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Te Mana Kounga Kai – Ahitereiria me Aotearoa

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FINAL ASSESSMENT REPORT

PROPOSAL P293

NUTRITION, HEALTH & RELATED CLAIMS

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to <http://www.foodstandards.gov.au/standardsdevelopment/>

Executive Summary

In December 2003, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) released the Policy Guideline on Nutrition, Health and Related Claims (Policy Guideline). In response to this Guideline, Food Standards Australia New Zealand (FSANZ) has developed a draft Standard for the regulation of nutrition, health and related claims (Standard 1.2.7 – Nutrition, Health and Related Claims). The Policy Guideline sets out the policy principles underpinning the regulation of nutrition content and health claims and aims to permit claims and encourage industry to innovate whilst ensuring consumers are not misled.

The purpose of the draft Standard is to provide regulatory arrangements for nutrition, health and related claims that enable industry to innovate giving consumers a wide range of healthy food choices, to expand the range of permitted claims, to ensure products carrying nutrition content and health claims provide adequate information for consumers and to prevent misleading or deceptive claims on food labels or in food advertising.

Current situation

Some nutrition content 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 (Code of Practice on Nutrient Claims in Food Labels and in Advertisements (CoPoNC)). 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 intake in women around the time of conception.

The current situation is considered by many to have limitations including difficulties in relation to the uneven playing field created by 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. Furthermore, there are difficulties in interpretation, application and enforcement of the transitional Standard.

Our process

FSANZ has considered three different regulatory options of status quo, co-regulation and full regulation, and the benefits and costs associated with each. Furthermore, in developing this Final Assessment Report FSANZ has:

- consulted with all stakeholder groups through open meetings, targeted consultations and invited public submissions to the Initial, Draft and Preliminary Final Assessment Reports and the Consultation Paper;
- received advice from expert and advisory groups;
- undertaken research to assess consumer understanding and use of nutrition content and health claims;
- prepared benefit-cost analyses to inform the choice of regulatory option and the regulatory impact statement;
- considered international regulations for health, nutrition and related claims;

- considered relevant research;
- developed the framework for substantiating health claims and applied the framework in assessing the evidence for a number of high level health claims;
- developed communication and education strategies; and
- developed an approach for the implementation and monitoring of the draft Standard.

This Report addresses issues arising from public submissions and targeted stakeholder consultations. While a summary of key submitter comments and FSANZ responses to these comments is included in each section as appropriate, complete summaries of submitter comments to the Initial and Draft Assessment Reports are provided on the FSANZ website. Submissions summaries for the Preliminary Final Assessment Report and the Consultation Paper are included in Attachments 13 and 14, respectively.

Our Proposal

On the basis of this evaluation, FSANZ recommends a regulated approach with the introduction of the draft Standard for nutrition, health and related claims for the management and substantiation of nutrition content, general level and high level health claims.

Claim definitions and the regulatory parameters (i.e. substantiation, claim criteria, food vehicle eligibility criteria and wording conditions) work together to identify and regulate nutrition content and health claims. Health claims will require reference to both the specific health effect and the property of the food¹ responsible for that health effect. The property will have to be present above or below defined levels (qualifying criteria) in order to avoid misleading consumers. Foods eligible to carry general and high level health claims must also meet nutrient profiling scoring criteria (food vehicle eligibility criteria). These criteria assess the overall nutritional profile of the food and are underpinned by national nutritional guidelines.

Some modifications to the criteria for nutrition 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. There are general conditions in the draft Standard which apply to all nutrition content claims. In addition, specific conditions for certain nutrition content claims (those which were evaluated to be important to meet public health objectives or which may otherwise mislead consumers) are specified.

Certain types of claims (such as glycemic index, weight loss or maintenance claims, and claims for biologically active substances) have required specific attention due to unique attributes and these have been addressed by specific provisions within the draft Standard.

All claims are to be substantiated

Nutrition content claims are to be substantiated by analysis or calculation of the value(s) of the nutrient content of the food. The Scientific Substantiation Framework in Schedule 2 of the draft Standard includes the requirements for the substantiation of general level health claims. Food-disease relationships are pre-approved by FSANZ and these form the basis for high level health claims.

¹ Refer to definition in draft Standard 1.2.7 at Attachment 1.

The requirements for pre-approval will be included in the FSANZ *Application Handbook*. Amendments to the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) in 2007 will allow applications for high level health claims to be confidential until the claim is approved unless the Applicant specifically requests that public submissions be invited.

There are a number of paths to substantiate general level health claims. They can be based on FSANZ's list of nutrient function statements provided in the Scientific Substantiation Framework, derived from the pre-approved food-disease relationships for high level health claims, supported by authoritative texts or supported by evidence prepared as specified in the Scientific Substantiation Framework. Holding the records to substantiate these claims is the responsibility of suppliers and pre-approval of general level health claims will not be required.

FSANZ has pre-approved seven food-disease relationships based upon commissioned expert reviews of several food-disease relationships. This has led to the inclusion of conditions for eight high level health claims as follows:

- dietary intake of calcium, vitamin D status, and reduced risk of persons 65 years and over from developing osteoporosis;
- increased dietary intake of calcium and enhanced bone mineral density;
- reduction in dietary intake of sodium and reduction in blood pressure;
- intake of folic acid in the peri-conceptual period and reduced risk of development of neural tube defects in the foetus;
- reduction in dietary intake of saturated fatty acids and reduction in blood cholesterol, total blood cholesterol, blood low-density lipoprotein (LDL)-cholesterol, serum LDL-cholesterol, total serum cholesterol or serum cholesterol levels;
- reduction in dietary intake of saturated and *trans* unsaturated fatty acids and reduction in blood cholesterol, total blood cholesterol, blood low-density lipoprotein (LDL)-cholesterol, serum LDL-cholesterol, total serum cholesterol or serum cholesterol levels;
- increased intake of vegetables and fruit and reduced risk of coronary heart disease; and
- high intake of vegetables and fruit and reduced risk of coronary heart disease.

Suppliers may use high level health claims based on these pre-approved food-disease relationships, subject to specific criteria and conditions.

Related claims

There are some particular types of claims that are referred to and/or regulated by the draft Standard. In this Report these have been designated 'related claims' and include endorsements, cause-related marketing statements and dietary information. Endorsements as captured by the definition of *endorsement* in the draft Standard are regulated by the draft Standard however, if a supplier has certain records about the endorsing organisation and makes those records available to the relevant authority, the draft Standard will not apply to the endorsement. Cause-related marketing statements as defined in the draft Standard are exempt from the draft Standard if accompanied by a disclaimer.

Dietary information is defined and its use managed by provisions within the draft Standard.

Due to the implications of pre-existing legislation, the draft Standard remains silent on trademarks.

Decision

That nutrition, health and related claims be regulated according to the draft Standard 1.2.7. Claim criteria, food vehicle eligibility criteria, wording conditions and requirements for substantiation are included in the draft Standard.

Reasons for the Decision

The reasons for this decision are:

- the draft Standard provides an expanded regulatory approach for nutrition, health and related claims;
- the draft Standard offers industry an opportunity to innovate and take advantage of incorporating health claims into their marketing strategies;
- consumers will have information on nutrition content and health claims on food at point of sale or in advertising, and will have the ability to make more informed purchasing decisions;
- the potential to mislead consumers under the current regulatory arrangements, either through non-regulated nutrition content claims or implied health claims, will be further mitigated as these issues are clearly addressed in the draft Standard;
- the draft Standard will resolve ambiguities and limitations under the current regulatory arrangements and facilitate effective enforcement actions by enforcement agencies;
- the draft Standard is broadly consistent with comparable arrangements overseas;
- the draft Standard is expected to deliver an improvement in the economic welfare of Australia and New Zealand; and
- the development of the draft Standard has had regard for the Policy Guideline and national nutrition policies.

Consultation

The draft Standard has been developed with extensive consultation since 2004, when the first of four assessment and consultation reports (the Initial Assessment Report) was released for public comment.

FSANZ has also conducted intensive targeted consultation through a range of consultative mechanisms to discuss key issues and impacts of the draft Standard with all stakeholder groups, namely the Australian and New Zealand food industry, government agencies, and consumer and public health organisations.

FSANZ has called on advisory and expert groups throughout the development of the draft Standard including a Standards Development Advisory Committee for health claims, the Technical Expert Group on general level health claims and the Scientific Advisory Group on the substantiation of health claims.

While the majority of stakeholders support the overall regulatory approach to develop a new Standard for nutrition and health claims with claim criteria, food vehicle eligibility criteria, substantiation and wording conditions included in the draft Standard, there has been a divergence of views about a number of issues amongst stakeholder groups. For example, many government, consumer and public health stakeholders support tighter controls around the use of claims whilst industry prefers a less stringent approach. As a result of extensive consultation that has been conducted over the last four years and taking into account the available evidence, FSANZ has developed a draft Standard that balances the needs of the broad community. These needs encompass industry's desire to innovate, public health concerns, jurisdictional concerns for enforceable arrangements as well as FSANZ objectives to provide consumers with adequate information to enable informed food choices and to prevent misleading or deceptive claims on food labels and in food advertising.

Implementation

Following approval of the draft variation to the Code by the FSANZ Board, the Board will notify the Ministerial Council of this decision. Subject to any request from the Ministerial Council for a review, the proposed draft variations to the Code (Attachment 1) will come into effect two years from gazettal.

FSANZ is developing a User Guide to assist industry, enforcement agencies and other stakeholders with the implementation of this Standard.

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5. Nutrition Content Claims
6. General Level Health Claims (Part 1 includes the nutrient profiling scoring criteria)
7. Regulatory Approach for High Level Health Claims
8. Substantiation of General Level Health Claims
9. Conditions applying to Related Claims
10. Consumer Research
11. Benefit Cost Analysis
12. International Benchmarking
13. Submission Summary – Preliminary Final Assessment Report
14. Submission Summary – Consultation Paper

SUPPORTING DOCUMENTATION (available on the FSANZ website)

1. [Benefit Cost Analysis Report](http://www.foodstandards.gov.au/srcfiles/P293_DAR_ATT3_Benefit_Cost_Analysis-CBA_Allens_report.pdf) (ALLEN Report):
http://www.foodstandards.gov.au/srcfiles/P293_DAR_ATT3_Benefit_Cost_Analysis-CBA_Allens_report.pdf
2. **Consumer Research Reports**
[Evaluation Report Series:](http://www.foodstandards.gov.au/newsroom/publications/evaluationreportseries/index.cfm)
<http://www.foodstandards.gov.au/newsroom/publications/evaluationreportseries/index.cfm>
[Technical Report: Consumer research on ‘no added sugar’ claims:](http://www.foodstandards.gov.au/srcfiles/P293%20PFAR%20Att%204%20-%20Consumer%20research%20no%20added%20sugar%20claim.pdf)
<http://www.foodstandards.gov.au/srcfiles/P293%20PFAR%20Att%204%20-%20Consumer%20research%20no%20added%20sugar%20claim.pdf>
[Technical Report: Consumer research on percentage daily intake labelling:](http://www.foodstandards.gov.au/srcfiles/P293%20PFAR%20Att%202%20-%20Technical%20Report%20Consumer%20Research.pdf)
<http://www.foodstandards.gov.au/srcfiles/P293%20PFAR%20Att%202%20-%20Technical%20Report%20Consumer%20Research.pdf>
3. [Food-Disease Relationships](http://www.foodstandards.gov.au/foodmatters/healthnutritionandrelatedclaims/reviewsforhighlevelc3090.cfm)
<http://www.foodstandards.gov.au/foodmatters/healthnutritionandrelatedclaims/reviewsforhighlevelc3090.cfm>

4. [**Label Monitoring Project Reports**](#)

<http://www.foodstandards.gov.au/newsroom/publications/evaluationreportseries/index.cfm>

5. [**P293 Initial Assessment Report**](#)

<http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp293nutritionhealthandrelatedclaims/p293initialassessment3500.cfm>

6. [**P293 Draft Assessment Report**](#)

<http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp293nutritionhealthandrelatedclaims/p293draftassessment3501.cfm>

7. [**P293 Preliminary Final Assessment Report**](#)

<http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp293nutritionhealthandrelatedclaims/index.cfm>

8. [**P293 Consultation Paper**](#)

http://www.foodstandards.gov.au/_srcfiles/P293_Consultation_Paper.pdf

9. [**Submission Summary – Initial Assessment Report**](#)

<http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp293nutritionhealthandrelatedclaims/p293draftassessment3501.cfm>

10. [**Submission Summary – Draft Assessment Report**](#)

<http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp293nutritionhealthandrelatedclaims/index.cfm>

11. [**Advisory Groups – Membership and Terms of Reference**](#)

[**Standard Development Advisory Committee:**](#)

<http://www.foodstandards.gov.au/foodmatters/healthnutritionandrelatedclaims/healthclaimssdacmembership/>

[**Scientific Advisory Group for the Development of the Substantiation Framework:**](#)

<http://www.foodstandards.gov.au/foodmatters/healthnutritionandrelatedclaims/scientificadvisorygroup/>

[**Technical Expert Group on General Level Claims:**](#)

<http://www.foodstandards.gov.au/foodmatters/healthnutritionandrelatedclaims/scientificadvisorygroup/healthclaimstechnica3088.cfm>

INTRODUCTION

This Final Assessment Report presents the preferred regulatory option and a new draft Standard for the management and regulation of nutrition, health and related claims. The development of regulation for nutrition, health and related claims was initiated following the provision of the Policy Guideline by the Ministerial Council in December 2003 and has evolved through extensive risk analysis by FSANZ in consultation with all stakeholder groups.

The Report provides a description of the regulatory approach, recommendations for the substantiation of nutrition content claims and health claims, the conditions and criteria for nutrition content, health and related claims, a benefit-cost analysis, consumer research, international benchmarking of the draft Standard and information on associated communication, implementation, education and enforcement matters. Issues arising from public submissions and targeted stakeholder consultations have also been addressed.

1. Final Assessment Report

The Final Assessment Report consists of three major parts, the Report itself, attachments and supporting documentation. The Report presents a summary of the development of the draft Standard with reference to previous documents, rather than a compilation of previous Reports and consultation documents. Web links to these documents are provided as appropriate. Issues which were not discussed in the Preliminary Final Assessment Report or the Consultation Paper (December 2007) are, however, considered in detail. The overall aim of the Report is to present the rationale for the final decisions for all issues and responses to key submitter comments.

The Report is structured such that chapters 6-9 discuss the regulatory options, chapters 10-11 present the regulatory approach, pages 28-31 cover the conditions for nutrition content claims and general level health claims (nutrient profiling scoring criteria is included in Part 1 of Attachment 6) and chapters 12-13 cover the conditions and criteria for high level health claims. Chapters 14-17 cover the substantiation of health claims. Chapters 18-21 include the conditions for related claims such as endorsements and chapters 22-26 cover the regulatory impact analysis. Communication and consultation, implementation, enforcement and monitoring, transitional arrangements, education and inter-related issues are discussed in chapters 27-43. Attachments 1 and 2 include the draft variation to the Code (Standard 1.2.7) and the Policy Guideline for Nutrition, Health and Related Claims, respectively.

Information and data on the evidence base, including submitter comments, the benefit cost analysis reports, international benchmarking, and consumer research and label monitoring reports can be accessed in attachments or through web links embedded in the electronic version of this Report. A complete list of attachments and web links is provided in the table of contents to this Report.

A complete summary of all submissions received in response to all consultation documents is provided as either a web link or as an attachment to this Report. However, a synopsis of key submitter comments and FSANZ responses to these are presented in each related section of the Report.

In a similar approach, details of international regulations and guidelines relevant to nutrition and health claims are presented in the international benchmarking section in Attachment 12. However, where appropriate, reference has been made to international regulations when discussing specific issues.

The Glossary is provided on page 74 of this Report and contains a list of the definitions and abbreviations used in this Report.

2. Current provisions in Australia and New Zealand

Currently in Australia and New Zealand, claims on food labels (encompassing nutrition content and health claims) are regulated by various means. Some claims are not permitted under the *Australia New Zealand Food Standards Code* (the Code); others are permitted and regulated under the Code, while others still are permitted with guidance for industry on their use set out in CoPoNC (in Australia). Some types of claims are not directly regulated under any of the above arrangements (such as function claims), but neither are they explicitly prohibited. These, as with 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, all of which will be impacted by the introduction of the draft Standard.

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:

- 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 nor 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 Standard 1.2.8 – Nutrition Information Requirements

Standard 1.2.8 of the Code regulates the use of some nutrition content claims including:

- polyunsaturated and monounsaturated fatty acid content;
- lactose content;
- gluten content;
- salt, sodium or potassium content;
- omega fatty acid content; and
- low joule (energy).

Standard 1.2.8 also specifies nutrition information requirements, including where certain nutrition content claims are made.

2.3 Standards relating to vitamins and minerals

Standard 1.3.2 – Vitamins and Minerals regulates the addition of vitamins and minerals to food and the claims which can be made about the vitamin and mineral content of foods. Other standards which also regulate the addition of vitamins and minerals to food include:

- Standard 2.1.1 – Cereal and Cereal Products (thiamine and folic acid to flour for bread making (for Australia only));
- Standard 2.4.2 – Edible Oil Spreads (vitamin D to table edible oil spreads and margarine (for Australia only));
- Standard 2.6.4 – Formulated Caffeinated Beverages;
- Part 2.9 – Special Purpose Foods; and
- Standard 2.10.2 – Salt and Salt Products (iodine to certain salt products).

2.4 Other relevant legislation (Australia and 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, when the new joint Code came into effect). While the regulations are no longer legally in force, the NZFSA, 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.

In New Zealand, in addition to complying with the Code, all information on food labels must comply with the New Zealand *Fair Trading Act 1986*. This Act 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 and where appropriate, accompanying information should be provided to show consumers that the claims are justified and substantiated.

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* (TPA). 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 TPA. Relevant State and Territory bodies enforce fair trading legislation in their jurisdictions.

2.5 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 claims can be made in relation to fat, saturated fat, sugar, fibre, cholesterol, salt and energy. It also provides conditions for 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 are expected to comply.

3. The Issue / Problem

The problems addressed in this Proposal are the:

- current limited permissions for general level and high level health claims;
- restrictions on adequate information about nutrition and health related aspects of foods for consumers at point of sale and in advertisements for food to enable them to make informed food choices;
- potential for misleading or deceptive conduct relating to nutrition and health claims on food labels and in food advertising;
- restrictions under the current regulatory arrangements that impede the ability of industry to innovate; and
- ambiguities and limitations under the current regulatory arrangements that diminish the effectiveness of enforcement actions by government enforcement agencies.

3.1 Limitations of the current arrangements

3.1.1 Lack of adequate information for consumers

The current arrangements generally do not permit health claims to be made on foods in Australia and in New Zealand. In these circumstances information with defining health characteristics about foods is essentially unavailable in advertising or at point of sale. Hence consumer choices at the point of sale have the potential to be compromised through lack of adequate, timely and relevant information about such health characteristics. Consumer research undertaken by FSANZ demonstrates that health claims on product labels do enhance consumer awareness of the health aspects of food products.

3.1.2 Potential for misleading or deceptive conduct – nutrition content claims

The current arrangements in Australia allow food manufacturers and retailers to make nutrition content claims on packaged foods, under CoPoNC, a voluntary code of practice. An independent study measuring the compliance of nutrient claims with CoPoNC was carried out in 2001 (Williams et al., 2003). While CoPoNC had significant acceptance within industry, the study findings revealed that in a sample of 6662 products, for the 3194 claims covered by CoPoNC, the level of non-compliance was 14.8%.

Sixty-one per cent of claims that failed to comply with CoPoNC did so because of breaches in requirements related to labelling format. The remaining 39% of the non-compliant claims (5.1% of all nutrient claims) did not meet established nutritional criteria for the claim and could therefore be considered potentially misleading (e.g. approximately 10% of % *fat free* claims were used on foods that contained more than 3% fat and therefore could mislead consumers into believing the product is a low fat food).

The signatories to the code of practice primarily comprise the large food and beverage manufacturers, and retailers, and would account for most processed foods and non-alcoholic beverages on the market. Some breaches of the code would be accidental, but others, such as the 90% *fat free* example above, may be intentional and made in the knowledge that such claims would contravene the code of practice. However, a voluntary code of practice cannot be enforced by the jurisdictions, a fact that would be known by companies intentionally breaching the code of practice. Non-compliance with the code of practice, and the fact that it cannot be enforced by the jurisdictions, are significant problems with the current arrangements governing nutrition content claims.

3.1.3 Potential for misleading or deceptive conduct – health claims

Notwithstanding the general prohibition on health claims (Transitional Standard 1.1A.2), nutrition content claims and health claims can currently be regulated under the more general areas of consumer protection provisions of fair trading legislation in Australia and New Zealand. The matters relevant to whether these provisions have been breached largely rely on the evidence of the reasonable consumers' view of a health claim. Some claims may therefore not be consistent with sound nutritional or public health principles. In FSANZ's view more reliance should be placed on the scientific evidence to support the claim being made, particularly with respect to general level health claims or high level health claims. In legal proceedings the objective Scientific Substantiation Framework document that has been drafted into the Standard would provide sufficient guidance and regulation with respect to the evidence to be relied upon when making a judgement concerning the health claim.

It is possible that non-compliance of general and high level health claims could reach similar proportions to the current non-compliance with the voluntary code of practice for nutrition content claims if managed outside of regulation. FSANZ is also concerned that there is an underlying potential for consumers to be misled by health claims if such claims are not aligned with sound nutrition or public health principles and this can be more effectively managed through provisions in a food standard.

FSANZ contends the extent that consumers would be adversely affected by misleading health claims would be commensurate with the level of claim. In the case of high level health claims which refer to a food-disease relationship, misleading claims that prompted inappropriate food choices could potentially have more adverse implications for the consumers concerned than, for example, nutrition content claims.

3.1.4 Impediments to industry innovation

The current arrangements generally do not permit health claims in Australia and in New Zealand and therefore have impeded the ability of industry to bring new and innovative food products onto the market.

Overseas, the capacity for food manufacturers to make health claims on particular niche products has been important to their marketing effort, and a factor in developing new products. However, only few such products are currently available in Australia and New Zealand. It would seem that the current restrictions are preventing local affiliates of global companies adequately marketing new health-related food products from overseas, or similarly, inhibiting development in Australia or New Zealand.

The current arrangements in Australia and New Zealand, while generally restrictive, in some particular aspects are ambiguous. Most food manufacturers have adopted a conservative approach in these circumstances and refrained from marketing any product with an overt or implied health claim. However there have been some instances where a manufacturer has marketed a product with a health claim in very implicit language, risking legal action by enforcement agencies but where the marketing success of these products is linked to the implicit health claim. The current arrangements are therefore having a distributive effect across the food industry, favouring companies to risk legal action, and to the disadvantage of those companies conservatively following the Code.

3.1.5 Ambiguities that diminish the effectiveness of enforcement actions

The ambiguities in some aspects of the regulations mean that there is considerable uncertainty as to whether some particular enforcement actions will succeed. The enforcement agencies of the jurisdictions advise that prosecution against infringements of Standard 1.1A.2 is difficult. This situation creates a management dilemma: whether to commit scarce resources to an uncertain project, or whether to essentially ignore a perceived breach of the Code.

4. Objectives

4.1 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 18 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.

4.2 Objectives of this Proposal

The objectives of this Proposal are to provide regulatory arrangements that:

- enable industry to innovate, giving consumers a wider range of healthy food choices;
- ensure that food labels bearing nutrition, health or related claims provide adequate information to enable consumers to make informed choices;
- prevent misleading or deceptive nutrition, health or related claims on food labels or in food advertising; and
- 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.

5 Background

5.1 Policy Guidance

FSANZ prepared this Proposal after receiving policy guidance from the Australian and New Zealand Food Regulation Ministerial Council on the regulation of nutrition, health and related claims (referred to as the Policy Guideline, which can be found at Attachment 2). 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.

This Proposal is the vehicle by which FSANZ has developed the new Standard 1.2.7 (hereafter referred to as the draft Standard) and management system for the regulation of nutrition, health and related claims.

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 such issues are addressed.

To assist in this, FSANZ commissioned an independent benefit cost analysis on the impact of the draft Standard on the food industry, government and consumers (refer to chapter 24).

5.2 Consultation process

The draft Standard has been developed with extensive consultation since 2004. In addition to the statutory Assessment Reports, FSANZ has conducted targeted consultation with stakeholders, presented specific issues in a range of forums and responded to a large number of requests for presentations to and discussions with industry, public health and consumer stakeholder groups (refer to chapter 28).

The Reports released by FSANZ were the Initial Assessment Report in August 2004, the Draft Assessment Report in December 2005, the Preliminary Final Assessment Report in April 2007, and an additional Consultation Paper in December 2007 (refer to chapter 30 for further details).

5.3 Assistance provided by advisory committees and expert committees

FSANZ has also called on advisory and expert groups. FSANZ has developed the draft Standard in consultation with a Standards Development Advisory Committee for health claims, the Technical Expert Group on general level health claims and the Scientific Advisory Group on the substantiation of health claims (refer to chapter 29).

5.4 Draft Standard in the Final Assessment Report

The draft Standard is presented at Attachment 1. The overall intent of the draft Standard, which was first released for public comment in the Draft Assessment Report, has been retained. However, refinements to the detail of some sections of the first iteration of the draft Standard have been made following consultation and feedback from stakeholders and advisory groups. This resulted in amendments contained in the draft Standard attached to the Preliminary Final Assessment Report and lastly to the draft Standard attached to this Final Assessment Report.

REGULATORY OPTIONS

6. Background

FSANZ is required to consider a range of regulatory options when progressing applications and proposals to amend the Code.

In formulating options for this Proposal, FSANZ considered the specific objectives and also had regard to the Policy Guideline provided by the Australia and New Zealand Food Regulation Ministerial Council. The Policy Guideline was comprehensive and highly detailed in addressing the issues of nutrition, health and related claims.

The Policy Guideline recommends that:

- the Code would set out the high order principles of the health claims system, the definitions of nutrition content, general and high level health claims, and provide prescriptive, individual detail for high level health claims.
- the Standard may also set out eligibility criteria including qualifying and disqualifying criteria for certain types of claims (e.g. nutrition content claims) and categories of foods which may be excluded from making claims (e.g. alcohol and ‘baby foods’²);
- a guideline document would provide the majority of the detail surrounding nutrition content and general level health 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 types of claims.

FSANZ established that the intent of the third dot point above was to have a ‘User Guide’ to clarify intent, rather than a ‘guideline’ that provides risk management measures that sit outside the legal document that is the Code.

7. Options Considered

The regulatory options considered are as follows:

7.1 Option 1: Maintain the *Status Quo*

Under this option:

- Standard 1.1A.2 (Transitional Standard for Health Claims) would need to be amended to ensure that the status quo remained. Currently it is stated that Standard 1.1A.2 will operate as an alternative Standard to Standard 1.2.7 for the two-year transition period after the commencement of Standard 1.2.7;
- specific nutrition content claims in Standard 1.2.8 – Nutrition Information Requirements 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 (e.g. nutrition content claims are currently in CoPoNC) would not be subject to any regulatory control and would be reliant on conformity with voluntary industry practices and fair trading legislation.

7.2 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. Standard 1.1A.2 would be revoked on gazettal of a new Standard³.

In relation to high level health claims:

² FSANZ has taken this to mean infant formula, as standardised under Standard 2.9.1.

³ Note that the terminology used in this section, and in the following section 7.3, reflects what was used in the Draft Assessment Report, but has since been modified (e.g. pre-approved claims are now referred to as pre-approved food-disease relationships).

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

In relation to general level health claims and nutrition content 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 user guides would be developed to facilitate understanding of the requirements in the Standard, provide a list of nutrient function statements and provide detail on how the Substantiation Framework should be applied.

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

- FSANZ would write the Guideline;
- a management committee would monitor the use of nutrition content and general level health 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.

7.3 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. Standard 1.1A.2 would be revoked on gazettal of a new Standard.

In relation to high level health 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 user guidance would be developed to facilitate understanding of the requirements in the Standard including the process for seeking pre-approval of high level health claims and review mechanisms.

In relation to general level health claims and nutrition content claims:

- prerequisite and wording conditions would be included in the Standard, and thus legally enforceable;
- claims criteria would be included in the Standard, and thus legally enforceable; and
- additional user guidance would be developed to facilitate understanding of the requirements in the Standard, provide a list of claims and provide detail on how the Substantiation Framework should be applied.

8. Recommended Option

Several elements of work were undertaken to provide an evidence base for consideration of the preferred regulatory option. These elements include:

- an independent benefit-cost analysis (Allen report)⁴;
- independent consumer research;
- extensive consultation with stakeholders including industry, jurisdictions, public health and consumers;
- consideration of submitters' views in response to the Initial and Draft Assessment Reports;
- evaluation of international practice; and
- consideration of national dietary guidelines and nutrition policies.

In the Draft Assessment Report FSANZ recommended Option 3 and this has remained the preferred approach. The rationale for this decision is based on the following:

1. Widespread support from all stakeholder groups for a new standard in submissions to the Draft Assessment Report. Comments in support of Option 3 included:
 - the need for a clearly enforceable standard;
 - it provides the greatest level of protection for consumers as it will apply to nutrition content claims, and general and high level health claims;
 - the use of a Standard rather than a Guideline will particularly assist smaller food companies to improve the quality and accuracy of the nutrition information they provide and will also be a better approach with respect to imported foods;
 - it will provide a 'level playing field' for all participants in the food industry;
 - it is the most workable and easiest system to regulate;
 - CoPoNC has not been entirely successful in preventing misleading nutrient claims;
 - it will give consumers greater confidence in the food supply; and
 - the long term benefits to consumers and industry outweigh the likely increase in government costs for education and enforcement.
2. The benefit-cost analysis indicated that the introduction of a new system for the regulation of nutrition content and health claims has greater benefit than maintaining the current system.

⁴ http://www.foodstandards.gov.au/_srcfiles/P293_DAR_ATT3_Benefit_Cost_Analysis-CBA_Allens_report.pdf

Options 2 and 3 received significantly higher scores than Option 1 in the benefit-cost analysis. Although Option 2 scored slightly higher than Option 3, it was noted that due to the high sensitivity of the final score to changes in the judging of criteria and the weights of the criteria, it should be concluded there is no significant difference in the impact of Options 2 and 3.

In the benefit-cost report it was considered that the level of compliance with a Guideline would be marginally lower than for a Standard. This arises from the greater certainty of enforcement where requirements are specified in a Standard rather than a Guideline. Jurisdictions noted the possible difficulty of enforcing compliance with disqualifying criteria under a Guideline since enforcement would entirely rely on fair trading provisions.

3. 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 with a number of new claims present in the market place (FSANZ, 2007). The types of potentially non-compliant claims include products with the word 'health' in relation to the product name and claims which may be presenting as non-compliant health claims. The ambiguity of the current transitional Standard means it is difficult to be categorical.
4. FSANZ considers there is no significant difference between Options 2 and 3 in terms of the potential for industry to innovate. In the benefit-cost analysis it was noted that Option 3 gives industry slightly less potential to innovate. This view was based on the assumption that industry would find it easier to make an amendment to a Guideline than to a Standard.

FSANZ considers the difference in the impact of a Standard or Guideline on opportunities for industry innovation is marginal, since only qualifying and disqualifying criteria rest in the Guideline or Standard. Furthermore since only some nutrition content claims (and similarly for general level health claims) are required to meet specific conditions as listed in the draft Standard other claims can be made without requiring a change to the Standard.

5. Submitters also raised the issue of the difficulty in 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.

9. Refinements to the Preferred Option since the release of the Draft Assessment Report

Throughout the development of the Final Assessment Report, the degree of regulation and the impacts of individual nutrition content, health and related claims on all stakeholder groups were key considerations as FSANZ progressed its work. FSANZ's extensive consultation processes with stakeholders have ensured views have been taken into account in the finalization of the draft Standard. Refer to Attachments 5, 6 and 7 for details of FSANZ's response to submitter comments about individual issues relating to nutrition content claims, general level health claims and high level health claims respectively.

Since the release of the Draft Assessment Report FSANZ has made a number of changes to the draft Standard ranging from minor to more significant changes. For example, the basis of the food vehicle eligibility criteria applied to general and high level health claims has changed substantially since the release of the Draft Assessment Report in response to submitter comment and stakeholder consultation.

In the Draft Assessment Report, the food vehicle eligibility criteria consisted of a simple approach based on levels of total sugar, saturated fat, and sodium per serve. In contrast, the revised approach consists of the allocation of baseline points for increasing amounts of energy, saturated fat, sodium and total sugars which are offset by ‘modifying’ points allocated for the increasing percentage of the product that is fruit/vegetable/nuts/legumes and the amount of fibre and in some cases protein.

Extensive comments on the revised criteria (nutrient profiling scoring criteria) presented in the Preliminary Final Assessment Report were received, however following further modelling work by FSANZ, only minor changes have been made such as the change in the first step for total sugars in the baseline table. Another example of a significant change in regulatory approach since the release of the Draft Assessment Report has been that related to endorsements. Evaluation of submitter comments and FSANZ consideration of legal issues led to the recommendation that endorsements meeting the definition in the draft Standard be exempt from the requirements of the draft Standard. A number of minor changes have been made to improve the intent of the Standard, for example issues relating to dietary information, application of the draft Standard, wording conditions relating to the property of the food and *cholesterol free* claims.

RECOMMENDED APPROACH FOR THE REGULATION OF NUTRITION, HEALTH AND RELATED CLAIMS

This part outlines the components of the draft Standard within the context of the preferred regulatory option. It also reflects how FSANZ had regard to the principles in the Policy Guideline during the development of the draft Standard, and what the draft Standard includes in relation to nutrition content claims and general and high level health claims and why. The draft Standard at Attachment 1 is the recommended regulatory measure.

The information provided is limited to a description of the outcome, not an analysis of the issues. Attachments 5 - 7 on nutrition content, general level and high level health claims provide an assessment of the rationale behind the various components of the draft Standard.

Comments provided by submitters in response to the Initial Assessment Report⁵ were integral to the development of the draft Standard. There were no new comments on the overall regulatory approach received in response to the Draft Assessment Report.

Submitters’ and stakeholders’ views (sought through public and targeted consultation processes) on each of the relevant topics are included in Attachments 5-7. An outline of the substantiation processes of general level health claims and high level health claims is given in chapters 14-17.

⁵<http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp293nutritionhealthandrelatedclaims/p293draftassessmentr3501.cfm>

10. Classification of nutrition content and health claims

In the Draft Assessment Report, a ‘Claims Classification Framework’ was proposed which comprised two levels of claims – general level claims and high level claims, as stated in the Policy Guideline. Within general level claims there were two types of claims, nutrition content claims and general level health claims. In response to confusion amongst stakeholders over the use of these terms FSANZ no longer refers to ‘general level claims’ but rather discusses these simply as nutrition content claims and general level health claims. The ‘step-up’ approach between these two types of claims has been retained (Figure 1).

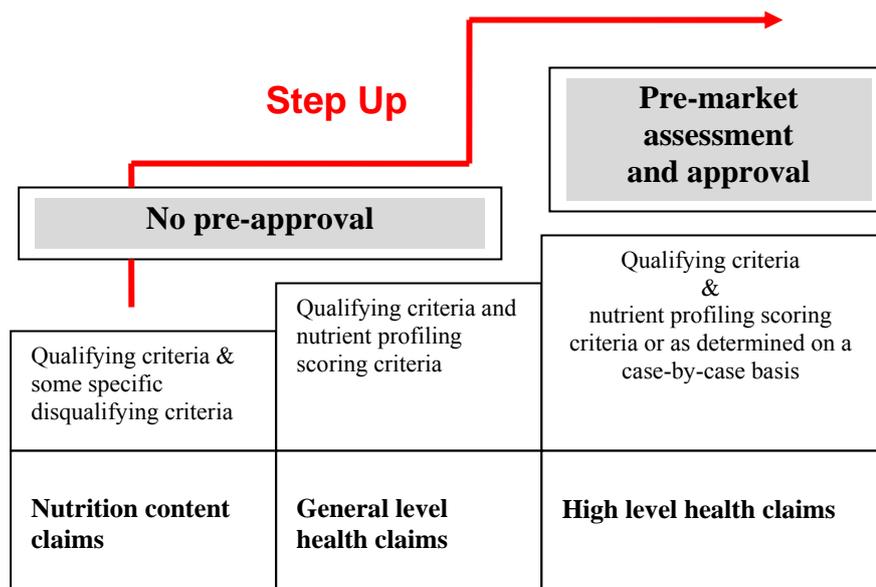


Figure 1: The ‘step-up’ approach to regulation of nutrition content and health claims

The draft Standard therefore sets out conditions for three types of claims: nutrition content claims, general level health claims and high level health claims. The level of a claim determines how the claim is regulated, including the process for substantiation⁶. The claims are described as follows.

- **Nutrition content claims** are claims regarding the presence or absence of a property of a food, including a nutrient, energy or a biologically active substance in the food (e.g. *this food contains X mg/100 g calcium; low in fat*).
- **General level health claims** are claims that refer to a relationship between a nutrient or substance in a food and to its effect on a health function (e.g. *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*). A general level health claim cannot refer to a serious disease or condition or to a biomarker of a serious disease (e.g. blood cholesterol).

⁶ The content of the Scientific Substantiation Framework differs from that in the Draft Assessment Report. The Scientific Substantiation Framework now only includes the requirements for the substantiation of general level health claims. See Chapter 7 for further details of the Scientific Substantiation Framework.

- **High level health claims** are those claims that make reference to a serious disease or biomarker of a serious disease (e.g. *A healthy diet high in calcium and vitamin D from a variety of foods may reduce the risk of osteoporosis in women 65 years and over*). Such food-disease relationships will need to be pre-approved by FSANZ with the resulting conditions for claims included in the draft Standard.

11. Regulatory approach

The regulatory parameters for nutrition content and health claims include general requirements that apply to all nutrition content and health claims irrespective of their classification and specific requirements according to the classification of the claim (i.e. the claimed property of the food, food vehicle eligibility criteria, substantiation and wording conditions). In order to be effective, the draft Standard firstly establishes a general prohibition on the use of nutrition content and health claims unless these regulatory parameters are met, and then incorporates a ‘step-up’ approach in regulation reflective of the degree of risk (refer to Figure 1).

The application of the draft Standard was discussed in the Draft Assessment Report (Chapter 5) and revised in the Preliminary Assessment Report (Section 3.1). In line with clause 13 of Standard 1.1.1, the requirements of the draft Standard apply where claims are made in relation to food for retail sale, whether on the label of the food or in advertising of the food to the public. Refer to Attachment 4 for further discussion of the application of the draft Standard.

The regulatory parameters for nutrition content claims and health claims are outlined in sections 11.3 and 11.4 respectively.

11.1 Ineligible foods

Nutrition content and health claims are prohibited on certain ‘ineligible’ foods. These are a food that contains more than 1.15% alcohol by volume (except for nutrition content claims about carbohydrate and energy), and kava. Claims about infant formula product will be permitted as currently permitted under Standard 2.9.1. Refer to Attachment 4 for further discussion on ineligible foods.

11.2 Capture of a claim and determination of claim type

There will be a broad capture of all claims through the application of the definition of ‘claim’ under Standard 1.1.1 whether presented explicitly or implicitly. The definition of ‘claim’ encompasses any voluntary representations made in relation to a food. This covers words or other artwork on food labels or conveyed through mediums such as advertisements and also verbal representations in relation to food. In order for something to constitute a nutrition content, general level health claim or high level health claim, it must first be captured by the definition of ‘claim’.

The definitions around ‘general level health claim’, ‘high level health claim’ and ‘health claim’ and ‘nutrition content claim’ will determine the types of claims, both explicit and implicit, that will be captured by the draft Standard. Claims that will not be captured are those claims that do not explicitly or implicitly indicate the presence or absence of a property of the 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*. These types of claims are subject to general fair trading legislation. FSANZ will provide further detail in a User Guide through the use of examples in relation to statements, representations, graphics, designs etc.

This approach will assist in addressing ‘implied claims’. It will do this firstly through the broad prohibition on nutrition content or health claims (including implied claims) and then only permitting the use of those claims, which explicitly reference a specific property of the food (for nutrition content claims) and health effect (for general level health claims). For more detail around FSANZ’s proposed approach for the regulation of implied claims refer to Attachment 4.

There are certain types of claims that are not regulated as a nutrition content claim or health claim but have specific conditions around their use in order to clarify their status within the draft Standard. Such claims include endorsements, cause-related marketing statements and dietary information (refer to Attachment 9 for details of these claims).

The following two sections outline the application of the regulatory parameters (i.e. criteria for the claimed property of the food, food vehicle eligibility criteria, substantiation and wording conditions) for nutrition content, general level and high level health claims.

11.3 Nutrition content claims

Certain general requirements must be met before a claim can be considered a compliant nutrition content claim.

For nutrition content claims the general requirements are:

- substantiation (by analysis or calculating the claimed nutrient content of the food); and
- wording conditions, e.g. the use of descriptors that indicate a certain level of a nutrient is present in the food.

In addition, specific conditions are prescribed for certain nutrition content claims:

- Qualifying criteria relate to the nutritional component of the claimed food that is the subject of the claim and must be met before the claim can be made.
- Specific ‘disqualifying criteria’ are applied to some nutrition content claims. Such criteria relate to other relevant properties of the food itself, rather than the claimed nutrient.

For example, for a nutrition content claim about *low cholesterol*:

- the qualifying criteria are that the food contains no more cholesterol than 10 mg per 100 ml for liquid food and 20 mg per 100 g for solid food; and
- the disqualifying criterion is that the food meets the conditions for a nutrition content claim in relation to a *low saturated fatty acid claim* (i.e. the food contains no more saturated and *trans* fatty acids than 0.75 g per 100 ml for liquid food and 1.5 g per 100 g for solid food).

These conditions are outlined in Attachment 5.

11.4 Health claims

For health claims the general requirements are:

- substantiation (for general level health claims, this must be done according to the Scientific Substantiation Framework). To substantiate general level health claims manufacturers must use either the FSANZ list of nutrient function statements, derive claims from the food-disease relationships for high level health claims, use authoritative sources or complete a systematic review as specified in the Scientific Substantiation Framework. Suppliers must have records to substantiate such claims and produce these records, on request, for enforcement agencies (see Attachment 8 for details);
- wording conditions, e.g. the claims make reference to a specific component of the food (except for whole foods – refer to Part 2 of Attachment 6) and to a specific health effect; and
- the food must meet the nutrient profiling scoring criteria (referred to as ‘disqualifying criteria’ in the Draft Assessment Report). These food vehicle eligibility criteria will apply to most foods that carry health claims, to avoid the promotion, through the use of health claims, of foods that are inconsistent with national nutrition guidelines. The conditions relating to the nutrient profiling scoring criteria are prescribed in Schedule 1 of the draft Standard (see Attachments 1 and 6 for details). Some high level health claims may have more specific food vehicle eligibility criteria applied (see Attachment 7).

In addition, qualifying criteria for certain general level health claims will be based on the applicable nutrition content claim criteria. For example, for a general level health claim that includes a reference to *fibre* the qualifying criteria will relate to the amount of fibre present in the food while the nutrient profiling scoring criteria relate to the food vehicle.

Figure 2 provides an overview of how claim definitions and the regulatory parameters for the claimed property of the food, food vehicle eligibility criteria, substantiation and wording conditions, work together to regulate general level health claims.

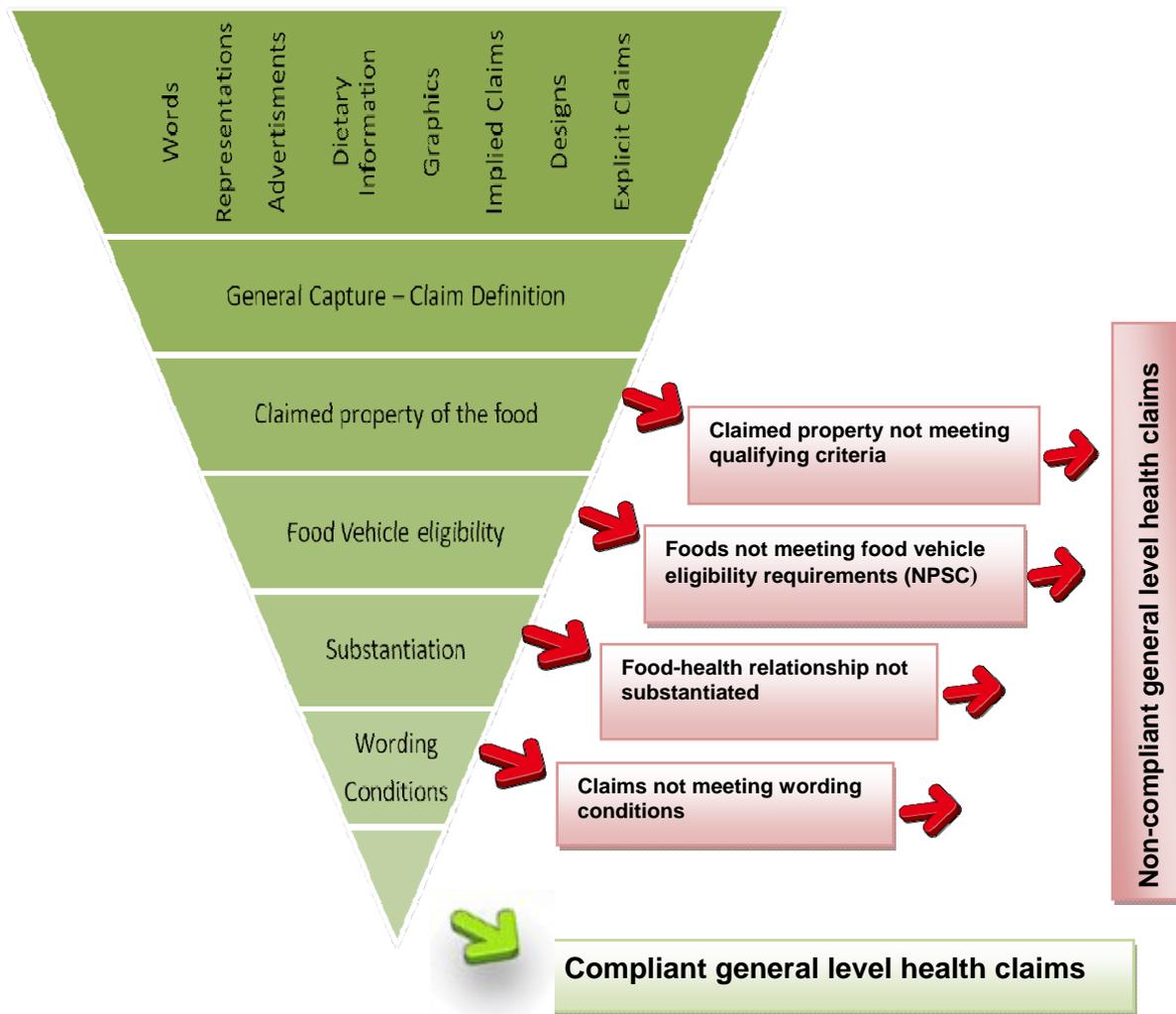


Figure 2: Application of the regulatory parameters for general level health claims

Specific conditions are also prescribed for health claims about weight loss and maintenance, maternal folic acid consumption for normal foetal development, and biologically active substances. For detail on these specific conditions, refer to Part 2 of Attachment 6.

11.5 Terminology

In order to understand and implement the draft Standard, a number of terms must be clearly defined. FSANZ included certain definitions and other terms in the Initial Assessment Report, which have been revised after taking into account submitter comments to the Initial, Draft and Preliminary Final Assessment Reports. In some cases, FSANZ has elected not to define some terms, some of which were recommended by submitters.

Full details of definitions and other terms are provided at Attachment 3. Definitions are also found at Attachment 1.

General terminology such as definitions/descriptors has been clarified such that:

Definitions – are those included in the draft Standard and other related standards. These will be, as necessary, further explained in the User Guide, 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 are those descriptive terms used to qualify a claim e.g. *low, high, light* etc. These will be discussed in a User Guide.

Other terms – other terms used throughout the Final Assessment Report and any supporting materials are referred to in the Glossary to this Report and will be discussed in the User Guide for clarity. This includes terms such as guideline, User Guide, conditions, criteria, etc.

Certain terms proposed in the Initial Assessment Report and referred to in the Draft Assessment Report, are not referred to in the draft Standard and it is now considered unnecessary to define these terms. These include:

- function claim;
- enhanced function claim;
- risk reduction claim in relation to a serious disease or condition;
- risk reduction claim in relation to a non-serious disease or condition;
- biomarker maintenance claim; and
- biomarker enhancement claim.

11.6 ‘Step-up’ approach to the regulation of nutrition content and health claims

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 consideration of the potential risks around not providing consumers with adequate information for informed choice and misleading or confusing consumers by encouraging consumer choices that may have adverse health impacts.

FSANZ considers a ‘step-up’ approach to regulation, meaning an increase in regulatory hurdles, is appropriate based on the spectrum of claims from nutrition content claims to general level health claims to high level health claims. This is founded on the principle that regulatory intervention is warranted where there is a potential for consumers to be misled. While there may be potential health benefits arising from the use of nutrition, health and related claims, in circumstances where these benefits are off-set by an increased risk to the consumer, the level of regulation to which the claim is subject should increase to mitigate the risk. This concept is described in the Policy Guideline in relation to the categorisation of a claim where it is proposed that claims offering a higher ‘degree of promise’ to the consumer should be more highly regulated. Figure 1 presented earlier illustrates the ‘step-up’ in the regulation between nutrition content claims, general and high level health claims. Submitter comments were received about the potential for consumers to interpret a claim as carrying an increased health significance from that stated. For example, a general level health claim about a healthy heart may imply reference to cardiovascular disease to some people while others may simply interpret it as a healthy heart. In these circumstances, FSANZ maintains that there are significant difficulties in regulating for potential individual interpretations of claims. However, FSANZ intends to monitor the impact of the draft Standard on consumer use and understanding of claims.

11.6.1 'Step-up' from Nutrition Content Claims to General Level Health Claims

As noted in chapter 10, nutrition content claims relate to the presence or absence of a nutrition related component in a food whereas general level health claims describe the relationship between the consumption of a nutrition related component in a food and a health effect. Due to the fundamental differences between these types of claims FSANZ has considered whether it is appropriate that some aspects of their regulation differ in terms of the stringency of regulation applied, in particular, whether a different approach to specifying criteria and wording conditions is warranted.

FSANZ has determined that greater regulatory control is appropriate around the use of general level health claims through the application of additional food compositional criteria (i.e. the application of the nutrient profiling scoring criteria in addition to qualifying criteria) and conditions around the wording of the health claim. The rationale for applying nutrient profiling scoring criteria to general level health claims is as follows:

- Application of the nutrient profiling scoring criteria means the focus is on the whole food, not just the claimed nutrient, effectively preventing foods that have high levels of risk increasing nutrients from making claims. This therefore supports the protection of public health and ensures that claims be *consistent with and complement Australian and New Zealand national policies and legislation including those relating to nutrition and health promotion* as stated in the Policy Guideline.
- The approach supports consumers in choosing foods as part of a diet that is consistent with nutrition and dietary guidelines. The baseline points in the nutrient profiling scoring criteria are based on nutrients of public health concern, and the system is designed to exclude foods that may contribute to intake of nutrients that are inconsistent with dietary intake recommendations. Hence there is less onus on consumers to interpret other labelling elements such as the nutrition information panel in order to determine whether the claimed food is a 'healthy' food choice in the overall diet. FSANZ's (2003) consumer research highlighted that when consumers are choosing between two similar products, consumers do not demonstrate an ability to understand the significance of differences in levels of nutrients and tend to only concentrate on one nutrient at a time.
- The approach provides certainty for consumers that the products carrying general level health claims are only on appropriate foods.
- The approach provides an incentive for industry to develop products that support national nutrition policies.
- The approach is consistent with the Codex Guidelines for use of Nutrition and Health Claims (2004) which state that claims should have a clear regulatory framework for qualifying and/or disqualifying conditions for eligibility.
- There is submitter support for the application of nutrient profiling scoring criteria to general level health claims. Public health submitters in particular have indicated that it is irresponsible to put any health claims on foods that contain high levels of risk increasing nutrients and noted the Policy Guideline states that claims *should not promote irresponsible food consumption patterns*.

Regardless of the differences between nutrition content claims and general level health claims, there are aspects of the regulatory approach that are consistent between the two types of claims as follows:

- 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 be required to be substantiated. For nutrition content claims this involves analysing or calculating the value of the nutrient content of the food. For the substantiation of general level health claims the supplier is required to assess the evidence supporting the claim prior to market, hold the records that substantiate the claim and produce them at the request of enforcement officials (refer to Attachment 1).

In a small number of cases, nutrition content claims or health claims are permitted under pre-existing provisions in the Code. In particular, Standard 2.9.2 – Foods for Infants, Standard 2.9.3 – Formulated Meal Replacements and Standard 2.9.4 – Formulated Supplementary Sports Foods, permit some claims to be made in relation to foods regulated under those Standards. Additional provisions may be placed on some of these claims by the introduction of Standard 1.2.7. The draft Standard 1.2.7 will not apply to Standard 2.9.1 – Infant Formula Products. Refer to Attachment 4 for further details on the relationship between the draft Standard and other parts of the Code.

11.6.2 ‘Step-up’ from General Level Health Claims to High Level Health Claims

The Policy Guideline proposes a ‘step-up’ for the regulation for high level health claims. Unlike general level health claims, where the supplier is required to substantiate the claim and hold the record that substantiates the claim, food-disease relationships provided as the basis for high level health claims are required to be pre-market assessed and approved by FSANZ. Other regulatory controls around the use of the high level health claims such as food compositional criteria⁷ or wording conditions will be assessed on a case-by-case basis (refer to Attachment 7) based on the substantiation of the claim, and may also result in a regulatory approach that creates a ‘step-up’ from general level health claims.

For instance, qualifying criteria for calcium in respect of a high level health claim about calcium and osteoporosis (the food must contain no less than 290 mg of calcium per serving) differ from the requirements for a general level health claim about calcium and strong bones (the food must contain no less than 80 mg calcium per serving).

FSANZ has pre-approved several food-disease relationships in the draft Standard. Attachment 7 presents a synopsis of the substantiation reviews commissioned by FSANZ and how the high level health claims referring to these food-disease relationships will be regulated.

⁷ Note the application of the nutrient profiling scoring criteria is the default position.

NUTRITION CONTENT CLAIMS

Nutrition content claims are claims about the presence or absence of a property of the food, including energy, nutrients and biologically active substances. With the introduction of the draft Standard, many nutrition content claims previously included in CoPoNC and therefore not enforceable will be regulated in the Code and will thereby become enforceable.

General conditions that will apply to all nutrition content claims have been developed and included in the draft Standard. In addition, FSANZ has evaluated which nutrition content claims should be subject to specific conditions on the basis of a risk management approach which takes account of public health recommendations and the need for consumer information. This has resulted in the development of additional specific conditions for certain nutrition content claims. In accordance with preferred regulatory Option 3 these conditions are drafted into regulation (refer to chapters 6-9). These conditions 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 recommendations, international regulations, Codex Alimentarius guidelines, to improve consistency in approach and to take account of stakeholder consultations and submissions.

The more generic conditions include:

- the use of descriptors and synonyms for certain descriptors in the claim, for example, *high, reduced*;
- conditions for claims about nutrients that are naturally present or absent in a food;
- voluntary declaration of percentage daily intake values;
- declaration of percentage RDI; and
- the form of the food (in its ‘as sold’ state or ‘as consumed’) to which the conditions for making the claim must be applied to.

In addition, as per the current requirement under clause 5 of Standard 1.2.8, the name and average quantity of any claimed nutrient or biologically active substance must be declared in the nutrition information panel. In accordance with the ‘step-up’ approach to regulation as described in section 11.6, nutrition content claims will not be subject to the nutrient profiling scoring criteria. As discussed in Part 1 of Attachment 5, key reasons for not applying the nutrient profiling scoring criteria include the lack of evidence that nutrition content claims are misleading in relation to the food vehicle, a reduced number of products with claims would restrict valuable information for some consumers and the increased cost to industry. More detail about the general conditions listed above can be found in Part 1 of Attachment 5.

Additional specific conditions have been developed that will apply to the use of certain nutrition content claims only, for example, *low fat, good source of protein*, and *reduced sugar* claims. These conditions include specific compositional requirements and in some cases, wording conditions.

The compositional requirements include qualifying criteria in order to ensure a minimum or maximum amount of the claimed property in the food, and for some claims, specific disqualifying criteria in relation to certain nutrients, e.g. the saturated fat content is included in the conditions for cholesterol claims. Specific wording conditions are included for comparative claims e.g. *reduced* claims.

Although CoPoNC was used as the basis to develop these conditions, there have been some amendments to the conditions in CoPoNC for most claims. These amendments range from minor, for example, for the *low fat* claim, where the conditions for liquid foods have been changed from a per 100 g basis to per 100 ml, to more substantial, for example, for fibre claims, the qualifying criteria have been increased such that increased levels of fibre are required to make a claim, compared with the criteria currently in CoPoNC. The existing conditions in the Code for certain nutrition claims have either remained unchanged, e.g. unsaturated fatty acid claims, or been subject to minor changes e.g. *reduced* lactose claims have been prohibited. For details on these specific conditions, refer to Part 2 of Attachment 5.

Nutrition content claims about vitamins and minerals will be subject to claim requirements set out in the draft Standard and where applicable, Standard 1.3.2. The ‘claimable food’ approach for foods carrying claims about vitamins and minerals, as currently determined by Standard 1.3.2 – Vitamins and Minerals, will be removed. The removal of ‘claimable food’ criteria does not affect qualifying criteria for vitamin and mineral fortification or permissions to fortify. The change simplifies the regulation of nutrition content claims generally and ensures parity between claims about vitamin and minerals, and macronutrients and other substances.

GENERAL LEVEL HEALTH CLAIMS

The draft Standard includes generic conditions that will apply to general level health claims. The application of these conditions depends on the subject of the claim but in general they include:

- qualifying criteria (refer to Part 1 of Attachment 6);
- the nutrient profiling scoring criteria (refer to Part 1 of Attachment 6),
- the Scientific Substantiation Framework (refer to Attachment 8); and
- wording conditions (refer to Part 1 of Attachment 6).

General level health claims about certain nutrients will be subject to the specific qualifying criteria that have been established for nutrition content claims about those nutrients. In general, in order to make a general level health claim about nutrients where increased consumption is recommended, the minimum qualifying criteria for making a claim must be met. For example, for a food carrying a general level health claim about dietary fibre, the food must contain at least 2 g of dietary fibre per serve. For foods carrying general level health claims in relation to nutrients where decreased consumption is recommended, the food will be required to meet the conditions for carrying a *low* nutrition content claim about that nutrient. For example, for food carrying a general level health claim about fat, the food must meet the conditions for making a nutrition content claim about *low fat*. The conditions for the state of the food (in its ‘as sold’ state or ‘as consumed’), to which these qualifying criteria should be applied to will also pertain.

For general level health claims relating to ingredients and nutrients without applicable criteria for making nutrition content claims, e.g. carbohydrate, *high energy*, it is the responsibility of the supplier to determine the appropriate level of the nutrient or ingredient that should be in the food before making the health claim.

General level health claims are a ‘step-up’ from nutrition content claims because they articulate an anticipated health effect in relation to the property of the food.

Therefore, food vehicle eligibility criteria will apply to most foods that carry general level health claims, to avoid the promotion, through the use of health claims, of foods that are inconsistent with national nutrition guidelines. This approach ensures that claims be *consistent with and complement Australian and New Zealand national policies and legislation including those relating to nutrition and health promotion* as stated in the Policy Guideline. In this Report, food vehicle eligibility criteria are referred to as ‘nutrient profiling scoring criteria’ and the criteria are prescribed in Schedule 1 of the draft Standard. ‘Baseline’ points are allocated for increasing amounts of energy, saturated fat, sodium and total sugars. These points are offset by ‘modifying’ points allocated for the increasing percentage of the product that is fruit/vegetables/nuts/legumes and the amount of fibre, and in some cases protein. There are three food categories (edible oils, spread and certain cheeses; other foods; and beverages) each with different cut-off points for determining eligibility for general level health claims.

The nutrient profiling scoring model being used by FSANZ is based on the UK Food Standards Agency Nutrient Profiling Model that was developed to determine eligibility/ineligibility for products to be advertised to children. The UK model has been amended by FSANZ to better meet the needs of the health claims system. Refer to Section 2 – Nutrient Profiling Scoring Criteria, in Attachment 6 for further information.

The nutrient profiling scoring criteria will apply generally to most foods carrying health claims, however some specific exemptions are recommended. These are for foods carrying health claims about lactose or gluten, (unless the food carries a claim about another property in addition to lactose or gluten), and for foods that are standardised in Part 2.9 – Special Purpose Foods). Foods for which general level health claims are made about the vitamin and mineral content will now be required to meet the nutrient profiling scoring criteria. This implements a consistency of approach with other general level health claims.

General wording conditions apply to general level and high level health claims. These include the requirement for the claim to explicitly state:

- the property of the food;
- the specific health effect claimed in relation to that property of the food;
- the specific population group, where the evidence used to substantiate the claim indicates that the health effect cannot be attributed to the general population but to specific population groups only; and
- that the health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods. The actual wording of the healthy diet context must be appropriate to the type of food bearing the claim, the property of the food and the specific health effect claimed.

These wording conditions have been implemented as a strategy to prevent the use of implied health claims which could otherwise mislead consumers. For further details regarding the wording conditions for health claims, refer to Part 1 of Attachment 6.

There are also specific conditions in the draft Standard for general level health claims about:

- weight management or weight loss;
- maternal folic acid consumption for normal foetal development;
- biologically active substances; and

- wholegrain.

For further information about these conditions, refer to Part 2 of Attachment 6.

HIGH LEVEL HEALTH CLAIMS

12. Regulatory approach for high level health claims

High level health claims are health claims that make reference to a serious disease or biomarker of a serious disease. Food-disease relationships will require pre-approval by FSANZ before incorporation into Standard 1.2.7 and these will form the basis of high level health claims available for use by industry. The process FSANZ will follow for assessment of food-disease relationships will be set out in the *Application Handbook*⁸. The evidence for a number of food-disease relationships has already been reviewed with some relationships being pre-approved and resulting in the inclusion of eight high level health claims in the draft Standard (refer to Attachment 7).

The same regulatory principles that apply to general level health claims in relation to food compositional requirements and wording conditions have been taken into account when establishing conditions for these pre-approved food-disease relationships. The substantiated evidence assessed for each food-disease relationship review was also drawn upon for setting compositional criteria, wording conditions and any additional criteria for each high level claim.

For consistency, all foods carrying a high level health claim based on the pre-approved food-disease relationships currently listed in the draft Standard are required to meet the compositional criteria based on the nutrient profiling scoring criteria (refer to Part 1 of Attachment 6). In some instances FSANZ may place additional restrictions on those food products permitted to carry individual high level health claims. Restrictions will generally be based on the substantiation evidence relating to a specific food-disease relationship, with consideration also given to dietary guidelines and foods not recommended for consumption by particular target populations or those at a particular life stage (e.g. there are a number of foods not recommended for consumption by pregnant women and these are not permitted to carry a folic acid-neural tube defect high level health claim).

Wording of the claim will generally *not* be prescribed; rather, the essential elements of each claim will be specified. In general these specifications will follow a similar format to those applied to general level health claims i.e. the claim must state the property of the food or foods and the specific health effect, and the health effect must be considered in the context of a healthy diet. Other wording conditions applicable to high level health claims may include the specific target population, any relevant lifestyle information, and any required advisory statement. In some instances, where warranted by the substantiated evidence underpinning the claim, specific wording may be prescribed for an individual claim.

⁸ It is intended that Chapter 3.2.7 of the *Application Handbook* will set out the information required by FSANZ to assess the validity of a food-disease relationship prior to approval of the relationship upon which a high level health claim can be based.

13. Reviews of food-disease relationships

During the development of Proposal P293, FSANZ commissioned seven reviews of food-disease relationships to provide a basis for including high level health claims in Standard 1.2.7. The criteria for selection of these food-disease relationships have been previously described (see Draft Assessment Report for Proposal P293, particularly section 6.3.2 and Attachment 10 of that Report). The reviews commissioned by FSANZ were prepared by experienced Australian and New Zealand scientists and were subsequently peer reviewed by a Scientific Advisory Group (SAG) convened by FSANZ. The methods described in the Substantiation Framework included in the Draft Assessment Report⁹ to evaluate the totality of evidence were used as the basis for determining the validity of a food-disease relationship. A food-disease relationship was substantiated if it met a ‘convincing’¹⁰ level of evidence as defined in the Substantiation Framework. The complete reports for each of the food-disease relationships are located on the FSANZ website¹¹.

Outcomes of the first four reviews were provided in the Draft Assessment Report, with six food-disease relationships being considered substantiated to a ‘convincing’ level (see reviews 1-4 in Table 1).

In the Preliminary Final Assessment Report, the outcomes of three further reviews were provided (see reviews 5-7 in Table 1). A further two food-disease relationships were considered substantiated to a ‘convincing’ level, both based on the outcome of the review on fruit, vegetables and coronary heart disease. Evidence of the relationship between wholegrains, bran and coronary heart disease was considered ‘not convincing’. Evidence in relation to long chain omega-3 fatty acids and cardiovascular disease was considered to be ‘probable’. An overview of conclusions from the reviews commissioned by FSANZ for each of these food-disease relationships and FSANZ’s assessment, including advice from the SAG, was provided in Attachment 5 of the Preliminary Final Assessment Report.

From the seven reviews commissioned, eight food-disease relationships were considered to be substantiated to a ‘convincing’ level (Table 1).

⁹ The Substantiation Framework at Attachment 8 of the Draft Assessment Report was used as the basis for evaluating all pre-approved food-disease relationships to date. In the future, guidelines in the *Application Handbook* will be used to substantiate high level health claims.

¹⁰ The ‘convincing’ and ‘probable’ terminology was used in the version of the Substantiation Framework included in the Draft Assessment Report. These terms are no longer used in the current approach to substantiating high level health claims; instead there are five criteria which will be considered in assessing the ‘strength of the evidence’.

¹¹ <http://www.foodstandards.gov.au/foodmatters/healthnutritionandrelatedclaims/reviewsforhighlevelc3090.cfm>

Table 1: Food-disease relationships assessed in FSANZ commissioned reviews

No.	Food-disease relationship assessed	Substantiated relationship(s)	Level of evidence*
1	Calcium, vitamin D and osteoporosis/enhanced bone density	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). Increased dietary intake of calcium and enhanced bone mineral density, particularly in women.	Convincing Convincing
2	Sodium and blood pressure	Reduction in dietary intake of sodium and reduction in blood pressure.	Convincing
3	Folic acid and neural tube defects	Intake of folic acid in the peri-conceptional period and risk of development of neural tube defects in the foetus.	Convincing
4	Saturated fatty acids [and <i>trans</i> fatty acids] and LDL cholesterol and heart disease	Reduction in dietary intake of saturated fatty acids and reduction in blood levels of low-density lipoprotein (LDL)-cholesterol.** Reduction in dietary intake of saturated and <i>trans</i> unsaturated fatty acids and reduction in blood levels of low-density lipoprotein (LDL)-cholesterol.**	Convincing Convincing
5	Fruit and vegetables and coronary heart disease	Increased intake of fruit and vegetables and coronary heart disease. High intake of fruit and vegetables and coronary heart disease.	Convincing Convincing
6	Wholegrains, bran and coronary heart disease	N/a	Not convincing
7	Long chain omega-3 fatty acids and cardiovascular disease	N/a	Probable

* For definition of the levels of evidence applied see Attachment 8 of the Draft Assessment Report¹². Note that the terms ‘convincing’ and ‘probable’ are no longer used (refer to chapter 15).

**On the basis of these two relationships for LDL-cholesterol, FSANZ has given 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.

SUBSTANTIATION OF GENERAL LEVEL AND HIGH LEVEL HEALTH CLAIMS

The following sections summarise substantiation requirements for nutrition content, general level health claims and high level health claims. Changes to the substantiation requirements for general level health claims that have been made since the release of the Draft Assessment report are also included. Refer to Attachment 8 for further details on the substantiation of general level health claims, including submitter comments to the Consultation Paper.

¹² http://www.foodstandards.gov.au/srcfiles/P293_DAR_ATT8_Substantiation_Framework.pdf

14. Changes to the Scientific Substantiation Framework

The Scientific Substantiation Framework has been restructured since the release of the Draft Assessment Report for the following reasons (see Schedule 2 – Scientific Substantiation Framework in the draft Standard):

- The language in the Substantiation Framework attached to the Draft Assessment Report, in relation to general level health claims, has been made more prescriptive in order to:
 - facilitate decision making by jurisdictions when considering enforcement action on the basis that a claim may not be substantiated, and
 - enable stakeholders to follow a specific and clear process in order to substantiate the claim.
- Substantiation of nutrition content claims has been taken out of the Scientific Substantiation Framework because this type of claim is verified by analysing or calculating the value of the nutrient content of the food.
- Substantiation of high level health claims has been removed from the Scientific Substantiation Framework because these types of claims are subject to pre-approval of food-disease relationships by FSANZ. The substantiation requirements for high level health claims will be specified in the *Application Handbook*.

15. Changes to the substantiation of general level health claims

The main changes to the substantiation requirements of general level health claims since the release of the Draft Assessment Report are documented below.

- A process for substantiating nutrition, health and related claims on foods (including general level and high level health claims) was described in Attachment 8 of the Draft Assessment Report¹³. The level of evidence required for high level health claims was ‘convincing’ (based on a four point scale of ‘convincing’, ‘probable’, ‘possible’ and ‘insufficient’) but for general level health claims the level of evidence required was not explicitly stated but was intended to be the same as for high level health claims.
- In the Preliminary Final Assessment Report, a ‘probable’ level of evidence was proposed for general level health claims. A ‘convincing’ level of evidence was retained for high level health claims. At this time, FSANZ concluded that the level of evidence for the relationship between long chain omega-3 fatty acids and cardiovascular disease was ‘probable’ and could be used to support a general level health claim, even though a high level health claim from this relationship had not be substantiated (see Section 6.5 in the Preliminary Final Assessment Report¹⁴ available on the FSANZ website).

¹³ http://www.foodstandards.gov.au/_srcfiles/P293_DAR_ATT8_Substantiation_Framework.pdf

¹⁴ <http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp293nutritionhealthandrelatedclaims/index.cfm>.

- FSANZ has now proposed a single strength of evidence that applies to general level and high level health claims. This amendment has arisen from jurisdictional concerns about lack of clarity and the enforceability of the substantiation requirements of health claims, concern about the tiered approach to substantiation and objection to a general level health claim being made based on a relationship not found to be convincing such as omega-3 fatty acids and heart health (see Section 3 of the Consultation Paper¹⁵ available on the FSANZ website). In addition, the use of the descriptors ‘probable’ and ‘convincing’ were discontinued because of possible confusion between the scientific and the legal use of these terms. Instead the ‘strength of scientific evidence’ comprising five key elements are the basis for assessing the totality of evidence.
- In the Final Assessment Report, the Scientific Substantiation Framework provides guidance on the quality and amount of evidence required to substantiate a food-health relationship.

Although there have been changes to the level of evidence required for general level health claims, FSANZ has made these changes in response to concerns raised in submissions. For high level health claims, although the ‘convincing’ descriptor is no longer proposed, the level of evidence required for pre-approval of the seven food-disease relationships (refer to Table 1 in chapter 13) has been consistent throughout the development process and will be applied to all assessments to pre-approve food-disease relationships in the future.

16. Substantiation of general level health claims

General level health claims are required to be scientifically substantiated. As pre-market assessment and approval by FSANZ is not required, the supplier must assess the evidence supporting the claim prior to market, hold the records for the substantiation of the claim and produce these records at the request of enforcement officials.

The following methods for the substantiation of general level health claims are permitted:

Method 1 List of nutrient function statements. These are provided by FSANZ as examples and may be used without further substantiation. They are based on a list of ‘well-established’ nutrient function statements with a high degree of certainty around the nutrient function. The list is not exhaustive and the wording is indicative only. Other nutrient function statements may be substantiated by using any of the other methods in the Scientific Substantiation Framework.

Method 2 Prescribed list of pre-approved food-disease relationships for high level health claims. These are pre-approved for high level health claims and may be used as the basis of a general level health claim without further substantiation providing that the general level health claim does not refer to a serious disease or to a biomarker of serious disease.

Method 3 Prescribed list of authoritative sources. This method lists a range of authoritative sources that can be used to substantiate a general level health claim. Only one source describing a definitive food-health relationship that is relevant to the Australian and New Zealand populations is required.

¹⁵ http://www.foodstandards.gov.au/srcfiles/P293_Consultation_Paper.pdf

Method 4 Systematic review. This method may be used instead of Methods 1, 2 and 3. A systematic review may be particularly useful when wanting to capture recently published material to add to the body of evidence for a relationship that has not yet been substantiated.

Each of these methods for substantiating general level health claims is described in greater detail at Schedule 2 - Scientific Substantiation Framework in the draft Standard.

The process for conducting a systematic review (Method 4) and the strength of evidence required to support a food-health relationship for a general level health claim is the same as that required to substantiate a food-disease relationship for a high level health claim and will be described in considerable detail in the *Application Handbook*.

17. Substantiation of high level health claims

Food-disease relationships which are the basis of high level health claims:

- refer to food-disease/biomarker relationships;
- are required to be scientifically substantiated; and
- must be pre-approved as they make reference to a serious disease or a biomarker of a serious disease.

The amendments to the *Application Handbook* incorporating the substantiation requirements for high level health claims are undergoing a consultation process at the time of writing this Report, hence details cannot be included here but will be finalised near the time of the Ministerial Council decision.

RELATED CLAIMS

Related claims are considered to be those referred to and/or regulated by the draft Standard, but not regulated as nutrition content claims or health claims as such. They include endorsements, trademarks, cause-related marketing statements and dietary information.

18. Endorsements

The requirements of the draft Standard that relate to a nutrition content claim or health claim do not apply to an endorsement made by an endorsing organisation if specific conditions are met. The supplier of the food is required to have records demonstrating that the organisation that certified the endorsement is an endorsing organisation as defined in the draft Standard and these records must be made available upon request to the relevant authority.

19. Trade marks

The draft Standard remains silent on trade marks. The registration of trade marks in Australia and New Zealand is regulated by the *Trade Marks Act 1995 (CTH)* and the *Trade Marks Act 2002 (NZ)* respectively. Exclusive rights to use the trade mark are linked to the registration process in both countries.

In Australia, if adopted, the draft Standard will be regulated by relevant State or Territory food legislation, which enforces the Code. If state law giving effect to the draft Standard provided that the registered owners of certain trade marks were prohibited from using those trade marks, this could potentially be inconsistent with section 20 of the *Trade Marks Act 1995* (Cth) and this may raise a constitutional issue in respect of section 109 of the Commonwealth of Australia Constitution. Broadly, section 109 provides that where there is an inconsistency between Commonwealth and State legislation, the Commonwealth law will prevail to the extent of the inconsistency.

In New Zealand, enforcement of the Code is undertaken using the *Food Act 1981*. In circumstances where registered trademarks infringe on a provision of the draft Standard, there is potential for any enforcement process to be undertaken through the provisions of the *Food Act 1981*.

20. Cause-related marketing statements

A cause-related marketing statement for food is defined to mean a nutrition content claim or health claim that is presented as a statement that the sale of food will contribute to fundraising for an organisation. These statements will be exempt from the draft Standard if accompanied by a disclaimer to the effect that the supplier makes no claims in relation to the food being beneficial for managing a health effect or to the effect that the supplier makes no claims that the food is a source of the property of the food referred to in the cause-related marketing statement.

However, if the food label or advertisement for food carries a nutrition content claim or health claim about the same property of the food or health effect respectively, as referred to in the cause-related marketing statement, the disclaimer is not required as it would be overridden by the nutrition content claim or health claim and their respective requirements.

21. Dietary information

Dietary information refers to the general dietary information that is derived from national nutrition guidelines or similar, highly credible sources. Its purpose is to educate the public about recommended healthy diet patterns; however, when dietary information appears on a food label or in an advertisement for a particular branded food, it may be seen as promoting the product. The draft Standard includes provisions which effectively restrict its use by requiring dietary information to:

- relate to an associated nutrition content claim or health claim;
- not exceed the associated nutrition content claim or health claim; and
- relate directly to the food, if the dietary information refers to food rather than a property of the food. In this instance, a nutrition content claim or health claim is not required to accompany the dietary information.

Dietary information statements about moderating the consumption of alcohol are exempt from these provisions.

The conditions for dietary information listed above apply to food for retail sale, which includes all food sold to the public (including food sold in restaurants) and food prior to retail sale and not intended for further processing, packaging or labelling.

The regulatory approach for endorsements, trademarks, cause-relating marketing statements and dietary information is outlined in Attachment 9.

REGULATORY IMPACT ANALYSIS

22. Affected Parties

Three principal sectors of the economy will be affected by this Proposal:

- consumers generally, and particularly those consumers with an interest in their nutrition, diet, health and wellbeing;
- The food industry broadly, including all sectors of food production, all suppliers of food products, and food retailers; and
- government enforcement agencies of the jurisdictions in Australia and New Zealand.

23. Broad Overview of the Impacts

During development of the draft Standard, FSANZ has considered the economic impact at a product level, considering impacts on industry and consumers. This was augmented by an assessment of potential health impacts considered at a population level.

Firstly, the *economic* analysis or *benefit cost* analysis of the impacts of the draft Standard in Australian and New Zealand was undertaken. On the basis of consultations with industry and data on consumer expenditure on new health related food products, the draft Standard was evaluated as likely to deliver a net benefit in present value terms of \$AUD95 million. This represents a benefit-cost ratio of 1.4:1 and an overall rate of return of about 16%, which would be a reasonable rate of return. This is an aggregate rate of return allowing for products going in and out of the market; the rate of return to the innovators would be significantly greater than this.

However it is conceivable industry will respond more actively to the draft Standard by taking full advantage of the opportunities for innovation and increase their rate of innovation in future years. If this case were to arise, the number of new products would be higher than industry conveyed in consultations, as would the value of new products and the indirect benefits for producers and consumers. If the number of new products were double that indicated by industry the net benefits in present value terms would increase by up to \$AUD180 million. If the indirect benefits to consumers and producers were double that indicated by industry and economic modelling, the net benefits in present value terms could grow by up to a further \$AUD180 million (refer to Figure 3).

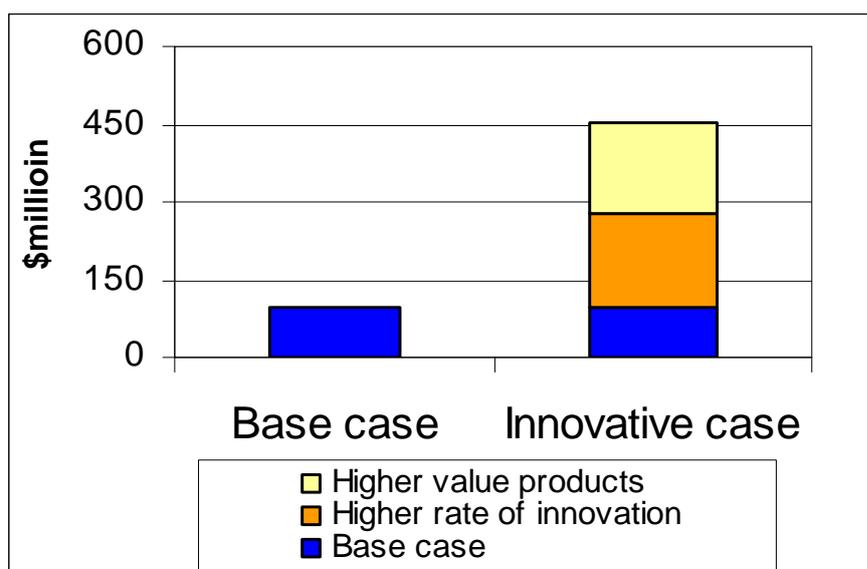


Figure 3: Net Economic Benefits of the draft Standard

Secondly, a *health economics* analysis was undertaken to illustrate the potential health benefits to the community which might arise from a ‘compositional shift’ in the food supply or from consumers switching to healthier foods on the basis of health claims. For this analysis the impacts of a reduction of sodium and saturated fat levels were assessed and the health impacts after a ten year period estimated. It should be noted that the benefits modelled are hypothetical and designed to show what could happen if the draft Standard encouraged reformulation of the food supply toward healthier foods. This analysis is illustrative not predictive. While we did not attempt to quantify the benefits in dollar terms, reductions in the burden of disease would subsequently reduce health interventions and therefore expenditure.

24. Benefit Cost Analysis

FSANZ commissioned the Centre for International Economics (CIE) to undertake a benefit cost analysis of the impact of the draft Standard for nutrition, health and related claims. CIE assessed the impacts on consumers and the food industry. FSANZ independently collected data on the impact on government enforcement agencies, which were incorporated into CIE’s overall results for Australia and New Zealand.

In summary, CIE found that the combined Australian and New Zealand net present value of the draft Standard to be estimated at \$AUD95 million. The draft Standard would provide a benefit cost ratio of 1.4:1. Over a four year period this represents a rate of return of about 9% per year above the discount rate, which at about 16% would be a reasonable commercial rate of return. This overall rate of return allows for products coming in and out of the market place; the rate of return for innovative products will be greater than this.

CIE found that the net-benefits of this Proposal are unevenly distributed across types of food. The largest benefits of the proposed changes were expected to be for fresh produce including fruit and vegetables, and non-alcoholic beverages, while net-costs were expected for confectionery and mixed foods.

As the modelling was based on industry estimates of the likely response to the draft Standard and it is difficult to accurately predict market reactions, FSANZ also requested that CIE consider other scenarios based on a greater rate of innovation in response to the draft Standard. Two scenarios were investigated: where a higher rate of new products would be facilitated by the draft Standard; and where the indirect benefits to consumers and producers would be higher than indicated in CIE's research and consultations. In each scenario the accessible net benefits of the draft Standard would increase by up to \$AUD180 million. The model results indicate that were the number of new products doubled, the benefit-cost ratio would rise from 1.4:1 to 2.4:1. Were the net indirect consumer and producer benefits also doubled, the aggregate benefit-cost ratio would rise from 2.4:1 to 3.3:1.

An overview of CIE's methodology, analysis and principal findings is presented in the following sections.

24.1 Methodology

The general approach adopted by CIE was to estimate the market impacts for consumers and the food industry in Australia, extend the results of this analysis to New Zealand on the basis of advice from trans-Tasman companies that their operations in Australia and New Zealand were very similar, then add the impact on the resources of government enforcement agencies as provided by FSANZ after a comprehensive consultation process, to obtain an overall net impact of the new Standard. The analysis estimated the net present value impact of the new Standard in Australia and New Zealand.

CIE consulted many large food and beverage manufacturers and retailers, some with trans-Tasman operations, which overall accounted for 55% of total food sales in Australia. CIE relied on these consultations to: verify the range of market outcomes that could be expected from the new Standard; provide data on the expected incidence of each outcome; and provide data on the expected benefit or cost of each outcome. CIE analysed these data through a financial / activity model to determine the direct impacts on industry. CIE obtained market data on the introduction of a new food product with an emphatic health attribute, and used an economic model of consumer preferences to analyse the change in consumer expenditures and infer consumers' willingness to pay for the claimed health attribute, as well as determining the indirect impacts on other, substitute products. These methodologies allowed CIE to estimate the market impacts for consumers and industry.

24.2 Potential market outcomes

Seven potential market outcomes are likely for any given food product if Proposal P293 on Nutrition, Health and Related Claims results in the gazettal of the draft Standard. The draft Standard will relax some existing restrictions on health claims and introduce new criteria and conditions for making certain claims.

The seven potential market outcomes are:

1. new products are developed to make use of new opportunities to make health claims;
2. existing products are re-marketed to make use of new opportunities to make claims;
3. existing products are not affected by the changes (no change);
4. existing products require small label changes to ensure compliance with the changed rules;

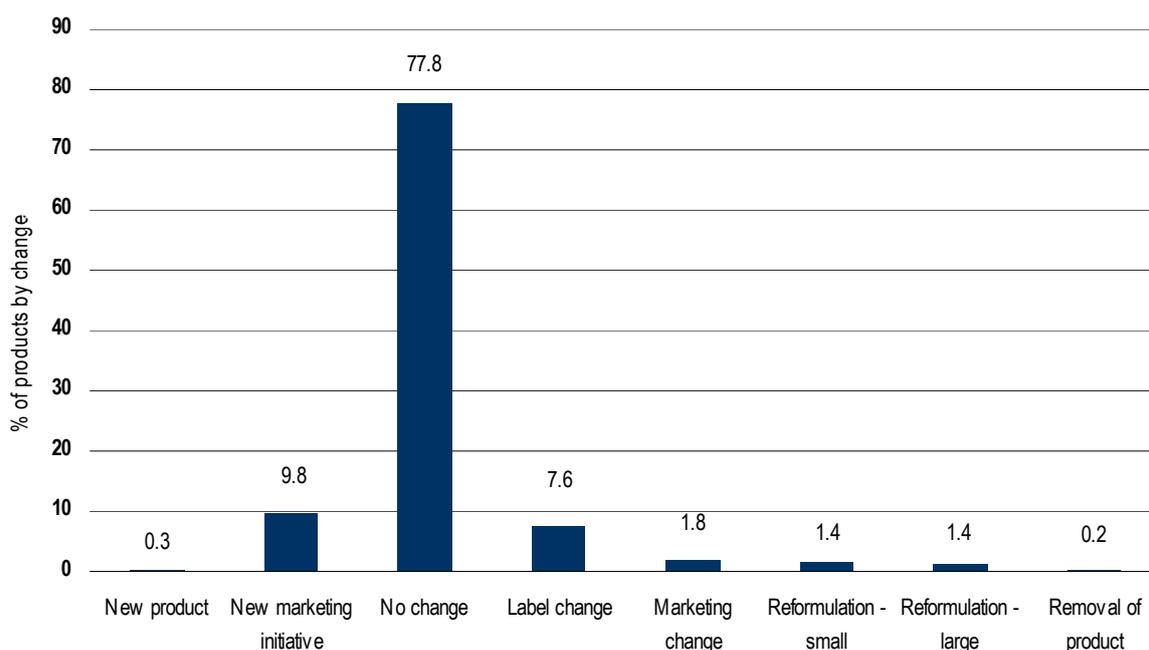
5. existing products require changes to their existing marketing strategies due to changed criteria;
6. changes to the formulation of existing products are made to meet changed criteria; and
7. existing products are removed from the market as they are no longer viable under the proposed changes.

24.3 Incidence of market outcomes

Consultations with food companies were carried out to assess the expected incidence of the seven potential market impacts. The results are set out in Figure 4.

The results indicate that almost 80% of products will be unaffected. Two broad groups of products will be unaffected – those that do not carry any kind of claim, and most products making nutrition content claims. Around 10% of products will be eligible to make new claims and therefore provide new marketing opportunities. However, negative impacts in total will affect about 12% of products.

In these cases, food companies will probably elect to make label changes, marketing changes or product reformulations. The industry predicted incidence of the proposed regulatory changes leading to new products is low at 0.3%, while the removal of products is 0.2%.



Data source: CIE consultations

Figure 4: Percentage of products affected by the Standard according to potential market outcome

The market outcomes can also be characterised in terms of the drivers for change. This is illustrated in Figure 5, below. In general industry indicated the ability to use general level and high level health claims were reasons for new products while nutrition profiling scoring criteria and changes to implied claims were the main reasons given for market outcomes four to seven.

<i>Market outcome</i>	<i>Use of a high level claim</i>	<i>Use of a general level claim</i>	<i>Nutrition profiling criteria</i>	<i>Changes to implied claims</i>	<i>Changes to dietary info</i>	<i>Changes to Glycemic Index</i>	<i>Changes to energy and diet</i>	<i>Changes to dietary fibre</i>	<i>Changes to saturated and TFA</i>	<i>Other reasons</i>
1. New product	√	√			√					
2. New marketing initiative	√	√	√	√	√	√		√		Protein claims
3. No change										
4. Label change			√	√	√	√	√	√		Vitamin claims
5. Marketing change			√	√	√		√	√		
6. Reformulation			√	√	√					
7. Removal of product			√	√	√					

Source: CIE consultations

Figure 5: Key elements of the draft Standard driving the market outcomes

24.4 Potential benefits and costs to food suppliers and consumers

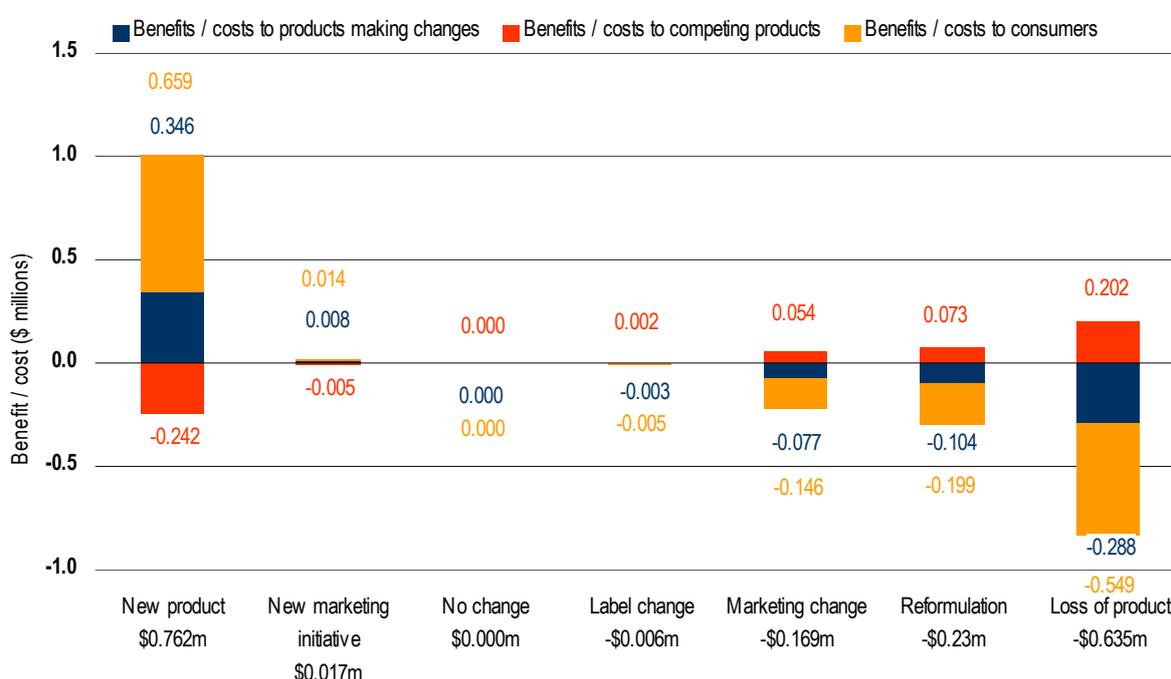
The seven potential market outcomes will create benefits and costs for food suppliers and consumers. Food suppliers may profit from new opportunities but incur costs due to lost opportunities or increased costs of compliance. Consumers might gain from the supply of new and better products, but lose if products are removed or their price is increased due to rising costs. In economic parlance, improved consumer satisfaction from new and better products is known as an improvement in consumer welfare¹⁶.

The estimated benefits and costs to food suppliers and consumers are presented in Figure 6 for each of the seven potential market outcomes for a generic product with \$AUD5 million in wholesale sales per year. These have been estimated using:

1. a detailed activity/financial model of a representative food manufacturing firm to estimate direct benefits and costs to food suppliers:
 - (a) the model is based on data collected from industry consultations;
 - (b) the incidence of market impacts is estimated from a comprehensive survey conducted of industry which obtained about 55 % coverage of total Australian food sales; and
 - (c) distribution of benefits and costs is highly skewed with new products providing large relative benefits, and withdrawal of products providing corresponding large costs.
2. an economic model of changes in consumer preferences due to health and nutrition claims in an important Australian food market segment, to estimate consumer and indirect food supplier benefits and costs:

¹⁶ Consumer welfare was measured by CIE in terms of consumers' willingness to pay for food products, also taking into account the addition of new products and the removal of some old products.

- (a) if new products or information are introduced, consumers stand to gain value over and above what they actually pay for the product, however when they substitute away from an alternative, old, product:
 - (i) the same consumers will lose some value, so it is the net increase in value that needs to be estimated by the model; and
 - (ii) food suppliers whose product is abandoned indirectly lose profits, so this is a cost that needs to be accounted for in addition to direct food supplier benefits (or costs) estimated using the activity/financial model;
- (c) if an existing product is withdrawn from the market as a result of a change in the regulation of health and nutrition claims, the opposite impact to the introduction of a new product occurs and these can be determined from the model.



Data source: CIE calculations

Figure 6: Consumer and food supplier impacts on a typical \$5 million product

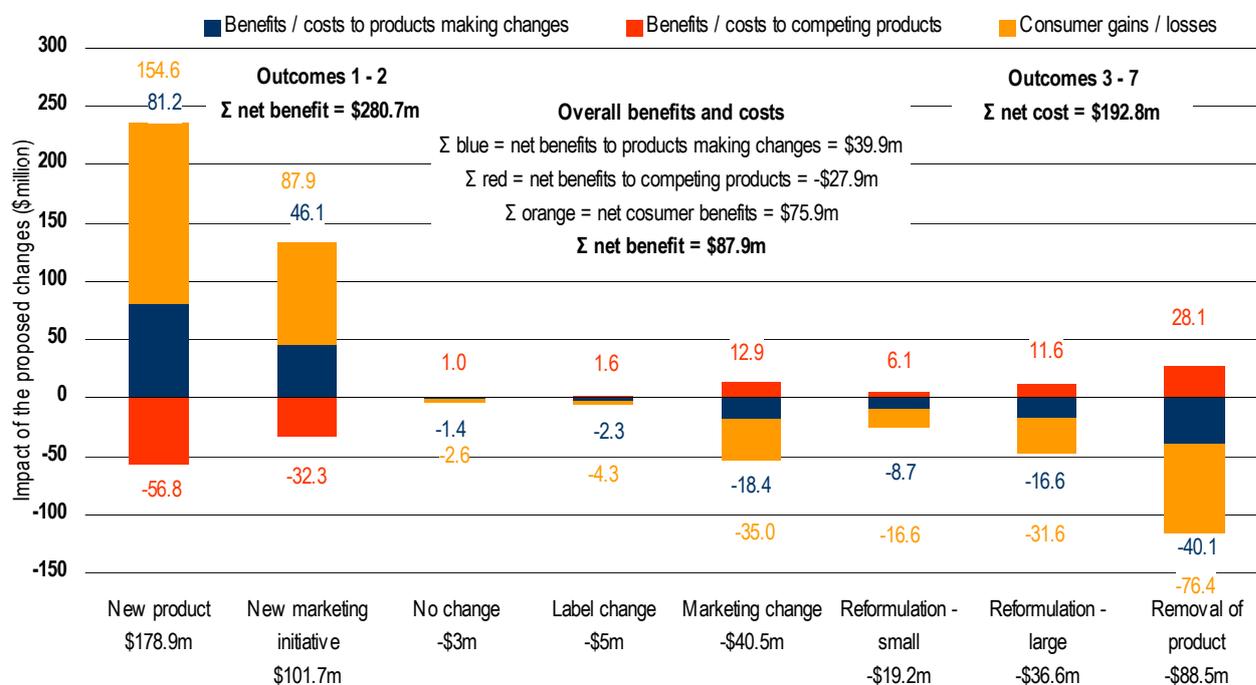
24.5 Innovators can do well

It is quite conceivable industry will respond to the draft Standard by taking full advantage of the opportunities for innovation. In this case the number of new products would be higher than industry conveyed in consultations, as would the value of new products and the indirect benefits for producers and consumers.

In the sensitivity analysis described in section 24.7 below, net benefits are calculated on the basis that the number of new products and the indirect benefit to consumers and producers was double that indicated during consultations with industry. The experience of FSANZ in its discussions with food companies over the past two years has revealed very strong interest in the opportunities for innovation under a health claims Standard. Hence an innovative response by industry is a probable outcome of the draft Standard.

24.6 Overall economic impact for Australia

Multiplying the incidence of impacts to industry (Figure 4) by the benefits and costs to industry and consumers per market outcome (Figure 6) calculates the financial impact on Australian food suppliers and consumers from the FSANZ Proposal (Figure 7).



Data source: CIE calculations.

Figure 7: Total net present value benefits by market outcome (\$AUDm)

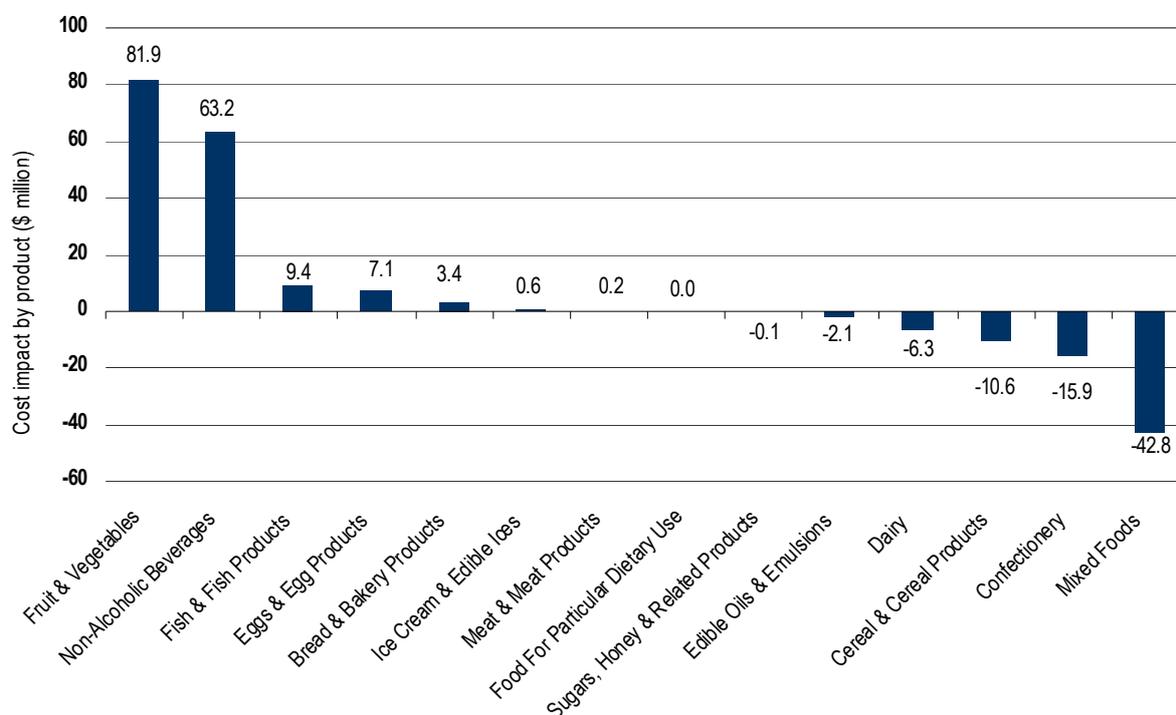
The present value benefits from high level and general level health claims which promotes new products and new marketing initiatives (outcomes 1 and 2) are large, at \$AUD280.7 million in aggregate. This is comprised of:

- direct benefits to consumers of \$AUD242.5 million (154.6 + 87.9);
- direct benefits to food suppliers of \$AUD127.3 million (81.2 + 46.1); and
- indirect losses to competing food suppliers of \$AUD89.1 million (-56.8 + -32.3).

For outcomes 3 to 7, the draft Standard will result in net present value costs of \$AUD192.8 million. Food suppliers that need to change products or marketing initiatives face costs of \$AUD87.5 million. This has flow-on impacts to consumers of \$AUD166.5 million, while competing food suppliers gain by \$AUD61.2 million. For the 80 % of products not affected by the draft Standard it still carries an \$AUD3 million cost due to firms having to inspect all products to ensure compliance with the changes.

Overall, the draft Standard provides net present value benefits of \$AUD87.9 million. However, these benefits are not evenly distributed by food type (Figure 8). Based on consultations with industry, the largest benefits of the proposed changes were expected to be for fresh produce including fruit and vegetables. Implicitly, this is based on the perceived healthy aspects of these foods.

Under the proposed changes, suppliers of these foods will now be able to further emphasise and market their produce using general level and high level health claims. This result also reflects the large proportion of food expenditure dedicated to fruit and vegetables.



Data source: CIE calculations.

Figure 8: Total net present value benefits by product category (\$m)

Figure 8 indicates the overall outcome for each product sector of the food industry, based on information and data provided by the food industry. (See sections 24.2 and 24.3 above for details of the range of potential market outcomes, including development of new products as well as labelling changes and reformulation.)

The relatively small impacts across all product sectors reflect three principal factors. First 80% of products will be unaffected, diminishing the capacity of the draft Standard to impact on industry. Second, industry data indicate that the major drivers of the benefits (development of new products) and of the costs (removal of existing products) are of the same order of magnitude and hence the overall net benefit will be small. Third, substitution within the food market of one product for another means that the gross benefits of introducing a new product will be largely offset by the gross costs to the producers of products it displaces.

The scope for industry-wide gains from new products is limited; a new product needs to be revolutionary to add much to consumer welfare and consumers' willingness to pay for it.

24.7 Sensitivity testing

CIE undertook sensitivity testing of the key parameters to determine the affect on total net benefits of a 10% change in each variable, providing an indication of the overall robustness of the results.

Sensitivity testing reveals that the results are most sensitive to changes in the number of new products, the removal of products and the extra gain in consumer value from changing patterns of consumption caused by the draft Standard. These also happen to be the most uncertain factors affecting the results.

Nonetheless, the results indicate there is an 87 % probability the benefits will exceed the costs. The range of net present value benefits is reasonably narrow with an estimated 90 % chance the net benefit lies between \$AUD46.7 and \$AUD178.3 million. The most likely situation leading to a net cost being imposed is where the number of new products generated is much smaller than estimated.

It is worth noting that it is possible that industry may ramp up its innovation rate in future years and it is conceivable that new products and the indirect consumer benefits from them could be greater than those estimated for the most likely case, which was based on estimates provided by industry.

24.7.1 Scenario Modelling

Additional modelling was undertaken on the basis that industry could respond more actively to a new health claims Standard and take full advantage of the opportunities to innovate. The results indicate that if:

- the number of new products doubled, the benefit-cost ratio would rise from 1.4:1 to 2.4:1;
- the net indirect consumer and producer benefits also doubled, the aggregated benefit-cost ratio would rise from 2.4:1 to 3.3:1.

CIE also evaluated a counterfactual situation where the nutrition profiling scoring criteria was applied to nutrition content claims, in addition to general level and high level health claims. CIE estimate that introducing nutrition profiling scoring criteria for nutrition content claims would increase industry costs by adding to labelling costs, changing marketing strategies, reformulation or removing products from the market of \$AUD44 million.

24.8 Impact including New Zealand

Results are based on Australian food company data only. Although no specific information on New Zealand firms was received, companies operating in both jurisdictions did not expect there to be significant differences between the two countries. Further, a comparison of the patterns of consumption between both countries reveals they are very similar.

New Zealand food consumption is equal to about 14.5 % of Australian food consumption. When the net benefits are scaled up to include New Zealand the net benefit increases from \$AUD88 million a year to \$AUD101 million. Net benefits to New Zealand are around \$AUD12.8 million or \$NZD14.1 million.

24.9 Impact of removing 'claimable food' criteria

FSANZ proposes to remove the special 'claimable food' criteria for vitamins and minerals, and instead require that vitamin and mineral claims are in accordance with the generic provisions of the draft Standard. See Attachments 5 and 6 for details.

FSANZ expects little overall impact from this change. Nutrition content claims for vitamins and minerals will be able to be used on a greater range of foods, while some general level health claims will not be able to continue to be made without changes to labelling, marketing, and potentially, product formulations.

24.10 Impact on government enforcement agencies

FSANZ undertook a comprehensive survey of the government enforcement agencies in Australia and New Zealand. The agencies were invited to enunciate their overall strategy to enforce the draft Standard, to identify the key elements or activities in this strategy, and then to estimate the upfront and ongoing resource costs associated with each activity.

The main activities that were identified and costed by the enforcement agencies were training and awareness raising, administration, and a range of enforcement actions including auditing, inspections, evaluating documentation, analytical testing of food products, and investigating complaints.

It should be noted that the activity cost estimates provided by the agencies are broad indications of the extra resources that would be required to enforce the draft Standard.

On the basis of this survey, and on the basis that these estimates provide broad indications of anticipated resource costs rather than precise measures, FSANZ prepared overall resource cost estimates. In Australia, upfront costs of the first year of enforcement would be around \$AUD140,000 and ongoing annual costs would be around \$AUD490,000. In New Zealand, upfront costs of the first year of enforcement are estimated to be around \$NZD32,000 and ongoing annual costs are estimated to be around \$NZD112,000.

These cost estimates were incorporated into the overall calculations by CIE of the net-benefits from the draft Standard.

24.11 Summary of benefits and costs

A summary of the benefits and costs estimated in the impact analysis is presented in the following table.

Table 2: Summary of the benefits and costs in present value terms

Market Impacts	Benefits Present value (\$AUDmillion)	Costs Present value (\$AUDmillion)	Net Impact Present value (\$AUDmillion)
<i>Australia</i>			
Consumers	242.5	166.5	76.0
Industry (direct impacts)	127.3	87.5	39.8
Industry (indirect impacts)	61.3	89.1	-27.8
Industry (total impacts)	188.6	176.6	12.0
Total Market Impacts - Aus	431.1	343.1	88.0
<i>New Zealand</i>			
Total Market Impacts - NZ	62.5	49.7	12.8
Total Market Impacts - Aus & NZ	493.6	392.8	100.8
Enforcement Costs - Aus & NZ		6.0	-6.0
Total Impact for AUS & NZ			94.7

Table 2 summarises the data provided in this chapter, drawing on the data presented in Figure 6, the extension of market impacts to New Zealand and the impact on the resources of government enforcement agencies.

24.11 Conclusions

After allowing for enforcement costs, the combined Australian and New Zealand net present value benefit of the draft Standard is estimated at \$AUD94.7 million. On this basis, it appears that the draft Standard may provide a benefit-cost ratio of 1.4:1. Over a four year period, a benefit-cost ratio of 1.4:1 represents a rate of return of about 9 % per year over and above the discount rate – a reasonable commercial rate of return.

Although it is highly likely that returns will be positive, the net benefits are not large based on industry estimates of the likely impact of the draft Standard.

The relatively small overall impact reflects industry information and data including:

- most products (80 %) are unaffected by the Proposal;
- net benefits from new products and new marketing initiatives are largely offset by net costs of changes on other products:
 - provisions in the draft Standard to allow use of general and high level health claims appear to promote the introduction of new products/marketing initiatives;
 - changes required under the draft Standard to food vehicle eligibility criteria and implied claims appear to require label changes, marketing changes, product reformulation and product removals;

- the incidence of new products and removed products, which have relatively high benefits and costs per product, are low at around 0.5 of one per cent of all products;
- the scope for gains from new products, while relatively large per product, are limited by the mature nature of the food sector:
 - consumers already have an immense number of products to choose from;
 - if consumers do not get a particular attribute they value from one product they can easily switch to a range of alternatives, so any new attribute, additional information or new product needs to be revolutionary to add much to consumer welfare, as indicated by consumers' willingness to pay, and results here confirm this; and
 - total consumer expenditure on food is relatively fixed, after allowing for inflation, and hence the total size of the food market is also relatively fixed. Therefore the net benefits from the draft Standard will come principally from redistribution within the food industry rather than any increase in the total size of the food market.

25. Potential health benefits

FSANZ commissioned additional analysis from the Centre for Health Economics Research and Evaluation (CHERE) to illustrate the health impacts of product reformulations. FSANZ notes that industry has already started to respond to consumer interest in foods more closely aligned with nutrition guidelines. The nutrient profiling scoring criteria will further encourage reformulation to reduce levels of risk increasing nutrients in the food supply.

The examples used by CHERE in their analyses were the removal of given levels of sodium and saturated fat from the food supply. This work complements the CIE analysis which did not consider benefits to consumers or the population beyond those expressed by a willingness to pay. The CHERE analysis is illustrative rather than predictive as it is not possible to accurately estimate the amount of reformulation that might occur as a consequence of the introduction of the draft Standard.

In the first study, the modelling focussed on reducing the intake of sodium from processed foods.

Excessive sodium intake is a significant risk factor for high blood pressure. The effect of sodium on blood pressure is greater in older and middle aged people, as well as individuals with diabetes or chronic kidney disease. High blood pressure, in turn, is one of the largest contributors to poor health outcomes from cardiovascular disease in Australia. It causes the third greatest burden of disease, second only to physical inactivity and tobacco smoking.

The majority (90 %) of dietary sodium consumed by adults comes from processed and manufactured foods. Hence reformulations of food products to reduce sodium content can have significant population wide effects and reduce the burden of disease.

CHERE followed a seven step procedure to indicate the possible reduction in the burden of disease that would be possible from reducing sodium intake, as encouraged by the draft Standard.

1. Identify current sodium consumption, focussing on the proportion obtained from processed food.
2. Identify realistic targets for the reduction of sodium in processed food.
3. Collect information regarding the relationship between sodium consumption, blood pressure and clinical events.
4. Describe the current incidence of clinical events.
5. Consider the effect of an ageing population on the number of clinical events in ten years.
6. Estimate the reduction in clinical events in the 2018 population based on changing levels of sodium from processed food.
7. Illustrate the impact of reducing the burden of disease through reductions in Disability Adjusted Life Years.

The analysis was based on pragmatic estimates of what reductions in sodium intakes from salt in processed foods could be achieved over a ten year period. Two scenarios were considered: a 15% reduction (low estimate) and a 25% reduction (high estimate). A 25% reduction over ten years is more conservative than the reductions suggested as achievable in the UK (Jebb and MacEvilly, 2007). A 15% reduction was modelled as a scenario that was more conservative again for comparative purposes.

The incidence of clinical events was adjusted for changes in population demographics associated with the ageing population. The analysis focussed on two clinical events in particular where the link with high blood pressure was well documented – stroke and myocardial infarction.

The incidence of stroke and myocardial infarction is expected to increase over the next ten years with the ageing of the population. Reduced sodium consumption, as modelled by CHERE, would counteract much of the increase in incidence associated with population ageing. Under the high estimate scenario, the reduction in sodium intake after ten years could reduce the burden of disease from stroke by 10% and the burden of disease from myocardial infarction by 12%.

CHERE applied the same approach and methodology to the hypothetical situation where reformulation of processed foods, ten years after the introduction of the draft Standard, enabled a reduction in saturated fat intakes in Australia and New Zealand by 15% (low scenario) or 25% (high scenario). CHERE estimated the possible reduction in the burden of disease of myocardial infarction.

CHERE reviewed the literature and reported that many studies centred on establishing an indirect link between saturated fat intakes, cholesterol and cardiovascular events. However establishing a direct link was difficult. The evidence of the scale of the association between saturated fat consumption and myocardial infarction is tentative at best, and limited to women. CHERE limited their results to this population group and suggest that this would likely underestimate the true effect of reduced saturated fat intake. Their results show a significant reduction in the burden of disease. For fatal events, which account for almost all outcomes, a reduced saturated fat intake would reduce the burden of disease in the range 5% to 8% in Australia and by 5.5% to 9% in New Zealand.

26. Conclusions

The draft Standard for nutrition, health and related claims would deliver an incremental improvement in the economic welfare of Australia and New Zealand. CIE estimate the impact in present value terms to be a net-benefit of \$AUD95 million. The benefits of the draft Standard exceed the costs by a ratio of 1.4:1. This represents a reasonable commercial rate of return of around 16% per annum. Further, there is a strong potential upside if industry were to respond more actively increasing its innovation rate under the new Standard. If the rate of new product innovation was double that indicated by industry, accessible present value net benefits could be increased by up to \$AUD180 million. A further \$AUD180 million may be accessible if the value of new products and hence their indirect benefit to consumers and producers was double that indicated in industry data and the economic modelling.

A health economics scenario analysis indicated that if industry was to reformulate to significantly reduce, for example, sodium levels in the food supply, substantial reductions in the burden of disease could occur for stroke and for myocardial infarction.

The draft Standard also delivers on the objectives of the Proposal. Consumers will have information on nutrition and health claims on food at point of sale or in advertising, and will have the ability to make more informed purchasing decisions. The potential to mislead consumers under the current arrangements, either through non-regulated nutrition content claims or implied health claims, will be further mitigated as these issues are clearly addressed in the draft Standard. The draft Standard offers industry an opportunity to innovate and take advantage of incorporating health claims into their marketing strategies. CIE found, through its consultations with industry, a material level of innovation that would occur under the draft Standard. The incentives under the draft Standard also encourage industry to reformulate their products in the direction of healthier food. CHERE found that the draft Standard could facilitate significant reductions in the burden of disease in Australia and New Zealand, to the benefit of the population.

Overall the draft Standard would achieve a net-benefit for Australia and New Zealand and would deliver against the objectives of this Proposal. The draft Standard should therefore be adopted.

27. Office of Best Practice Regulation

FSANZ has provided the Final Assessment Report to the Office of Best Practice Regulation (OBPR), for an assessment against requirements identified in the Council of Australian Governments (COAG) Best Practice Regulation guide. The OBPR agreed that the Final Assessment Report followed Regulatory Impact Statement (RIS) guidelines and agreed that the type and level of analysis is adequate and commensurate with the potential economic and social impacts of the Proposal. Although the OBPR held some initial reservations about whether a clear net benefit to the community was demonstrated, it was decided that on balance it is likely there would be a net benefit. The advice that has been provided by the OBPR is included in Attachment 11, in accordance with COAG requirements.

COMMUNICATION AND CONSULTATION STRATEGY

28. Consultation process

Proposal P293 – Nutrition, Health and Related Claims has been developed in conjunction with some of the most extensive consultation ever undertaken by FSANZ. Over its five year history, four notified public consultation documents have been released, three dedicated advisory groups have conducted a combined total of 17 meetings, at least 10 public stakeholder forums have been held throughout Australia and New Zealand, and a significant number of meetings have been held with interested stakeholders as either groups or individuals. FSANZ has also regularly reported to intergovernmental, parliamentary, jurisdictional and formalised liaison groups, presented on health claims at conferences and other such forums both domestically and internationally, and provided regular written updates and web-based material.

29. Advisory Groups

Prior to the release of the Initial Assessment Report, FSANZ convened several committees to provide advice on the development of the Standard and associated documentation. These were the Scientific Advisory Group (SAG), the Technical Expert Group (TEG) on General Level Claims and the Standard Development Advisory Committee (SDAC). The Standard Development Advisory Committee forum has met on a total of nine occasions.

The membership and terms of reference for each of these committees (SAG¹⁷, TEG¹⁸, SDAC¹⁹) can be found on the FSANZ website. FSANZ would like to express its appreciation to the members of each of these groups for their significant contributions to the recommendations arising from Proposal P293, and acknowledge the significant time and effort contributed by each member.

30. Notified reports

FSANZ has a statutory requirement to publicly notify consultation documents for consideration by the public at large. These reports are notified nationally through newspapers in Australia and New Zealand, and made available on the FSANZ website. Over 8000 subscribers to FSANZ standards development processes are also advised directly by email.

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. Further detail on this consultation process was provided in the Draft Assessment Report.

¹⁷ <http://www.foodstandards.gov.au/foodmatters/healthnutritionandrelatedclaims/scientificadvisorygroup/>

¹⁸ <http://www.foodstandards.gov.au/foodmatters/healthnutritionandrelatedclaims/scientificadvisorygroup/healthclaimstechnica3088.cfm>

¹⁹ <http://www.foodstandards.gov.au/foodmatters/healthnutritionandrelatedclaims/healthclaimssdacmembershiplist/>

In November 2005, FSANZ released the Draft Assessment Report for public comment. This report also included the draft Standard and the preferred regulatory option, which set out the criteria and conditions for making nutrition content claims, health claims and related claims, and included composition of foods able to make claims, wording conditions and exemptions from the general approach, and incorporated substantiation requirements. In total, FSANZ received 131 substantial submissions to this extensive report.

Following analysis of these submissions FSANZ recommended some significant elements should be modified. In April 2007, FSANZ conducted an extraordinary round of public consultation through the provision of a Preliminary Final Assessment Report which outlined the modified recommendations and sought public comment on the proposed changes.

The key areas for consideration were:

- risk management of nutrition content claims;
- eligibility criteria for food vehicles;
- endorsements;
- dietary information;
- application of the Standard; and
- some other minor issues around certain nutrition content claims.

This report also provided the outcomes of the assessment of additional food-disease relationships, not available at the time when the Draft Assessment Report was released.

Following consideration of the 92 written submissions to the Preliminary Final Assessment Report and a substantial amount of targeted consultation throughout the year, FSANZ considered it important to consult further on three specific issues, *viz*, food eligibility criteria for vitamin and mineral claims, an additional claim around saturated fatty acids, and the Scientific Substantiation Framework. These were the subject of a further Consultation Paper disseminated publicly in December 2007. Sixty-five submissions were received in response to this document and the views of submitters have been taken into account in finalising the recommendations in this report. A summary of submissions made in response to the Preliminary Final Assessment Report and the December 2007 Consultation Paper can be found in Attachments 13 and 14, respectively.

31. Future communications

The Final Assessment Report will be published on the FSANZ website with a Short Guide when the Australia and New Zealand Food Regulation Ministerial Council is notified. An education strategy is being prepared for when the Standard is finalised (see chapter 37 – Education).

32. World Trade Organization (WTO)

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.

The Proposal to allow foods to carry nutrition content claims, health claims and related claims if they meet certain conditions, is likely to have a significant effect on international trade. This is because other countries such as the United Kingdom, Canada and the United States have developed their own regulations for such claims, and these regulations are more likely than not to differ from what is proposed for Australia and New Zealand (refer to Attachment 12 – International Benchmarking). Imported food products that carry claims that comply with the regulations in the originating country, might not comply with the proposed measures in the draft Standard.

This issue was considered in the Draft Assessment Report and in December 2005, notification was made to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade Agreement. Other WTO member countries were invited to comment by 22 February 2006 on the draft Standard, where it might have a significant impact on them. No comments were received.

IMPLEMENTATION, ENFORCEMENT AND MONITORING

33. Implementation

33.1 Implementation Sub-Committee

33.1.1 Role of the Health Claims Watchdog Working Group

The Health Claims Watchdog Working Group has been established under the Implementation Sub-Committee (ISC), which is a sub-committee of the Food Regulation Standing Committee. The ISC's role is to develop and oversee a consistent approach to implementation and enforcement of food regulation and standards across jurisdictions. 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 original terms of reference of the Health Claims Watchdog Working Group were to: serve as the public face of the health claims system; receive and record complaints; assist FSANZ in the creation and maintenance of the guideline document; provide periodic reports to the Food Regulation Standing Committee (FRSC); and provide proposed amendments to the Standard or the Guideline document. The Health Claims Watchdog Working Group was also to be responsible for establishing an Advisory Panel i.e. an independent register of experts for use by jurisdictions for independent assessment of supporting evidence for claims.

33.1.2 Draft Assessment Report – submitter comments

A number of comments were received regarding the Health Claims Watchdog Working Groups' role and potential activities around health claims. It was recommended that consideration be given to enabling the working group to have broader powers and perform a more proactive role in seeking out breaches, rather than just a secretariat for complaints. The value of the working groups' role was also questioned noting respective jurisdictions will still need to be notified of complaints directly, and complaints from all possible sources will be need to be monitored, e.g. those received by self-regulatory agencies such as the Advertising Standards Bureau, rather than just from jurisdictions. Questions were raised regarding what other sorts of roles it may play, for example, as a public point of contact, or for pre-appraisal of proposed claims.

Concerns raised included the make-up of the working group with views that it should have broad stakeholder representation; these views may have misinterpreted the limited role of the working group (i.e. as simply a secretariat for complaints) but may relate more closely to the suggestion that a technical complaint panel be formed to determine action on receipt of complaints to the working group, and that such activities should be transparent and any decisions appealable. A particular point of concern was regarding the proposed Advisory Panel – specifically with regard to how it might be funded suggesting this should not be a jurisdictional burden.

All comments were passed on to the Health Claims Watchdog Working Group for their consideration. The working group was not a topic for discussion in the Preliminary Final Assessment Report and no further comments were received.

33.1.3 Approach being taken

The Health Claims Watchdog Working Group activities under the original terms of reference were largely completed by mid 2007, except for assistance with user guidance documentation which is still under development by FSANZ. However, a need for further undertakings by the working group was recognised in 2007 given the draft Standard was not yet finalised, and in recognition of enforcement related comments received by FSANZ from submitters following the Draft Assessment Report. In November 2006, ISC agreed the working group should continue, including in its revised terms of reference the need to provide advice to ISC regarding communication, implementation, compliance and enforcement issues relating to the new nutrition, health and related claims Standard.

The working group subsequently commissioned the assistance of a consultant to provide information and recommendations to the working group to inform its reporting to ISC on the best regulatory and compliance tools and approach for implementing and enforcing the draft Standard. At the time of writing this report a draft report has been prepared and is due for completion by March 2008.

The Advisory Panel was recommended in the Policy Guideline in order to assist enforcement agencies in providing expert opinion on potential breaches including advice on the adequacy of evidence that food companies hold to support their claims.

Considerations by the working group have led to a re-consideration of the ‘Advisory Panel’ insofar as there are concerns around its establishment and implementation and this task has subsequently been held in abeyance.

33.2 User Guide

A User Guide, intended to provide helpful explanations on the intended operation of this Standard, is being developed by FSANZ as part of its functions under section 13(c) of the FSANZ Act. This guide is targeted for use by government agencies for enforcing the requirements in the draft Standard as well as for manufacturers seeking guidance on compliance. Unlike the Standard itself, this User Guide is not legally binding.

33.2.1 Initial, Draft and Preliminary Final Assessment Reports – submitter comments

Submissions in response to the Initial, Draft and Preliminary Final Assessment Reports contained several general comments related to the User Guide as well as specific comments related to the draft Standard for inclusion in the User Guide. It was indicated that the success of the draft Standard will depend on the interpretive guidelines provided in the User Guide. The importance of working closely with the food industry and jurisdictions in developing the User Guide was also highlighted. There was also the view that the User Guide be available at the time the Standard is gazetted to enable the manufacturers to commence the labelling and advertising changes as well as for maximum compliance.

The comments relating to the draft Standard for inclusion in the User Guide covered several areas including clarifying meanings of terms, explanation on the claims classification framework, application of regulatory framework to food-disease relationships, rules related to the use of a disclaimer for cause-related marketing, wording conditions in relation to particular type of claims, advertising guidelines specifically related to implied claims, and clarifying the form in which dietary information can be provided by a food company. There was a request for the development of a list of indicative but not exhaustive synonyms specific to nutrition content claims. The use of examples in the User Guide was considered a preferred approach, with the request of some examples to illustrate non-compliance.

All comments have been given the due consideration and will be incorporated in the User Guide where appropriate.

33.2.2 Recommended approach

Based on submitters' comments and consultations with the food industry and jurisdictions, FSANZ is progressing the development of a single User Guide for food businesses and enforcement agencies. The format of the User Guide will follow a clause by clause approach similar to the FSANZ Safe Food User Guide. Flowcharts, questions and answers and examples will be incorporated on relevant topics. Some parts of the document may contain sections specific for enforcement purposes. Similarly, areas specific to food businesses will also form part of the User Guide.

This User Guide will provide explanations and examples that may assist but will not specify ways in which food businesses comply with the requirements.

Food businesses seeking guidance on compliance with Standard 1.2.7 will be required to contact their local enforcement agency or an appropriate consultant for advice. A list of enforcement agency contacts will be provided as part of this User Guide.

Questions and answers and examples will be included where they are helpful in explaining the meaning of a clause. Flowcharts will also be provided on a topic by topic basis to further enhance the ease of interpretations. For example, a food business that wishes to use a general level health claim on one of their products will be able to follow the pathways in the flowchart to ascertain the conditions and the required steps to achieve the final outcome.

It is FSANZ's intention to progress the development of the User Guide with significant input from the food industry and the jurisdictions.

The updating of existing User Guides (e.g. the User Guide to Standard 1.2.8 – Nutrition Information Requirements) that will be impacted by the draft Standard will also be considered. The timeline for the completion of the User Guide is dependent on several externalities including the input from the food industry and jurisdictions. The release of a comprehensive User Guide at the time the Standard is gazetted may not be possible however, FSANZ will provide a preliminary version containing the more critical elements at the time of Ministerial Council consideration of the draft Standard. FSANZ will release the complete document as soon as possible after gazettal of the Standard.

34. Enforcement

Enforcement of the Standard, including assessing possible breaches and undertaking prosecutions, will be the responsibility of the State/Territory and New Zealand enforcement agencies and the Australia Quarantine and Inspection Service. It is recognised that there is potential inconsistency between the jurisdictions in relation to court systems (not all have magistrates, local, county and supreme courts) and procedural rules in regard to prosecution of food act offences, enforcement policies in each jurisdiction (what is the method of enforcement – compliance, prosecutions etc), substantive laws affecting food act cases, rules of evidence affecting food act cases and case law that affect the operation of the health claims regime. Enforcement will therefore be subject to the individual operations of each jurisdiction. However, in order to increase effectiveness and facilitate consistency as far as possible, the Health Claims Watchdog Working Group, on behalf of the jurisdictions, is currently commissioning an investigation into these aspects, as noted above in section 33.1.

Issues in relation to fair trading or other aspects, such as weights and measures, will be the responsibility of the respective agencies including the Australian Competition and Consumer Commission, jurisdictional fair trading offices, and trade measurement offices.

The above activities will be augmented by the actions of self regulatory agencies such as the self-regulatory Advertising Standards Board in Australia, which investigates complaints in relation to health and safety, not misleading conduct. In New Zealand, the Advertising Standards Authority is the self-regulatory body that administers a code for advertising of food.

35. Monitoring and Review

35.1 Monitoring

Monitoring the implementation of the Standard and any associated comments from the Initial Assessment Report were considered in the Draft Assessment Report. Relevant comments can also be found in section 35.2.

35.1.1 Draft and Preliminary Final Assessment Reports – submitter comments

A view was provided that nutrition and health claims have the potential to distort the food supply in favour of manufactured foods and therefore, nutritional data should be tracked in order to assess impacts on public health. Within this context reference was made to the need for updated national nutrition and food composition data. There were concerns that these claims will alter consumer understanding of a healthy diet and this aspect should be monitored.

Monitoring was not raised in the Preliminary Final Assessment Report however some comments were received. It was suggested that any monitoring be nationally agreed and resourced with provision for regular review to ensure the dual objectives of industry development and public health protection are being achieved. In particular, it was requested that consumer understanding of different levels of claims, including endorsements, be considered by the time of the Final Assessment Report to ensure the draft Standard is providing the right framework.

35.1.2 Recommended approach

The jurisdictions will continue to be responsible for receiving complaints about health claims in relation to alleged breaches of the Code, either directly or through the Health Claims Watchdog Working Group. Any complaints received by the working group will automatically be forwarded on to the relevant jurisdiction, as the working groups' role is limited to that of a 'mail box'.

As part of its reporting function, the ISC will periodically collect and collate information on the complaints received by the working group 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 these data will contribute to the Health Claims Watchdog Working Group's report to the FRSC, analysing the effectiveness of the Standard.

As part of its role in establishing the Health Claims Watchdog Working Group, the ISC has been collecting information since 2005. Information at this point in time indicates the majority of complaints are received via the jurisdictions themselves rather than the working group. This may change once the Standard is implemented and the working groups' function is more clearly known. New South Wales, Victoria and Queensland continue to receive the major share of complaints, which are predominantly from food business competitors. New Zealand data are not included in this reporting as they are collecting separate data.

FSANZ will also monitor labelling as part of its ongoing label monitoring program (refer to the most recent report – Report on the Assessment of 2005 Labels for Nutrition, Health and Related Claims²⁰). FSANZ will continue to conduct research on consumers' awareness of and use of nutrition content and health claims.

Research in this area was commissioned by FSANZ in 2003 and 2005 and these reports provide baseline data for consumers' awareness of and use of nutrition content and health claims (FSANZ, 2003, 2005a and 2005b).

FSANZ is also interested in monitoring the appropriate implementation of the draft Standard by industry. One area of particular interest is serve sizes. As noted in previous reports for Proposal P293, serving sizes are not standardised in Australian or New Zealand food regulation, and as a number of claim criteria are expressed on a per serve basis, serve size has a pivotal role in the qualification to make a claim. This has been previously referred to specifically in relation to fibre and protein claims. Fair trading laws provide a safeguard against blatant manipulation of serve sizes however, should indications of inappropriate manipulation of serve sizes become apparent during the transitional period FSANZ will consider actively monitoring these.

²⁰ <http://www.foodstandards.gov.au/newsroom/publications/evaluationreportseries/index.cfm>

With respect to the suggestion that consumer understanding of different levels of claims, including endorsements, be considered by the time of the Final Assessment Report, in developing the approach to Proposal P293, FSANZ commissioned consumer research to understand how consumers interpreted the different levels of claims and endorsements. This research was incorporated into section 7.2 of the Draft Assessment Report and extracts were included in Attachment 4 of that Report. A brief review of the findings has also been revisited in section 1.2 of Attachment 10 of the Final Assessment Report.

35.2 Review

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 draft 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 by industry.

35.2.1 Initial, Draft and Preliminary Final Assessment Reports - submitter comments

Submissions to the Initial, Draft and Preliminary Final Assessment Reports identified further essential review elements as effectiveness of enforcement and compliance, consumer understanding and use of nutrition content and 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. Submissions also gave consideration as to how such a review might be conducted and by whom. Further detail is available in the Draft Assessment Report. These views were repeated in response to the Draft Assessment Report and included that the working group, committee or body undertaking the review should be independent and processes transparent. 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, and the need to consider avoidance of those with vested interests particularly where scientific opinion was required.

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 impact of nutrition content and health claims on consumers.

A review of the Standard two years from commencement was supported, however, note was made of the impact of the proposed two-year stock-in-trade provision and there was divergence of views as to whether the review should actually be conducted two, three or four years after gazettal of the Standard. Review of high level health claims was also discussed with five years commonly suggested, or when significant new evidence becomes available. Close liaison and avoidance of duplication between Australia and New Zealand was highlighted.

This topic was not raised for discussion in the Preliminary Final Assessment Report, however, comment was received that an extensive review [of standards] was undertaken in the late 1990s resulting in significant changes to labelling standards that were implemented between 2000 and 2002.

The submitter expressed concern that a further review of labelling standards in the short term would not be appropriate if it were to potentially result in further significant changes within a 10 year period. It would be more appropriate to review consumer understanding of label elements and provide education as necessary.

FSANZ has directed these comments to the Health Claims Watchdog Working Group.

35.2.2 *Recommended approach*

The approach taken should be in accordance with the Policy Guideline outlined above however, further discussion is required to determine when the most effective time will be to conduct such a review, and also which particular elements should be included. Such a discussion will be better informed once the draft Standard is finalised and implemented. FSANZ has included the nutrition and health claims Standard in its 2004-2008 evaluation strategy and baseline data were collected in 2006. The actual timing of gazettal of the Standard is unknown at the time of writing this Report, however, in order to allow at least two years after implementation, a review would not be conducted any earlier than 2010. In relation to a review of existing food-disease relationships, FSANZ would consider reviewing these if sufficient evidence emerged to question the relationship and/or an application was received to trigger this process.

Prior to a review of the new Standard however, it will be useful to conduct a preliminary scan of general level health claims being used in the market place to ascertain trends and usage of statements from the prescribed list of nutrient function statements that have been provided in Schedule 2 of the draft Standard. This information could assist the Health Claims Watchdog Working Group by indicating how many general level health claims are being substantiated by a systematic review and therefore may need separate verification by jurisdictions, rather than simply referring to the list provided by FSANZ.

It is noted that, in August 2007, the Food Regulation Standing Committee agreed that the Advisory Panel should not be established at this point in time but that the need for the Advisory Panel and its role should be reassessed in the event that the need arises. This need may be better informed by the above scan.

36. Transitional Arrangements

36.1 Decision

FSANZ recommends there be a transition period of 24 months for the implementation of the draft Standard, which will be inclusive of a 24-month transition period for stock-in-trade.

36.2 Draft Assessment Report – approach taken and submitter comments

Three possible options for phasing in the draft Standard were identified in the Draft Assessment Report. These included:

1. a 12-month transition period for stock in trade and Standard implementation (the default transitional period);
2. a 24-month transition period for stock in trade and Standard implementation to run concurrently; and

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

FSANZ indicated Option 2 was the preferred option in order to address stock in trade and to allow a longer period for suppliers to comply with new requirements for claims.

The majority of submitters to the Draft Assessment Report were in favour of a transition period longer than the 12-month default period. Some submitters made the distinction between transition for the draft Standard itself and a transition period for stock in trade. Whilst a 12-month implementation period was considered adequate by most submitters, a longer transition period for stock in trade was preferred to minimise losses and to ensure that the labelling of existing products carrying claims could be assessed and updated.

36.3 Preliminary Final Assessment Report – approach taken and submitter comments

Although further comment on the transition period was not sought in the Preliminary Final Assessment Report, some submitters provided additional recommendations or noted their concerns.

The common industry view was that a transition period of longer than two years would be warranted, for the purposes of reviewing product lines and implementing labelling changes to affected products. Suggestions for extension of the transition period ranged from three to five years (accommodating both Standard implementation and stock in trade provisions). Some submitters also noted that a longer transition would allow for labelling changes arising from other proposals to be made, such as proposals dealing with fortification or the consideration of 2006 nutrient reference values by FSANZ. An initial evaluation period of 12 months was also proposed by one submitter, with a view to imposing more stringent criteria which could be relaxed on the basis of evaluation results and further consultation. One jurisdiction considered that the preferred option of two years for Standard implementation and stock in trade would result in significant enforcement difficulties and recommended the default 12-month transition period be adopted.

Whilst one submitter from industry was concerned that health claims could not be made within the transition period, this will not be the case. While Standard 1.1A.2 operates as a transitional alternative standard to the draft Standard for a period of two years from the commencement of the draft Standard, during this time, the labelling of food can comply with either Standard 1.1A.2 or the draft Standard, which will allow health claims.

36.4 Rationale for final decision

FSANZ has retained its recommendation that a 24-month transition period which includes both the implementation of the Standard and stock in trade provisions is appropriate for several reasons.

The CIE Benefit Cost Analysis Report (refer to Attachment 11) has indicated that 80% of existing products would not be affected by the new labelling requirements of draft Standard, and although the Standard is new, relatively large and complex, much of it represents existing criteria around nutrition content claims (carried over from CoPoNC).

However, industry submissions and advice to FSANZ suggest there is considerable interest in taking up new provisions from the draft Standard and that it will have a significant impact. Accordingly, the information is conflicting and the size of the actual impact is unclear. Given that the proposed transition period is of longer duration than the 12-month default period, the additional time should be sufficient for suppliers to re-label the affected products. It would also assist industry in minimising losses from stock in trade.

Although some industry stakeholders would prefer a longer transition period, FSANZ considers that increased consumer confusion could result in the long term from some food products complying with the Transitional Standard 1.1A.2 and other products adopting new labelling under the draft Standard. Furthermore, a longer transition period in which two standards are operating simultaneously would lead to greater difficulties for enforcement agencies.

37. Education

In accordance with the FSANZ Act, one of FSANZ's functions is to develop, in co-operation with the jurisdictions, food education initiatives, including the publication of information to increase public awareness of food standards and food labels.

Other organisations also assist in providing information to complement and strengthen FSANZ initiatives to increase public awareness of food labels. Where possible, FSANZ works with these organisations to ensure consistency of information and to maximise the effectiveness of available resources.

Educational considerations were consulted on in the Initial Assessment Report and responses discussed in the Draft Assessment Report. This aspect has not been consulted on further.

37.1 Submitter comments to Draft Assessment Report

Submitters noted that education was a joint responsibility and recommended undertakings by various agencies such as: FSANZ, the NZFSA, Governments (Australian, 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 (CSIRO) Human Nutrition Division. A number of detailed comments were provided and emphasised the need for a comprehensive and consistent approach with focus on consumer understanding of healthy eating generally. Other aspects to note were consumer understanding of a complaints system, and the need to reach consumers in lower socio-economic areas. The establishment of a working group was also recommended, or that FSANZ coordinate the educational process and target groups such as suppliers, health professionals, consumers and enforcement agencies.

The limited role of food labelling as simply one element of consumer education was acknowledged and whilst FSANZ's intention to initiate a consumer education program around claims was commended, the effectiveness of this approach with respect to consumers making healthier choices was questioned and note made that current campaigns in place (such as 5+ a day) should be promoted and resourced. The importance of non-labelled foods, for example, fresh fruit and vegetables, was also highlighted.

There are concerns nutrition content and health claims will alter consumers' understanding of a healthy diet. Submitters considered that education should be provided by governments around examples, context and meanings of claims. It was also commented that the role of education is to enhance regulation, rather than being a substitute for it.

The broad range of audiences was also noted to include manufacturers, advertisers, consumers and nutrition and health professionals and the need for different methods and/or materials to target different audiences, including aural and visual multilingual resources. Comment was made on the need for adequate resourcing, and the suggestion made that industry should assist government with such funding. Industry has offered to assist FSANZ with development of user guidance and also recommends the establishment of a short-term premarket advisory service to ensure users have effective understanding and confidence in the system. The Dietitians Association of Australia offered to assist with education of health professionals.

The FSANZ website was seen as a useful avenue for information but inadequate on its own, and suggestions made that fact sheets, posters etc be distributed through supermarkets and other food outlets.

Education was not a topic for discussion in the Preliminary Final Assessment Report and no new comments were received.

37.2 Recommended Approach

It is noted that a number of submitter comments reflected interest in food and health education and/or labelling generally, rather than education specifically regarding use of the nutrition, health and related claims Standard.

Whilst FSANZ is keen to support broader health education initiatives, our role is limited by relevance to the development and implementation of food standards. Education regarding food labelling generally is a key responsibility for FSANZ however, within the context of this Proposal only matters relating to the draft Standard will be addressed.

FSANZ's educational initiatives to accompany the implementation of the draft Standard will include:

- participation in workshops, conferences, seminars, briefing sessions etc. as appropriate post gazettal of the standard;
- preparation of a specific fact sheet/brochure on the new nutrition and health claims requirements;
- development of a User Guide; and
- updating the FSANZ consumer education package on food labelling that currently consists of: website information, Choosing the Right Stuff- the official shoppers' guide to food additives and labels, kilojoules and fat content, an illustrated food labelling poster, and schools educational material prepared by Video Education Australasia.

INTER-RELATED ISSUES

38. 2006 Nutrient Reference Values

Currently the Code prescribes reference values (Recommended Dietary Intakes and Estimated Safe and Adequate Daily Dietary Intakes) for three age groups as the basis for various vitamin and mineral claims criteria for nutrition labelling. Reference values for energy, protein, fat, saturated fatty acids, carbohydrate, sodium, sugars and dietary fibre are also prescribed for the purposes of calculating percentage daily intakes of these food components in the nutrition information panel. These reference values date from before 2000.

Nutrient Reference Values (NRVs) for Australia and New Zealand were published in May 2006 (NHMRC and NZ Ministry of Health, 2006). The revised suite of NRVs extends the range of recommended nutrient intakes to encompass measures of dietary adequacy and safety. The expanded range of values includes Estimated Average Requirements and Recommended Dietary Intakes, or alternatively Adequate Intakes, for most nutrients as well as Upper Levels of Intake for some nutrients. Values for these requirements are stipulated for several age/sex groups and the life stages of pregnancy and lactation.

The revision to the NRVs has also expanded the number of nutrients (vitamins, minerals, protein and energy) having reference values from 20 to 37. These comprise nine macronutrients (energy, protein, carbohydrate and fat, and their subcomponents), and 28 vitamins and minerals. A second set of values representing recommendations on reduction of chronic disease risk has also been established for 13 nutrients.

Stakeholder comment on the impact of the 2006 NRVs on the draft Standard was not sought by FSANZ in the Draft Assessment Report. However, some submitters raised this issue and the general view was that there is a need to adopt the 2006 NRVs into the Code before the draft Standard is gazetted.

FSANZ acknowledged in the Preliminary Final Assessment Report that:

- consideration of the NRVs for the Code is expected to be a complex process. Many factors must be considered before one value per nutrient is selected from the broad range of NRV values for each of the specified population groups; and
- revision of these reference values also has wide implications for other aspects of food regulation, including fortification of both general purpose foods and special purpose foods. FSANZ noted that although this work is of a high priority, it could not be included within the scope of the current project as it would delay the timeframes.

An undertaking was given by FSANZ at this time to consider the 2006 NRVs as a high priority, subject to workloads and available resources.

Further comment on the issue was provided by submitters to the Preliminary Final Assessment Report. The view that the updating of NRVs in the Code should take place as soon as possible, and should align with the timelines of the draft Standard, was restated by many submitters. Others warned that the cost to suppliers of re-labelling and the impact on products carry nutrition content claims would be high, and that consumer confusion over changes to label claims would prevail as a result of such re-labelling.

One submitter highlighted that FSANZ has already used the revised NRVs in other proposals (for example, those Proposals pertaining to fortification such as Proposal P295 – Consideration of Mandatory Fortification with Folic Acid).

Whilst it is correct that FSANZ has chosen to use revised values in nutritional and safety risk assessments, on the occasions where this has occurred it has been in relation to a single nutrient. Consideration of the 2006 NRVs across the Code and in relation to the draft Standard is considerably more complex, as already indicated. In addition, earlier discussion with the health claims SDAC on this topic indicated a reluctance to introduce any further delays to the implementation of the new health claims Standard.

FSANZ is committed to maintaining a solid nutritional rationale underpinning health claims regulations as for all food regulations, and planning has commenced on the consideration of the 2006 NRVs across the Code. This work will be commenced in 2008 and, if possible, completed during the transitional period of the draft Standard, which would mitigate labelling costs to industry.

39. Front-of-Pack Labelling

Whilst the widespread interest in such schemes is acknowledged by FSANZ, the issue of front-of-pack labelling falls outside the scope of this Proposal.

Although this issue was not specifically raised, two stakeholders provided comment on front-of-pack labelling in their submissions to the Preliminary Final Assessment Report. Given that front-of-pack labelling is being considered by an inter-governmental group under a separate process, one submitter noted that Ministerial Council Policy Guideline on front-of-pack labelling systems should precede the introduction of the draft Standard. The other submitter was of the view that a combined approach of a UK-type traffic light system and the nutrient profiling system as proposed in this Final Assessment Report would be more useful to consumers than the approach being proposed for the regulation of nutrition content and health claims.

At present, the Code does not prescribe or specifically determine the use of front-of-pack labelling, such as the ‘traffic light’ approach or thumbnails for percentage daily intake (%DI) information. However under current provisions, %DI may be voluntarily presented in the nutrition information panel, which then triggers a requirement for %DI for all designated nutrients. If all or any of these values are then displayed on the front-of-pack, they will be considered as nutrition claim(s) and as such would need to meet the proposed claim requirements. Some %DI values may not be eligible as claims on the basis of not meeting qualifying criteria. This creates a dilemma which we have addressed under Proposal P293 by permitting the voluntary use of %DI labelling outside the nutrition information panel, without the properties of such claims being required to meet the qualifying criteria for nutrition content claims.

A voluntary front-of-pack labelling scheme based on %DI information was launched in Australia in November 2006 by the Parliamentary Secretary to the Minister for Health and Ageing and the Minister for Agriculture, Fisheries and Forestry, in conjunction with the Australian Food and Grocery Council. The scheme is non-interpretive – it does not identify foods as ‘good’ or ‘bad’ as occurs in a ‘traffic light’ type labelling scheme.

The uptake of this scheme in Australia and New Zealand has been particularly noticeable in the cereal and beverage categories. The Australian Food and Grocery Council have been actively working with industry to develop a consistent format of front-of-pack labelling.

In October 2006, the Ministerial Council asked the Food Regulation Standing Committee (FRSC) to review whether the use of a front-of-pack labelling system, designed to guide consumer choice to healthier food options, would be an effective health strategy.

40. Labelling Review

FSANZ has committed to undertake a targeted labelling review that will consider a number of specific labelling requirements in Part 1.2 of the Code. Whilst the review will not address any issues relevant to health claims, it may impact on the timing of labelling changes.

41. 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, the Ministerial Council also requested FRSC to 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.

A working group was formed and tasked by the FRSC to develop a consultation paper and draft policy guideline. In November 2007, FRSC sought comments from a targeted group of stakeholders on the Draft Policy Guideline – Addition to Food of Substances other than Vitamins and Minerals. The responses from this consultation will inform the finalisation of this document for consideration by the Ministerial Council in 2008.

This guidance is likely to require FSANZ to consider compositional requirements for the addition to foods of substances other than vitamins and minerals. Such substances are generally considered under Proposal P293 as biologically active substances. Any provisions arising from Proposal P293 in relation to these substances will only address labelling elements i.e. claims that can be made, as Proposal P293 does not address compositional permissions. Therefore the policy guidance referred to above and where it may relate to biologically active substances maintains separate and complementary relevance. FSANZ will consider how to respond to the policy guidance once it is received.

Provisions in respect of claims about biologically active substances are addressed in this report in Attachments 5 (nutrition content claims) and 6 (general level health claims).

42. Interface between Foods and Medicines

42.1 Draft Assessment Report – proposed approach and submitter comments

The Draft Assessment Report noted that some stakeholders had concerns over the blurring of the boundaries between foods and drugs once foods were permitted to make health claims. Stakeholders were advised that 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 had been formed.

This group's task has been to develop a tool for determining the regulatory status of products at the food/medicine interface to facilitate clearer demarcation between products considered foods and those considered to be complementary medicines.

A significant number of comments were received on this matter. There was particular interest in the interface between complementary medicines or dietary supplements, and foods carrying similar claims. Issues raised included inequity of levels of regulatory intervention between the respective regulatory systems, for example, the lack of pre-market approval for general level health claims on foods; concerns regarding the lack of definition of *therapeutic* in the Code; concerns that certain food type dietary supplements will not be captured by the health claims regulation; and a query as to whether substantiation for claims on dietary supplements could be used as a 'short-cut' to substantiation for similar claims on foods.

There was support for prohibiting comparisons between foods and therapeutic goods, and a comment that the Australian *Therapeutic Goods Act 1989* and the Therapeutic Goods Advertising Code 2005 should provide similar prohibitions. Similarly there was support for New Zealand to move to a two category system (i.e. foods and medicines) similar to Australia i.e. remove the '3rd' category for dietary supplements. The suggestion was made that dosage information be specifically prohibited on foods to facilitate a clear demarcation between foods and therapeutic goods.

Trans Tasman trade was raised as being potentially unfair to Australian manufacturers, due to the ability for New Zealand manufacturers to make claims on products produced under New Zealand dietary supplement regulations that would not be permitted on Australian manufactured products under the draft Standard.

Concerns around enforcement were raised noting that some stakeholders consider that there is a high rate of non-compliance with the dietary supplements regulations and that a pre-approval process could avert this problem.

There were also a number of comments regarding foods under Part 2.9 of the Code; these are addressed separately in Attachment 4 of this report.

The matter of foods for special medical purposes was specifically raised noting these are yet to be addressed in Part 2.9 of the Code, and the view that those in existence on the market are effectively carrying what could be construed as high level health claims.

42.2 Preliminary Final Assessment Report – submitter comments

This topic was not raised in the Preliminary Final Assessment Report however a small number of comments were received from industry and jurisdictional representatives. Support was noted for any necessary changes to be made to the New Zealand Medicines and/or Food Act(s) to allow foods with health claims to be manufactured and sold in New Zealand, and the New Zealand Safety Food Authority advised FSANZ of consultation processes underway in New Zealand mid 2007 on this matter.

A request was made for a definition of *therapeutic* to be incorporated by FSANZ into the draft Standard. This has not been done by FSANZ as the term is not used in the draft Standard, and any attempts to define *therapeutic* would be inconsistent with the Australian *Therapeutic Goods Act 1989*.

Comparisons were also made with complementary medicines that may make very similar claims to those that may appear on foods and noting there are differing requirements between the two regimes, for example, around substantiation and advertising provisions. Support was again provided for the restriction on therapeutic claims or comparisons of food with therapeutic products. One jurisdiction had concerns regarding the potential loss of certain provisions provided by the current Standard 1.1A.2 clause 3(2)²¹, which prohibits the word ‘health’ or any word of similar import, as part of or in conjunction with the name of the food, and considered it important that these provisions be maintained.

42.3 Proposed approach

As noted above an ad hoc Trans-Tasman Working group on the Food/Medicine Interface was formed as part of the establishment of the Joint Agency for regulating therapeutic products. The Joint Agency is no longer proceeding as originally proposed and the food/medicine interface working group now sits within the jurisdiction of the Implementation Sub Committee. Chaired by NZFSA, the group includes MedSafe (the New Zealand medicines regulator), Therapeutic Goods Administration (the Australian medicines regulator) and the jurisdictions. The Ministerial Council will be asked to agree to its operational processes later in 2008.

This working group has continued the work of developing assistance in determining appropriate regulatory status of foods at the interface and has done so through the development of an electronic web-based portal, via which product suppliers may gain guidance as to the appropriate regulatory pathway for their product(s). However, the ultimate determination as to the status of a product remains with the respective jurisdiction. This process and the guidance tool in the form of a decision tree will assist regulatory agencies, such as FSANZ, NZFSA, the Therapeutic Goods Administration and MedSafe to identify the regulatory regime which is most appropriate to deal with a particular product or group of products at the food/medicine interface.

Within New Zealand this area is further impacted by the provisions for dietary supplements under the *Dietary Supplement Regulations 1984*. The New Zealand Government is currently developing a supplemented food standard to sit under the New Zealand Food Act, to cater for food type dietary supplements. A policy statement is to be released by the NZFSA in 2008.

With regard to the particular concerns around clause 3(b) in the Transitional Standard 1.1A.2, under the proposed approach, the use of the words ‘health’ or ‘healthy’ in a label would not adequately meet the requirements of the draft Standard. Any claims on foods that present as nutrition or health-related claims must be substantiated and explicit, and require additional wording conditions that would need to be met (refer draft Standard 1.2.7, clauses 5 and 6, at Attachment 1).

Issues concerning substantiation of health claims compared to complementary medicines are addressed by the requirements of the Scientific Substantiation Framework – refer to Attachment 1 for more detail. Evidence of substantiation would not be directly transferable from that used for complementary medicines as the food vehicles serve different purposes and are therefore used in different ways. Similarly it can be argued that equity in appropriate levels of substantiation is not directly comparable between foods and medicines.

²¹ Clause 3(2) was referred to. In the absence of a clause 3(2) FSANZ has assumed this means clause 3(b).

Evidence used for complementary medicines may nonetheless provide a useful and potentially substantial starting point for evidence to underpin health claims.

FSANZ notes the comments raised by submitters concerning the facility for Trans Tasman trade, relating to dietary supplements manufactured in New Zealand. However, this facility is governed by the Trans Tasman Mutual Recognition Arrangement, consideration of which sits outside the parameters of this Proposal.

43. New Zealand Medicines Act

In New Zealand, when the folate health claims pilot was proposed, it was found that an exemption was required under the *Medicines Act 1981* to allow a health claim to be made for foods fortified with folate. This exemption was provided by the Medicines (Related Products (Exempted Foods)) Regulations. To ensure that the draft Standard 1.2.7 – Nutrition, Health and Related Claims has legal effect in New Zealand, an amendment or a new regulation will be required under the Medicines Act to provide for the operation of the Standard in New Zealand. Section 96 of the Medicines Act imposes a barrier on the sale of food for which certain health claims are made (effectiveness for a therapeutic purpose).

Article 5 of the Treaty requires New Zealand to take legislative or other steps as are necessary to adopt or incorporate food standards that are developed and approved by FSANZ.

CONCLUSION

44. Conclusions and Recommendations

FSANZ has prepared a draft Standard for Nutrition, Health and Related Claims. In doing so it has consulted widely with industry, consumers, public health and jurisdictional stakeholders. In developing an appropriate evidence base, FSANZ has commissioned social and economic research and drawn extensively on experiences and science from other countries such as Canada, the United Kingdom and the USA. Throughout development of the draft Standard, FSANZ has had regard to the Policy Guideline on Nutrition, Health and Related Claims provided by the Ministerial Council in 2003.

Currently in New Zealand and Australia nutrition content and health claims are regulated by the Code, fair trading acts and by voluntary guidelines. This situation has limitations including difficulties in relation to the enforcement of a voluntary code of practice, the lack of incentive for innovation by industry and a restriction on claims that could inform consumers about food products. Furthermore there are difficulties in interpretation, application and enforcement of the current Standard 1.1A.2.

Three options for the regulation of nutrition, health and related claims were evaluated; status quo, co-regulation and full regulation.

FSANZ used an evidence-based approach to evaluate the regulatory options which has included benefit-cost analyses, consumer research, label monitoring studies, consideration of international approaches to the regulation of nutrition and health claims, and advice sought via public submissions, targeted consultation of stakeholder groups and expert advisory groups. The introduction of a new Standard was evaluated by the benefit-cost analysis as having significant advantages over maintaining the *status quo*.

FSANZ recommends a regulated approach with the introduction of the draft Standard for the implementation of nutrition content, general level and high level health claims. The regulatory framework developed includes a 'step-up' approach that recognises the degree of promise associated with different types of claims and requires scientific substantiation of all claims. In reaching this decision consideration has been given to minimizing the degree of regulation commensurate with the risk to consumers of not providing adequate information for informed choice and the risk of misleading claims. It is considered that the approach provides overall benefits to the community, government and industry that outweigh the costs arising from the food regulatory measure.

The Final Assessment Report includes numerous specific recommendations in relation to the regulation of health, nutrition and related claims. Some modifications to the criteria for nutrition content claims as currently set out in the Code and in CoPoNC are being proposed. Criteria for specific nutrition content claims (those which were evaluated to require criteria in order to meet public health objectives or which may otherwise mislead consumers) are specified in the draft Standard. Other nutrition content claims can continue to be made providing they are not misleading. For some nutrition content claims specific disqualifying criteria will apply.

General level health claims will require explicit reference to both the specific health effect and the property of the food responsible for that health effect. The property will need to be present above defined levels (qualifying criteria) in order to avoid misleading consumers. Foods able to carry general level health claims must meet the generic nutrient profiling scoring criteria. All general level health claims are either to be based on a list of nutrient function statements included in the draft Standard, derived from the pre-approved food-disease relationships for high level health claims, supported by authoritative texts or supported by evidence prepared as specified in the Scientific Substantiation Framework. Holding the records 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 health claims based on the substantiated food-disease relationships specified in the draft Standard, subject to defined specific criteria and conditions. Any new food-disease relationships which underpin high level health claims are required to be pre-approved by FSANZ by the normal application process to vary the Code, which will be specified in the *Application Handbook*.

Following approval of the draft variation to the Code by the FSANZ Board, the Board will notify the Ministerial Council of this decision. The proposed draft variations to the Code (Attachment 1) will come into effect two years from gazettal. FSANZ is developing a User Guide to assist industry, enforcement agencies and other stakeholders with the implementation of the draft Standard.

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GLOSSARY

Other terms, abbreviations and acronyms

CHERE	Centre for Health Economics Research and Evaluation
CIE	Centre for International Economics
Claims Classification Framework	A framework outlining the categories of claims (nutrition content claims, general level health claims and high level health claims) and examples of each. The framework is based on the FSANZ interpretation of the Claims Classification Framework in the Policy Guideline.
COAG	Council of Australian Governments
Conditions, refers to	Requirements that a nutrition content claim or health claim must comply with, such as qualifying criteria for nutrition content claims; and <u>Wording conditions</u> including mandatory statements, additional labelling statements, and options around the relative positioning of the various elements.
CoPoNC	Code of Practice on Nutrient Claims in Food Labels and in Advertisements.
Criteria, refers to:	<u>Qualifying criteria</u> – 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 <u>Disqualifying criteria</u> – where specific disqualifying criteria are applied to some nutrition content claims. Such criteria relate to other properties of the food itself, rather than the claimed nutrient. <u>Food vehicle eligibility criteria</u> – which relate to the food vehicle, in which the food must meet nutrient profiling scoring criteria to be eligible to carry a general level health claim. Nutrient profiling scoring criteria are also applied as the default for high level health claims.
EFSA	European Food Safety Authority
Food-disease relationship	Refers to the relationship between the consumption of food and disease that underpins an application for a high level health claim. The relationship must be substantiated as part of the pre-approval process for a high level health claim.

Food-health relationship	Refers to the relationship between the consumption of food and the impact on health in relation to a general level health claim.
FRSC	Food Regulation Standing Committee
FSANZ	Food Standards Australia New Zealand
FSANZ Conceptual Framework	Consists of three inter-related elements; the Claims Classification Framework, the FSANZ Claims descriptors and the FSANZ Regulatory Model. The Conceptual Framework proposes a system for categorising nutrition, health and related claims and how they might be regulated.
GI	Glycemic Index
Guideline	A Guideline is a form of quasi regulation. 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.
NHMRC	National Health and Medical Research Council, Australia.
NPSC	Nutrient profiling scoring criteria
NRVs	Nutrient Reference Values, released by the National Health and Medical Research Council (Australia) and the Ministry of Health (New Zealand) in 2006.
NZFSA	New Zealand Food Safety Authority
%DI	Percentage daily intake
RDI	Recommended Dietary Intake.
Supplier	means the packer, manufacturer, vendor or importer of the food in question.
TPA	<i>Trade Practices Act 1974</i>
User Guide	A user guide is a document that provides guidance on matters set out in a food standard.
WTO	World Trade Organization.

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

Standards or variations to Standards are considered to be legislative instruments for the purposes of the Legislative Instruments Act (2003) and are not subject to disallowance or sunseting.

To commence: on gazettal

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

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

[1.2] *inserting in clause 2 –*

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

[2] *The Australia New Zealand Food Standards Code is varied by omitting Reserved; substituting –*

STANDARD 1.2.7

NUTRITION, HEALTH AND RELATED CLAIMS

Purpose

This Standard is designed to regulate nutrition content claims, health claims, dietary information, 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.

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Division 1 – Preliminary

Clauses

1 Interpretation

- (1) In this Standard, unless the contrary intention appears –

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 for a food means a nutrition content claim or health claim that is presented as a statement that the sale of the food will contribute to fundraising for an organisation.

dietary information means general dietary information that –

- (a) does not relate to a health effect; and
- (b) relates to food or a property of the food; and
- (c) is provided for educational purposes.

Editorial note:

An example of general dietary information is the information contained in national nutrition guidelines such as –

- (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) New Zealand Ministry of Health food and nutrition guidelines. |

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, other than –

- (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 organisation, including a government organisation, formed for nutrition or health purposes, the name of which may include a serious disease, other than an organisation established or controlled by a supplier or their representatives of food or food ingredients.

food group means, in this Standard, any of the following groups –

- (a) bread (both leavened or unleavened), grains, rice, pasta and noodles; or
- (b) fruit, vegetables, herbs, spices and fungi that is one ingredient or more than one ingredient of that class; or
- (c) milk and milk products as standardised in Part 2.5 and analogues derived from legumes and cereals mentioned in column 1 of the Table to clause 3 in Standard 1.3.2; or
- (d) meat, fish, eggs and legumes that is one ingredient or more than one ingredient of that class; or
- (e) fats including butter, edible oils and edible oil spreads.

Editorial note:

For the purposes of (b) an example of one ingredient for fruit is an apple and an example of more than one ingredient of that class is apples and oranges.

For the purposes of (d) an example of one ingredient for meat is poultry and an example of more than one ingredient of that class is poultry and rabbit.

fruit means fruit other than nuts, spices, herbs, fungi, dried pulses and seeds and includes the edible portion of a plant or constituents of the edible portion that are present in the typical proportion of the whole fruit (with or without the peel or water).

general level health claim means a health claim that does not, directly or indirectly, refer to a serious disease or a biomarker.

glycemic index (GI) means the property of the carbohydrates in different foods, specifically the blood glucose raising ability of the digestible carbohydrates in a given food.

Editorial note:

The method for determining glycemic index of carbohydrates in foods is described in the Standards Australia *Australian Standard Glycemic index of foods* (AS 4694 – 2007). In particular, glycemic index testing is carried out by the determination of glycemic (blood glucose) responses in human volunteers (in-vivo testing).

The objective of AS 4694 - 2007 is to establish the recognised scientific method as the Standard method for the determination of glycemic index [GI] in foods.

The Standard can be obtained from Standards Australia (www.Standards.org.au).

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

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

health effect means an effect on the functioning of the human body including a disease state or physical or mental performance or maintenance of a healthy functioning body.

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

nutrition content claim means a claim about the presence or absence of a property of the food, other than a claim about alcohol content.

property of the food means any of the following, that is associated with a nutrition or health purpose –

- (a) energy, a nutrient, or a biologically active substance; or
- (b) a component, ingredient or any other feature or constituent of the food; or
- (c) glycemic index.

reference food means a food that is –

- (a) of the same type as the food for which a claim is made and that has not been further processed, formulated, reformulated or modified to increase or decrease the energy value or the amount of the nutrient for which the claim is made; or
- (b) a dietary substitute for the food in the same food group as the food for which a claim is made.

Editorial note:

An example for paragraph (a) is reduced fat milk compared to whole milk (the reference food).

An example for paragraph (b) is that milk products may be compared with milk alternatives but not with meat.

reference value means RDI, ESADDI or a reference value under the Table to subclause 7(8) of Standard 1.2.8.

serious disease means a disease, ailment, defect or condition for which it 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 being overweight.

vegetable means vegetable other than nuts, spices, herbs, fungi, dried pulses and seeds and includes the edible portion of a plant or constituents of the edible portion that are present in the typical proportion of the whole vegetable (with or without the peel or water).

(2) Unless the contrary intention appears, the definitions in Standard 1.2.8 apply in this Standard.

2 Application

(1) This Standard applies to

- (a) food for retail sale; and
- (b) food for sale to the public; and
- (c) food prior to retail sale which is –
 - (i) manufactured or otherwise prepared, or distributed, transported or stored; and
 - (ii) not intended for further processing, packaging or labelling.

(2) This Standard does not apply to –

- (a) a meal provided to a client of a delivered meal organisation; or
- (b) food, other than in a package, provided to a patient in a hospital or an institution mentioned in Schedule 3;
- (c) an infant formula product standardised under Standard 2.9.1; or
- (d) subclause 8(3) of Standard 2.6.2.

(3) Subclause 1(2) of Standard 1.1.1 does not apply to this Standard.

(4) 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.

(5) In this clause –

food product means a food product produced either before or after the commencement of this Standard.

Division 2 – General Requirements

3 Claims, dietary information and statement prohibition

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

(2) A claim must not refer to the prevention, diagnosis, cure, alleviation or symptom of a disease, ailment, defect or condition.

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

4 Nutrition content claims, general level and high level health claims - ineligible foods

(1) Subject to subclause (2), a nutrition content claim, general level health claim or high level health claim must not be made for –

- (a) a food that contains more than 1.15% alcohol by volume; or
- (b) kava as standardised under Standard 2.6.3.

(2) If permitted by clause 5, a nutrition content claim may be made for a food that contains more than 1.15% alcohol by volume, if the claim mentions –

- (a) energy content; or
- (b) carbohydrate content.

(3) A nutrition information panel that contains the prescribed declarations in paragraphs 5(1)(a) to 5(1)(f) of Standard 1.2.8 may be included on a food that contains more than 1.15% alcohol by volume. The information in the panel is taken not to constitute a nutrition content claim.

5 Conditions for nutrition content claims

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

- (a) the supplier of the food has records that substantiate the claim; and
- (b) the food meets any conditions mentioned in clause 11 that apply to the claim; and
- (c) if the claim relates to a property of the food that is naturally present or absent in other similar foods, the claim must refer to the food and not the brand of food; and

- (d) the conditions for making the claim mentioned in the Table to clause 11 apply to the food in accordance with the Table to clause 6; and
- (e) the following applies –
 - (i) the claim may only include descriptors for the property of the food, if there is a reference value for the property of the food in the Code or applicable conditions in the Table to clause 11 in relation to the property of the food; or
 - (ii) if there is no reference value for the property of the food in the Code and no applicable conditions in the Table to clause 11 in relation to the property of the food, the claim may include a descriptor that is a numerical value for the property of the food.

Editorial note:

For paragraph (e)(i), examples of descriptors that refer to the level of the property of the food present for making specific nutrition content claims are mentioned in Column 2 of the Table to clause 11.

For paragraph (e)(ii) an example of a claim where the descriptor is the numerical value of the property of the food is ‘GL = 12’.

Examples of claims that are permitted but do not include a descriptor in relation to the level of the property of the food are ‘source of’ or ‘contains’ for the presence of a property of the food.

- (2) For a nutrition content claim, the following applies –
 - (a) the nutrition information panel must include particulars of the average energy content and average quantities of nutrients and biologically active substances in accordance with subclause 6(6) and the Table to clause 6; or
 - (b) if a nutrition content claim is made about a food in a small package, the label must include particulars of the average energy content and average quantities of nutrients and biologically active substances in accordance with subclause 6(6) and the Table to clause 6; or
 - (c) if a nutrition content claim is made and the labelling requirements in clause 2 of Standard 1.2.1 applies particulars of the average energy content and average quantities of nutrients and biologically active substances in accordance with subclause 6(6) and the Table to clause 6 must be provided –
 - (i) in a nutrition information panel displayed on or in connection with the display of the food; or
 - (ii) to the purchaser upon request.

6 Conditions for general level and high level health claims

- (1) A general level health claim may be made only if the following conditions are met –

- (a) the food meets the nutrient profiling scoring criteria for making a health claim mentioned in Schedule 1 based on the food's nutrient profile, other than a claim about gluten or lactose, or about a food standardised under Part 2.9; and
- (b) the supplier of the food has records that substantiate the claim, and –
 - (i) the Scientific Substantiation Framework mentioned in Schedule 2 has been applied to the claim; and
 - (ii) the supplier of the food makes the records available to the relevant authority, upon request; and
- (c) the food meets any applicable conditions under Division 3 for making a general level health claim; and
- (d) the food meets any applicable conditions under Division 3 for making a nutrition content claim about the property of the food that is the subject of the general level health claim, in particular in the Table to clause 11 –
 - (i) if the property of the food is dietary fibre, monounsaturated fatty acids, omega-3 fatty acids, omega-6 fatty acids, omega-9 fatty acids, polyunsaturated fatty acids, potassium, protein, vitamins or minerals, the minimum conditions in the applicable conditions must be met;
 - (ii) if the property of the food is cholesterol, low energy, fat, salt or sodium, saturated and trans fatty acids, saturated fatty acids or sugar, the low descriptor criteria in the applicable conditions must be met; and
- (e) the claim expressly states –
 - (i) the property of the food or if the claim is based on the food itself, the food; and
 - (ii) the specific health effect claimed for the property of the food or the food; and
 - (iii) if applicable, the population group to which the associated 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, the property of the food that is the subject of the claim and the specific health effect claimed; and
- (f) the entire claim is presented together.

(2) For paragraph (1)(f), 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 (1)(f) is placed.

(3) For health claims, the following applies –

- (a) the nutrition information panel must include particulars of the average energy content and average quantities of nutrients and biologically active substances in accordance with subclause (6) and the Table to clause 6; or
- (b) if a health claim is made about a food in a small package, the label must include particulars of the average energy content and average quantities of nutrients and biologically active substances in accordance with subclause (6) and the Table to clause 6; or
- (c) if a health claim is made and the labelling requirements under clause 2 of Standard 1.2.1 applies, particulars of the average energy content and average quantities of nutrients and biologically active substances in accordance with subclause (6) and the Table to clause 6 must be provided –
 - (i) in a nutrition information panel displayed on or in connection with the display of the food; or
 - (ii) to the purchaser upon request; and

(4) For the purpose of enabling a food to be eligible to have a health claim, a claim about glycemic index or a diet claim made about it as calculated in accordance with the nutrient profiling scoring criteria mentioned in Schedule 1, the following information must be provided on the label –

- (a) the dietary fibre content where applicable, specified in the nutrition information panel; and
- (b) the calcium content of cheese where applicable, specified in the nutrition information panel; and
- (c) the percentage of the fruits, vegetables, nuts and legumes including coconut, spices, herbs, fungi, seeds or algae where applicable, calculated and expressed in accordance with Standard 1.2.10.

(5) Paragraph 4(c) does not apply to a high level health claim for vegetables and fruit and coronary heart disease.

(6) The claim must clearly indicate the form of the food to which the conditions for making the claim apply in accordance with the Table to clause 6.

(7) For the purpose of meeting the nutrient profiling scoring criteria mentioned in Schedule 1 for making a health claim, the Table to clause 6 does not apply for calculating the percentage of fruits, vegetables, nuts and legumes including coconut, spices, herbs, fungi, seeds or algae that are present in the food.

(8) The conditions for making the claim mentioned in paragraph 6(1)(a), subclause (3) and the Tables to clauses 7, 11 and 12 apply to the food in accordance with the Table to clause 6.

(9) The information on the label for the food including the directions for use and the information provided in an advertisement for the food must be taken into account for the purposes of the Table to clause 6.

Table to clause 6

Form of the food	Form of the food to which conditions apply for making a claim
Food that can be either prepared with other food, or consumed as sold	The claim is based on the food as sold
Food that is required to be prepared and consumed according to directions	The claim is based on the food as prepared
Food that requires reconstituting with water	The claim is based on the food after it is reconstituted with water and ready for consumption
Food that requires draining before consuming	The claim is based on the food after it is drained and ready for consumption

7 Specific conditions for high level health claims

(1) A high level health claim may be made only if the following conditions are met –

- (a) the food-disease relationship that is the subject of the claim is mentioned in column 1 of the Table to this clause; and
- (b) the food meets any conditions mentioned in column 2 of the Table to this clause for the food-disease relationship; and
- (c) the claim expressly states, in words to the effect of those mentioned in column 3 of the Table to this clause for the food-disease relationship –
 - (i) the property of the food or the food, and the specific health effect claimed in relation to that property of the food or the food; and
 - (ii) if applicable, the population group to which the specific health effect relates; and
 - (iii) 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, the property of the food that is the subject of the claim and the specific health effect claimed; and
- (d) the entire claim is presented together.

(2) For paragraph (1)(d), 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 (1)(d) is placed.

Table to clause 7

Column 1	Column 2	Column 3
Substantiated food-disease relationship	Conditions	Claim statements
Calcium, vitamin D and osteoporosis	<p>(a) the food contains no less than 290 mg of calcium per serving; and</p> <p>(b) the food not including food standardised in Standards 2.9.2, 2.9.3 or 2.9.4 meets the nutrient profiling scoring criteria in Schedule 1 for making a health claim based on the food's nutrient profile.</p>	<p>(a) the property of the food is calcium; and</p> <p>(b) vitamin D may also be included as the property of the food if the food complies with any applicable conditions under clause 11 for making a nutrition content claim about vitamin D; and</p> <p>(c) the specific health effect is reduced risk of osteoporosis, enhanced bone mineral density or reduced risk of osteoporotic fracture; and</p> <p>(d) the population group is persons 65 years and over; and</p> <p>(e) the context is a healthy diet with a high intake of calcium from a variety of foods and adequate vitamin D status.</p>
Calcium and enhanced bone density	<p>(a) the food contains no less than 200 mg of calcium per serving; and</p> <p>(b) the food not including food standardised in Standards 2.9.2, 2.9.3 or 2.9.4 meets the nutrient profiling scoring criteria in Schedule 1 for making a health claim based on the food's nutrient profile.</p>	<p>(a) the property of the food is calcium; and</p> <p>(b) the specific health effect is enhanced bone mineral density; and</p> <p>(c) the context is a healthy diet with a high intake of calcium from a variety of foods.</p>

Table to clause 7 (continued)

Column 1	Column 2	Column 3
Substantiated food-disease relationship	Conditions	Claim statements
Folic acid and neural tube defect	<p>(a) the food contains no less than 40 µg folic acid per serving; and</p> <p>(b) the food not including food standardised in Standard 2.9.3 meets the nutrient profiling scoring criteria in Schedule 1 for making a health claim based on the food's nutrient profile; and</p> <p>(c) the food is not –</p> <ul style="list-style-type: none"> (i) soft cheese; or (ii) pâté; or (iii) liver or liver product; or (iv) foods containing added phytosterol esters or added tall oil phytosterols; or (v) food standardised in Standard 2.6.4; or (vi) food standardised in Part 2.7; or (vii) food standardised in standards 2.9.2 and 2.9.4; or (viii) a formulated meal replacement standardised in Division 2 of Standard 2.9.3. 	<p>(a) the property of the food is folic acid; and</p> <p>(b) the specific health effect is reduced risk of foetal neural tube defects; and</p> <p>(c) the population group is women of child bearing age; and</p> <p>(d) the context is a varied diet including food sources of folate and a recommendation that women consume at least 400 µg of folic acid per day, at least the month before and three months after conception.</p>
Saturated fatty acids and LDL cholesterol	<p>(a) the food meets the conditions under clause 11 for a nutrition content claim about low saturated fatty acids; and</p> <p>(b) the food not including food standardised in Standards 2.9.2, 2.9.3 or 2.9.4 meets the nutrient profiling scoring criteria in Schedule 1 for making a health claim based on the food's nutrient profile.</p>	<p>(a) the property of the food is saturated fatty acids; and</p> <p>(b) the specific health effect is reduction of blood cholesterol, total blood cholesterol, blood LDL cholesterol, serum LDL cholesterol, total serum cholesterol or serum cholesterol levels; and</p> <p>(c) the context is a healthy diet with a variety of foods low in saturated fatty acids.</p>

Table to clause 7 (continued)

Column 1	Column 2	Column 3
Substantiated food-disease relationship	Conditions	Claim statements
Saturated and trans fatty acids and LDL cholesterol	<p>(a) the food meets the conditions under clause 11 for a nutrition content claim about low saturated and trans fatty acids; and</p> <p>(b) the food not including food standardised in Standards 2.9.2, 2.9.3 or 2.9.4 meets the nutrient profiling scoring criteria in Schedule 1 for making a health claim based on the food's nutrient profile.</p>	<p>(a) the property of the food is saturated and trans fatty acids; and</p> <p>(b) the specific health effect is reduction of blood cholesterol, total blood cholesterol, blood LDL cholesterol, serum LDL cholesterol, total serum cholesterol or serum cholesterol levels; and</p> <p>(c) the context is a healthy diet with a variety of foods low in saturated and trans fatty acids.</p>
Sodium and blood pressure	<p>(a) the food meets the conditions under clause 11 for a nutrition content claim about low salt; and</p> <p>(b) the food not including food standardised in Standards 2.9.2, 2.9.3 or 2.9.4 meets the nutrient profiling scoring criteria in Schedule 1 for making a health claim based on the food's nutrient profile.</p>	<p>(a) the property of the food is sodium or salt; and</p> <p>(b) the specific health effect is maintenance of normal blood pressure or reduced blood pressure; and</p> <p>(c) the population group is the general adult population; and</p> <p>(d) the context is a healthy diet with a variety of foods low in salt or sodium.</p>
Increased intake of fruit and vegetables and coronary heart disease	<p>(a) claims are not permitted on –</p> <p>(i) fruit juice or vegetable juice standardised under Standard 2.6.1; or</p> <p>(ii) food standardised under Standard 2.6.2; and</p> <p>(b) the food contains no less than 90% fruit or vegetable by weight; and</p> <p>(c) the food not including food standardised in Standards 2.9.2, 2.9.3 or 2.9.4 meets the nutrient profiling scoring criteria in Schedule 1 for making a health claim based on the food's nutrient profile.</p>	<p>(a) the specific health effect is reduced risk of coronary heart disease; and</p> <p>(b) the context is a healthy diet with an increased intake of both fruit and vegetables and consisting of a variety of foods.</p>

Table to clause 7 (continued)

Column 1	Column 2	Column 3
Substantiated food-disease relationship	Conditions	Claim statements
A high intake of fruit and vegetables and coronary heart disease	(a) claims are not permitted on – <ul style="list-style-type: none"> (i) fruit juice or vegetable juice standardised under Standard 2.6.1; or (ii) non alcoholic beverages and brewed soft drinks standardised under Standard 2.6.2; and (b) the food contains no less than 90% fruit or vegetable by weight; and (c) the food not including food standardised in Standards 2.9.2, 2.9.3 or 2.9.4 meets the nutrient profiling scoring criteria in Schedule 1 for making a health claim based on the food’s nutrient profile.	(a) the specific health effect is reduced risk of coronary heart disease; and (b) the context is a healthy diet high in both fruit and vegetables and consisting of a variety of foods.

8 Conditions for cause-related marketing statements for food

(1) The requirements of this Standard relating to a nutrition content claim do not apply to a cause-related marketing statement for food, if words to the following effect appear in the same place as the cause-related marketing statement –

[insert supplier name] makes no claims that this food contains [property of the food].

(2) If a nutrition content claim separate to the cause related marketing statement for food is made that is about the same property of the food, the words under subclause (1) are not required.

(3) The requirements of this Standard relating to a health claim do not apply to a cause-related marketing statement for food, if words to the following effect 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 the health effect].

(4) If a health claim separate to the cause related marketing statement for food is made that is about the same health effect, the words under subclause (3) are not required.

9 Conditions for dietary information

- (1) Subject to this clause, dietary information must not be provided in a label on, or in advertising for, a food.
- (2) Dietary information may be provided in a label on, or in advertising for, a food if the dietary information –
- (a) does not relate to a property of the food; and
 - (b) directly relates to the food.

Editorial note:

An example for subclause (2) is that an advertisement for oranges could include the following dietary information; ‘Dietary Guidelines recommend that you eat [X] serves of fruit daily’.

- (3) Dietary information about a property of the food may be provided in a label on, or in advertising for, the food if the dietary information is directly associated with a nutrition content claim or health claim.

Editorial note:

An example for subclause (3) is if the label of a snack food carried the nutrition content claim ‘low salt’, the label can also include the following dietary information; ‘Dietary Guidelines recommend that you choose foods low in salt’.

- (4) Dietary information in a label on, or in an advertisement, for the food must not exceed the information in the associated nutrition content claim or health claim.
- (5) This clause does not apply to dietary information that relates to moderating the consumption of alcohol.

10 Conditions for small packages

If a health claim is made about a food in a small package, the label on the package is exempt from conditions mentioned in –

- (a) subparagraphs 6(1)(e)(iv) and 7(1)(c)(iii); and
- (b) subclause 6(4); and
- (c) item (c) under the conditions for weight loss or maintenance claims in the Table to clause 12.

10A Conditions for endorsements

The requirements of this Standard that relate to a nutrition content claim or health claim do not apply to an endorsement, if the supplier of the food –

- (a) has records demonstrating that the endorsing organisation that certified the endorsement is an endorsing organisation as defined in this Standard; and
- (b) makes the records available to the relevant authority, upon request.

Division 3 – Conditions for making specific nutrition content claims and general level health claims

11 Conditions for making specific nutrition content claims

(1) A nutrition content claim about the property of the food mentioned in column 1 in the Table to this clause using the descriptor or a descriptor synonymous with the descriptor mentioned in column 2 of the Table to this clause may be made if the conditions in column 3 of the Table to this clause are met.

(2) If there is no descriptor in column 2 in the Table to this clause, any nutrition content claim made about the property of the food mentioned in column 1 in the Table to this clause must meet the applicable conditions in column 3 of the Table to this clause.

(3) For subclause (1), slimming is not synonymous with diet.

(4) A claim about gluten or lactose may only be made if the applicable descriptor mentioned in column 2 in the Table to this clause is used and if the applicable conditions in column 3 of the Table to this clause are met.

(5) A claim about low or percentage free trans fatty acids must not be made.

(6) A claim must not be made 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.

Editorial note:

The Table to clause 11 provides conditions for specific nutrition content claims that may be made, however, the Table does not provide an exclusive list of nutrition content claims that may be made or an exclusive list of descriptors that can be used.

If the claim mentions light or lite, and this descriptor is intended to only describe a sensory attribute such as the colour, flavour or texture of the food, then claims of this nature are intended to be solely regulated under State or Territory Fair Trading legislation, the *Trade Practices Act 1974 (Cth)* or the *Fair Trading Act 1986 (NZ)*.

Table to clause 11

Column 1	Column 2	Column 3
Property of the food	Descriptor	Nutrition content claim conditions
Cholesterol		(a) the food meets the conditions for a nutrition content claim about low saturated fatty acids.
	Low	(a) the food meets the conditions for a nutrition content claim about low saturated fatty acids; and (b) the food contains no more cholesterol than – (i) 10 mg per 100 mL for liquid food; or (ii) 20 mg per 100 g for solid food.
	Reduced or Light/lite	(a) the food meets the conditions for a nutrition content claim about low saturated fatty acids; and (b) the food contains at least 25% less cholesterol than 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 entire claim is presented together.
Dietary fibre		(a) a serving of the food contains at least 2 g of dietary fibre unless the claim is about low or reduced dietary fibre or similar dietary fibre claims.
	Good source	(a) a serving of the food contains at least 4 g of dietary fibre
	Increased	(a) the food contains at least 25% more dietary fibre than the same quantity of reference food; and (b) the reference food meets the conditions for a nutrition content claim about dietary fibre; and (c) 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 (d) the entire claim is presented together.
	Excellent source	(a) a serving of the food contains at least 7 g of dietary fibre.
Energy	Low	(a) the average energy content of the food is no more than – (i) 80 kJ per 100 mL for liquid food; or (ii) 170 kJ per 100 g for solid food.
	Reduced or Light/Lite	(a) the food contains at least 25% less energy than 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 entire claim is presented together.

Table to clause 11 (continued)

Column 1	Column 2	Column 3
Property of the food	Descriptor	Nutrition content claim conditions
	Diet	<p>(a) the food meets the nutrient profiling scoring criteria in Schedule 1 for making a health claim based on the food's nutrient profile; and</p> <p>(b) the food –</p> <p>(i) meets the conditions for a nutrition content claim about low energy; or</p> <p>(ii) contains at least 40% less energy than the same quantity of reference food; and</p> <p>(c) if (b)(ii) applies, the claim states –</p> <p>(i) the identity of the reference food; and</p> <p>(ii) the difference between the energy content of the food and the reference food; and</p> <p>(d) the entire claim is presented together.</p>
Fat	% Free	(a) the food meets the conditions for a nutrition content claim about low fat.
	Low	<p>(a) the food contains no more fat than –</p> <p>(i) 1.5 g per 100 mL for liquid food; or</p> <p>(ii) 3 g per 100 g for solid food.</p>
	Reduced or Light/Lite	<p>(a) the food contains at least 25% less fat than the same quantity of reference food; and</p> <p>(b) the claim states –</p> <p>(i) the identity of the reference food; and</p> <p>(ii) the difference between the fat content of the food and the reference food; and</p> <p>(c) the entire claim is presented together.</p>
Gluten	Free	<p>(a) the food must not contain –</p> <p>(i) detectable gluten; or</p> <p>(ii) oats or their products; or</p> <p>(iii) cereals containing gluten that have been malted, or their products.</p>
	Low	(a) the food contains no more than 20 mg gluten per 100 g of the food.
Glycemic Index		<p>(a) the food meets the nutrient profiling scoring criteria in Schedule 1 for making a health claim based on the food's nutrient profile; and</p> <p>(b) the claim or the nutrition information panel under Standard 1.2.8 includes the numerical value of the glycemic index of the food.</p>
	Low	(a) the numerical value of the glycemic index of the food is indicated at 55 and below.
	Medium	(a) the numerical value of the glycemic index of the food is indicated between 56 and 69.
	High	(a) the numerical value of the glycemic index of the food is indicated at 70 and above.

Table to clause 11 (continued)

Column 1	Column 2	Column 3
Property of the food	Descriptor	Nutrition content claim conditions
Lactose	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
Monounsaturated fatty acids		(a) the food contains, as a proportion of the total fatty acid content – (i) no more than 28% saturated fatty acids and trans fatty acids; and (ii) no less than 40% monounsaturated fatty acids.
	Increased	(a) the food contains, as a proportion of the total fatty acid content – (i) no more than 28% saturated fatty acids and trans fatty acids; and (ii) no less than 40% monounsaturated fatty acids; and (b) the food contains at least 25% more monounsaturated fatty acids than the same quantity of reference food; and (c) the reference food meets the minimum conditions for a nutrition content claim about monounsaturated fatty acids; and (d) the claim states – (i) the identity of the reference food; and (ii) the difference between the monounsaturated fatty acid content of the food and the reference food; and (e) the entire claim is presented together.
Omega fatty acids		(a) the type of omega fatty acid is specified immediately after the word ‘omega’.

Table to clause 11 (continued)

Column 1	Column 2	Column 3
Property of the food	Descriptor	Nutrition content claim conditions
Omega-3 fatty acids		<p>(a) the food meets the conditions for a nutrition content claim about omega fatty acids; and</p> <p>(b) the food contains no less than –</p> <p style="padding-left: 40px;">(i) 200 mg alpha-linolenic acid per serving; or</p> <p style="padding-left: 40px;">(ii) 30 mg total eicosapentaenoic acid and docosahexaenoic acid per serving; and</p> <p>(c) other than for fish or fish products with no added saturated fatty acids, the food contains –</p> <p style="padding-left: 40px;">(i) as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and trans fatty acids; or</p> <p style="padding-left: 40px;">(ii) no more saturated fatty acids and trans fatty acids than 5 g per 100 g; and</p> <p>(d) the nutrition information panel indicates the source and amount of omega-3 fatty acids, that is, alpha-linolenic acid, docosahexaenoic acid or eicosapentaenoic acid.</p>
	Good source	<p>(a) the food meets the conditions for a nutrition content claim about omega fatty acids; and</p> <p>(b) other than for fish or fish products with no added saturated fatty acids, the food contains –</p> <p style="padding-left: 40px;">(i) as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and trans fatty acids; or</p> <p style="padding-left: 40px;">(ii) no more saturated fatty acids and trans fatty acids than 5 g per 100 g; and</p> <p>(c) the nutrition information panel indicates the source and amount of omega-3 fatty acids, that is, alpha-linolenic acid, docosahexaenoic acid or eicosapentaenoic acid; and</p> <p>(d) the food contains no less than 60 mg total eicosapentaenoic acid and docosahexaenoic acid per serving.</p>

Table to clause 11 (continued)

Column 1	Column 2	Column 3
Property of the food	Descriptor	Nutrition content claim conditions
	Increased	<p>(a) the food meets the conditions for a nutrition content claim about omega fatty acids; and</p> <p>(b) the food contains no less than –</p> <p style="padding-left: 40px;">(i) 200 mg alpha-linolenic acid per serving; or</p> <p style="padding-left: 40px;">(ii) 30 mg total eicosapentaenoic acid and docosahexaenoic acid per serving; and</p> <p>(c) other than for fish or fish products with no added saturated fatty acids, the food contains –</p> <p style="padding-left: 40px;">(i) as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and trans fatty acids; or</p> <p style="padding-left: 40px;">(ii) no more saturated fatty acids and trans fatty acids than 5 g per 100 g; and</p> <p>(d) the nutrition information panel indicates the source and amount of omega-3 fatty acids, that is, alpha-linolenic acid, docosahexaenoic acid or eicosapentaenoic acid; and</p> <p>(e) the food contains at least 25% more omega-3 fatty acids than the same quantity of reference food; and</p> <p>(f) the reference food meets the minimum conditions for a nutrition content claim about omega-3 fatty acids; and</p> <p>(g) the claim states –</p> <p style="padding-left: 40px;">(i) the identity of the reference food; and</p> <p style="padding-left: 40px;">(ii) the difference between the omega-3 fatty acid content of the food and the reference food; and</p> <p>(h) the entire claim is presented together.</p>
Omega-6 fatty acids		<p>(a) the food meets the conditions for a nutrition content claim about omega fatty acids; and</p> <p>(b) the food contains, as a proportion of the total fatty acid content –</p> <p style="padding-left: 40px;">(i) no more than 28% saturated fatty acids and trans fatty acids; and</p> <p style="padding-left: 40px;">(ii) no less than 40% omega-6 fatty acids.</p>

Table to clause 11 (continued)

Column 1	Column 2	Column 3
Property of the food	Descriptor	Nutrition content claim conditions
	Increased	<p>(a) the food meets the conditions for a nutrition content claim about omega fatty acids; and</p> <p>(b) the food contains, as a proportion of the total fatty acid content –</p> <p style="padding-left: 20px;">(i) no more than 28% saturated fatty acids and trans fatty acids; and</p> <p style="padding-left: 20px;">(ii) no less than 40% omega-6 fatty acids.</p> <p>(c) the food contains at least 25% more omega-6 fatty acids than the same quantity of reference food; and</p> <p>(d) the reference food meets the minimum conditions for a nutrition content claim about omega-6 fatty acids; and</p> <p>(e) the claim states –</p> <p style="padding-left: 20px;">(i) the identity of the reference food; and</p> <p style="padding-left: 20px;">(ii) the difference between the omega-6 fatty acid content of the food and the reference food; and</p> <p>(f) the entire claim is presented together.</p>
Omega-9 fatty acids		<p>(a) the food meets the conditions for a nutrition content claim about omega fatty acids; and</p> <p>(b) the food contains, as a proportion of the total fatty acid content –</p> <p style="padding-left: 20px;">(i) no more than 28% saturated fatty acids and trans fatty acids; and</p> <p style="padding-left: 20px;">(ii) no less than 40% omega-9 fatty acids.</p>
	Increased	<p>(a) the food meets the conditions for a nutrition content claim about omega fatty acids; and</p> <p>(b) the food contains, as a proportion of the total fatty acid content –</p> <p style="padding-left: 20px;">(i) no more than 28% saturated fatty acids and trans fatty acids; and</p> <p style="padding-left: 20px;">(ii) no less than 40% omega-9 fatty acids</p> <p>(c) the food contains at least 25% more omega -9 fatty acids than the same quantity of reference food; and</p> <p>(d) the reference food meets the minimum conditions for a nutrition content claim in relation to omega-9 fatty acids; and</p> <p>(e) the claim states –</p> <p style="padding-left: 20px;">(i) the identity of the reference food; and</p> <p style="padding-left: 20px;">(ii) the difference between the omega-9 fatty acid content of the food and the reference food; and</p> <p>(f) the entire claim is presented together.</p>

Table to clause 11 (continued)

Column 1	Column 2	Column 3
Property of the food	Descriptor	Nutrition content claim conditions
Polyunsaturated fatty acids		<p>(a) the food contains, as a proportion of the total fatty acid content –</p> <p>(i) no more than 28% saturated fatty acids and trans fatty acids; and</p> <p>(ii) no less than 40% polyunsaturated fatty acids.</p>
	Increased	<p>(a) the food contains, as a proportion of the total fatty acid content –</p> <p>(i) no more than 28% saturated fatty acids and trans fatty acids; and</p> <p>(ii) no less than 40% polyunsaturated fatty acids; and</p> <p>(b) the food contains at least 25% more polyunsaturated fatty acids than the same quantity of reference food; and</p> <p>(c) the reference food meets the minimum conditions for a nutrition content claim about polyunsaturated fatty acids; and</p> <p>(d) the claim states –</p> <p>(i) the identity of the reference food; and</p> <p>(ii) the difference between the polyunsaturated fatty acid content of the food and the reference food; and</p> <p>(e) the entire claim is presented together.</p>
Potassium		(a) the nutrition information panel indicates the sodium and potassium content.
Protein		(a) the food contains at least 5 g of protein per serving unless the claim is about low or reduced protein or similar protein claims.
	Good source	(a) the food contains at least 10 g of protein per serving.
	Increased	<p>(a) the food contains at least 25% more protein than the same quantity of reference food; and</p> <p>(b) the reference food meets the conditions for a nutrition content claim about protein; and</p> <p>(c) the claim states –</p> <p>(i) the identity of the reference food; and</p> <p>(ii) the difference between the protein content of the food and the reference food; and</p> <p>(d) the entire claim is presented together.</p>

Table to clause 11 (continued)

Column 1	Column 2	Column 3
Property of the food	Descriptor	Nutrition content claim conditions
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; or (ii) 120 mg per 100 g for solid food.
	Reduced or Light/Lite	(a) the food contains at least 25% less sodium than 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 or salt content of the food and the reference food; and (c) the entire claim is presented together.
	No added	(a) the food contains no added sodium compound including no added salt; and (b) the ingredients of the food contain no added sodium compound including no added salt.
	Unsalted	(a) the food meets the conditions for a nutrition content claim about no added salt.
Saturated and trans fatty acids	Low	(a) the food contains no more saturated and trans fatty acids than – (i) 0.75 g per 100 mL for liquid food; or (ii) 1.5 g per 100 g for solid food.
	Reduced or Light/Lite	(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 entire claim is presented together.
	Low proportion	(a) the food contains as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and trans fatty acids; and (b) the claim expressly states in words to the effect of “low proportion of saturated and trans fatty acids of total fatty acid content”.

Table to clause 11 (continued)

Column 1	Column 2	Column 3
Property of the food	Descriptor	Nutrition content claim conditions
Saturated fatty acids	Free	(a) the food contains no detectable saturated fatty acids; and (b) the food contains no detectable trans fatty acids.
	Low	(a) the food contains no more saturated and trans fatty acids than – (i) 0.75 g per 100 mL for liquid food; or (ii) 1.5 g per 100 g for solid food.
	Reduced or Light or Lite	(a) the food contains – (i) at least 25% less saturated fatty acids than the same quantity of reference food; and (ii) no more trans fatty acids than 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 entire claim is presented together.
	Low proportion	(a) the food contains as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and trans fatty acids; and (b) the claim expressly states in words to the effect of “low proportion of saturated fatty acids of total fatty acid content”.
Trans fatty acids	Free	(a) the food contains no more saturated fatty acids than – (i) 0.75 g per 100 mL of liquid food; or (ii) 1.5 g per 100 g of solid food; and (b) the food contains as a proportion of the total fatty acid content, no more than 28% saturated fatty acids; and (c) the food contains no detectable trans fatty acids
	Reduced or Light/Lite	(a) the food contains – (i) at least 25% less trans fatty acids than the same quantity of reference food; and (ii) the food contains no more saturated fatty acids 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 trans fatty acid content of the food and the reference food; and (c) the entire claim is presented together.

Table to clause 11 (continued)

Column 1	Column 2	Column 3
Property of the food	Descriptor	Nutrition content claim conditions
Sugar or Sugars	% Free	(a) the food meets the conditions for a nutrition content claim about low sugar.
	Low	(a) the food contains no more sugars as standardised in clause 1 of Standard 1.2.8 than – (i) 2.5 g per 100 mL for liquid food; or (ii) 5 g per 100 g for solid food.
	Reduced or Light/Lite	(a) the food contains at least 25% less sugars as standardised in clause 1 of Standard 1.2.8 than 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 entire claim is presented together
	No added	(a) the food contains no added sugars as standardised in clause 1 of Standard 2.8.1, honey, malt, malt extracts; and (b) the food contains no added concentrated fruit juice or deionised fruit juice, unless the food is standardised in Standards 2.6.1 or 2.6.2.
	Unsweetened	(a) the food meets the conditions for a nutrition content claim about 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 mentioned in column 1 of the Schedule to Standard 1.1.1; and (b) a serving of the food contains at least 10% of the RDI or ESADDI, for that vitamin or mineral; and (c) the claim meets the conditions, if any, in clause 4 of Standard 1.3.2.
	Good source	(a) the vitamin or mineral is mentioned in column 1 of the Schedule to Standard 1.1.1; and (b) a serving of the food contains no less than 25% of the RDI or ESADDI for that vitamin or mineral; and (c) the claim meets the conditions, if any, in clause 4 of Standard 1.3.2.

12 Conditions for making specific general level health claims

A general level health claim that refers directly or indirectly to a matter mentioned in column 1 of the Table to this clause may be made, if the claim meets the conditions in column 2 of the Table to this clause.

Table to clause 12

Column 1	Column 2
General level health claim	General level health claim conditions
Biologically active substance	<p>(a) the claim states –</p> <ul style="list-style-type: none"> (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 health effect; and <p>(b) a serve of the food contains at least 10% of the amount mentioned in subparagraph (a)(ii).</p>
Maternal folic acid consumption for normal foetal development	<p>(a) the food contains no less than 40µg folic acid per serving; and</p> <p>(b) the food is not –</p> <ul style="list-style-type: none"> (i) soft cheese; or (ii) pâté; or (iii) liver or liver product; or (iv) foods containing added phytosterol esters or added tall oil phytosterols; or (v) food standardised in Standard 2.6.4; or (vi) food standardised in Part 2.7; or (vii) food standardised in Standards 2.9.2 or 2.9.4; or (viii) a formulated meal replacement standardised in Division 2 of Standard 2.9.3; and <p>(c) the claim states that the context is a varied diet including food sources of folate and a recommendation that women consume at least 400 µg of folic acid per day, at least the month before and three months after conception.</p>
Weight loss or maintenance	<p>(a) the food –</p> <ul style="list-style-type: none"> (i) meets the conditions for making a low energy claim mentioned in the Table to clause 11; or (ii) contains at least 40% less energy as the same quantity of reference food, and <p>(b) if subparagraph (a)(ii) applies, the claim states –</p> <ul style="list-style-type: none"> (i) the identity of the reference food; and (ii) the difference between the energy content of the food and the reference food; and <p>(c) the claim states that the specific health effect must be considered in the context of the importance of regular exercise.</p>
Whole grain	<p>(a) the claim states –</p> <ul style="list-style-type: none"> (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 health effect; and <p>(b) a serve of the food contains at least 10% of the amount mentioned in subparagraph (a)(ii).</p>

SCHEDULE 1

NUTRIENT PROFILING SCORING CRITERIA

Part A – Preliminary

To determine if a food product meets the nutrient profiling scoring criteria to be eligible to carry a health claim, glycemic index claim or a diet claim, the following steps must be taken under the following Parts in Table 1–

Table 1

Part	Steps
Part B	For all food products — determine the category of food product.
Part C	For Category 1 and 2 food products – (a) calculate baseline points; (b) calculate the fruit and vegetable points (V points); (c) calculate protein points (P points); (d) calculate fibre points (F points); (e) calculate final score.
Part D	For Category 3 food products – (a) calculate baseline points; (b) calculate the fruit and vegetable points (V points); (c) calculate protein points (P points); (d) calculate fibre points (F points); (e) calculate final score.
Part E	For all food products assess the final score to determine if the food meets the scoring criteria.

Part B – Determine the category of food product

Use Table 2 to determine the applicable category of food product.

Table 2

Category	Food product
Category 1	Beverages
Category 2	Foods other than those included in Category 1 or 3.
Category 3	(a) cheese and processed cheese as defined in Standard 2.5.4 (with calcium content >320 mg/100 g); and (b) edible oil as defined in Standard 2.4.1; and (c) edible oil spreads as defined in Standard 2.4.2; and (d) margarine as defined in Standard 2.4.2; and (e) butter as defined in Standard 2.5.5 All other cheeses (with calcium content ≤320 mg/100g) are classified as a category 2 food product.

Part C – Calculate points for Category 1 and 2 food products

STEP 1 – BASELINE POINTS

1.1 Use the formula in clause 1.3 and the information in Table 3 to work out the baseline points (up to 10 for each nutrient), for the content of each nutrient in 100 g or 100 mL of the food product (based on the units used in the nutrition information panel).

1.2 The information mentioned in Table 3 must be worked out in accordance with the Table to clause 6 of this Standard.

Table 3

Baseline points	Average energy content (kJ) per 100 g/100 mL	Saturated fatty acids (g) per 100 g/100 mL	Total sugars (g) per 100 g/100 mL	Sodium (mg) per 100 g/100 mL
0	≤335	≤1.0	≤5.0	≤90
1	>335	>1.0	>5.0	>90
2	>670	>2.0	>9.0	>180
3	>1005	>3.0	>13.5	>270
4	>1340	>4.0	>18.0	>360
5	>1675	>5.0	>22.5	>450
6	>2010	>6.0	>27.0	>540
7	>2345	>7.0	>31.0	>630
8	>2680	>8.0	>36.0	>720
9	>3015	>9.0	>40.0	>810
10	>3350	>10.0	>45.0	>900

1.3 Calculate the baseline points using the following formula:

$\text{Total baseline points} = (\text{points for average energy content}) + (\text{points for saturated fatty acids}) + (\text{points for total sugars}) + (\text{points for sodium})$

STEP 2 – CALCULATE FRUIT AND VEGETABLE POINTS (V POINTS)

2.1 V points can be scored for –

- (a) fruits, vegetables, nuts and legumes including coconut, spices, herbs, fungi, seeds and algae (*fvl*).
- (b) *fvl* that are fresh, cooked, frozen, tinned, pickled or preserved.
- (c) *fvl* that have been peeled, reduced in size, puréed or dried.
- (d) fruit juice or vegetable juice as standardised in Standard 2.6.1 including concentrated juices and purees.

2.2 V points cannot be scored for –

- (a) a constituent or extract of the food mentioned in clause 2.1 (e.g. oil derived from peanuts).
- (b) food mentioned in clause 2.1, if the edible portion is not present in a typical proportion of the food (e.g. fruit, where the fibre has been removed).
- (c) cereal grains mentioned as a class of food in Schedule 4 of Standard 1.4.2.

Examples

A 100% spreadable fruit jam (ingredients figs (55%), de-ionised grape juice, fruit pectin and lemon juice) cannot score the maximum V points, as V points cannot be scored for deionised fruit juice and fruit pectin.

2.3 For coconut –

- (a) the coconut flesh can be scored as nut; and
- (b) the water in the centre of the coconut can be scored as 100% fruit juice; and
- (c) V points cannot be scored for coconut that is processed beyond the original product being juiced or dried (e.g. coconut cream, coconut milk, copha).

2.4 Calculate the percentage of *fvnl* in the food in accordance with the appropriate method in Standard 1.2.10.

2.5 Use Column 1 of Table 4 if the fruit or vegetables in the food product are all concentrated (including dried).

Example

If dried fruit and tomato paste are the components of the food product for which V points can be scored, column 1 should be used.

2.6 Use Column 2 of Table 4 if –

- (a) there are no concentrated (or dried) fruit or vegetables in the food product;
or
- (b) the percentage of all concentrated ingredients are calculated based on the ingredient when reconstituted (according to subclauses 3(3) or (4) of Standard 1.2.10); or
- (c) the food product contains a mixture of concentrated and not concentrated *fvnl* sources (after following the formula mentioned in clause 2.8); or
- (d) the food product is potato crisps or a similar low moisture vegetable product.

2.7 Work out the V points (to a maximum of 8) in accordance with Table 4 –

Table 4

	Column 1	Column 2
Points	% concentrated fruit or vegetable	% <i>fvl</i>
0	<25	≤40
1	≥25	>40
2	≥43	>60
5	≥67	>80
8	=100	=100

2.8 If the food product contains a mixture of concentrated and non concentrated *fvl* sources, the percentage must be worked out as follows –

$$\frac{(\% \text{ non concentrated } fvl) + (2 \times \% \text{ concentrated } fvl)}{(\% \text{ non concentrated } fvl) + (2 \times \% \text{ concentrated } fvl) + \% \text{ non } fvl \text{ ingredient}} \times \frac{100}{1}$$

where –

% non concentrated/concentrated *fvl* means the percentage of *fvl* in the food determined using the appropriate calculation methods outlined in Standard 1.2.10.

fvl means fruits, vegetables, nuts, and legumes including coconut, spices, herbs, fungi, seeds and algae.

2.9 For the formula in clause 2.8, potato crisps and similar low moisture vegetable products are taken to be non-concentrated.

STEP 3 – CALCULATE PROTEIN POINTS (P POINTS)

3.1 Use Table 5 to determine the ‘P Points’ scored, depending on the amount of protein in the food product. A maximum of five points can be awarded.

3.2 Food products that score ≥13 baseline points are not permitted to score points for protein unless they score five or more points for *fvl*.

Table 5

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

STEP 4 – CALCULATE FIBRE POINTS (F POINTS)

4.1 Use Table 6 to determine the ‘F Points’ scored, depending on the amount of dietary fibre in the food product. A maximum of five points can be awarded.

4.2 The prescribed method of analysis to determine total dietary fibre is outlined in clause 12 of Standard 1.2.8.

Table 6

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

STEP 5 – CALCULATE FINAL SCORE

5.1 Calculate the final score using the following formula:

$$\text{Final Score} = \text{baseline points} - (\text{V points}) - (\text{P points}) - (\text{F points})$$

5.2 Determine whether the food product meets the nutrient profiling scoring criteria set out in Table 8 in Part E in order to be eligible to carry a health claim, glycemic index claim or diet claim.

PART D – Calculate points for category 3 food products

Part D is to be completed for category 3 food products only.

STEP 1 – CALCULATE BASELINE POINTS

1.1 Use the formula in clause 1.2 and the information about the content of each nutrient in 100 g or 100 mL of the food product mentioned in Table 7, to determine the baseline points scored.

Table 7

Points	Average energy content (kJ) per 100 g or 100 mL	Saturated fatty acids (g) per 100 g or 100 mL	Total sugars (g) per 100 g or 100 mL	Sodium (mg) per 100 g or 100 mL
0	≤ 335	≤1.0	≤ 5.0	≤ 90
1	>335	>1.0	>5.0	>90
2	>670	>2.0	>9.0	>180
3	>1005	>3.0	>13.5	>270
4	>1340	>4.0	>18.0	>360
5	>1675	>5.0	>22.5	>450
6	>2010	>6.0	>27.0	>540
7	>2345	>7.0	>31.0	>630
8	>2680	>8.0	>36.0	>720
9	>3015	>9.0	>40.0	>810
10	>3350	>10.0	>45.0	>900
11	>3685	>11.0		>990
12		>12.0		>1080
13		>13.0		>1170
14		>14.0		>1260
15		>15.0		>1350
16		>16.0		>1440
17		>17.0		>1530
18		>18		>1620
19		>19.0		>1710
20		>20.0		>1800
21		>21.0		>1890
22		>22.0		>1980
23		>23.0		>2070
24		>24.0		>2160
25		>25.0		>2250
26		>26.0		>2340
27		>27.0		>2430
28		>28.0		>2520
29		>29.0		>2610
30		>30.0		>2700

1.2 Calculate the baseline points using the following formula:

$\text{Total baseline points} = (\text{points for average energy content}) + (\text{points for saturated fatty acids}) + (\text{points for total sugars}) + (\text{points for sodium})$

STEP 2 – CALCULATE FRUIT AND VEGETABLE POINTS (V POINTS)

Use the clauses in step 2 of Part C to calculate the fruit and vegetable points.

STEP 3 – CALCULATE PROTEIN POINTS (P POINTS)

Use the clauses in step 3 of Part C to calculate protein points.

STEP 4 – CALCULATE FIBRE POINTS (F POINTS)

Use the clauses in step 4 of Part C to calculate fibre points.

STEP 5 – CALCULATE FINAL SCORE

5.1 Calculate the final score using the following formula:

$$\text{Final Score} = \text{baseline points} - (\text{V points}) - (\text{P points}) - (\text{F points})$$

5.2 Determine whether the food product meets the nutrient profiling scoring criteria set out in Table 8 in Part E in order to be eligible to carry a health claim, glycemic index claim or diet claim.

PART E – Assessment of the Final Score

Use Table 8 to compare the final score to ascertain if the food product meets the nutrient profiling scoring criteria, in order to be eligible to carry a health claim, glycemic index claim or diet claim.

Table 8

Food product	Final score	Meets the nutrient profiling scoring criteria to make a health claim, glycemic index claim or diet claim
Category 1	< 1	Yes
Category 2	< 4	Yes
Category 3	< 28	Yes

SCHEDULE 2

SCIENTIFIC SUBSTANTIATION FRAMEWORK

Methods for Substantiation

This Schedule describes the approach to scientific substantiation of food-health relationships that are proposed to form the subject of a general level health claim. Substantiation is the process of deciding whether a body of scientific evidence supports a relationship between food or a property of the food and a health effect. The Scientific Substantiation Framework is referred to in paragraph 6(1)(b) of this Standard.

Any one of the following four methods may be used to substantiate a general level health claim:

- Method 1 List of nutrient function statements.
- Method 2 Prescribed list of pre-approved food-disease relationships for high level health claims.
- Method 3 Prescribed list of authoritative sources.
- Method 4 Systematic review.

1. Method 1 – List of nutrient function statements

1.1 The nutrient function statements mentioned in Table 1 may be used as the basis of a general level health claim.

1.2 The wording of the nutrient function statement is not prescribed for the purpose of making a claim, however, the general level health claim must be consistent with the scientific intent of the nutrient function statement.

Table 1

Nutrient	Nutrient function statement
Vitamin A	Vitamin A is necessary for normal vision
Vitamin D	Vitamin D is necessary for the normal absorption and utilisation of calcium and phosphorus
Vitamin E	Vitamin E is necessary for cell protection from the damage caused by free radicals (such as oxidation of polyunsaturated fatty acids in red blood cell membranes)
Vitamin K	Vitamin K is necessary for normal coagulation (blood clotting)
Thiamin	Thiamin is necessary for the normal metabolism of carbohydrates
Riboflavin	Riboflavin contributes to the normal release of energy from food
Niacin	Niacin is necessary for the normal release of energy from food
Pantothenic acid	Pantothenic acid is necessary for the normal metabolism of fat
Vitamin B ₆	Vitamin B ₆ is necessary for the normal metabolism of protein
Folate	Folate is necessary for normal blood formation
Vitamin B ₁₂	Vitamin B ₁₂ contributes to normal blood formation
Biotin	Biotin contributes to normal fat metabolism and energy production
Vitamin C	Vitamin C is necessary for normal structure and function of connective tissue (such as that required for normal gums, skin, healing processes, bone and cartilage)
Calcium	Calcium is necessary for normal structure of bones and teeth
Magnesium	Magnesium is necessary for normal energy metabolism
Iron	Iron contributes to normal blood formation

Table 1 (continued)

Nutrient	Nutrient function statement
Copper	Copper is necessary for the normal function of the immune system
Iodine	Iodine is necessary for normal production of thyroid hormones
Iodine	Iodine is necessary for normal brain development in the unborn child, babies and young children
Zinc	Zinc contributes to the normal structure of skin and normal wound healing
Manganese	Manganese contributes to normal bone function
Phosphorus	Phosphorus is necessary for the normal structure of bone and teeth
Selenium	Selenium is necessary for cell protection from some types of damage caused by free radicals
Protein	Protein helps to build and repair body tissues
Dietary fibre	Dietary fibre contributes to regular laxation

2. Method 2 Prescribed list of pre-approved food-disease relationships for high level health claims

2.1 The food-disease relationship supporting a pre-approved high level health claim may be used as the basis of a general level health claim. However, no reference must be made to the disease or biomarker in the general level health claim. For example, the general level health claim may refer to the benefit of fruit and vegetables and heart health, not coronary heart disease.

2.2 The food-disease relationships mentioned in Table 2 are taken from the pre-approved high level health claims mentioned in the Table to clause 7 of this Standard.

Table 2

Specifically characterised diet, food or food component	Disease/biomarker	Association
Calcium (with or without vitamin D)	Osteoporosis	Inverse
Calcium	Bone density	Positive
Folic acid	Neural tube defects	Inverse
Saturated fatty acids	Low density lipoprotein cholesterol	Positive
Saturated and <i>trans</i> fatty acids	Low density lipoprotein cholesterol	Positive
Sodium	Blood pressure	Positive
Increased intake of Fruits and vegetables	Coronary heart disease	Inverse
High intake of fruit and vegetables	Coronary heart disease	Inverse

3. Method 3 Prescribed list of authoritative sources

3.1 Subject to subclause 3.2, the food-health relationship that is the basis of a general level health claim can be substantiated using the authoritative sources mentioned in Table 3.

3.2 The following paragraphs apply in order to substantiate the general level health claim using the authoritative sources mentioned in Table 3 –

- (a) The most recent version of the scientific source documents mentioned in Table 3 must be used at the time that the claim is made.
- (b) If the authoritative source originates external to Australia and New Zealand, the food-health relationship must be capable of being generalised to the Australian and New Zealand populations.

- (c) The food-health relationship must be confident and definitive and not rely on qualified, equivocal or unsupportive evidence.

Table 3

Authoritative sources
Nutrient Reference Values for Australia and New Zealand, National Health and Medical Research Council and New Zealand Ministry of Health. (http://www.nhmrc.gov.au/publications/synopses/n35syn.htm)
Health Canada. Health claims that meet Significant Scientific Agreement. (http://www.hc-sc.gc.ca/)
Institute of Medicine Dietary Reference Intake series. (http://www.iom.edu/CMS/3788/4574/45127.aspx)
The United States Food and Drug Administration: Health Claims that meet Significant Scientific Agreement. (http://www.cfsan.fda.gov/~dms/lab-ssa.html)
The United States Food and Drug Administration: Health claims approved under the <i>Food and Drug Administration Modernization Act of 1997</i> (FDAMA claims). (http://www.cfsan.fda.gov/~dms/labfdama.html)
The Cochrane Database of Systematic Reviews. (http://www.mrw.interscience.wiley.com/cochrane/cochrane_clsystrev_subjcts_fs.html)
The UK Joint Health Claims Initiative. (http://www.jhci.org.uk/)

4. Method 4 Systematic Review

4.1 A systematic review can be used to substantiate a general level health claim instead of methods 1, 2 or 3.

4.2 To substantiate the general level health claim the following applies –

- (a) If mechanistic, laboratory and animal evidence is available this must be generally supportive of the human food-health relationship.
- (b) If the food-health relationship is found in people from countries other than Australia and New Zealand, the relationship must be able to be generalised to the Australian and New Zealand populations.

4.3 The process of conducting a systematic review requires the following steps to be satisfied –

- Step 1 Develop a comprehensive search strategy that captures all of the evidence relevant to the food-health relationship.

- Step 2 Categorise studies into groups comprising experimental (interventional) studies of humans, observational studies of humans, systematic reviews and supporting evidence (animal and *in vitro* studies). Reviews are not limited to articles published in peer reviewed scientific journals and can include reports or position papers prepared by government or non government entities.
- Step 3 Assess study quality based on a number of factors. The study must have a clearly stated hypothesis and minimise bias and control confounding. Substantiation must be based on human data, preferably including intervention studies, the design of which includes –
- (i) Study groups that are representative of the proposed target group.
 - (ii) An appropriate control group.
 - (iii) Durations of exposure and follow-up adequate to demonstrate the intended health effect.
 - (iv) An assessment of the participants' background diets and other relevant aspects of lifestyle.
 - (v) Monitoring of participants' compliance concerning intake of food or food component under test.
 - (vi) The statistical power to test the hypothesis.
- Step 4 Interpret the results of individual studies by completing the following:
- (i) assess the relationship between the exposure and outcome under the study conditions, and
 - (ii) consider the relationship in the context of the effect in the general population or relevant subgroups within the population, and
 - (iii) assess the change in the outcome parameter which must be statistically significant and biologically meaningful for the target group consistent with the claim.
- Step 5 In order to assess the totality of scientific evidence to evaluate the weight of evidence supporting a food-health relationship, the following applies –
- (i) the evidence must support a consistent association between the property of a food and the claimed health effect, and
 - (ii) the evidence must comprise a number of supportive, acceptable quality human studies preferably including some experimental studies, and
 - (iii) the evidence must support a food-health relationship that is biologically plausible, and
 - (iv) there must be a causal relationship in which it is shown that consumption of a diet, food or component causes the health effect independent of other factors, and
 - (v) to assess causality and the weight of evidence, most weight is given to well-designed experimental studies in humans.

SCHEDULE 3

HOSPITALS AND SIMILAR INSTITUTIONS

Column 1	Column 2
Facility	Definition
Acute care hospitals	<p>Establishments which provide at least minimal medical, surgical or obstetric services for inpatient treatment or care, and which provide round-the-clock comprehensive qualified nursing services as well as other necessary professional services. Most patients have acute conditions or temporary ailments and the average stay per admission is relatively short. Acute care hospitals include:</p> <ul style="list-style-type: none"> (a) Hospitals specialising in dental, ophthalmic aids and other specialised medical or surgical care; (b) Public acute care hospitals; (c) Private acute care hospitals; (d) Veterans' Affairs hospitals.
Psychiatric hospitals	<p>Establishments devoted primarily to the treatment and care of inpatients with psychiatric, mental or behavioural disorders including any:</p> <ul style="list-style-type: none"> (a) Public psychiatric hospital; (b) Private psychiatric hospital.
Nursing homes for the aged	<p>Establishments which provide long-term care involving regular basic nursing care to aged persons and including any:</p> <ul style="list-style-type: none"> (a) Private charitable nursing home for the aged; (b) Private profit nursing home for the aged; (c) Government nursing home for the aged.
Hospices	<p>Freestanding establishments providing palliative care to terminally ill patients, including any:</p> <ul style="list-style-type: none"> (a) Public hospice; (b) Private hospice.

Schedule (continued)

Column 1	Column 2
Facility	Definition
Same day establishments for chemotherapy and renal dialysis services	<p>Including both the traditional day centre/hospital that provides chemotherapy and/or renal dialysis services and also freestanding day surgery centres that provide chemotherapy and/or renal dialysis services including any:</p> <ul style="list-style-type: none"> (a) Public day centre/hospital (b) Public freestanding day surgery centre (c) Private day centre/hospital (d) Private freestanding day surgery centre that provides those services. <p>Day centres/ hospitals are establishments providing a course of acute treatment on a full-day or part-day non- residential attendance basis at specified intervals over a period of time.</p> <p>Freestanding day surgery centres are hospital facilities providing investigation and treatment for acute conditions on a day-only basis.</p>
Respite care establishments for the Aged	Establishments which provide short-term care including personal care and regular basic nursing care to aged persons.
Same – day aged care establishments	Establishments where aged persons attend for day or part-day rehabilitative or therapeutic treatment.
Low care aged care establishments	Establishments where aged persons live independently but on-call assistance, including the provision of meals, is provided if needed.
Child care centres	<p>A facility which is not a private residential dwelling and is designated for the purpose of childcare and provides long day care, employer sponsored childcare, or occasional care, for children four years of age or less, but does not include the following:</p> <ul style="list-style-type: none"> (a) a service for providing preschool education conducted by a school; (b) a service principally conducted to provide: <ul style="list-style-type: none"> (i) therapeutic services; (ii) residential facilities; (iii) instruction in a particular activity e.g. dance, music or a sport; (iv) tutoring, coaching or religious instruction; (v) a recreational activity, for example, a camp or party. (c) a service for which, ordinarily, the children in care are entirely or mostly different on each occasion child care is provided, for example, resort care for children of guests of the resort.

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

[3.1] *omitting the Purpose, substituting –*

This Standard sets out nutrition information requirements in relation to food that is required to be labelled under this Code and for food exempt from these labelling requirements. This Standard prescribes when nutritional information must be provided, and the manner in which such information is provided. Standard 1.2.7 – Nutrition, Health and Related Claims also sets out additional nutrition information requirements in relation to nutrition content claims and health claims.

This Standard does not apply to infant formula products standardised in Standard 2.9.1 – Infant Formula Products. Standard 2.9.1 sets out specific nutrition labelling requirements that apply to infant formula products.

[3.2] *omitting from clause 1 the definition average energy content substituting –*

average energy content has the meaning given by clause 1B.

[3.3] *inserting after clause 1 –*

1A Unless the contrary intention appears, the definitions in Standard 1.2.7 apply in this Standard.

[3.4] *inserting after clause 1A –*

1B **average energy content** is worked out as follows –

- (a) multiply the average amount of each food component per 100 g of the food by the energy factor for that food component;
- (b) add the amounts calculated for each food component using the following formula:

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

Where:

W_i means the average weight of the food component (g/100 g food).

F_i means the energy factor assigned to that food component (kJ/g).

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

[3.6] *omitting clause 4 substituting –*

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

(1) Where a nutrition content claim or health claim is made the following conditions must be met–

- (a) a nutrition information panel is included on the label on the package of the food; and
- (b) if the nutrition information panel includes percentage daily intake information, the information meets the requirements of clause 7.

(2) A nutrition content claim or health claim about a food not required to bear a label under clause 2 of Standard 1.2.1, may be made only if the information mentioned in clauses 5 and 7A is provided –

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

(3) If a nutrition content claim or health claim is made about a food in a small package, the conditions mentioned in clause 8 must be met.

[3.7] *omitting the nutrition information panel following subclause 5(1), substituting –*

NUTRITION INFORMATION		
Servings per package: (insert number of servings)		
Serving size: g (or mL or other units as appropriate)		
	Quantity per Serving	Quantity per 100 g (or 100 mL)
Energy	kJ (Cal)	kJ (Cal)
Protein	g	g
Fat, total	g	g
– saturated	g	g
Carbohydrate	g	g
– sugars	g	g
Sodium	mg (mmol)	mg (mmol)
(insert any other nutrient , biologically active substance to be declared)	g, mg, µg (or other units as appropriate)	g, mg, µg (or other units as appropriate)
reference to glycemic index, if not in the claim		

[3.8] *omitting from paragraph 5(1)(e) subject to clause 12,*

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

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

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

(2A) For foods that have compositional requirements in Standards 2.4.1 or 2.4.2, the quantity of saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids and trans fatty acids may be set out in the panel as a minimum or maximum quantity in a serving of the food and per 100 g/mL.

[3.11] *omitting from subclause 5(8) clause 18, substituting clause 12*

[3.12] *inserting after subclause 5(8) –*

(9) Less than 2g of dietary fibre may be declared in a nutrition information panel and is taken not to constitute a nutrition content claim.

[3.13] *omitting clause 7 substituting –*

7 Percentage daily intake information

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

(2) If percentage daily intake information is included in a nutrition information panel the following matters must be included in the panel –

- (a) the percentage daily intake of energy, protein, fat, saturated fatty acids, carbohydrate, sugars, and sodium per serving; 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’

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

(4) If percentage daily intake of energy, protein, fat, saturated fatty acids, carbohydrate, sugars, and sodium per serving is set out in the panel –

- (a) percentage daily intake of energy, protein, fat, saturated fatty acids, carbohydrate, sugars, and sodium per serving including the serving size may also be presented in one place outside the panel; or
- (b) the percentage daily intake of energy per serving including the serving size may be presented in one place outside the panel.

(5) Percentage daily intake of nutrients and energy that is presented outside a nutrition information panel under subclause (4) is taken not to constitute a nutrition content claim.

(6) The percentage daily intake of nutrients and energy for food, that contains more than 1.15% alcohol by volume, may not be presented outside the nutrition information panel.

(7) The percentage daily intake values must be calculated based on the nutrient values mentioned in the nutrition information panel.

Editorial note:

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

EXAMPLES

NUTRITION INFORMATION			
Servings per package: (insert number of servings)			
Serving size: g (or mL or other units as appropriate)			
	Quantity per Serving	% Daily Intake* (per Serving)	Quantity per 100 g (or 100 mL)
Energy	kJ (Cal)	%	kJ (Cal)
Protein	g	%	g
Fat, total	g	%	g
– saturated	g	%	g
Carbohydrate	g	%	g
– sugars	g	%	g
Sodium	mg (mmol)	%	mg (mmol)
(insert any other nutrient or biologically active substance to be declared)	g, mg, µg (or other units as appropriate)	%	g, mg, µg (or other units as appropriate)
*based on an average adult diet of 8700 kJ			
reference to glycemic index, if not in the claim			

NUTRITION INFORMATION		
Servings per package: (insert number of servings)		
Serving size: g (or mL or other units as appropriate)		
	Quantity per Serving	Quantity per 100 g (or 100 mL)
Energy	kJ (Cal) (%DI*)	kJ (Cal)
Protein	g (%DI)	g
Fat, total	g (%DI)	g
– saturated	g (%DI)	g

Carbohydrate	g (%DI)	g
– sugars	g (%DI)	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		
Reference to glycemic index, if not in claim		

(8) The percentage daily intakes of a food component mentioned in Column 1 of the Table to this subclause, that is included in the nutrition information panel, must be calculated using the corresponding reference value mentioned in Column 2.

Table to subclause 7(8)

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

7A Percentage Recommended Dietary Intake

- (1) If a nutrition content claim or health claim is made about the presence of a vitamin or mineral, the percentage RDI, where applicable, of that vitamin or mineral contributed by one serving of food must be set out in a nutrition information panel.
- (2) The percentage RDI of a vitamin or mineral that is included in the panel must be calculated –
 - (a) using the reference values mentioned in the Schedule to Standard 1.1.1; and
 - (b) using the nutrient values set out in the nutrition information panel.
- (3) Percentage RDI of a vitamin or mineral included in a nutrition information panel, may also be presented outside the panel if the information including the serving size is presented together.
- (4) Percentage RDI of a vitamin or mineral that is presented outside a nutrition information panel under subclause (3) is taken not to constitute a nutrition content claim.
- (5) Percentage RDI of a vitamin or mineral for food that contains more than 1.15% alcohol by volume, may not be presented outside the nutrition information panel.

Editorial note:

For nutrition content claims and health claims about vitamins and minerals for which an ESADDI has been prescribed in the Schedule to Standard 1.1.1, the average quantity of the vitamin or mineral per serving and per 100 g/mL of the food must be set out in the nutrition information panel.

[3.14] *omitting clause 8 substituting –*

8 Food in small packages

(1) If a nutrition content claim or health claim is made about a food in a small package clause 7 applies and the following conditions must be met –

- (a) the label must include a declaration of the name and the average quantity of energy, any nutrient or biologically active substance in respect of which a nutrition content claim or health claim is made, expressed in grams, milligrams or micrograms or other units as appropriate, that is in a serving of the food; and
- (b) the label must include a declaration of the average quantity of the food in a serving expressed, in the case of a solid or semi-solid food, in grams or, in the case of a beverage or other liquid food, in millilitres; and
- (c) the label must clearly indicate that the average quantities are average quantities and any minimum and maximum quantities are minimum and maximum quantities; and
- (d) the label must include declarations of unavailable carbohydrate where the unavailable carbohydrate has been subtracted in the calculation of ‘carbohydrate by difference’ as defined in clause 1 of this Standard; and
- (e) the reference to ‘unavailable carbohydrate’ in paragraph (d) does not include dietary fibre; and
- (f) the label must include individual declarations of those substances listed in column 1 of Table 2 to subclause 2(2) if they are present, either singly or in combination, in the final food in an amount of no less than 5g/100g, and
 - (i) if any of the substances listed in column 1 have been subtracted in the calculation of ‘carbohydrate by difference’ as defined in clause 1; or
 - (ii) if any of the substances listed in column 1 have been quantified or added to the food, if ‘available carbohydrate’ as defined in clause 1 is used; and
- (g) the reference to substances listed in column 1 of Table 2 to subclause 2(2) in paragraph (f) does not include organic acids; and
- (h) if the claim relates to fibre, sugars or any other type of carbohydrate, the average quantity of energy, carbohydrate, sugars and dietary fibre present per serving of the food, must be declared; and
- (i) the declaration of dietary fibre must be a declaration of dietary fibre determined in accordance with clause 12; and

- (j) if the claim relates to cholesterol, saturated fatty acids, trans fatty acids, polyunsaturated fatty acids or monounsaturated fatty acids or omega-3, omega-6 or omega-9 fatty acids, the saturated fatty acids, trans fatty acids, polyunsaturated fatty acids and monounsaturated fatty acids content per serving of the food, must be declared; and
- (k) if the claim is made that the food is fat-free, low energy or any similar term the average quantity of energy present per serving of the food must be declared; and
- (l) if the claim is made about a vitamin or mineral, the % RDI of a vitamin or mineral must be declared in accordance with clause 7A. The information required to be declared in clause 7A is not required to be set out in a nutrition information panel.

(2) If a nutrition content or health claim is made about a property of the food mentioned in the Table to this subclause and the food is in a small package, the additional information in column 2 must also be presented on the label.

Table to subclause 8(2)

Column 1	Column 2
Property of the Food	Additional information
omega-3 fatty acid	the source and amount per serving of omega-3 fatty acids, namely, alpha-linolenic acid, docosahexaenoic acid or eicosapentaenoic acid;
potassium	the sodium and potassium content per serving of the food
sodium or salt	potassium content per serving of the food
lactose	galactose content per serving of the food

- (3) The prescribed panel format in clause 5 does not apply to the information required in subclauses (1) and (2).
- (4) For the purposes of clause 8, the word ‘serving’ may be replaced by –
 - (a) the word ‘slice’, ‘pack’ or ‘package’; or
 - (b) the words ‘metric cup’ or ‘metric tablespoon’ or other appropriate word or words expressing a unit or common measure.

Editorial note:
 Standard 1.2.1 defines ‘small package’ as a package with a surface area of less than 100 cm². Food in a small package is not required to have a nutrition information panel however the information that must be declared under clause 8 may be set out in a panel.

[3.15] *omitting* Division 3 *and* Division 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 information requirements 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, 17 th Edition, 1 st 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, 17 th Edition, 1 st Revision (2002)

(2) The results obtained using the analytical methods outlined in column 2 of the Table to subclause 12(1) must be added together after ensuring that there is no double counting of any specifically named fibre.

Editorial note:

For the purposes of subclause 12(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 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.

[4] **Standard 1.3.1** of the Australia New Zealand Food Standards Code is varied by omitting the Editorial note after clause 4, substituting –

Editorial note:

In general, the use of intense sweeteners is limited to –

1. foods meeting the definition of ‘reduced energy’ or ‘low energy’;
2. ‘no added sugars’ food e.g. artificially sweetened canned fruit without added sugar; or
3. specific foods in which the use of the sweetener is in addition to sugar rather than as an alternative e.g. chewing gum, brewed soft drink (these foods are listed in Schedule 1 on a case-by-case basis).

Polyols, isomalt and polydextrose may be considered to be food additives when used as humectants and texturisers. Where these substances constitute a significant part of the final food they would be regarded as a food in their own right rather than food additives. Polyols, isomalt and polydextrose are not considered to be bulking agents if used in large amounts to replace sugars as they may contribute significantly to the available energy of the food.

[5] **Standard 1.3.2** of the Australia New Zealand Food Standards Code is varied by –

[5.1] *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.

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

Table of Provisions

- 1 Interpretation
- 2 Prohibition on adding vitamins and minerals to food
- 3 Permitted addition of vitamins and minerals to food
- 4 Claims in relation to the vitamin or mineral content of foods listed in the Table to clause 3
- 5 Calculation of maximum quantity of a vitamin or mineral which may be claimed in a reference quantity of a claimable food

[5.3] *omitting clause 1 substituting –*

reference quantity means –

- (a) for a food mentioned in the Table to clause 3 –
 - (i) the quantity specified in the Table for the food or,

- (ii) for a food that requires dilution or reconstitution according to directions – the quantity of the food that, when diluted or reconstituted, produces the quantity mentioned in column 2 of the Table; or
- (b) for all other foods –
 - (i) a normal serving; or
 - (ii) for a food that requires dilution, reconstitution, draining or preparation according to directions, the quantity of the food which when diluted, reconstituted, drained or prepared produces a normal serving.

[5.4] *omitting clause 4 substituting –*

4 Claims in relation to the vitamin and mineral content of foods listed in the Table to clause 3

For a food listed in column 1 of the Table to clause 3 to which a vitamin or mineral has been added, a claim must not be made that the food contains that vitamin or mineral, both added or naturally present, in the reference quantity of the food in greater proportions than that specified in column 4.

[5.5] *omitting clause 5 substituting –*

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

(1) Where a food, containing at least one ingredient with added vitamins or minerals under this Standard, contains more than one ingredient, the maximum claim permitted in relation to a vitamin or mineral present in a reference quantity of the 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 whole number.

(2) In this subclause –

A means the maximum quantity of a vitamin or mineral permitted to be claimed per 100 g/mL of the food calculated in accordance with the formula –

$$A = B_1 + B_2 + \dots + B_i$$

Where –

B_1, B_2, B_i is the quantity of a vitamin or mineral permitted to be claimed for each ingredient in 100 g/mL of the final food

To calculate B –

$$B = C \times 100 \text{ g/reference quantity} \times \text{proportion of ingredient in 100 g or mL final food}$$

Where C 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.

Editorial note:

Example Calculations

1. Vitamin C claim for an apple and blackcurrant fruit drink (42% juice in total, comprised of apple juice 40%, blackcurrant juice 2%) in a reference quantity of 200 mL –

Maximum claim per reference quantity for vitamin C in apple juice = 120 mg/200 mL
Maximum claim per reference quantity for vitamin C in blackcurrant juice = 500 mg/200 mL

$$B_1 = 120 \times 100/200 \times 40/100 = 24 \text{ mg vitamin C}$$

$$B_2 = 500 \times 100/200 \times 2/100 = 5 \text{ mg vitamin C}$$

$A = B_1 + B_2 = 24 + 5 = 29$ mg vitamin C/100 mL juice (maximum quantity of vitamin C permitted to be claimed per 100 mL of the food) (or 58 mg vitamin C per 200 mL juice).

2. Iron claim for beef schnitzel with iron fortified breadcrumbs –
145 g piece of schnitzel with 115 g meat and 30 g breadcrumbs

Average concentration of iron in meat = 2.5 mg/100 g approximately
Maximum claim per reference quantity for iron in bread = 3 mg/50 g bread

$$B_1 = 2.5 \times 100/100 \times 115/145 = 2.06 \text{ mg iron in 100 g meat}$$

$$B_2 = 3 \times 100/50 \times 30/145 = 1.24 \text{ mg iron/100 g fortified breadcrumbs}$$

$A = B_1 + B_2 = 2.06 + 1.24 = 3.3$ mg iron/100 g schnitzel (maximum quantity of iron permitted to be claimed per 100 g of the food) (or 4.8 mg) rounded to 5 mg iron/145 g schnitzel).

[5.6] *omitting clauses 6 to 9*

[6] *Standard 2.6.2 of the Australia New Zealand Food Standards Code is varied by inserting after subclause 8(3) –*

- (4) A claim that an electrolyte drink is isotonic is taken not to constitute a nutrition content claim for the purposes of Standard 1.2.7 or Standard 1.2.8 of this Code.

[7] *Standard 2.6.4 of the Australia New Zealand Food Standards Code is varied by omitting subclause 3(6) substituting –*

- (6) The label on a package of formulated caffeinated beverage must not include a claim about the presence of a vitamin or mineral.

[8] *Standard 2.9.2 of the Australia New Zealand Food Standards Code is varied by –*

[8.1] *omitting paragraphs 9(1)(e) and 9(1)(f) substituting –*

(e) clause 9.

[8.2] *inserting after subclause 9(1) –*

(1A) The conditions in the Table to clause 11 of Standard 1.2.7 that require the salt, sodium or potassium content of a food to be indicated in the nutrition information panel does not apply to this Standard.

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

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

[10] *Standard 2.9.4 of the Australia New Zealand Food Standards Code is varied by omitting paragraphs 5(2)(b) and 5(2)(c) substituting –*

(b) the amount claimed does not exceed the amount specified in column 2 of the Table to paragraph 2(a).

[11] *Standard 2.10.2 of the Australia New Zealand Food Standards Code is varied by omitting subclause 5(2) substituting –*

(2) A declaration in accordance with subclause (1) is taken not to constitute a nutrition content claim or health claim for the purposes of Standard 1.2.7.

To commence: two years after gazettal

[12] *The Australia New Zealand Food Standards Code is varied by omitting Standard 1.1A.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:

1. favour pre-market approval rather than post-market reaction;
2. enable better engagement of sectors other than government in providing nutritional advice and information;
3. 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
4. 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.

- biomarker²² 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 page 8 of this guideline.

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

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

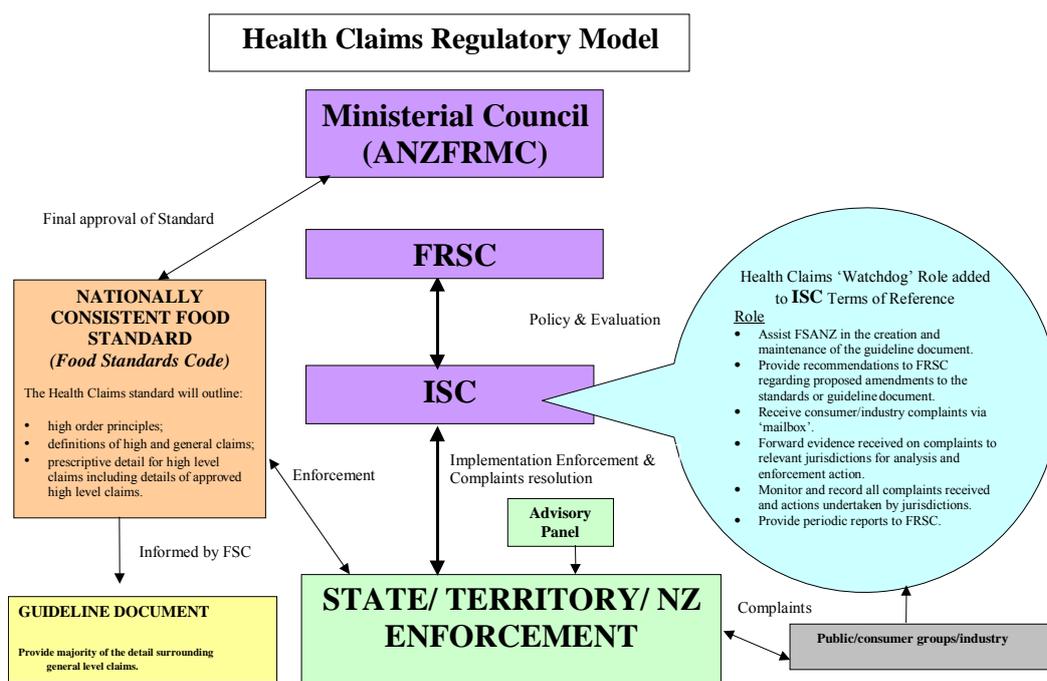
It is recommended that the “watchdog” function be funded by jurisdictions on a pro-rata to population basis, similar to the AHMAC model. This would be re-assessed in a review to be undertaken two years after implementation of the standard.

Advisory Panel

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

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

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



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.

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

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

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

- copies of the relevant studies;
- an outline of all the evidence available and a summary evaluation of the totality of evidence;

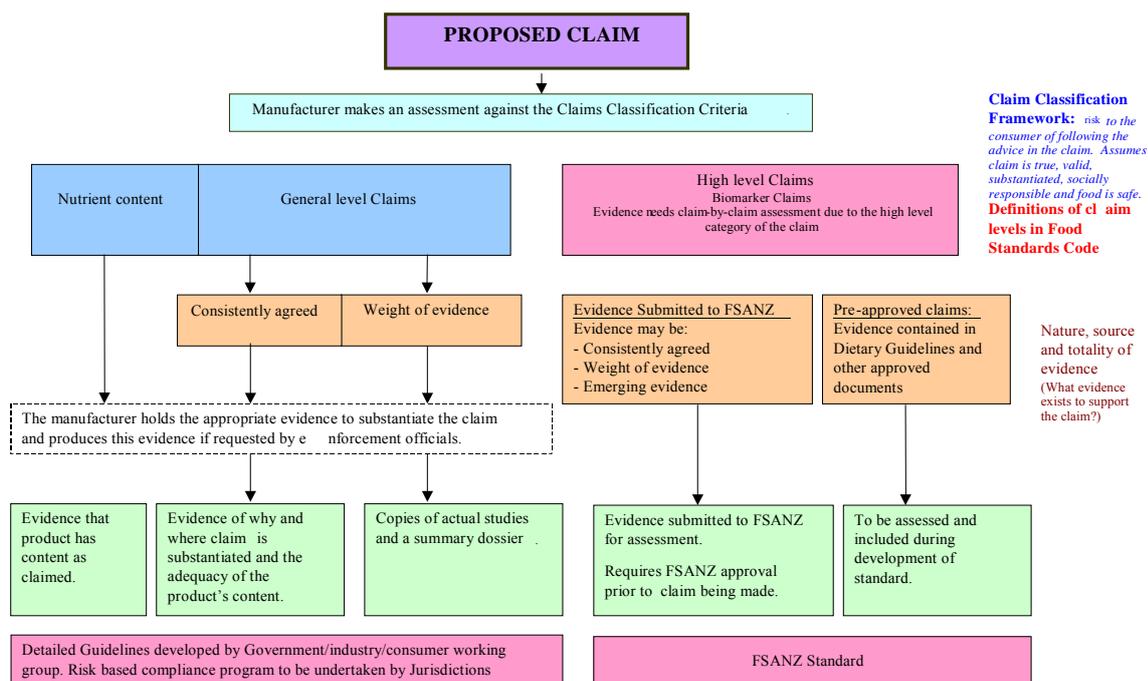
- together with evidence that the product contains an adequate amount of the relevant component(s).

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

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

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

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



Substantiation requirements Diagram

Additional guidance

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

- **A communication strategy** to educate and inform the food industry about what is expected under the new framework, to reduce the risk of inappropriate claims. This will include a clear strategy for general level claims, as well as guidance on the forms of media captured in the framework (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 reassessed 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.