions.

3.3.3 Reduced calorie, reduced joule, reduced energy

The rationale for criteria relating to the 25% reduction in energy content is the same as the other comparative claims (see above). CoPoNC has additional conditions (food must contain at least 170 kJ less energy per 100 g of food or 80 kJ less per 100 g liquid food compared with the same quantity of reference food). The P234 External Advisory Group's Working Group previously decided that this was unnecessarily complicated from a consumer education perspective.

Again there was general support from submitters to the P234 Draft Assessment Report for the claim and criteria.

3.3.4 FSANZ's preferred criteria for energy claims

Claim	Preferred criteria (and conditions)
Low calorie, low joule, low energy (as per Std 1.2.8 Clause 14)	The average energy content of the food is no more than 80 kJ per 100 ml of beverages or other liquid foods and no more than 170 kJ per 100 g of solid or semi-solid foods. For claims relating to 'calories', the energy declaration in the nutrition information panel must be expressed as calories as well as kilojoules.
Reduced calorie, reduced joule, reduced energy	The comparison should be based on a relative difference of at least 25% in the energy value. The identity of the reference food and the percent, fraction or amount of difference in energy value should be indicated adjacent to the comparative claim. For claims relating to 'calories', the energy declaration in the nutrition information panel must be expressed as calories as well as kilojoules.
Calorie free	No provisions.

Questions:

13. Should these energy claims be permitted? Briefly explain.

14. If so, do you agree with FSANZ's preferred criteria?

3.4 Protein

3.4.1 Policy context

3.4.1.1 Australia

The dietary guideline to 'include lean meat, fish, poultry and/or alternatives' (such as eggs, liver, kidney, shellfish, legumes, nuts and nuts pastes, and certain seeds such as sunflower and sesame seed), whilst not a specific recommendation about protein per se, outlines the food categories considered to be some of the most significant sources of protein in the Australian diet (National Health and Medical Research Council 2003).

The current recommended adult nutrient intake for protein is based on a value of 0.75 g/kg/day. For men all ages, 55 g/day is recommended and for women 45 g/day. In pregnancy, an additional 6 g/day is recommended and in lactation, an additional 16 g/day. According to the 1995 National Nutrition Survey, Australian men were consuming, on average, 109 g of protein and women 74 g per day.

3.4.1.2 New Zealand

The 2003 New Zealand Food and Nutrition Guideline for Healthy Adults to 'include lean meat, poultry, seafood, eggs or alternatives' highlights the main sources of protein for New Zealanders (Ministry of Health 2003).

The 1997 New Zealand National Nutrition Survey (NNS97) found that the dietary protein intake of most adults was almost double the Reference Nutrient Intake (from the United Kingdom Daily Reference Value) for both men and women (Russell et al. 1999) and contributed 15–16% of total energy. The New Zealand Recommended Dietary Intake for protein for adults is 0.75 g/kg/day, which equates to approximately 11–15% of total energy.

3.4.2 Rationale for protein claims

Dietary guidelines and national nutrition surveys indicate that inadequate protein intake is not considered to be of concern in Australian and New Zealand diets. FSANZ's consumer research (2003 p. 51) found that most participants had little to say about protein claims (such as 'high in', 'low in' and 'source of'): participants, believing they had no dietary need for such claims, ignored or avoided them. The claims were considered relevant for sports people and occasionally for those who are underweight.

The University of Wollongong (Williams et al. 2003), however, demonstrated that in 2001 a small percentage of products across a wide range of product categories were carrying protein claims – mostly 'source' (30%), 'high' (29%) and 'good source' (22%) claims. Different criteria were being used, although most foods (88%) met the Australian Food Standards Code (Volume 1) requirements. There is therefore a need to ensure consistency where such claims are made. Criteria for protein claims may also be necessary if health claims are based on products meeting criteria for certain content claims (for example, 'high in protein').

3.4.3 International comparison of protein claims

There is no consistency between countries and Codex in terms of the basis for the criteria for protein claims. The different approaches depend largely on the extent to which protein quality criteria have been taken into consideration in order to assure minimal protein values of processed foods and to provide standards of quality for commercial food products.

United States criteria, except for foods for infants under one year of age, are based on a 'corrected amount of protein' determined using the protein digestibility corrected amino acid score. This score, however, underestimates the quality of very high quality protein sources, such as milk, eggs, meat and fish, which may have an impact, particularly when these are used as complementary sources of protein (for example, milk with cereal).

In contrast to the United States approach, protein claims in Canada continue to be based on protein quality determined using the protein efficiency ratio (PER). A 'protein rating' is calculated as the product of the PER of the protein of a food, multiplied by the grams of protein in Recommended Dietary Intake of food.

Codex criteria are based on percentages of the Nutrient Reference Value (NRV) per 100 g or per 100 ml or per kcal or per serving. The United Kingdom legislation and the European Union proposal base protein on a percentage of the energy value of the food.

3.4.4 Source of protein

Codex, Canada and the European Union proposal all provide for 'source of protein' claims. Codex's criteria are ≥10% NRV per 100g (solids) and ≥5% of NRV per 100 mL (liquids) or 5% of NRV per 100 kcal or 10% of NRV per serving. The European Union proposed criteria are for ≥12% of the energy value of the food provided by protein.

If NRV is replaced by dietary reference value (DRV) on the basis that that is what is referenced in the Code (table to sub clause 7(3) of Standard 1.2.8) and the values in the table were calculated by converting %DRV (protein = 50g) to grams, the criteria would equate to ≥2.5 grams of protein per 100 mL or ≥5 grams of protein per 100 grams. Examination of the food composition tables reveals that the main sources of protein would meet the criteria except for milk. In addition, foods such as sponge cakes, mars bars, milk chocolate, condensed or evaporated milk and sausage rolls would qualify.

Using Codex criteria of 10% of the NRV per serving and a protein reference value of 50 g, the 'per serving' equivalent would be ≥5 g protein per serving. Milk with serve sizes of 125 ml would qualify, as would yoghurts with a serve size greater than 100 g, most cheeses and breads, baked beans, nuts, soy milks, cooked pastas and noodles without meat or cheese, some cakes, soups and breakfast cereals and all other expected sources of protein. The European Union proposed criteria of ≥12% of the energy value of the food provided by protein, produces similar foods to Codex's per serve criteria. Most milks and yoghurts qualify for a 'source of' claim.

A combination of at least 12% energy from protein plus at least 5 g protein per serve would prevent food with large serving sizes but low protein levels from making the claim. Whole milk, soy milk and some cheeses would qualify.

3.4.5 High in/good source of protein

Codex requirements for 'high protein' are twice their requirements for 'source of protein' claims. 'High protein' claims are permitted in Canada (equivalent to Canada's 'source of protein' claims), have been proposed in the European Union (≥20% of energy from protein, which is equivalent to the United Kingdom's 'rich/excellent source of protein' claim) and are in the repealed NZFR (>33% more protein compared with the normal counterpart and >15 g protein per serving and a statement of comparison with the named normal counterpart).

Codex criteria for 'high protein' translate to ≥5 grams of protein per 100 mL or ≥10 grams of protein per 100 grams. Examination of the food composition tables reveals that foods such as red meats, poultry, fish, shellfish, cheese, eggs, seeds, most nuts and some legumes and breakfast cereals qualify. Milk does not qualify but foods that can contribute significantly to saturated fat intake such as meat pies, hamburgers and pizzas topped with meat, and foods with small serving sizes such as cocoa and coffee powder meet the criteria.

Most submitters to the P234 Draft Assessment Report favoured criteria based on 'per serving' rather than per '100 g' on the basis that protein quality would be better addressed. Using Codex criteria of 20% of the NRV per serving and a protein reference value of 50 g, the 'per serving' equivalent would be ≥10 g protein per serving. Similar foods are represented in this category as given for 'g per 100 g'; although some protein-enriched milks would be included if the serve size is 250 ml as well as flavoured milks packed in 500 ml and marketed as a single serve. The European Union's proposed criteria of ≥20% of energy from protein, includes some milks and yoghurts.

3.4.6 Other protein claims

Other protein claims are permitted internationally but there is no consistency in the claims. For instance 'low protein' is provided in the now repealed NZFR and in Canada, 'very high protein/excellent source of protein' are given in Canada and the United Kingdom and 'more protein' is regulated in Canada and the United States.

3.4.7 FSANZ's preferred criteria for protein claims

Claim	**Preferred criteria (and conditions)**
'source of protein'	≥5 grams of protein per serving and ≥12% of energy value of the food must be provided by protein
'good source/ high in protein'	≥10 grams of protein per serving and ≥20% of energy value of the food must be provided by protein

Questions:

15. Should these protein claims be permitted? Briefly explain.

16. If so, do you agree with FSANZ's preferred criteria?

3.5 Fats

3.5.1 Policy context

3.5.1.1 Australia

The Dietary Guidelines for Australian Adults recommend limiting saturated fat and moderating total fat intake (National Health and Medical Research Council 2003). Fat in foods is recognised as a major determinant of energy density and is associated with overweight and obesity. The National Taskforce on the Prevention and Treatment of Obesity (2000) recently reviewed the health risks of being overweight or obese. The risk of morbidity and mortality from coronary heart disease, type 2 diabetes mellitus, hypertension and dyslipidemia, increases with the degree of obesity.

The 1995 National Nutrition Survey indicated that 55.2% of Australians aged 19 years and older were overweight or obese. This represented an increase of 41% in adult women and 29% in adult men since 1983.

The 1995 National Nutrition Survey estimated that mean total fat intake of adult Australians contributed to one-third of total energy, which represented a slight decline between 1983 and 1995. This data suggests that reducing fat intake alone is not sufficient in dealing with overweight and obesity. The importance of physical activity in weight management is reflected in the draft guideline 'Prevent weight gain: be physically active and eat according to your energy needs' (National Health and Medical Research Council 2003).

3.5.1.2 New Zealand

The New Zealand Food and Nutrition Guidelines for Healthy Adults recommend preparing foods or choosing pre-prepared foods, drinks and snacks with minimal added fat, especially saturated fat. The 1997 New Zealand National Nutrition Survey showed that 35% of energy came from fat in the diet of both males and females, a reduction of 2.5% since 1989. The New Zealand Nutrition Taskforce (1991) set a guideline of 30–33% of energy from total fat. The Food and Nutrition Guidelines for Healthy Adults also set out criteria for considering the lower limits of acceptable fat intake.

3.5.2 Low (in) fat

CoPoNC, Codex and the European Union proposal set the criteria at ≤3g per 100g solids or ≤1.5 ml per 100 ml liquid food. The solids criterion is the same for meal and main dishes in the United States and for liquid and solid foods in the United Kingdom. Criteria for Canada and the United States are generally based on reference amounts.

The majority of submitters supported the claim and the criteria at the Initial and Draft Assessment stages for P234.

Participants in FSANZ's consumer research (FSANZ 2003b) used 'low' claims interchangeably with 'reduced', though after more focused discussion and a word sort exercise, they tended to agree that 'low' was probably lower than 'reduced' and referred to products intrinsically low in the claimed nutrient.

3.5.3 Reduced (in) fat

The preferred criterion of a minimum reduction of 25% is the approach taken by CoPoNC, Canada, the United States and Codex. CoPoNC has further conditions that require a reduction of at least 3 g of fat per 100 g of food but this was previously considered by the P234 External Advisory Group's Working Group to be unnecessarily complicated from a consumer education perspective.

A large number of submitters agreed with the claim and the criterion, although the issue of an additional reduction (for example, 25%) in energy content compared with a reference food was raised. TEG did not support disqualifying criteria for energy but considered a disclosure statement, such as 'See nutrition information panel for energy content' to be appropriate. Please note that the paper by La Fontaine et al. (2004) as discussed under comparative claims was not available at the time of the TEG meeting.

3.5.4 '% fat free'

NZFR, CoPoNC, the United States, Canada, and Codex all require '% fat free' claims to meet the requirements for 'low fat' claims in their respective regulations. The United Kingdom FSA guidelines state that '% fat free' claims should not be made and the European Union propose that the claim should be prohibited. Canada and the United States have additional requirements for '100% fat free'.

Submitter comments to the P234 Draft Assessment Report demonstrated that there was considerable controversy on the issue of '% fat free'. Four submitters supported 'low fat' criterion and a declaration of the actual fat content in conjunction with the claim and two supported the 'low fat' criterion, as a means of ensuring consumers will not be misled. However, 11 other submitters (health professionals and a consumer organisation) recommended a prohibition, on the basis that the claim is potentially misleading, does not provide any new information to 'low fat' claims, is misused in the marketplace (many products carry claims that are less than '97% fat free'), and that a prohibition is consistent with United Kingdom legislation.

Eleven submitters opposed the 'low fat' criterion, arguing that it is not misleading under fair trading to make '% fat free' claims on foods that are not low in fat and it limits consumer choice in comparing with high fat foods. Suggestions were for claims to be either ≤5 g fat per 100 g for solids or ≤10 g fat per 100 g for solids. Finally, eight industry submitters objected to the declaration of the actual total fat content in conjunction with the claim, principally because it duplicates the mandatory information in the nutrition information panel, does not provide for minimum effective regulation, is inconsistent with other claims and requires label changes.

FSANZ's consumer research on the issue of '% fat free' (FSANZ 2003b, p. 44) demonstrated that consumers were positive about these claims as they considered them to be exact and therefore reliable. They also felt it was easier to make food comparisons. The limitation was that the claims did not immediately tell the consumer how much fat was in the product as few consciously looked beyond the percentage to think about the amount of fat they would be consuming from the product. FSANZ's previous quantitative research found that 75% of consumers said that '94% fat free' meant the food was a 'low fat food', whereas only 16% described it as a 'medium fat food' (FSANZ, 2003a).

3.5.5 FSANZ's preferred criteria for fat claims

Claim	**Preferred criteria (and conditions)**
Low (in) fat	≤3g per 100g; ≤1.5 ml per 100 ml liquid food.
Reduced (in) fat	The comparison should be based on a relative difference of at least 25% in the fat content. The identity of the reference food and the percent, fraction or amount of difference in fat content should be indicated adjacent to the comparative claim.
Fat free	No provisions.
% fat free	The food must meet the requirements specified for the 'low fat' claim.

Questions:

17. Should these fat claims be permitted? Briefly explain.

18. If so, do you agree with FSANZ's preferred criteria?

19.	Should there be an additional criterion that relates to energy for 'reduced fat' claims? If so, what criteria should apply and what evidence supports such an approach?

3.6 Saturated and trans fat

3.6.1 Policy context

3.6.1.1 Australia

The Dietary Guidelines for Australian Adults (National Health and Medical Research Council 2003) recommend limiting saturated fat and moderating total fat intake. Saturated fats contain no double bonds and are usually solid at room temperature. They are the predominant type of fat in dairy products, in some meats and in palm oil and coconut oil (National Health and Medical Research Council 2003). There is good evidence that an increase in consumption of saturated fatty acids, specifically, myristic, palmitic and lauric acids, and trans fatty acids, rather than total fat, is associated with an increase in the risk of coronary heart disease. Compared to carbohydrate, polyunsaturated and monounsaturated fatty acids, an increase in the consumption of saturated fatty acids results in an increase in the concentration of total and low density lipoprotein cholesterol, an established risk factor for coronary heart disease (National Heart Foundation of Australia 1999).

Trans fatty acids are a form of unsaturated fatty acids that is straight at a double bond rather than bent, as in the usual *cis* form. They are not common in nature but are formed during some manufacturing processes, for example, hydrogenation of edible oils to make margarines. There is good evidence that compared to polyunsaturated and monounsaturated fatty acids, trans fatty acids increase the concentration of total and low density lipoprotein cholesterol, and lower high density lipoprotein cholesterol. There is also moderate evidence that, at high levels of intake, trans fatty acids increase the risk of coronary heart disease (National Heart Foundation of Australia 1999). It should be noted, however, that consumption of trans fatty acids in Australia is not high.

The 1995 National Nutrition Survey showed that saturated plus trans fatty acid intakes by Australians averaged over 12.5% of energy. A population average of 10% saturated plus trans fatty acids of total energy is recommended in the Dietary Guidelines for Australian Adults (National Health and Medical Research Council 2003).

3.6.1.2 New Zealand

Food and Nutrition Guidelines for Healthy Adults recommends preparing foods or choosing pre-prepared foods, drinks and snacks with minimal added fat, especially saturated fat. Data collected from the NNS97 survey showed that saturated fat contributed 15% of energy in the diets of males and females. This figure is higher than the target set by the New Zealand Nutrition Taskforce (1991) for a maximum of 12% of total energy intake from saturated fatty acids and trans fatty acids. Like Australia, most table spreads, which contribute the major source of trans fatty acids, now only contain a small proportion of trans fatty acids.

3.6.2 Low in saturated fat

CoPoNC criteria for saturated fat are consistent with Codex in this instance (≤1.5 g saturated fat/100 g solids or ≤0.75 g/100 ml liquids), whereas in the United Kingdom, the FSA's guidelines stipulate ≤1.5 g per 100 g (solids) or per 100 ml (liquids). In addition, CoPoNC requires that foods comply with the conditions for a 'low fat' claim. There is, however, evidence of positive health benefits from replacing intake of saturated fatty acids with unsaturated fatty acids, without necessarily reducing the total fat content of the diet.

Canada's recent revision of 'low saturated fat' includes trans fatty acid content in the criteria (≤2 g saturated and trans fatty acids combined per reference amount and per labelled serving). The United States is currently considering criteria for trans fat too and whether statements about trans fat, either alone or in combination with saturated fat and cholesterol, should be provided as a footnote in the nutrition panel or as a disclosure statement in conjunction with the claim. In addition, Codex, the United States, Canada, the European Union proposal and the United Kingdom FSA guidelines all set disqualifying criteria around the percentage of energy from saturated fat. For instance Codex, the United Kingdom FSA, the United States and the European Union proposal have a condition that the saturates provide ≤10% of total energy, whereas Canada's recent criterion is ≤15% energy from saturated and trans fatty acids per reference amount and per labelled serving. The NZFR claim for 'low saturated fat' was the same as the NZFR claim for 'reduced saturated fat'.

Twelve submitters supported the preferred claim and criteria at P234 Draft Assessment. One submitter, however, preferred the criterion that saturated fatty acids and trans fatty acids should be ≤28% of the total fatty acid of the food, on the basis that it would be consistent with other fatty acid claims in the Code, would not restrict oils from making the claim and supports the notion that the ratio of saturated to polyunsaturated fatty acids is more important than a reduction in saturated fatty acids alone.

3.6.3 Reduced in saturated fat

A 25% minimum reduction of saturated fat is provided for all comparative claims in CoPoNC, Canada and the United States. Additional criteria also apply in these countries but they are not the same. For instance, Canada stipulates that there must not be an increase in the content of trans fatty acids; and that the percent, fraction or amount of difference in saturated fatty acid content must be indicated adjacent to the most prominent claim.

CoPoNC, however, specifies that there must be a reduction of at least 2 g saturated fatty acid per 100 g of food compared with the same quantity of reference food (or 1 g saturated fatty acids per 100 g of liquid food) and either ≤20% of the fatty acid portion may be derived from saturated fatty acids and ≥40% of *cis*-monounsaturated and *cis*-polyunsaturated fatty acids or ≤15% of total energy may be derived from saturated fatty acids.

Additional criteria for the United States relate to disclosure statements if cholesterol and total fat exceed certain levels. They are also currently considering criteria for trans fat too and whether statements about trans fat, either alone or in combination with saturated fat and cholesterol, should be provided as a footnote in the nutrition panel or as a disclosure statement in conjunction with the claim.

Most submitters supported criteria for a 25% reduction in saturated and trans fatty acid content at P234 Draft Assessment. However, other criteria were recommended. These criteria included a reduction of at least 25% saturated fatty acids, a statement of comparison with a reference food and a total of combined trans and saturated fatty acids of ≤28% of the total fatty acids of the food in order to ensure consistency with fatty acid claims in the Code or an additional disqualifying criteria for total fat. It should also be noted that Canada did not favour criterion that related to the combined amount of saturated and trans fatty acids, as foods with no reduction in saturated fatty acids (or even an increase) could carry the claim (for example, a food with 2 g saturated and 4 g trans fatty acids could be modified to contain 2.5 g saturated and 2 g trans fatty acids and could therefore be labelled 'reduced in saturated fatty acids'). The amount of trans fatty acids in foods in Australia and New Zealand are, however, considered to be small compared to those in Canada.

3.6.4 Trans fat

Canada allows claims for trans fatty acids to help consumers make food choices in line with dietary guidance. Criteria for 'trans fat free' are 0.2 g trans fatty acids per reference amount and per labelled serving and 'low' in saturates. Criteria for 'reduced trans fat' are a 25% minimum reduction in trans fatty acids, no increase in saturated fatty acid content and the reference food must be 'low' in saturated fatty acids. The reference food and the percent, fraction or amount of difference in trans fatty acid content must be indicated adjacent to the most prominent comparative claim. No other country or Codex has provisions for 'trans fat free' claims.

In light of the small amounts of trans fatty acids consumed in Australia and New Zealand and emerging evidence indicating that certain trans fatty acids may potentially have beneficial physiological effects, trans fatty acid claims do not seem necessary. Trans fatty acids could, however, be made in conjunction with saturated fat claims (for example, 'low in saturated and trans fat'), given that the criteria include trans fatty acids.

3.6.5 FSANZ preferred criteria for saturated and trans fat claims

Claim	**Preferred criteria (and conditions)**
Low (in) saturated fat/ Low in saturated and trans fat	≤1.5 g in total of saturated and trans fatty acids per 100g of solids; ≤0.75 g in total of saturated and trans fatty acids per 100 ml of liquids. The nutrition information panel must include declarations of the trans, polyunsaturated and monounsaturated fatty acid content of the food in accordance with Standard 1.2.8 sub-clauses 5(4) and 5(7).
Reduced (in) saturated fat/ Reduced in saturated and trans fat	The comparison should be based on a relative difference of at least 25% in the saturated and trans fatty acid intake. The identity of the reference food and the percent, fraction or amount of difference in fat content should be indicated adjacent to the comparative claim. The nutrition information panel must include declarations of the trans, polyunsaturated and monounsaturated fatty acid content of the food in accordance with Standard 1.2.8 sub-clauses 5(4) and 5(7).
Saturated fat free	No provisions.

Questions:

20. Should these saturated and trans fat claims be permitted? Briefly explain?
21. If so, do you agree with FSANZ's preferred criteria?
22. Is there merit in a disqualifier for 'low in saturated fat/low in saturated and trans fat'? A possible option is that saturated fat must not provide more than 10% of energy.
23. Is there justification in considering a new criterion for 'low in saturated fat/low in saturated and trans fat' claims, such that the total of saturated fatty acids and trans fatty acids comprises no more than 28% of the total fatty acid content of the food? What advantages and disadvantages would such a criterion provide in comparison to FSANZ's preferred option?
24. Is there merit in a disqualifier for 'reduced in saturated fat/reduced in saturated and trans fat', such that there should be no increase in trans fatty acids?

3.7 Polyunsaturated, monounsaturated and omega fatty acids

3.7.1 Policy context

The scientific evidence supporting monounsaturated, polyunsaturated and omega fatty acids claims was considered during the review of the Australia New Zealand Food Standards Code and has more recently been reviewed in dietary guidelines in Australia and New Zealand.

3.7.1.1 Polyunsaturated and omega fatty acids

Australia

There is good evidence that replacing saturated fatty acids with omega-6 polyunsaturated fatty acids reduces the risk of coronary events and deaths and lowers the concentration of low density lipoprotein cholesterol, total cholesterol and plasma triglycerides.

The Australian 1995 National Nutrition Survey showed that mean intakes of polyunsaturated fat in adults contribute 4.5% of total energy. In view of the strong evidence supporting the role of omega-6 polyunsaturated fatty acids in protecting against coronary heart disease, the Dietary Guidelines for Australian Adults recommend that intakes of these fatty acids be in the range of 6–8% of total energy. In addition, due to the low intake of long chain omega-3 polyunsaturated fatty acids (approx. 200 mg from fish and a few vegetable oils), intake of these fatty acids should be doubled as a measure to reduce the risk of coronary heart disease, though such a recommendation poses challenges for both the environment and the fats and oils industry (National Health and Medical Research Council 2003).

New Zealand

Results from the 1997 New Zealand National Nutrition Survey showed that 5% of total energy was provided from polyunsaturated fatty acids, which falls short of the target of 6–10% of total energy set by the New Zealand Nutrition Taskforce (1991).

3.7.1.2 Monounsaturated fatty acids

Australia

Replacing saturated fatty acids with monounsaturated fatty acids lowers total and low density lipoprotein cholesterol although not to the same extent as polyunsaturated fatty acids (National Heart Foundation of Australia 1999). The Australian National Heart Foundation notes there is little evidence that monounsaturated fatty acids have an independent effect on coronary outcomes. The Foundation's position statement recommends that a proportion of dietary saturated fatty acids should be replaced by monounsaturated fatty acids as a strategy for reducing the intake of saturated fatty acids (National Heart Foundation of Australia 1999).

In adult Australians, present intake levels of monounsaturated fats are around 11.5% and would appear to be satisfactory except in individuals who need to reduce fat as part of body weight management (National Health and Medical Research Council 2003).

New Zealand

In New Zealand, the 1997 Survey showed monounsaturated fat provided 12% and 11% of energy in males and females respectively. This is within the range of 10–20% set by the New Zealand Nutrition Taskforce (1991).

3.7.2 Polyunsaturated and monounsaturated fatty acid claims

Of the countries considered, Australia and New Zealand are the only ones that have provisions for polyunsaturated and monounsaturated fatty acid claims, as given in Standard 1.2.8 of the Code. At the P234 Draft Assessment stage it was recommended that existing claims and criteria in the Code be retained, given that they were reviewed as part of the review of the Code and there is scientific evidence to support them.

All but one submitter supported the claims and criteria at P234 Draft Assessment. Several submitters did, however, want clarification with respect to different types of claims.

3.7.3 Omega fatty acid claims

Only Australia, New Zealand and Canada have requirements for omega fatty acid claims. Canada has criteria for 'source of' omega-3 fatty acids and 'source of 'omega-6 fatty acid claims; however, these criteria are different to those contained in the Code in that they are based on grams of omega-3 or omega-6 polyunsaturates per reference amount and per labelled serving and there is no disqualifying criterion. Australia and New Zealand also have a 'good source' of omega-3 fatty acids claim. At P234 Draft Assessment stage, it was proposed that the claims in the Code be retained, as there is scientific evidence to support their use, the values have been recently reviewed, and Canada's criteria were only proposals at that time.

Submitters to the P234 Draft Assessment Report raised several issues. Firstly, some industry submitters argued that saturated fat disqualifying criteria should not apply (sub-clause 13(2)(b)), given that saturated fat information is mandatory in the nutrition information panel, the criteria are inconsistent with international regulations (Canada is the only other country with omega-3 fatty acid claims and there is no disqualifying criterion for saturated fatty acids) and disqualifying criteria are only relevant to health claims where the overall nutrition profile is important to the claimed benefit.

Secondly, two submitters opposed omega-6 and omega-9 fatty acid claims on the basis that the Australian diet is too rich in linoleic acid. It was thought that a disclosure statement should accompany the claim explaining the differences between omega-3, omega-6 and omega-9 fatty acids and the overall aims for dietary balance.

A third issue is whether docosapentaenoic acid (DPA) content should be included in the calculation of the total content of omega-3 fatty acids. Criteria for an omega-3 fatty acid claim are based on eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) content of foods, as these particular omega-3 fatty acids have been strongly linked in scientific literature to a reduced risk of developing cardiovascular disease. Alpha-linolenic acid (ALA) is also included in the criteria as it acts as a precursor for EPA and DHA and over the long term has a more pronounced impact on the physiological roles and benefits associated with n-3 fatty acids than with EPA and DHA intakes (Simopoulos 1999).

Docosapentaenoic acid (DPA), however, is not included in the criteria for an omega-3 fatty acid claim. DPA is an omega-3 fatty acid occurring naturally in fish and meat, which acts as a precursor of DHA. A submitter to P234 argued that the presence of DPA in a food should, therefore, be considered relevant for an omega-3 fatty acid claim. A study was also provided, which supports the position that DPA in conjunction with DHA contributes to a reduction in the risk of developing cardiovascular disease. This information does not, however, indicate the amount of DPA that should be consumed to produce a significant reduction in cardiovascular risk, nor has any evidence been provided that quantifies the bioconversion of DPA into DHA. Without this information, FSANZ is unable to determine the amount of DPA that produces a similar health outcome to that of DHA, and therefore the amount needed in a food before an omega-3 fatty acid claim can be made.

3.7.4 FSANZ's preferred criteria for polyunsaturated, monounsaturated and omega fatty acid claims

Claim	Preferred criteria (and conditions)
Polyunsaturated or monounsaturated fatty acid content of a food	See Standard 1.2.8, clause 12 of the Code. Also, the nutrition information panel must include declarations of the trans, polyunsaturated and monounsaturated fatty acid content of the food in accordance with Standard 1.2.8 sub-clauses 5(4) and 5(7).
In relation to omega-3 fatty acids	See Standard 1.2.8, sub-clauses 13 (1), (2) and (3) of the Code. Also, the nutrition information panel must include declarations of the trans, polyunsaturated and monounsaturated fatty acid content of the food in accordance with Standard 1.2.8 sub-clauses 5(4) and 5(7), and the source of omega-3 fatty acids in accordance with sub-clause 13(5) and the editorial note following sub-clause 13(6).
Good source of omega-3 fatty acids	See Standard 1.2.8, sub-clause 13(4) of the Code. Also, the nutrition information panel must include declarations of the trans, polyunsaturated and monounsaturated fatty acid content of the food in accordance with Standard 1.2.8 sub-clauses 5(4) and 5(7), and the source of omega-3 fatty acids in accordance with sub-clause 13(5) and the editorial note following sub-clause 13(6).

In relation to omega-6 or omega-9 fatty acids	See Standard 1.2.8, sub-clause 13(6) of the Code. The nutrition information panel must include declarations of the trans, polyunsaturated and monounsaturated fatty acid content of the food in accordance with Standard 1.2.8 sub-clauses 5(4) and 5(7), and the editorial note following sub clause 13(6).

Questions:

25. Should these polyunsaturated, monounsaturated and omega fatty acid claims be permitted? Briefly explain.

26. If so, do you agree with FSANZ's preferred criteria?

27. Should the Code be clarified in relation to polyunsaturated and monounsaturated fat claims? Two possible options are that:
    a) the provisions should only relate to 'source of' claims in order to ensure consistency with omega-6 and omega-9 claims; and
    b) there should be provisions for 'source', 'good source' and 'increased' claims to ensure consistency with other content claims.

3.8 Cholesterol

3.8.1 Policy context

3.8.1.1 Australia

Dietary cholesterol only occurs in animal fats, which are also the major sources of saturated fatty acids in the diet (Australian Bureau of Statistics 1995). There is moderate evidence that dietary cholesterol increases total cholesterol and low density lipoprotein cholesterol but substantially less so than saturated and trans fatty acids (National Heart Foundation of Australia 1999). Australian public health policy recommends a reduction in saturated fat intake, which will bring about smaller cholesterol intakes, as these two lipid classes usually occur in the same foods (National Health and Medical Research Council 2003).

3.8.1.2 New Zealand

The New Zealand Nutrition Taskforce (1991) does not have a separate recommendation for cholesterol, given its lesser role as a determinant of low density lipoprotein cholesterol, and there is no mention of cholesterol in the Food and Nutrition Guidelines for Healthy Adults (2003).

3.8.2 P234 Draft Assessment

A prohibition on all cholesterol claims was recommended at P234 Draft Assessment on the basis that the then draft Australian Dietary Guidelines (National Health and Medical Research Council 2001) and the New Zealand Nutrition Taskforce (1991) place a greater emphasis on reducing the intake of saturated fats, rather than dietary cholesterol, as a strategy to reduce coronary heart disease. There was also the belief that consumer knowledge about the relationship between blood cholesterol and dietary cholesterol is poor. The Draft Assessment Report acknowledged that efforts to harmonise with international practice was not a priority in this instance; rather the priority was consideration of current scientific evidence about the links between dietary cholesterol and health. It also stated that there is little harmony in existing criteria for cholesterol claims between countries that currently provide for cholesterol claims.

Opinion was divided on the issue of a prohibition at P234 Draft Assessment, though more submitters supported the prohibition than opposed. When the TEG met in May 2004, their preferred approach was to continue with the proposed prohibition.

3.8.3 FSANZ consumer research

FSANZ's consumer research (FSANZ 2003b, p. 48) found that only consumers with a special interest in blood cholesterol or heart disease, or those in the upper age groups paid any attention to cholesterol claims. People with high blood cholesterol or heart disease tended to be highly knowledgeable about reading labels and using the nutrition information panel to evaluate products. Few based their product choice solely on cholesterol claims; instead most used fat claims and the saturated fat information in the nutrition information panel. There were various opinions about cholesterol claims: those with diagnosed cholesterol and heart disease conditions were not concerned with a prohibition, whereas regular or infrequent dietary cholesterol 'watchers' were more concerned because they tended to rely more heavily on cholesterol claims as they did not understand the importance of saturated fat. A smaller group objected to a prohibition because of the 'big brother' approach, which they saw as always changing. 'Cholesterol free' was the only cholesterol claim that was deemed 'reliable'.

3.8.4 Low in cholesterol

CoPoNC, Canada, Codex and the United States have all defined criteria for 'low cholesterol' claims on the basis of no more than 20 mg cholesterol per 100 g food (in the United States, such criteria only apply to meals, while they only apply to solids under Codex). In each instance, with the exception of Codex, there are additional conditions accompanying the above criteria, but no harmony between them. NZFR was less than 20 mg cholesterol per specified serving and at least one-third less than the normal named counterpart. The United Kingdom prohibits 'low cholesterol' claims.

3.8.5 Reduced in cholesterol

CoPoNC, the NZFR and Canada have provisions for 'reduced cholesterol' claims, but there is no consistency in these provisions.

3.8.6 Cholesterol free

Canada's criteria are similar to the United States (<2 mg cholesterol per reference amount and per labelled serving), but different to those in CoPoNC, which is again different to Codex criteria. The United Kingdom prohibits this claim.

3.8.7 FSANZ's preferred criteria for cholesterol claims

Claim	**Preferred criteria (and conditions)**
Low (in) cholesterol	Prohibited.
Reduced (in) cholesterol,	Prohibited.
Cholesterol free	Prohibited.

Questions:

28. Should these cholesterol claims be permitted? Briefly explain.

29. If so, do you agree with FSANZ's preferred criteria?

3.9 Carbohydrate

3.9.1 Policy context

3.9.1.1 Australia

The Dietary Guidelines for Australian Adults do not provide specific comment on carbohydrates.

3.9.1.2 New Zealand

The New Zealand Nutrition Taskforce target for percent energy from carbohydrate is 50–55%. The NNS97 demonstrated that adults consume less than this, with 45% of energy being provided by carbohydrates for males and 47% for females. The Food and Nutrition Guidelines for Healthy Adults encourage adults to achieve a desirable carbohydrate intake by increasing consumption of vegetables, fruits, legumes, and breads and cereals.

3.9.2 International comparison of claims and use of carbohydrate claims

The NZFR were the only regulations with specific criteria for carbohydrate claims, namely 'low carbohydrate'. These regulations have been repealed. The rationale for excluding carbohydrate claims in most countries and in Codex is that they would be misleading, if not ambiguous, in that they do not allow for the distinction between high levels of complex carbohydrates and high levels of sugars.

3.9.3 Rationale for carbohydrate claims

A rationale for stipulating carbohydrate claims is that consistency would be assured where such claims are made. The University of Wollongong results (Williams et al. 2003) demonstrated that nearly all carbohydrate claims (14%) in Australia appeared on cereal products (except for sports foods) and that the most prevalent claims were 'high' (61%) and 'source of' claims (19%). There is also considerable public interest in low carbohydrate diets overseas, which may result in an increase in 'low carbohydrate' claims being used in Australia and New Zealand over the next few years.

Another rationale for providing carbohydrate claims is that criteria may be necessary if health claims are based on products meeting certain criteria for content claims (for example, 'high in carbohydrate').

In contrast, the rationale for not providing carbohydrate claims is that there is no evidence of market failure and they are not regulated internationally (carbohydrate claims for sports foods are regulated separately). There is also concern that consumers might consider all 'carbohydrates' to be the same and they may confuse such claims with the issue of Glycaemic Index/Glycamic Load. Furthermore, FSANZ's consumer research (2003b) found that participants had little interest in carbohydrate claims. Awareness of carbohydrate claims was lower than protein claims, but both were associated with sports and energy drinks and powders and were thought to be relevant for such people as athletes and body builders.

3.9.4 'Low' and 'high' in carbohydrates

The repealed NZFR state that the product must contain at least one-third less carbohydrate compared with its normal counterpart; and must have a statement of comparison with its counterpart; and less than 5% energy of food derived from carbohydrate.

No country or Codex has provisions for this claim. Preferences around disqualifying criteria at P234 Draft Assessment were for dietary fibre and energy density criteria, or sugar and dietary fibre criteria.

3.9.5 Technical Expert Group on General Level Claims

The TEG believed that provisions should probably be made for carbohydrate claims. Some members also believed that Glycaemic Index and Glycaemic Load were nutrition content claims because they specifically related to foods, rather than to health outcomes. In order to maintain consistency with claims for other nutrients and to provide criteria for all possible carbohydrate claims, TEG therefore believed that FSANZ should seek comment on providing criteria for 'low', 'reduced' and 'high' carbohydrate claims as well as criteria for Glycaemic Index and Glycaemic Load. It was pointed out that while products manufactured in Australia are carrying claims in relation to Glycaemic Index, New Zealand Crop and Food Research is working with industry to promote Glycaemic Load and products are expected to carry such claims later this year.

3.9.6 Glycaemic Index and Glycaemic Load

3.9.6.1 Glycaemic Index

The Glycaemic Index (GI) is a measure of the blood glucose response to carbohydrate in a food as a percentage of the response to an equal weight of glucose. For foods containing the same amount of carbohydrate, the GI indicates what effect the food will have on an individual's blood glucose levels. Foods with a high GI contain carbohydrates that are quickly digested and absorbed and low GI foods contain carbohydrates that generally break down slower.

In recent times, significant thought to GI foods has occurred as a result of its connection with dieting and the effect it has on the body's blood sugar levels. While a low GI food may help control diabetes and the body's sensitivity to insulin, high GI foods are thought to be helpful in quickly replenishing the body's carbohydrate stores after exercise or when blood glucose levels fall below normal in people with diabetes, especially insulin dependent diabetes.

There is no compelling evidence yet that a low GI diet will help healthy people lose weight or reduce the risk of heart disease, although some research has shown that diets made up mainly of high GI foods are associated with increased risk of coronary heart disease, type 2 diabetes and associated conditions (Liu et al. 2000).

A food packaging symbol 'G – Glycaemic index tested' was launched in Australia by Glycaemic Index Limited (a non-profit company, whose members are the University of Sydney, Diabetes Australia and the Juvenile Diabetes Research Foundation) in July 2002 as a strategy for comparing the effect of different foods on blood sugar. Food must not be high in fat, salt, sugar or calories and must contain significant amounts of fibre in order to be eligible for the symbol. Certain foods are excluded, such as high and intermediate GI soft drinks, cordials, syrups, confectionery, sugars. The criteria for GI are:

- High GI ≥70
- Medium GI = 56–69
- Low GI <55

3.9.6.2 Glycaemic Load

Glycaemic Load (GL) is a measure of the relative amount that blood glucose levels will change after a serving of a food (Liu et al. 2003; Munro 2004). GL is divided into three categories with Glycaemic Glucose Equivalents (GGEs) as units:

- Low 0–10 GGEs
- Medium 11–19 GGEs
- High 20 GGEs

The categories indicate the effect of one serve of food on blood glucose levels. New Zealand Crop and Food Research proposes that GL is only applied to foods that have general nutritional benefits, are low in saturated fat and meet established nutritional guidelines.

A compelling limitation to using GI is that it is based on glycaemic carbohydrate only, not on the response of the whole food. Because foods contain differing amounts of carbohydrate, ranking foods by GI will not necessarily rank them according to the effect they have on blood sugars. For example, if the GI of an apricot is 57 and the GI of a banana is 58, it would be assumed that if an individual ate either of these it would result in the same blood glucose response. However, an apricot has only 5 g of available carbohydrate and a banana has 31 g; an apricot weighs approximately 50 g and a banana weighs approximately 130 g. As a result, the banana will raise blood glucose levels six times higher than an apricot will because it contains six times more carbohydrate and is over double the size of the apricot. Therefore Glycaemic Load, or GL, effectively communicates the real blood glucose impact of the food to a consumer – the GL of banana, is 18 and the GL of an apricot is three.

In addition, as GI is a ratio it does not change with food intake. So a muesli bar has the same GI whether the person eats 50 g of the bar or 150 g, whilst obviously the impact on blood glucose for 150 g of the bar should be three times the impact of 50 g of the bar.

GL accounts for these problems by measuring the glycaemic impact of the whole food rather than just the carbohydrate portion. GL is the weight of glucose that will induce the same glycaemic response as a given weight of food. As GL is not just a ratio, it is responsive to changes in food intake and, as it measures the blood glucose response of the whole food, it can be used to compare foods containing different amounts of carbohydrates.

3.9.6.3 Nutrition information panel declaration for Glycaemic Index

GI does not directly relate to a nutrient or a biologically active substance as provided in the working definition for content claim. Currently no entry can be given in the nutrition information panel. Consideration must therefore be given to resolving whether an entry should go in the nutrition information panel, and if so what, given that the GI does not relate to the carbohydrate content of the food, nor is GI entirely a response to the type of carbohydrate. Alternatively, an amendment to Standard 1.2.8 could be made, which requires a quantification of the GI of the food and an explanation of what it means.

3.9.7 FSANZ's preferred approach for carbohydrate claims

Questions:

30. Is there merit in including provisions for making 'carbohydrate claims'? Please provide evidence to support any criteria for preferred 'carbohydrate claims', and suggest, with the support of evidence, where disqualifying criteria such as maximum sugar levels or minimum fibre levels would be required for foods to carry such carbohydrate claims.
31. Are Glycaemic Index and Glycaemic Load content claims? If so, what criteria should apply and what provisions should be made in relation to declaring the quantity for GI?

3.10 Sugar

3.10.1 Policy context

The Dietary Guidelines for Australians (National Health and Medical Research Council 2003) include advice to 'consume only moderate amounts of sugars and foods containing added sugars'. This is consistent with the New Zealand Food and Nutrition Guideline that advises people to prepare foods or choose pre-prepared foods, drinks and snacks with little added sugar and to limit intake of high-sugar foods.

The Dietary Guidelines for Australian Adults conclude that the evidence for sugar's role in the aetiology of dental caries is strong. The Food and Nutrition Guidelines for Healthy Adults state that because the impact of sugars on dental caries is dependent on many factors, health promotion initiatives should also emphasise fluoridation, adequate oral hygiene and reduced frequency of sucrose intake.

The links between sugar intake and obesity are not clear as many studies show no links but others suggest there may be cause for concern. The Dietary Guidelines for Australian Adults conclude that when energy intake exceeds energy expenditure over a sustained period, overweight or obesity will result. Excess dietary energy intake, from whatever source, including sugars, can thus contribute to weight gain, overweight and obesity. Inappropriately high levels of intake of sugars may also displace other nutrients from the diet. On the other hand, moderate use of sugars as sweeteners or to add flavour may actually improve the palatability of food and increase overall nutrient consumption. The Dietary Guidelines for Australian Adults believe there is no evidence that, for most Australians, consumption of up to 15–20% of energy as sugars is incompatible with a healthy diet. Consumption of greater amounts than this could lead to a decrease in nutrient density.

3.10.2 Low in sugar(s) and reduced in sugar(s)

For solid foods, both CoPoNC and the United Kingdom require that a food must not contain more than 5 g total sugars per 100 g of the food in order to make a 'low in sugar(s)' claim. CoPoNC criteria are more stringent than United Kingdom criteria for liquid foods where the serve size of the liquid is expected to be 200 mL or more, in that CoPoNC sets the amount at no more than 2.5 g total sugars per 100 g liquid food and the United Kingdom criterion for liquids is twice that amount. The United States and Codex do not define a criterion here. Criteria are set in New Zealand and Canada on a different basis, defining a maximum percentage of energy coming from sugars and maximum percentage sugars on a dry basis, respectively.

The minimum percentage reduction required to make 'reduced in sugar(s)' claims in CoPoNC, Canada and the United States is 25%, as previously discussed. For comparative claims, Codex states 'the comparison should be based on a relative difference of at least 25% in the energy value or nutrient content'. The now repealed NZFR was the only regulation of those considered that set criteria for 'reduced' claims at one-third less than the normal counterpart.

There were few specific comments provided to the P234 Draft Assessment Report in relation to 'low in sugar(s)' and 'reduced in sugar(s)' other than a recommendation to include an additional criterion of a reduction of at least 25% energy for 'reduced in sugar(s)' claims. TEG did not support disqualifying criteria for energy but considered a disclosure statement, such as 'See nutrition information panel for energy content' to be appropriate.

3.10.3 No added sugar(s)

CoPoNC refers to the regulations in the Australian Food Standards Code where there is a general prohibition on the claim unless the food contains no added sugar or related products (as defined in Standard K1) no added honey (as defined in Standard K2) and no added malt, malt extract or maltose. The NZFR permitted such claims if the food did not contain added carbohydrate sweetener or added sugar alcohol (>1%) as an ingredient in the food.

In the United Kingdom, the United States and Canada the intent of provisions for this claim seem similar to those in New Zealand and Australia (that is, that no sugars or ingredient containing added sugars – or for the United Kingdom 'composed mainly of sugars' – can be added in processing). For the United States and Canada this includes a prohibition on use of enzymes except where the functional effect is not to increase the sugar content of the food. The European Union proposal defines the claim in terms of no added monosaccharides or disaccharides or any other food used for sweetening purposes. Codex does not provide criteria for this claim.

The Australia New Zealand Food Standards Code provides definitions of sugars (as foods) and related products and honey (Part 2.8). However, it does not make any provisions in regard to claims about sugar. Standard 1.2.8 currently defines sugars as nutrients (that is, monosaccharides and disaccharides).

3.10.3.1 A disclosure statement

At P234 Draft Assessment, FSANZ proposed that a reference to the declaration of sugars in the nutrition information panel must be made in conjunction with the claim to alert consumers to the sugar content of the food. This approach is consistent with the United States, although the required disclosure statement in the United States is different in that it must indicate that the food is not low or reduced in calories (unless it meets the requirements for a low or reduced calorie food) and must direct consumers' attention to the nutrition information panel for further information on sugars and calorie content. Canada proposed a 'not sugar-free' disclosure statement but later rejected it in light of stakeholders questioning its usefulness and identification of a potential problem for foods sweetened with sugar-alcohols. In such cases they would not contain any sugars yet would have had to carry the disclaimer 'not sugar-free'.

Submitter comments to the P234 Draft Assessment Report were divided on the issue of the proposed disclosure statement. The eight industry submitters who opposed, argued that it amounts to double labelling and that there is no evidence that consumers misunderstand the claim. Seventeen submitters, from a range of stakeholders groups, supported a disclosure statement, believing it would provide clarity for the consumer.

3.10.3.2 FSANZ consumer research

FSANZ's consumer research (2003b, p. 55) found that 'no added sugar' was unequivocally understood to mean the product had only 'natural sugar'. Participants were far less sceptical of 'no added' claims compared to most other claims, so use of the nutrition information panel for verification was considered less necessary. 'No added sugar' claims were believed to be potentially misleading when a product contained a high amount of intrinsic sugar. Reactions to use of three disclosure statements were mixed. 'Inquirers' and those with special health needs felt that disclosure statements that made reference to the nutrition information panel or to the presence of 'natural sugar' were unnecessary. Other consumers responded positively to the 'contains natural sugar' disclosure statement because it removed the ambiguity by clarifying whether the product was free of sugar. Previous to FSANZ's study on content claims, a labelling quantitative study by FSANZ found that less than two-fifths of 934 respondents (38%) knew that a 'no added sugar' claims meant the food could be a low, medium or high sugar food.

Given that consumers may not use the nutrition information panel for 'no added sugar' claims and that there is potential for shoppers to be misled, a disclosure statement seems warranted.

3.10.4 Unsweetened

As per the conditions for making 'no added sugar' claims, CoPoNC refers to regulations in the Australian Food Standards Code. Accordingly, CoPoNC allows this claim where the product meets the criteria for 'no added sugar' claims and, in addition, it contains no added artificial sweetening substance, no added sorbitol, mannitol, glycerol, xylitol, hydrogenated glucose syrup or isomalt. The now repealed NZFR extended criteria for 'no added sugar' claims in this instance to include the condition that the food also contains no artificial sweetener as an ingredient. In the United States and United Kingdom 'unsweetened' is permitted where it is a factual statement, though the United Kingdom has additional provisions for condensed milk and dried milk products. Codex does not provide criteria for this claim.

3.10.5 FSANZ's preferred criteria for sugar claims

Claim	**Preferred criteria (and conditions)**
Low (in) sugar(s)	≤5 g total sugars per 100 g of food ≤2.5 g total sugars per 100 mL of liquid food. The nutrition information panel must include a declaration of the presence or absence of dietary fibre in accordance with sub-clauses (5) and (7) of clause 5 of Standard 1.2.8 of the Code.
Reduced (in) sugar(s)	The comparison should be based on a relative difference of at least 25% in the sugar content. The identity of the reference food and the percent, fraction or amount of difference in fat content should be indicated adjacent to the comparative claim. The nutrition information panel must include a declaration of the presence or absence of dietary fibre in accordance with sub-clauses (5) and (7) of clause 5 of Standard 1.2.8 of the Code.
No added sugar/sugars	The claims cannot be made unless the food contains no added: (i) hexose monosaccharides and disaccharides, including dextrose, fructose, sucrose and lactose; or (ii) starch hydrolysate; or (iii) glucose syrups, maltodextrin and similar products; or (iv) products derived at a sugar refinery, including brown sugar and molasses; or (v) icing sugar; or (vi) invert sugar; or (vii) fruit sugar syrup; (viii) malt or malt extracts; or (ix) honey; or (x) concentrated and/or deionised fruit juice where it does not constitute the essential character of the food; and (xi) a reference to the declaration of sugars in the nutrition information panel must be made in conjunction with the claim to alert consumers to the sugar content of the food.

Unsweetened	The claims cannot be made unless the food contains no added: (i) hexose monosaccharides and disaccharides, including dextrose, fructose, sucrose and lactose; or (ii) starch hydrolysate; or (iii) glucose syrups, maltodextrin and similar products; or (iv) products derived at a sugar refinery, including brown sugar and molasses; or (v) icing sugar; or (vi) invert sugar; or (vii) fruit sugar syrup; (viii) malt or malt extracts; or (ix) honey; or (x) concentrated and/or deionised fruit juice where it does not constitute the essential character of the food; and no (xi) intense sweeteners; or (xii) sorbitol, mannitol, glycerol, xylitol, isomalt, maltitol syrup or lactitol; and (xiii) a reference to the declaration of sugars in the nutrition information panel must be made in conjunction with the claim to alert consumers to the sugar content of the food.
Sugar free	No provisions.

Questions:

32. Should these sugar claims be permitted? Briefly explain.

33. If so, do you agree with FSANZ's preferred criteria?

34. Should there be an additional criterion that relates to energy for 'reduced sugar' claims? If so, what criteria should apply and what evidence supports such an approach?

3.11 Fibre

3.11.1 Policy context

The Dietary Guidelines for Australians (National Health and Medical Research Council 2003) recommends consumers 'eat plenty of cereals (including breads, rice, pasta and noodles), preferably wholegrain'. This guideline, whilst different to the 1992 Dietary Guidelines (National Health and Medical Research Council 1992) retains the emphasis on wholegrain due to the growing body of evidence of the health benefits of wholegrain compared to refined cereal products. The New Zealand Food and Nutrition Guidelines for Healthy Adults (2003) recommend a similar approach.

In 1999, the United States Food and Drug Administration approved the health claim: 'diets rich in whole-grain foods and other plant foods and low in total fat, saturated fat and cholesterol; may reduce the risk of heart disease and certain cancers' (National Health and Medical Research Council 2003). The CSIRO (2000) indicates there is mounting evidence that a diet high in unprocessed grains helps protect against various cancers and heart disease. The beneficial effects of cereal fibre and whole grains in relation to the decreased risk of coronary heart disease and some cancers is discussed in the Dietary Guidelines for Australian Adults (National Health and Medical Research Council 2003).

3.11.1.1 Coronary heart disease

The published results of over 200 human trials have led to the general conclusion that foods rich in soluble fibre can lower plasma cholesterol (National Health and Medical Research Council 2003). The Australian National Heart Foundation (1997) has stated that consumption of dietary fibre, especially cereal fibre, is associated with a lower risk of coronary heart disease. The Go Grains Advisory Committee (2001) supports this opinion with evidence showing the decreased risk of heart disease may be up to 30%.

3.11.1.2 Cancer

Two major reviews of the relationship between cereal consumption and cancer prevention have been published (World Cancer Research Fund and American Institute for Cancer Research 1997; European Cancer Prevention Organisation Consensus Panel on Cereals and Cancer 1998). The Dietary Guidelines for Australian Adults note that it is difficult to evaluate many studies because of the scarcity of biological markers; the inadequacy of many food-intake measurements, which often do not distinguish the degree of refinements of cereal foods; and the low overall intakes of cereal fibre in many studies from the United States. There is, however, emerging agreement on the probable protective roles of cereals in relation to some important cancer types. In particular, it appears that wholegrain intake confers benefits. The World Cancer Research Fund and American Institute for Cancer Research global review also concluded that there is 'convincing' evidence of a protective effect of fruit and vegetables for cancers of the mouth, pharynx, oesophagus, stomach, colon, rectum and lung (World Cancer Research Fund and American Institute for Cancer Research 1997; United Kingdom Dept of Health 1998). In contrast though, the Committee on Medical Aspects of Food and Nutrition (COMA) study found no 'strong' association between fruit and vegetable consumption and cancer at any site, while a 'moderate' association was noted for cancers of the stomach, colon and rectum.

CSIRO research indicates that substances in the outer layers of grains help to combat the incidence of bowel cancer and possibly breast cancer (CSIRO 2000). The outer layers of grains from which brans are made, besides being the richest source of insoluble dietary fibre, also contain a range of substances likely to be active against cancers including phytates, lignans, flavonoids, phytosterols, vitamins E and B and certain trace elements such as selenium (CSIRO 2000).

3.11.1.3 Obesity

The Dietary Guidelines for Australian Adults (National Health and Medical Research Council 2003) recommend a high fibre, low fat diet for maintenance of body weight and prevention of obesity. Obesity is associated with low fibre intake.

3.11.1.4 Constipation

According to the Dietary Guidelines for Australian Adults (National Health and Medical Research Council 2003) cereal fibre has been found to improve bowel function by increasing faecal bulk and reducing transit time, resulting in softer, larger stools and more frequent bowel action. The New Zealand Food and Nutrition Guidelines for Healthy Pregnant Women also note the merit of increasing fibre intakes during pregnancy to avoid constipation that commonly occurs at this time due to specific hormonal changes.

Constipation, diverticular disease and diabetes are common problems in older people. Fibre-rich foods are therefore recommended, though the New Zealand Ministry of Health discourages people from relying on wheat bran as a major source of dietary fibre due to adverse effects on mineral absorption. Awareness of the need to increase fibre intake is high amongst older New Zealanders.

Data from the Australian National Nutrition Survey (Australian Bureau of Statistics 1995) show that, amongst adults with the highest intakes (those aged 19–24 years of age) on the day of the survey, only 34% of men and 21% of women met recommended intake targets for the cereal group of seven serves per day. According to the CSIRO, Australians are not eating enough of the healthy protective substances found in wholegrains and other plant foods. The average person consumes about 75% of the relevant dietary fibres considered necessary to protect them properly (CSIRO 2000).

The New Zealand 1997 National Nutrition Survey found that the usual mean intake for dietary fibre was 20 g per day, which is lower than the Nutrition Taskforce target of 25–30 g per day. Of this, 10 g of soluble non-starch polysaccharides were consumed, compared to the Taskforce target of approximately a quarter of total dietary fibre.

3.11.2 International comparison of dietary fibre claims

There is little consistency in the criteria for fibre claims across the countries considered in this review. There is also inconsistency in definitions for fibre, which therefore affects the comparability of criteria. In many cases, the criteria and claims do not align. For example, in the United Kingdom a ‘high fibre’ claim can be made on a food with at least 6 g fibre per 100 g but under CoPoNC main dishes or meal type products are able to be labelled as an ‘excellent or very high source of fibre’.

CoPoNC has and the now repealed NZFR had criteria expressed as dietary fibre (grams) per serving of food; the United Kingdom FSA guidelines express it as dietary fibre (grams) per 100 g or per 100 ml or in terms of the reasonable expected daily intake of food; and Codex draft guidelines are per 100 g or per 100 kcal or per serving. The European Union proposal is similar to Codex except that it is not defined in terms of per serving. Canada has changed its criteria to dietary fibre per reference amount (which is consistent with the United States) and per labelled serving. For pre-packaged meals and main dish entrees in Canada, at least one ingredient must meet the criteria for the particular fibre claim that is being made.

Taking the definition of dietary fibre in the Code into consideration, the recommendation at P234 Draft Assessment was that the existing CoPoNC fibre claims and criteria should be retained, given the general support from submitters and members of the EAG at Initial Assessment and in light of the effort invested in developing CoPoNC criteria, which were more recently developed than the now repealed NZFR standards. There was no scientific basis for departing significantly from the CoPoNC approach at that time and no apparent means for improving harmony internationally, given the general lack of consistency in criteria and conditions for making fibre claims.

3.11.3 Submissions to P234 on fibre claims

There was general support from a large number of industry stakeholders and a New Zealand consumer organisation at Draft Assessment for CoPoNC criteria. Several issues were, however, noted:

- Several submitters believed there are too many fibre claims. Preferred claims were 'source of fibre' and 'high fibre' only.
- Several submitters recommended criteria based on 'g per 100 g' because manufacturers can manipulate serving sizes, although one submitter proposed that fruit and vegetables be assessed on a 'per serve' basis.
- Several submitters expressed concern about the definition of dietary fibre in terms of whether there is such a thing as dietary fibre, whether there is enough information on fibre and its effects, whether analysis can keep apace with science and whether the AOAC method should be prescribed, given that the New Zealand Food Composition Database uses the modified Englyst method.

3.11.4 Disqualifier to prevent high fat foods making fibre claims

Under CoPoNC, fibre claims are discouraged on foods having significant fat content. CoPoNC states that where ≥30% of energy is derived from fats there must be a statement on the label drawing attention to the fat content of the food in the nutrition information panel. At P234 Draft Assessment, this approach was not considered sufficient in addressing the issue of manufacturers making fibre claims on products high in fat or saturated fat. FSANZ therefore sought comment on the merit of disqualifying criteria for fibre claims if the products were ≥30% energy from fat or saturated fat ≥10% energy from saturated fat. The issue is now of greater relevance for two reasons:

1. In March 2004 the FSANZ Board approved the Final Assessment Report for A495 – Polydextrose as Dietary Fibre. Polydextrose is now included as a specifically-named fibre with an AOAC method of analysis specified in Standard 1.2.8. FSANZ is also reviewing A491 – Resistant Maltodextrin as Dietary Fibre. A Final Assessment Report was presented to the FSANZ Board in July. If approved and gazetted the resulting amendments mean dietary fibre content claims can therefore be added to foods of low nutritional value and inappropriate claims, including any future health claims, can potentially be made.

2. On 28 May 2004 the Ministerial Council agreed to a Policy Guideline for the Fortification of Foods with Vitamins and Minerals. The policy covers both mandatory and voluntary fortification of food. Ministers agreed that vitamins and minerals may be added to food where there is, for example, demonstrated evidence of a potential health benefit, and it is clear that the fortification of a food will not result in harm. One of the specific order policy principles on voluntary fortification on vitamins and minerals is that:

   – permission to fortify should not promote consumption patterns inconsistent with the nutrition policies and guidelines of Australia and New Zealand;

   – permission to fortify should not promote increased consumption of foods high in salt, sugar or fat.

   These policy principles could be extended to dietary fibre or to all 'positive nutrients'.

FSANZ therefore wishes to give further consideration to disqualifying criteria for dietary fibre claims. This could include saturated fat, salt, sugar and or energy. The TEG did not provide specific criteria but supported FSANZ's approach to seek comments from submitters.

3.11.5 Source of fibre

CoPoNC uses the criteria ≥1.5 g dietary fibre per serving of food. With main meal or meal type products it increases to ≥2 g dietary fibre per 100 g meal. Canada's criteria are ≥2 g per reference amount and per labelled serving. The United Kingdom FSA guidance notes, the European Union proposal and the draft Codex stipulate criteria of ≥3 g per 100 g (Codex also has ≥1.5 g per serve or per 100 kcal), while the former NZFR and United States have no criteria.

The issue of whether the criteria for 'source of fibre' are high enough was raised at P234 Draft Assessment. Some members of the TEG also queried the levels and wished to seek comment from stakeholders. In addition, the criteria for main dishes and meal type products were questioned by submitters to P234 Draft Assessment and by some members of the TEG. One preferred option was that the value for individual foods should be trebled on a per serving basis.

3.11.6 High fibre or good source of fibre

CoPoNC criteria is ≥3 g dietary fibre per serving except for main dishes or meal type products which must have ≥4 g dietary fibre per 100 g meal. This is consistent with the draft Codex guidelines (≥3 g per serve or per 100 kcal or ≥6 g per 100 g or 100 ml). Criteria for the United Kingdom FSA guidance notes and European Union proposal are ≥6 g per 100 g. The NZFR required ≥4 g dietary fibre per serving, at least one-third more fibre compared with its normal counterparts and a statement of comparison with the normal counterpart. Canada also uses ≥4 g dietary fibre per labelled serving as well as per reference amount. The approach is slightly different in the United States in that meals and main dishes must use the 'good source' claims with criteria of 2.5–4.75 g per reference amount for and for all other foods 'high fibre' is used with criteria of ≥5g per reference amount.

Again, the issue of whether the criteria for 'high fibre' claims are high enough, was raised at P234 Draft Assessment and by some members of the TEG. The criteria for main dishes and meal type products were also questioned by both submitters to P234 Draft Assessment and by some members of the TEG. One preferred option was that the value for individual foods should be trebled on a per serving basis.

3.11.7 Very high fibre or excellent source of fibre

CoPoNC and Canada are the only countries considered that have criteria for 'very high fibre' or 'excellent source of fibre'. Both stipulate ≥6 g dietary fibre per serving, although Canada also has a criterion for ≥6 g dietary fibre per reference amount.

3.11.8 Increased fibre, fibre enriched and higher fibre

CoPoNC criteria for these claims are the same as for claims for 'high fibre' or 'good source of fibre' except that the claims can only be applied to foods which contain, prior to enrichment with dietary fibre, at least 1.5 g of dietary fibre per serving. There must also be a statement of comparison with the reference food. Canadian criteria are the same as for their 'source of fibre' claims (≥2 g fibre per reference amount and per labelled serving) except that there must be a minimum 25% increase in dietary fibre, totally ≥1 g fibre. The identity of the reference food and the difference in dietary fibre content must also be stated adjacent to the most prominent comparative claim. Likewise, the United Kingdom uses their 'source of fibre' criteria (≥3 g fibre per 100 g or 100 ml or in the reasonable daily intake of a food) and a 25% minimum increase in dietary fibre. There was little comment on this claim at P234 Draft Assessment.

3.11.9 Fibre added

In CoPoNC the criterion for these claims is that the food must meet the criteria for 'high fibre' claims and must have a statement of comparison with the reference food. The United States stipulates 2.5 g more per serving than a reference food.

3.11.10 FSANZ's approach to fibre claims

Questions:

35. Is there merit to including disqualifying criteria for fibre claims? If so, what nutrients should be considered and what specific criteria should be applied?
36. On what basis should criteria be set for fibre claims?
37. What qualifying criteria should apply to fibre claims?
38. Is a 'very high fibre' claim necessary, given that there are no claims for 'very high' for any other nutrient?
39. Should there be specific provisions for main dishes and meal type products? If so, what criteria should apply?

3.12 Salt

3.12.1 Policy context

The Dietary Guidelines for Australian Adults (National Health and Medical Research Council 2003) recommend choosing foods low in salt. In New Zealand, the Food and Nutrition Guidelines for Healthy Adults (Ministry of Health 2003) advise consumers to prepare foods or choose pre-prepared foods, drinks and snacks that are low in salt and if using salt, to choose iodised salt.

It is well established that a reduction in dietary sodium intake will decrease the mean population blood pressure and will reduce the prevalence of hypertension. Hypertension is the most common identifiable disease in western society with a prevalence that increases steadily with age. It affects around 16% of urban Australians, when all age groups are considered, almost one-third of those over 50 years, and almost half of those aged 65–69 years (Risk Factor Prevalence Study Management Committee 1990). While it has not yet been conclusively established that a mean dietary intake of sodium within the range recommended for Australian adults will result in lower morbidity and mortality rates than at present, the balance of evidence suggests it will (National Health and Medical Research Council 2003).

Major cohort studies have shown the risk of stroke and ischemic heart disease increases with increasing blood pressure (National Health and Medical Research Council 2003). Within the range of diastolic blood pressure studied (about 70–110 mm Hg) there is no evidence of a threshold below which the relationship alters.

The New Zealand Nutrition Taskforce (1991) recommendations for healthy adults are to reduce dietary sodium intake to 120 mmol per day or less in order to decrease the average blood pressure levels in the general population and thereby reduce the general incidence of cerebrovascular and cardiovascular disease. Dietary sodium intake was not included in the NNS97 because of the difficulty in assessing discretionary salt added to food.

However, a regional study in New Zealand found a mean sodium excretion of 3105 mg per day, which corresponds to a mean sodium intake of 3473 mg per day (Thomson & Colls 1998), which is well above the Recommended Dietary Intake (920–2300 mg). In addition, the NNS97 survey, revealed that approximately 22% of men and 18% of women had high blood pressure (those taking hypertensive medication plus those with a systolic pressure ≥160 mmHg and a diastolic pressure ≥95 mmHg).

In a cross-sectional analysis of 52 populations (Intersalt study), a significant positive correlation was found between median 24-hour urinary sodium excretion and prevalence of hypertension within each population (National Blood Pressure Advisory Committee 2001). Populations with higher rates of sodium excretion showed a steeper rise in blood pressure with increasing age compared with those with lower sodium excretion rates.

3.12.2 Low (in) salt/sodium

The Code, CoPoNC, NZFR, European Union proposal and Codex all set the cut-off for making 'low salt' claims at ≤120 mg sodium per 100 g food. Standard 1.2.8 mandates inclusion of sodium as well as potassium content details in nutrition information panels where a content claim is made in respect of salt or sodium. Canada and United States criteria are based on reference amount (and per labelled serving in Canada) with specific criteria for meals and main dishes (≤140 mg or less per 100 g). United Kingdom criteria are the same as the Code and Codex criteria for 'very low salt/sodium' claims.

At P234 Draft Assessment the recommendation was to retain the existing criterion in the Code, as it is consistent with Codex, was revised as a part of the review of the Code and required no change in practice in New Zealand. No new issue was raised at P234 Draft Assessment.

3.12.3 Very Low (in) salt/sodium

CoPoNC, the European Union proposal and Codex have criteria for 'very low salt/sodium' claims (≤40 mg per 100 g). This is equivalent to the value at which the United Kingdom defines a 'low salt' claim and the value for 'low salt' meals and main dishes in the United States. United States criteria for 'very low' are ≤35 mg sodium per 100 g meal.

The TEG did not consider a 'very low salt/sodium' claim to be necessary. There are also no provisions for 'very low' claims for any other nutrient.

3.12.4 Reduced (in) salt/sodium, less salt/sodium

The minimum percentage reduction required to make 'reduced' claims in CoPoNC, Canada and the United States is 25% as discussed under 'comparative claims'. CoPoNC also stipulates additional conditions (maximum of 600 mg sodium per 100 g food and at least 90 mg less sodium per 100 g compared with reference food). The repealed NZFR criterion is one-third less than the normal counterpart.

The P234 External Advisory Group supported retention of the claim because of the need to reduce sodium at a population level and because it may encourage manufacturers to produce reduced salt products. Implementation of a 25% reduction in sodium content will provide consistency with Canada, the United States and Codex. No new issue was raised at P234 Draft Assessment.

3.12.5 No added salt/sodium

CoPoNC, the United Kingdom and Canada permit this claim when a food (and all of its ingredients) contain no added sodium compound or no added salt during processing. In Canada, if potassium has been added to the food, the amount must be declared. The United States, the European Union proposal and Codex have no provisions for this claim.

The issue of manufacturers being able to declare that a product has 'no added salt' when the natural sodium content is quite high was raised at the TEG meeting. Two alternatives were considered: a disclosure statement, which draws attention to the sodium content of the product as outlined in the nutrition information panel (for example, See nutrition information panel for sodium content) or a new criterion that the sodium content of the food must be 'low in salt' (≤120 mg per 100 g). No consensus was reached.

FSANZ's consumer research (2003b, p. 55) found that 'no added sodium/salt' claims were looked for on chips, baked beans and canned vegetables. Respondents were familiar with the claim, though they did not look for it as often as 'no added sugar' claims. They were much less sceptical of the claim compared to most of the other eight content claims examined and therefore used the nutrition information panel less frequently to verify it. They unequivocally understood it to mean the product had only 'natural' salt, with nothing added. While they also understood that a 'no added' product did not imply that the product had no salt, there was an underlying feeling that the product would be 'low' in salt. Participants were uncertain as to whether the 'no added' claim referred to the food itself, such as corn in 'no added salt' canned corn, or whether it also included canning and packing agents such as brine. Reactions to disclaimers were mixed. 'Inquirers' and those with special health needs felt that disclaimers that made reference to the nutrition information panel or to the presence of 'natural salt' were unnecessary as they used the nutrition information panel as needed. Others, however, strongly felt that the disclaimer 'contains natural salt/sugar' should appear with 'no added' claims because it removed the ambiguity by clarifying whether the product was free of salt.

3.12.6 FSANZ's preferred approach for salt/sodium claims

Claim	**Preferred criteria (and conditions)**
Low salt/sodium	≤120 mg sodium per 100 g food.
Very low salt/sodium	No provisions.
Reduced salt/sodium	The comparison should be based on a relative difference of at least 25% in the sodium value. The identity of the reference food and the percent, fraction or amount of difference in sodium value should be indicated adjacent to the comparative claim.
No added salt/sodium	The food and the ingredients of that food contain no added sodium compound, no added salt or, as the case may be, are unsalted.
Salt free	No provisions.

Questions:

40. Should these salt/sodium claims be permitted? Briefly explain.

41. If so, do you agree with FSANZ's preferred criteria?

42. Should there be additional criteria for 'no added salt/sodium' claims to address the issue of manufacturers making the claim on products that are not low in sodium? Please comment on the usefulness of either of the following two criteria:
    a) The label or advertisement must include a statement adjacent to the claim drawing attention to the sodium content of the product as outlined in the nutrition information panel (for example, 'See nutrition information panel for sodium content'); or
    b) The food must be 'low in salt'.

3.13 Gluten and lactose

3.13.1 Gluten

3.13.1.1 Policy context and P234 Draft Assessment

Specific criteria for gluten are listed in the Code. These claims are regulated on the basis that consumption of foods containing gluten may have adverse health consequences in certain individuals, particularly those suffering from coeliac disease. At P234 Draft Assessment it was recommended that the existing criteria for gluten claims be retained, as they were addressed during the review of the Code.

3.13.1.2 Proposal P264

Since release of the P234 Draft Assessment Report, P264 (Review of Gluten Claims with Specific Reference to Oats and Malt) has been prepared. The FSANZ Board approved a change in Clause 16 of Standard 1.2.8 at P264 Final Assessment such that:

– for 'gluten free' claims – the prohibition of 'gluten free' claims be extended to foods containing oats or their products or cereals containing gluten that have been malted or their products;
– for 'low gluten' claims – the prohibition of 'low gluten' claims on foods containing oats or malt be removed.

It was thought that Clause 16, Standard 1.2.8 would provide a high level of protection of public health and safety for those people most sensitive to coeliac disease when purchasing 'gluten free' foods. At the same time, removal of the prohibition of oats and malt on 'low gluten' claims would allow an appropriate level of protection of public health and safety for people less sensitive to coeliac disease, who are able to tolerate small amounts of gluten in the diet, including gluten from oats or malted gluten containing cereals. However, the Ministerial Council recently asked for a review of P264. This review is due to be completed by 17 August 2004.

3.13.1.2 'No detectable' gluten

There is potential inconsistency between the 'no detectable' criteria for 'gluten free' and no provisions being given for other 'free' claims. FSANZ and TEG consider there is justification for the inconsistency on the basis of public health and safety, but wish to seek comment from stakeholders.

3.13.2 Lactose

3.13.2.1 Policy context and P234 Draft Assessment

Specific criteria for lactose claims are listed in the Code. These claims are regulated on the basis that consumption of foods containing lactose may have adverse health consequences in certain individuals, particularly those suffering from lactose intolerance. At P234 Draft Assessment it was recommended that existing criteria for lactose claims be retained, as they were addressed during the review of the Code.

3.13.2.2 International comparison of lactose claims

Codex provides the same criteria as given in the Code for 'low lactose' and 'lactose free'. Codex has no provision for 'reduced lactose'. In the United Kingdom, the FSA recommend that it should be at least 25% less than normal milk, but some products can contain as much as 95%.

The issue of whether the criteria for 'low lactose' claims are too low was raised during P234 Draft Assessment. An alternative recommendation was to use the same criteria as the 'low sugar' claims (that is, ≤5 g total lactose per 100 g of food and ≤2.5 g total lactose per 100 mL of liquid food). The issue of whether a 'reduced lactose' claim was necessary was also raised. It was argued that products may still contain a significant amount of lactose and dietitians advise those with lactose intolerance to only consume a diet free or low in lactose.

3.13.2.3 'No detectable' lactose

There is potential inconsistency between the 'no detectable' criteria for 'lactose free' and no provisions being given for other 'free' claims apart from gluten. FSANZ and TEG consider there is justification for the inconsistency on the basis of public health and safety, but wish to seek comment from stakeholders.

3.13.3 FSANZ's preferred approach for gluten and lactose claims

Claim	**Preferred criteria (and conditions)**
gluten free	To be defined after the Ministerial review
'low' gluten	To be defined after the Ministerial review
lactose free#	no detectable lactose
'low' lactose#	≤0.3g of lactose per 100 g of the food
Lactose reduced#	The comparison should be based on a relative difference of at least 25% of the nutrient content. The identity of the reference food and the percent, fraction or amount of difference in energy value or nutrient content should be indicated adjacent to the comparative claim.
# Where a claim is made in relation to the lactose content of a food, particulars of the lactose and galactose content of the food must be provided in the nutrition information panel.	

Questions:

43. Should these gluten and lactose claims be permitted? Briefly explain.

44. If so, do you agree with FSANZ's preferred criteria?

3.14 Diet

3.14.1 International comparison of 'diet' claims

Specific provisions for 'diet' claims are stipulated in CoPoNC and the now repealed NZFR. The United States, Canada, United Kingdom and Codex do not, however, define criteria for this claim. The existing criteria for 'diet' claims in CoPoNC permit two alternatives:

1. The food must comply with the regulations for a 'low joule' claim in Volume 1 of the Food Standards Code.
2. The food must meet the following conditions:
    a) the energy content of the food must not be more than 60% of the energy content of the same quantity of the reference food; and
    b) there must be a reduction in energy content of at least 170 kJ per 100 g of food, or 80 kJ per 100 g of liquid food, compared with the same quantity of the reference food; and
    c) there must be a statement of comparison with the reference food.

The now repealed NZFR permitted the claim if the food is a meal replacement for weight reduction or weight maintenance diet; or conform to 'low energy' regulations (NZFR 241) or 'low energy' and 'reduced energy' claims (NZFR 13b and 13c).

3.14.2 P234 Draft Assessment

The preferred criterion at P234 Draft Assessment was that products must meet a 'low joule' claim. It was argued that this approach minimises change in New Zealand as existing provisions for 'low joule' claims in Australia and New Zealand are the same. It also simplifies the provisions for manufacturers and makes it easier for consumers to understand what 'diet' means (that is, 'diet' means 'low joule' and nothing else). Stakeholder opinions were divided on the issue, with many either opposing the claim or supporting it and recommending criteria that are not limited to 'low joule'.

3.14.3 FSANZ consumer research

FSANZ's consumer research (2003b, p. 59) found that participants viewed 'diet' claims as the least trustworthy, most ambiguous and most irrelevant of all the claims examined. It was associated with weight loss products and therefore foods that taste bad and was considered to be only relevant to a certain group of people. Participants found the claim ambiguous because they believed the criteria were different for different product categories (for example, in soft drinks, 'diet' was thought to be low in calories, contains artificial sweeteners and possibly has some sugar; but in yoghurts the view was that it has artificial sweeteners and less milk or fat). Overall, many viewed the claim as a 'nothing' term and as being similar to 'light' claims in terms of its ambiguity. Others viewed it as being an 'old' term because they saw claims as being much more specific nowadays (for example, '99% fat free').

3.14.4 FSANZ's preferred approach for 'diet' claims

Claim	Preferred criteria (and conditions)
Diet	The food must meet the conditions for 'low joule' claims. The average energy content of the food is no more than 80 kJ per 100 mL of beverages or other liquid foods and no more than 170 kJ per 100 g of solid or semi-solid foods.

Questions:

45. Should this diet claim be permitted? Briefly explain.

46. If so, do you agree with FSANZ's preferred criteria?

3.15 Light/lite

3.15.1 International comparison of 'light/lite' claims

CoPoNC requires that the characteristic that makes the food 'light' be stated on the label. The food must also comply with conditions for the corresponding 'reduced' or 'low' claim, when the claim refers to a nutrient or energy. NZFR had the same criteria for 'light' as for 'diet'. Codex notes that in all instances, 'light' should follow the same criteria as for 'reduced' and include an indication of the characteristic that makes the food 'light'. The European Union's proposal is the same as for Codex. Canada's new requirements are that the claim must only be made in relation to 'reduced' in energy or fat and that a statement of the reduction for calories or fat or both be made, depending on the reduction that meets the criteria for the claim. Criteria in the United States are dependent on the amount of calories from fat in a food. When ≥50%, the fat must be reduced by ≥50% per reference amount; when <50% fat must be reduced by ≥50% or the calories must be reduced at least one-third per reference amount. Meals must meet 'low fat' or 'low calorie' criteria.

The University of Wollongong's study on content claims (Williams et al. 2003) found that 69% of 'light/lite' claims did not include a statement of the characteristic that is light, as stipulated in CoPoNC.

3.15.2 FSANZ consumer research

FSANZ's consumer research (2003b, p. 56) showed that consumers used the claims but with different levels of understanding. 'Inquirers' were overwhelmingly negative towards these claims, viewing them as ambiguous, misleading, confusing and/or outright 'trickery'. However, less well-informed or label-educated consumers regarded them as an attractive and easy way to identify a healthier version of the product. Some participants in the study identified the claim with fat and sugar, but the majority were uncertain and confused as to what the term referred to. In the absence of clarity, most consumers assumed that the claim referred to the nutrient in the food that most needed reducing, and the default assumption was that 'light/lite' referred to fat. The notion of confusion and scepticism is confirmed by results from earlier ANZFA qualitative (2001) and quantitative (2003a) studies.

There was a general unprompted view that the claim should be accompanied by a comparative claim (for example, 'has less fat than our normal ice cream'). Therefore, when prompted, participants favoured a disclaimer in conjunction with the claim that identifies the nutritional or non-nutritional characteristic of the food to which the claim refers. Participants felt this would increase their understanding of the claim and the credibility of the claim. Respondents also felt that the disclaimer should be in a font and colour that was equally as noticeable as the claim, though they did not believe it had to be exactly the same size and colour as the claim.

3.15.3 FSANZ's preferred approach for 'light/lite' claims

Claim	**Preferred criteria (and conditions)**
Light or Lite	The characteristic that makes the food 'light/lite' must be stated adjacent to the claim, regardless of whether the term applies to energy, a nutrient or a non-nutritional characteristic of the food. If the claim relates to a nutrient or energy, then the food must comply with the conditions for the corresponding 'low' or 'reduced'.

Questions:

47. Should these light/lite claims be permitted? Briefly explain.

48. If so, do you agree with FSANZ's preferred criteria.

3.16 Biologically active substances

The definition for 'nutrition claim' in the Code applies to biologically active substances. This ensures that claims such as 'rich in phytoestrogens' and 'contains lycopene' have to declare the average quantity in the nutrition information panel (Standard 1.2.8 sub-clause 4(2) and paragraph 5(1)(g)). At present there are no officially recognised health reference standards for biologically active substances and no country has yet set criteria for content claims. Countries such as Canada do, however, permit quantitative claims for these substances (for example, '14 mg of lycopene per 50 g serving').

Members of the TEG did not consider that a generic approach could be applied for claims that relate to biologically active substances. They did, however, consider there is sufficient information for criteria to be set for certain claims.

Questions:

49. What are the most common claims in relation to biologically active substances? What criteria have been applied and what evidence is there to support them?

50. Should criteria be set for certain claims and if so, what types of claims should be made and what criteria should apply? Please provide evidence and a cohesive argument to support your views.

3.17 Implied claims

Implied content claims are generally handled on a case-by-case basis by enforcement agencies in the United States, Canada, the United Kingdom, Australia and New Zealand. Canada and the United States both, however, have requirements for 'lean' and 'extra lean' (and 'modified' in the United States), while in Australia and New Zealand, Clause 5, Standard 2.2.1 – Meat and Meat Products of the Code regulates mandatory fat declaration where an express or implied reference is made to the fat content of minced meat. In addition, the United States defines implied claims as:

- Claims about a food or ingredient that suggests that the nutrient or ingredient are absent or present in a certain amount or claims about a food that suggests a food may be useful in maintaining healthy dietary practices and which are made with an explicit claim (for example, 'healthy, contains 3 grams of fat'). These claims are prohibited unless provided for in a regulation. The Food and Drug Administration has a petition system whereby specific additional claims may be considered.
- Claims that a food contains or is made with an ingredient that is known to contain a particular nutrient. These can be made if a product is 'low' in or a 'good source of' the nutrient associated with the claim (for example, 'good source of oat bran').
- Equivalence claims such as 'contains as much [nutrient] as a [food]' may be made. These may be made if both the reference food and the labelled food are a 'good source' of a nutrient on a per serving basis (for example, 'contains as much vitamin C as an 8 ounce glass of orange juice'.

The United States does not generally consider the following label statements to be implied claims unless they are made in a nutrition context:

- Avoidance claims for religious, food intolerance, or other non-nutrition related reasons (for example, '100% milk free').
- Statements about non-nutritive substances (for example, 'no artificial colours').
- Added value statements (for example, 'made with real butter').
- Statements of identity (for example, 'corn oil' or 'corn oil margarine').
- Special dietary statements made in compliance with a specific provision.

The TEG did not consider it necessary to define claims such as 'lean' or 'extra lean'. They also believed the present system of a case-by-case basis by enforcement agencies to be appropriate.

Questions:

51. Should 'lean' and 'extra lean' claims be defined? If so, what criteria should apply?
52. Should FSANZ develop a definition for implied content claims? If so, why?

3.18 Vitamins and minerals

Claims that relate to vitamins and minerals were reviewed as part of the development of the joint Code and are regulated in Standard 1.3.2 of the Code. In May 2004, however, the Ministerial Council agreed to a Policy Guideline on the Fortification of Food with Vitamins and Minerals. Because the permissions for fortification should be aligned with the eligibility of vitamin and mineral claims on fortified foods, and also because it is desirable to apply the same claims criteria to natural content as well as fortified content, it is proposed to review the criteria for vitamin and mineral claims as part of the proposals to be prepared and developed, having regard to fortification policy.

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Appendix 1: International comparison of content and related claims

Energy/calories	
Low calorie/energy/joule	**Food composition criteria**
CoPoNC	Regulated by Standard R2 of Volume 1 of the Food Standards Code
Volume 1	Standard R2 specifies the maximum energy which may be contained in prescribed reference quantities of a range of foods if they are described by one of these terms. If the food is not listed in Standard R2, then clause A1(8) of the Food Standards Code prohibits these terms being used to describe the food
New Zealand Food Regs (NZFR)	Contains at least 1/3 less energy compared with normal counterpart; and must be statement of comparison with named normal counterpart; and for food specified in table to subclause (1) of regulation 241, <70 kJ energy per reference quantity specified; and for all other foods, <170 kJ energy per serving, and a) Solid foods: energy density < 170 kJ/100g; b) Liquid foods: energy density < 80 kJ/100 mL
The Code Standard 1.2.8, Subclause 14(1)	Solid or semi-solid foods: average energy content is ≤170 kJ per 100 g Beverages or other liquid foods: average energy content is ≤ 80 kJ per 100 mL
Canada New requirements: Food and Drug Regs B.01.513, item 2	Old requirements (still current): ≥50% reduced in calories compared to the same food not calorie-reduced and ≤ 15 Kcal/ average serving and ≤ 30 Kcal/ reasonable daily intake New requirements: ≤ 40 Calories or 167 KJ per ref amount and per labelled serving and ≤ 40 Calories per 50 g food if ref amount is ≤ 30 g or 30 mL(for prepackaged meal, ≤ 120 Cal or 500 KJ less per 100g)
United States 21 CFR 101.60(b) of Code of Fed Regs and A food labelling guide – Appendix A	≤ 40 cal per ref amt (and per 50 g if ref amt is small) Meals and main dishes: ≤120 cal per 100 g
European Union Proposal 2003/0165(COD)	< 40 kcal (170 KJ) per 100 g and <20 kcal (80 KJ) per 100 ml
United Kingdom Nutrition claims in food labelling and advertising guidance notes and Food Labelling Regulations (FLR) 1996, schedule 6, part II	Guidance notes refers to FLR for conditions on energy. FLR – energy value of food ≤167 KJ (40 kcal) per 100 g or 100 ml (unless food is an intense sweetener or contains an intense sweetener); energy value of normal serving of the food ≤167 KJ (40 kcal)
Codex Guidelines for use of nutrition claims	≤ 40 kcal (170 kJ) per 100 g (solids) or ≤20 kcal (80 kJ) per 100 ml (liquids)
Reduced energy/calorie/ Joules **Lower in energy/calories/ Joules**	**Food Composition criteria**
CoPoNC and Less energy and Fewer calories/joules	≤75% of the energy of the same quantity of ref food; and food must contain at least 170 kJ less energy per 100 g of food, or 80 kJ less per 100 g liquid food, compared with the same quantity of ref food; and must be statement of comparison with ref food
New Zealand Food Regs (NZFR)	Contains at least 1/3 less energy compared with normal counterparts and must be statement of comparison with named normal counterpart
Canada New requirements: Food and Drug Regs B.01.513, item 3 and 4 (Lower in energy refers to ref food of same food group rather than similar ref food)	Old requirements (still current): ≥ 50% reduced in calories compared to the same food not calorie-reduced New requirements: ≥25% less energy per ref amount of food than ref amount of similar ref food (per 100 g, than 100 g similar ref food if prepackaged meal) and similar ref food does not meet food composition conditions of 'low' in energy

United States 21CFR 101.60(b) of Code of Fed Regs and A food labelling guide – Appendix A	At least 25% fewer calories per ref amt than an appropriate ref food Ref food may not be 'low calorie'
European Union Proposal 2003/0165(COD)	Energy value must be reduced by at least 30% and there must be an indication of the characteristic(s) which make(s) the food reduced in total energy value.
United Kingdom Nutrition claims in food labelling and advertising guidance notes and Food Labelling Regulations (FLR) 1996, schedule 6, part II	At least 25% reduction of energy contained in the food by comparison with the normal product
Calorie free	**Food composition criteria**
Canada New requirements: Food and Drug Regs B.01.513, item 1	New requirements: < 5 calories or 21 KJ per ref amount and per labelled serving
United States 21 CFR 101.60(b) of Code of Fed Regs and A food labelling guide – Appendix A	<5 cal per ref amt and per labelled serving
European Union Proposal 2003/0165(COD) Energy free	<4 kcal (17KJ) per 100 ml
Codex Guidelines for use of nutrition claims	≤4 kcal per 100 ml (liquids)
Less calories	**Food composition criteria**
Canada New requirements: Food and Drug Regs B.01.513, item 4	Old requirements (still current): ≥25% less calories and ≥ 30 fewer calories per serving than appropriate ref food New requirements: As for reduced calorie/energy above
United States 21 CFR 101.60(b) of Code of Fed Regs and A food labelling guide – Appendix A	As 'reduced'. Although using the term 'fewer' rather than 'less' is suggested.
Source of energy/calories	**Food composition criteria**
Canada New requirements: Food and Drug Regs B.01.513, item 5	New requirements: ≥ 100 Cal or 420 KJ per ref amount and per labelled serving
More energy/calories	**Food composition criteria**
Canada New requirements: Food and Drug Regs B.01.513, item 6	New requirements: ≥25% more energy, totalling ≥100 more cal or 420 KJ per ref amount of food than the ref amount of the ref food of same food group or similar ref food (per 100 g, than 100 g of the ref food of same food group or similar ref food, if prepackaged meal)

PROTEIN	
Low protein	**Food composition criteria**
New Zealand Food Regs (NZFR)	Contains at least 1/3 less protein compared with normal counterpart; and must have a statement of comparison with named normal counterpart; and <5% of energy of food derived from protein
Canada *New requirements:* Food and Drug Regs B.01.513, item 7	*New requirements:* food must contain ≤ 1g protein per 100g of food
Source of protein	**Food composition criteria**
Volume 1	At least 12% of the energy value of the food is derived from protein; and the amount of food stated as a serve in the nutrition information panel contains at least 5g of protein
Codex	Not less than 10% of nutrient recommended value (NRV) per 100g (solids), 5% of NRV per 100 mL (liquids) or 5% of NRV per

	100 kcal (12% of NRV per 1 MJ) or 10% of NRV per serving
Canada *New requirements:* Food and Drug Regs B.01.513, item 8 and high protein	*New requirements:* Food must have a protein rating of ≥20 per reasonable daily intake or per 30 g of breakfast cereal with 125 mL of milk
European Union Proposal 2003/0165(COD)	At least 12% of the energy value of the food is provided by protein
Nutrition claims in food labelling and advertising guidance notes and Food Labelling Regulations (FLR) 1996, schedule 6, part II	Guidelines refer to FLR FLR – quantity of the food that can reasonably be expected to be consumed in one day ≥ 12g protein and ≥ 12% of energy value of the food must be provided by protein
High protein	**Food composition criteria**
New Zealand Food Regs (NZFR)	Contains at least 1/3 more protein compared with normal counterpart; and must have a statement of comparison with named normal counterpart; and > 15 g protein per serving
Canada *New requirements:* Food and Drug Regs B.01.513, item 8 and Source of protein	*New requirements:* same food composition conditions as 'source of protein'
United States – A food labelling guide – Appendix B	≥ 10 g per ref amount for meals or main dishes
European Union Proposal 2003/0165(COD)	At least 20% of the energy value of the food is provided by protein
Codex	2 times the value for 'source of protein'
Very high protein/excellent source of protein	**Food composition criteria**
Canada *New requirements:* Food and Drug Regs B.01.513, item 9	*New requirements:* Protein rating ≥40 per reasonable daily intake or per 30 g of breakfast cereal with 125 mL of milk
United Kingdom Nutrition claims in food labelling and advertising guidance notes and Food Labelling Regulations (FLR) 1996, schedule 6, part II (inc. rich source)	Guidelines refer to FLR FLR – quantity of the food that can reasonably be expected to be consumed in one day ≥ 12g protein and ≥ 20% of energy value of the food must be provided by protein
More protein	**Food composition criteria**
Canada *New requirements:* Food and Drug Regs B.01.513, item 10	*New requirements:* Protein rating ≥ 20 per reasonable daily intake (or 30g of breakfast cereal with 125 mL of milk) and ≥ 25% increase in protein totaling at least 7 g or more, per reasonable daily intake than ref food of same food group or similar ref food
United States – A food labelling guide – Appendix B	≥5 per reference amount

Total fat	
Low-fat	**Food composition criteria**
CoPoNC	≤3 g total fat/100 g food or ≤1.5 g total fat/100 g liquid food
New Zealand Food Regs (NZFR)	Contains at least 1/3 less fat compared with normal counterpart; and must have a statement of comparison with named normal counterpart; and <10% of energy of food derived from fat
Canada New requirements: Food and Drug Regs B.01.513, item 12	*Old requirements (still current):* ≤3 g fat per serving and ≤15% fat on dry basis *New requirements:* ≤3 g fat per ref amount and per serving of stated size and ≤3 g fat per 50 g if ref amount is ≤30 g or 30 mL or if food is a prepackaged meal ≤3g fat per 100g and ≤ 30% energy from fat.

United States 21 CFR 101.62(b) of Code of Fed Regs and A food labelling guide – Appendix A	≤3 g per ref amt + (and per 50 g if ref amt is small ^) Meals and main dishes: ≤3 g per 100 g and ≤30% of calories from fat
European Union Proposal 2003/0165(COD)	≤3 g fat per 100 g or ≤1.5 g fat per 100 ml (or ≤1.8 g of fat per 100 ml semi-skimmed milk)
United Kingdom Nutrition claims in food labelling and advertising guidance notes	≤3 g per 100 g (solids) or per 100 ml (liquids)
Codex Guidelines for use of nutrition claims	≤3 g per 100 g (solids); ≤1.5 g per 100 ml (liquids)
Reduced/less fat	**Food composition criteria**
CoPoNC and Low Fat	≤75% of total fat content of the same quantity of ref food; and must be reduction of at least 3 g fat per 100 g food, or 1.5 g fat per 100 g liquid food, compared with same quantity of ref food; and must be a statement of comparison with ref food
New Zealand Food Regs (NZFR)	Contains at least 1/3 less fat compared with normal counterpart; and must have a statement of comparison with named normal counterpart
Canada *New requirements:* Food and Drug Regs B.01.513, item 13 and Lower in fat	*Old requirements (still current)*: ≥25% less fat and ≥1.5 g less fat per serving than appropriate ref food and no increase in energy from ref food *New requirements:* ≥25% less fat per ref amount than ref amount of similar ref food and ref food not 'low' fat
United States 21 CFR 101.62(b) of Code of Fed Regs and A food labelling guide – Appendix A	At least 25% less saturated fat per ref amt than an appropriate ref food Ref food may not be 'low fat'
United Kingdom FSA Fact Sheet	Should only be used with foods that contain less than ¾ of the amount of fat compared to the standard product.
X% fat free	**Food composition criteria**
CoPoNC	Meet requirements for 'low fat' and must carry statement of actual total fat content (expressed as a percentage of food) in close proximity to claim
Canada *New requirements:* Food and Drug Regs B.01.513, item 16	*Old requirements (no longer current for this claim)*: As for reduced/less fat claim *New requirements*: Meets food composition conditions for 'low' fat 100% fat free – meets food composition requirements for 'fat free' and <0.5 g fat per 100 g and contains no added fat
United States 21 CRF 101.62(b) of Code of Fed Regs and A food labelling guide – Appendix A	Must meet requirements for 'low fat' 100% fat free – must be 'fat free'
European Union Proposal 2003/0165(COD)	Claims expressed as X% fat-free shall be prohibited
United Kingdom Nutrition claims in food labelling and advertising guidance notes	Should not be made
New Zealand Food Regs (NZFR)	Must meet requirements for 'low fat'
Fat free	**Food composition criteria**
CoPoNC	≤ 0.15 g total fat per 100 g food
Canada *New requirements:* Food and Drug Regs B.01.513, item 11	*New requirements:* <0.5 g fat per ref amount and per labelled serving or if a prepackaged meal <0.5g fat per serving of stated size
United States 21 CFR 101.62(b) of Code of Fed Regs and A food labelling guide – Appendix A	<0.5 g per ref amt and per labelled serving (meals and main meals: <0.5 g per labelled serving)
European Union Proposal 2003/0165(COD)	≤0.5 g fat per 100 g or 100 ml

United Kingdom Nutrition claims in food labelling and advertising guidance notes	≤0.15 g per 100 g or 100 ml
Codex Guidelines for use of nutrition claims	≤0.5 g per 100 g (solids) or 100 ml (liquids)
No added fat	**Food composition criteria**
Canada *New requirements:* Food and Drug Regs B.01.513, item 17	*New requirements:* Food or ingredients contain no added fats and oils or added butter or ghee. The similar ref food contains added fats or oils or added butter or ghee.
Lean	**Food composition criteria**
United States A food labelling guide – Appendix B	Seafood or game meat and must contain <10 g total fat, ≤4.5 g saturated fat and <95 mg cholesterol per ref amount and pre 100 g (for meals and main, meets criteria per 100 g and per labelled serving)
Canada *New requirements:* Food and Drug Regs B.01.513, item 46	*New requirements:* Food is meat or poultry that has not been ground, marine or fresh water animals or a product of any of these and ≥10% less fat. (no criteria when related to prepackaged meals for use in weight-reduction or weight-management diets (B.01.502(2))
Extra lean	**Food composition criteria**
United States A food labelling guide – Appendix B	Seafood or game meat and must contain <5 g total fat, <2 g saturated fat and <95 mg cholesterol per ref amount and pre 100 g (for meals and main, meets criteria per 100 g and per labelled serving)
Canada *New requirements:* Food and Drug Regs B.01.513, item 47	*New requirements:* Food is meat or poultry that has not been ground, marine or fresh water animals or a product of any of these and ≥ 7.5% less fat.

Saturated fat	
Low saturated fat	**Food composition criteria**
CoPoNC	Must comply with 'low fat' claim; and food must contain ≤1.5 g sat fatty acids per 100 g of food or ≤0.75 g of sat fatty acids per 100 g liquid food
NZFR	Contains at least 1/3 less saturated fat compared with normal counterpart; and must have a statement of comparison with named normal counterpart
Canada *New requirements:* Food and Drug Regs B.01.513, item 19	*Current:* ≤ 2 g sat fatty acids per serving and ≤ 15% energy from sat fatty acids *New requirements:* ≤ 2 g sat and trans fatty acids combined per ref amount and per labelled serving (per 100g in the case of prepackaged meals) and ≤ 15% energy from sat and trans fatty acids combined per ref amount and per labelled serving
United States 21 CFR 101.62(c) of Code of Fed Regs and A food labelling guide – Appendix A	≤1 g per ref amt and ≤15% of calories from sat fat meals and main dishes: ≤1 g per 100 g and <10% of calories from sat fat note: next to all sat fat claims, must declare amt of chol if ≥2 mg per ref amt; and the amt of total fat if >3 g per ref amt (or ≥0.5 g total fat for 'saturated fat free')
European Union Proposal 2003/0165(COD)	≤1.5 g of saturates per 100 g for solids or ≤0.75 g of saturates per 100 ml for liquids and saturated fat must not provide more than 10% of energy for both liquids and solids.
United Kingdom Nutrition claims in food labelling and advertising guidance notes	≤1.5 g per 100 g for solids or per 100 ml for liquids and should not make up more than 10% of the total energy of product for both liquid and solids.
Codex Guidelines for use of nutrition claims	≤1.5 g per 100 g (solids) ≤0.75 g per 100 ml (liquids) and 10% of energy Trans fatty acids should be taken into account where applicable

Reduced/less saturated fat	**Food composition criteria**
CoPoNC and Lower Saturated Fat	≤75% sat fatty acid content of same quantity of ref food; and must be reduction in sat fatty acid content of at least 2 g per 100 g food compared with same quantity ref food (or 1 g sat fatty acids per 100 g of liquid food); and either fatty acid portion of food must contain ≤20% of sat fatty acids, and must contain ≥40% in total of *cis*-monounsat and *cis*-poly fatty acids; or ≤15% of total energy in food derived from sat fatty acids; and must be a statement of comparison with ref food
New Zealand Food Regs (NZFR)	Contains at least 1/3 less sat fatty acid compared with named normal counterpart; and must have a statement of comparison with named normal counterpart (Clause 3 of Regulation 13C specifies the conditions which apply to 'reduced' claims. With the exception of Clause 3(c) which refers to energy claims, no other nutrients are specified)
Canada New requirements: Food and Drug Regs Reduced B.01.513, item 20 Lower/less/fewer B.01.513, item 21	*Old requirements (still current)*: ≥25% less sat fatty acids and ≥1 g less sat fatty acids per serving than appropriate ref food and no increase in energy from ref food *New requirements:* ≥ 25% less sat fatty acids per ref amount than ref food (or per 100g for prepackaged meal) and no increase in content of trans fatty acids and ref food not 'low' in sat fatty acids *New requirements:* ≥25% less sat fatty acids per ref amount than ref food (or per 100 g for prepackaged meal) and no content of trans fatty acids is not higher and ref food not 'low' in sat fatty acids
United States 21 CFR 101.62(c) of Code of Fed Regs and A food labelling guide – Appendix A	≥25% less sat fat per ref amt than an appropriate ref food ref food may not be 'low saturated fat' note: next to all sat fat claims, must declare amt of chol if ≥2 mg per ref amt; and the amt of total fat if >3 g per ref amt (or ≥0.5 g total fat for 'saturated fat free')
Saturated fat free	**Food composition criteria**
Canada New requirements: Food and Drug Regs B.01.513, item 18	*New requirements*: <0.2 g sat fatty acids and <0.2 g trans fatty acids per ref amount and per labelled serving (or per serving of stated size for prepackaged meal)
United States 21 CFR 101.62(c) of Code of Fed Regs and A food labelling guide – Appendix A	<0.5 g sat fat and <0.5 g trans fatty acids per ref amt and per labelled serving (meals and main meals: <0.5 g sat fat and <0.5 g trans fatty acids per labelled serving) note: next to all sat fat claims, must declare amt of chol if ≥2 mg per ref amt; and the amt of total fat if >3 g per ref amt (or ≥0.5 g total fat for 'saturated fat free')
European Union Proposal 2003/0165(COD)	≤0.1 g saturated fat per 100 g or 100 ml
United Kingdom Nutrition claims in food labelling and advertising guidance notes	≤0.1 g per 100 g or 100 ml
Codex Guidelines for use of nutrition claims	≤0.1 g per 100 g (solids), ≤0.1 per 100 ml (liquids)

Trans fat	
Trans fat free	**Food composition criteria**
Canada *New requirements:* Food and Drug Regs B.01.513, item 22	*New requirements*: <0.2 g trans fatty acids per ref amount and per labelled serving (or per serving of stated size if prepackaged meal) and meets food composition conditions of 'low in sat fat'
Reduced/lower trans fat	**Food composition criteria**

Canada *New requirements:* Food and Drug Regs B.01.513, item 22	*New requirements:* ≥25% less trans fatty acids per ref amount than ref food (per 100g, than 100g of similar ref food for prepackaged meal), no increase in content of saturated fatty acids and ref food not 'low' in saturated fatty acids
New Zealand Food Regulations (NZFR)	Contains at least 1/3 less trans fatty acids compared with normal counterpart; must have a statement of comparison with named normal counterpart (Clause 3 of Regulation 13C specifies the conditions which apply to 'reduced' claims. With the exception of Clause 3(c) which refers to energy claims, no other nutrients are specified.)

Polyunsaturated fatty acids	
Polyunsaturated fatty acids claims	**Food composition criteria**
New Zealand Food Regs (NZFR)	Contains at least 1/3 more polyunsaturated fatty acids compared with normal counterpart; and must have a statement of comparison with named normal counterpart; and ≥ 40% of fat is polyunsaturated and ≤20% of fat is saturated and ≥50% of energy is derived from fat
The Code Standard 1.2.8, Subclause 12(1)	Total of sat fatty acids and trans fatty acids ≤28% of total fatty acid content of food; and polyunsat fatty acid ≥40% of total fatty acid content of food

Monounsaturated fatty acids	
Monounsaturated fatty acids claims	**Food composition criteria**
New Zealand Food Regs (NZFR)	Contains at least 1/3 more polyunsaturated fatty acids compared with normal counterpart; and must have a statement of comparison with named normal counterpart
The Code Standard 1.2.8, Subclause 12(1)	Total of sat fatty acids and trans fatty acids ≤28% of total fatty acid content of food; and monounsat fatty acid ≥40% of total fatty acid content of food

Omega-3 Polyunsaturated fatty acids	
Source of/contains omega-3 polyunsaturated fatty acids	**Food composition criteria**
The Code Omega-3 fatty acid claims Standard 1.2.8, Subclause 13(2) and 13(3)	Other than fish and fish products, the total of sat fatty acids and trans fatty acids <28% of total fatty acid content of food; or Food contains ≤5 g sat fatty acids and trans fatty acids per 100 g of food; and Food contains ≥200 mg alpha-linolenic acid per serving; or Food contains ≥30 mg total eicosapentaenoic acid and docosahexaenoic acid per serving
Canada New requirements: Food and Drug Regs B.01.513, item 25	New requirements: (0.3 g omega-3 polyunsaturates per ref amount and per labelled serving (or per 100 g if food is prepackaged meal)
Good source of omega-3 fatty acids	**Food composition criteria**
The Code Standard 1.2.8, Subclause 13(4)	Other than for fish and fish products that have no added sat fatty acids, the total of sat fatty acids and trans fatty acids <28% of total fatty acid content of food; or Food contains ≤5 g sat fatty acids and trans fatty acids per 100 g of food; and food contains ≥60 mg total eicosapentaenoic acid and docosahexaenoic acid per serving

Omega 6-polyunsaturated fatty acids	
Source of/contains omega-6 polyunsaturated fatty acids	**Food composition criteria**

The Code Polyunsat claims Standard 1.2.8, Subclause 13(6)	Total of sat fatty acids and trans fatty acids of food ≤28% of total fatty acid content of food; and Omega-6 polyunsat fatty acids ≥40% of total fatty acid content of food
Canada New requirements: Food and Drug Regs B.01.513, item 26	New requirements: (2 g omega-6 polyunsaturates per ref amount and per labelled serving (or per 100 g if food is a prepackaged meal)

Omega-9 polyunsaturated fatty acids	
Source of/contains omega-9 polyunsaturated fatty acids claims	**Food composition criteria**
The Code Standard 1.2.8, Subclause 13(6)	Total of sat fatty acids and trans fatty acids of food ≤28% of total fatty acid content of food; and Omega-9 polyunsat fatty acids ≥40% of total fatty acid content of food

Cholesterol	
Low cholesterol	**Food composition criteria**
CoPoNC	(20 mg chol per 100 g food; and food must either meet conditions for 'low fat' claim or fatty acid component of food must contain (20% sat fatty acids and (40% of *cis*-poly or of *cis*-mono fatty acids
New Zealand Food Regs (NZFR)	Contains at least 1/3 less cholesterol compared with normal counterpart; and must have a statement of comparison with named normal counterpart; and <20 mg cholesterol per specified serving of food
Canada New requirements: Food and Drug Regs B.01.513, item 28	Old requirements (still current): (20 mg chol per 100 g and per serving, and (2 g sat fatty acids per serving, and 15% energy from sat fatty acids New requirements: (20 mg chol per ref amount and per labelled serving and per 50 g food if ref amount is (30 g or 30 mL (per 100 g if food is a prepackaged meal) and food meets food composition criteria for 'low' in saturates
United States 21 CFR 101.62(d) of Code of Fed Regs and A food labelling guide – Appendix A	Food must contain (20 mg per ref amt (and per 50 g of food if ref amt is small) (meals and main meals: (20 mg/100 g) chol claims only allowed when food contains (2 g sat fat per ref amt Further qual/disqual conditions apply where the food qualifies by special processing and total fat >13 g per ref and labelled serving.
United Kingdom Nutrition claims in food labelling and advertising guidance notes and Food Labelling Regulations (FLR) 1996, schedule 6, part II	Guidance notes suggest that cholesterol claims should not be made. However, FLR states for presence or absence claims (0.005% cholesterol;
Codex Guidelines for use of nutrition claims	(0.02 g per 100 g (solids); (0.01 g per 100 ml (liquids) and, <1.5 g sat fat per 100 g (solids), <0.75 g sat fat (liquids) and <10% energy from sat fat Trans fatty acids should be taken into account where applicable
Reduced/less cholesterol	**Food composition criteria**
CoPoNC and Lower Cholesterol	Must meet conditions for 'low chol' claim and must carry statement of comparison with ref food; and food must either meet conditions for a 'low fat' claim, or the fatty acid component of the food must contain ≤20% sat fatty acids and ≥40% *cis*-poly or of *cis*-mono fatty acids
New Zealand Food Regs (NZFR)	Contains at least 1/3 less cholesterol compared with normal counterpart; and must have a statement of comparison with named normal counterpart (Clause 3 of Reg 13C specifies the conditions which apply to 'reduced' claims. With the exception of Clause 3(c) which refers to energy claims, no other nutrients are specified.)

Canada *New requirements:* Food and Drug Regs B.01.513, item 29 and Lower Cholesterol (but refers to same food group rather than similar food) B.01.513, item 30	*Old requirements (still current)*: ≥25% less chol and sat fatty acids per serving, ≤20 mg less chol and ≤1 g less sat fatty acids per serving than appropriate ref food, and no increases from ref food *New requirements*: ≥25% less chol per ref amount than ref food (per 100 g than 100 g of similar food if food is a prepackaged meal) and food meets food composition criteria of 'low' in saturates and similar ref food does not meet food composition criteria of 'low' in chol
United States 21 CFR 101.62(d) of Code of Fed Regs and A food labelling guide – Appendix A	Food must contain ≥25% cholesterol per ref amount than an appropriate ref food. Ref food may not be low cholesterol. chol claims only allowed when food contains ≤2 g sat fat per ref amt
United Kingdom Nutrition claims in food labelling and advertising guidance notes and Food Labelling Regulations (FLR) 1996, schedule 6, part II	Guidance notes suggest that cholesterol claims should not be made. However, FLR states cholesterol must be ≤0.005% of food or claim can only be made as part of an indication of the true nature of the food, as part of an indication of the treatment of the food, within the list of ingredients or as a footnote in respect of prescribed nutrition labelling.
Cholesterol free	**Food composition criteria**
CoPoNC	≤3 mg chol per 100 g food; and the food must either meet the conditions for 'low fat' claim or the fatty acid component of the food must contain ≤20% sat fatty acids and ≥40% of *cis*-poly or of *cis*-mono fatty acids
Canada *New requirements:* Food and Drug Regs B.01.513, item 27	*Old requirements (still current)*: N/A *New requirements:* <2 mg chol per ref amount and per labelled serving (or per serving of stated size if food is a prepackaged meal) and food meets the food composition criteria of 'low' saturates
United States 21 CFR 101.62(d) of Code of Fed Regs and A food labelling guide – Appendix A	<2 mg per ref amt and per labelled serving (meals and main meals: <2 mg per labelled serve) No ingredient containing cholesterol Further qual/disqual conditions apply where the food qualifies by special processing and total fat >13 g per ref and labelled serving.
United Kingdom Nutrition claims in food labelling and advertising guidance notes and Food Labelling Regulations (FLR) 1996, schedule 6, part II	Guidance notes suggest that cholesterol claims should not be made. However, FLR states cholesterol must be ≤0.005% of food or if claim is a removal of cholesterol claim can only be made as part of an indication of the true nature of the food, as part of an indication of the treatment of the food, within the list of ingredients or as a footnote in respect of prescribed nutrition labelling.
Codex Guidelines for use of nutrition claims	≤0.005 g per 100 g (solids), ≤0.005 g per 100 ml (liquids) and, <1.5 g sat fat per 100 g (solids), <0.75 g sat fat (liquids) and <10% energy from sat fat Trans fatty acids should be taken into account where applicable

Sugars	
Low sugar	**Food composition criteria**
CoPoNC	≤5 g total sugars per 100 g of the food, or ≤2.5 g total sugars per 100 g liquid food
New Zealand Food Regs (NZFR)	Contains at least 1/3 less sugar compared with normal counterpart; and must be statement of comparison with counterpart; and <5% of energy of food derived from sugars
Canada	*Old requirements (still current):* ≤2 g sugars per serving and ≤10% sugars on a dry basis
United States 21 CFR 101.60(c) of Code of Fed Regs and A food labelling guide – Appendix A	Not defined. No basis for recommended intake

European Union Proposal 2003/0165(COD)	≤5 g total sugars per 100 g or 100 ml
United Kingdom Nutrition claims in food labelling and advertising guidance notes	≤5 g per 100 g or 100 ml
Reduced/less sugar	**Food composition criteria**
CoPoNC and Lower Sugar	≤75% of the total sugars content of the same quantity of the ref food; and must be a reduction of at least 5 g total sugars per 100 g food, or 2.5 g total sugars per 100 g liquid food, compared with same quantity of ref food; and must be a statement of comparison with ref food
New Zealand Food Regs (NZFR)	Contains at least 1/3 less sugar compared with normal counterpart; and must have a statement of comparison with named normal counterpart (Clause 3 of Regulation 13C specifies conditions which apply to 'reduced' claims. With exception of Clause 3(c) which refers to energy claims, no other nutrients are specified.)
Canada *New requirements:* Food and Drug Regs B.01.513, item 38 and lower in sugars (but refers to same food group rather than similar food) B.01.513, item 39	*Old requirements (still current):* ≥25% less sugars and ≥5 g less sugars per serving than appropriate ref food, and no energy increase from ref food *New requirements:* ≥25% less sugars and totalling ≥5g less per ref amount than ref amount of similar ref food (or per 100 g, than 100 g of a similar ref food, if the food is a prepackaged meal)
United States 21 CFR 101.60(c) of Code of Fed Regs and A food labelling guide – Appendix A	≥25% less sugars per ref amt than an appropriate ref food (may not be used on dietary supplements of vitamins and minerals)
European Union Proposal 2003/0165(COD)	reduction in the sugar content is at least 30% compared to a similar product
Sugar free	**Food composition criteria**
CoPoNC	Food must contain ≤0.2 g sugars per 100 g food, or ≤0.1 g of sugars per 100 g liquid food
New Zealand Food Regs (NZFR)	Claim allowed if food does not contain sugars; or sugar alcohol
Canada *New requirements:* Food and Drug Regs B.01.513, item 38	*New requirements:* <0.5 g sugars per ref amount and per labelled serving and with the exception of chewing gum, meets food composition criteria for 'free' of energy
United States 21 CFR 101.60(c) of Code of Fed Regs and A food labelling guide – Appendix A	<0.5 g sugars per ref amt and per labelled serving Disclose calorie profile (for example, 'low calorie') (meals and main meals: <0.5 g sugars/labelled serve)
European Union Proposal 2003/0165(COD)	≤0.5 g per 100 g or 100 ml
United Kingdom Nutrition claims in food labelling and advertising guidance notes	≤0.2 g per 100 g or 100 ml
Codex Guidelines for use of nutrition claims	≤0.5 g per 100 g (solids), ≤0.5 g per 100 ml (liquids)
No added sugar(s)	**Food composition criteria**
CoPoNC	Regulated by clause A1(10) of Food Standards Code
Volume 1	A1(10) prohibits the claim unless the food contains no added sugar or related products as defined in Standard K1; no added honey as defined in Standard K2; and no added malt, malt extract or maltose
New Zealand Food Regs (NZFR)	Claim allowed if food does not contain added carbohydrate sweetener; or added sugar alcohol (>1%) as an ingredient in that food

Canada *New requirements:* Food and Drug Regs B.01.513, item 40	*New requirements:* No added sugars or other ingredients containing added sugars or ingredients that contain sugars that functionally substitute for added sugars and the sugar content not increased through other means e.g. use of enzymes except where functional effect is not to increase sugar content of food and; similar ref food must have added sugars
United States 21 CFR 101.60(c) of Code of Fed Regs and A food labelling guide – Appendix A	Claim allowed if no sugar or sugar containing ingredient is added during processing. State if food is not 'low' or 'reduced calorie'
European Union Proposal 2003/0165(COD)	Claim allowed if the product does not contain any added mono- or disaccharides or any other food used for its sweetening purposes.
United Kingdom Nutrition claims in food labelling and advertising guidance notes	No sugars or foods composed mainly of sugars added to the food or to any of its ingredients
Unsweetened	**Food composition criteria**
CoPoNC	Regulated by clause A1(10A) of Food Standards Code
Volume 1	Clause A1(10A) prohibits the claim unless the product contains no added sugars as defined in Standard K1, no added honey as defined in Standard K2, malt, malt extract or maltose, no added artificial sweetening substance as defined in Standard A8; and no added sorbitol, mannitol, glycerol, xylitol, maltitol, maltitol syrup, isomalt or lactitol
New Zealand Food Regs (NZFR)	Claim allowed if food does not contain added carbohydrate sweetener; or added sugar alcohol (>1%) as ingredient; or any artificial sweetener as ingredient
United States 21 CFR 101.60(c) of Code of Fed Regs and A food labelling guide – Appendix A	The terms 'unsweetened' and 'no added sweeteners' remain as factual statements
Canada *New requirements:* Food and Drug Regs B.01.509	*New requirements:* meet food composition requirements for 'no added sugars' and the food does not contain a sweetener
United Kingdom Nutrition claims in food labelling and advertising guidance notes	No sugars or foods composed mainly of sugars added to the food or to any of its ingredients except in accordance with provision of Condensed Milk and Dried Milk Regulation 1977 (as amended)

Fibre	
CoPoNC	Claims relating to fibre are discouraged on foods with sign fat content. Conditions apply where ≥30% energy is derived from fat.
Source of fibre/contains fibre	**Food composition criteria**
CoPoNC	≥1.5 g dietary fibre per serving of food Main dish or meal type products: ≥2 g dietary fibre per 100 g meal
Canada *New requirements:* Food and Drug Regs B.01.513, item 41	*Old requirements (still current):* ≥2 g dietary fibre per serving *New requirements:* ≥2 g dietary fibre per ref amount and per labelled serving when a specific fibre source is not mentioned, or ≥2 g of each named dietary fibre per ref amount and per labelled serving when a specific fibre source is mentioned Prepackaged meals and main dish entrees: Must contain at least one ingredient that meets food composition criteria for 'source of dietary fibre'
European Union Proposal 2003/0165(COD)	≥3 g of fibre per 100 g or ≥1.5 g of fibre per 100 kcal
United Kingdom Nutrition claims in food labelling and advertising guidance notes	Either 3 g per 100 g or 100 ml; or ≥3 g in the reasonable expected daily intake of food

Codex Draft table to the guidelines for the use of nutrition claims (step 6)	≥3 g per 100 g or ≥1.5 g per 100 kcal or per serving Liquid foods: ≥ 1.5 g per 100 ml (serving size to be determined at national level)
High fibre/good source of fibre	**Food composition criteria**
CoPoNC	≥3 g dietary fibre per serving of the food Main dish or meal type products: ≥4 g dietary fibre per 100 g meal
New Zealand Food Regs (NZFR)	Contains at least 1/3 more fibre compared with normal counterparts; and must have a statement of comparison with named normal counterpart; and >4 g dietary fibre per specified serving of food
Canada *New requirements:* Food and Drug Regs B.01.513, item 42	*Old requirements (still current):* ≥4 g dietary fibre per serving *New requirements:* ≥4 g fibre per ref amount and per labelled serving when a specific fibre source is not mentioned, or ≥4 g of each named dietary fibre per ref amount and per labelled serving when a specific fibre source is mentioned Prepackaged meals and main dish entrees: must contain at least one ingredient that meets criteria for 'high source of fibre'
United States - A food labelling guide – Appendix B	≥5 g per ref amount (high fibre) 2.5 g to 4.75 g per ref amount (good source – only to be used for meals or main dishes)
European Union Proposal 2003/0165(COD) Only refers to high fibre	≥6 g of fibre per 100 g or ≥3 g of fibre per 100 kcal
United Kingdom Nutrition claims in food labelling and advertising guidance notes	Either ≥6 g per 100 g or 100 ml or ≥6 g in the reasonable expected daily intake of the foods
Codex Draft table to the guidelines for the use of nutrition claims (step 6)	≥6 g per 100 g or ≥3 g per 100 kcal or per serving Liquid foods: ≥3 g per 100 ml (serving size to be determined at national level)
Very high fibre excellent source of fibre	**Food composition criteria**
CoPoNC	≥6 g dietary fibre per serving of food Main dish or meal type products: ≥6 g dietary fibre per 100 g of the meal
Canada *New requirements:* Food and Drug Regs B.01.513, item 43	*Old requirements (still current):* ≥6 g dietary fibre per serving *New requirements:* ≥6 g fibre per ref amount and per labelled serving when a specific fibre source is not mentioned, or ≥6 g of each named dietary fibre per ref amount and per labelled serving when a specific fibre source is mentioned Prepackaged meals and main dish entrees: must contain at least one ingredient that meets criteria for 'very high' in dietary fibre
Increased fibre/fibre enriched/higher fibre	**Food composition criteria**
CoPoNC	≥3 g dietary fibre per serving of food; claims may only be applied to foods which contain, prior to enrichment with dietary fibre, at least 1.5 g of dietary fibre per serving; and must have a statement of comparison with ref food; the ref food must be a similar food made from the same ingredients but without enrichment with dietary fibre
Canada *New requirements:* Food and Drug Regs B.01.513, item 44 Refers only to more/higher fibre	*New requirements:*≥2 g fibre per ref amount and per labelled serving when a specific fibre source is not mentioned or ≥2 g of each named dietary fibre per ref amount and per labelled serving when a specific fibre source is mentioned and ≥25% increase in fibre totalling ≥1 g fibre when a specific fibre source is not mentioned, or ≥25% increase in the named fibre, totalling ≥1 g fibre when a specific fibre source is mentioned. Also prepackaged meal requirements.

European Union Proposal 2003/0165(COD)	Product must meet conditions of 'source of' and the increase in content is at least 30% compared to a similar product
United Kingdom Nutrition claims in food labelling and advertising guidance notes	≥25% more than a similar food for which no claim is made and ≥3 g in either the reasonable daily intake of a food for which this is lower than 100 g or 100 ml or in 100 g or 100 ml
Fibre added	**Food composition criteria**
CoPoNC	Food must meet conditions for 'high fibre' claim; and must be statement of comparison with ref food
United States – A food labelling guide – Appendix B	≥2.5 g more per serving than ref food

Salt and sodium	
Low salt/ sodium light in salt/ sodium	**Food composition criteria**
CoPoNC	Regulated by Standard R8 of the Food Standards Code
Volume 1	Standard R8 states that food must not contain >120 mg sodium per 100 g or not >50% of the sodium content of the normal counterpart food, whichever is less
New Zealand Food Regs (NZFR)	Contains at least 1/3 less sodium compared with normal counterpart; and must have a statement of comparison with counterpart; and <120 mg sodium per 100 g when ready for consumption
The Code Standard 1.2.8, Subclause 17(1)	≤120 mg sodium per 100 g Particulars relating to both the sodium and potassium content of food must be provided in accordance with 5(1) (+ other conditions)
Canada *New requirements:* Food and Drug Regs B.01.513, item 32 only refers to low salt/ sodium	*Old requirements (still current)*: Only for foods for special dietary use ≤50% of sodium that would be present if the food were not a low sodium food and ≤40 mg sodium/100 g (except ≤50 mg/100 g for cheddar cheese, and ≤80 mg/100 g for meat, poultry and fish); and except for salt substitutes, contains no added salts of sodium *New requirements:* ≤140 mg sodium per reference amount and per labelled serving and per 50 g if reference amount is ≤30 g or 30 mL (or per 100 g if food is a prepackaged meal)
United States 21 CFR 101.61 of Code of Fed Regs and A food labelling guide – Appendix A	≤140 mg per ref amt (and per 50 g if ref amt is small) meals and main dishes: ≤140 mg per 100 g (+ conditions)
European Union Proposal 2003/0165(COD) refers only to low salt/ sodium	≤0.12g sodium per 100 g or 100 ml
United Kingdom Nutrition claims in food labelling and advertising guidance notes	≤40 mg sodium per 100 g or 100 ml
Codex Guidelines for use of nutrition claims (Only refers to Low Sodium)	≤0.12 g per 100
Very low salt/sodium	**Food composition criteria**
CoPoNC	≤40 mg sodium per 100 g of food
United States 21 CFR 101.61 of Code of Fed Regs and A food labelling guide – Appendix A	≤35 mg per ref amt (and per 50 g if ref amt is small) (meals and main meals: ≤35 mg/100 g)
European Union Proposal 2003/0165(COD)	≤0.04 g of sodium per 100 g or 100 ml
Codex Guidelines for use of nutrition claims	≤0.04 g per 100 g
Reduced salt/ sodium less salt/sodium	Food composition criteria

CoPoNC does not include 'Less Salt/Sodium'	≤75% of sodium content of same quantity of the ref food; and food must contain at least 90 mg less sodium per 100 g of food than same quantity of ref food; and food must contain ≤600 mg sodium per 100 g food; and must be a statement of comparison with reference food
New Zealand Food Regs (NZFR)	Contains ≤1/3 sodium or salt compared with normal counterpart; and must have a statement of comparison of the amount of sodium with named normal counterpart
Canada *New requirements:* Food and Drug Regs B.01.513, item 33 and Lower in Sodium (but refers to same food group rather than similar food) B.01.513, item 34	*Old requirements (still current):* Compared to ref food it must have: ≥25% less sodium; and ≥100 mg less sodium/serving *New requirements:* ≥25% less sodium per ref amount than ref amount of similar food (per 100 g of a similar food, if food is prepackaged meal) and similar ref food does not meet food composition criteria for 'low' in sodium
United States 21 CFR 101.61 of Code of Fed Regs and A food labelling guide – Appendix A	At least 25% less sodium per ref amt than an appropriate ref food Ref food. May not be 'low sodium'
European Union Proposal 2003/0165(COD)	Reduction in the content is at least 30% compared to a similar product, except micronutrients where a 10% difference in the reference values as set in Council Directive 90/496/EEC shall be accepted
United Kingdom FSA Fact Sheet	Law doesn't say how much less salt or sodium a 'reduced salt' product should contain, it is recommended that it should be at least 25% less than a standard product.
Salt/sodium free/no salt/sodium	**Food composition criteria**
CoPoNC	≤5 mg sodium per 100 g of food, or ≤2.5 mg sodium per 100 g liquid food
Canada *New requirements:* Food and Drug Regs B.01.513, item 31	*Old requirements (still current):* ≤5 mg sodium/100 g food *New requirements:* <5 mg sodium per ref amount and per labelled serving (per serving of stated size if food is a prepackaged meal)
United States 21 CFR 101.61 of Code of Fed Regs and A food labelling guide – Appendix A	<5 mg per ref amt and per labeled serving (meals and main meals: <5 mg/labeled serving)
European Union Proposal 2003/0165(COD)	≤0.005 g of sodium per 100 g
United Kingdom Nutrition claims in food labelling and advertising guidance notes	≤5 mg sodium per 100 g or 100 ml
Codex Guidelines for use of nutrition claims (Only refers to salt/sodium free)	≤0.005 g per 100 g
No added salt/sodium/unsalted	**Food composition criteria**
CoPoNC	Regulated by clause A1(24) of the Food Standards Code
Volume 1	Clause A1(24) states that the food and its ingredients must contain no added salt, no added sodium compound and must be unsalted
Canada *New requirements:* Food and Drug Regs B.01.513, item 35	*Old requirements (still current):* No salt (NaCl) or other salts of sodium have been added directly to the food; and no ingredient or component contributes a significant amt of sodium to the food *New requirements:* No added salt or other sodium salts or ingredients that contain sodium that functionally substitute for added salt. The similar ref food does not meet the food composition criteria for 'low' in sodium.
United Kingdom Nutrition claims in food labelling and advertising guidance notes	No salt or sodium shall have been added to the food or to any of its ingredients
Lightly salted	**Food composition criteria**

CoPoNC	≤75% of sodium content of same quantity of the ref food; and food must contain at least 90 mg less sodium per 100 g of food than same quantity of ref food; and food must contain ≤600 mg sodium per 100 g food; and must be a statement of comparison with reference food
Canada *New requirements:* Food and Drug Regs B.01.513, item 36	*New requirements:* ≥50% less added sodium than added to similar ref food and similar ref food does not meet compositional criteria for 'low sodium' food
United States 21 CFR 101.61 of Code of Fed Regs and A food labelling guide – Appendix A	Food must have 50% less sodium than normally added to ref food

Gluten	
Contains gluten/ high in gluten	**Food composition criteria**
The Code Standard 1.2.8, Subclause 16(4)	May be made without any criteria been met
Low gluten	**Food composition criteria**
The Code Standard 1.2.8, Subclause 16(3)	Cannot be made unless the food contains no more than 20 mg gluten per 100 g of the food; and oats or malt (this is subject to amendment pending the outcome of P264, that is, removal of oats or malt)
Gluten free	**Food composition criteria**
The Code Standard 1.2.8, Subclause 16(2)	Cannot be made unless the food contains no detectable gluten; and oats or malt (this is subject to minor amendment pending the outcome of P264)
Codex Guidelines for Gluten free foods	Gluten free food shall be based on: a. total nitrogen content of the gluten-containing cereal grains used in the product ≤0.05g per 100 g of these grains on a dry matter basis; or b. ingredients which do not contain gluten in substitution for the ingredients containing gluten which are normally used in food of that kind; or c. any mixture of two or more ingredients as in a. and b.

Lactose	
Low lactose	**Food composition criteria**
The Code Standard 1.2.8, Subclause 15(1)	≤0.3g lactose per 100g
Lactose free	**Food composition criteria**
The Code Standard 1.2.8, Subclause 15(2)	Cannot be made unless the food contains no detectable lactose
Canada *New requirements:* B.01.502(2)	Cannot be made unless the food contains no detectable lactose
Reduced lactose	**Food composition criteria**
United Kingdom FSA Fact Sheet	There are no rules to say how much less lactose a 'reduced lactose' milk must contain, it is recommended that it should be at least 25% less than normal milk, but some products can contain as much as 95%.

Diet	
Diet	**Food composition criteria**
CoPoNC	Must comply with Standard R2 of Vol 1; or energy content of food must contain ≤60% of the energy content of the same quantity of ref food; and food must contain at least 170 kJ less energy per 100 g of food, or 80 kJ less per 100 g liquid food, compared with the same quantity of ref food; and must be statement of comparison with ref food

Volume 1	Must comply with Standard R2 of Volume 1 of the Food Standards Code – Low joule foods
The Code Standard 1.2.8, clause 14	Must comply with Clause 14 of Standard 1.2.8 – Low Joule Claims (that is, is a claim to the effect that a food is low joule)

Light or lite	
Light or lite	**Food composition criteria**
CoPoNC	'light' characteristic of food to be stated on label. If claim refers to nutrient or energy, food must comply with conditions for corresponding 'reduced' or 'low' claim
New Zealand Food Regs (NZFR)	Permitted only if food is a meal replacement for weight reduction or weight maintenance diet; or conforms with regulation 241 – low energy foods; or conforms with regulations 13b and 13c – low energy and reduced energy claims
Canada *New requirements:* Food and Drug Regs B.01.513, item 45	*New requirements:* Food must meet food composition conditions for 'reduced' in energy or fat: Not allowed with respect to nutrients other than fat and energy
United States 21 CFR 101.60(b) of Code of Fed Regs and A food labelling guide – Appendix A	If ≥50% of calories are from fat, fat must be reduced by ≥50% per ref amount If <50% of calories are from fat, fat must be reduced by ≥50% or calories reduced at least 1/3 per ref amount Generally % reduction for both fat and calories must be stated For meal or main dish: must meet definition for 'low calorie' or 'low fat' and labelled to indicate which definition is met
European Union Proposal 2003/0165(COD)	Must meet the requirements for 'reduced' and be accompanied by an indication of the characteristic(s) which make the food light or lite
United Kingdom FSA Fact Sheet	There are no requirements that need to be met for light or lite claims. It is recommended that manufacturers explain exactly what their claim means.
Codex Guidelines for use of nutrition claims	Follow the same criteria as for 'reduced'

General	
X% free (other than fat)	**Food composition criteria**
CoPoNC	Not permitted
Modified	**Food composition criteria**
United States A food labelling guide – Appendix B	May be used in statement of identity that bears a relative claim (eg 'Modified Fat Cheese Cake, contains 35% Less Fat than our Regular Cheese Cake)
Reduced (name of nutrient)	**Food composition criteria**
European Union Proposal 2003/0165(COD)	Reduction in the content is at least 30% compared to a similar product, except micronutrients where a 10% difference in the reference values as set in Council Directive 90/496/EEC shall be accepted
Increased (name of nutrient)	**Food composition criteria**
European Union Proposal 2003/0165(COD)	Product must meet conditions of 'source of' and the increase in content is at least 30% compared to a similar product

1.1.1 United States definitions

Reference amount refers to the reference amount customarily consumed (Code of Fed Regs)

Small reference amount refers to reference amount of 30 g or less or 2 tablespoons or less (Code of Fed Regs)

1.1.2 Canadian definitions

Food group means one of the four following categories of foods:

- milk products and milk product alternatives such as fortified plant-based beverages;
- meat, poultry and fish, and alternatives such as legumes, eggs, tofu and peanut butter;
- bread and grain products; and
- vegetables and fruit.

Similar reference food means a food of the same type as the food to which it is compared and that has not been processed, formulated, reformulated or otherwise modified in a manner that increases or decreases either the energy value or the amount of a nutrient that is the subject of the comparison. ie whole milk is a similar reference food for partly skimmed milk.

1.1.3 Transition period for new Canadian requirements

Transition period for the new Canadian Nutrition Facts Table of the Food and Drug Regulations ends on 12 December 2005 for most businesses (a three year transition period) and 12 December 2007 for small businesses (a five year transition period). However, if claims are made in relation to the following: 100% fat free, % fat free, free of trans fatty acids, reduced in trans fatty acids, lower in trans fatty acids, source of omega-3 or omega-6 polyunsaturated fatty acids, the label must comply fully with the new requirements.

1.1.4 European Union Proposal

The European Union Proposal for regulation of the European Parliament and of the Council on Nutrition and Health Claims made on Foods is currently held up by the European Parliament's Environment Committee. The Committee decided against voting on the Proposal because there were too many areas of disagreement. The Proposal will not be considered again by Parliament until September 2004 at the earliest.

Attachment 7

PRELIMINARY ADVICE ON ESTABLISHING PRIORITIES FOR HIGH-LEVEL CLAIMS FOR FSANZ PRE-APPROVAL

Report on workshop and survey

Dr Peter Williams and Ms Leisa Ridges

National Centre of Excellence in Functional Foods

9 June 2004

Contents

Section 1 Background information and methods

Background

The Australia New Zealand Food Regulation Ministerial Council (ANZFRMC) released a Policy Guideline on Nutrition, Health and related Claims in December 2003 which is now being implemented by Food Standards Australia New Zealand (FSANZ).

In preparation for the Initial Assessment Report for Proposal P293 (Nutrition, Health and Related Claims) FSANZ recognised that it would be necessary to undertake preliminary consultation with key stakeholders to provide initial advice on identification of priority high-level health claims to be assessed and possibly approved for inclusion in the new Standard. The National Centre of Excellence in Functional Foods (NCEFF) was approached to develop a proposal for how such a consultation could be undertaken.

At a planning meeting on 6 May with staff from FSANZ and NCEFF, it was agreed that a targeted two-stage process would be adopted. There would be one exploratory workshop to be held in Sydney, with public health and industry stakeholders, to discuss key issues and concerns and undertake a preliminary ranking of potential food component/health conditions that could be the subject of health claims that require pre-approval. This would be followed by an electronic (email) survey to a wider cross-section of stakeholders. It was recognised that because of the very short deadlines required by FSANZ, the extent of consultation would necessarily be limited and the final results could only be indicative, rather than definitive.

Methods

FSANZ identified a list of potential stakeholders, supplemented by additional contacts lists provided by NCEFF. Invitations to the workshop to be held in Sydney on 26 May were sent on 14 May by mail and email. Forty-one people attended the workshop. Participants considered and ranked a list of 30 diet–disease relationships that form the basis of existing approved claims in Australia New Zealand, the United States, Canada, the United Kingdom and Sweden. NCEFF provided a preliminary report on workshop outcomes to FSANZ on 27 May (see section 3).

An email survey was sent on 31 May to the same list of stakeholders, plus additional people identified by participants at the workshop (a total of 241), asking respondents to rank a list of 23 diet–disease relationships that form the basis of the 30 health claims considered at the workshop. This revised list was agreed between FSANZ and NCEFF staff to reduce overlap and duplication of diet–disease relationships identified in the workshop. The results from the survey were collated by NCEFF staff and are presented in the full survey report in section 4. A number of respondents to the survey provided written comments rather than a numerical ranking of potential claims, and these are included in the summary of received comments, provided in appendix 3 of this report.

Section 2 Summary of results

The full details of the results from the workshop and survey are provided in sections 3 and 4 respectively. In summary, there was generally consistent agreement between the participants in the workshop and the survey, and between the rankings obtained from public health and food industry respondents.

The following relationships were ranked among the top 12 by food industry and public health participants in the survey. There were some differences in the rank ordering within these 12 from each sector. At the workshop there was agreement that these claims are consistent with current national dietary guidelines.

Food/food component	Disease/condition
Calcium +/- vitamin D	Osteoporosis
Dietary saturated fat. cholesterol, trans fat	Coronary heart disease
Fibre-containing grain products, fruits and vegetables	Cancer
Fruits, vegetables, and grain products that contain fibre, particularly soluble fibre	Coronary heart disease
Energy	Obesity
Saturated fat, dietary fatty acids	Blood cholesterol
Sodium (salt) +/- potassium	High blood pressure
Omega-3 fatty acids	Factors affecting blood cholesterol, blood pressure and atherosclerosis
Fruits and vegetables	Some cancers
Folate	Neural tube defects
Whole grain foods	Heart disease and some cancers
Dietary fat	Cancer

Limitations of the consultation

The short timeframes limited the extent of consultation possible. The initial invitation list for the survey had a greater number of public health than industry contacts, however all invitees were encouraged to forward the survey to other interested colleagues and approximately two-thirds of the final ranked scores were returned from industry sources. A total of 62 surveys were returned. While this represents a relatively good response rate of 26%, the small number means results must be treated cautiously.

Many respondents found it difficult to rank the suggested pre-approved relationships, particularly as some of them still had some degree of overlap in content, and because the exact wording of the potential claims was not provided. A number of respondents also commented that all claims already approved for use overseas should be accepted for use in Australia without further substantiation.

The electronic survey was limited to consideration of only 23 well-established claims already used in other jurisdictions. A number of other potential claims were identified by workshop participants but were not included for consideration in the survey, because most of these are less likely to have the same extent of consistently agreed convincing scientific evidence that will be required for substantiation.

Conclusions and recommendations

1. The criteria for prioritisation identified at the workshop may assist FSANZ in further consideration of this issue.

2. The list of 12 diet–disease relationships identified by industry and public health representatives from both Australia and New Zealand could form the basis of FSANZ planning for the high-level claims to be assessed and possibly approved for inclusion in the new standard.

3. Based on comments from the survey, further input on priority high level health claims would benefit from clearer definition of the actual wording elements of the potential claims, and an outline of the substantiation process for claims that are currently approved in other countries.

Section 3 Report from FSANZ/NCEFF workshop

The aims of the workshop were to:

1. Identify key issues for consideration when prioritising pre-approved health claims.
2. Identify potential additional informants to include in a broader electronic survey.
3. Agree on the ranking of potential food component/health conditions identified by participants at the workshop.

Attendees

Invitations were sent to around 200 potential attendees representing key public health and food industry groups in Australia and New Zealand. The names of invitees were taken from existing contact lists held by FSANZ and NCEFF.

Forty-one participants attended, in addition to FSANZ and NCEFF staff: 20 from the food industry, 13 from public health and non-government organisations, and eight others (including legal firms, consultants, New Zealand Advertising Standards Council and Australian Consumer Affairs). Three attendees were from New Zealand (see appendix 1).

Process

The workshop was held from 9.30am to 1pm at Grosvenor House in Sydney on 26 May, facilitated by Dr Peter Williams from NCEFF.

Michelle Fraser from FSANZ presented an overview of the policy context and the planned process for development of a Standard for health claims.

It was explained that the purpose of the workshop was to help prioritise pre-approved health claims that would be included in the new Standard, as directed in the Ministerial Policy guidelines.

Participants were provided with a list of 30 diet–disease relationships that form the basis of existing approved claims from the United States, Canada, the United Kingdom, Sweden, Australia and New Zealand, sample wording of claims, the ministerial policy guidelines on health claims and summaries of current dietary guidelines and national health priorities.

Participants were asked to rank their top 10 priorities from the list of 30. After that there was a discussion of the factors/criteria considered of importance in making such a ranking. These were discussed and prioritised. Additional potential claims were also identified.

Results of the first round of voting were presented. After general discussion of issues related to pre-approved claims, participants were asked to again rank all 30 claims, considering the agreed priorities for the criteria to be used in making these decisions. Participants were also asked to note those claims they would not regard as consistent with current dietary guidelines. Finally participants were presented with the potential contact list for the full electronic survey and asked to nominate additional potential contacts.

Outcomes

1. Criteria for prioritisation

The following factors (in order) were identified as the most important factors to consider:

1. Consistently agreed quality of evidence for the claim.
2. Consistency with dietary guidelines (and other public health nutrition guidance policies such as Australian Guide to Healthy Eating and Eat Well Australia).
3. Potential population health impact in Australia and New Zealand (including the likelihood of potential dietary change).
4. Claims likely to be used by food marketers or health promotion organisations.
5. Existing consumer understanding, confusion or knowledge about the claim.
6. Those that encourage new product development or reformulation.

Other factors mentioned but not ranked as highly were:

- Whether claims are approved elsewhere (although this is likely to be related to criterion 1 above).
- Potential additional health benefits that might come from the food component (eg folate and heart disease).
- Preferences for positive messages rather than warnings.
- Current food purchase patterns.
- Disease burden (related to criterion 3 above).
- Support for the food industry's commercial success.

2. Potential diet–disease relationships identified that might form the basis of additional health claims

Food component	**Disease or Condition**
Resistant starch	Colorectal cancer
Soluble fibre	Colorectal cancer
Omega-3 fats	Mental health/depression
Iodine*	Thyroid
Selenium	Cancer
Probiotics	Immunity
Cheese	Dental Caries
Soy protein	Some Cancers
Fruits, vegetables and wholegrains	Obesity
Glycemic index	Diabetes
Omega-6 fatty acids	Cholesterol/heart disease
Omega-9 fatty acids	Cholesterol/heart disease
Antioxidants in fruit and vegetables	Heart disease
Calcium	Overweight
Calcium	Colorectal cancer
Sodium, potassium, calcium	Hypertension
Saturated fat	Cancer

* In discussion of these potential claims it was agreed that food fortification is likely to be the preferred public health approach for iodine deficiency, not health claims.

3. Ranking of potential pre-approved claims

Thirty-two participants completed the final ranking survey. Using these results, Table 1 ranks the 30 claims from highest to lowest priority, based on the mean scores. The percentage of people agreeing that the claims were consistent with current dietary guidelines is also shown. Two participants stated they were unable to rank the claims: one suggested all claims approved elsewhere should be acceptable; another stated that claims should pertain to food groups, not nutrients.

Table 1: Ranking of potential claims by participants at the workshop

Final ranking order	Food component	Disease/condition	Mean votes (sum of rankings/total number of votes)	% agreeing claim consistent with dietary guidelines
1	Fibre-containing grain products, fruit and vegetables	Cancer	4.97	96%
2	Dietary sat fat and cholesterol	Coronary heart disease	5.32	96%
3	Wholegrain foods	Heart disease and cancers	5.97	100%
4	Fruit, vegetables and grain products that contain fibre (especially soluble fibre)	Coronary heart disease	6.34	96%
5	Dietary saturated fat and trans fat	Heart disease	7.25	91%
6	Fruit and vegetables	Some cancers	7.26	100%
7	Wholegrain foods	Heart disease	7.70	100%
8	Wholegrain foods	Heart health	7.85	100%
9	Vegetables	Bowel cancers	8.50	96%
10	Saturated fat	Blood cholesterol	9.00	87%
11	Sodium and potassium	High blood pressure and stroke	9.62	91%
12	Calcium	Osteoporosis	9.63	100%
13	Calcium and vitamin D	Osteoporosis	9.89	100%
14	Energy	Obesity	10.59	83%
15	Sodium	Hypertension	10.76	96%
16	Dietary fatty acids	Blood cholesterol	10.84	65%
17	Dietary fat	Cancer	11.30	74%
18	Omega-3 fatty acids	Factors affecting blood cholesterol, blood pressure, atherosclerosis	11.90	52%
19	Fruit	Lung cancer	12.14	74%
20	Folate	Neural tube defects	13.71	43%
21	Soluble fibre from certain foods (oats and psyllium)	Coronary heart disease	13.96	74%
22	Fruit and vegetables	Stomach cancers	15.92	87%
23	Whole or chopped nuts	Heart disease	16.54	39%
24	Soluble gel-forming diet fibre	Blood cholesterol	16.64	52%
25	Plant sterol/stanol esters	Coronary heart disease	16.68	26%
26	Soy protein	Blood cholesterol	17.54	22%
27	Soy protein	Coronary heart disease	17.73	22%
28	Dietary sugar alcohol	Dental caries	17.80	61%
29	Walnuts	Heart disease	19.52	30%
30	Fermentable carbohydrates	Dental caries	20.36	35%

4. Other issues raised in discussion

The Dietary Guideline background papers give a variety of reasons for development of the guidelines, but cannot automatically be used to substantiate individual health claims. That will depend on the substantiation framework finally decided upon.

Some participants questioned why dietary guideline type claims could not be just accepted without an assessment process.

Due to statutory requirements, FSANZ believes it is not possible to simply accept claim assessments undertaken by other countries. Assessment reports on pre-approved claims will be commissioned by local experts, taking into account the substantiation framework that is agreed upon. This process will occur between the Initial Assessment Report and release of the Draft Standard, anticipated in May 2005.

To keep to the proposed timeline for standard development, it may be necessary to limit the number of pre-approved claims.

The three United Kingdom claims that are noted as 'not approved for use' in the summary table have all been fully substantiated, but fall into the category of medical claims.

The question of whether the existing Australia New Zealand folate health claim would be automatically continued was raised. Many participants assumed this would occur; others thought it would be reviewed in the same manner as other approved claims.

The Ministerial Council guidelines are not clear on claims about obesity and energy. Would obesity be defined as a serious disease or a biomarker? Some participants said a health claim might be misleading as no food causes weight loss.

There was a suggestion that FSANZ could rank potential claims separately by a variety of different criteria: for example, strength of evidence, use of claim in other countries, health priorities in Australia and/or New Zealand.

All participants agreed that consistently agreed scientific substantiation was essential for all claims. There may need to be a legislated time-span for permitted health claims to ensure the evidence is reviewed regularly.

There was a suggestion that the likelihood of use by marketers was an irrelevant consideration for FSANZ, but others argued it was important that resources not be spent on approving claims that were not going to be used.

There are some differences in the New Zealand context. The health of indigenous Maori and Pacific Islander populations is a significant concern, especially rates of obesity. In New Zealand also sub-optimal iodine and selenium status was important.

A question was raised as to whether there will be an inequity between foods and therapeutic goods, in that foods do not have to have such rigorous control of ingredient content.

There is some overlap between the 30 claims in the survey, with slightly different emphasis between countries (for example, several claims cover saturated fat, cholesterol and trans fats, in relation to heart disease)

5. Additional contacts

Workshop participants identified 35 additional potential contacts for the follow-up email survey and the Australian Food and Grocery Council and the New Zealand Advertising Standards Council also offered to make their contact lists available.

Follow-up

It was agreed that the report from the workshop would be circulated to all participants. All the workshop participants will also be invited again to participate in the wider electronic survey.

Section 4 Report from electronic survey

The aim of the survey was to rank, in priority order, a list of 23 diet–disease relationships that form the basis of currently approved health claims in other countries.

Participants

Email invitations were sent to 241 informants, representing key public health and food industry groups in Australia and New Zealand. The names of contacts were taken from existing contact lists held by FSANZ and NCEFF, supplemented by those identified by participants at the workshop. The covering letter encouraged participants to forward the survey to any other interested colleagues to participate.

Process

Following discussions of the workshop outcomes between FSANZ and NCEFF staff, it was decided that in order to avoid overlap and duplication of claims the number of diet–disease relationships for potential pre-approved claims would be reduced from the 30 used at the workshop to 23. The invitation email and survey form, along with the report from the workshop (see section 3) and a copy of the background presentation from Michelle Fraser of FSANZ, were sent out on Monday 31 May, inviting respondents to reply by email or fax, with a response deadline of Friday 4 June. Copies of the invitation letter and survey form are in appendix 2.

Sixty-two responses were received, including seven from New Zealand. Of these, 46 contained useable completed surveys (30 from industry, 16 from public health sources); the others provided comments only. Fifteen of the 46 responses were from people who had also attended the workshop. Where multiple identical copies of the survey form were received from different individuals in the same organisation, only one set of results was included in the 46 summarised results.

Survey responses were collated and summarised both separately for industry and public health responses, and combined. The mean ranking scores for each of the 23 potential claims were calculated, with the lowest score representing the highest priority.

Results

Tables 2 to 4 present the survey results. A number of respondents provided more detailed comments which have been provided verbatim in confidence to FSANZ. The common issues expressed in these comments are summarised in appendixes 3 and 4.

Table 2: Ranking of food/diet and disease/condition relationships based on survey responses from Food Industry and Public Health representatives combined (n=46).

Rank	Food/food component	Disease/condition	Sum of rankings/total number of votes
1	Calcium +/- Vit D	Osteoporosis	5.9
2	Dietary saturated fat +/- cholesterol, trans fat	Coronary Heart Disease	6.0
3	Fibre-containing grain products, fruits and vegetables	Cancer	6.3
4	Fruits, vegetables and grain products that contain fibre particularly soluble fibre	Coronary Heart Disease	7.3
5	Energy	Obesity	8.2
6	Sodium (salt) +/- Potassium	High blood pressure and stroke	8.5
7	Saturated fat/dietary fatty acids	Blood cholesterol	8.6
8	Omega-3 fatty acids	Factors affecting blood cholesterol, and blood pressure, atherosclerosis	8.8
9	Fruits and vegetables	Some cancers	9.6
10	Folate	Neural Tube defects	9.7
11	Whole grain foods	Heart Disease and certain cancers	10.0
12	Dietary Fat	Cancer	10.6
13	Whole grain foods	Heart disease/heart health	10.9
14	Soluble fibre from certain foods (oats and psyllium)	Coronary Heart Disease	12.2
15	Plant sterol/stanol esters	Coronary Heart Disease	12.3
16	Soluble gel-forming dietary fibre	Blood cholesterol	12.4
17	Soy protein	Coronary Heart Disease	13.8
18	Fruits	Lung cancer	14.1
19	Soy protein	Blood cholesterol	14.6
20	Dietary sugar alcohol	Dental Carries	15.6
21	Fermentable carbohydrates	Dental Carries	16.3
22	Walnuts	Heart Disease	18.1
23	Whole or chopped nuts	Heart disease	18.1

Table 3. Ranking of food/food component and disease/condition relationships based on survey responses from Public Health representatives only (n = 16).

Rank	Food/food component	Disease/condition	Sum of rankings/total number of votes
1	Fibre-containing grain products, fruits and vegetables	Cancer	6.0
2	Fruits and vegetables	Some cancers	7.1
3	Dietary saturated fat +/- cholesterol, trans fat	Coronary Heart Disease	7.7
4	Fruits, vegetables and grain products that contain fibre particularly soluble fibre	Coronary Heart Disease	8.1
5	Calcium +/- Vit D	Osteoporosis	8.2
6	Energy	Obesity	8.6
7	Saturated fat/dietary fatty acids	Blood cholesterol	9.5
8	Whole grain foods	heart disease/heart health	10.0
9	Folate	Neural Tube defects	10.1
10	Whole grain foods	Heart Disease and certain cancers	10.1
11	Sodium (salt) +/- Potassium	High blood pressure and stroke	10.6
12	Omega-3 fatty acids	Factors affecting blood cholesterol, and blood pressure, atherosclerosis	11.1
13	Dietary Fat	Cancer	12.3
14	Fruits, vegetables and grain products that contain fibre particularly soluble fibre	Lung cancer	12.5
15	Soluble fibre from certain foods (oats and psyllium)	Coronary Heart Disease	12.6
16	Plant sterol/stanol esters	Coronary Heart Disease	14.6
17	Soluble gel-forming dietary fibre	Blood cholesterol	14.7
18	Dietary sugar alcohol	Dental Carries	15.0
19	Fermentable carbohydrates	Dental Carries	15.3
20	Soy protein	Coronary Heart Disease	16.9
21	Whole or chopped nuts	Heart disease	17.9
22	Walnuts	Heart Disease	18.3
23	Soy protein	Blood cholesterol	18.3

Table 4: Ranking of food/diet and disease/condition relationships based on survey responses from Food Industry representatives only (n=30).

Rank	Food/food component	Disease/condition	Sum of rankings/total number of votes
1	Calcium +/- Vit D	Osteoporosis	4.7
2	Dietary saturated fat +/- cholesterol, trans fat	Coronary Heart Disease	5.4
3	Fruits, vegetables and grain products that contain fibre particularly soluble fibre	Coronary Heart Disease	6.8
4	Fibre-containing grain products, fruits and vegetables	Cancer	6.9
5	Sodium (salt) +/- Potassium	High blood pressure and stroke	7.5
6	Energy	Obesity	7.6
7	Omega-3 fatty acids	Factors affecting blood cholesterol, and blood pressure, atherosclerosis	7.7
8	Saturated fat/dietary fatty acids	Blood cholesterol	8.5
9	Dietary Fat	Cancer	9.4
10	Folate	Neural Tube defects	9.5
11	Whole grain foods	Heart Disease and certain cancers	10.5
12	Fruits and vegetables	Some cancers	11.0
13	Plant sterol/stanol esters	Coronary Heart Disease	11.0
14	Soluble gel-forming dietary fibre	Blood cholesterol	11.2
15	Whole grain foods	Heart disease/heart health	11.4
16	Soluble fibre from certain foods (oats and psyllium)	Coronary Heart Disease	11.7
17	Soy protein	Coronary Heart Disease	11.8
18	Soy protein	Blood cholesterol	12.3
19	Fruits, vegetables and grain products that contain fibre particularly soluble fibre	Lung cancer	14.9
20	Dietary sugar alcohol	Dental Carries	15.9
21	Fermentable carbohydrates	Dental Carries	16.5
22	Whole or chopped nuts	Heart disease	17.9
23	Walnuts	Heart Disease	18.0

Appendix 1 Attendees at workshop

Name	Company/Department
Ms Bronwyn Ashton	Queensland Health
Mr Alan Barclay	DAA & Health Professionals Council of Australia
Ms Leanne Batcheldor	Kellogg (Aust) Pty Ltd
Ms Jane Barnes	Foodsense
Mr David Bill	Axiome Pty Ltd
Ms Nola Caffin	Nutrition Australia
Ms Kathy Chapman	The Cancer Council Australia
Professor Alan Coates	The Australian Cancer Society
Ms Janine Cornell	Australian Dairy Corporation
Mr Alan Crossway	Complimentary Health Care Council
Mr Tony Downer	Australian Food and Grocery Council
Ms Veronique Droulez	Meat and Livestock Australia
Ms Toni Fear	National Heart Foundation of Australia
Ms Justine Gayer	Solae Company
Ms Catherine Gibbons	National Heart Foundation of Australia
Ms Emma Gibson	Speciality Ingredients - Proteins, ADM Australia
Ms Kirsten Grinter	Goodman Fielder
Ms Trish Guy	Sanitarium Health Food Company
Ms Bronwen Hannay	New Zealand Nutrition Foundation
Ms Natalie Hazel	Blake Dawson Waldron
Ms Claire Hughes	Australian Consumer's Association
Professor Peter Howe	University of Adelaide
Mr Gary Layton	International Diabetes Institute
Dr Iain Moore	Dairy Farmers
Ms Wendy Morgan	Innovations and Solutions
Ms Sharon Natoli	Food and Nutrition Australia
Ms Julie Newlans	Unilever Australasia
Mr David Panasiak	Gavin Anderson & Co
Dr Allan Poynton	Kraft Foods Limited
Dr David Roberts	Australian Food & Grocery Council
Ms Sue Roe	Tarac Technologies Pty Ltd
Ms Jennifer Savenake	Tasmanian Dept of Health
Dr Rosemary Stanton	Nutrition Consultant
*Ms Elizabeth Stewart	Diabetes New Zealand
Ms Jennifer Thompson	Confectionery Manufacturers of Australasia
Ms Alison Tickle	Sanitarium Health Food Company
Mrs Kim Tikellis	National Foods Ltd
Mr Richard Tupper	The Uncle Toby's Company
Mr John Ward	AgriQuality
Ms Lisa Warren	Heinz Australia
Mr Glen Wiggs	New Zealand Advertising Standards Authority Inc

Appendix 2 Email survey invitation and survey form

RE: Survey establishing priorities for high-level health claims for FSANZ pre-approval

Dear Colleague

On behalf of Food Standards Australia New Zealand (FSANZ) I would like to invite you to participate in a survey to consider the priorities for pre-approval of high-level health claims to be included in the development of a new Australia New Zealand food standard. The National Centre of Excellence in Functional Foods (NCEFF) is working with FSANZ staff to coordinate this consultation process. This survey is additional to FSANZ's formal consultation on health claims that will occur later this year.

On 12 December 2003, the Australia New Zealand Food Regulation Ministerial Council released Policy Guidelines for nutrition, health and related claims that provide the framework for the development of health claims regulations including a new standard: <http://www.foodsecretariat.health.gov.au/pdf/nutrition_guidelines.pdf>.

Of high priority to FSANZ is the identification of those high-level health claims to be assessed and possibly approved for inclusion in the new standard. High-level claims are those that refer to a serious disease or change in level of biomarker. Due to statutory requirements, FSANZ believes it is not possible to simply accept claim assessments undertaken by other countries. Instead, once a set of potential high-level claims has been selected, FSANZ will assess these claims in accordance with a draft substantiation framework. This process will occur between the public release of the Initial Assessment Report anticipated in July and release of the Draft Assessment Report in about May 2005.

An exploratory workshop was held in Sydney on 26 May, with both industry and public health inputs. The report from this workshop is attached. Now NCEFF is organising an online survey to widen this initial consultation and seeks your input to provide advice to FSANZ on which high-level health claims should be considered to be of highest priority. To provide further information on the project timelines, a copy of the presentation made at the workshop by Michelle Fraser of FSANZ is attached.

The workshop suggested the following criteria were the most important to consider when prioritising possible claims:

1. Consistently agreed quality evidence for the claim
2. Consistency with dietary guidelines and other public health nutrition guidance policies such as Australian Guide to Healthy Eating and Eat Well Australia
3. Potential population health impact in Australia and New Zealand (including the likelihood of potential dietary change)
4. Claims likely to be used by food marketers or health promotion organisations
5. Existing consumer understanding, confusion or knowledge about the claim
6. Those that encourage new product development or reformulation.

A survey form is attached and is being sent to over 200 selected public health and food industry contacts in Australia and New Zealand. The survey form consists of a summary table of the 23 diet–disease relationships that form the basis of health claims currently approved for use in the United States, Canada, Sweden, the United Kingdom and Australia New Zealand. This list has been condensed from the list of 30 considered at the workshop, to reduce identified duplication and overlap. Could you please consider these claims and number them from 1 to 23 in the priority order you believe most important for FSANZ to consider. A ranking of 1 is the highest and 23 the lowest. If you wish to forward this survey to other interested colleagues, please feel free to do so.

You may either type your numbers into the Word document file and return the completed table as an attachment to this email or fax a completed copy to:

Leisa Ridges
Regulatory Affairs Analyst
National Centre of Excellence in Functional Foods
FAX: (02) 4221 4844.

To meet the short timeframes requested by FSANZ we are seeking all responses by **Friday 4 June**. There will however be a substantial period for more detailed comments to be made to FSANZ during the public consultation on the Initial Assessment Report in August and September.

If you have any questions please contact Leisa Ridges:
Email: leisa@uow.edu.au
Tel: +61 (0)2 4221 5796

Yours sincerely

Dr Peter Williams
Cluster Coordinator - Regulatory Affairs
National Centre of Excellence in Functional Foods

Attachments:

1. Workshop Summary
2. Overview of policy and FSANZ work plan
3. Survey Table (to be returned)

Priorities for development of pre-approved health claims

NAME: _____

ORGANISATION: _____

The 23 diet/disease relationships in the table below form the basis of approved health claims in different countries around the world (as indicated by the shaded boxes).

Please indicate your ranking of the priorities for the development of pre-approved high-level health claims for inclusion in Australia/New Zealand food standards, by numbering them from 1 (most important) to 23 (least important).

Please email or fax your response by Friday 4 June to:
Leisa Ridges
Regulatory Affairs Analyst
National Centre of Excellence in Functional Foods
Email: leisa@uow.edu.au
Fax: (02) 4221 4844.

Rank	Food/ food component	Disease/condition	USA	UK	Sweden	Canada	Aust./ NZ
	Calcium +/- Vit D	Osteoporosis	■		■	■	
	Sodium (salt) +/- Potassium	High blood pressure and stroke	■		■	■	
	Dietary fat	Cancer	■				
	Dietary saturated fat +/- cholesterol, trans fat	Coronary heart disease	■			■	
	Fibre-containing grain products, fruits, and vegetables	Cancer	■				
	Fruits, vegetables and grain products that contain fibre particularly soluble fibre	Coronary Heart disease	■				
	Soluble fibre from certain foods (oats and psyllium)	Coronary heart disease	■				
	Fruit	Lung cancer		■*			
	Fruits and vegetables	Some cancers	■	■*		■	
	Folate	Neural tube defects	■				■
	Dietary sugar alcohol	Dental caries	■			■	
	Fermentable carbohydrates	Dental caries			■		
	Soy protein	Coronary heart disease	■				
	Soy protein	Blood cholesterol		■			
	Saturated fat/dietary fatty acids	Blood cholesterol		■	■		

	Soluble, gel-forming dietary fibre	Blood cholesterol			■		
	Plant sterol/stanol esters	Coronary heart disease	■				
	Whole grain foods	Heart disease and certain cancers	■				
	Wholegrain foods	Heart disease/ heart health		■	■		
	Whole or chopped nuts	Heart disease	■#				
	Walnuts	Heart disease	■#				
	Energy	Obesity			■		
	Omega-3 fatty acids	Factors affecting blood cholesterol and blood pressure, atherosclerosis			■		

*These JHCI claims are considered to have been substantiated by available evidence, but they are not approved for use.

These two United States Food and Drug Administration claims are qualified claims that have not met the test of significant scientific agreement, that is, the level of substantiation that has been satisfied by the other 14 United States Food and Drug Administration claims. The Food and Drug Administration is using its enforcement discretion to allow manufacturers to make these claims under interim arrangements, until such time as a final rule with regard to qualified health claims is made.

Appendix 3 Summary of comments received in surveys from public health representatives

The main points raised in comments made by public health representatives were:

1. More information about Australian's dietary composition and food intake, inclusion and exclusion criteria for potential foods likely to carry FSANZ approved high-level health claims and scientific evidence to substantiate the 23 food/food component and disease/condition relationships provided, would have enabled a more informed decision to be made when ranking the contents of the survey table.

2. Overall concern as to the impact and potential benefits of health claims on consumers' diets was expressed with some survey respondents opposing the use of health claims on food labels.

3. It was difficult to separate out some food/food component and disease/condition relationships and thus rank them in priority order. A number of survey respondents also felt that evidence may be stronger for specific biomarkers in place of some diseases in the diet/disease relationships provided in the survey table.

Appendix 4 Summary of comments received in surveys from food industry representatives

The main issues raised in comments received with survey responses from food industry representatives were:

1. The timeframe for the survey was too short to enable a considered response based on the criteria agreed to at the workshop, for determining priorities.

2. There was a strong feeling amongst the majority of industry respondents who provided additional comments, that claims which have been approved in other countries (the United States, Canada, the United Kingdom, Sweden) (especially in more than one country) and thus the scientific evidence supporting such claims reviewed and evaluated by international regulatory bodies, should be prioritised for approval in the Australian setting. Consequently, the process for approval by FSANZ should require minimal resource expenditure.

3. In contrast to the point raised above, a couple of survey respondents felt that the process of scientific evaluation of claims should start afresh and be conducted at the highest standard of scientific evaluation.

4. A number of respondents recommended additional diet–disease relationships for consideration of high-level health claim prioritisation, which have been forwarded to FSANZ.

A comparison of the Australian regulatory system for complementary medicines and foods

Efficacy

Parameter	Foods	Complementary medicines
Health claims permitted?	To be permitted	Yes
Therapeutic claims permitted?	No	**Yes**
Approval process for general level claims	**No pre-approval**	Pre-approval through the Electronic Lodgement Facility. However, manufacturers generally select from a list of acceptable coded indications
For general level claims, do manufacturers have to submit efficacy data prior to product release?	No	No
For general level claims, can efficacy data be called in by enforcement agencies?	Yes	Yes
Evidence required for substantiation of general level claims	Authoritative texts or structured review of totality of evidence. Evidence that food contains the component of interest	Authoritative texts or structured review of totality of evidence. Evidence that medicine contains the component of interest
Traditional evidence permitted?	No – Scientific evidence only	**Yes**
For high level claims, do manufacturers have to submit efficacy data prior to product release?	Yes, unless claim has previously been approved	Yes – these medicines would be registered. Level of information required to be submitted may depend on the degree of acceptance of efficacy
Does reference to a serious disease require a high level approval process	Yes	Yes, via product registration instead of listing, although some listable coded indications refer to serious diseases (for example, osteoporosis)
For high level claims, time/process required for approval	12 months (excluding stop-clocks) with two rounds of public consultation	**No public consultation. Time required depends on extent of evaluation required.**

Exclusive benefit?	No – pre-approved high level claims can be used by any food meeting qualifying criteria	**Yes – each separate product undergoes evaluation**

Safety

Parameter	**Foods**	**Complementary medicines**
Assessment of individual products required?	**No – provided approved additives and novel foods used and fortification is within Code requirements**	Yes – through listing or registration
Assessment of new active ingredients required?	Yes – under the novel foods process	Yes
Cost of pre-approval of new ingredients?	**Free, unless manufacturer chooses to pay for evaluation or derives an exclusive capturable commercial benefit**	Charges apply, up to $35,105 plus application fee of $755.

Quality

Parameter	**Foods**	**Complementary medicines**
Licensing	**Generally no product-specific licensing requirements**	Products must be produced in premises licensed for that specific activity in accordance with GMP. Premises subject to audit.

Advertising

Parameter	**Foods**	**Complementary medicines**
Pre-approval of advertising?	**No**	Yes

Other fees

Parameter	**Foods**	**Complementary medicines**
Application fees for product listing or registration	**None, unless manufacturer chooses to pay a fee to expedite the application.**	$755 for registration + $690 per annum $475 for listing + $505 per annum

Bolded text represents areas likely to benefit that sector.

Standard Development Advisory Committee

1. Membership

Government	
Ms Sonia Neilson	Australian Government Department of Agriculture, Forestry and Fisheries
Ms Sarah Major	Australian Government Department of Health and Ageing
Ms Catherine Gay	Australian Government Department of Health and Ageing
Dr Fiona Cumming	Therapeutic Goods Administration
Dr Fay Jenkins	South Australian Department of Human Services
Ms Joeanne Riddiford	Australian Competition and Consumer Commission
Ms Yvette Popovic	New Zealand Commerce Commission
Mr Michael Apollonov	New South Wales Food Authority
Ms Jenny Reid	New Zealand Food Safety Authority
Ms Charlotte Channer	New Zealand Food Safety Authority
Consumer groups	
Ms Clare Hughes	Australian Consumers Association
Dr Rosemary Stanton	The Coalition for a Healthy Food Supply
Ms Belinda Allan	The New Zealand Consumer Institute
Industry	
Dr Dave Roberts	Australian Food & Grocery Council
Ms Brenda Cuttress	New Zealand Food and Grocery Council
Ms Priscilla Dreghorn	Australian Chamber of Commerce and Industry
Ms Juliet Seifert	Australian Self Medication Industry
Public	
Mr Bruce Shaw	Australian Medical Association
Health	
Dr Mark Lawrence	Public Health Association of Australia
Professionals	
Dr Peter Williams	Dietitians Association of Australia
Dr Gaye Keating	Public Health Association of New Zealand
FSANZ	Mr Graham Peachey, Chair Ms Melanie Fisher Ms Margaret Curran Dr Bob Boyd Associate Professor Heather Yeatman, FSANZ Board, Observer

2. Terms of Reference

The purpose of the Standards Development Advisory Committee SDAC is to provide advice to FSANZ regarding:

1. the development of a Nutrition, Health and Related claims standard in accordance with:
    a. the requirements of the *Food Standards Australia New Zealand Act 1991*; and
    b. the Australia New Zealand Food Regulation Ministerial Council Policy Guideline on Nutrition, Health and Related Claims; and
2. any scientific, technical, policy, regulatory/enforcement, cost benefit or other information that may be relevant to the standard development process including any associated documentation for the Nutrition, Health and Related Claims proposal.

Technical Expert Group

1. Membership

Dr Bob Boyd	FSANZ Chief Medical Adviser, Chair
Dr Dave Roberts	Australian Food and Grocery Council
Ms Jenny Reid	New Zealand Food Safety Authority
Dr Peter Williams	University of Wollongong
Ms Christine Cook	New Zealand Dietitians Association
Mr Mark Lawrence	Dietitians Association Australia
Ms Rosemary Stanton	Consultant
Ms Sonia Bradley	FSANZ
Dr Vicky Scott	FSANZ
Associate Professor Heather Yeatman	FSANZ Board, Observer

2. Terms of Reference

Within the scope of nutrition, health and related claims, the Technical Expert Group on General Level Claims will consider and provide advice on the development of the Initial Assessment Report for Proposal P293 – Nutrition, Health and Related Claims. The terms of reference for the Technical Expert Group on General Level Claims are to:

1. Consider and advise on issues that relate to general level claims.
2. Advise on the specific criteria and conditions for content claims.

Scientific Advisory Group

1. Membership

Dr Bob Boyd	FSANZ Chief Medical Advisor, Chairperson
Professor Colin Binns	Professor of Public Health, Curtin University
Professor Lynnette Ferguson	Head, Discipline of Nutrition, The University of Auckland
Professor Robyn McDermott	Professor of Public Health and Tropical Medicine, James Cook University
Professor John McNeil	FSANZ Fellow, Head of Department, Epidemiology and Preventive Medicine, Monash University
Associate Professor C Murray Skeaff	Department of Human Nutrition, University of Otago
Emeritus Professor A Stewart Truswell	University of Sydney
Dr Fiona Cumming	Therapeutic Goods Administration, Observer
Professor Kerin O'Dea	Director, Menzies School of Health Research, Darwin, FSANZ Board Observer
Associate Professor Heather Yeatman	Head of Graduate School of Public Health, University of Wollongong, Alternate FSANZ Board Observer

2. Terms of Reference

The Scientific Advisory Group SAG has been established to provide advice to FSANZ on the Substantiation Framework for Nutrition, Health and Related Claims.