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

10-05
7 December 2005

DRAFT ASSESSMENT REPORT

PROPOSAL P293

NUTRITION, HEALTH AND RELATED CLAIMS

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 22 February 2006
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

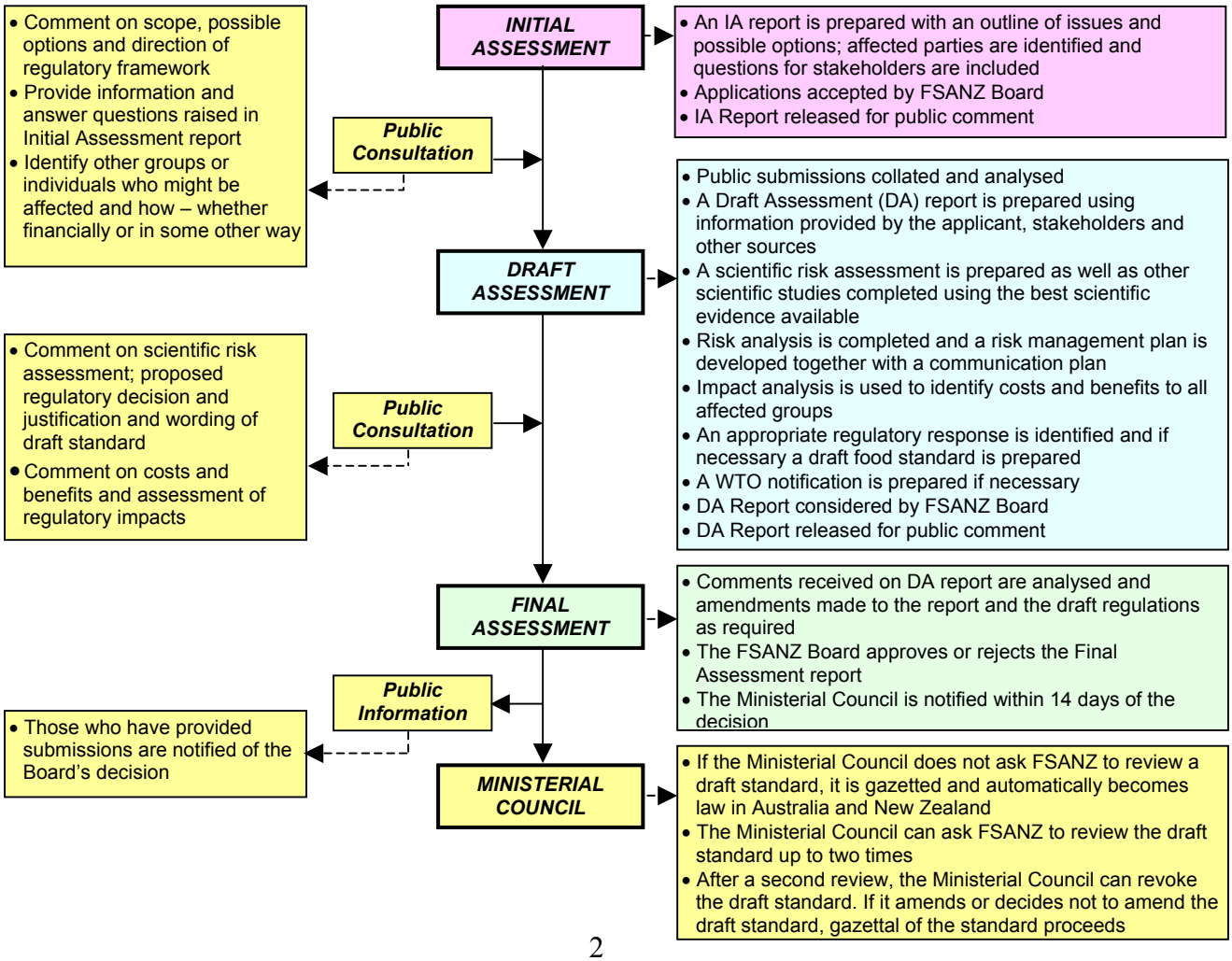
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 a Draft Assessment Report of Proposal P293 Nutrition, Health and Related Claims; and prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code).

FSANZ invites public comment on this Draft 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 Final Assessment for this Proposal. Submissions should, where possible, address 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 need to be <u>received</u> by FSANZ <u>by 6pm (Canberra time) 22 February 2006</u>.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ Website and will apply to all submitters.

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 <u>Standards Development</u> tab and then through <u>Documents for Public Comment</u>.

It would be helpful if you provide cross-references to the section number of the Draft Assessment Report alongside individual comments when possible. 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.

Call for information relating to endorsements

FSANZ is also proposing to pre-approve some endorsement[1] programs. Information is therefore sought on pre-existing endorsement programs that meet the definition outlined in this Report and accompanying Draft Standard. You are asked to provide information on the endorsing organisation and the criteria for approving endorsements, if known. Information on pre-existing endorsements should clearly be marked with the word 'Information on Endorsements' and quoting Proposal P293. It should be clearly distinguishable and separate from submissions to the Draft Assessment Report. The information 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

This information needs to be received by FSANZ by 6pm (Canberra time) 22 February 2006.

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[1] Refer to Attachment 1 Draft Standard 1.2.7 for definition.

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Executive Summary And Statement Of Reasons

Food Standards Australia New Zealand (FSANZ) had careful regard to the Policy Guidance on Nutrition, Health and Related Claims provided by the Australia and New Zealand Food Regulatory Ministerial Council (Ministerial Council) in 2003 when developing a regulatory framework for nutrition, health and related claims. The Policy Guideline sets out the policy principles underpinning the regulation of nutrition, health and related claims. It differentiates two main types of health claims – general level and high level – in terms of the reference to a serious disease or biomarker of a serious disease in the case of the latter, and indicates the possible approaches to be taken to regulate these health claims and nutrition content claims[2]. The policy guideline aims to allow claims in order to achieve public health benefits and to encourage industry to develop new products, whilst ensuring that consumers are not misled.

Some nutrition claims in Australia and New Zealand are currently regulated by the *Australia New Zealand Food Standards Code* (the Code). Additionally some members of the Australian food industry follow a voluntary code of practice on nutrient claims. The New Zealand food industry uses the former *Food Regulations 1984* for guidance in the same manner as the code of practice. Fair trading legislation in both countries serves to regulate false and misleading claims. The Code has a transitional standard for health claims, which prohibits all health claims except for one relating to folate ingestion in women around the time of conception.

This situation is deemed to have limitations including difficulties in relation to compliance with a voluntary code of practice, the lack of incentive for innovation by industry and a restriction on claims that could be of value to consumers and could enhance public health. Furthermore, there are difficulties in interpretation, application and enforcement of the transitional Standard.

FSANZ has therefore considered the benefits and costs of the introduction of a new standard allowing health claims and the different regulatory options that could be applied to health, nutrition and related claims. In developing this Draft Assessment Report FSANZ has:

- consulted with a wide variety of stakeholders through open meetings, targeted consultations and analysed detailed submissions to the Initial Assessment Report from 147 submitters;
- undertaken research to assess the use of nutrition and health claims and the consumer understanding and use of these claims;
- prepared a benefit-cost analysis;
- considered international regulations for health, nutrition and related claims;
- considered relevant research;
- developed further the framework substantiating health claims, applied the framework in assessing the evidence for a number of high level claims[3] and considered approaches used elsewhere for substantiating general level claims[4]; and
- received advice from expert and advisory groups.

[2] Refer to definitions in Draft Standard 1.2.7 at Attachment 1.
[3] ibid.
[4] ibid.

On the basis of this evaluation FSANZ recommends the introduction of a new standard for health, nutrition and related claims, with the management of both general level and high level claims being predominantly by a standard (refer Attachment 1 for Draft Standard). A user guide will include interpretive advice concerning the requirements of the Standard, and guidance on substantiation of general level claims and seeking pre-market approval of high level health claims. The Substantiation Framework will be in a guideline, which will be incorporated by reference into the health claims Standard. This means claims will be legally required to be substantiated in accordance with the Framework.

Some modifications to the criteria for content claims as presently set out in the Code and in the voluntary code of practice are being proposed to improve consistency, to update recommendations and to support a risk management approach based on public health concerns and the provision of information to consumers. In addition, all labels carrying content claims will be required to indicate the percentage daily intake (%DI) represented by the claimed component in the nutrient information panel, where a %DI value applies, together with the %DI for energy to allow consumers to make informed choices. Criteria for specific nutrient content claims (those which were evaluated to be important to meet public health objectives or which may otherwise mislead consumers) will be specified in the standard. Other content claims can continue to be made providing they are not misleading. Specific disqualifying criteria will apply to some content claims.

Claim definitions and the regulatory parameters (i.e. pre-requisite conditions, specific criteria and wording conditions) work together to identify and regulate nutrition and health claims. These requirements will apply to both general level and high level claims. All health claims will require reference to both the specific health benefit and the property[5] of the food responsible for that benefit. The property will have to be present above defined levels (qualifying criteria) in order to avoid misleading consumers. Foods able to carry claims must also meet generic disqualifying criteria, as applicable, based primarily on total sugars, saturated fat and sodium.

All general level health claims are either to be based on a list of pre-approved nutrient function statements provided in the Substantiation Framework, or supported by authoritative, generally accepted information sources outlined by the Substantiation Framework for general level health claims, or evidence prepared as specified in a substantiation user guide. Holding the evidence for substantiation of these claims is the responsibility of individual suppliers and pre-approval of any general level health claims will not be required. In addition there are some specific wording conditions in relation to the claims.

FSANZ is proposing to approve a number of high level claims that will be available to use at the time the Standard comes into effect. FSANZ has therefore commissioned expert reviews of a number of diet-disease relationships. Health claims based on the following diet-disease relationships have been substantiated[6]:

- a relationship between dietary intake of calcium, vitamin D status and risk of the frail elderly, particularly women, developing osteoporosis;
- a relationship between increased dietary intake of calcium and enhanced bone mineral density, particularly in women;

[5] Refer to definition in Draft Standard 1.2.7 at Attachment 1.
[6] ibid.

- a relationship between reduction in dietary intake of sodium and reduction in blood pressure;
- a relationship between intake of folic acid in the peri-conceptional period and risk of development of neural tube defects in the foetus;
- a relationship between saturated fatty acids and LDL-cholesterol levels; and
- a relationship between unsaturated *trans* fatty acids and saturated fatty acids and LDL-cholesterol levels.

A review of the evidence supporting the following diet-disease relationships is underway for:

- long chain Omega-3 fatty acid intake and risk of developing heart disease;
- wholegrains and heart disease; and proposed for
- fruit and vegetable intake and heart disease or other biomarkers, at a later date.

Suppliers may use high level claims based on substantiated relationships, subject to defined specific criteria and conditions. Any new high level claims require pre-approval by FSANZ through the application process to vary the Code. Recently the Ministerial Council recommended changes to the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), which when implemented will also mean it will be possible to keep applications for high level claims confidential, until any claim is approved.

Whilst the proposed new Standard will consolidate a number of aspects in relation to health, nutrition and related claims, at this stage the criteria around claims relating to vitamins and minerals presently specified in the Code will not be changed. The exception to this is that the criteria will be based on a per serve basis rather than a reference quantity as is currently prescribed in Standard 1.3.2. A review of the actual criteria will be done subsequent to the present proposal when new nationally applicable Nutrient Reference Values have been finalised. The existing application for vitamin and mineral content claims of disqualifying criteria on the basis of 'claimable foods' will apply to both content and health claims for vitamins and minerals, pending the above review.

Claims that have been deemed to fall outside the framework have been designated 'related claims' and are subject to separate provisions. These include cause-related marketing statements that will require a disclosure statement, but no other criteria or conditions apply; and some existing endorsements[7] will be pre-approved by FSANZ and will be exempt from the Standard. Other present endorsements will be considered as general level health claims or high level claims and will need to conform to the relevant claims criteria and conditions. Future endorsements will need to meet selected elements of the claims classification framework, according to the nature of the endorsements.

FSANZ has given consideration to specific types of claims (such as dietary interaction claims, glycaemic index, gluten claims, weight management claims and 'diet' claims) and specific food types (such as whole foods and foods containing biologically active substances). Some specific recommendations apply to such cases.

[7] Refer to definition in Draft Standard 1.2.87 in Attachment 1.

1. Introduction

FSANZ and its predecessor, the Australia New Zealand Food Authority (ANZFA), have 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.

1.1 The Draft Assessment Report for Proposal P293 Nutrition, Health and Related Claims

FSANZ prepared this Proposal after receiving policy guidance on the regulation of nutrition, health and related claims from the Ministerial Council in December 2003 (referred to as the Policy Guideline, which can be found at Attachment 2). This Proposal is the vehicle by which FSANZ will develop a standard and an appropriate management system for the regulation of nutrition, health and related claims.

In August 2004, FSANZ released the first of two consultation documents, an Initial Assessment Report, for public comment. The Initial Assessment Report canvassed stakeholder views on a broad range of issues including how FSANZ should have regard to the Policy Guideline and which of three proposed regulatory options was preferred. FSANZ received 147 written submissions in response to the release of the Initial Assessment Report.

This Draft Assessment Report is the second consultation document for the development of a new standard for nutrition health and related claims. The Draft Assessment Report includes:

- consideration of the key issues raised by stakeholders in response to the Initial Assessment Report;
- the results of research undertaken by FSANZ to inform the development of the new standard for nutrition, health and related claims; including both qualitative and quantitative consumer research, a label monitoring survey, and a benefit cost analysis of the proposed regulatory options;
- outcomes of Expert reviews of key diet-disease relationships and proposed high level claims; and
- a Draft Standard for the regulation of nutrition, health and related claims.

FSANZ has prepared this Draft Assessment Report in consultation with the Standards Development Advisory Committee for health claims and other advisory groups.

1.1.1 Structure of the Report

The Draft Assessment Report comprises a comprehensive overview of the framework and regulatory model that has been developed since Initial Assessment for regulation of nutrition, health and related claims. It indicates the key factors that have been taken into account and used to inform the framework development, and the preferred regulatory option.

Detail on the evidence base, submitter comments, substantiation frameworks, some of the detail relating to general level claims and the rationale underpinning the decision-making is provided at the end of this report in a series of attachments. Attachments 5 and 6 provide an assessment of the rationale behind the various parts of the regulatory framework for nutrition, health and related claims.

Detail on the evidence base used to develop the framework can be found in Section 7 of this report and Attachment 4. Comments provided by submitters are summarised at Attachment 7. An outline of the substantiation processes underpinning the approach to regulation of general level claims and high level claims is given in Section 6, with further explanation provided at Attachments 8 and 10.

These Attachments are also readily available electronically through embedded web links that cross-reference from the main body of the Draft Assessment Report to the respective document. Full reports on commissioned work, further information that is more lengthy and detailed (e.g. submitters comments), and inter-related materials that sit outside of this Proposal may also be accessed through web links embedded in the electronic version of this report. A complete list of attachments and web links is provided on the last page of this document.

1.2 Briefings at Draft Assessment for Proposal P293 – Nutrition, Health and Related Claims

Public briefings will be held in Sydney, Melbourne, Adelaide, Auckland and Wellington during the two weeks from 28 November to 9 December 2005. The purpose of the public briefings is to inform a broad group of interested stakeholders on the key recommendations contained in the Draft Assessment Report and to explain the rationale behind these. It is envisaged this approach should improve the information base of stakeholders in considering some very complex issues and enhance the quality of stakeholder submissions in responding to the Draft Assessment Report. FSANZ has notified those stakeholders who made submissions to the Initial Assessment Report and other interested parties of the public briefings and has sought the support of the health claims Standards Development Advisory Committee to publicise the briefings to their constituents.

FSANZ will consider the submissions made regarding the Draft Assessment Report and where necessary, follow up with particular stakeholders where more detailed information has the potential to improve the quality of the Final Assessment Report.

1.3 Notification to the World Trade Organization

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

This issue has been fully considered at Draft Assessment and notification is being given in accordance with Australia's and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) Agreement, to enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

Amending the Code to allow nutrition, health and related claims will have possible impacts on international trade because imported packaged foods carrying nutrition content claims will need to comply with the new labelling requirements. Additionally the new provisions allowing health claims may provide new international markets for foods that have beneficial health effects.

2. Regulatory problem

2.1 Introduction

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 Council of Australian Governments' publication, *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies*[8]. 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.

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. To assist in this, FSANZ commissioned an independent benefit-cost analysis of the regulatory options under consideration (refer Attachment 3).

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. In relation to the current proposal, the Ministerial Council has provided detailed guidance to FSANZ, to be taken into account in developing a new food standard.

2.2 Current provisions in Australia and New Zealand

Currently in Australia and New Zealand, regulation of claims on food labels (encompassing content and health claims) are regulated by various means. Some claims are not permitted under the Code; others are permitted but regulated under the Code, while others still are permitted with guidance for industry on their use set out in an industry code of practice on nutrient claims (CoPoNC) (in Australia). Some types of claims are not directly regulated under any of the above arrangements (such as, function claims), but are also not explicitly prohibited. These, like all claims made on food labels, must abide by fair trading legislation in relation to making false or misleading statements.

This section provides information on the various parts of the current regulatory approach.

2.2.1 Standard 1.1A.2 Transitional Standard – Health Claims

In Australia and New Zealand, health claims are prohibited by Standard 1.1A.2, with the exception of the permitted claim regarding maternal folate consumption and reduced risk of foetal neural tube defects.

Standard 1.1A.2 sets out the following restrictions on the use of health claims in food labels or in advertising:

[8] http://www.coag.gov.au/meetings/250604/coagpg04.pdf

- 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.

- 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.

- 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.

- 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.

- 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.

2.2.2 Standard 1.2.8

Standard 1.2.8 of the Code regulates the use of nutrition claims, both by prescribing the type of claims that can be used, and the characteristics of those foods for which the claims can be used (for example, the Standard prescribes that a claim for 'low sodium' can only be used for foods which contain no more than 120 mg of sodium per 100 g of food). The Standard regulates the use of claims in relation to:

- Polyunsaturated and monounsaturated fatty acid content
- Lactose
- Gluten content
- Salt, sodium or potassium content
- Omega fatty acid content
- Low joule

The Standard also specifies nutrition information requirements, including where certain nutrition content claims are made

2.2.3 The Code of Practice on nutrient claims in food labels and in advertisements

(CoPoNC is administered by the Australian Food and Grocery Council and applies to all Australian food industry firms who are signatories. The objective of CoPoNC is to provide a basis for voluntary self-regulation of nutrient claims by the food industry. CoPoNC establishes the conditions under which the following types of claims can be made, in relation to content and comparative claims for fat and saturated fat, sugar, fibre, cholesterol, salt and energy. It also prescribes the use of the terms 'light', 'lite' and 'diet'. Parties with allegations or complaints are directed to pursue their complaint with the company or person making the claim. In the event that the complaint remains unresolved, the complainant may then lodge the complaint with the Food Industry Code Management Committee.

While there is no legal obligation to comply with CoPoNC, food manufacturers who are signatories to CoPoNC have a moral obligation to comply with it.

2.2.4 Other forms of guidance in New Zealand

In New Zealand, the former *Food Regulations 1984* provide guidance in the same manner as a code of practice. (The Regulations were revoked in December 2002, on entry into effect of the Code.) While the regulations are no longer legally in force, the New Zealand Food Safety Authority advised industry at the time that they should continue to be used for the purposes of providing guidance on claims. This remains the current practice.

2.2.5 New Zealand fair trading legislation

In New Zealand, in addition to complying with the Code, all information on food labels must comply with the New Zealand Fair Trading Act that regulates the use of claims on food labels to ensure that the information provided to consumers is not deceptive or misleading. The Act prescribes that claims should be restricted to those that are based on facts. Where appropriate, accompanying information should be provided to show consumers that the claims are justified and substantiated.

2.2.6 Australian fair trading legislation

In Australia, in addition to regulation under the Code, all information on food labels must comply with section 52 of the *Trade Practices Act 1974*. This section prohibits a corporation in trade or commerce from engaging in conduct which is 'misleading or deceptive or is likely to mislead or deceive'. It is mirrored in fair trading legislation in each State or Territory. The Australian Competition and Consumer Commission enforces the Trade Practices Act. Relevant State and Territory bodies enforce fair trading legislation in their jurisdictions.

2.3 Limitations of the current arrangements

The current regulatory arrangements limit the opportunities for product development and placement while also limiting the benefits that might be achieved for consumers. 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 from making nutrition, health and related claims.

The current transitional Standard 1.1A.2 that regulates health claims is ambiguous in terms of its clarity around claims that are legal/illegal. This limits the ability of government enforcement agencies to effectively enforce it. In addition to this, the drafting of the Standard does not reflect the intent to restrict the use of health claims, particularly in relation to 'implied' health claims. The experience of the enforcement agencies is that prosecution against infringements of the Standard is quite difficult.

2.3.1 Folate/neural tube defects health claim

The current Standard does allow one health claim in relation to maternal folate consumption and reduced risk of foetal neural tube defects.

This claim formed the basis of a pilot of a regulatory framework for health claims at a time when a range of other educational activities were taking place in relation to the benefits of folate at the time of conception. The folate health claims pilot and its evaluation took place within a limited time period and both fresh and processed food industry groups were encouraged to participate by having suitable products assessed for approval to carry the folate health claim.

Unlike the claim-by-claim approval system in the current Proposal, the piloted regulatory framework for folate health claims used a product-by-product approval system, with approved products listed in the Code. Such a system was shown to be resource intensive and resulted in only a limited of number of products in the market actually carrying the claim, even though many products were approved to carry the claim. The FSANZ label monitoring survey (refer Attachment 4) found only one health claim relating to folate and neural tube defects amongst 1262 labels that were analysed.

The pilot project was started in March 1998 and an evaluation of the effectiveness of the piloted framework was conducted in 1999[9]. The evaluation looked at how health claims should be managed and the socio-cultural impact in terms of buying and consumption or changed knowledge about which foods are sources of folate. The evaluation was not intended to ascertain the impact of folate health claims on the incidence of neural tube defects due to an inadequate implementation time frame for evaluating longer term effects. The evaluation found that it was unlikely that there were any substantial changes in dietary behaviour during the survey period and there was no change in sales of approved products.

This outcome is likely to be indicative of the limited sub-population group for which the claim is applicable and the low uptake by manufacturers due to the pilot nature of the project and the very tight time frame for introduction of the pilot and subsequent evaluation. The consultant noted that the folate health claim is a very specific health claim, and the extent to which the findings of this claim can be applied to other claims, especially those more generic in nature, is debatable. It should also be noted that the folate/neural tube defect health claim equates to a high level health claim in the system that is currently being proposed. Given this, the outcomes of the evaluation relate more directly to the proposed system for managing high level health claims rather than for the full spectrum of nutrition, health and related claims.

As part of the evaluation of the folate/neural tube defects health claims pilot, the consultant commented that funding the implementation and regulation of health claims is a major and continuing task and that adequate resources will need to be made available[10]. They indicated that without sufficient resources and uniformity of health claims, there is the potential to cause considerable confusion to consumers and that health claims may be highly counterproductive to nutrition education. The evaluation did not link the effects on health outcome to the permission to carry claims due to the inherent difficulties of such an analysis. Some of the recommendations from the pilot trial are relevant for consideration of options for drafting the new Standard. For example, they addressed the need for detailed guidelines for substantiating health claims; the need for an expert advisory panel; the establishment of eligibility criteria for foods, including both qualifying and disqualifying criteria and stated approved foods should support the aims of the national nutrition guidelines.

[9] ANZFA (2000) Evaluating the Folate-Neural Tube Defect Health Claim Pilot.
[10] ANZFA (2000) Evaluating the folate-neural tube defect health claim pilot. Process evaluation of the management framework. Outcome evaluation.

Some of the recommendations have not stood the test of time, in particular the recommendation for pre-approval of individual health claims on a product-by-product basis.

2.4 Potential risks to public health and safety

The need for regulation around the types of nutrition content and health claims that food suppliers 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 self-regulated through guidance provided in 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 claims that are not consistent with CoPoNC. This disadvantages those businesses that do comply with CoPoNC and make claims in accordance with the criteria. An independent study of compliance with the CoPoNC found that, in a sample of 6662 products, for the 3194 claims covered by the CoPoNC, the level of non-compliance was 14.8%[11].

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.

Claims relating to nutrition and health may also involve other risks. Consumers may focus on the claim and not 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, but consumers may not be evaluating the total nutritional profile of the food in making their choice. 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 that may carry nutrition or health claims. Such a shift in consumption patterns could have potential major adverse health consequences.

While there is clearly potential for these impacts, the actual level of risk arising from misunderstanding of content and health claims and subsequent impact on consumer behaviour is unclear as studies to date have not been conclusive. This area of study is complex, with several studies with conflicting outcomes, partly reflecting different study designs, different levels of label awareness and nutritional knowledge in different countries and changes in awareness of nutritional and health information over time.

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[11] Williams, P., Yeatman, H., Zakrzewski, S., Aboozaid, B., Henshaw, S., Ingram, K., Rankine, A., Walcott, S. and Ghani, F. (2003) Nutrition and related claims used on packaged Australian foods – implications for regulation. *Asia Pacific J Clin Nutr*, **12** (2): 138-150.

Consumer understanding and use of content claims and health claims has been taken into account when considering the specific risks associated with different types of claims and in determining the appropriate regulatory approach. More detailed evaluations of the research and the risk management option taken to manage the risks associated with individual claims and types of claims are given in Attachments 5 and 6.

There is also the risk that consumer confidence in health claims could be undermined by the use of health claims, which mislead or are untruthful. A lack of consumer confidence in claims for these or other reasons may also have a negative impact for suppliers through reduction in sales and loss of revenue.

The use of a regulatory system that is trusted by the public, and supports responsible suppliers, provides benefit to consumers, public health professionals and industry due to consumer confidence in the veracity of claims.

In order to ensure that consumers are not placed at risk through a permission to use health claims, a system needs to be established that meets the following criteria:

- encourages health claims on foods that have properties consistent with public health recommendations;
- ensures the levels of the property of the food about which the claim is made are sufficient to confer the claimed benefit;
- ensures the claims are sufficiently explicit to enable consumers to interpret the claim in such a way as they will not be misled; and
- enables enforcement agencies to appropriately assess the claim.

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 and notified to FSANZ.

3.2 Objectives of this Proposal

The objectives of this Proposal are:

1. to protect the health and safety of the population in their consumption of foods bearing nutrition, health or related claims;

2. to ensure that food labels bearing nutrition, health or related claims provide adequate information to enable consumers to make informed choices;

3. to prevent misleading or deceptive nutrition, health or related claims on food labels or in food advertising; and

4. to have regard to the policy principles enunciated by the Ministerial Council, in particular that any intervention to permit nutrition, health or related claims should:

    - enable the responsible use of scientifically valid nutrient, health and related claims;
    - support government, community and industry initiatives that promote healthy food choices by the population;
    - be cost effective overall;
    - contain a process of substantiation that aligns levels of scientific evidence with the level of claims along the theoretical continuum of claims, at minimum costs to the community;
    - draw on the best elements of international regulatory systems for nutrition, health and related claims; and
    - allow for effective monitoring and effective enforcement.

4. Regulatory Options

4.1 Policy Guidance

The Policy Guideline, agreed to by the Ministerial Council in December 2003 aims to provide guidance to the standard development process and 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 should 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.

The Policy Guideline recommended that:

- the 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 (e.g. nutrient content claims) and categories of foods which may be excluded from making claims (e.g. alcohol and 'baby foods[12]');

- 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; and

- the Standard should provide sufficient detail to enable enforcement to be taken against all breaches, for all levels of claims.

FSANZ sought advice on the second dot point above and established that the intent in this instance was to have an interpretive 'user guide', which provides interpretation and advice on application of the Standard, rather than a 'guideline' that provides risk management measures that sit outside the legal document that is the Code. Such a guideline may, or may not, be incorporated by reference into the Code thereby, making it legally enforceable.

In having regard for the recommendations outlined above and considering the objectives of the Proposal as outlined in Section 3.2, FSANZ formulated options that allowed an assessment relating to the incorporation of criteria for content claims in either a standard or a guideline.

The recommendations of the Policy Guideline were reviewed initially within FSANZ. They were then reviewed throughout the Initial and Draft Assessment phases in the context of recommendations made by stakeholders regarding the proposed regulatory options and in the light of the evidence base, in consultation with the Standards Development Advisory Committee.

4.2 Approach Taken to Determine Preferred Regulatory Option

In addition to the Policy Guideline, a number of elements of work have been undertaken to provide evidence upon which to base a determination of the preferred regulatory option.

One of the elements that contributed to FSANZ's decision-making was an independent benefit-cost analysis of the three regulatory options (refer Attachment 3) commissioned by FSANZ. Other elements included consumer research, submitters' views and regard to national dietary guidelines and nutrition policies.

A broad range of evidence was examined as part of the benefit-cost analysis, including:

- the results of the consumer research and label monitoring research undertaken by FSANZ (refer Attachment 4);
- input from representatives of a range of stakeholder groups including industry, enforcement agencies, consumer groups and public health professionals through targeted consultation;

[12] FSANZ has taken this to mean infant formula, as standardised under Standard 2.9.1.

- literature focusing on the regulation of health claims overseas, particularly in the United States; and
- issues raised in the submissions to the Initial Assessment Report (refer Attachment 7).

A multi-criteria analysis was used to provide an evaluation of the benefits and costs. This was based on the following set of criteria (weightings in brackets):

- Adjustment costs for industry (10);
- Impact on opportunities for industry innovation (30);
- Impact on consistency and credibility of claims made in the market place (10);
- Impact on consumer welfare (40); and
- Impact on enforcement costs for government (10).

Each option was ranked against each criteria and an illustrative score derived. The evidence used to derive each score is discussed in the benefit-cost report. This report was one of the inputs used by FSANZ in determining the most appropriate regulatory option.

The benefit-cost analysis only addressed the options as set out in the Initial Assessment Report, with minor amendment in relation to the differences between option 2 and 3 (see below). FSANZ did not consider in depth any alternative options because no other options were identified in regard to the framework for regulating high and general level claims which were sufficiently aligned with FSANZ's objectives as outlined in Section 3.1 above. However, throughout the DAR process the degree of regulation of individual health, nutrition and related claims was kept under review.

FSANZ's recommendations for individual claims are based on the minimal degree of regulation consistent with meeting its objectives. For example, a decision process was made for the regulation of nutrition content claims on the basis of alignment with public health guidelines for individual nutrients, together with an evaluation of whether regulation was required to prevent consumer deception. As a further example, consumer research indicated the high value placed on endorsements so FSANZ is proposing to regulate these in a way consistent with their degree of risk in providing the consumer with nutritional and health information.

The decision-making process and recommendations in relation to individual types of claims is discussed in Attachments 5 and 6.

4.3 Options Considered

The regulatory options that have been considered were developed in order to have regard to the Policy Guideline as required by FSANZ legislation (section 10 of the FSANZ Act) that states that 'in reviewing food regulatory measures, the Authority must also have regard to.(e) any written policy guidelines formulated by the council'. While the principles and more specific guidance of the Policy Guideline were given significant consideration, there have been some deviations regarding specific elements of the regulatory options based on the need for effective and practical regulatory measures. The options considered were as follows:

4.3.1 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;

- specific nutrition content claims in Standard 1.2.8 and a small number of related claims in certain commodity standards, such as those that regulate electrolyte drinks and formulated supplementary sports foods, would be retained; and

- Other claims would not be subject to any regulatory control and would be reliant on conformity with voluntary industry practices and fair trading legislation.

4.3.2 Option 2: Develop a New Standard and Guideline(s) for Nutrition, Health and Related Claims

FSANZ would develop a new Standard that would allow food suppliers 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[13] regarding the application of the claim would be included in the Standard; and

- additional interpretive user guides 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:

- prerequisite conditions and wording conditions would be included in the Standard, thus legally enforceable;

- claims criteria (other than certain claims specified in the Code) would be included in a Guideline document, and not legally enforceable; and

- additional interpretive user guides would be developed to facilitate understanding of the requirements in the Standard, provide a pre-approved list of nutrient function statements and provide detail on how the substantiation framework should be applied.

[13] As a point of clarification, the Initial Assessment Report introduced the terminology – claim prerequisites; claim criteria; and claim conditions. For the purposes of the Draft Assessment Report, this terminology will be referred to as pre-requisite conditions (i.e. conditions that a claim must comply with); claims criteria; (i.e. qualifying and disqualifying criteria that allow a specific food product to carry a claim), and wording conditions. See section 5.2.1. for details

The Guideline would operate under a co-regulatory management system, where:

- FSANZ would write the Guideline;
- a management committee would monitor the use of general level claims;
- the management committee would consist of representation from food industry, jurisdictions, consumer groups, public health groups, and FSANZ;
- the management committee could be integrated with the monitoring of claims by the Implementation Sub-Committee watchdog;
- the management committee would have no enforcement power in a legal sense although it could implement other 'quasi' regulatory mechanisms such as various forms of moral suasion;
- the management committee would evaluate the performance of the guideline annually and its report would be publicly available;
- the management of a Guideline could be funded either wholly by Government or jointly by Government and industry; and
- despite the establishment of a management committee, regulatory agencies are likely to be the first point of contact for many enquiries.

4.3.3 Option 3: Develop a New Standard for Nutrition, Health and Related Claims

FSANZ would develop a new Standard that would allow food suppliers 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 user guides 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:

- prerequisite and wording conditions would be included in the Standard, and thus legally enforceable;
- claims criteria (qualifying and disqualifying) would be included in the standard, and thus legally enforceable; and
- additional interpretive user guides would be developed to facilitate understanding of the requirements in the Standard, provide a list of pre-approved claims and provide detail on how the substantiation framework should be applied.

4.4 Rationale for Choice of Options

The regulatory options assessed as part of the Draft Assessment, differ slightly from those originally posed in the Initial Assessment Report. Specifically, the margin of difference between Options 2 and 3 has become smaller. In the Initial Assessment Report, Option 2, with respect to general level claims included:

- prerequisites conditions in the Standard; and
- qualifying and disqualifying criteria and wording conditions in a Guideline.

As part of the Draft Assessment, Option 2, with regard to general level claims incorporates:

- prerequisite conditions and wording conditions in the standard (rather than a guideline); and
- qualifying and disqualifying criteria in a Guideline.

The reason for altering Option 2 as outlined above was that:

1. It is considered essential that the prerequisite conditions (including the need to substantiate the claim, reference the food property and the specific health effect[14] that are the subject of the claim) are met in order to make a claim which is enforceable, truthful and which does not mislead consumers. It is also essential for these conditions to be met in order to ensure consistency across the system and in turn, promote consumer confidence in the system. Therefore it is considered that the prerequisite conditions need to be part of the Standard.

2. The wording conditions, such as the need to incorporate a statement regarding a healthy diet context; the need to reference specific population subgroups if they are the subject of the claim; and the need for appropriate advisory/warning statements, have been specifically referenced in the Policy Guideline. FSANZ considers these are important elements that need to be able to be enforced and therefore they would need to be incorporated in the Standard.

3. Furthermore these aspects also apply to high level claims, which will be regulated in a standard so it is rational to include the requirements together for consistency and ease of use.

As part of the consultation process for the Initial Assessment Report, submitters suggested alternatives to the models proposed, including a model where content claims are regulated in a standard and other general level claims are included in a guideline. Suggestions such as this were considered and while alternative models may have led to different benefits, the regulatory options that have formed the basis of the Draft Assessment were considered to align with the Policy Guideline and address the various risks and benefits of a health claims system that were raised by submitters in response to the Initial Assessment Report and were evident to FSANZ from its evaluation of research on the use of health claims.

The regulation of biomarkers was also raised during the Draft Assessment Report process. The policy guidance included biomarker claims (which it described as indicators of a person's risk of developing a serious disease) as high level claims. Objections were raised by industry to the perceived higher cost of substantiating these claims. Consumer advocates and public health groups supported the regulation of biomarkers as high level claims. The guidance in relation to biomarker maintenance claims was reviewed and upheld by the Ministerial Council in March 2005.

[14] Refer to definition in Draft Standard 1.2.7 at Attachment 1.

FSANZ followed the Ministerial Council guidance on this point because it is considered to reflect consumer understanding of the association of biomarkers with serious disease and their inability to distinguish biomarker maintenance claims and biomarker enhancement claims and thus the need for regulation as high level claims is justified. This is supported by FSANZ's consumer research, which indicated that a biomarker maintenance claim had a high influence on intent to purchase compared to other claims.

4.5 Preferred Regulatory Option

The benefit-cost analysis (refer Attachment 3,) scored each of the regulatory options given against five criteria in a multi-criteria analysis. It is clear from the benefit-cost analysis, that both Options 2 and 3 were given significantly higher scores than Option 1, indicating that the introduction of a new system for the regulation of nutrition and health claims has greater benefit than maintaining the current system.

In the benefit-cost analysis, the Consultant noted there was a marginal difference in scores between Options 2 and 3 and acknowledges that the final result is highly sensitive to small changes in the underlying judgement of the criteria. Multi-criteria analysis is subjective by its nature and therefore the results are debatable according to alternative perspectives. FSANZ has determined that Option 3 is a more appropriate system for the regulation of nutrition and health claims. The rationale for this decision is based on the following:

1. FSANZ considers that potentially there is a greater positive impact from the use of a standard because it will be very difficult to enforce the compliance with disqualifying criteria under a guideline since enforcement will entirely rely on fair trading provisions. Disqualifying criteria were introduced in order to ensure that health claims are restricted to foods with a suitable nutrient profile. Such criteria would not be enforceable under fair trading legislation. The Consultant considers the level of compliance with a guideline will be only marginally lower than for a standard. This is based on available published evidence. While high levels of compliance may be achievable, additional information available to FSANZ indicates there has been an increase in non-compliance with the transitional health claims standard over the past year, with a number of new claims present in the market place. These include products with the word 'health' in relation to the product name, which is currently illegal. Additionally, 25% of industry submitters to the Initial Assessment Report indicated that CoPoNC was ineffectual because of the numerous breaches. With regard to compliance over 40% of submitters noted problems with companies who chose not to follow the guideline, as it was not legally enforceable. Submitters to the Initial Assessment Report commented on the unfair disadvantage arising from the non-compliance of others with the voluntary code. In consultation this point was also made in the context of the non-compliance of some firms leading to the defection of others from compliance. Given these concerns, it was considered that including the criteria in a standard would ensure greater compliance.

2. FSANZ considers there is no significant difference between Options 2 and 3 in terms of the potential for industry to innovate. The Consultant considers that Option 3 gives industry lower potential to innovate. This is based on the assumption that industry would find it easier to make an amendment to a guideline than to a standard. In fact, since changes would only be needed rarely, for example when changes in the science underlying content claims changed, then the impact on innovation would likely be minimal.

Thus FSANZ considers the difference in the impact on opportunities for industry innovation is marginal, since only qualifying and disqualifying criteria rest in the guideline or standard. Furthermore the list of content claims specified in the Standard will not be exhaustive. Only those that FSANZ has considered need to have criteria or conditions on the basis of public health recommendations or to provide adequate consumer information, will be included. Other claims can be made without requiring a change to the Standard.

If additional criteria had been incorporated into the multi-criteria analysis, such as 'ease of use of the regulatory system' and/or 'ease of enforcement of regulatory parameters', it is likely that Option 3 would have scored more highly. Submitters raised the issue of difficulty of having to refer to both a Standard and a guideline under the present arrangements. The same objection would apply to Option 2. Also, there would be a need to consider two separate management systems for updating the guideline and the Standard, involving a duplication of resources. Under Option 2, enforcement would rest on fair trading laws only and would be difficult and unlikely to be pursued rigorously

4.6 Draft Standard

The Draft Standard is presented at Attachment 1. The purpose of this Standard is to regulate nutrition content claims, health claims, and related claims that are endorsements and cause related marketing[15] statements[16], whether appearing on food labels or in advertisements. It also unites a number of requirements relating to claims made under the Code that were previously spread across a number of Standards, such as Standards 1.2.8 and 1.3.2.

A user guide based on the substantiation framework at Attachment 8 will be prepared to guide applicants for approval of high level claims and for suppliers and enforcement agencies on the substantiation requirements for general level health claims. An additional user guide will be produced which provides guidance to industry in using the regulatory model and to enforcers to aid interpretation.

4.7 Impact on other Standards of the Code

There are certain nutrition content claims and health claims already regulated by the Code. As part of the proposed Standard, it is proposed to consolidate these requirements under Standard 1.2.7, except for those for special purpose foods under Part 2.9 of the Code, which will remain unchanged at this stage, pending further review. This will provide a single point of reference for determining Code requirements generally in relation to nutrition content claims and health claims. This is designed to assist industry, government, consumers and public health groups in understanding the legal requirements in relation to these claims, and is consistent with the structure of the Code.

Currently, claims about the presence of certain vitamins or minerals are regulated by Standard 1.3.2. This Standard both provides fortification permissions, and permissions for vitamin or mineral content claims. It is located in Part 1.3 of the Code, which deals with substances added to food. Part 1.2 deals with labelling and other information requirements.

[15] Refer to definition in Draft Standard 1.2.7 at Attachment 1
[16] ibid.

Accordingly, the permissions for vitamin or mineral content claims sit more logically within Part 1.2 than in their current location in Standard 1.3.2 under Part 1.3. For this reason, the drafting moves these claims permissions into Standard 1.2.7. Except for a change to a per serve basis from a per reference quantity, the substance of these permissions has not been changed, though they have been presented in a shorter and simpler format, pending other FSANZ work on fortification matters.

Under present arrangements, certain nutrition claims are regulated by Standard 1.2.8. These include conditions for making claims in relation to:

- Lactose;
- Gluten;
- Polyunsaturated or monounsaturated fatty acid content;
- Omega fatty acid content;
- Low joule; and
- Salt, sodium or potassium.

These conditions have been shifted to Division 3 of the new Draft Standard 1.2.7. The substance of these has not been changed except in the case of lactose claims, though they have been presented in a shorter and simpler format.

A more general nutrition information requirement where claims are made has been included as part of amendments to Standard 1.2.8 (see below). Pre-existing conditions for specific nutrition content claims to include information in a nutrition information panel are now covered by the new, more general requirement and so have been omitted. Other specific requirements that duplicate more general requirements in the drafting have also have been excluded (for example, subclauses 4(a) and 6(a) of Standard 1.3.2). The proposed changes to the regulation of nutrition, health and related claims are outlined in Figure 1.

4.7. Standard 1.2.8

As a result of the consolidation of nutrition content claims and health claims requirements under Standard 1.2.7, the terminology currently used in Standard 1.2.8 may cause confusion.

In particular, the term 'nutrition claim' as currently defined in Standard 1.2.8 differs considerably from the proposed definition of 'nutrition content claim', and it can encompass some of what are now to be called health claims (such as function claims).

In addition, this definition is not consistent with the definition of claim under Standard 1.1.1. Paragraphs (g) to (j) of the definition of nutrition claim expressly exclude a number of references that are mandatory under the Code, and hence that do not constitute claims at any rate.

Accordingly, it is proposed that the definition of nutrition claim is removed from Standard 1.2.8. All references to nutrition claim are replaced with references to nutrition content claim or health claim. This will mean that whenever this type of claim is made, nutrition labelling requirements will be triggered.

A significant change to Standard 1.2.8 is to require certain percentage daily intake information to be included in a nutrition information panel whenever a nutrition content claim or health claim is made. It is generally optional to include percentage daily intake information in a nutrition information panel. However, FSANZ considers that where a nutrition content claim or health claim is made, it is appropriate that the inclusion of percentage daily intake information in relation to energy and any other property that is the subject of the claim becomes mandatory (provided there is a reference value for the property in the Code).

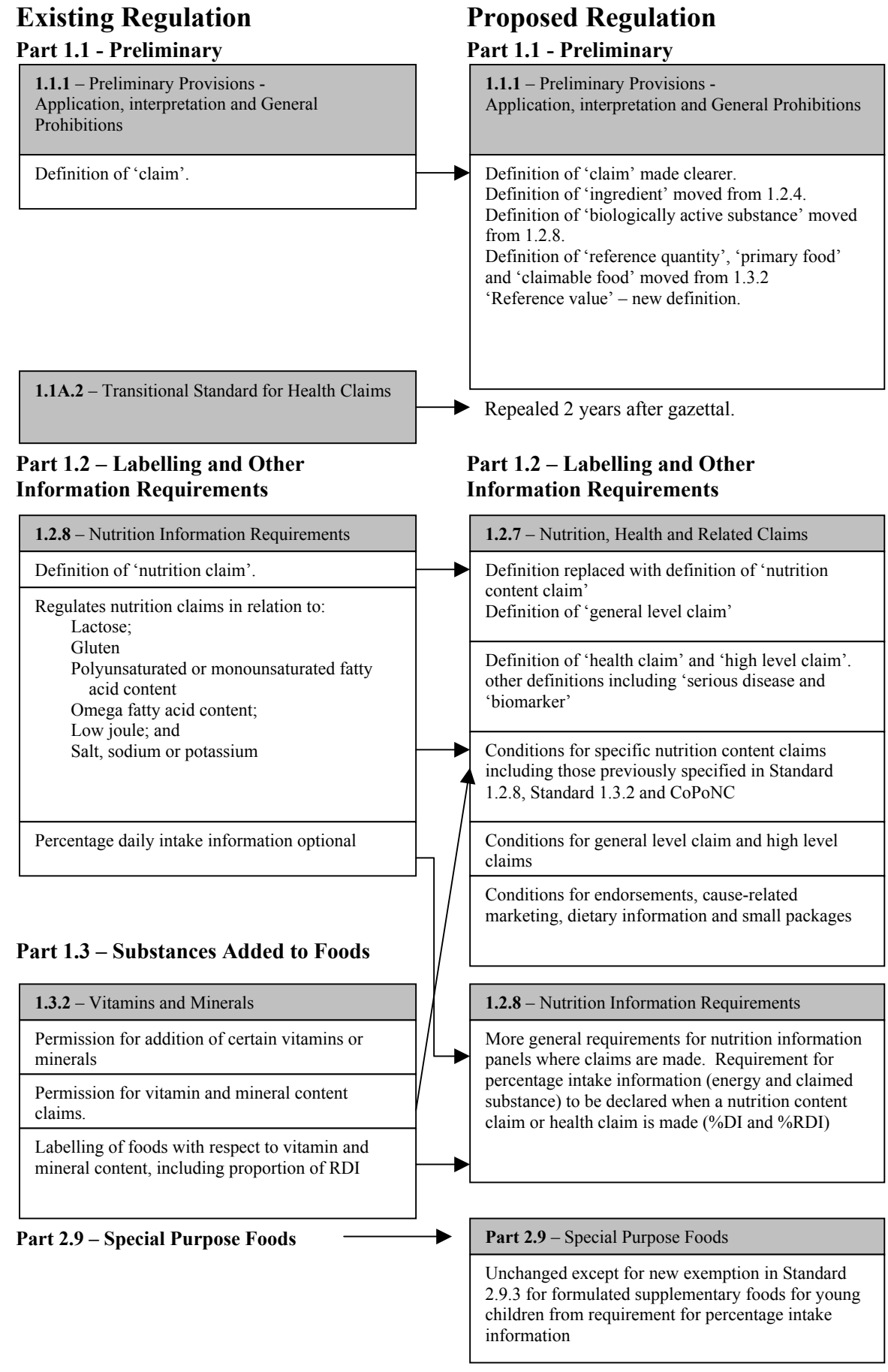

Figure 1: Proposed changes to the Australia New Zealand Foods Standards Code.

4.7.2 Standard 1.3.2

As a consequence of removing the claims requirements from Standard 1.3.2, the remaining Standard now covers permissions for the additions of vitamins or minerals to foods. This brings it into line with the other standards within Part 1.3 of the Code, which deal with substances added to food, rather than labelling requirements.

5. Recommended Approach to Regulation of Nutrition Health and Related Claims

This section summarises the components of the regulatory framework and their application to nutrition and health claims within the context of the preferred regulatory option. This also reflects how FSANZ had regard to the principles in the Policy Guideline in the Draft Standard, what the Draft Standard includes in relation to high level claims and general level claims and why. The Draft Standard at Attachment 1 is the recommended regulatory measure based on this framework. The explanatory notes attached to the Draft Standard (also at Attachment 1), provide further explanation as to the intention and inclusions of the Draft Standard and inter-relationships with other sections of the Code.

The information provided in this section is limited to a description of the outcome, not an analysis of the issues. Attachments 5 and 6 on the regulatory framework for nutrition, health and related claims provide an assessment of the rationale behind the various components of the framework. Attachment 5 describes the generic application of the framework while Attachment 6 addresses specific application to particular claims or food types, and other exceptions to the generic framework.

Submitters and stakeholders' views (sought through targeted consultation processes) are also addressed in each of the relevant topic-specific assessments provided as part of Attachments 5 and 6. An outline of the substantiation processes underpinning the approach to regulation of general level claims and high level claims is given in Section 6, with a full explanation provided at Attachment 8.

Further detail on the evidence base used to develop the framework is found in Section 7 of this report, Attachment 4 . Comments provided by submitters were integral to the development of the framework and are summarised at Attachment 7, with full details accessible through Submitters' Comments.

5.1 Conceptual Framework for Claims

The objective of the FSANZ Conceptual Framework as described at Initial Assessment was to illustrate the key components of the regulatory framework for nutrition, health and related claims and to guide decision-making in relation to the regulatory parameters to be developed for inclusion in the new Standard. The FSANZ Conceptual Framework, underpinned by the Substantiation Framework, consisted of three interrelated elements: the Claims Classification Framework,[17] the FSANZ Claim Descriptors, and the FSANZ Regulatory Model for Nutrition, Health and Related Claims.

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

Figure 2 below is a diagrammatical representation of the FSANZ Conceptual Framework and FSANZ has now further refined the three key elements of this framework, particularly in relation to the FSANZ Claim Descriptors and the components that comprise the FSANZ Regulatory Model, which are discussed below.

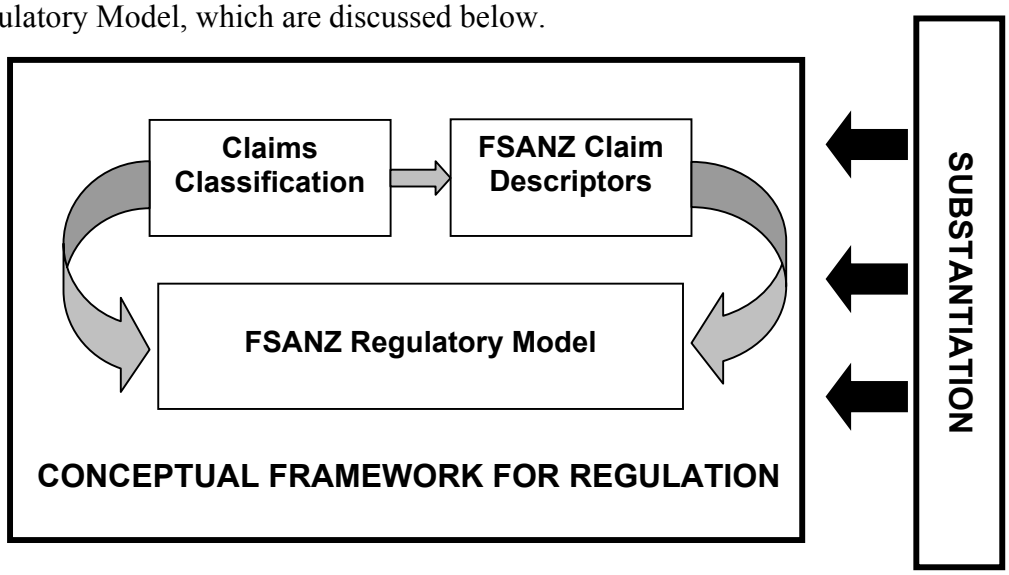

Figure 2: The FSANZ Conceptual Framework for Regulation

The Substantiation Framework is a key component underpinning the FSANZ Conceptual Framework. The Substantiation Framework applies to all claims that fall within the scope of the Claims Classification Framework. It will be a requirement of the new Standard that all nutrition, health and related claims on food labels or in advertising are substantiated by scientific evidence. Further information regarding the Substantiation Framework can be found in Section 6 of this report.

5.2 Claims Classification Framework

The Claims Classification Framework (see Figure 3) comprises two levels of claims – general level claims and high level claims, as stated in the Policy Guideline. Within general level claims there are two types of claims, these are nutrition content claims and general level health claims.

Underpinning the framework are conditions and criteria (refer Section 5.2.2), all of which must be taken into consideration in order to make a nutrition or health claim.

Increasing degree of regulation

Not subject to pre-market assessment and approval.
Manufacturer required to hold evidence in support of the claim.

Subject to pre-market assessment and approval

General Level Claims (Do not reference a serious disease or biomarker of a serious disease)		**High Level Health Claims** (Reference a serious disease or biomarker of a serious disease)
Nutrition Content Claims	**General Level Health Claims**	
Examples: <u>Absolute content claim</u> 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'; this food is low in fat'. <u>Comparative content claim</u> Describe or indicate the presence of a component in a food in comparison to other similar foods. For example 'reduced fat'	Examples: <u>Function claim</u> 'A healthy diet high in calcium from a variety of foods helps build strong bones and teeth. This food is a good source of calcium'. <u>Enhanced Function Claim</u> 'Exercise and a healthy diet high in calcium from a variety of foods contributes to stronger bones. This food is a good source of calcium.' <u>Risk reduction Claim (non-serious disease)</u> 'A healthy diet high in fibre reduces the risk of bowel irregularity.'	Examples: <u>Biomarker Claim</u> 'A healthy diet high in calcium from a variety of foods assists in improving bone mineral density, which has particular importance in women. [Food] is a good source of calcium.' <u>Risk Reduction (ref. to serious disease) claim</u> 'A healthy diet high in calcium and adequate vitamin D from a variety of foods may [reduce the risk of osteoporosis] in women and men aged 65 years and over. [Food] is high in calcium.'

Note – this is not an exhaustive list of examples.

Figure 3: Claims Classification Framework

5.2.1 Definitions and other terminology

In order to understand and implement the Claims Classification Framework a number of terms must be clearly defined. These definitions were derived on the basis of submitters' comments and further consideration by FSANZ since Initial Assessment. Full details of definitions, descriptors and other terms and how they have been developed since Initial Assessment are provided at Attachment 9. The definitions are also found in Draft Standard 1.2.7 at Attachment 1.

In this process the terminology used, such as definition/ descriptors has also been clarified, such that:

Definitions – are those included in the Draft Standard 1.2.7, and are as necessary, further explained in supporting documentation in order to ensure absolute certainty around terminology used within the context of this specific Standard.

Descriptors – are also referred to in the Draft Standard and include those descriptive terms used to qualify a claim, such as, low, high, light etc. These will be discussed in a user guide.

Other terms – are those terms used throughout the Draft Assessment Report and any supporting materials and will be discussed in a user guide for clarity. This includes terms such as guideline, user guide, conditions, criteria, risk reduction etc.

One of the results of the consolidation of claim requirements under Standard 1.2.7 is that various definitions currently located in Standards 1.2.4, 1.2.8 and 1.3.2 and which at present only apply to those standards, will also need to apply to Standard 1.2.7. Accordingly, these definitions will be moved into Standard 1.1.1 and will apply generally across the Code. In this respect the following terms are affected –

- biologically active substance;
- claimable food;
- ingredient;
- primary food; and
- reference quantity.

Furthermore, the fundamental definition of 'claim' under Standard 1.1.1 is proposed to be amended to put it beyond doubt that it encompasses implied claims. By implied claims, we mean claims that direct the attention or thoughts of an average consumer to a matter, though that matter is not expressly stated as part of the claim. As this meaning is consistent with common dictionary definitions, it is not necessary to define 'implied claims' under Standard 1.1.1. This is consistent with general drafting practice in the Code.

5.2.1.1 Changes to Current Terminology Around Nutrition Content Claims and Health Claims

There are two basic types of claims that are encompassed by the Standard. These are:

- Nutrition content claim[18]; and
- Health claim.

A nutrition content claim is a claim about the presence or absence of a property of a food. This is a broad concept designed to capture traditional claims as well as newer or emerging forms of claims. A 'property of a food' covers energy, a nutrient, a component (refer Standard 1.1.1), an ingredient (refer Standard 1.2.4), or any other feature or constituent of the food including a biologically active substance (refer Standard 1.1.1). Properties must, however, have a linkage with a health effect. This is a critical point as otherwise the definition of nutrition content claim has the potential to capture many claims about the content of food that are not related to health or nutrition, which is not the intent of Standard 1.2.7.

The definitions around 'general level claim', 'high level claims', 'health claim' and 'nutrition content claim' will determine the types of claims, both explicit and implicit, that will be captured in the regulatory framework for nutrition, health and related claims.

[18] Previously referred to as 'nutrition claim'

The claims that will not be captured are those claims that do not indicate the presence or absence of a property of food, or claims that do not describe or indicate the relationship between food or a specific component of food and a health effect, as per the definitions for 'nutrition content claim' and 'health claim' respectively. Examples of such claims are *this food is organic*, *Halal food* or *farm fresh*, and other more nebulous terms sometimes referred to as marketing puffery. These types of claims are subject to general fair-trading legislation. FSANZ will provide further detail through the use of examples in relation to statements, representations, graphics, designs etc. that fall in or out of the scope of Standard 1.2.7, and the issue of 'puffery' is also mentioned in Section 9.3 of this Report within the context of advertising.

A health claim goes further than a nutrition content claim, to refer to a relationship between a food, either singly or as a category, or a property of a food, and a health effect. 'Health claim' includes what have been previously referred to as function claims and enhanced function claims – that is, claims that describe the link between a food or a property or component of food and its function in the human body. The definition of 'health effect' is designed to encompass such measures of health status as morbidity, life expectancy, birth defects, cancer incidence or recurrence, obesity rates, and nutritional status. Health effects can be positive or negative and are primarily physiological in basis, including impacts on physical or mental performance. In the context of proposed draft Standard 1.2.7, a 'health claim' now refers to both general level claims (specifically function claims) and high level claims. If a claim does not refer to a serious disease or a biomarker, it is a general level claim. If a claim does refer to a serious disease or a biomarker, it is a high level claim. Accordingly, 'general level claim' and 'high level claim' are defined in Draft Standard 1.2.7, as are 'serious disease' and 'biomarker'.

Draft Standard 1.2.7 at Attachment 1, and Attachment 9, give key definitions integral to the understanding of the Claims Classification Framework and the Regulatory Model (refer Section 5.2.2). The rationale for defining some particular terms is noted below.

The definition of serious disease has been developed with reference to those used in the regulation of therapeutic goods, and is intended to be consistent with (though not identical to) these definitions.

The definition of cause-related marketing statement is needed, as such statements will be subject to separate regulation outside of the claims classification framework.

Similarly, endorsement is defined to encompass health or nutrition-related endorsements, which will be subject to different requirements to other types of claims. This definition is only intended to capture endorsements that have health or nutrition purposes.

Dietary information[19] will not, in general, be regulated under the Standard and needs to be defined in order to be expressly excluded from the requirements of the Standard.

The definition of substantiate has been included to link the requirement for all nutrition and health claims to be substantiated, with the Substantiation Framework to be set out in a guideline (refer Attachment 8).

[19] Referred to at Initial Assessment as 'dietary advice'.

At present, FSANZ lacks legislative power to incorporate documents into food standards without specifying the document as in existence at a certain date. That is, FSANZ cannot incorporate into a food standard a document as amended from time to time. The reason for this is that it would permit the standard to be amended indirectly through amending the document, without the need to go through the standards setting process.

The term health effect has also been adopted and defined since Initial Assessment. This has arisen from the definition of health claim and the need to link the property that is the subject of the claim with an 'outcome'. Neither 'outcome' or 'health outcome' were defined at Initial Assessment.

FSANZ now considers that 'health effect' is a more appropriate and encompassing term that allows for intermediate end points as the subject of claims, as well as the absolute, clear-cut endpoint of the results of dietary intake.

The meaning of 'health effect' therefore includes intermediate endpoints that relate to healthy functioning of the human body such as claims about nutrition function that refer to biochemical or physiological effects. The term also refers to other impacts on health and includes impacts on mental or physical performance associated with particular dietary intake. Because of interest in health maintenance claims, the meaning of 'impact' not only includes dynamic change, but also maintenance.

5.2.1.2 Other Terminology

Within the context of this Report there are other terms that will also benefit from clarification. Some of these are:

User guide

A user guide is an interpretive document that provides guidance on matters set out in a food standard. This may also be referred to as an 'interpretive user guide'.

Guideline

A Guideline is a form of quasi regulation[20]. A Guideline is an alternative to a food standard. It is not legally binding and is not legally enforceable, unless adopted by reference into a standard.

Conditions, refers to:

1. Pre-requisite conditions that a nutrition or health claim must comply with; and
2. Wording conditions including mandatory statements, additional labelling statements, and options around the relative positioning of the various elements.

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

Criteria, refers to:

1. Qualifying criteria – which relate to the nutritional component of the food that is the subject of the claim, and will (in various forms) apply to all claims; and
2. Disqualifying criteria – which relate to the composition of the food bearing the claim, and will apply to some content claims and virtually all general and high level health claims (there are specific exceptions).

For example, in relation to a claim which includes a reference to a particular nutrient the qualifying criteria will directly relate to the amount of the nutrient present in the food (e.g. 'fibre'), while the disqualifying criteria for various claims will relate to other properties of the food such as the amount of saturated fat, total fat, sodium, sugar or energy.

5.2.2 The Regulatory Model

The Regulatory Model for claims takes into account the need to set regulatory parameters to delineate between core requirements that apply to all claims, irrespective of the classification, and specific requirements triggered by the position of the claim within the Claims Classification Framework. In order to be effective Standard 1.2.7 will firstly establish a general prohibition on the use of nutrition and health claims – unless these regulatory parameters are met, and then incorporate a 'step-up' approach in regulation reflective of the degree of risk.

The regulatory parameters are:

1. **Pre-requisite conditions** to qualify as a nutrition or health related claim;
2. **Criteria** including qualifying criteria and where applicable, disqualifying criteria; and
3. **Wording conditions** in the form of essential elements of the claim, including additional statements in some cases to clarify the context of the claim.

These parameters are reflected below in Figure 4.

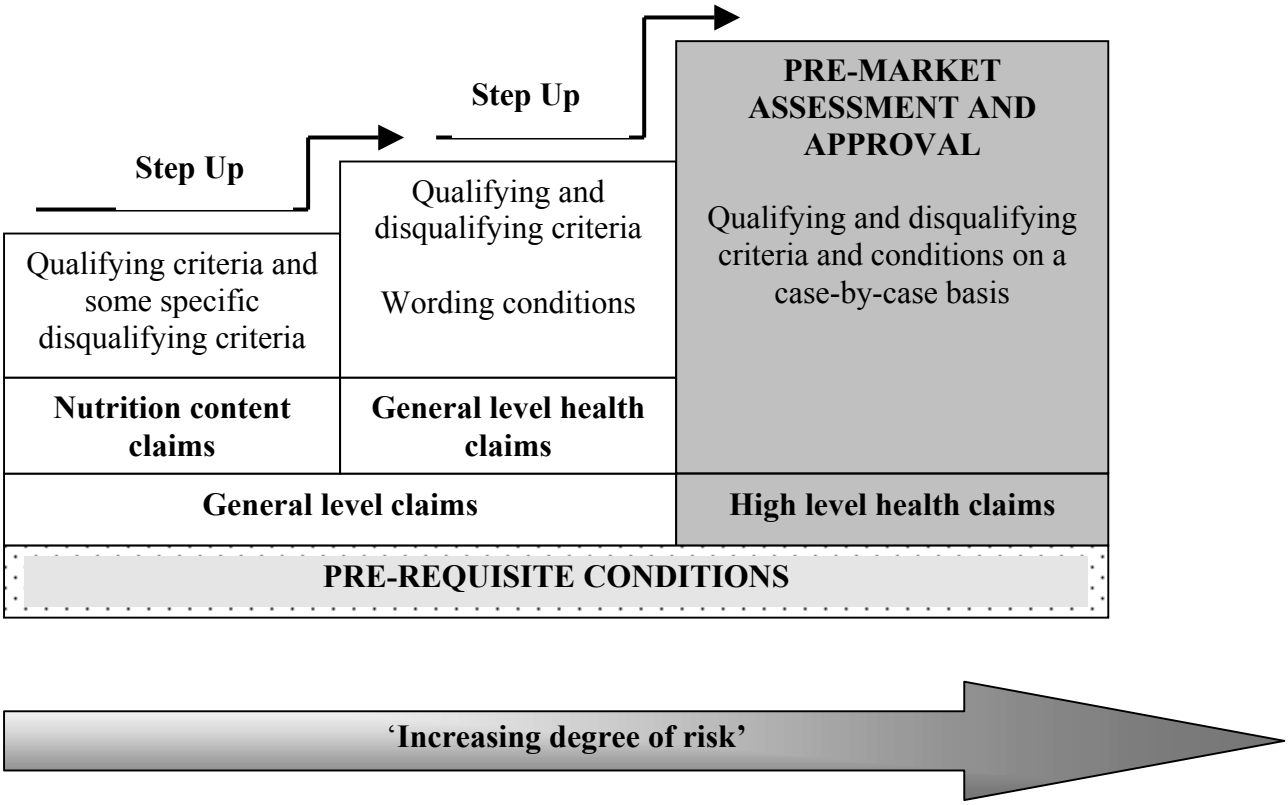

Figure 4: The Regulatory Model

Underpinning this Regulatory Model are the pre-requisite conditions that directly relate to the definitions of nutrition content claims and health claims.

Pre-requisite Conditions

Nutrition and health claims must:

- Be substantiated according to the substantiation framework;
- Make reference to a specific property[21,22] of the food; and
- Other than nutrition content claims, make reference to a specific health effect.

5.2.3 Application of the Regulatory Model

In line with clause 13 of Standard 1.1.1, these requirements apply where the claims are made in relation to food for sale, whether on the label of the food or in advertising.

[21] Where 'property of the food' means –
energy; or
a nutrient; or
a component; or
an ingredient; or
any other feature or constituent of the food that is associated with a health effect, including a biologically active substance.

[22] The Draft Standard allows for exemption to this where the substantiation concludes it is not scientifically practical to identify the specific property, in which case a class of properties, or the whole food may be referred to.

Labelling requirements under this Regulatory Model apply in two ways:

1. Foods for retail sale (that is, sale to the public) or for catering purposes must be labelled in compliance with the requirements under Standard 1.2.7.

2. A wholesale purchaser or relevant authority can request information from a supplier to enable the purchaser to comply with the labelling requirements under Standard 1.2.7.

Where food is not for sale to the public or not for catering purposes, then the labelling requirements under this Model do not generally apply. For example, where a supplier of ingredients to food manufacturers makes claims to their customers, this in itself does not trigger Standard 1.2.7 labelling requirements. This approach flows from the general application of all labelling requirements under the Code, as set out in Standard 1.2.1.

'Label' is defined in Standard 1.1.1, as meaning 'any tag, brand, mark or statement in writing or any representation or design or descriptive matter on or attached to or used in connection with or accompanying any food or package'. 'Advertisement' is defined separately in food legislation, and broadly captures '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 of food.' (Subsection 2(1), Annex A, Model Food Act).

Given the breadth of these definitions, the following types of material are examples of what would be considered labelling or advertising:

- leaflets beside displays of food products;
- panels or posters displayed in shops;
- shelf wobblers; and
- all forms of advertising, including through print, radio, television, and Internet, whether presented as pure advertising or as 'advertorial' material.

In addition, the definition of 'claim' includes the concept of a claim having to be made in relation to a food or property of a food. Hence, the prohibition on making nutrition content claims or health claims does not need to state that these claims are made 'in relation to a food or property of a food', as this is intrinsic to a claim, as defined in Standard 1.1.1. Similarly, the definitions of endorsement[23] and cause related marketing statement make it clear that these must relate to food.

In a small number of cases, nutrition content claims or health claims are permitted under pre-existing provisions of the Code. In particular, Part 2.9 of the Code permit some health claims to be made in relation to foods. Subclause 2(1) of Standard 1.2.7 is drafted to allow these permissions to continue to operate.

Subclause 2(2) of Standard 1.2.7 is designed to prohibit therapeutic claims in relation to food. It reflects the definition of therapeutic use under the *Therapeutic Goods Act 1989*, in particular, paragraph (a) of that definition.

[23] Refer to definition in Draft Standard 1.2.7 at Attachment 1

However, it does not encompass paragraph (b) of that definition, which refers to influencing, inhibiting or modifying a physiological process in persons. Although appropriate for therapeutic goods, paragraph (b) is not appropriate for food, as in the context of food it may be seen as capturing many health claims. Similarly, the other paragraphs of the definition of therapeutic use under the *Therapeutic Goods Act 1989* are not appropriate in the context of food and therefore have not been included in subclause 2(2).

There is currently one therapeutic claim permitted under the Code, in relation to electrolyte drinks and the prevention or treatment of mild dehydration. This is the reason for the exemption for subclause 8(3) of Standard 2.6.2 from subclause 2(2) of Standard 1.2.7.

There are also a number of claims or other information that are not readily identified as, or maybe confused with, nutrition content or health claims. This includes related claims, such as endorsements and cause related marketing statements; and information such as dietary information (referred to at Initial Assessment as 'dietary advice') and trade marks. Draft Standard 1.2.7 has been drafted in such a way that related claims are captured and have specific provisions around them, and other more general information is explicitly excluded.

This also raises the issue of 'implied claims' including those represented through, for example, graphics, key words, endorsements, performance or well-being claims, etc. It is proposed that the approach outlined will assist in filtering out or otherwise addressing such claims. It will do this by putting in place a broad prohibition on nutrition or health claims including implied claims and then only permitting the use of those claims which include reference to a specific property (or whole food if applicable) and health effect. Thus, non-specific claims, including implied claims, will be caught by the general prohibition, and will not be able to meet the claim prerequisite conditions. Accordingly, they will be prohibited.

There are certain types of claims that are not considered within the Claims Classification Framework however, they have specific conditions around their use in order to clarify their status within the proposed Standard.

5.2.3.1 Endorsements

Some endorsements[24] from independent, non-profit health organisations in current use have been assessed by FSANZ and those that have been pre-approved will be excluded from regulation by the draft Standard under subclause 2(2). Others will be considered prior to gazetting[25].

Endorsements that are nutrition/health-related arising after the implementation of the Standard will need to comply with specific requirements under the Standard.

5.2.3.2 Cause-related marketing

Cause-related marketing statements on foods are not nutrition or health claims and should not be construed as such.

[24] Refer to Draft Standard 1.2.7 at Attachment 1 for definition

[25] Information on programs to be considered for pre-approval should be submitted to FSANZ. See information on page 4

In order to avoid misleading consumers it is recommended at Draft Assessment that these statements that in particular mention a serious disease be required to be accompanied by a disclaimer, for example: *[Supplier's name] makes no claims in relation to Food Y being beneficial for managing [serious disease]*.

5.2.3.4 Dietary Information

Broadly applicable dietary information that does not link a specific brand of food to a health effect will not, in general, be regulated under the Standard. The circumstances in which some conditions will apply to the use of dietary information is where it is used on a food label or in food advertising (thereby linking that brand of food to the information), in which case it must be reflective of a general level claim or high level claim made in relation to the product. The exception to this is where the dietary information relates to moderating consumption of the food, in which case an associated claim is not required. For example, statements in relation to responsible alcohol consumption.

5.2.3.5 Trademarks

In order to ensure the Standard has complete coverage of nutrition content claims, health claims, endorsements and cause-related marketing statements, the Standard will apply to these even where they are trade marked and thus subject to separate regulation. The exclusion of trademarks from the Standard would provide a clear loophole enabling free use of what would otherwise be regulated in accordance with the Standard. This would have obvious potential to undermine the entire Standard.

However, only those trade marks registered after the commencement of the Standard will be subject to the Standard. Legal problems prevent the application of the Standard to trade marks registered before the commencement of the Standard.

5.2.3.6 Ineligible foods

There are also certain foods that are excluded from making health claims hence the Regulatory Model will not apply to these foods. The Draft Standard sets out the general rule that alcohol and infant formula must not have general or high level claims made in relation to them unless specifically permitted.

As special purpose foods, infant formula and infant foods are regulated under Part 2.9 of the Code. Specific claim permissions are already included in that Part for such foods as appropriate – for example, where infant formula is specifically formulated for infants with particular diseases.

In relation to alcohol, claims that refer to the energy content and/or alcohol content may continue to be made. The requirements for low alcohol, non-alcoholic and non-intoxicating claims under the Standard 2.7.1 –Labelling of Alcoholic Beverages and Food Containing Alcohol, remain unchanged.

5.2.4 Integration of the Regulatory Model

Claim definitions and the regulatory parameters (i.e. the pre-requisite conditions, specific criteria, and wording conditions) work together to identify and regulate nutrition, health and related claims. Figure 5 provides a diagrammatic representation of this integration, depicted as a series of 'filters'. Further detail on this conceptual approach can be found in Attachment 5, Chapter 1.

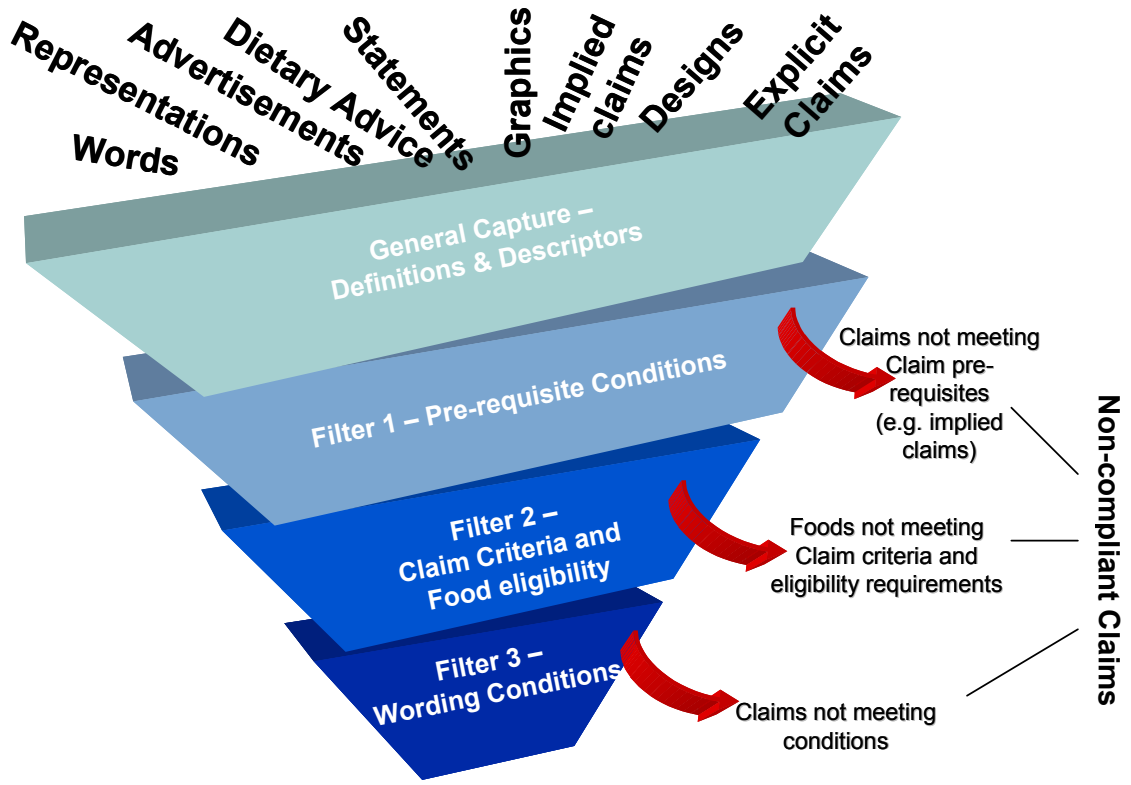

Figure 5: Application of the Regulatory Model

5.3 The Regulatory Framework for General Level Claims

Within the general level claim classification, FSANZ has described two categories of claims; nutrition content claims and general level health claims[26]. FSANZ considers it is appropriate that some aspects of their regulation differ in terms of the stringency of regulation applied. In particular, a different approach to specifying criteria and wording conditions 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. This concept is described in the Policy Guideline (refer Attachment 2) in relation to the categorisation of a claim where it is proposed that claims offering a higher 'degree of promise' to the consumer should be more highly regulated.

[26] For clarity, it should be noted that the drafting of Standard 1.2.7 does not use the general level health claim terminology but refers to general level health claims as 'general level claims, other than nutrition content claims'.

Notwithstanding the differences between nutrition content claims and general level health claims, there are some aspects of the regulatory framework that are consistent between the two types of claims because of their general level classification. These are:

- nutrition content claims and general level health claims will not be subject to pre-market assessment and approval by FSANZ because they do not reference a serious disease or a biomarker of a serious disease; and

- nutrition content claims and general level health claims will nonetheless be required to be scientifically substantiated. This requires the supplier to assess the evidence supporting the claim prior to market, holding this evidence and producing it at the request of enforcement officials.

In a small number of cases, nutrition content claims or health claims are permitted under pre-existing provisions of the Code. In particular, Standard 2.9.3 – Formulated Meal Replacements and Standard 2.9.4 – Formulated Supplementary Sports Foods, permit some health claims to be made in relation to foods regulated under those Standards.

Draft Standard 1.2.7 has been drafted to include a general prohibition on the use of claims in relation to these foods but will allow the current permissions in Standard 2.9.3 and 2.9.4 to continue to operate.

The following sections discuss the criteria and conditions that apply specifically to nutrition content claims (Section 5.3.1) and general level health claims (Section 5.3.2).

5.3.1 Nutrition content claims

Nutrition content claims include claims about energy, nutrients, biologically active substances, and other aspects of food associated with health effects as specified in the draft Standard. Below is a short discussion on the two main types of nutrition content claims, namely: nutrient content claims and claims about biologically active substances. Other types of nutrition content claims, such as wholegrain claims and claims in relation to Glycaemic Index and Glycaemic Load are discussed in Attachment 6.

5.3.1.1 Nutrient Content Claims

FSANZ has evaluated which content claims should have defined criteria, on the basis of a risk management approach which takes account of public health recommendations and the need for consumer information. Further details of this approach can be found at Attachment 5 and Attachment 6.

The recommended criteria for nutrient content claims have been based on those presently specified in Standard 1.2.8 and CoPoNC, with some modifications to update values on the basis of more recent public health advice, to improve consistency in approach and to take account of stakeholder consultations and submissions. Claims considered warranting risk management through the specification of criteria will be included in the Draft Standard. Other claims not referred to in the Draft Standard may be used providing they are not misleading.

Nutrient content claims will be subject to qualifying criteria in order to ensure the presence of a minimum or maximum amount of the claimed nutrient/energy in the food. It is important to note at this point in time that these newly developed criteria only relate to the macronutrients and sodium. Criteria for claims around vitamins and minerals are addressed in the Code under Standard 1.3.2 and this will remain the case until further review pending the publication of the new Nutrient Reference Values (refer Section 11.2), although the claims themselves will be relocated into the draft Standard. Thus until this review occurs, content claims in relation to minerals and vitamins will remain subject to the current requirements (presently located in Standard 1.3.2), which are based on a system of 'claimable foods', with the exception that the foods must now attain the qualifying criteria per serve rather than per reference value.

Nutrient content claims will not be generically[27] subject to disqualifying criteria. FSANZ considers that to overlay any further requirements in relation to the foods able to carry the claims would be overly prescriptive as they are simply statements of 'fact' (i.e. they do not specify a particular health outcome or effect). However, FSANZ proposes to introduce new requirements for the expression of percentage daily intake (%DI) values for all products carrying content and health claims. These will provide information, albeit limited, on which consumers can make a partial assessment of their overall contribution of the food to a healthy diet. This provision is particularly important for content claims where in the majority of cases the food vehicle is not otherwise addressed in terms of 'healthfulness', such as, by use of disqualifying criteria.

However, specific disqualifying criteria for claims in relation to certain nutrients do apply due to the particular nature of the claim. For example, currently under Standard 1.2.8, omega fatty acid claims have specific disqualifying criteria around the saturated fat and *trans* fat content of the food.

5.3.1.2 Biologically Active Substances

Biologically active substances refer to dietary substances that are not traditionally recognised as 'nutrients', but which are associated with health effects (for example, flavonoids, carotenoids, co-enzymes, phytoestrogens). At this point in time these substances do not have officially recommended reference intakes. Criteria as applied to 'source' and 'good source' content claims for nutrients i.e. based on a percentage of an officially recognised nutrient reference value, are therefore not similarly applicable to content claims for biologically active substances.

However, in order to ensure that a meaningful amount of the biologically active substance underpins the claim, the qualifying criterion of '10%' of nominated 'per day reference intake' per serve basis will apply to claims around biologically active substances. That is, 10% of a self nominated 'per day intake' of the substantiated efficacious 'per day' amount will need to be present in the food. It is recognised that the 'per day' amount may differ according to the claim, and because it will be self nominated, potentially between products. However, this information will be required on the label and thus be transparent to consumers.

[27] Some content claims have specific disqualifying criteria due to the nature of the property being claimed. Details are provided at Attachment 6.

Furthermore, FSANZ recommends at Draft Assessment that claims can only be made to the effect that a food 'contains' a biologically active substance and should not characterise the level of the substance in that food as being in greater amounts, such as, 'good source', or 'rich in'. The amount of the substance per serving is to be stated in the Nutrition Information Panel.

Recommendations in relation to specific nutrition content claims are presented in Attachment 6, together with the rationale for the recommended criteria and conditions.

5.3.2 General Level Health Claims

General level health claims are also managed within the Regulatory Framework according to qualifying and disqualifying criteria and wording conditions.

5.3.2.1 Criteria – Qualifying and Disqualifying

General level health claims will be subject to qualifying criteria based on the property of the food, which will be the criteria established for nutrition content claims.

In order to make a general level health claim in relation to nutrients where increased consumption is recommended (i.e. 'risk-reducing nutrients' such as vitamins and minerals, proteins, omega-3 fatty acids and fibre), the minimum requirement will be to meet the relevant 'source of' content claim criteria, or in the case of general level health claims for cholesterol, omega-6, 9 fatty acids or poly/monounsaturated fatty acids, the criteria currently specified in Standard 1.2.8.

General level health claims in relation to nutrients where decreased consumption is recommended (i.e. risk increasing nutrients such as, fat, saturated fat, sodium, total sugars) will be required to meet the relevant 'low' content claim criteria. Foods meeting 'reduced' content claims criteria will not be eligible to make general level health claims, unless this amount is also commensurate with the amount for a 'low' claim.

General level health claims are a 'step-up' from content claims by articulating an anticipated health effect in relation to the property of the food. Therefore, in accordance with the overarching framework, generic disqualifying criteria will also apply to disqualify foods with higher levels of 'risk increasing nutrients' i.e., saturated fat, sodium and total sugars (where total sugars is used as a *de facto* measure of nutrient density). That is, food eligibility conditions will be applied in order to avoid the promotion, through the use of general level health claims, of certain categories of foods that are inconsistent with national dietary guidelines.

The disqualifying criteria for general level health claims proposed by FSANZ at draft assessment are greater than or equal to:

- sodium – 325 mg/serve;
- saturated fat – 4 g/serve; and
- total sugars – 16 g/serve

Discussion on the development of these criteria can be found at Attachment 5.

5.3.2.2 Exceptions

There are some exceptions to application of the above disqualifying criteria. FSANZ proposes that the generic disqualifying criteria will not apply to general level health claims that refer to gluten and lactose. This is because consumers who rely on these products should be able to choose from a full range of suitable products (based on the need to avoid undesirable reactions to chemical sensitivities), rather than being restricted to choosing from only those that meet nutritional criteria based on different and additional objectives (i.e. the 'healthy' diet). It is therefore important that messages about foods meeting the related qualifying criteria as currently specified in Standard 1.2.8 (i.e. 'low lactose', 'lactose free' or 'lactose reduced' and 'gluten free' or 'low gluten') are not restricted by the generic disqualifying criteria applicable to other general level health claims.

FSANZ also considers it is not necessary to apply the generic disqualifying criteria where general level health claims are made in relation to infant foods because of compositional requirements that are specified in clause 2 of Standard 2.9.2. In particular, these compositional requirements take into account sugars and salt, two of the three risk increasing nutrients for generic disqualifying criteria. In addition, the Dietary Guidelines for Children and Adolescents in Australia specify that low fat diets are not suitable for infants and therefore, imposing a saturated fat disqualifier around the use of general level health claims in relation to infant foods is not appropriate.

Vitamins and minerals covered under Standard 1.3.2 of the Code present a particular case in relation to disqualifying criteria. These nutrients are subject to 'claimable food' criteria, which in essence, serves the same purpose as disqualifying criteria. At the time of developing the concept of 'claimable foods', FSANZ devised the above definition to act as a criterion that ensured claims made in relation to vitamins and minerals were placed only on foods consistent with healthy eating guidelines. Therefore, the 'claimable food' criterion is acting in a similar way to the generic disqualifying criteria that have been developed for general level health claims.

Whilst there are merits in having a consistent approach to the application of disqualifiers across all general level health claims, including claims in relation to vitamins and minerals, FSANZ considers that this is an issue that would be more appropriately considered once the new Nutrient Reference Values are adopted (this matter is discussed further in Section 11.2). At this time there is likely to be a review of several standards in the Code which are underpinned by nutrient reference values, including Standard 1.3.2 and FSANZ will need to consider general level health claims (and high level claims) made in relation to vitamins and minerals and determine whether the 'claimable food' criterion should be replaced by the generic disqualifying criteria. Subsequently for the time being, general level health claims in relation to vitamins and minerals will not be subject to generic disqualifying criteria but will be required to meet the claimable food criterion.

5.3.2.3 Ineligible Foods

FSANZ has also considered the appropriateness of prohibiting certain levels of claims (i.e. nutrition content claims, general level health claims and high level claims) on particular categories of foods, largely guided by the examples of 'alcohol' and 'baby foods' provided in the Policy Guideline.

Given the recognised social issues regarding the abuse of alcoholic beverages, FSANZ also considers that claims that attribute a health benefit are not appropriate on foods regulated in Part 2.7 of the Code and therefore a prohibition on the use of general level health claims and high level claims is warranted and is reflected as such in Draft Standard 1.2.7. However, claims in relation to alcohol and energy content on alcoholic beverages and food containing alcohol will continue to be permitted. These claims, particularly low alcohol claims, have been established for some time, and serve a useful purpose in promoting responsible alcohol consumption.

It should be noted that the Policy Guideline refers to 'baby foods' and 'infant foods', somewhat interchangeably. Within the context of food regulation and for purposes of clarity, FSANZ has interpreted these terms to mean reference to infant formula products, as standardised under Standard 2.9.1. Currently, representations made in relation to the nutritional composition of infant formula are prohibited unless expressly permitted in Standard 2.9.1. As nutrition content claims may act against policies to promote breast feeding, FSANZ considers there is no justification to relax the current requirements of Standard 2.9.1.

On the other hand, FSANZ sees no reason to discontinue claims in relation to certain vitamins and minerals that are currently permitted (by virtue of not being prohibited) by Standard 2.9.2 – Infant Foods, this includes function claims. As discussed above, general level health claims that are permitted on infant foods will not be subject to generic disqualifying criteria. However, all permitted general level claims made in relation to infant foods will be required to meet conditions around wording set out in Standard 1.2.7.

5.3.2.4 Summary of recommendations for regulation of general level health claims

In summary, the approach to the regulation of general level health claims at Draft Assessment is as follows:

- Qualifying criteria for general level health claims will be based on content claim criteria;

- Generic Disqualifying Criteria will be applied to general level health claims. Foods which will be disqualified from carrying claims will have greater than or equal to:

    - sodium – 325 mg/serve
    - saturated fat – 4 g/serve
    - total sugars – 16 g/serve;

- general level health claims, where the property of the food relates to low/free gluten or low/free/reduced lactose, are exempt from meeting the generic disqualifying criteria;

- general level health claims in relation to Infant foods are exempt from meeting disqualifying criteria;

- general level health claims in relation to vitamins and minerals will be required to meet the existing criterion of 'claimable food' rather than generic disqualifying criteria until such time that a review of Standard 1.3.2 takes place; and

- the following categories of foods are not eligible to make general level health claims:

    - alcoholic beverages as per standard 2.7.1; and
    - infant formula products as standardised by Standard 2.9.1.

Appendix 5.2 at Attachment 5 provides a matrix of qualifying and disqualifying criteria relating to nutrient content claims and general level health claims.

5.3.3 Wording Conditions for Claims

General wording conditions relate to wording requirements that are applicable to all claims, with the exception of certain types of related claims and other information. The exceptions include:

- pre-approved endorsements;
- cause-related marketing (specific requirements apply); and
- trade marks.

This section is written in the context of general level health claims however, most of the principles discussed here also relate to the wording conditions that will be applied to high level claims on a case-by-case basis as they are approved. Section 6.3.3 of this Report identifies the particular criteria and conditions relating to the high level claims that have been pre-approved by FSANZ.

Nutrition content claims state only the 'property of the food', and need to meet any compositional criteria for use of descriptor terms such as, 'low fat' or 'high fibre' etc. Once a health effect is also stated, the claim becomes a general level or high level claim, and depending on the nature of the stated health effect, will need to meet further requirements as outlined below and summarised in Table 1a.

5.3.3.1 Property of Food and Specific Benefit

Some wording conditions, proposed to be mandatory elements of health claims, have already been determined through the development of the 'FSANZ claim pre-requisites' (refer Section 5.2.2), a strategy designed to minimise the use of implied claims.

These are that the claim must state:

- the property of the food[28]; and
- the specific health effect in relation to the property of the food.

[28] Where 'property of the food' means – means energy, a nutrient, or a biologically active substance, or –
(a) a component; or
(b) an ingredient; or
(c) any other feature or constituent of the food;
that is associated with a health effect, including glycaemic index and glycaemic load.

These pre-requisites are implemented to provide consumers with adequate information to make an informed choice and to assist in preventing misleading or deceptive claims. For simplicity and consistency the qualifying criteria for general level health claims are based on the qualifying criteria for nutrition content claims. The 'property of the food' for general level health claims is therefore expressed in terms of the respective nutrition content claim, for example 'low in saturated fat,' 'low in sugar'; 'good source of vitamin C' (subject to any additional provisions around health claims). This links the general level health claim wording requirement to the corresponding qualifying criteria for the nutrition content claim.

5.3.3.2 Percentage Daily Intake

When a content claim is made there will be a requirement for provision of percentage daily intake (%DI) of energy and the claimed property (if there is a reference value for it in the Code) in the nutrition information panel. This represents a change from the current requirements under Standard 1.2.8 where %DI declaration is voluntary, but if used, all respective macronutrients and sodium must be declared. The %DI declaration will now be mandatory in the presence of a content claim, but only for energy and the claimed property. Although more prescriptive insofar as it is now mandatory, this change is less onerous than current requirements where all six %DI values must be declared when %DI values are used. FSANZ is also recommending in this Report that the mandatory statement be reduced from:

Percentage Daily Intakes are based on an average adult diet of 8700 kJ. Your daily intakes may be higher or lower depending on your energy needs to:

Percentage Daily Intakes are […an asterisk or alternate marker may be used] *based on an average adult diet of 8700 kJ.*

This is also less onerous than the current requirements.

Furthermore, the %DI value is calculated from values already required for the nutrition information panel. Therefore, although this will require a labelling change, no further analytical work is required.

This change also provides greater consistency within the nutrition information panel, as vitamins and minerals are already required under Standard 1.3.2 to make a similar declaration in the form of % Recommended Dietary Intake (or alternate measure) declarations.

This requirement is being recommended to provide extra information to consumers from which they can make a value judgement as to the nutritional contribution of the food to the overall diet. %DI values can assist consumers in understanding the relationship between the nutrient content in a serving of the product and recommended intakes of particular nutrients, and can also be used to make comparisons between products. FSANZ considers this is particularly important for content claims where in the majority of cases the food vehicle is not otherwise addressed in terms of 'healthfulness' by the use of disqualifying criteria. Disqualifying criteria could be applied to content claims instead of the recommended %DI approach however, this would be a significantly more prescriptive approach.

The %DI requirement will apply in all cases except: alcoholic beverages (because they are exempt from the requirements of a nutrition information panel); and infant foods and infant formulae because the %DI values used relate to adults and, as such, are inappropriate for foods targeted specifically to infants. Division 4 of Standard 2.9.3 (Formulated Supplementary Food for Young Children) will also be exempted for the same reason.

5.3.3.3 Total Dietary Context

FSANZ has interpreted the reference in the Policy Guideline to the *context of the appropriate total diet (that must be described)* as indicating that the claim should communicate that the specific health effect is achieved from consuming a healthy diet that has adequate amounts of the claimed nutrient (or property of the food) from a variety of foods, so that consumers do not perceive that the claimed food alone will provide the specific health effect.

As there is evidence to suggest that the term 'total diet' is not well understood by consumers, the drafting of the Standard should relate to a 'varied and healthy diet' context to ensure suppliers use terminology to this effect instead of 'total diet'. As the substantiation requirements for general level health claims are based on the total diet-health relationship, it is also important to emphasise this relationship in the claim.

For example, if a supplier makes a claim about strong bones and teeth (specific health effect) and calcium (property of the food related to the specific health effect), the claim could be worded in the following way to convey the total diet context:

A healthy diet consisting of a variety of foods rich in calcium helps to achieve strong bones and teeth. Golden Valley Milk is a good source of calcium.

The type of food bearing the claim also determines the way in which the health context should be phrased. This is particularly relevant in the case of claims on infant foods where the variety of foods will be more limited, especially at the time an infant is weaning from breast milk or formulae to solid foods. Another example is in relation to some biologically active substances that may be functional ingredients with limited application, or naturally occurring substances that are not widely present in the normal food supply. In these cases reference to a 'variety of foods' may not be applicable and more suitable words would need to be used. This aspect is addressed in the drafting by requiring that dietary context statements be appropriate to the type of food and specific health effect claimed.

5.3.3.4 Additional or Different Wording Requirements

Additional or different wording conditions are those that may apply only to certain types of claims depending on the specific health effect claimed, or the food that bears the claim. Additional information includes considerations around specific population groups that the claim refers to, and advisory or warning statements.

FSANZ proposes that Standard 1.2.7 includes a wording condition that requires the specific population subgroup to be included as part of the claim where the evidence supports that the specific health effect cannot be attributed to the general population but to specific population subgroups only.

Different requirements may also be triggered by the type of claim, specifically: weight management claims, claims about biologically active substances, cause related marketing claims, dietary interaction claims, and particular foods including alcoholic beverages, infant foods and infant formulae. These particular claims are discussed further below in Section 5.5 However the following points summarise the respective wording conditions:

- as weight management is subject to not only dietary behaviour but also the need for exercise, it is proposed that claims in this respect also should refer to the importance of regular exercise;

- as cause related marketing claims will not be subject to the other conditions described (as they are not health claims), those that mention a serious disease will require a disclaimer regarding their lack of association with health effects;

- dietary interaction claims are inherently different by virtue of the additional statement that relates the intermediary step[29];

- general level health claims about biologically active substances will need to have an additional statement stating the self-recommended daily amount of the substance that provides the substantiated health effect, as there are no nationally recognised reference values for recommended intake; and

- claims about alcoholic beverages, infant foods and infant formula have particular restrictions due to the nature of the foods. Infant formulae and infant foods are also subject to specific provisions within Parts 2.9.1 and 2.9.2 of the Code respectively.

The wording conditions discussed above for general level claims, and for high level claims discussed below in Section 5.4, are summarised below in Table 1a.

5.3.3.5 Positioning of Claim Elements

If all the above elements are presented together, the claim itself together with additional warning or advisory statements may mean the total message becomes long and wordy. This raises issues of space limitations on labels, and of complexity and impact for consumers. It also raises the issue of whether this results in a reduced flexibility for suppliers' use of claims to promote products.

It is important that the objective of educating consumers on healthier food choices and the benefits of maintaining a healthy diet are maintained through the use of health claims on foods. This enables consumers to make informed choices and relate the information to their own health status or health concerns. This context may be lost if the essential elements of the claim were permitted to be separated.

FSANZ recognises that there needs to be a balance between ensuring the full context of the claim is provided, and that the information has an effective impact for consumers. Whilst FSANZ considers that the essential elements of the claim should always be stated together, the following options allow suppliers to provide information in a location on the package that is separate to the claim in its entirety.

[29] Refer to Section 5.5.1 of this Report for discussion of dietary interaction claims

It is proposed that suppliers will have the option to have shorter statements on the front of packages, so long as the health claim in its entirety, and any associated warning or advisory statements, are stated elsewhere on the package and consumers are directed to this.

Both general level health claims and high level claims must communicate all essential elements together and display these in one place on the label. There is also the option to state, in addition, just some of the elements on the front of the package i.e.:

(a) the property of the food; or
(b) the property of the food and the specific health effect;

so long as there is a statement (message device) in conjunction with either a) or b) that directs the consumer to the health claim stated in its entirety elsewhere on the package of food.

This option allows manufactures to have 'short punchy' claim elements on the front of the package such as:

- *Good Source of Calcium*; or
- *Rich in calcium for strong bones and teeth*.

These claim elements would be accompanied by an additional statement to direct the consumer to the health claim in its entirety, such as *see back of pack.*

In this case, the back of the package would have the entire health claim with all essential claim elements:

A healthy diet consisting of a variety of foods rich in calcium helps to achieve strong bones and teeth. Golden Valley Milk is a good source of calcium.

FSANZ considers that the directive statement that refers the consumer to the claim in its entirety would need to be positioned near the claim element in order for it to be noticed by the consumer.

5.3.3.6 Small Packages

Special consideration has been given to packages with limited labelling space, that is, less than 100 sq cm, however, there is still a need for essential elements of information to be provided to consumers.

The following approach in respect of claims on labels is recommended at Draft Assessment:

For content claims:

- *Property of food* must be stated as for the generic content claim requirements;
- for no added sugar or salt content claims, the additional statement about naturally occurring sugar or sodium will still be required;
- claims about lactose must still include the reference to lactose and galactose levels;
- where required, advisory or warning statements must be made in conjunction with the claim; and

- requirements for small packages as per Clause 8 of Standard 1.2.8 (i.e., an abbreviated Nutrition Information Panel) apply, including the new requirement for %DI.

For health claims:

As per requirements for content claims, plus,

- the health claim must state the specific health effect;
- no splitting of claims;
- where required, advisory or warning statements must be made in conjunction with the claim;
- for biologically active substance claims, the additional requirement for the substantiated daily amount to achieve the health effect must be provided; and
- for weight management claims, the additional statement about regular exercise to be included.

Specific exemptions for small packages

Small packages are exempt from a number of provisions in Standard 1.2.7, such as, statements around total dietary context, and specific statements associated with particular content claims. The details can be found in clause 10 of Draft Standard 1.2.7, at Attachment 1.

Any advertising material associated with the food in a small package is to comply with the usual requirements.

Table 1a: Summary of wording conditions in relation to particular types of claims

	Property of food	Specific benefit	Total diet context	Target population	Advisory	%DI or %RDI	Additional / Different
Content	Required. Bio-actives cannot be claimed beyond 'presence'	N/A	N/A	N/A	Refer Std 1.2.7; and Std 1.2.3	Claimed nutrient and energy %DI. Statement re average adult diet	'No added sugar'; 'No added salt/sodium' require disclaimer re naturally occurring sugars/sodium
General level health claim	Required	Required.	Claim to include how the benefit is achieved as part of a healthy diet and variety of foods, As appropriate.	As per substantiation.	As for content claims	Claimed nutrient and energy %DI. Statement re average adult diet	'No added sugar'; 'No added salt/sodium' require disclaimer re naturally occurring sugars/sodium.
High level claim Refer to detailed table for specific high level claims and associated requirements	Required	Required	As for general level health claim. Additional requirements may apply	As per substantiation. Additional requirements may apply.	As for content claims Additional requirements may apply (e.g. high intakes folic acid)	Claimed nutrient and energy %DI. Statement re average adult diet	
Special cases:							
Dietary interaction claims	As for content claim	Required for general level health claim. The 'interaction' element will also be present	As for general level health claim	As per substantiation	As for content claims	Claimed nutrient and energy %DI. Statement re average adult diet	
Weight management claims	N/A because 'slimming' or similar terms may not be used for property	'Slimming' or similar terms may be used for benefit	As for general level health claim; and reference to importance of regular exercise	As per substantiation	As for content claims	Claimed nutrient and energy %DI. Statement re average adult diet	

Table 1b: Summary of wording conditions in relation to particular types of foods

	Property of food	Specific benefit	Total diet context	Target population	Advisory	%DI or %RDI	Additional / Different
Alcoholic beverages	Only certain descriptors allowed for alcohol and energy content	Prohibited	N/A	N/A	As for content claims	Exempted	'Standard drinks' and alcohol labelling as per Std 2.7.1
Infant formulae	Prohibition except for permissions in Std 2.9.1					%DI not applicable	
Infant foods	Provisions in Std 2.9.2 also apply	Required for general level health claim	Appropriate to infant foods	Refer Std 2.9.2	As for content claims	%DI not applicable	Refer Std 2.9.2
Formulated Supplementary Foods	Provisions in Std 2.9.3 also apply	Required for general level health claim	Appropriate to the food and its intended use	Refer Std 2.9.3	As for content claims	%DI not applicable to Div 4 of Std 2.9.3	Refer Std 2.9.3

5.4 The Regulatory Framework for High Level Claims

High level claims will be subject to qualifying criteria based on the substantiating evidence and the distribution of the claimed nutrient source in the food supply; and the generic disqualifying criteria for general level health claims unless case by case amendments are required. In general, the wording conditions for high level claims will be the same as for general level health claims i.e. the claim must state the property of the food and the specific health effect and the health effect must be considered in the context of a healthy diet. These requirements are summarised in Table 1a above. However, specific wording related to the substantiation of individual diet-disease relationships, may apply to individual claims, and may differ slightly from the actual substantiated relationship to allow for more user-friendly terms in claims on labels. Although specific wording will not be prescribed, the essential elements for each high level claim will be specified. These may include the specific target population and any required advisory statements. Details on high level claim wording conditions are provided in Table 2, Section 6.3 of this Report.

As for general level health claims, FSANZ proposes to require the %DI or %RDI for the claimed nutrient to be declared in the nutrition information panel whenever a high level health claim is made in relation to a property for which there is a reference value in the Code. Also there will be a requirement for the %DI for energy when any high level claim is made.

High level claims will require pre-approval by FSANZ before incorporation into the new Standard 1.2.7. The processes FSANZ will follow in assessing high level claims are set out in the Substantiation Framework at Attachment 8. This Framework has been tested through FSANZ's development of a set of pre-approved claims (refer Section 6.3.2). The substantiated diet-disease relationship, and any associated criteria for making a claim will be inserted into the Table to Clause 6 of Standard 1.2.7.

For further detail on the Regulatory Framework for high level claims refer to Attachment 5, Chapter 5.

5.5 Particular Nutrition and Health Claims

Certain types of nutrition or health related claims were raised for discussion at Initial Assessment or have come to the attention of FSANZ in the intervening period. Most of these will fall within the Claims Classification Framework and will be treated in the same way as other general level claims or high level claims. However, they are briefly discussed here for clarification. Further detail can be found at Attachment 6.

5.5.1 Dietary Interaction Claims

Dietary interaction claims are claims based on the effect of a nutrient or substance on a target substance or nutrient (this may be a synergistic or antagonistic type of action). The health effect then arises as a result of the target substance.

A large number of such dietary interactions have been described in the literature and claims that promise a desired health outcome by increasing bioavailability of a variety of nutrients and biologically active substances through the presence or absence of a food or substance are becoming common.

In a recent comparison of market trends with nutrition science underpinnings formulations enhancing bioavailability were included in the top category (Tapsell 2005[30]).

Examples are:

- *[This food] is low in phytates (80% reduced, less than x g per serve). Consuming foods with phytate content reduced by at least 50% as part of a healthy diet increases the availability of zinc. Zinc contributes to the normal structure of skin; or*

- *[This food] is an excellent source of Vitamin C. A healthy diet high in Vitamin C increase the availability of iron from a diet including iron rich foods. Iron contributes to normal blood formation.*

In essence, a dietary interaction claim has three elements: synergist (which is acting in concert with another substance to increase an effect) or an antagonist (which decreases an effect), specific target substance and specific health effect. The subject of the intermediary step (i.e. the target substance) may not necessarily be in the food on which the claim is being made, e.g. the zinc or iron in the examples above.

Such claims were not discussed at Initial Assessment however, due to the presence of these claims in the marketplace and potential increase in such claims, FSANZ considers the position of these claims within the Claims Classification Framework needs to be clarified.

5.5.1.1 Pre-requisite Conditions

As for other claims, in order to qualify these claims need to meet the pre-requisite conditions required by the framework. In this context:

- the synergist/antagonist is the 'property' of a dietary interaction claim;
- the 'health effect' is the effect arising from the target substance; and
- all links in the chain need to be substantiated.

5.5.1.2 Criteria

- all qualifying and disqualifying criteria that apply to nutritional content claims apply to the synergist /antagonist;
- the generic disqualifying criteria for general level health claims apply;
- the target substance does not have to be contained in the delivery vehicle, but has to be present in sufficient amounts in the ordinary diet, and the health effect must be obtainable through ordinary consumption patterns; and
- synergistic high level claims will be required to undergo pre-approval as for to other high level claims.

5.5.1.3 Wording Conditions

- all three elements of the claim must be specified i.e. the synergist/ antagonist, the target substance and the health outcome;

[30] Tapsell LC (2005) Functional foods: definition and commercialisation. *Food Australia*, 57 (9),.p 385

- the claim may be split such that the property and target substance are presented together, without the health effect, but must then refer to the complete claim elsewhere on the label; and
- the total dietary context as appropriate must be included in the claim.

An example of such a claim would be:

Front of pack:
Contains selenium, which strengthens the activity of Vitamin E.

Elsewhere on pack:
Contains selenium, which strengthens the activity of vitamin E when consumed as part of a healthy diet rich in Vitamin E.

5.5.2 Life Stage Claims

The Policy Guideline does not specifically refer to 'life stage' claims however, FSANZ is aware of the potential for claims to refer to a life stage such as menopause or pregnancy. Such claims can be considered in a continuum of claims ranging from those that refer to different life stages, such as puberty, menopause and old age and associated symptoms, through to serious diseases associated with different life stages. For example, puberty can be associated with minor skin conditions through to severe acne, while old age can be associated with conditions such as hair loss through to serious diseases such as age-related macular degeneration.

FSANZ has identified at Draft Assessment that such claims can be readily managed in accordance with the Claims Classification Framework. Claims that refer to a biomarker or serious disease will be regulated as high level claims while those that do not refer to a biomarker or serious disease will be regulated as general level health claims. The life stage itself does not determine whether a claim is classified as a high level claim or a general level health claim.

This approach is consistent with the Policy Guideline, which differentiates between high level claims and general level health claims on this basis, and is also supported by submitters' comments. It is not considered appropriate to pre-approve all life stage claims as high level claims, given that life stage claims could potentially refer to a broad spectrum of conditions ranging from non-serious to serious diseases.

Claims that refer to a life stage will be required to comply with all other conditions for making a general level health claim or high level claim, as appropriate (refer Sections 5.3 and 5.4). For example, where the health effect relates to a specific population group, the general level health claim will be required to state the specific population group to which the health effect relates. FSANZ considers that these conditions, together with the prohibition on making therapeutic claims will address specific concerns raised by submitters regarding life stage claims. Further detail on the rational underpinning the approach is available at Attachment 6, Part 2, Chapter 5, and in submitters' comments at Attachment 7.

5.5.3 Weight Management Claims

FSANZ has identified the following recommendations at Draft Assessment in relation to 'slimming' claims (hereafter referred to as 'weight management' claims):

- Weight management claims will be permitted and regulated in accordance with the Claims Classification Framework. Claims that refer to a biomarker or serious disease[31] will be regulated as high level claims while those that do not refer to a biomarker or serious disease will be regulated as general level health claims.

- The following criteria and conditions will apply to weight management claims that are regulated as general level health claims:

    - the food will be required to meet the qualifying criteria of 'low calorie/joule/energy';
    - the food will be required to meet the generic general level health claim disqualifying criteria; and
    - the percentage of the Daily Intake (%DI) of energy that is contributed by one serving of the food; and
    - the claim will be required to state the property of the food (i.e. energy), the specific benefit in relation to the property of the food and how the specific benefit is achieved as part of a healthy diet; and
    - the claim will be required to state the importance of regular exercise.

An example of such a claim would be:

This food is low in energy. A diet that is low in energy can assist in weight loss as part of a weight reduction program and combined with regular exercise.

5.5.4 Claims in Relation to Glycaemic Index / Glycaemic Load

Glycaemic Index (GI) and Glycaemic load (GL) relate to the effect on blood glucose levels in response to carbohydrate in foods, and does not specifically relate to a nutrient or a biologically active substance, nor does it have units of measurement. For these reasons, GI and GL do not easily fit into the Claims Classification Framework and need to be considered separately.

Recently, significant attention has been paid to GI as a result of its connection with weight control 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.

The Glycemic Index Symbol Program is an endorsement program that was launched in Australia by Glycaemic Index Limited and involves the use of a recognised symbol, 'G – Glycaemic Index Tested' on licensed food products, the statement of the GI value on food labels, and a consistent explanation of the GI.

[31] For regulatory purposes, FSANZ considers 'obesity' to be a serious disease and 'overweight' to be a non-serious disease

Standards Australia, a non-government standards development body, is currently developing a Standard for the determination of GI in foods. One of its objectives in standardising the scientific method is to discourage the use of less rigorous methods of testing that may result in unreliable GI values.

GL is a measure of the relative amount that blood glucose levels will change after a serving of a food (Liu et al. 2003[32]; Munro 2004[33]). GL is calculated by multiplying the GI with the amount of carbohydrate in the food, divided by 100. While GI describes the qualitative effect of a food on blood glucose levels, GL also considers the quantity of the carbohydrate available from the food.

At this stage, FSANZ is not aware of any claims being made in relation to the GL of a food, nor to the existence of any endorsement programs in relation to GL.

At Draft Assessment, FSANZ is recommending the following approach to the regulation of GI and GL claims.

- **GI and GL claims that are linked with an endorsement,** as defined in the Draft Standard, will be considered in accordance with the conditions relating to the regulation of endorsements. These conditions are outlined in Section 5.6.1.

- **GI and GL claims that are not linked with an endorsement,** as defined in the Draft Standard**,** will be considered in terms of whether:

  (a) the claim refers to a GI or GL index only; or
  (b) the claim refers to a GI or GL index and a health effect.

- **If the claim refers to a GI or GL index only** it will be regulated as a content claim as follows:

  - the GI or GL can only be claimed in the form of an index (e.g. GI = 35);
  - descriptor terms such as 'reduced', 'low', 'medium' or 'high' GI or GL will not be permitted; and
  - a declaration of the percentage daily intake (%DI) for energy is required in the nutrition information panel.

- **If the claim refers to a GI or GL index and a health effect**, it will be regulated as either a general level health claim or high level claim, depending on the nature of the claim made. In addition to meeting the regulatory requirements for content claims above, the following conditions will apply to general level health claims:

  - the food will be required to meet the generic general level health claim disqualifying criteria;

[32] Liu S, Willett WC, Stampfer MJ, et al., 2000, 'A prospective study of dietary glycemic load, carbohydrate intake, and risk of coronary heart disease in United States women', *Am J Clin Nutr* 71(6):1455–1461.
[33] Munro, JA 2004, 'Virtual food components: functional food effects expressed as food components', *Euro J Clin Nutr* 133: 4256–4258.

- the claim will be required to state the property of the food (i.e. GI or GL), the specific health effect claimed in relation to the property of the food and how the specific health effect is achieved as part of a healthy diet; and
- the claim will need to meet the general level health claim substantiation framework.

High level claims will be subject to pre-market assessment and approval by FSANZ.

Further detail and the rationale underpinning this approach can be found at Attachment 6, Part 2, Chapter 7.

5.5.5 Claims in Relation to Whole Foods

General level health claims in relation to whole foods are a particular aspect of the regulatory framework that FSANZ needs to be addressed separately because, by their very nature, whole foods do not meet the second claim pre-requisite condition underpinning the Regulatory Model i.e. they do not *make reference to a specific 'property' of the food.*

A whole food could be substantiated on the basis of the food itself, rather than evidence of health effects due to specific components. Alternatively, consumption of the whole food could have an effect that is greater than the effect of a single component of that food (food synergy)[34].

To set enforceable parameters, ensure consistency with national nutrition guidelines[35], and provide flexibility around foods that are eligible to make whole food general level health claims, it is recommended the definition of whole foods is based on foods that consist of at least 90% by weight of primary foods where, 'primary food' means fruit, vegetables, grains, legumes, meat, milk, eggs, nuts, seeds and fish, as defined under Standard 1.3.2.

This approach will allow some processed primary foods to carry a whole food general level health claim. However, because the generic disqualifying criteria apply, foods with high sodium, saturated fat or sugar content would not be able to make a claim.

To allow whole food general level health claims within the Regulatory Framework they will be exempted through the substantiation process from the prerequisite condition that a health claim must make reference to a specific property of the food. The prerequisite conditions that require a claim to be substantiated according to the Substantiation Framework, and to make reference to a specific health effect will still apply.

The Policy Guideline states that claims must not imply that a healthy diet is reliant on the inclusion of a single food. There is the possibility that a whole food claim could mislead consumers by implying that a health effect of a food is unique to the particular brand or type of product. Therefore, limitations are placed around the use of general level health claims in relation to whole foods to prevent these claims being made with regard to specific foods, products or brands. The wording of the claim needs to make clear that the claim refers to the whole class of similar food not to the particular food making the claim.

[34] Jacobs D.R., Steffen L.M 2003. Nutrients, foods, and dietary patterns as exposures in research: a framework for food synergy. *American Journal of Clinical Nutrition* 78(suppl):508S-513S.
[35] Refer to back of report for definition.

General level health claims in relation to whole foods should be worded such that the generic primary food type e.g. 'apples' is referred to in the claim rather than specific brand names such as 'Blogg's apples'.

In summary, FSANZ recommends the following approach at Draft Assessment to the regulatory management of general level health claims in relation to whole foods:

- general level health claims in relation to whole foods do not need to state the specific property of the food;

- general level health claims in relation to whole foods must make reference to a specific health effect;

- whole foods are foods that consist of at least 90% by weight of primary foods defined in Standard 1.3.2;

- the generic disqualifying criteria and conditions for general level health claims apply to claims on whole foods;

- claims can only be made in reference to generic food types; and

- in respect of substantiation processes:

    - general level health claims in relation to whole foods are to be substantiated according to the substantiation framework for general level claims;
    - the evidence supporting the claim must point to the health effects being attributed to the whole food; and
    - there is no or very little evidence of appropriate quality substantiating the relationship between specific component/s of the whole food and the health effect of the claim.

Further detail on the rationale underpinning this approach can be found in Attachment 6, Part 2, Chapter 8, and detailed submitters comments are at Attachment 7.

5.5.6 Claims in Relation to 'Meals'

Increasingly, foods are being presented in more convenient forms for the consumer including ready-to-serve meals comprising a number of different serves of individual foods. Due to the combination into one package these meals will not qualify for claims under the serve-based model for qualifying and disqualifying criteria; or if the criteria were to be applied to each food within the meal (e.g., chicken, peas, carrots, potato, sauce etc) the whole meal may be disqualified due to one individual food only, which may not be appropriate. FSANZ therefore considers 'meals' require special consideration.

FSANZ proposes a definition that covers both meals and main dish products. The only qualifying criteria that are specific for meals and main dish products are those in relation to fibre. The disqualifying criteria that will be applied to meal products are increased in relation to the generic disqualifying criteria to take account of the larger contribution of these products to the daily intake. Details are provided in Attachment 6, Part 2, Chapter 10.

5.6 Conditions Applying to Related Claims

In the context of Draft Standard 1.2.7, 'related claims' have been taken to specifically refer to endorsements and cause related marketing statements. These claims have been captured by the standard due to their potential to be interpreted as nutrition or health claims, but sit outside the Claims Classification Framework and are subject to different requirements.

5.6.1 Endorsements

The Policy Guideline defines 'endorsement program' as *in the commercial sense – an advertising testimonial: an instance of public endorsement of a product for advertising purposes;* and 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. They will require a statement to explain why the endorsement has been granted (e.g. meets the nutrient criteria required by the endorsement program).*

Although the Policy Guideline recommendations regarding endorsements have been followed as far as possible, there has been some deviation from them based on the FSANZ consumer research and submitters' comments in response to the Initial Assessment Report. The rationale is further discussed in Attachment 5, Chapter 6. The proposed approach has taken account of many factors including the recommendations of the Policy Guideline, stakeholder comments, results of the FSANZ consumer research and international practice.

FSANZ is recommending that the management of endorsements be based on a two phase system focusing on current endorsement programs; and future endorsement programs.

5.6.1.1 Current Programs

Endorsements that are currently in existence will need to be pre-approved by FSANZ to continue unchanged. To be pre-approved, they will need to:

- fit within the definition of endorsement as outlined above; and
- the nutrition criteria that the endorsement program applies to products will need to be consistent with Australia / New Zealand nutrition policy principles.

Pre-approved endorsements will be listed in the Standard as being exempt from the requirements of the Standard.

Any current endorsement program that is not pre-approved by FSANZ will have to be regulated as a nutrition or health claim and therefore meet the relevant requirements of the Claims Classification Framework, depending on the nature of the claim made. See Figure 6 below for a diagrammatic representation of the regulation of current endorsements.

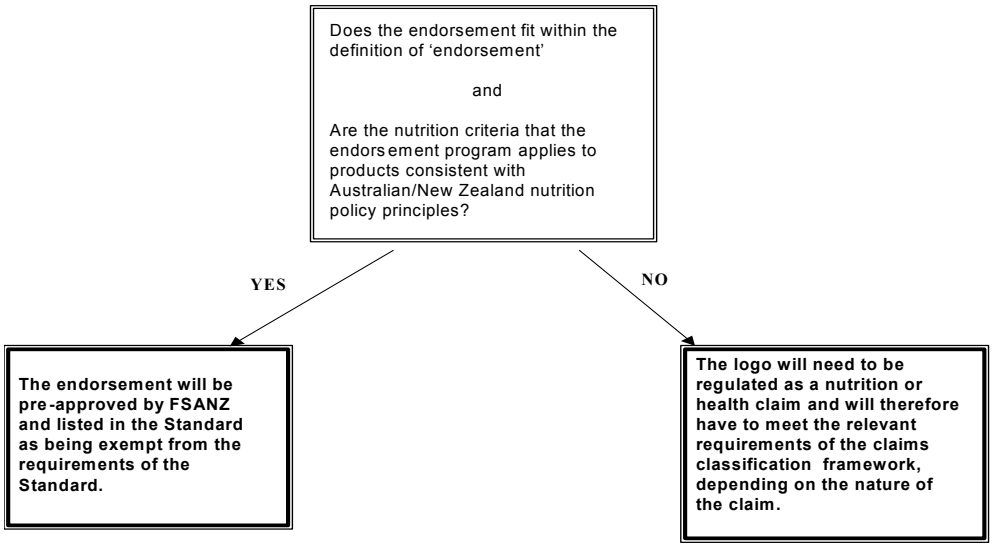

Figure 6: Regulatory Framework for current endorsements

5.6.1.2 Future Endorsement Programs

Like current endorsements, future endorsements will need to fit within the definition of 'endorsement' as specified.

In addition to this:

1. If the endorsement **does not reference a serious disease**:

   - the endorsement will need to meet the general level health claim substantiation framework;
   - the food carrying the endorsement will need to meet the general level health claim disqualifying criteria; and
   - the food carrying the endorsement will need to meet relevant qualifying criteria if the endorsement specifically relates to a property of the food.

2. If the endorsement **does reference a serious disease where it is in the name of the** organisation and the serious disease or condition is not associated with gluten or lactose:

   - the endorsement will need to meet the general level health claim substantiation framework;
   - the food carrying the endorsement will need to meet the general level health claim disqualifying criteria; and
   - the food carrying the endorsement will need to meet relevant qualifying criteria if the endorsement specifically relates to a property of the food.

3. If the endorsement **does reference a serious disease where it is in the name of an organisation that relates to a serious disease or condition associated with gluten or lactose**:

   - the endorsement will need to meet the general level health claim substantiation requirements; and
   - the food carrying the endorsement will need to meet any related qualifying criteria as specified in the Code - for example, gluten free criteria.

The regulation of future endorsement is represented diagrammatically below in Figure 7.

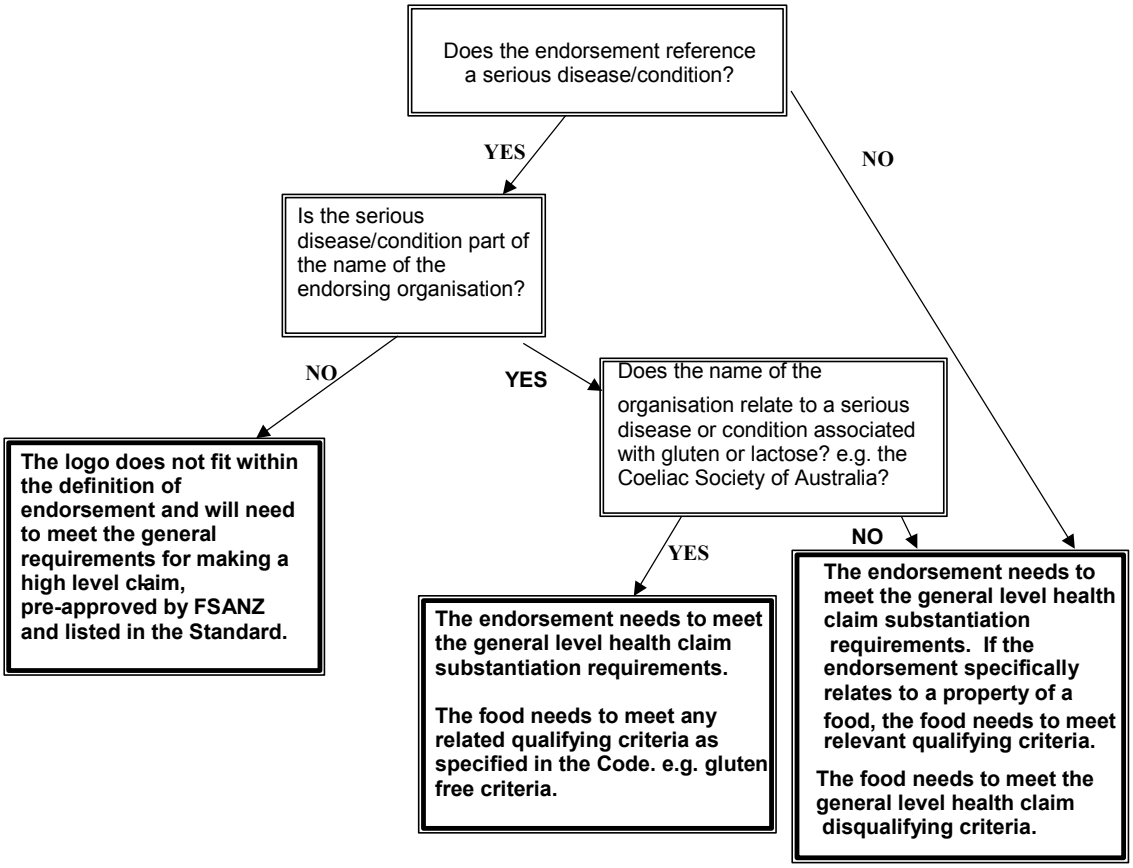

Figure 7: Regulatory Framework for future endorsements[36]

If the endorsement incorporates a nutrition or health claim, then the same conditions apply as outlined above. If an endorsement is accompanied by a claim that is not technically part of the endorsement, the claim will need to comply with the relevant requirements of the Claims Classification Framework, depending on whether it is a nutrition claim, a general level health claim, or a high level claim. This can be seen below in Figure 8.

[36] Based on the premise that the endorsement fits within the definition of 'endorsement'

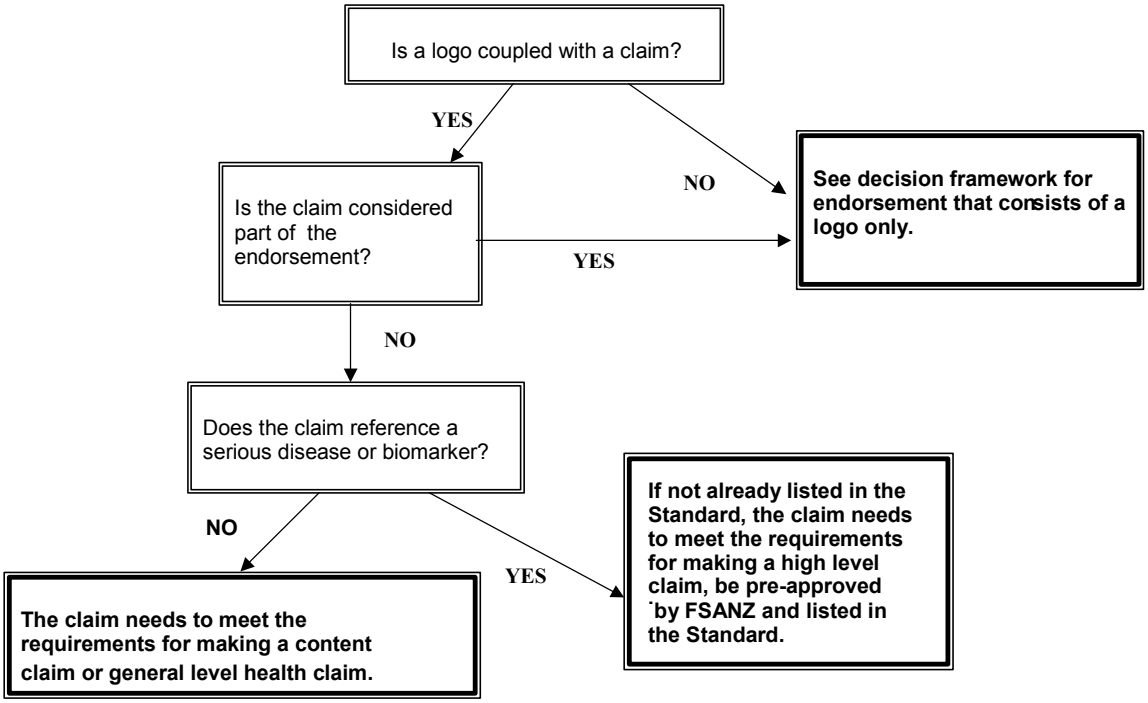

Figure 8: Regulatory Framework for future endorsement coupled with a claim[37]

If a **logo references a serious disease that is not in the name of an organisation**, it is technically not an 'endorsement', as the definition of endorsement excludes *a design that includes a reference to a serious disease other than in the name of the endorsing organisation*[38]. In this case, the logo will need to meet the general requirements for making a high level claim.

Further detail on endorsements can be seen at Attachment 5, Chapter 6.

5.6.2 Cause-related Marketing

In the context of the regulatory framework for nutrition, health and related claims, the definition of 'cause-related marketing statement' has been narrowly defined so that it only captures organisations where the name of the organisation references a serious disease rather than other types of organisations of individuals. As such, FSANZ has devised the following definition:

> ***Cause-related marketing*** *means a statement that the sale of the food will contribute to fundraising for an organisation, the name of which refers to a serious disease.*

Cause-related marketing is not considered to be health claim as such and therefore, is not subject to the criteria and conditions for health claims.

[37] Based on the premise that the endorsement fits within the definition of 'endorsement'
[38] Refer to Draft Standard 12.7 for definition.

However, the quantitative consumer research commissioned by FSANZ in 2004 found that consumers attribute health-related meaning(s) to the cause-related marketing statement studied; respondents believed that the product with a cause-related marketing statement was more beneficial to health than the product without a cause-related marketing statement. On this basis, and also being cognisant of the Policy Guideline in this respect, FSANZ recommends that where cause-related marketing is used in association with a food and a serious disease an associated disclaimer statement must be provided, to the effect:

[Insert supplier name] makes no claim in relation to this food being beneficial for managing [insert serious disease].

This disclaimer is not required where a high level claim is also made in relation to the serious disease that is the subject of the cause-related marketing. Further detail on cause-related marketing statements is in Attachment 5, Chapter 7.

6. Substantiation of Health Claims

6.1 Introduction to Substantiation Framework

FSANZ released a draft substantiation framework at Initial Assessment which contemplated substantiation of diet-health relationships discussed in the dietary guidelines or other authoritative texts for general level health claims, or from a comprehensive review of the evidence as a basis for both general and high level health claims. Submitter comments, and testing of the evidence for diet-health relationships in the case of general level health claims, or diet-disease relationships for high level claims, through FSANZ's review process including the Scientific Advisory Group, have advanced consideration of the Substantiation Framework. This is presented in Attachment 8. The Substantiation Framework document addresses the principles for considering evidence to substantiate diet-disease relationships, the process for substantiating high level claims, including the steps to be taken to assess and interpret the evidence, the mechanisms for substantiating diet-disease and diet health relationships (for high level and general level claims respectively) and the substantiation of content claims. The Substantiation Framework will be incorporated by reference into the Code to give it legal status. The Framework is summarised below.

6.2 General Level Claims

6.2.1 Framework for substantiating general level claims

Content claims are considered in Chapter 5 of the Substantiation Framework (refer Attachment 8). Substantiation requirements for content claims have not undergone substantial revision since Initial Assessment, which stated that 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. It is preferable to undertake laboratory analysis to measure the component content using appropriate and recognised methods of analysis, and a structured and validated sampling plan. While food composition tables and tools such as the Nutrition Panel Calculator (available at http://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.

Substantiation requirements for general level health claims have been further considered since Initial Assessment, taking into account the submitter comments to the Initial Assessment report. The following principles apply to the substantiation of diet-health relationships for general level claims:

- the evidence must be relevant to Australians and New Zealanders;
- the strength of the diet-health relationship must be considered;
- the limitation of the evidence must be considered;
- the totality of the evidence with a significant degree of confidence should be relied on; and
- the information used must include up-to-date evidence when available.

General level claims can be substantiated by a number of mechanisms:

- selection of a nutrient function statement from a list of pre-approved nutrient function statements prepared by FSANZ;

- a streamlined process of evidence collection based on use of authoritative, generally accepted information sources; and

- an assessment of all available scientific evidence of suitable quality can be undertaken in instances where there is no suitable pre-approved nutrient function statement and no suitable authoritative evidence source can be identified.

Further details of these mechanisms are given in Attachment 8.

FSANZ intends to develop user-guidance documents to assist with implementation of the Substantiation Framework. Further development of the Substantiation Framework for general level claims may be suggested during development of these documents.

6.2.2 Pre-approved Nutrient Function Statements for General Level Health Claims

FSANZ has developed a list of nutrient function statements comprising pre-approved statements on which nutrient function claims may be based (refer Appendix 2 to Attachment 8). Suppliers will be able to draw on these statements without undertaking further substantiation of the underlying diet-health relationship. However, wording conditions also apply when developing an appropriate claim from a substantiated statement.

The pre-approved nutrient function statements have been prepared taking into account the well understood and generally accepted roles of nutrients in the human body, and was based on a list of scientifically substantiated nutrient function statements published by the United Kingdom Joint Health Claims Initiative in relation to vitamins and minerals, and from other sources including Health Canada's list of biological role claims. The relationships included in this list of nutrient function statements are those considered to be substantiated to FSANZ's requirements for standards of evidence (refer Attachment 8). Attachment 10 provides further detail around the rationale used to develop this list.

6.3 High Level Health Claims

6.3.1 Framework for Substantiating Diet-disease Relationships Underpinning High Level Claims

Since its first release in the Initial Assessment Report, the Substantiation Framework for high level claims has been amended, taking account of the process of review of selected diet-disease relationships (refer Section 6.3.2). The amendments:

- Provide a streamlined review process based on existing reviews developed overseas for the purposes of substantiating claims on foods.

- Streamline the 5-step full review process into a 3-step process:

  - identifying and categorising the evidence;
  - assessing and interpreting the evidence; and
  - evaluating the totality of the evidence

- Provide more detail about bioavailability, use of evidence derived from studies of dietary supplements and use of animal studies.

- Provide guidance on the delineation between statistical and clinical significance.

- Provide summary flow charts of the two major substantiation approaches.

6.3.2 Review of Diet-disease Relationships

FSANZ has commissioned a series of reviews of diet-disease relationships for possible inclusion as high level claims in the draft Standard. The criteria for selecting the diet-disease relationships are outlined in Attachment 10. The priority list of diet-disease relationships for review was developed using the selection criteria and comments provided by stakeholders to the Initial Assessment Report, FSANZ workshops and the Standards Development Advisory Committee. These reviews drew on reviews that formed the basis of claims approved in Canada and were prepared by experienced Australian and New Zealand scientists using the streamlined approach set out in the revised draft Substantiation Framework and were peer-reviewed by a Scientific Advisory Group (SAG) convened by FSANZ.

Four reviews have been finalised and from these the following six diet-health relationships substantiated.

6.3.2.1 Calcium, Vitamin D and Osteoporosis

FSANZ considers there is convincing evidence of a relationship between dietary intake of calcium, vitamin D status, and risk of the frail elderly, particularly women, developing osteoporosis (expressed either as bone mineral density or as fracture incidence).

6.3.2.2 Calcium and Bone Mineral Density

FSANZ considers there is convincing evidence of a relationship between increased dietary intake of calcium and enhanced bone mineral density, particularly in women.

6.3.2.3 Sodium and Blood Pressure

FSANZ considers there is a convincing relationship between reduction in dietary intake of sodium and reduction in blood pressure.

6.3.2.4 Folic Acid and Neural Tube Defects

FSANZ considers there is convincing evidence of a relationship between intake of folic acid in the peri-conceptional period and risk of development of neural tube defects in the foetus.

6.3.2.5 Saturated Fatty Acids and LDL Cholesterol

FSANZ considers there is a convincing relationship between reduction in dietary intake of saturated fatty acids and reduction in blood levels of low-density lipoprotein (LDL)-cholesterol.

6.3.2.6 Saturated and *Trans* Fatty Acids and LDL Cholesterol

FSANZ considers there is convincing evidence of a relationship between reduction in dietary intake of saturated and *trans* unsaturated fatty acids and reduction in blood level of LDL-cholesterol.

On the basis of the two above relationships for LDL-cholesterol, FSANZ provides approval for claims made on the basis of saturated fatty acids and LDL-cholesterol, or saturated fatty acids and *trans* unsaturated fatty acids and LDL-cholesterol. However, claims in relation to *trans* unsaturated fatty acids alone and LDL-cholesterol have not been approved. This is because it is not clear whether the effect of trans fatty acids on LDL cholesterol is biologically meaningful at low levels of intake, which is likely to be the case in Australia and New Zealand.

6.3.2.7 Further reviews

Three further reviews of diet-health relationships have been selected and it is anticipated these will form the basis of another set of approved high level claims. These are:

- Omega-3 fatty acids and coronary heart disease;
- wholegrain and bran intake and coronary heart disease; and
- fruits, vegetables and heart disease.

The first two of these reviews are in progress. However, the third has been delayed. FSANZ may conduct further diet-health relationship reviews on an ad hoc basis, depending on resource availability. Specific diet-health reviews selected for review will be drawn from the priority list developed during the Initial Assessment for this Proposal, and consideration given to advice received through public and expert consultations.

Attachment 10 provides a summary of the completed relationships and an assessment of the circumstances under which the relationships have been substantiated.

6.3.3 Conditions and Criteria Relating to Substantiated Diet-disease Relationships

On the basis of the substantiation evidence the specific requirements relating to the use of claims based on the currently pre-approved diet-disease relationships have been determined (Table 2). The approved diet-disease relationships are listed in the Table to Clause 6 of the Draft Standard 1.2.7.

No additional disqualifying criteria have been identified for claims based on the relationship between folic acid and neural tube defects; sodium and blood pressure; saturated fatty acids and LDL cholesterol or saturated and trans fatty acids and LDL cholesterol. Thus the generic disqualifying criteria will apply in these cases. However, for claims based on:

- sodium and blood pressure, the disqualifying criteria will be limited to the generic criteria related to saturated fat and total sugars;
- saturated fatty acids and LDL cholesterol, the disqualifying criteria will be limited to the generic criteria related to sodium and total sugars;
- saturated and *trans* fatty acids and LDL cholesterol, the disqualifying criteria will be limited to the generic criteria related to sodium and total sugars.

This is consistent with the approach that precludes specifying a disqualifying criteria relating to the nutrient, which is the subject of a claim and reflects the generally higher stringency of the qualifying criteria than the disqualifying criteria.

For the claims related to calcium the requirement would be that the food meets the requirement of a 'claimable food' pending the review of the Nutritional Reference Values. This approach is consistent with the requirements for making general level health claims in relation to vitamin and minerals.

6.3.4 Special Consideration Relating to Folate Claims

Folate claims are permitted under the current transitional health claims Standard. Whilst there is a low level of use of this claim, most of the claims do not reference the risk of foetal neural tube defects. FSANZ recognizes that suppliers may also choose not to use the pre-approved high level claim because the reference to the serious disease or condition may attribute negative connotations to the product. FSANZ considers that general level health claims relating to maternal folic acid consumption and normal foetal development should be regulated in the same way as the pre-approved high level claim, given the evidence substantiating both types of claims are identical. Therefore it is proposed that the food compositional criteria and conditions that apply to the pre-approved high level claim for folic acid and foetal neural tube defects will also apply to the corresponding general level health claim.

Table 2: Application of the Regulatory Framework to diet disease relationships

	Restriction on Use of Claim	Food Compositional Criteria	Wording Conditions in the Standard					Additional information on lifestyle factors (in guideline document)[39]	EXAMPLE CLAIM
			Property of Food	Specific Health Effect	'Healthy Diet' Context	Population Subgroup	Advisory Statements/ Other labelling		
Calcium, Vitamin D and Osteoporosis	N/A	Qualifying Criteria: The food contains no less than 300 mg calcium/serve Must be a 'claimable food'. NB. Subject to Nutrition Reference Values' review	Calcium to be stated as the property of the food and expressed in terms of a content claim (i.e. 'High in Calcium', 'good source of calcium' etc). Vitamin D can also be stated as a property of the food (in addition to calcium above) if the food meets requirements of clause 6 or 7 of std 1.3.2. *NB. This is not a qualifier to make the claim - there is no minimum level of Vit D required to be in the food before making this high level claim*	'Reduced risk of osteoporosis' OR 'enhanced bone mineral density' OR 'reduced risk of osteoporotic fracture'	A healthy diet with a high intake of calcium from a variety of foods and that provides for adequate Vitamin D status	Women and men aged 65 years and over	%RDI Calcium in nutrition information panel % DI Energy in nutrition information panel	N/A	*A healthy diet consisting of a variety of foods high in calcium and that provides for adequate vitamin D status may [reduce the risk of osteoporosis] in women and men aged 65 years and over. [Food] is high in calcium.*

[39] Additional information on lifestyle factors can be included as part of the claim where the evidence compiled for the substantiated diet disease relationship also references lifestyle factors, however this is not a wording requirement. FSANZ will provide more detail in a user guide.

	Restriction on Use of Claim	Food Compositional Criteria	Wording Conditions in the Standard					Additional information on lifestyle factors (in guideline document)[39]	EXAMPLE CLAIM
			Property of Food	Specific Health Effect	'Healthy Diet' Context	Population Subgroup	Advisory Statements/ Other labelling		
Calcium and Enhanced Bone Density	N/A	Qualifying Criteria: The food contains no less than 200 mg calcium/serve Must be a claimable food. NB. Subject to Nutrition Reference Values review	Calcium to be stated as the property of the food and expressed in terms of a content claim (i.e.' High in Calcium', 'good source of calcium' etc).	'enhanced bone mineral density'	A healthy diet with a high calcium intake from a variety of foods	General population particularly women	%RDI Calcium in nutrition information panel % DI Energy in nutrition information panel	The importance of weight bearing exercise	*A healthy diet high in calcium from a variety of foods assists in improving bone density, which has particular importance in women. [Food] is a good source of calcium.*
Sodium and Blood Pressure	N/A	Qualifying Criteria: The food contains no more than 120 mg of sodium per 100 g of food, or 120 mg per 100 mL of liquid food Disqualifying Criteria: No more than 4g/serve of Saturated Fat and 16g/serve of Total Sugars	'Low in Sodium' or 'Low in salt' (This terminology links to QC) 'Sodium/salt free' OR 'Free of sodium/salt' can be stated as the property of the food if the food has nil sodium/salt.	'Maintenance of normal blood pressure' OR 'reduced blood pressure'	A healthy diet consisting of a variety of foods low in sodium/salt	General adult population	%DI Sodium in nutrition information panel % DI Energy in nutrition information panel Potassium content must be indicated in the nutrition information panel (links to content claim requirement for 'low sodium claim')	The importance of maintaining a healthy body weight.	[Food] is sodium free. A healthy varied diet including foods low in sodium assists adults in reducing blood pressure.

	Restriction on Use of Claim	Food Compositional Criteria	Wording Conditions in the Standard					Additional information on lifestyle factors (in guideline document)[39]	EXAMPLE CLAIM
			Property of Food	Specific Health Effect	'Healthy Diet' Context	Population Subgroup	Advisory Statements/ Other labelling		
Folic Acid and Neural Tube Defect	Claim is not permitted on foods that are recommended to be avoided during pregnancy	Qualifying Criteria: The food contains no less than 65 µg folate and/or folic acid per serve Disqualifying Criteria: No more than - 4g/serve of Saturated Fat; 325 mg/serve of Sodium; and 16g/serve of Total Sugars	Folate to be stated as the property of the food and expressed in terms of a content claim. (e.g. 'Good source of' etc)	'increased maternal folate consumption in at least the month before and 3 months following conception may reduce the risk of foetal neural tube defects'	'recommendation that women consume at least 680 micrograms of dietary folate equivalents per day at least 1 month before and 3 months after conception'	Women of child bearing age	%RDI folate in nutrition information panel % DI Energy in nutrition information panel	N/A	*This [food] is high in folates. Consumption of at least 680 micrograms of folates a day at least 1 month before and 3 months after conception may reduce the risk of foetal neural tube defects.*
Saturated fatty acids and LDL Cholesterol	N/A	Qualifying Criteria The food contains no more saturated and *trans* fatty acids than (a) 0.75 g per 100 ml for liquid food; and (b) 1.5 g per 100 g for solid food Disqualifying Criteria No more than - ; 325 mg/serve of Sodium and 16g/serve of Total Sugars	'Low in saturated fatty acids' (this terminology links to QC)	'May help reduce [blood LDL cholesterol] OR [serum LDL cholesterol] OR [total blood cholesterol] OR [total serum cholesterol] OR [blood cholesterol] OR [serum cholesterol] levels'	A healthy diet consisting of a variety of foods low in saturated fatty acids	General population	%DI saturated fatty acids in nutrition information panel % DI Energy in nutrition information panel 'Energy needs' statement included	N/A	*A healthy diet consisting of a variety of foods low in saturated fatty acids may help reduce total serum cholesterol levels. This [food] is low is saturated fatty acids.*

	Restriction on Use of Claim	Food Compositional Criteria	Wording Conditions in the Standard					Additional information on lifestyle factors (in guideline document)[39]	EXAMPLE CLAIM
			Property of Food	Specific Health Effect	'Healthy Diet' Context	Population Subgroup	Advisory Statements/ Other labelling		
Saturated & *trans* fatty acids and LDL Cholesterol	Claims in relation to *trans* fatty acids alone will not be permitted	Qualifying Criteria The food contains no more saturated and *trans* fatty acids than (a) 0.75 g per 100 ml for liquid food; and (b) 1.5 g per 100 g for solid food Disqualifying Criteria No more than - ; 325 mg/serve of Sodium and 16 g/serve of Total Sugars	'Low in saturated and *trans* fatty acids' (this terminology links to QC)	'May help reduce [blood LDL cholesterol] OR [serum LDL cholesterol] OR [total blood cholesterol] OR [total serum cholesterol] OR [blood cholesterol] OR [serum cholesterol] levels'	A healthy diet consisting of a variety of foods low in saturated fatty acids and *trans* fatty acids	General population	%DI saturated fatty acids in nutrition information panel % DI Energy in nutrition information panel 'Energy needs' statement included	N/A	*This [food] is low in saturated and* trans *fatty acids. Total blood cholesterol may be reduced when consuming a healthy diet consisting a variety of foods low in saturated and* trans *fatty acids.*

7. Assessment Tools and Evidence Base

7.1 Sources of Information

The development of the Claims Classification Framework and Regulatory Model has been informed by an evidence base and professional advice that drew on a variety of sources including; submitters' views and provision of new information, expert advisory groups, monitoring of international practice and policy developments, and utilisation of domestic and international research. These sources of information have been referred to where appropriate throughout the Draft Assessment Report and associated attachments.

In order to address particular aspects of the work, FSANZ also commissioned its own research which includes consumer research on uses and perceptions of health claims, a label monitoring survey, and a benefit-cost analysis on the regulatory options. Each of these is discussed below, with further detail provided at Attachments 3 and 4 and full report.

7.2 Commissioned Research

7.2.1 Consumer Research

FSANZ contracted TNS Social Research to undertake consumer research to collect baseline data on consumers' perceptions and use of nutrition, health and related claims before implementation of the new Standard for nutrition, health and related claims.

The research has been designed in two stages: Stage 1 Qualitative Research and Stage 2 Quantitative Research.

7.2.1.2 Qualitative Research

TNS Social Research in four major cities in New Zealand and Australia completed qualitative fieldwork comprising 69 in-depth interviews in October 2004. A representative sample of adults aged 18 years and over was selected based on demographic variables and responsibility for food purchase, level of health consciousness and use of complementary medicines.

The research design incorporated four interview protocols that covered the following areas:

- consumers' perception and potential use of foods carrying a range of calcium nutrition and health claims;
- consumers' perception and potential use of foods carrying a range of omega 6 nutrition and health claims, foods carrying slimming claims;
- consumers' perception and use of implied health claims; attitudes and behaviour towards claims on foods versus complementary medicines and towards claims on foods versus related advertising materials; and
- consumers' perception and use of message devices[40] to qualify claims.

[40] Message devices (disclaimers, disclosures, advisory statements and specific wordings) are extra sentence(s) that may be included on a food label to further contextualise the nutrition, health or related claim, with the intention of enhancing participants' understanding of the claim

7.2.2.2 Quantitative Research

The key function of this component of the research was to quantify certain findings from the qualitative research.

This research aimed to:

- Provide quantitative baseline data (status quo) of consumers' current understanding of nutrition and health related claims and their use of such claims to inform their purchase decisions.

- Inform an analysis of the benefits and costs of moving away from the status quo (where claims, other than content claims and nutrition function claims, are not permitted) to a system where claims in relation to nutrition and health, if substantiated, are permitted.

- Inform risk management decisions in relation to drafting and implementing regulatory measures as appropriate.

The results of the quantitative research were used to inform the benefit-cost analysis undertaken in relation to the proposed regulatory options.

7.2.2 Label Monitoring Project

FSANZ contracted AgriQuality to undertake the collection of baseline data regarding the current use of nutrition labelling and nutrition and health related claims on food products, as part of an ongoing label monitoring project. A total of 1262 labels was collected in Australia and New Zealand in 2003 and assessed against the labelling provisions in the Code, the CoPoNC, the New Zealand Dietary Supplements Regulations and the fair trading legislation in both Australia and New Zealand. These data have assisted FSANZ to assess the current use of claims and the level of consistency with the provisions. In the longer term they will be used to measure changes in labelling information once a new regulatory regime is implemented.

7.2.3 Benefit-cost Analysis

FSANZ contracted The Allen Consulting Group to prepare a benefit-cost analysis of the current Proposal on nutrition, health and related claims. They were provided with 3 options, covering the *status quo* and two options to permit health claims with the regulation for general level claims being either predominantly within a standard or partially within a guideline. These options are detailed in Section 4.3.

Representatives of public health organisations, industry in Australasia and overseas, and enforcement agencies were consulted to develop their impact assessment. The impact of changes in the regulation of health claims in the United States was also considered, together with consultations with industry to assess the opportunities for new product innovation. The Label Monitoring Project (refer Section 7.2.2 above), discussions with enforcement agencies and external publications were used to help in the assessment of compliance with the current legislative and guidance arrangements.

The Label Monitoring Project also enabled an assessment of the degree of use of nutrition and health claims and this, together with submitter comments and stakeholder consultations, was used as the basis of the assessment of the impact of changes proposed in the regulation of health, nutrition and related claims. The outcomes of the FSANZ consumer research (refer Section 7.2.1 above) and external research were used to assess the possible impact of health claims on usage by consumers and subsequent impact on dietary benefits.

A multi-criteria analysis was used to provide a semi-quantitative evaluation of the benefits and costs. This was based on the following set of criteria:

- adjustment costs for industry;
- impact on opportunities for industry innovation;
- impact on consistency and credibility of claims made in the market place;
- impact on consumer welfare; and
- impact on enforcement costs for government.

Each option was ranked against each criteria and an illustrative score derived. The Executive Summary of this analysis is presented in Attachment 3.

8. Consultation since Initial Assessment

8.1 Consultation at Initial Assessment

In August 2004, FSANZ released the Initial Assessment Report, for public comment. The Initial Assessment Report canvassed stakeholder views on a broad range of issues including how FSANZ could most effectively have regard to the Policy Guideline and which of three proposed regulatory options was preferred. FSANZ received 147 written submissions in response to the Initial Assessment Report.

The following list is a broad summary of common issues raised by submitters. These issues and other issues raised by submitters have been considered in the development of the Regulatory Framework for nutrition, health and related claims.

- equitable regulatory arrangements between foods and medicines regarding permissions for, management of and enforcement of claims;
- the scope, extent and capacity for monitoring and enforcing nutrition, health and related claims on food labels and advertising;
- regulation of advertising and distinguishing between dietary advice provided by health professionals and industry and promotional material;
- representation of claims and risks to health arising from consumer misunderstanding and misinterpretation of claims;
- the need to educate consumers, industry and enforcement agencies;
- the negative impact of a pre-market assessment and approval process on intellectual property and industry investment; and
- the evidential requirements and degree of complexity for the substantiation of both general level and high level claims.

8.2 Written Submissions on Proposal P293 –Nutrition, Health and Related Claims

Initially, FSANZ proposed a nine-week consultation period for the Initial Assessment Report. This was extended by one week to 20 October 2004, due to stakeholder requests. Stakeholders were advised of the change by an email alert (or by a letter where email was not available) and an update on the FSANZ website.

Some submissions were received after the closing date. Late submissions were assessed on a case-by-case basis and were only accepted if there were exceptional circumstances that prevented the submission from being submitted by the due date. FSANZ has not acknowledged these late submissions in the Draft Assessment Report. However, relevant issues raised by submissions not received in time can still be considered by FSANZ in its decision-making processes.

In total, FSANZ received 147 submissions. Table 3 below illustrates the spread of submissions across stakeholder groups and between Australia and New Zealand. Around 50% of submitters used a Submitter Response Book, which accompanied the Initial Assessment Report.

Table 3: Submissions Received: Proposal P293 Nutrition, Health and Related Claims

Country	Government	Industry		Consumers	Public Health*	Other #	**TOTAL**
Australia	9	Food	41	13	18	5	**90**
		Therapeutic	3				
		Media	1				
		TOTAL	45				
New Zealand	2	Food	16	1	13	3	**46**
		Therapeutic	5				
		Media	6				
		TOTAL	27				
Trans-Tasman	-	Food	6	1	-	-	**7**
		Therapeutic					
		Media					
		TOTAL	6				
International	-	Food	4	-	-	-	**4**
		Therapeutic					
		Media					
		TOTAL	4				
TOTAL	**11**		**82**	**15**	**31**	**8**	**147**

* Includes nutritionists/dietitians, public health and non-government organisations.
\# Includes research institutions, partnerships and other various sectors.

8.3 Advisory Groups

At Initial Assessment FSANZ convened several committees to provide advice on the development of the Standard and associated documentation. The membership of these Advisory Groups and their Terms of Reference are at http://www.foodstandards.gov.au/whatsinfood/healthnutritionandrelatedclaims/scientificadvisorygr2854.cfm.

8.3.1 Standards Development Advisory Committee

The Nutrition and Health Related Claims Standards Development Advisory Committee was established under section 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. The Standards Development Advisory Committee has met on three occasions since the Initial Assessment Report, with the most recent two day-long meetings being face to face. Attendance at these meetings has been excellent with strong representation across the various stakeholder groups and Standards Development Advisory Committee members contributed significantly to the development of Draft Standard 1.2.7.

8.3.2 Technical Expert Group on General Level Claims

The Technical Expert Group on General Level Claims was convened at Initial Assessment to advise FSANZ on matters related to general level claims and the criteria and conditions for nutrition content claims. Members were chosen on the basis of a strong background in nutrition and/or dietetics. This Group has not been convened since Initial Assessment as any further issues have been addressed by the Standards Development Advisory Committee, which had many members in common with the smaller Technical Expert Group.

8.3.3 Scientific Advisory Group

The Scientific Advisory Group was established to provide advice to FSANZ on the Substantiation Framework for nutrition, health and related claims and on the external reviews underpinning those high level claims considered for inclusion in the new Standard. Membership is comprised of experts from a range of relevant scientific disciplines including nutrition and epidemiology. The Group has met four times since Initial Assessment to review progress of the diet-disease relationships and to comment on the Substantiation Framework. At the second meeting in May 2005 and the third meeting in September 2005, the Group was able to assess the Framework in the light of its application to the group's evaluation of four external reviews of selected diet-disease relationships. Members also gave advice on the applicability of the Framework for general level claims.

External reviews of four of the original seven diet-disease relationships selected high level claims have been provided to the group for their consideration and advice.

8.4 Specific Consultations

There is significant public interest in the development of the Draft Standard 1.2.7 on the part of Governments, consumers, public health professionals and industry.

To assist those people who were interested in being better informed about the review of nutrition, health and related claims and to assist those who may have been interested in preparing a written submission to the Initial Assessment Report, a series of one-day workshops were held by FSANZ during August and September 2004. The workshops were held in various locations in Australia (Sydney, Melbourne and Perth) and New Zealand (Auckland and Wellington) and were attended by over 300 participants representing industry, government, public health and consumers.

8.4.1 One Day Workshop Program

The program for the one day briefing workshops comprised a small number of FSANZ led presentations on issues considered in the Initial Assessment Report and three interactive breakout sessions.

In the first breakout session participants were asked to consider a small number of sample claims and to categorise the claims as either a general level claim, a high level claim or a therapeutic claim by referring to the descriptions of these claim types outlined in the Initial Assessment Report. In the second breakout session, participants were asked to identify issues arising from the substantiation of general level claims and high level claims. In the third breakout session, participants were asked to compare and contrast the regulation of general level claims in a Standard versus a Guideline in relation to the impact on government, industry and consumers.

A copy of the outcome notes from the briefing workshops are available by clicking on the following link: FSANZ: Health claims - Outcomes of Stakeholder Briefings.

8.4.2 Other Stakeholder Briefings

Additional targeted stakeholder briefings were conducted at Initial Assessment with the:

- Dietitians' Association of Australia in Canberra, Adelaide, Brisbane and Hobart and with the New Zealand Dietetic Association in Dunedin;
- Complementary Healthcare Council and the Australian Self Medication Industry in Sydney; and
- Strategic Intergovernmental Nutrition Alliance in Darwin.

8.4.3 Targeted Consultation Regarding Implementation

Targeted consultations were held with relevant stakeholders to discuss the practical aspects of implementing the framework under development for Draft Assessment i.e. a form of 'road testing'. It was considered important to discuss the practical implementation with industry and enforcement agencies. Towards this end, meetings were held around consideration of actual products currently on the market, and those that may be in the future. Meetings were held with the New Zealand Food Safety Authority; the New South Wales Food Authority; and a broadly representative industry group convened by the Australian Food and Grocery Council.

9. Implementation, Enforcement & Monitoring

9.1 Role of the Implementation Sub Committee Watchdog

The Policy Guideline on Nutrition, Health and Related Claims proposed the Implementation Sub Committee to be the 'watchdog' with respect to the Policy Guideline. The Implementation Sub-Committee is a sub-committee of the Food Regulation Standing Committee and its role is to develop and oversee a consistent approach across jurisdictions to implementation and enforcement of food regulation and standards. Membership of the Implementation Sub-Committee is cross-jurisdictional, including representatives from the Australian and New Zealand Governments and the Australian States and Territories and the Australian Local Government Association.

The Implementation Sub-Committee has formed the Implementation Sub-Committee Health Claims Watchdog Working Group. It will:

- serve as the public face of the health claims system;
- receive complaints through a mailbox and refer any complaint to the relevant jurisdiction(s) for analysis and enforcement action;
- record complaints received (either by the watchdog or jurisdiction) and monitor enforcement actions undertaken by jurisdictions in response to those complaints;
- assist FSANZ in the creation and maintenance of the guideline document;
- provide periodic reports to FRSC; and
- provide proposed amendments to the Standard or the guideline document.

A Support Officer has been appointed to support the Implementation Sub Committee in developing and undertaking its 'watchdog' role. It should be noted that the choice of regulatory Option 3 (refer Section 4.3) means a role in relation to the guideline document will be redundant.

9.2 Enforcement

Under the new Nutrition, Health and Related Claims Standard, it is envisaged that jurisdictions will continue to be responsible for receiving complaints about health claims in relation to breaches of the Code, either directly or through the health claims watchdog. The Implementation Sub-Committee will establish a central, public point of contact for the watchdog. Any complaints it receives through this point of contact will automatically be forwarded on to the relevant jurisdiction, as the watchdog itself has no enforcement power.

It is envisaged that enforcement of the Standard, including assessing possible breaches and undertaking prosecutions, will be the responsibility of the Australia Quarantine and Inspection Service and the State/Territory and New Zealand enforcement agencies. Issues in relation to fair trading or other aspects, such as weights and measures, will be the responsibility of the respective enforcement agencies.

9.3 Advertising

Advertisements for foods must not contain any statement, information, designs or representations that are prohibited by the Code from being included in a label for that food (Standard 1.1.1).

Thus the recommendations made in this Draft Assessment Report for health, nutrition and related claims apply to both the labelling and advertising of foods.

In Australia, the self-regulatory Advertising Standards Board will only investigate complaints in relation to health and safety, not misleading conduct. The Australian Competition and Consumer Commission is responsible for investigating the truth and accuracy of advertising through all media.

In New Zealand, the Advertising Standards Authority is the self-regulatory body, applicable to all media. It administers a code for advertising of food (under review) that is consistent with the provisions in the proposed recommendations on regulation of health, nutrition and related claims.

These two bodies administer their own requirements in relation to food advertising. It will be necessary for these requirements and the provisions of the new food standard in respect of advertising to be consistent, to ensure effective regulation and maximise industry compliance.

It is anticipated that one of the areas where it will be important to achieve consistency in interpretation will be in the area of implied claims. The Australian Competition and Consumer Commission distinguishes misleading advertising from 'puffery', which it defines as *a term used to describe wildly exaggerated, fanciful or vague claims for a product or service that nobody could possibly treat seriously, and that nobody could reasonably be misled by*. It states that puffery in advertising is generally not prohibited by the Trade Practices Act. The definition distinguishes this from 'implied' health, nutrition and related claims, as discussed in Section 5.2.1. However, it is acknowledged that the distinction between 'implied claims' and 'puffery' is subjective and steps will be taken to minimise inconsistent interpretation by preparation of a detailed user guide and discussions with enforcement agencies and advertising self-regulators.

9.4 Monitoring and Review

A component of the role of the Implementation Sub Committee Health claims watchdog is to report and monitor elements of the draft Standard. It is proposed as part of its reporting function, the Implementation Sub-Committee will periodically collect and collate information on the complaints received by the watchdog and the jurisdictions in regard to health claims. In addition, it will collect information on the pro-active action that jurisdictions are undertaking in regard to health claims. All of this data will contribute to the Implementation Sub-Committee's watchdog report to the Food Regulation Standing Committee, analysing the effectiveness of the Standard; and help inform the development and maintenance of the FSANZ guideline document.

As part of its role in establishing the watchdog, the Implementation Sub-Committee has already commenced collecting information, including about various enforcement activities about health claim complaints.

9.5 Education

In accordance with paragraph 7(1)(i) of the FSANZ Act, one of FSANZ's functions is to develop, in co-operation with the States and Territories, food education initiatives, including the publication of information to increase public awareness of food standards and food labels.

Such initiatives can increase consumer knowledge and understanding by providing information on how to interpret and apply food labelling and help to create a supportive environment whereby healthy choices are possible or easier for individuals and communities.

Other organisations can also assist in providing information to complement and strengthen FSANZ initiatives to increase public awareness of food labels. FSANZ will work cooperatively with these organisations to ensure consistency of information and to maximise the effectiveness of available resources.

9.5.1 Approach at Initial Assessment

At Initial Assessment questions were asked regarding FSANZ's role and approach to educational activities to support the introduction of health claims. Approximately half the submitters from both New Zealand and Australia responded to the questions with the majority being from industry, but government and public health professionals were also well represented. Details of comments received can be seen at Attachment 7.

Submitters' responses indicated that essential components of an education strategy for nutrition and health claims included defining the target groups, understanding their knowledge (through quantitative survey or focus groups), developing communication campaigns, testing and modifying campaign messages for comprehension, defining relevant communication vehicles, implementing communication/education programs, and defining evaluation methods to test the effectiveness of the messages and the campaigns. Another suggestion related to a management system that is independent of the food industry. Many of the submitters expressed recommendations relating to industry and consumer education, stakeholders and other aspects of communication (e.g. use of websites).

It was recommended that education should be undertaken by various combinations of sectors which included the following organisations: FSANZ, New Zealand Food Safety Authority, governments (federal, New Zealand, states and territories), non-government organisations, state and territory health departments, public health associations, the National Centre of Excellence for Functional Foods, health professionals, the food industry, industry associations, universities, schools, consumer organisations and the Commonwealth Scientific and Industrial Research Organisation Human Nutrition division. Some submitters clarified that the education process was a joint responsibility by all parties. Others stated that each sector should be responsible for specific tasks. However, some submitters recommended that FSANZ be responsible for undertaking education activities in consultation with other sectors.

The question was also asked as to how stakeholders could work together to develop and implement an education strategy for industry, health professionals and consumers.

Some submitters recommended the establishment of a working group with aims that included reviewing proposed claims, developing and implementing an education strategy and orchestrating an appropriate communication strategy. Some submitters suggested that the working group should represent various stakeholder groups (e.g. industry, health professionals, consumers, government, non-government organisations, and consumer communication experts). It was also recommended that FSANZ, supported by specific combinations of other groups, coordinate the educational process to target groups such as suppliers, health professionals, consumers and enforcement agencies.

9.5.2 FSANZ's Proposed Educational Activities for Health Claims

The type of educational activities undertaken by FSANZ in the past include initiatives for consumers such as the production of posters, web links, booklets, and stakeholder briefing sessions, provision of an industry Advice Line and the development of Industry User Guides and Fact Sheets.

In respect of health claims, FSANZ proposes to:

- Prepare a specific fact sheet/brochure on the new Health Claims requirements.

- Update the consumer education package on food labelling that currently consists of:

    - Website information,
    - the Official Shopper's Guide to Food Additives and Labels,
    - the food labelling poster with the illustration of the yoghurt, and
    - the schools' educational material prepared by Video Education Australasia.

- Present on various aspects of health claims at conferences, seminars etc. as appropriate.

- Participate in workshops, briefing sessions etc. as appropriate post release of the Draft Assessment Report.

- Develop user guides and fact sheets on the new Health Claims requirements for use by industry, jurisdictions and the FSANZ Advice Line.

9.6 Review of Health Claims

The Policy Guideline recommended that a review of the nutrition, health 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. The Advisory Panel was recommended in the Policy Guideline. It has now been renamed as the Register of Independent Experts, composed of technical and legal experts. It will assist enforcement agencies to provide their expert opinions on potential breaches. This will include advice on the adequacy of supporting evidence that food companies hold to support their claims and will also assist jurisdictions to build an enforcement capacity with regard to health claims.

Submissions to the Initial Assessment Report generally supported the need for review, with priorities for the essential review elements given to the effectiveness of enforcement and compliance, consumer understanding and use of health claims, the impacts on health outcomes, monitoring of changes in the food supply and in labelling, the substantiation requirements and the pre-approval process and the usefulness of supporting guidelines and user guides.

Several submitters believed that the working group, committee or body undertaking the review should be independent. Many submitters suggested either general stakeholder participation or specific stakeholders should be represented during the review process. Government, public health, industry, enforcement agencies and consumers were the stakeholders most commonly identified.

Suggestions provided around how the review might be undertaken included interactive workshops, using different working groups, requiring FSANZ to repeat quantitative research on food labelling issues, industry to conduct product surveys, assessment of complaints and successful prosecutions, and a process to assess the health claims impact on consumers. FSANZ will direct these suggestions to the Implementation Sub-Committee watchdog.

FSANZ also intends to consider the effectiveness of the new Standard. It will do this by monitoring labelling as part of its ongoing label monitoring program and will also monitor consumers' awareness of and use of health claims by research into these areas. The consumer research commissioned by FSANZ in 2004 and reported at Attachment 4 provides baseline data for consumers' awareness of and use of health claims.

10. Transitional Arrangements

10.1 Considerations at Initial Assessment

In the Initial Assessment Report it was noted that if this proposal results in changes to 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 would be crucial to such considerations.

In addition, 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 seemed advisable that CoPoNC is updated or withdrawn, as appropriate, following commencement of Standard 1.2.7.

FSANZ suggested at Initial Assessment that a uniform transition period be set for the new 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 proposed that a uniform 12-month transitional period apply to Standard 1.2.7. For example:

- 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.

The question was asked: Are there any reasons why the proposed transitional arrangements should be shortened, lengthened or otherwise changed?

10.1.1 Submitters' Views

Most submitters preferred a longer transition period than 12 months. Some made the distinction between transition for the standard itself and a transition period for stock in trade.

10.1.1.1 12 months

Those preferring 12 months were primarily from government or health agencies, and some industry representatives. The main reasons for this preference were:

- it is a voluntary standard therefore less imposition as such;

- shorter period means less confusion;
- this period would be adequate for industry to make any necessary changes, and for 'FSANZ to process applications'; and
- this period is adequate for standard compliance, but longer (24 months) would be needed for stock in trade.

10.1.1.2 Longer period

Those preferring a longer period did not necessarily specify how long, but 24 months was mentioned in a number of cases (predominantly industry submitters), particularly as a minimum in relation to stock in trade. The reasons given included:

- time required to minimise losses from stock in trade;
- non-pre-approved endorsements may need time to be approved as high level claims; and
- 'implied' claims would need time for assessment and adjustment if necessary.

10.1.1.3 Shorter period

Only one submitter preferred a shorter period of transition. This was in order to reduce the 'current ambiguity and abuse' allowing consumers greater choice and health benefits. A specific time period was not mentioned.

10.2 Analysis and Further Issues

Submitters highlighted the need to differentiate between implementation of the Standard, and allowances for stock in trade, in relation to a transition period. Indications were that 24 months is clearly required to address stock in trade. Although submitters' indications were largely that 12 months would be adequate for implementation of the new standard, given the recommended changes impact on existing content claims as well as health claims, FSANZ considers a longer time period would be warranted.

A further issue that has arisen in relation to potential labelling changes is that of the development of new bi-national Nutrient Reference Values. These will ultimately impact on both labelling and compositional aspects of many food products, as the current reference values have been used to underpin criteria for and expression of claims. Further detail is provided in Section 11 – Inter-related Issues. Rather than delay the implementation of Standard 1.2.7, FSANZ has chosen to proceed with the current Proposal. However, it is noted that when the new Nutrient Reference Values are adopted, this may necessitate further labelling (and possibly compositional) changes for suppliers. If this is the case, and if further transitional time is subsequently required, FSANZ will give consideration to extending any of the transition periods options provided here.

10.3 Preferred Approach

The possible options identified at Draft assessment are:

1. 12-month transition period for stock in trade and standard implementation;
2. 24-month transition period for stock in trade and standard implementation; and

3. 24-month transition period for stock in trade and 12 month transition period for the standard implementation.

Of these, **Option 2** is recommended, that is:

- that a 24 month transition period for the standard implementation be applied and be inclusive of a 24 month transition period for stock in trade; and
- that consideration be given to future extension if necessary as a result of changed Nutrient Reference Values (refer Section 11.2).

11. Inter-related Issues

11.1 Vitamins and Minerals

In May 2004, the Ministerial Council adopted a Policy Guideline on *Fortification of Food with Vitamins and Minerals*, which provides guidance on both the mandatory and voluntary addition of vitamins and minerals to food.

The development of the Standard for nutrition, health and related claims includes within its scope the management of claims made in association with vitamin and mineral fortified foods. The fortification Policy Guideline notes this relationship by stating that *claims should be permitted on fortified foods providing that all conditions for the claim are met in accordance with the relevant Standard.*

However as the permissions for fortification are aligned with the eligibility of vitamin and mineral claims on fortified foods (e.g. prescribed maximum claim amounts), and also because it is desirable to apply the same claims criteria to natural content as well as fortified content, at this point consideration of vitamin and mineral content claims has been excluded from the proposed standard (except for a change in the basis of the criteria from a per reference quantity to per serve).

The criteria for making vitamin and mineral claims will be considered as part of future fortification work and in relation to FSANZ's review of the impact of the new Nutrient Reference Values (refer Section 11.2.) In doing so FSANZ will seek consistency between the regulation of nutrition and health claims more broadly, including qualifying and disqualifying criteria, as currently being considered by the proposed Standard. In the meantime the disqualifying criteria in relation to vitamins and minerals will rely on the disqualification system of 'claimable foods' rather than the generic nutrient disqualifying criteria being proposed under the present Proposal.

11.2 Nutrient Reference Values

Australia and New Zealand are in the process of officially adopting revised Nutrient Reference Values. Currently the Code prescribes Nutrient Reference Values (Recommended Dietary Intakes, and Estimated Safe and Adequate Daily Dietary Intakes) for 3 age groups as the basis for various vitamin and mineral claims criteria for nutrition labelling and fortification. When the new Nutrient Reference Values are official and as resources permit, FSANZ proposes to revise the prescribed Nutrient Reference Values in the Code and in so doing, determine whether there should be modifications to the derivative criteria for claims and controls on voluntary fortification.

11.3 Exclusivity of Claims

The introduction of a wide variety of health claims raises the issue of intellectual property associated with these claims. It is important that investment in the innovation process is encouraged and protected. Without protection innovation could be stifled and lack of protection could be a disincentive for further investment. Protection of claims might provide a strong incentive for investment, resulting in an increase in innovative claims, in more consumer choice, and health benefits to consumers.

It is equally important that the public health benefits that flow from innovation in food science and technology benefit the Australian and New Zealand population. In particular, exclusivity of claims could restrict or block claims with public health benefits, healthy foods might become out of the reach of some consumers, and exclusive claims may limit consumer choice.

FSANZ aims to balance the concerns in regards to the potential flow-on effects of exclusive claims on public health with protecting intellectual property where appropriate and feasible, and to provide a regulatory environment that is conducive to research innovation in the food industry. Under the current legislative regime, regulatory options in this context are limited. However, recent proposals endorsed by the Ministerial Council are expected to result in changes to the FSANZ Act to provide the legal basis for a new approach to applications for approval of high level health claims. This approach will involve treating these applications as confidential, until any claim is approved. An approved claim would be able to be used by anyone, however the applicant would receive a first to market advantage due to the confidentiality of the application.

11.3.1 Policy Guideline

The Policy Guideline states that high-level claims are to be carried out on a 'claim-by-claim' basis and not 'product-by-product'. Any pre-approved high-level claim is available for use by the food industry generally, rather than only by an individual food supplier. This 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 also minimises regulatory costs, because 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 suppliers.

11.3.2 Issues Raised by Submitters

The Initial Assessment Report sought submitters' comments on the occurrence and impact of exclusive health claims. Submissions suggested that consideration must be given to questions of intellectual property, patents, trademarks and copyright. In this context, it was recommended that intellectual property issues be examined in more detail by FSANZ.

A number of submissions stated that the claim-by-claim process was less likely to give individual manufacturers exclusivity. However, most submitters thought that exclusive claim are possible in reference to patentable ingredients, technologies, or information. A minority of submissions stated that exclusivity of claims was unlikely in *any* circumstance.

Some submissions suggested that exclusive claims would be to the detriment of public health, and increase inequalities between socio-economic groups. They felt that health claims widely accepted as beneficial should be widely available. It was also considered likely that exclusive claims would favour larger companies. In this context, some acknowledgement was made that some return on research and development investment would be reasonable. Other submissions stated that exclusivity of claims did not present a problem for the broader regulatory framework. Most submitters were of the view that exclusivity of claims was of benefit to industry and consumers; and considered such claims free of problems. Others gave qualified support, provided that claims were sufficiently substantiated and consumer choice would not be limited by exclusive claims.

Another view was that lack of exclusivity would be an investment disincentive. A number of submissions thought that companies deserved a return from establishing claims. They stated that exclusive claims would ensure return on investments; otherwise companies might be hesitant to apply for claims, and the framework may become unworkable. In this regard, exclusive access to a claim could be an incentive for manufacturers to develop novel foods that improve health.

11.3.3 Regulatory Approach

Suppliers may gain an exclusive right to a claim as a result of:

- a patent held on an ingredient for which a claim is made;
- a patent held on a process that results in a health claim;
- a patent held on a concept or platform technology that enables a health claim.
- a trademark;
- exclusive intellectual property on data or enabling technology that allows substantiation or otherwise is necessary to realise a claim, e.g. exclusive access to analytical technology required to substantiate a claim, exclusive expertise in a research area that is required for substantiating a claim;
- complete control over the supply chain of an ingredient and/or the food matrix necessary to deliver the benefit; and
- previously approved novel food in a matrix unique to one player blocking the introduction of additional delivery vehicles due to safety concerns.

In essence, the regulatory options in regards to exclusivity of claims are limited. Much of what may be played out by industry to try to obtain access to or protect claims must be seen in the context of normal commercial practice and cannot be regulated by FSANZ.

In general, the Code sets generic standards that apply across classes of food, rather than providing individual permissions for particular companies or products. While FSANZ currently has the power under section 9(2) of the FSANZ Act to approve a standard that relates to a particular brand of food (as it has done in relation to folate claims), these are exceptions rather than the rule. However, it is possible for standards to provide a form of individual permission in two main ways:

Where a permission relates to a product that is the subject of patent rights – for instance, a claim may be exclusive where it relates to a unique feature of a patented product – so that the patent owner controls who may use the product and hence the related claim.

Where a permission relates to a particular brand of food – it would be possible for the Standard to establish a system whereby an applicant would seek permission for high-level claims for use specifically in relation to the applicant's particular brand/s of food. The transitional health claims standard, Standard 1.1A.2, is an example of this approach of granting permissions to use a health claim in relation to specific branded foods.

Granting permission for a particular brand of food is in contradiction to the Policy Guideline, and has other disadvantages. Where claims relate to a particular brand of food this may lead to an increase in applications. Rather than applying for a general amendment to a Standard, a number of applicants may apply for specific products that are similar in nature. This may impact on the resources available for the rest of the FSANZ work program. It is likely that such a system would be inefficient and would require continuous updating. For example, for the folate trials permissions continue to be in existence for products that no longer exist.

Under the current legislative system, FSANZ lacks the legal capacity to provide for exclusivity of claims. There are two aspects to this situation. First, applications are publicly notified at various stages of assessment, so that the nature of a high-level claim application would become public knowledge. Second, FSANZ does not have the power to reject applications from other companies for use of the same or similar claim in relation to their brands of food, in order to grant exclusivity to a pre-existing application. However, as part of the Food Regulation Standing Committee's Review of FSANZ's Assessment and Approval Processes and Treatment of Confidential Commercial Information, it has been proposed that a new system be established. This would involve applications for high level claims being treated as confidential, and being assessed in accordance with the Standard, with the advice of food regulatory agencies in all jurisdictions, and of an expert committee. It is also proposed that FSANZ would consider including a consumer representative on the expert committee, and that both the criteria for selection of committee members and the membership of the committee would be made public. The Ministerial Council has now endorsed these proposals. Work is under way on the process of amending the FSANZ Act to give effect to the new system. The exact timeframe for these changes is not yet set.

11.4 Review of Addition of Substances Other Than Vitamins and Minerals

In May 2004, the Ministerial Council endorsed a Policy Guideline on the *Fortification of Food with Vitamins and Minerals.* At this time, it also requested the Food Regulation Standing Committee consider whether the principles of this policy could also be applied to substances other than vitamins and minerals, which would include biologically active substances that have been added to food.

The terms of reference for the Food Regulation Standing Committee subgroup undertaking the scoping work were to progress with a view to developing a Policy Guideline with respect to the additions of substances other than vitamins and minerals to food, and to provide additional advice on issues identified during the policy development process that are not considered appropriate to include in the Policy Guideline.

The final Ministerial Policy Guideline on *Fortification of Food with Vitamins and Minerals,* anticipated in 2006, should enable FSANZ to consider the regulation of substances other than vitamins and minerals, including the development or amendment of standards if appropriate.

11.5 Interface Between Foods and Medicines

Some stakeholders have raised concerns over the blurring of the boundaries between foods and drugs once foods are permitted to make health claims. As part of the establishment of the Joint Agency for regulating therapeutic products an *ad hoc* Trans-Tasman Working group on the Food/Medicine Interface has been formed. The purpose of this group is to develop a tool for determining the regulatory status of products at the food/medicine interface. This will aim to ensure that there is a clear demarcation between products considered to be foods and those considered to be complementary medicines.

12. Conclusions and Recommendations

FSANZ has considered the Policy Guideline on Nutrition, Health and Related claims provided by the Ministerial Council in 2003. Currently, nutrition content and health claims in Australia and New Zealand are regulated by the Code, fair trading acts and by voluntary guidelines. This situation is deemed to have limitations including difficulties in relation to compliance with CoPoNC, the lack of incentive for innovation by industry and a restriction on claims that could be of value to consumers and could enhance public health. Furthermore there are difficulties in interpretation, application and enforcement of the current Transitional Standard 1.1A.2.

FSANZ recommends the introduction of a new standard for health, nutrition and related claims, with the control of both general level claims and high level claims being predominantly by a standard. In reaching this decision consideration was given to minimizing the degree of regulation, commensurate with the risk to public health and of misleading information. FSANZ used an evidence-based approach to reach this recommendation, which included consumer research, label monitoring, a benefit-cost analysis, and advice sought from public submissions and expert advisory groups. The introduction of a new health, nutrition and related claims standard, enabling health claims which were previously not permitted, was evaluated by the benefit-cost analysis as having significant advantages over maintaining the status quo.

Two further regulatory options were considered, differing in the extent to which general level claims were controlled by a standard and a guideline. Based on the benefit-cost analysis, together with consideration of supplementary information, a recommendation is made to include the criteria and conditions for general level health claims and those aspects that are common to both general level claims and high level claims in a standard. Other aspects of general level claims, particularly the details relating to substantiation, will be managed outside the standard in a guideline and incorporated into the standard by reference. It is considered the approach provides benefits to the community, government and industry that outweigh the costs arising from the food regulatory measure.

The Draft Assessment Report includes numerous specific recommendations in relation to the regulation of health, nutrition and related claims. Some modifications to the criteria for content claims, as presently set out in the Code and in CoPoNC are being proposed. In addition, all labels carrying content claims will be required to indicate the %DI represented by the claimed property in the nutrient information panel (where there is a reference value for the component in the food), together with the %DI for energy to allow consumers to make informed choices.

Criteria for specific content claims (those which were evaluated to require criteria in order to meet public health objectives or which may otherwise mislead consumers) will be specified in the Standard. Other content claims can continue to be made providing they are not misleading. For a few content claims specific disqualifying criteria will apply.

General level health claims will require reference to both the specific health benefit and the property of the food responsible for that benefit. The property will need to be present above defined levels (qualifying criteria) in order to avoid misleading consumers. Foods able to carry claims must meet generic disqualifying criteria based on total sugars, saturated fat and sodium per serve). All general level health claims are either to be based on a list of pre-approved diet-health relationships provided in a guideline or supported by authoritative texts or by evidence prepared as specified in a substantiation guideline. Holding the evidence for substantiation of these claims is the responsibility of individual suppliers and pre-approval of general level health claims will not be required. In addition there are some specific wording conditions in relation to the context of the claim.

Suppliers may use high level claims based on substantiated diet-disease relationships specified in the Standard, subject to defined specific criteria and conditions. Any new high level claims require pre-approval by FSANZ by the normal application process to vary the Code.

Whilst the proposed new Standard will consolidate a number of aspects in relation to health, nutrition and related claims at this stage the criteria around claims relating to vitamins and minerals presently specified in the Code will not be changed, except for a change from a per reference quantity to a per serve basis. The actual criteria will be reviewed subsequent to the present proposal when the new Nutrient Reference Values have been finalised. Therefore at this stage the existing application of disqualifying criteria on the basis of claimable foods will apply to both content and health claims for vitamins and minerals only.

Attachments

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Policy Guideline Nutrition, Health and Related Claims
3. Cost Benefit Analysis – report by Allens Consulting
4. Consumer Research; Label Monitoring – Executive Summaries
5. Regulatory Framework - generic
6. Regulatory Framework – specific
7. Summary of Submissions
8. Substantiation Framework
9. Development of Terminology
10. Substantiated high level and general level claims

Web links to External Documents

Health Claims Consumer Research
Benefit Cost Analysis
Label Monitoring Project
Submissions
Advisory Groups Terms of Reference
Food Regulation Standing Committee Policy Review
Policy Guidance on Fortification of Foods
Full Reviews of Substantiated Diet-Disease Relationships

Attachment 1

Draft variations to the *Australia New Zealand Food Standards Code*

To commence: on gazettal

[1] ***Standard 1.1.1*** *of the Australia New Zealand Standards Code is varied by –*

[1.1] *omitting from clause 2, the definition of* claim

[1.2] *inserting in clause 2 –*

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

claim means any statement, representation, design or information in relation to a food or property of a food which is not mandatory in this Code, and includes an implied claim.

claimable food means a food which consists of at least 90% by weight of –

(a)	(i)	primary foods; or
	(ii)	foods listed in the Table to clause 2 of Standard 1.3.2; or
(b)	(i)	a mixture of primary foods; and/or
	(ii)	water; and/or;
	(iii)	foods listed in the Table to clause 2 of Standard 1.3.2 excluding butter, cream and cream products, edible oils, edible oil spreads and margarine.

ingredient means any substance, including a food additive, used in the preparation, manufacture or handling of food.

primary food means fruit, vegetables, grains, legumes, meat, milk, eggs, nuts, seeds and fish.

reference quantity means –

(a) in relation to a food specified in the Table to clause 2 of Standard 1.3.2, either the quantity specified in that Table for that food or, in relation to a food which requires dilution or reconstitution according to directions, the quantity of the food which when diluted or reconstituted produces the quantity specified in column 2 of the Table; or

(b) in relation to all other claimable foods, either a normal serve or, in relation to a food which requires dilution, reconstitution, draining or preparation according to directions, the quantity of the food which when diluted, reconstituted, drained or prepared produces a normal serve.

reference value means RDI, ESADDI or a reference value under the Table to subclause 7(4) of Standard 1.2.8.

[2] ***Standard 1.1A.2*** *of the Australia New Zealand Standards Code is varied by omitting subclause (1C), substituting –*

Deleted

[3] ***Standard 1.2.4*** *of the Australia New Zealand Standards Code is varied by omitting from clause 1, the definition of* ingredient.

[4] ***Standard 1.2.7*** *of the Code is varied by substituting –*

STANDARD 1.2.7

NUTRITION, HEALTH AND RELATED CLAIMS

Purpose

This Standard is designed to regulate nutrition content claims, health claims, endorsements and cause related marketing statements, whether appearing on food labels or in advertisements. It also consolidates a number of requirements relating to claims made under the Code that were previously spread across a number of standards, such as Standards 1.2.8 and 1.3.2.

This Standard imposes requirements in relation to the contents of food labels and advertisements for food. Food legislation applies the requirements of the Code in relation to food intended for sale or for sale, and to the conduct of food businesses. It does not apply the requirements of the Code to other types of activities, for example, government health promotional campaigns or public health materials published by community based organisations.

Table of Provisions

Division 1 – Preliminary

Clauses

1 Interpretation

In this Code –

biomarker means a measurable biological parameter which, when present at an abnormal level in the human body, is predictive of the risk of a serious disease.

cause related marketing statement means a statement that the sale of the food will contribute to fundraising for an organisation, the name of which refers to a serious disease.

dietary information means general dietary information, and includes information from national nutrition guidelines, but does not include information that refers to a specific brand of food and a health effect.

Editorial note

Current national nutrition guidelines are as follows –

(a) National Health and Medical Research Council (2003) Dietary guidelines for Australian Adults
(b) National Health and Medical Research Council (2003) Dietary guidelines for Children and Adolescents in Australia
(c) National Health and Medical Research Council (1999) Dietary Guidelines for Older Australians
(c) New Zealand Ministry of Health 2003. Food and Nutrition Guidelines for Healthy Adults
(d) New Zealand Ministry of Health 1997. Food and Nutrition Guidelines for Healthy Children aged 2-12 years
(e) New Zealand Ministry of Health 1997. Guidelines for Healthy Pregnant Women
(f) New Zealand Ministry of Health 1997. Guidelines for Healthy Breastfeeding Women
(g) New Zealand Ministry of Health 1996. Guidelines for Healthy Older People
(h) New Zealand Ministry of Health 1998. Food and Nutrition Guidelines for Healthy Adolescents

endorsement means a design used, or intended to be used, to distinguish food certified by an endorsing organisation in relation to its nutrition or health features from other foods not so certified, and includes a certification trade mark, but does not include –

(a) a design that distinguishes food in relation to ethical, religious or environmental features including vegetarian, halal, kosher or organic designs; or
(b) a design that includes a reference to a serious disease other than as part of the name of the endorsing organisation.

endorsing organisation means an independent, non-profit or not-for-profit organisation formed for nutrition, health, community or government purposes, the name of which may include a serious disease, but does not include an organisation established by suppliers or their representatives.

food group means –

(a) bread and other cereal products; or
(b) fruit and/or vegetables; or
(c) milk and milk products; or
(d) meat, fish, eggs, nuts, seeds and legumes;

and does not include sauces, condiments, coatings, stuffings or garnishes unless a single ingredient of one of these is –

(e) at least 40 g per serve of the meal/main dish product; and
(f) falls within (a), (b), (c) or (d).

general level claim means –

(a) a nutrition content claim; or
(b) a health claim that does not, directly or indirectly, refer to a serious disease or a biomarker.

health claim means a claim that directly or indirectly refers to a relationship between –

(a) a food; or
(b) a category of food; or
(c) a property of a food, and

a health effect, but does not include an endorsement, dietary information or a cause related marketing statement.

health effect means –

(a) a measure of the impact of a substance on the healthy functioning of the human body; or

(b) a measure of the impact on the health or performance of a specific population, where the impact is associated with a particular dietary intake;

and for the purposes of this definition, 'impact' includes maintenance.

high level claim means a health claim that directly or indirectly refers to a serious disease or a biomarker.

meal/main dish product means a food that contains, per serve –

(a) at least 170 g of food; and
(b) at least two ingredients (including compound ingredients) from at least two different food groups, of at least 40g each.

nutrition content claim means a claim about the presence or absence of a property of a food, but does not include an endorsement, dietary information or a cause related marketing statement.

property of a food means energy, a nutrient, or a biologically active substance, or –

(a) a component; or
(b) an ingredient; or
(c) any other feature or constituent of the food;

that is associated with a health effect, including glycaemic index and glycaemic load.

reference food means a food that is –

(a) equivalent to the food in relation to which the claim is being made; and
(b) a regular product in the same category of food as that food in relation to which a claim is being made.

serious disease means a disease, ailment, defect or condition that is not appropriate to diagnose, treat or manage without consultation with or supervision by a health care professional, and includes obesity, but does not include overweight.

substantiate means substantiate in accordance with the [insert Title of Substantiation Framework], dated [dd mm yyyy].

2 Application

(1) This Standard applies to trade marks registered in Australia or New Zealand after the commencement of this Standard if the trade marks constitute general level claims, high level claims, cause-related marketing statements or endorsements.

(2) This Standard does not apply to –

(a) the National Heart Foundation's Tick Food Information Program;
(b) Glycemic Index Limited's Glycemic Index Symbol Program;
(c) Toothfriendly International's 'Happy Tooth' logo;
(d) NSW School Canteen Association's 'Healthy Kids' Product Registration Scheme;
(e) Federation of Canteens in School's 'Star Choice' Product Registration Scheme;
(f) Coeliac Society of Australia Inc.'s Gluten Free Symbol.

(3) A food product is taken to comply with this Standard for a period of 24 months after the commencement of this Standard, if the food product otherwise complied with this Code before the Standard commenced.

(4) To avoid doubt, subclause 1(2) of Standard 1.1.1 does not apply to this Standard.

Division 2 – General Requirements

3 Claims, endorsement and statement prohibition

(1) Unless permitted by this Standard or under Part 2.9 of the Code, a general level claim, a high level claim, an endorsement or a cause related marketing statement must not be made on a label or in an advertisement for food.

(2) Unless permitted by subclause 8(3) of Standard 2.6.2, a claim must not refer to the prevention, diagnosis, cure or alleviation of a disease, ailment, defect or condition, or the symptoms of any of these.

(3) A claim must not compare a food and a therapeutic good.

4 Foods that must not have general level and high level claims made in relation to them, except in limited circumstances

(1) Subject to subclause (2) and Part 2.9 of the Code, a general level claim or high level claim must not be made in relation to –

(a) a food that, if packaged, would be required to include a statement of alcohol content under clause 2 of Standard 2.7.1; or
(b) an infant formula product as standardised under Standard 2.9.1.

(2) A nutrition content claim that refers to –

(a) alcohol content; or
(b) energy content;

may be made in relation to a food that, if packaged, would be required to include a statement of alcohol content under clause 2 of Standard 2.7.1.

5 Conditions for general level claims

(1) A nutrition content claim may be made if the following conditions are complied with –

(a) the supplier of the food has records substantiating the claim; and
(b) the food complies with any applicable conditions under clause 11 of this Standard for making the nutrition content claim; and
(c) for claims that the food is a 'source' of the property, there is a reference value for the property in the Code; and
(d) for claims that the food is a 'good source' of the property –

(i) there is a reference value for the property in the Code; or
(ii) there are criteria in the Code for use of a 'good source' claim in relation to the property; and

(e) if the claim relates to a property of a food that is present or absent in similar food in the same category, the claim must refer to the category of food and not the individual food.

(2) A general level claim, other than a nutrition content claim, may be made if the following conditions are complied with –

(a) except for a claim in relation to a vitamin, mineral, gluten or lactose, or an infant food as standardised under Standard 2.9.2 –

(i) subject to paragraph (ii), the food to which the claim relates contains no more than –

(A) 325 mg of sodium per serve; and
(B) 4 g of saturated fatty acids per serve; and
(C) 16 g of total sugars per serve; and

(ii) for meal/main dish products, the food to which the claim relates contains no more than –

(A) 775 mg of sodium per serve; and
(B) 7 g of saturated fatty acids per serve; and
(C) 31 g of total sugars per serve; and

(b) if the claim relates to a food rather than a property of a food, the food consists of no less than 90% by weight of primary food; and
(c) the supplier of the food has records substantiating the claim and/or the claim is based on the nutrition function statements in [Title of FSANZ pre-approved list of nutrition function statements], dated [dd mm yyyy]; and
(d) the food complies with any applicable conditions under Division 3 of this Standard for –

(i) making a nutrition content claim in relation to the property of the food that is the subject of the general level claim; and
(ii) making a general level claim, other than a nutrition content claim;

(e) the claim states –

(i) the property of the food (unless the substantiation is based on the food itself and the specific health effect, in which case it states the food itself); and
(ii) the specific health effect claimed in relation to the property or the food, and
(iii) if applicable, the population group to which the specific health effect relates; and
(iv) that the health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods, as appropriate to the type of food and the specific health effect claimed; and

(f) the claim is presented so that all elements of the claim are in the one place; and
(g) the property of the food, or the property of the food and the specific health effect of the food, may be presented separately with a statement indicating where the complete claim under paragraph (f) is placed.

6 Conditions for high level claims

(1) A high level claim may be made if –

(a) the diet-disease relationship that is the subject of the claim is listed in column 1 of the Table to this subclause; and
(b) the food complies with any conditions listed in column 2 of the Table to this subclause; and
(c) the claim states, in words to the effect of those listed in column 3 of the Table to this subclause –

(i) the property of the food; and
(ii) the specific health effect claimed in relation to the property or the food, and
(iii) the population group to which the specific health effect relates; and
(iv) that the health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods, as appropriate to the type of food and the specific health effect claimed; and

(d) the claim is presented so that all elements of the claim are in the one place.

(2) The property of the food, or the property of the food and the specific health effect of the food, may be presented separately with a statement indicating where the complete claim under subclause 1(c) is placed.

Table to clause 6

Column 1	Column 2	Column 3
Substantiated diet-disease relationship	**Conditions**	**Claim statements**
Calcium, vitamin D and osteoporosis	(a) the food contains no less than 300 mg of calcium per serve; and (b) the food is a claimable food;	(a) the property of the food is calcium; and (b) vitamin D may also be included as the property of the food if the food complies with any applicable conditions under clause 11 of this Standard for making a nutrition content claim in relation to vitamin D; and (c) the specific health effect is reduced risk of osteoporosis, enhanced bone mineral density or reduced risk of osteoporotic fracture; and (d) the population group is persons 65 years and over; and (e) the context is a healthy diet with a high intake of calcium from a variety of foods and adequate vitamin D status.
Calcium and enhanced bone density	(a) the food contains no less than 200 mg of calcium per serve; and (b) the food is a claimable food	(a) the property of the food is calcium; and (b) the specific health effect is enhanced bone mineral density; and (c) the population group is the general population; and (d) the context is a healthy diet with a high intake of calcium from a variety of foods.
Folic acid and neural tube defect	(a) the food contains no less than 65µg folate and/or folic acid per serve; and (b) the food complies with the conditions for a general level claim other than a nutrition content claim in relation to the sodium, saturated fatty acid and sugars content of the food (c) the food is not – (i) soft cheese; or (ii) pâté; or (iii) liver or liver product; or (iv) regulated in Standard 2.4.2 containing phytosterol esters or tall oil phytosterols; (v) food standardised in Standard 2.6.4; or (vi) food standardised in Part 2.7; or (vii) food standardised in Standard 2.9.1, 2.9.2 or 2.9.4; or (viii) a formulated meal replacement standardised in Standard 2.9.3.	(a) the property of the food is folate; and (b) the specific health effect is reduced risk of foetal neural tube defects; and (c) the population group is women of child bearing age; and (d) the context is a recommendation that women consume at least 680µg of dietary folate equivalents per day or 400µg of folic acid per day, at least the month before and three months after conception.

Saturated fatty acids and LDL cholesterol	(a) the food complies with the conditions under clause 11 of this Standard for a nutrition content claim in relation to low saturated fatty acids; and (b) the food complies with the conditions for a general level claim other than a nutrition content claim in relation to the sodium and sugars content of the food.	(a) the property of the food is saturated fatty acids; and (b) the specific health effect is may help reduce blood cholesterol, total blood cholesterol, blood LDL cholesterol, serum LDL cholesterol, total serum cholesterol or serum cholesterol levels; and (c) the population group is the general population; and (d) the context is a healthy diet with a variety of foods low in saturated fatty acids.
Saturated and trans fatty acids and LDL cholesterol	(a) the food complies with the conditions under clause 11 of this Standard for a nutrition content claim in relation to low saturated and trans fatty acids; and (b) the food complies with the conditions for a general level claim other than a nutrition content claim in relation to the sodium and sugars content of the food.	(a) the property of the food is saturated and trans fatty acids; and (b) the specific health effect is may help reduce blood cholesterol, total blood cholesterol, blood LDL cholesterol, serum LDL cholesterol, total serum cholesterol or serum cholesterol levels; and (c) the population group is the general population; and (d) the context is a healthy diet with a variety of foods low in saturated and trans fatty acids.
Sodium and blood pressure	(a) the food complies with the conditions under clause 11 of this Standard for a nutrition content claim in relation to low salt; and (b) the food complies with the conditions for a general level claim other than a nutrition content claim in relation to the saturated fatty acid and sugars content of the food.	(a) the property of the food is sodium; and (b) the specific health effect is maintenance of normal blood pressure or reduced blood pressure; and (c) the population group is the general adult population; and (d) the context is a healthy diet of a variety of foods low in salt.

7 Conditions for cause-related marketing statements

(1) Subject to subclause (2), a cause related marketing statement may be made if words to the effect of the following disclaimer appear in the same place as the cause related marketing statement –

[insert supplier name] makes no claims in relation to this food being beneficial for managing [insert serious disease].

(2) If a high level claim is made that refers to the serious disease that is included in the cause related marketing statement, the disclaimer under subclause (1) is not required.

8 Conditions for endorsements

(1) Subject to subclauses (2) and (3), an endorsement may be used if –

(a) the endorsement complies with conditions for a general level claim other than a nutrition content claim in relation to substantiation; and

(b) the food complies with the conditions for a general level claim other than a nutrition content claim in relation to the sodium, saturated fatty acid and sugars content of the food.

(2) If the endorsement relates to a property of the food, then the food must comply with any applicable conditions under clause 11 of this Standard for making a nutrition content claim in relation to the property.

(3) An endorsement intended to distinguish food in relation to its gluten or lactose content must comply with –

(a) requirements for a general level claim other than a nutrition content claim in relation to substantiation; and
(b) applicable conditions under clause 11 of this Standard for making nutrition content claims in relation to gluten or lactose.

(4) To avoid doubt –

(a) a reference to a serious disease in an endorsing organisation's name does not constitute a high level health claim; and
(b) an endorsing organisation may reference a serious disease in its information or education materials.

9 Conditions for dietary information

(1) Subject to subclause (2) and (3), if dietary information is provided on a label or in an advertisement, it must relate to the property of the food that is the subject of a claim.

(2) If the property of the food is not part of the claim under subparagraph 5(2)(d)(i), then any dietary information provided must relate to the food.

(3) This clause does not apply where dietary information relates to moderating the consumption of food.

10 Conditions for small packages

(1) Where a nutrition content claim is made in relation to a food in a small package, the label on that package is exempt from conditions under the following provisions of this Standard –

(a) subparagraphs 5(2)(d)(iii) and (iv); and
(b) paragraph 5(2)(f); and
(c) subparagraphs 6(1)(iii) and (iv); and
(d) subclause 6(2); and
(e) item (c) under the conditions for reduced cholesterol claims in Table to clause 11; and
(f) item (c) under the conditions for increased dietary fibre claims in the Table to clause 11; and
(g) item (b) under the conditions for reduced energy claims in the Table to clause 11; and
(h) item (c) under the conditions for diet claims in the Table to clause 11; and
(i) item (b) under the conditions for reduced fat claims in the Table to clause 11; and

(j) item (d) under the conditions for omega-3 fatty acid claims in the Table to clause 11; and
(k) item (b) under the conditions for low salt or sodium claims in the Table to clause 11; and
(l) item (d) under the conditions for reduced salt or sodium claims in the Table to clause 11; and
(m) item (c) under the conditions for no added salt or sodium claims in the Table to clause 11; and
(n) item (b) under the conditions for reduced saturated and trans fatty acids claims in the Table to clause 11; and
(o) item (b) under the conditions for reduced saturated fatty acids claims in the Table to clause 11; and
(p) item (b) under the conditions for reduced sugar or sugars claims in the Table to clause 11; and
(q) item (c) under the conditions for no added sugar or sugars claims in the Table to clause 11; and
(r) item (a)(iii) under the conditions for biologically active substances claims in the Table to clause 12.

Division 3 – Conditions for making certain general level claims

11 Conditions for specific nutrition content claims

(1) Subject to compliance with the conditions in column 3 to the Table, a nutrition content claim may be made –

(a) in relation to the property or a property synonymous with that listed in column 1 of the Table to this clause; and
(b) using the descriptor or a descriptor synonymous with that listed in column 2 of the Table to this clause, if any.

Table to clause 11

Column 1	Column 2	Column 3
Property	**Descriptor**	**Nutrition content claim conditions**
Biologically active substance	Not applicable	(a) the claim refers to the presence of the substance; and (b) subject to (c), the claim does not include any descriptors in relation to the level of the substance that is present; and (c) if any statement is made indicating that a certain amount of the food or property be consumed in a given period of time, the supplier of the food has records substantiating the basis for this statement and the statement describes this basis.
Cholesterol	Free	(a) the food complies with the conditions for a nutrition content claim in relation to low saturated fatty acids.
	Low	(a) the food complies with the conditions for a nutrition content claim in relation to cholesterol free; and (b) the food contains no more than 20 mg cholesterol per 100 g.

	Reduced	(a) the food complies with the conditions for a nutrition content claim in relation to cholesterol free; and (b) the food contains at least 25% less cholesterol as the same quantity of reference food; and (c) the claim states – (i) the identity of the reference food; and (ii) the difference between the cholesterol content of the food and the reference food; and (d) the claim is presented so that all elements of the claim are in the one place.
Dietary fibre		(a) for meal/main dish products – a serve of the food contains at least 5.5g of dietary fibre; and (b) for all other foods – a serve of the food contains at least 2g of dietary fibre.
	Good source	(a) for meal/main dish products – a serve of the food contains at least 11g of dietary fibre; and (b) for all other foods – a serve of the food contains at least 4g of dietary fibre
	Increased	(a) for meal/main dish products – a serve of the food contains at least 5.5g of dietary fibre; and (b) for all other foods – a serve of the food contains at least 2g of dietary fibre; and (c) the food contains at least 25% more dietary fibre as the same quantity of reference food; and (d) the claim states – (i) the identity of the reference food; and (ii) the difference between the dietary fibre content of the food and the reference food; and (e) the claim is presented so that all elements of the claim are in the one place.
Energy	Low	(a) the average energy content of the food is no more than – (i) 80 kJ per 100 mL for liquid food; and (ii) 170 kJ per 100 g for solid food; and (b) 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.
	Reduced	(a) the food contains at least 25% less energy as the same quantity of reference food; and (b) the claim states – (i) the identity of the reference food; and (ii) the difference between the energy content of the food and the reference food; and (c) the claim is presented so that all elements of the claim are in the one place.

	Diet	(a) the food complies with conditions for a general level claim other than a nutrition content claim in relation to the sodium, saturated fatty acid and sugars content of the food; and (b) the food – (i) complies with conditions for a nutrition content claim in relation to low energy; or (ii) the food contains at least 40% less energy as the same quantity of reference food, and the energy content of the food has been reduced by at least 170 kJ per 100g for solid food or 80 kJ per 100 mL for liquid food relative to the reference food; and (c) if (b)(ii) applies, the claim states – (i) the identity of the reference food; and (ii) the difference between the energy content of the food and the reference food; and (d) the claim is presented so that all elements of the claim are in the one place.
Fat	% Free	(a) the food complies with the conditions for a nutrition content claim in relation to low fat.
	Low	(b) the food contains no more fat than – (i) 1.5 g per 100 mL for liquid food; and (ii) 3 g per 100 g for solid food.
	Reduced	(a) the food contains at least 25% less fat as the same quantity of reference food; and (b) the claim states – (i) the identity of the reference food; and (ii) the difference between the fat content of the food and the reference food; and (c) the claim is presented so that all elements of the claim are in the one place.
Gluten		(a) the claim states whether it is a gluten free or low gluten claim.
	Free	(a) the food contains – (i) no detectable gluten; and (ii) no – (A) oats or their products; or (B) cereals containing gluten that have been malted, or their products.
	Low	(a) the food contains no more than 20 mg gluten per 100 g of the food
Glycaemic Index or Load		(a) the claim refers to the presence of the property; and (b) subject to (c), the claim does not include any descriptors in relation to the level of the property that is present; and (c) the claim may include the numeric value of the glycaemic index or load of the food.

Lactose		(a) the claim states whether it is a lactose free or low lactose claim.
	Free	(a) the food contains no detectable lactose; and (b) the nutrition information panel indicates the lactose and galactose content.
	Low	(a) the food contains no more than 2 g of lactose per 100 g of the food; and (b) the nutrition information panel indicates the lactose and galactose content.
Light or lite		(a) the claim states the characteristic of the food to which the claim relates; and (b) if the claim relates to a nutrient, energy or salt, the food complies with the conditions for a reduced nutrition content claim in relation to that nutrient, energy or salt; and (c) the claim is presented so that all elements of the claim are in the one place.
Monounsaturated fatty acid		(a) the food contains, as a proportion of the total fatty acids content – (i) no more than 28% saturated fatty acids and trans fatty acids; and (ii) no less than 40% monounsaturated fatty acid.
Omega fatty acid		(a) the type of omega fatty acid is specified immediately after the word 'omega'.
Omega-3 fatty acid		(a) the food complies with the conditions for a nutrition content claim in relation to omega fatty acid; and (b) the food contains no less than – (i) 200 mg alpha-linolenic acid per serve; or (ii) 30 mg total eicosapentaenoic acid and docosahexaenoic acid per serve; and (c) other than for fish or fish products with no added saturated fatty acids, the food contains – (i) as a proportion of the total fatty acids content, no more than 28% saturated fatty acids and trans fatty acids; or (ii) no more saturated fatty acids and trans fatty acids than 5 g per 100 g; and (d) the nutrition information panel indicates the source of omega 3 fatty acids, that is, alpha-linolenic acid, docosahexaenoic acid and/or eicosapentaenoic acid.
	Good source	(a) the food complies with the conditions for a nutrition content claim in relation to omega-3 fatty acid; and (b) the food contains no less than 60 mg total eicosapentaenoic acid and docosahexaenoic acid per serve.
Omega-6 fatty acid		(a) the food complies with the conditions for a nutrition content claim in relation to omega fatty acid; and (b) the food contains, as a proportion of the total fatty acids content – (i) no more than 28% saturated fatty acids and trans fatty acids; and (ii) no less than 40% omega-6 fatty acid.

Omega-9 fatty acid		(a) the food complies with the conditions for a nutrition content claim in relation to omega fatty acid; and (b) the food contains, as a proportion of the total fatty acids content – (i) no more than 28% saturated fatty acids and trans fatty acids; and (ii) no less than 40% omega-9 fatty acid.
Polyunsaturated fatty acid		(a) the food contains, as a proportion of the total fatty acids content – (i) no more than 28% saturated fatty acids and trans fatty acids; and (ii) no less than 40% polyunsaturated fatty acid.
Potassium		(a) the nutrition information panel indicates the sodium and potassium content.
Protein		(a) the food contains at least 5 g of protein per serve.
	Good source	(a) the food contains at least 10 g of protein per serve.
	Increased	(a) the food complies with the conditions for a nutrition content claim in relation to protein, before the food is enriched with protein; and (b) the food contains at least 25% more protein as the same quantity of reference food; and (c) the claim states – (i) the identity of the reference food; and (ii) the difference between the protein content of the food and the reference food; and (d) the claim is presented so that all elements of the claim are in the one place.
Salt or sodium		(a) the nutrition information panel indicates the potassium content.
	Low	(a) the food contains no more sodium than – (i) 120 mg per 100 mL for liquid food; and (ii) 120 mg per 100 g for solid food.
	Reduced	(a) the food contains at least 25% less sodium as the same quantity of reference food; and (b) the claim states – (i) the identity of the reference food; and (ii) the difference between the sodium content of the food and the reference food; and (d) the nutrition information panel indicates the potassium content.
	No added	(a) the food contains no added sodium compound and no added salt; and (b) the ingredients of the food contain no added sodium compound and no added salt; (c) if the food naturally contains sodium, the claim states that the food contains naturally occurring sodium.
	Unsalted	(a) the food complies with the conditions for a nutrition content claim in relation to no added salt.

Saturated and trans fatty acid	Low	(a) the food contains no more saturated and trans fatty acids than – (i) 0.75 g per 100 mL for liquid food; and (ii) 1.5 g per 100 g for solid food.
	Reduced	(a) the food contains – (i) at least 25% less saturated and trans fatty acids as the same quantity of reference food; and (ii) both saturated and trans fatty acids are reduced relative to the same quantity of reference food; and (b) the claim states – (i) the identity of the reference food; and (ii) the difference between the saturated and trans fatty acids content of the food and the reference food; and (c) the claim is presented so that all elements of the claim are in the one place.
Saturated fatty acid	Low	(a) the food contains no more saturated and trans fatty acids than – (i) 0.75 g per 100 mL for liquid food; and (ii) 1.5 g per 100 g for solid food.
	Reduced	(a) the food contains – (i) at least 25% less saturated fatty acids as the same quantity of reference food; and (ii) no more trans fatty acids as the same quantity of reference food; and (b) the claim states – (i) the identity of the reference food; and (ii) the difference between the saturated fatty acid content of the food and the reference food; and (c) the claim is presented so that all elements of the claim are in the one place.
Sugar or Sugars	% Free	(a) the food complies with the conditions for a nutrition content claim in relation to low sugar.
	Low	(a) the food contains no more sugars than – (i) 2.5 g per 100 mL for liquid food; and (ii) 5 g per 100 g for solid food.
	Reduced	(a) the food contains at least 25% less sugars as the same quantity of reference food; and (b) the claim states – (i) the identity of the reference food; and (ii) the difference between the sugars content of the food and the reference food; and (c) the claim is presented so that all elements of the claim are in the one place.

	No added	(a) the food contains no added sugars, honey, malt, malt extracts; and (b) the food contains no added concentrated fruit juice or deionised fruit juice, unless the food is standardised under Standard 2.6.1 or 2.6.2; and (c) if the food naturally contains sugars, the claim states that the food contains naturally occurring sugars; and (d) the claim is presented so that all elements of the claim are in the one place.
	Unsweetened	(a) the food complies with the conditions for a nutrition content claim in relation to no added sugar; and (b) the food contains no intense sweeteners, sorbitol, mannitol, glycerol, xylitol, isomalt, maltitol syrup or lactitol.
Vitamin or mineral		(a) the vitamin or mineral is listed in column 1 of the Schedule to Standard 1.1.1; and (b) the food is a claimable food; and (c) a serve of the food contains at least 10% of the RDI or ESADDI, for that vitamin or mineral; and (d) a claim must not be made – (i) comparing, whether expressed or implied, the vitamin or mineral content of the food with that of any other food except where expressly permitted in this Code; or (ii) that a food listed in column 1 of the Table to clause 2 of Standard 1.3.2 to which a vitamin or mineral has been added, contains in a reference quantity of the food, that vitamin or mineral, both added and naturally present, in greater proportion than that specified in column 4.
	Good source	(a) the food complies with the conditions for a nutrition content claim in relation to that vitamin or mineral; and (b) a serve of the food contains no less than 25% of the RDI or ESADDI for that vitamin or mineral.
Wholegrain		(a) a serve of the food contains at least 8g of wholegrain
	Good source	(a) serve of the food contains at least 15g of wholegrain

(2) To avoid doubt, 'slimming' is not synonymous with 'diet'.

12 Conditions for making specific general level claims, other than nutrition content claims

Subject to compliance with the conditions in column 2 to the Table, a general level claim, other than a nutrition content claim, that refers directly or indirectly to a matter listed in column 1 of the Table may be made.

Table to clause 12

Column 1	Column 2
General level claim	**General level claim conditions**
Biologically active substance	(a) the claim states – (i) the level of the substance in the food; and (ii) the amount of the substance that is required to be consumed per day to achieve the specific benefit; and (iii) the basis for the statement under (ii); and (b) a serve of the food contains at least 10% of the amount stated under (a)(ii); and (c) the supplier of the food has records substantiating the basis for the statement under (a)(ii).
Maternal folate consumption and normal foetal development	(a) the food complies with the conditions for a high level claim in relation to folic acid and neural tube defect; and (b) the claim states the context as required for a high level claim in relation to folic acid and neural tube defect.
Weight loss or maintenance	(a) the food complies with the conditions for making a low joule claim in the Table to clause 11; and (b) the claim states that the specific health effect must be considered in the context of the importance of regular exercise.

13 Calculation of maximum quantity of a vitamin or mineral which may be claimed in a reference quantity of a claimable food

(1) Where a claimable food contains more than one ingredient, the maximum claim permitted in relation to a vitamin or mineral present in a reference quantity of the claimable food, is calculated by adding together the quantity calculated for each ingredient in accordance with the formula set out in subclause (2), rounding to the nearest multiple of 5.

(2) In this subclause –

A means the quantity of a vitamin or mineral permitted to be claimed in relation to each ingredient calculated in accordance with the formula.

B means, whichever is the lesser of the –

(a) quantity of the vitamin or mineral present in a reference quantity of the ingredient; or

(b) maximum permitted claim for the vitamin or mineral in a reference quantity of the ingredient.

C means the proportion of the ingredient in the food.

D means the reference quantity of the claimable food.

E means the reference quantity of the ingredient.

Formula:

$$A = B \times C \times {}^{D}/_{E} \text{ (rounded to the nearest multiple of 5)}$$

Editorial note:
EXAMPLE CALCULATION
Vitamin C claim for an apple and blackcurrant fruit drink (42% juice, apple 40%, blackcurrant 2%) in a reference quantity of 200 mL:

(a) Apple juice: 120 mg (maximum claim) x 40/100 (proportion of juice in final product) = 48 mg
Blackcurrant juice: 500 mg (maximum claim) x 2/100 (proportion of juice in final product) = 10 mg

(b) 48 mg + 10 mg = 58 mg

(c) Maximum claim for the food is 60 mg (result rounded to nearest multiple of 5 mg)

[5] ***Standard 1.2.8*** *of the Australia New Zealand Food Standards Code is varied by –*

[5.1] *omitting from clause 1, the definition of* nutrition claim *and the associated* Editorial note

[5.2] *substituting* nutrition content claim or health claim *for* nutrition claim*, wherever occurring*

[5.3] *omitting clause 4, substituting –*

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

(1) Subject to subclause (4), where a nutrition content claim or health claim is made –

(a) a nutrition information panel must be included on the label on the package of the food; and
(b) the nutrition information panel must include percentage intake information in accordance with clause 7 of this Standard.

(2) Subject to subclauses (3) and (4), where a nutrition content claim or health 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 clauses 5 and 7, 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 content claim or health claim is made in relation to a food in a small package, the label must include the information prescribed in clause 8.

(4) Where a nutrition content claim is made in relation to a food that, if packaged, would be required to include a statement of alcohol content under clause 2 of Standard 2.7.1, a nutrition information panel or other nutrition information is not required.

[5.4] *omitting from the* Editorial note *following clause 5 –*

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

[5.5] *inserting after subclause 5(2) –*

(2A) For 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 serve of the food.

[5.6] *omitting clause 7, substituting –*

7 Percentage intake information

(1) Where a nutrition content claim or health claim is made, the following matters must be included in the panel –

(a) the percentage daily intake of energy per serve; and
(b) the percentage daily intake or RDI of any property that is the subject of the claim, if there is a reference value for the property in the Code, per serve; and
(c) the statement –

'*based on an average adult diet of 8700 kJ'; or

'Percentage daily intakes are based on an average adult diet of 8700 kJ'.

(2) Where a nutrition content claim or health claim is not made, information relating to the percentage daily intake or RDI of nutrients may be set out in a nutrition information panel.

(3) Where information is included in a panel under subclause (2), the following matters must be included in the panel –

(a) the percentage daily intake of energy per serve; and
(b) the statement –

'*based on an average adult diet of 8700 kJ'; or

'Percentage daily intakes are based on an average adult diet of 8700 kJ'

EXAMPLES

NUTRITION INFORMATION Serves per package: (insert number of serves) Serve size: g (or mL or other units as appropriate)			
	Quantity per Serve	% Daily Intake* (per Serve)	Quantity per 100 g (or 100 mL)
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)
*based on an average adult diet of 8700 kJ			

NUTRITION INFORMATION Serves per package: (insert number of serves) Serve size: g (or mL or other units as appropriate)		
	Quantity per Serve	Quantity per 100 g (or 100 mL)
Energy	kJ (Cal) (%DI*)	kJ (Cal)
Protein	g (%DI)	g
Fat, total – saturated	g (%DI) g (%DI)	g g
Carbohydrate – sugars	g (%DI) g (%DI)	g g
Sodium	mg (mmol) (%DI)	mg (mmol)
(insert any other nutrient or biologically active substance to be declared)	g, mg, μg (or other units as appropriate) (%DI or RDI as appropriate)	g, mg, μg (or other units as appropriate)
*Percentage daily intakes are based on an average adult diet of 8700 kJ		

(4) 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(4)

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

(5) The percentage RDI of vitamins or minerals that are included in the panel must be calculated using the reference values specified in the Schedule to Standard 1.1.1.

(6) To avoid doubt, a claim in relation to salt is a claim in relation to sodium.

[5.7] *omitting clause 8, substituting –*

8 Food in small packages

(1) Subject to subclause (3), where a nutrition content claim or health 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 content claim or health 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 content claim or health 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 content claim or health claim is made that the food is fat-free, sugar-free, low joule or any similar term.

(2) Where a nutrition content claim or health claim is made in relation to a food in a small package, the label on that package must include percentage intake information in accordance with clause 7 of this Standard.

(3) The information required to be declared in subclauses (1) and (2) 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.

[5.8] *omitting Divisions 3 and 4, substituting –*

Division 3 – Miscellaneous

12 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 12(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).
Total dietary fibre (including resistant maltodextrins)	Section 2001.03 of the AOAC, 17th Edition, 1st Revision (2002)
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 12(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.

Total dietary fibre as determined by Section 985.29, or Section 991.43 of the AOAC, 17th Edition (2000) may include resistant maltodextrins. However, these methods cannot fully determine resistant maltodextrins as total dietary fibre, and should not be used for this purpose. Section 2001.03 of the AOAC, 17th Edition, 1st Revision (2002) is an accurate method for determining resistant maltodextrins as dietary fibre, and should be used to ascertain total dietary fibre content where full analysis of resistant maltodextrins is required.

Added resistant maltodextrins must comply with Standard 1.3.4 – Identity and Purity.

[6] ***Standard 1.3.2*** *of the Code is varied by –*

[6.1] *omitting the* Purpose*, substituting –*

This Standard regulates the addition of vitamins and minerals to foods, other than those special purpose foods standardised in Part 2.9, the addition of iodine to certain salt products in Standard 2.10.2, the addition of thiamin to flour for bread making in Standard 2.1.1, the addition of vitamin D to table edible oil spreads and margarine in Standard 2.4.2, and the addition of vitamins to formulated caffeinated beverages in Standard 2.6.4.

[6.2] *omitting the* Table of Provisions, *substituting –*

1 Prohibition on adding vitamins and minerals to food
2 Permitted addition of vitamins and minerals to food

[6.3] *omitting clause 1*

[6.4] *omitting the heading of clause 2, substituting –*

1 Prohibition on adding vitamins and minerals to food

[6.5] *omitting the heading of clause 3, substituting –*

2 Permitted addition of vitamins and minerals to food

[6.6] *omitting the heading of the* Table to clause 3*, substituting –*

Table to clause 2

[6.7] *omitting clauses 4 to 9*

[7] ***Standard 2.9.3*** *of the Australia New Zealand Food Standards Code is varied by inserting after subclause 7(4) –*

(5) Clause 7 of Standard 1.2.8 does not apply to formulated supplementary foods for young children.

To commence: two years after gazettal

[8] ***Standard 1.1A.2*** *of the Australia New Zealand Food Standards Code is deleted.*

Explanatory notes for P293 drafting

This drafting includes a standard regulating nutrition content claims, health claims, endorsements and cause related marketing statements. It is also designed to unite a number of requirements relating to claims made under the *Australia New Zealand Food Standards Code* (the Code) that are currently spread across a number of standards.

Interpretation – Definitions

Standard 1.1.1

One of the results of the consolidation of claim requirements under Standard 1.2.7 is that various definitions currently located in Standards 1.2.4, 1.2.8 and 1.3.2 and which at present only apply to those standards, will also need to apply to Standard 1.2.7. Accordingly, these definitions will be moved into Standard 1.1.1 and will apply generally across the Code. The following terms are affected –

- biologically active substance;
- claimable food;
- ingredient;
- primary food;
- reference quantity.

In addition, the fundamental definition of 'claim' under Standard 1.1.1 is proposed to be amended to put it beyond doubt that it encompasses implied claims. By implied claims, we mean claims that direct the attention or thoughts of an average consumer to a matter, though that matter is not expressly stated as part of the claim. As this meaning is consistent with common dictionary definitions, it is not necessary to define 'implied claims' under Standard 1.1.1. This is consistent with general drafting practice in the Code.

It should also be noted that although the definition of claim does not limit the context in which these may occur (e.g. to commercial contexts), the Code acquires its legal force through the operation of food legislation. This legislation applies the Code in relation to the conduct of a food business, to food intended for sale, and food for sale. It does not apply the Code to other contexts. Accordingly, it is not necessary to limit the definition of 'claim' to claims made in a particular context.

Standard 1.2.7

There are a number of fundamental concepts in Standard 1.2.7 that require definition.

First, there are two basic types of claims that are encompassed by the standard. These are –

- nutrition content claim; and
- health claim

A nutrition content claim is a claim about the presence or absence of a property of a food. This is a broad concept designed to capture traditional claims as well as newer or emerging forms of claims.

A ‘property of a food’ covers energy, a nutrient, or a biologically active substance (see Standard 1.1.1). It also covers a component (see Standard 1.1.1), an ingredient (see Standard 1.2.4), or any other feature or constituent of the food, provided that it is associated with a health effect. Otherwise, the definition of nutrition content claim has the potential to capture many claims about the content of food which do not have health or nutrition overtones.

Thus, ingredients such as wholegrains which are linked with a health effect are considered properties of food. Other aspects of foods, such as food additives, are not associated with a health effect and therefore do not constitute properties of food for the purposes of Standard 1.2.7.

Nutrition content claims are the most basic level of claims, and include –

- claims about vitamins and minerals, such as ‘this food is a source of vitamin C’ or ‘this food is a good source of iron’;
- claims about energy, such as ‘this food is low in kilojoules’
- claims about biologically active substances, such as ‘this food contains acidophilus’
- claims about components of food, such as ‘contains anti-oxidants’
- claims about nutrients, such as ‘with fibre’
- claims about ingredients, such as ‘contains wholegrains’.

A health claim goes further than a nutrition content claim, to refer to a relationship between a food, either singly or as a category, or a property of a food, and a health effect. ‘Health claim’ includes what have been referred to in previous health claims proposals as function claims and enhanced function claims – that is, claims that describe the link between a food or a property or component of food and its function in the human body. The definition of ‘health effect’ is designed to encompass such measures of health status as morbidity, life expectancy, birth defects, cancer incidence or recurrence, obesity rates, and nutritional status. Health effects can be positive or negative, can involve change or maintenance, and are physiological in nature.

However, the basic division between levels of regulation for nutrition content and health claims turns on whether the claim refers to a serious disease or a biomarker in relation to serious disease. If a claim does not refer to a serious disease or a biomarker, it is a general level claim. If a claim does refer to a serious disease or a biomarker, it is a high level claim.

Accordingly, general level claim and high level claim are defined in Standard 1.2.7, as are serious disease and biomarker.

The definition of serious disease has been developed with reference to those used in the regulation of therapeutic goods, and is intended to be consistent with (though not identical to) these definitions.

The definition of ‘therapeutic use’ under the *Therapeutic Goods Act 1989* (TGA Act) refers to ‘use in or in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons…’.

Under the Therapeutic Goods Advertising Code (TGAC), serious disease is defined as ‘a form of the disease, condition, ailment or defect that is:

(a) generally accepted as not being appropriate to be diagnosed or treated without consulting a suitably qualified health care professional; or
(b) generally accepted to be beyond the ability of the average person to evaluate accurately, or treat safely, without regular supervision by a suitably qualified health care professional.'

The difference between these definitions is that TGA Act includes reference to 'injury' whereas the TGAC includes reference to 'condition'.

Given this inconsistency in terminology between the TGA Act and the TGAC, FSANZ has opted for consistency with the TGAC. This is because in a dietary context, reference to 'condition' is more appropriate than a reference to 'injury'. In addition, 'ailment' appears sufficiently broad to cover at least some injuries. Accordingly, the definition of serious disease refers to 'disease, ailment, defect or condition'.

In addition, paragraph (b) of the definition of serious disease under the TGAC seems directed at conditions requiring ongoing supervision by a health care professional, rather than those requiring more limited term treatment. To address both these situations, the proposed definition of serious disease refers to disease, ailments, defects or conditions that are not appropriate to diagnose, manage or treat without consulting a health care professional. The addition of the reference to management of diseases, ailments, defects or conditions is designed to cover those things requiring ongoing supervision. Therefore, paragraph (b) of the TGAC definition of serious disease has not been included in the proposed definition of serious disease for Standard 1.2.7.

Finally, the TGAC reference to a health-care professional having to be 'suitably qualified' has not been included in the definition of serious disease for Standard 1.2.7. This concept introduces a level of uncertainty into the definition because the obvious question becomes, who decides whether a health-care professional is suitably qualified? In using the term 'professional' it is intended that only health-care providers with broadly recognised scientific qualifications be captured. This does not appear to have a substantive impact on the operation of the definition of serious disease.

For the purposes of this Standard, 'biomarker' is defined in terms of serious disease because other biomarkers that relate to non-serious disease are simply regulated as a form of general level claim and do not require differentiation. If all biomarkers, including those for non-serious disease, were treated as high level claims this would lead to an anomalous situation whereby biomarkers for non-serious disease would be subject to FSANZ assessment and pre-approval, but claims in relation to non-serious disease would not be – they would simply be regulated as general level claims. Therefore, the standard uses 'biomarker' as a shorthand for biomarkers in relation to serious disease. This should not be understood as affecting other biomarkers for non-serious disease.

An example of a biomarker that relates to serious disease is blood pressure. An example of a biomarker that relates to non-serious disease is acne.

The definition of cause related marketing statement is needed as such statements will be subject to separate regulation outside of the claims classification framework.

Similarly, endorsement is defined to encompass health or nutrition-related endorsements, which will be subject to different requirements to other types of claims. This definition is only intended to capture endorsements that have health or nutrition purposes. Endorsements with ethical, religious or environmental purposes, such as vegetarian, halal, kosher or organic endorsements, are not intended to be captured and regulated by the Standard. Unless the name of the endorsing organisation is the source of the reference to a serious disease, endorsements that refer to a serious disease are not considered endorsements for the purpose of the Standard, but rather are high level claims.

The definition of endorsement is intended to only include designs that indicate bona fide third party certification. For example, an 'endorsement' used under a scheme established by a manufacturer to enable them to endorse their own goods would not be considered to be an endorsement for the purposes of this Standard.

Endorsing organisations must be independent, non-profit or not-for-profit organisations that are formed for limited purposes: namely, health, nutrition, community or government purposes. This is designed to encompass groups such as the Cancer Council of Australia, Cancer Society of New Zealand, the Coeliac Society of Australia or New Zealand, and Diabetes Australia or New Zealand. It is also designed to encompass, for example, community-based organisations formed to promote the selection and sale of healthy foods by school canteens.

Dietary information will not, in general, be regulated under the Standard. It needs to be defined in order to be expressly excluded from the requirements of the Standard. The only circumstance in which some conditions will apply to the use of dietary information is where it is included on a food label or in an advertisement.

The definition of substantiate has been included to link the requirement for all nutrition and health claims to be substantiated, with the substantiation framework as set out in [document, date]. At present, FSANZ lacks legislative power to incorporate documents into food standards without specifying the document as in existence at a certain date. That is, FSANZ cannot incorporate into a food standard a document as amended from time to time. The reason for this is that it would permit the standard to be amended indirectly through amending the document, without the need to go through the standards setting process.

Interpretation – Application

Trade marks

In order to ensure the standard has complete coverage of nutrition content claims, health claims, endorsements and cause related marketing statements, the standard will apply to these even where they are subject to separate regulation as trade marks. The exclusion of trade marks from the standard would provide a clear loophole enabling free use of what would otherwise be regulated in accordance with the standard. This would have obvious potential to undermine the entire standard.

However, only those trade marks registered after the commencement of the Standard will be subject to the Standard. Legal problems prevent the application of the Standard to trade marks registered before the commencement of the Standard, including currently registered trade marks.

Endorsements

Health-related endorsements from independent, non-profit health organisations in current use have been assessed by FSANZ and where they meet certain criteria they have been excluded from regulation by the standard under subclause 2(2).

New health-related endorsements will need to comply with specific requirements under the Standard.

Transition

There will be a period of two years transition to Standard 1.2.7. There is no separate period for stock in trade: stock in trade is included in the overall transition period. During this time, suppliers must comply with either the Code requirements in respect of claims that exist prior to the commencement of Standard 1.2.7, or with the new Standard. Partial compliance with parts of the old requirements and parts of Standard 1.2.7 is not permitted: suppliers must comply with either set of requirements in their entirety.

General prohibitions

The starting point is that nutrition content claims, health claims, endorsements and cause related marketing statements must not be made unless they comply with the requirements of Standard 1.2.7. In line with clause 13 of Standard 1.1.1, these restrictions apply where the claims, endorsements or statements are made in relation to food for sale, whether on the label of the food or in advertising.

'Label' is defined in Standard 1.1.1, as meaning 'any tag, brand, mark or statement in writing or any representation or design or descriptive matter on or attached to or used in connection with or accompanying any food or package'. 'Advertisement' is defined separately in food legislation, and broadly captures '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 of food.' (subsection 2(1), Annex A, Model Food Act).

Given the breadth of these definitions, the following types of material are examples of what would be considered labelling or advertising –

- leaflets beside displays of food products;
- panels or posters displayed in shops;
- shelf wobblers;
- all forms of advertising, including via print, radio, television, and Internet, whether presented as pure advertising or as 'advertorial' material.

In addition, the definition of 'claim' includes the concept of a claim having to be made in relation to a food or property of a food. Hence, the prohibition on making nutrition content claims or health claims does not need to state that these claims are made 'in relation to a food or property of a food', as this is intrinsic to a claim, as defined in Standard 1.1.1. Similarly, the definitions of endorsement and cause related marketing statement make it clear that these must relate to food.

For clarity, however, the prohibition is clearly worded as only relating to food labels and advertisements. That is, it does not capture all information about food in general: only that in food labels or advertisements.

In a small number of cases, nutrition content claims or health claims are permitted under pre-existing provisions of the Code. In particular, Part 2.9 of the Code (Special Purpose Foods) permits some health claims to be made in relation to foods. Subclause 3(1) of Standard 1.2.7 is drafted to allow these permissions to continue to operate.

Subclause 3(2) of Standard 1.2.7 is designed to prohibit therapeutic claims in relation to food. It reflects the definition of therapeutic use under the *Therapeutic Goods Act 1989*, in particular, paragraph (a) of that definition. However, it does not encompass paragraph (b) of that definition, which refers to influencing, inhibiting or modifying a physiological process in persons. Although appropriate for therapeutic goods, paragraph (b) is not appropriate for food, as in the context of food it may be seen as capturing many health claims. Similarly, the other paragraphs of the definition of therapeutic use under the *Therapeutic Goods Act 1989* are not appropriate in the context of food and therefore have not been included in subclause 3(2).

There is currently one therapeutic claim permitted under the Code, in relation to electrolyte drinks and the prevention or treatment of mild dehydration. This is the reason for the exemption for subclause 8(3) of Standard 2.6.2 from subclause 3(2) of Standard 1.2.7.

Non-claim foods

Clause 4 sets out the general rule that alcohol and infant formula must not have general or high level claims made in relation to them unless specifically permitted.

As a special purpose food, infant formula is regulated under Part 2.9 of the Code. Specific claim permissions have been included in Standard 2.9.1 for such foods as appropriate – for example, where infant formula is specifically formulated for infants with particular diseases. No other general or high level claims besides those expressly permitted under Standard 2.9.1 may be made in relation to infant formula.

In relation to alcohol, only content claims that refer to alcohol content (including where 'light' is used to describe low or reduced alcohol), or claims that refer to the energy content of alcohol may continue to be made. The requirements for low alcohol, non-alcoholic and non-intoxicating claims under Standard 2.7.1 remain unchanged.

Nutrition content claims

Clause 5 sets out the general conditions for making nutrition content claims.

The most basic of these is that the supplier has records substantiating the claim; that is, they have records demonstrating that the property of the food that is the subject of the claim is in fact present in the food.

In addition, the food must comply with any applicable conditions for the specific nutrition content claim under clause 11 of Standard 1.2.7.

For claims that a food is a 'source' of a property, there must be a reference value for the property under the Code. For claims that a food is a 'good source' of a property, there must either be a reference value for the property or a specific criteria for the use of that term in relation to the property under the Code. These terms have an established meaning in relation to particular nutrients (especially vitamins and minerals), linked to the proportion of the reference value of the nutrient that a consumer can expect to find in the food. For other properties, there are no generally recognised, scientifically confirmed reference values – there is no established quantity of the substance that should be consumed to avoid nutritional deficiency. To avoid the potential for confusion, the terms 'source' and 'good source' are to be confined to traditional usage where reference values have been established.

If the claim relates to a property of a food that is present or absent in similar food in the same category, the claim must refer to the category of food and not the individual food. For example, a claim in relation to lycopene in tomatoes must state that 'tomatoes contain lycopene', not 'X brand tomatoes contain lycopene'.

General level claims

Clause 5 also sets out the conditions for making general level claims, other than nutrition content claims (referred to in this section below as 'general level claims').

The requirements under paragraph (a) are designed to ensure that general level claims are only made in relation to foods that meet certain nutritional parameters. These requirements do not apply in relation to vitamin and mineral claims, as these are subject to discrete requirements to be made only in relation to 'claimable foods'. The definition of 'claimable foods' under Standard 1.1.1 provides a separate set of nutritional parameters for foods where vitamin and mineral claims are made.

The requirements under (a) do not apply in relation to infant foods either, as these are subject to separate compositional requirements under Standard 2.9.2. Nor do they apply in relation to gluten and lactose claims, because the principal aim of these claims is to assist coeliacs and the lactose intolerant to select food from as wide a variety as possible that they can tolerate, not only food that is 'healthy' in the more general sense.

General level claims must be substantiated. There are two pathways to substantiation. Either the supplier must hold records demonstrating such substantiation, or the claim must be based on nutrition function statements listed in [document]. Part of a claim could be substantiated, and the other part of a claim could be based on the listed nutrition function statements.

General level claims must comply with any requirements under clause 11 of Standard 1.2.7 for the related nutrition content claim. For instance, if a general level claim is made about omega-3 fatty acids, the nutrition content claim conditions for omega-3 fatty acids must be complied with. General level claims must also comply with any applicable requirements for the specific claim under clause 11 of Standard 1.2.7.

The requirements under paragraph (d) are designed to minimise the use of vague, ambiguous or imprecise claims, by requiring specific types of information to be provided where a claim is made. For example, a claim cannot simply imply a non-specific health benefit: it must include a specific health benefit.

The requirement for claims to be made in the context of a healthy diet also assists in differentiating claims in relation to food, from claims in relation to therapeutic goods. This is because claims in relation to therapeutic goods are generally framed without reference to diet, as a therapeutic good has an impact in and of itself. In contrast, foods can only have a sustained health effect when supported by an appropriate diet.

The reference under subparagraph (d)(iv) to the 'healthy diet' aspect of the claim having to be appropriate to the type of food and the health effect being claimed, is designed to do several things.

First, it enables this statement to be tailored where the claim is being made on infant foods. Where infants are weaning, it is not necessary for their diet to contain a wide variety of foods in order to be healthy. A more appropriate statement may be something like, 'in the context of a healthy, age-appropriate diet'.

Second, it enables this statement to include reference to particular foods that may assist in achieving a claimed benefit. For instance, where a claim relates to a dietary interaction: 'A good source of vitamin C. Vitamin C increases the absorption of iron from the diet. Iron contributes to normal blood formation'. Consumption of vitamin C is only going to assist in the absorption of iron from the diet, if foods containing iron are consumed. In this case, it may be appropriate for the statement to be modified to include 'as part of a healthy diet involving the consumption of a variety of foods, including iron rich foods such as red meat [etc]'.

A claim must be presented so that all elements are in the one location, whether on a package or in advertisements. In addition, the property of the food, or the property and the specific health effect, may also be presented separately, provided that they indicate where the complete claim (including property and specific health effect) is located.

The threshold requirement for general level claims about a food itself, rather than a property of a food, is that these may only be made where no specific property of the food is responsible for the claimed benefit. Where this is the case, the claim may only be made if a further requirement is met: that the food consists of at least 90% by weight of primary food.

High level claims

Clause 6 sets out the approved diet-disease relationships upon which high level claims may be based, and the other conditions for making high level claims.

High level claims may only be made in relation to those diet-disease relationships included in Column 1 of the Table to clause 6.

In addition, the food to which a high level claim relates must comply with the conditions in Column 2 of the Table to clause 6.

The claim must be worded in accordance with the claim statements in Column 3 of the Table to clause 6. The claim does not need to use the exact words included in the Table. However, the claim must use words to this effect, that is, words that convey the same essential meaning as those included in the Table.

Cause related marketing statements

Where cause related marketing statements are used, a disclaimer is required in conjunction with the statement, to minimise the chance of consumer confusion. The disclaimer is not required where a high level claim is made in addition to a cause related marketing statement, and both refer to the same serious disease. For example, 'For each box of cereal sold, [supplier] will donate 50c to the Foetal Neural Tube Defect Support Fund' and 'Increased maternal folate consumption in at least the month before and 3 months following conception may reduce the risk of foetal neural tube defects'. A disclaimer in relation to foetal neural tube defects for the cause related marketing statement would not make sense in this context, and so is not required.

Endorsements

This clause gives effect to the decision to regulate new health or nutrition related endorsements, and to apply some general level claims requirements to such endorsements.

The definition of endorsement only refers to designs, rather than to statements, representations and information. It is only intended to encompass graphics or logos. Designs may of course include text in the graphic or logo. The definition is intended to exclude any other material, such as associated claim text not included in the graphic or logo. Any associated claims will be subject to the general requirements in respect of claims, including high level claims.

To avoid disadvantaging endorsing organisations whose name includes the name of a serious disease, all endorsements will be subject to the requirements applied to general level claims (subclause 8(1)). For endorsements in relation to gluten and lactose, only nutrition content claim requirements and substantiation requirements must be complied with (subclause 8(2)). This is because the principal aim of these endorsements is to assist coeliacs and the lactose intolerant to select food that they can tolerate from as wide a range as possible, not only food that is 'healthy' in the more general sense.

To avoid confusion, subclause 8(3) provides for education or information materials of the endorsing organisation. This is intended to permit an endorsing organisation to produce and publish such materials, for example on its website, without the need for compliance with general level claims requirements. This recognises that these materials should be treated similarly to dietary information, rather than to advertising materials aimed at promoting the sale of certain food/s.

'Endorsements' that do not fit within the definition of endorsement, for instance because they are by individuals or food industry groups, will be considered general level or high level claims (depending upon the form they take) and must meet the applicable requirements of Standard 1.2.7 for these types of claims.

Dietary information

Clause 9 sets out the requirements in relation to dietary information that appears on a food label or in an advertisement for food.

To ensure that dietary information is relevant to the food in relation to which it is used, such information must relate to the property of the food that is part of a claim. This means that dietary information cannot be provided on a food label or in an advertisement where no claim is made.

However, where dietary information relates to moderating the consumption of food, it is recognised that a claim may not be appropriate due to the nature of the food. In these circumstances, dietary information alone may be provided on a label or in an advertisement.

Small packages

Due to the limited label size available on small packages, there are currently exemptions for small packages from a variety of labelling requirements under the Code. Consistent with this, small packages have been exempted from a variety of labelling requirements in relation to nutrition content claims and health claims.

Conditions for making specific nutrition content claims

Consolidation of existing nutrition content claims and health claims requirements

There are certain nutrition content claims and health claims already regulated by the Code. As part of P293, it is proposed to consolidate these requirements under Standard 1.2.7, except for those for special purpose foods under Part 2.9 of the Code which will remain unchanged. This will provide a single point of reference for determining Code requirements generally in relation to nutrition content claims and health claims. This is designed to assist industry, government, consumers and public health groups in ascertaining the legal requirements in relation to such claims, and is consistent with the structure of the Code.

Currently, claims about the presence of certain vitamins or minerals are regulated via Standard 1.3.2. This standard both provides fortification permissions, and permissions for vitamin or mineral content claims. It is located in Part 1.3 of the Code, which deals with substances added to food. Part 1.2 deals with labelling and other information requirements. Accordingly, the permissions for vitamin or mineral content claims sit more logically within Part 1.2 than in their current location in Standard 1.3.2 under Part 1.3. For this reason, the drafting moves these claims permissions into Standard 1.2.7. The substance of these permissions has not been changed, though they have been presented in a shorter and simpler format. They have been quarantined from the P293 process pending other FSANZ work on fortification matters.

Under present arrangements, certain nutrition claims are regulated via Standard 1.2.8. These include conditions for making claims in relation to:

- lactose;
- gluten;
- polyunsaturated or monounsaturated fatty acid content;
- omega fatty acid content;
- low joule; and
- salt, sodium or potassium.

These conditions have been shifted to Division 3 of the new Standard 1.2.7. The substance of these has not generally been changed, though they have been presented in a shorter and simpler format.

There has been an amendment to the conditions for vitamins or minerals. Previously, content claims about vitamins and minerals were only permitted where a specified percentage of the RDI or ESADDI of the vitamin or mineral was contained in a 'reference quantity' of the food. This is now proposed to be based on a 'serving' of the food. This is designed to prevent content claims being made on foods containing less than the specified percentage of the RDI or ESADDI. This may occur where the reference quantity is relatively large (e.g. 600 mL) and the package size is small (e.g. 200 mL): in these circumstances, the food as sold could contain less than the specified percentage of the RDI or ESADDI and still carry a content claim. Calculating on the basis of a serving of the food rather than the reference quantity means that this cannot occur.

In addition, the criteria for reduced lactose claims have been removed and the criterion for 'low lactose' claims has been increased. Only free and low claims may be made in relation to lactose and gluten.

A more general nutrition information requirement where claims are made has been included as part of amendments to Standard 1.2.8 (see below). Pre-existing conditions for specific nutrition content claims to include information in a nutrition information panel are now covered by the new, more general requirement and so have been omitted. Other specific requirements that duplicate more general requirements in the drafting have also have been excluded (for example, subclauses 4(a) and 6(a) of Standard 1.3.2).

Conditions for specific nutrition content claims

Clause 11 provides the conditions for making nutrition content claims in relation to particular properties of food.

Many of these conditions relate to where a nutrition content claim is made in relation to a particular property and using a particular descriptor, such as low or reduced. However, some conditions relate to where a nutrition content claim is made in relation to a particular property, regardless of the descriptor used – or where no descriptor is used.

Where Column 2 of the Table to clause 11 is blank, where <u>any</u> nutrition content claim is made that refers to the property listed in Column 1, the conditions in Column 3 apply. For example, for any nutrition content claim that is made in relation to wholegrain, the condition that a serving of the food contains at least 8g of wholegrain must be met.

In relation to the conditions for vitamin and mineral claims, these have been changed in one respect. Previously, minimum qualifying content criteria were based only on the prescribed reference quantity of the food. This has been changed, to require such foods to meet the minimum qualifying content criteria for a claim in a serve of the food. This is to provide a more equitable minimum amount that could be declared across the range of fortified foods.

The minimum criterion for vitamin and minerals claims is 10% Recommended Dietary Intake (RDI)/reference quantity. Currently the prescribed reference quantity and a manufacturer's nominated serve size shown in the nutrition information panel can differ significantly.

In cases where the reference quantity is significantly larger than the nominated serve size, the amount and %RDI of vitamin or mineral declared on the label could be significantly lower than for foods where the reference quantity and serve were comparable. For example, a maximum claim of 25% RDI in 1000 mL translates to 5% RDI in 200 mL whereas foods with greater comparability would not dip below 10% RDI/serve.

Standard 1.2.8

As a result of the consolidation of nutrition content claims and health claims requirements under Standard 1.2.7, the terminology currently used in Standard 1.2.8 may cause confusion.

In particular, the term 'nutrition claim' as currently defined in Standard 1.2.8 differs considerably from the proposed definition of 'nutrition content claim', and it can encompass some of what are now to be called health claims (such as function claims).

In addition, this definition is not consistent with the definition of claim under Standard 1.1.1. Paragraphs (g) to (j) of the definition of nutrition claim expressly exclude a number of references that are mandatory under the Code, and hence that do not constitute claims at any rate.

Accordingly, it is proposed that the definition of nutrition claim is removed from Standard 1.2.8. All references to nutrition claim are replaced with references to nutrition content claim or health claim. This will meant that whenever this type of claim is made, nutrition labelling requirements will be triggered.

A significant change to Standard 1.2.8 is to require certain percentage daily intake information to be included in a nutrition information panel whenever a nutrition content claim or health claim is made. It is generally optional to include percentage daily intake information in a nutrition information panel. However, FSANZ considers that where a nutrition content claim or health claim is made, it is appropriate that the inclusion of percentage daily intake information in relation to energy and any other property that is the subject of the claim and that has a reference value in the Code becomes mandatory. Where a claim relates to a property that does not have a reference value in the Code, only percentage daily intake information in relation to energy is required.

Standard 1.3.2

As a consequence of removing the claims requirements from Standard 1.3.2, the remaining Standard now covers permissions for the additions of vitamins or minerals to foods. This brings it into line with the other standards within Part 1.3 of the Code, which deal with substances added to food, rather than labelling requirements.

ATTACHMENT 2

AUSTRALIA AND NEW ZEALAND FOOD REGULATION MINISTERIAL COUNCIL

Policy Guideline 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 (e.g. 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) (*e.g. 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'. E.g. 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. (E.g. 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 (e.g. 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 medium.

9. 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 medium.

10 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 category.

11. 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 (e.g. meets nutrient criteria required by the endorsement program).

12. Marketing activities that promote charities or non-profit organisations (i.e. 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 claim.

13. Communication to health professionals of a nutrition, health, or related claim about specific food products or food types (e.g. 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 (e.g. 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) *(e.g. 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) (e.g. helps keep you regular as part of a high fibre diet). This includes claims that describe the component and its function in the body (e.g. Calcium is good for strong bones and teeth); or

- refer to specific benefits for performance and wellbeing in relation to foods (e.g. 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 (e.g. 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 *(e.g. 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 (*e.g. 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);

  E.g. 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;

  E.g. 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;

  E.g. 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[41] maintenance claims;

  E.g. this food is high in Y, which may help maintain healthy cholesterol levels through Z.

- biomarker enhancement claims; and

  E.g. this food is low in Y, which may reduce your blood pressure through Z.

- biomarker claims that make reference to a serious disease.

  E.g. 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 (e.g. nutrient content claims) and categories of foods which may be excluded from making claims (e.g. 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 Figure 1 below.

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.

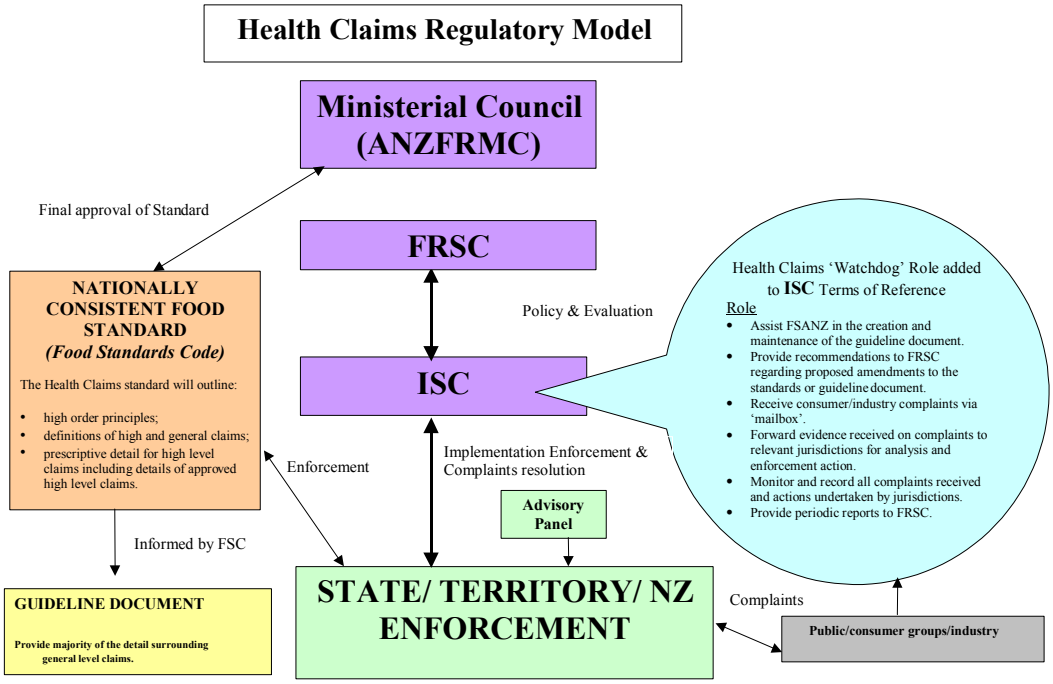

Figure : . Health Claims Regulatory Model

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 to make an assessment as to the classification of the claim they wish to use. Figure 2 below outlines the process.

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.

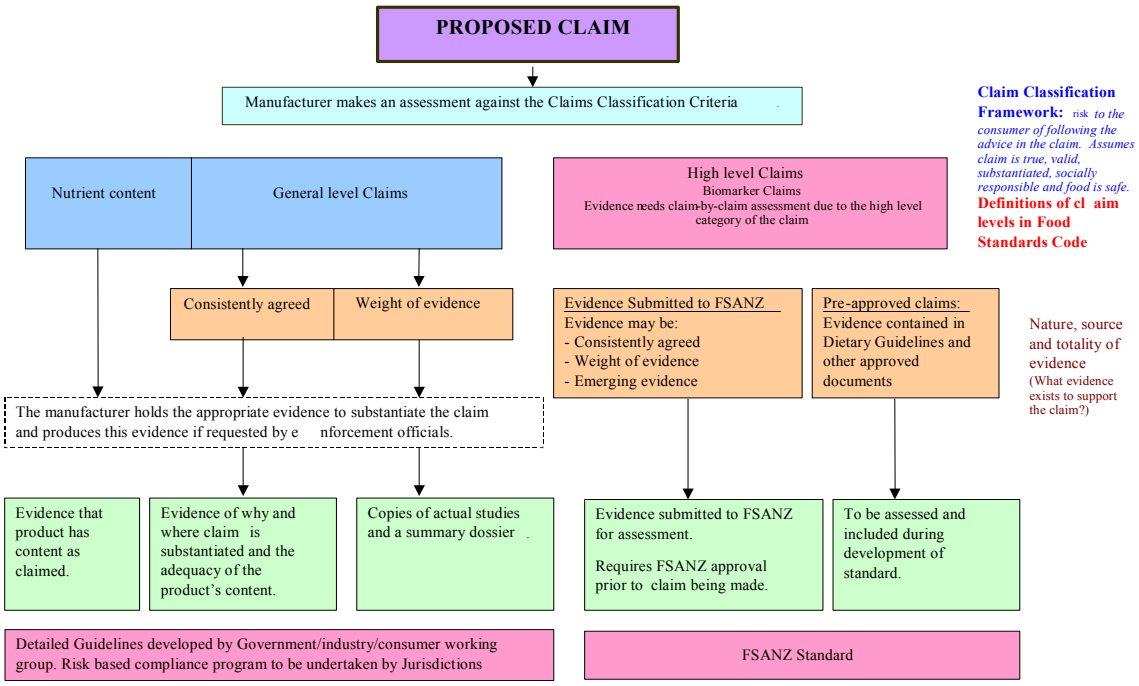

Figure : . Substantiation requirements

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 (i.e. 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 (e.g. qualifying and disqualifying criteria) (or exclusions for certain categories of food e.g. 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 be consumed 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 X g 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 that communicate the appropriate total diet required to achieve the stated benefit.