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

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PRELIMINARY FINAL ASSESSMENT REPORT

PROPOSAL P293

NUTRITION, HEALTH AND RELATED CLAIMS

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 16 May 2007
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

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

Purpose

Food Standards Australia New Zealand (FSANZ) issued a Draft Assessment Report in November 2005 setting out a proposed approach to the regulation of Nutrition, Health and Related claims together with the proposed new Standard 1.2.7 – Nutrition, Health and Related claims. The proposed draft Standard set out the criteria and conditions for making 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. Extensive comment was received from stakeholders on the proposal. Following review of these comments FSANZ is not recommending a change to the regulatory approach (criteria and conditions for content and health claims within a standard), claims classification and requirements for substantiation or to many minor recommendations. FSANZ is recommending that some significant elements should be modified and this report outlines the modified recommendations and seeks public comment on the proposed changes. Furthermore it provides the outcomes of the assessment of additional diet disease relationships, not available at the time of the Draft Assessment, which were reviewed to determine whether high level health claims based on these relationships could be substantiated and pre-approved.

A guide to the Preliminary Final Assessment report is available on the FSANZ website to provide interested parties with an overview of the issues discussed. That document also lists the key issues that FSANZ is not reconsidering at Preliminary Final Assessment.

Risk management of content claims

The appropriate risk management of nutrition content claims has been a subject of intense and widely divergent stakeholder views. At Draft Assessment, FSANZ proposed that an additional labelling requirement, the inclusion of percentage daily intake information, should be required in association with nutrition content claims. There was considerable opposition to this approach as presented in the Draft Assessment Report on the grounds of its cost in relation to the large number of existing products with content claims, its limited value for consumer information and a perception by some of the public health sector that it was an inadequate risk management option. FSANZ reconsidered its approach and conducted a literature review and further consumer research on the understanding and likely value of the use of percentage daily intake information to resolve the perceived problem.

As a result FSANZ concludes that percentage daily intake labelling is not likely to be an effective risk management tool in helping consumers to interpret nutrition content claims. In addition there has been little research carried out investigating the extent of consumer confusion with content claims, hence FSANZ considers there is insufficient evidence to change the risk management of content claims from the status quo. FSANZ acknowledges that further evidence on the level of risk and appropriate risk management strategies is needed and intends to investigate this prior to the completion of the Final Assessment Report. The Preliminary Final Assessment Report therefore proposes the removal of the mandatory requirement for percentage daily intake on products with nutrition content claims. However, more flexible provisions for its voluntary use and associated ‘signposting’ are provided.

Eligibility of food to carry health claims

Another area of considerable stakeholder and media comment was the generic disqualifying criteria for health claims. The purpose of applying criteria to foods to determine eligibility to carry health claims is to promote the responsible use of such claims and to prevent consumers being mislead or deceived about the overall 'healthiness' of a food carrying a health claim. It is recognized that the use of health claims on foods has a part to play in the overall promotion of foods contributing to a healthy diet. At Draft Assessment a simple approach, based on levels of three nutrients (total sugar, saturated fat and sodium) per serve, was recommended.

The primary concern raised was that the approach failed to discriminate between foods considered appropriate to carry claims on the basis of dietary guidance (e.g. some fruits and dairy products), which would have been unable to do so under the model proposed at Draft Assessment, and those foods considered inappropriate to carry health claims (e.g. some biscuits and confectionery) which passed on the basis of their small serve size.

FSANZ has therefore investigated a number of alternative models, including the original approach presented at Draft Assessment, a category-based model suggested by the Dietitians Association of Australia, a nutrient profile model and a threshold model based on energy density, and tested these on a database of approximately 10 000 Australian and New Zealand products. A nutrient profiling model, modified from a model prepared by the UK Food Standards Agency, is the preferred approach. This applies a scoring system with incremental 'baseline' points based on levels of total energy, saturated fat, total sugars and sodium per 100 grams. To take account of beneficial nutrients present in the food there are 'modifying' points based on the levels of protein, fibre and fruit and vegetables and the model also takes account of calcium levels for cheeses.

Products are categorised into three groups: foods (including milk), beverages, and other foods (including oils, edible spreads and cheeses). There are different cut-off points for these three broad groups, which determine whether the product is eligible to carry health claims. The performance of the models, a step-by-step guide to the calculations and an assessment of the model against a pre-determined set of desirable characteristics of a good model for determining whether foods are eligible to carry a health claim are presented in this report.

Endorsements

At Draft Assessment, FSANZ proposed to pre-approve a number of nutrition and health related endorsements and to require subsequent endorsements to comply with the regulatory requirements for health claims. Disadvantages of this approach were the creation of an inequitable situation between pre-existing and future endorsements, and legal and management issues with approval of future endorsements. Therefore at Preliminary Final Assessment, endorsements which meet a definition based on the set-up and intent of the endorsing organisation are proposed to be exempted from Standard 1.2.7.

Dietary information

Dietary information that complied with certain conditions was exempted from the proposed health claims Standard at Draft Assessment. However, the definition presented was problematic – there was an overlap with health claims and a lack of clarity over which products would be captured by it. Therefore, whilst the intent of this aspect of the regulation has not changed, the definition for dietary information has been amended.

High level health claims

The evidence linking consumption of fruit and vegetables with a lowered risk of coronary heart disease was considered by FSANZ's Scientific Advisory Group on the substantiation of health claims to be convincing. Therefore two pre-approved high level health claims relating to fruit and vegetable consumption have been added to the list of claims available for use on products which meet the defined qualifying criteria and food composition criteria based on the nutrient profile model. FSANZ considers the evidence relating to wholegrains, bran and coronary heart disease is not convincing and has not pre-approved a health claim arising from this relationship. FSANZ considers that the evidence for a benefit of long-chain omega-3 fatty acids on cardiovascular disease mortality and morbidity can be rated as 'probable' and therefore constitutes sufficient evidence to support a general level health claim based on this relationship. However, FSANZ has not pre-approved a high-level health claim based on dietary intake of long chain omega-3 fatty acids and cardiovascular disease because the Scientific Advisory Group considers it does not reach the 'convincing' level of evidence required for a pre-approved high level claim.

For high level health claims relating to vitamins and minerals, incorporation of conditions currently associated with 'claimable foods' has been dropped. All foods carrying the pre-approved high level health claims are required to meet the compositional criteria based on the nutrient profile model for consistency.

Other components for consultation

Clarification has been provided on the application of Standard 1.2.7. FSANZ intends that the Standard will apply to food for retail sale only and not to foods provided to clients of delivered meal organisations, hospitals and similar institutions. The Standard will not apply to foods for catering purposes.

A number of more minor amendments to the proposed Standard are presented and discussed in this Report, including the addition of kava as an ineligible food and a clarification of the alcohol level in products permitted to make claims, permission of specific nutrition content claims for foods containing more than 1.15% alcohol, and modifications to conditions around fibre, saturated and trans fatty acids, wholegrain, 'no added', glycemic index, 'lite', comparative, weight management and diet claims. There are also proposed modifications to the labelling requirements for small packages and split claims.

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ATTACHMENT 7: Calculation method for foods eligible to make health claims

INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Preliminary Final Assessment Report based on regulation impact principles and the draft variation/s to the *Australia New Zealand Food Standards Code* (the Code) for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

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

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

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

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

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

Submissions need to be received by FSANZ by 6pm (Canberra time) 16 May 2007.

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

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

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

1. INTRODUCTION

1.1. The Preliminary Final Assessment Report for Nutrition, Health and Related Claims

The Preliminary Final Assessment Report provides for consultation on recommendations for a number of issues, which have changed since the Draft Assessment Report was released in November 2005. The elements of the proposed Standard which are not addressed in this report will not undergo any further consultation. Where appropriate, further research has been performed to form a stronger evidence base on which to base the recommendations to be presented in the Final Assessment. Targeted consultations have been conducted when appropriate to make decisions. Some of the comments have highlighted areas where further clarity is desirable and where possible this will be addressed in user guides.

FSANZ has prepared this Preliminary Final Assessment Report in consultation with the Standards Development Advisory Committee for health claims and the Scientific Advisory Group on the substantiation of health claims.

The topics on which FSANZ are seeking stakeholder views are addressed in sections 3 to 8 inclusive and include:

- Application of the Standard.
- Conditions for certain nutrition content claims.
- Percentage daily intake (%DI) declaration.
- Nutrient profiling criteria for determining eligibility of foods to carry health claims.
- Weight management and 'diet' claims.
- Further diet disease relationships.
- Dietary information.
- Endorsements.
- Wording conditions (small packages and split claims).

Each of the preferred options is derived from an analysis of the impact of the options, which takes account of different stakeholder groups. FSANZ specifically seeks further and more detailed information on the costs and /or benefits of the various options for stakeholders.

The report is structured such that Chapter 3 addresses issues related to the overall application of the Standard, Chapters 4 and 5 address content claims (generic aspects and specific claims respectively), Chapter 6 refers to health claims (food eligibility criteria, weight management and 'diet' claims and criteria and conditions for high level health claims), Chapter 7 refers to related claims (endorsements and dietary information) and Chapter 8 refers to wording conditions. In Chapter 9 minor editorial and technical changes to the drafting are identified. Chapter 11 provides information on other relevant decisions made by FSANZ that have a bearing on the Proposal for Nutrition, Health and Related Claims and clarification of some specific issues. These matters include:

- The new Nutrient Reference Values (NRVs)
- Trademarks
- Special purpose foods
- Reference amounts for vitamins and minerals

- Requirement for amendment to the New Zealand Medicines Act to permit the use of health claims on foods

The amended draft Standard 1.2.7 is provided at Attachment 1. The development of Standard 1.2.7 is guided by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) policy guidance on the regulation of nutrition, health and related claims (referred to as the Policy Guideline), which is available at the following link: Nutrition, Health and Related Claims Policy Guideline .

1.2 Background

The Nutrition, Health and Related Claims Policy Guideline was endorsed by the Ministerial Council in December 2003. Following the release of the guideline, FSANZ started work on the Proposal for Nutrition, Health and Related Claims. This proposal is the vehicle by which FSANZ is developing a Standard (Standard 1.2.7) and management system for the regulation of nutrition, health and related claims.

In August 2004, FSANZ released the first of two consultation documents, an Initial Assessment Report, for public comment, and in November 2005 released the second consultation document - the Draft Assessment Report. FSANZ received 147 submissions in response to the Initial Assessment and 131 written submissions in response to the Draft Assessment Report. Whilst the preferred regulatory option has been supported, new information provided at Draft Assessment indicated certain aspects of the proposal were not satisfactorily addressed and required further consideration. This has given rise to re-appraisal of specific sub-clauses of the draft Standard, some of which have resulted in changed recommendations.

1.2.1 Standard proposed at Draft Assessment

At Draft Assessment, FSANZ recommended the introduction of a new standard for health, nutrition and related claims, with the management of both general level and high level health claims being predominantly by a standard, and the Substantiation Framework for general level and high level health claims to be in a guideline incorporated by reference into the health claims Standard. This means claims will be legally required to be substantiated in accordance with the Framework.

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

As noted at Draft Assessment, claim definitions and the regulatory parameters (i.e. pre-requisite conditions, specific criteria and wording conditions) work together to identify and regulate nutrition and health claims. These requirements apply to both general level and high level health claims. All health claims require reference to both the specific health effect and the property[1] of the food responsible for that benefit. The property has to be present at defined levels, termed qualifying criteria (except in the case of whole foods) in order to avoid misleading consumers.

Foods able to carry health claims must also meet a scoring criteria based on their nutrient profile. At Draft Assessment a generic system was proposed based on total sugars, saturated fat and sodium.

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

FSANZ also approved a number of high level health claims at Draft Assessment which will be available to use at the time the Standard comes into effect. Health claims based on the following diet-disease relationships were substantiated:

- a relationship between dietary intake of calcium, vitamin D status and risk of developing osteoporosis, particularly in the 65 year and over age group;
- a relationship between increased dietary intake of calcium and enhanced bone mineral density;
- a relationship between reduction in dietary intake of sodium and reduction in blood pressure;
- a relationship between intake of folic acid in the period of peri-conception and risk of development of neural tube defects in the foetus;
- a relationship between saturated fatty acids and LDL-cholesterol levels; and
- a relationship between unsaturated *trans* fatty acids and saturated fatty acids and LDL-cholesterol levels.

At that time a review of the evidence supporting the following diet-disease relationships was underway for:

- long chain omega-3 fatty acid intake and risk of cardiovascular disease;
- wholegrains and coronary heart disease; and
- fruit and vegetable intake and coronary heart disease.

Claims that effectively fall outside the framework were designated ‘related claims’ and subject to separate provisions, such as cause-related marketing statements. Endorsements were also considered as a special case – for which a two-phase system was proposed.

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

It was recommended that existing endorsements be pre-approved by FSANZ, listed in the draft Standard and then specifically exempted from the Standard. Non pre-approved endorsements would need to meet selected elements of the claims classification framework, according to the nature of the endorsements.

Recommendations were also made in relation to certain types of claims (such as dietary interaction claims, glycemic index, gluten claims, weight management claims and 'diet' claims) and specific food types (such as whole foods and foods containing biologically active substances).

1.3 Current Standards

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

This section provides information on the various parts of the current regulatory approach, all of which will be impacted by the introduction of the new Standard 1.2.7.

1.3.1 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.

This Standard will be revoked on gazettal of Standard 1.2.7

1.3.2 Standard 1.2.8 Nutrition Information Requirements

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

- polyunsaturated and monounsaturated fatty acid content
- lactose
- gluten content
- salt, sodium or potassium content
- omega fatty acid content
- low joule

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

The Standard will undergo consequential amendments as a result of Standard 1.2.7. These amendments are provided at Attachment 1.

1.3.3 The Code of Practice on Nutrient Claims

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

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

On gazettal of Standard 1.2.7, the Standard will regulate most of those matters which CoPoNC gives guidance on.

1.3.4 Other forms of guidance

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

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* that regulates the use of claims on food labels to ensure that the information provided to consumers is not deceptive or misleading. The Act prescribes that claims should be restricted to those that are based on facts. Where appropriate, accompanying information should be provided to show consumers that the claims are justified and substantiated.

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

1.4 FSANZ objectives

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

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

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

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

3. ISSUES RELATED TO APPLICATION OF THE STANDARD

3.1 Application of Standard 1.2.7

3.1.1 Recommendations

FSANZ proposes the following recommendations for the application of Standard 1.2.7 at Preliminary Final Assessment:

1. Standard 1.2.7 will apply to food for retail sale only (this includes food at the time it is manufactured or otherwise prepared, or distributed, or transported or stored prior to retail sale, where the food is not intended for further processing, packaging or labelling).
2. Standard 1.2.7 will regulate nutrition content claims, health claims, dietary information and cause-related marketing statements that appear on either food labels or in advertising of food for retail sale.

3. Standard 1.2.7 will not apply to foods for catering purposes.
4. Standard 1.2.7 will not apply to:

   (a) packaged meals delivered to clients of delivered meal organisations; and
   (b) food provided to patients in hospitals and similar institutions, when the food is not in a 'package'.

5. As outlined at Draft Assessment, Standard 1.2.7 will not apply to activities such as government health promotional campaigns or public health materials published by community based organisations.

3.1.2 Introduction

The general labelling provisions in Part 1.2 of the Code currently apply to foods for retail sale (i.e. sale to the public) and to foods for catering purposes. Proposal P272 – Labelling Requirements for Food for Catering Purposes and Retail Sale, is presently assessing the application of labelling standards to foods at various points in the food chain.

In line with clause 13 of Standard 1.1.1[2], the requirements and restrictions under Part 1.2 of the Code apply to a label on food or in advertising for the food i.e. Part 1.2 does not capture all information about food in general, only that in food labels or advertisements. This will apply to the Nutrition, Health and Related Claims Standard when gazetted, as the proposed standard will be incorporated into Part 1.2 of the Code (Standard 1.2.7). In practice this will mean that information provided via activities such as government health promotion campaigns and public health materials published by community based organisations, for example Nutrition Australia and the New Zealand Dietetic Association, would not be regulated by Standard 1.2.7.

'Label' is defined in Standard 1.1.1, as meaning 'any tag, brand, mark or statement in writing or any representation or design or descriptive matter on or attached to or used in connection with or accompanying any food or package'. 'Advertisement' is defined separately in food legislation, and broadly captures 'any words, whether written or spoken; or any pictorial representation or design; or any other representation by any means at all, used or apparently used to promote, directly or indirectly, the sale of food.' (Subsection 2(1), Annex A, Model Food Act).

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

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

[2] Advertisements for food must not contain any statement, information, designs or representations which are prohibited by this Code from being included in a label for that food.

3.1.3 Approach at Draft Assessment

At Draft Assessment for Proposal P293, FSANZ proposed that Standard 1.2.7 would apply to foods for retail sale and foods for catering purposes as defined in Standard 1.2.1.

In line with Clause 13 of Standard 1.1.1, the restrictions under Standard 1.2.7 apply to food labels and to advertising for the food.

The application of the Code was described in the Purpose of draft Standard 1.2.7 as follows:

> *This Standard is designed to regulate nutrition content claims, health claims, endorsements and cause related marketing statements, whether appearing on food labels or in advertisements. It also consolidates a number of requirements relating to claims made under the Code that were previously spread across a number of standards, such as Standards 1.2.8 and 1.3.2.*
>
> *This Standard imposes requirements in relation to the contents of food labels and advertisements for food. Food legislation applies the requirements of the Code in relation to food intended for sale or for sale, and to the conduct of food businesses. It does not apply the requirements of the Code to other types of activities, for example, government health promotional campaigns or public health materials published by community based organisations.*

3.1.4 The issue/problem

The regulation of nutrition and health related information in educational materials provided to schools, manufacturers, caterers and to medical professionals such as doctors or dietitians has been raised as an issue of concern within FSANZ and by stakeholders.

The definitions of 'food for retail sale' and 'foods for catering purposes' and the labelling requirements applicable to each are currently being considered under Proposal P272 – Labelling Requirements for Food for Catering Purposes and Retail Sale. It needs to be considered whether draft Standard 1.2.7 should apply to both 'food for retail sale' and 'foods for catering purposes'.

The regulation of claims on foods sold to clients of delivered meal organisations and to meals provided in hospitals and similar institutions was also not specifically considered in Standard 1.2.7 at Draft Assessment. FSANZ is aware that delivered meal organisations, hospitals and similar institutions label meals (this includes tray tickets accompanying a meal) with reference to disease states and/or nutrition claims to facilitate meal delivery. Unless exempted, the use of terms such as 'diabetic' or 'cardiac' on the label of a meal would constitute a breach of the proposed health claims standard. Nutrition claims such as 'low fat' or 'low sodium' would trigger the requirements proposed under draft Standard 1.2.7 and also under Standard 1.2.8 – Nutrition Information Requirements for the provision of a nutrition information panel. This level of regulation is considered unnecessarily complex for this type of food service.

In addition, concerns have been raised by a number of submitters about the application of Standard 1.2.7 and the potential subsequent restrictions on providing important dietary information.

3.1.5 Comments from stakeholders at draft assessment

Concerns were raised that general dietary advice provided in various media would be prohibited by the proposed Standard. This included information provided in the form of:

- editorials, booklets, leaflets, pamphlets, fact sheets;
- recommendations for branded products as ingredients in recipe sheets;
- educative materials provided to consumers/schools/health professionals that are sponsored by industry and display corporate names or logos;
- the provision of scientific information by food manufacturers to health professionals;
- nutrition education materials and campaigns provided by health professional associations that are recognised experts in food and nutrition;
- shelf wobblers; and
- television broadcasts that include *bona fide* news, public interest and entertainment programmes.

It was recommended that some of these information vehicles and/or content be exempted from the proposed Standard.

One submitter believed that it was unclear what was meant by 'community based organisations', or the intent of this exemption.

There was also concern that the scope of the draft Standard is too narrow by focusing on foods that are sold, or intended to be sold, and that there is a potential for foods to carry unregulated health claims when supplied (not sold) to vulnerable groups.

3.1.6 Factors relevant to the regulatory option

The Draft Assessment Report for Proposal P272 states that food for retail sale means food sold to the public and therefore would be considered to be an end product. Food for catering purposes however, refers to *foods for use in restaurants, canteens, schools, caterers or self catering institutions, where food is offered for immediate consumption*. At this point, the food is likely to be subject to further processing before retail sale. An example of food for catering purposes is pasta that is sold to a restaurant to be used in the preparation of a meal. When the meal is sold to the public it becomes food for retail sale.

In the Draft Assessment Report for Proposal P272, the following definitions were proposed:

> **food for retail sale** includes food at the time it is manufactured or otherwise prepared, or distributed, transported or stored prior to retail sale, where the food is not intended for further processing, packaging or labelling.
>
> **food for catering purposes** includes food supplied to catering establishments, restaurants, canteens, schools, hospitals, and institutions where food is prepared or offered for immediate consumption.

package means any container or wrapper in or by which food intended for sale is wholly or partly encased, covered, enclosed, contained or packaged and, in the case of food carried or sold or intended to be carried and sold in more than one package, includes every such package, but does not include –

(a) bulk cargo containers; or
(b) pallet overwraps; or
(c) crates and packages which do not obscure labels on the food; or
(d) transportation vehicles; or
(e) a vending machine; or
(f) a hamper; or
(g) food served on a covered plate, cup, tray or other food container in prisons, hospitals or other similar institutions listed in the Table to clause 8 of Standard 1.2.1.

Under this proposed definition, meals provided by hospitals and similar institutions presented on a plate, bowl, cup or tray covered by plastic, foil or a hard covered dome would not be considered to be packaged. An exemption from draft Standard 1.2.7 for unpackaged foods provided in hospitals and similar institutions could therefore be considered. This exemption would not capture pre-packaged components of meals served in hospitals or similar institutions which are also generally available for retail sale, such as packaged breakfast cereals, yoghurt or fruit juices.

In addition, under Proposal P272 it has been proposed that a list that identifies and defines hospitals and 'other similar institutions' is provided in Standard 1.2.1. These definitions could be referred to in draft Standard 1.2.7.

3.1.7 Analysis of options

Option 1 – Approach taken at Draft Assessment: Draft Standard 1.2.7 would apply to foods for retail sale, food for catering purposes and foods provided to clients of delivered meal organisations and hospitals and other similar institutions.

Benefits

- provides a tighter regulatory regime that would prohibit foods from carrying unregulated nutrition content or health claims on foods being sold from a broad range of points in the food chain, potentially protecting vulnerable consumers.

Disadvantages

- the criteria and conditions would be overly prescriptive for hospitals and similar institutions where the service being provided is overseen by medical professionals and claims are made for medical purposes; and
- restricts provision of valuable dietary advice in certain situations.

Option 2 – Draft Standard 1.2.7 applies to foods for retail sale only. Foods for catering, packaged meals provided to clients of delivered meal organisations and unpackaged foods provided to patients in hospitals and other similar institutions are specifically exempt from the provisions of Standard 1.2.7.

Benefits

- the exemption for packaged meals from delivered meal organisations, and unpackaged foods in hospitals and similar institutions would enable these organisations to continue to label meals making reference to disease states or claims such as 'low fat' without triggering the criteria and conditions for making a nutrition content claim or health claim under the proposed Standard; and
- permits provision of valuable nutrition or health related information when it is appropriately restricted to target audiences such as medical professionals or manufacturers, but still regulates food sold directly to the public, including vulnerable individuals.

Disadvantages

- permits provision of some nutrition or health related information that is not regulated by the proposed Standard and may by misused by suppliers.

FSANZ's preferred approach at Preliminary Final Assessment is Option 2.

FSANZ considers that many of the provisions in draft Standard 1.2.7, for example compositional requirements of foods eligible to carry claims, may not be relevant for hospital meals, where the use of such claims is for medical purposes. In practice, an exemption from the proposed requirements would allow hospitals and similar institutions to continue to label meals making reference to disease states such as 'diabetic', and allow the use of claims such as 'low fat' and 'low sodium' on the meal label or tray ticket.

The application of draft Standard 1.2.7 to foods for retail sale and not to foods for catering purposes allows for the exchange of important dietary information relating to foods in certain circumstances. Examples include information provided in educational materials for schools, and information provided by ingredient suppliers to manufacturers or caterers, manufacturers to health professionals, or health professionals to manufacturers (when the label or advertisement does not apply to food for retail sale). However, in the case of retail sale of food to the public, because the ultimate responsibility for correct labelling lies with the supplier of the food, consumers are protected from misleading information or inappropriate claims.

As outlined above, Standard 1.2.1 is currently under consideration as part of Proposal P272. Any relevant amendments will be taken into account in the final drafting of Standard 1.2.7.

3.2 Ineligible foods

3.2.1 Recommendations

FSANZ proposes the following recommendations for ineligible foods at Preliminary Final Assessment:

1. Kava is prohibited from making nutrition content claims and health claims under Standard 1.2.7.
2. Nutrition content claims and health claims will be permitted for foods that contain equal to or less than 1.15% alcohol.
3. Nutrition content claims will not be permitted for foods that contain more than 1.15% alcohol, except for energy, alcohol and carbohydrate.
4. A nutrition information panel will be required when a claim is made in relation to energy or carbohydrate content.

- The Ministerial policy guideline indicates that consideration should be given to *exclusions for certain categories of food such as alcohol and baby foods* and that any parameters should be specifically stated in the standard. Currently, Standard 1.1A.2 – Transitional Standard for Health Claims prohibits health claims on foods that are standardised in Part 2.7 of the Code (Alcoholic Beverages). The draft Standard has incorporated this with the prohibition of general and high level health claims on foods containing more than 1.15% alcohol and only permitting nutrient content claims relating to alcohol, energy and carbohydrate on foods containing more than 1.15% alcohol. Prohibition of nutrition and health claims on kava is consistent with FSANZ's approach for regulating alcohol claims and it is also consistent with the Australian, State and Territory Governments' restrictions of the promotion and advertising of kava.

  The approach taken for alcoholic products and kava is also supported by the high order principles 1, 3, 4 in the policy guideline: *give priority to protecting and improving the health of the population*; *support government, community and industry initiatives that promote healthy food choices by the population*; *be consistent with and complement Australian and New Zealand national policies and legislation including those relating to nutrition and health promotion*…; and claim prerequisite 1 which states that *the claim is socially responsible and does not promote irresponsible food consumption patterns*.

3.2.2 Kava

3.2.2.1 Introduction

In Australia the sale and distribution of kava (other than as a therapeutic) is regulated by means of Standard 2.6.3 of the Code in conjunction with the *National Code of Management on the Restriction of the Sale and Advertising of Kava* (the National Code of Kava Management). In New Zealand, Standard 2.6.3 applies to all foods containing kava other than for those which comply with the Dietary Supplement Regulations. While recognizing the cultural significance of kava to South Pacific communities living in Australia and New Zealand, Standard 2.6.3 and the National Code of Kava Management were developed to minimize the detrimental effects associated with kava abuse.

The National Code prohibits the advertising or promotion of kava and the distribution of samples as part of the responsible sale of kava to minimize harm.

3.2.2.2 Approach at Draft Assessment

Permission for making claims on kava was not considered at either Initial or Draft Assessment for Proposal P293.

3.2.2.3 Comments from Stakeholders at Draft Assessment

The New Zealand Food Safety Authority recommended that kava, as regulated under Standard 2.6.3, also be excluded from making nutrition content claims and health claims, as the rationale for excluding alcoholic beverages is equally applicable to kava.

3.2.2.4 Evidence base

A FSANZ human health risk assessment of kava (FSANZ, 2004) describes kava as an intoxicating water-based beverage prepared from the root of the plant *Piper methysticum.* Kava has a long history of use as a beverage in social ceremonies particularly by South Pacific communities, and was introduced into Australian Indigenous communities in the 1980s. In some Northern Territory Indigenous communities, the rate of kava consumption was found to exceed traditional consumption in Pacific Island populations by 100 times. Heavy use of kava can cause weight loss, malnutrition, liver damage, hypertension and skin disorders.

3.2.2.5 Analysis of Options

Option 1 – Approach taken at Draft Assessment: kava is not specifically prohibited from making nutrition content claims and health claims

Benefits

- Consumers would be provided with information on the potential benefits of the kava consumption.

Disadvantages

- Permissions for claims might promote the non-traditional use of kava, and the intoxicating nature of kava might lead to substance abuse in some consumers.
- Adverse health outcomes from long-term substance abuse of kava could negatively impact on public health resources.
- Conflicting public health messages in relation to permissions for kava to carry claims when the sale and advertising of kava is restricted for the purposes of minimising harm.

Option 2 – Prohibit kava from making nutrition content claims and health claims

Benefits

- A prohibition will support public health objectives in terms of minimising harm from non-traditional use of kava.

- The approach would be compatible with the current regulations that govern the sale and advertising of kava.
- Consistency with the prohibition for alcohol to carry health claims.
- Consumers will be protected from inappropriate health claims.
- Use of kava for traditional purposes would not be affected.

Disadvantages

- Consumers will not be made aware of any potential health benefits of kava.
- Industry will be prevented from making nutrition content claims or health claims on kava.

FSANZ's preferred option at Preliminary Final Assessment is Option 2.

Kava is an intoxicating beverage which is used by certain population groups, e.g. South Pacific Islanders. The Australian Government and State and Territory Governments recognise the use of kava as having potential adverse health and social consequences and there are prohibitions on the promotion and advertising of kava as a food in Australia. FSANZ considers permitting health claims would be incompatible with these restrictions. Furthermore, associating kava with health claims would give credibility to its non-traditional use; it is more appropriately treated in a similar way to alcohol in the regulation of health claims.

3.2.3 Alcoholic beverages and food containing alcohol

3.2.3.1 Introduction

At Draft Assessment, it was proposed that general level and high level health claims would be prohibited on foods containing alcohol. This decision took into consideration the Ministerial Council policy guidance which states that consideration should be given to excluding certain categories of food, such as alcohol, from content and health claims and making any exclusions explicit in the standard. Currently the Code permits nutrition content claims on foods containing alcohol, and these claims are regulated as for any other food. Beer is not permitted to be fortified with vitamins or minerals, but may have added herbs.

Alcoholic beverages standardised in Standards 2.7.2 to 2.7.5 of the Code (beer, fruit wine, vegetable wine, wine and wine products, and sprits) are currently exempt from the requirement to label with a nutrition information panel, except where a nutrition claim is made.

At present, alcohol labelling is regulated under Standard 2.7.1 – Labelling of Alcoholic Beverages and Food Containing Alcohol. This Standard requires a statement of alcohol content on packaged beverages with more than 0.5% alcohol by volume. The Standard prohibits 'low alcohol' claims when the alcohol content of the beverage is more than 1.15% alcohol by volume. Clause 5 of the Standard states that representations of the term 'non-intoxicating' are only permitted where the beverage contains less than 0.5% alcohol by volume.

Brewed soft drinks are regulated in Standard 2.6.2 – Non-Alcoholic Beverages and Brewed Soft Drinks.

This Standard prescribes the composition of such drinks, including the alcohol levels that are present as a result of the fermentation process from water with fruit and/or vegetable extractives or fruit and/or vegetable infusions, and sugar. By definition, brewed soft drinks may contain up to 1.15% alcohol by volume.

3.2.3.2 Approach at Draft Assessment

The proposed approach at Draft Assessment was as follows:

- Nutrition content claims referring to alcohol content or energy content would be permitted on foods that, if packaged, would be required to include a statement of alcohol content under clause 2 of Standard 2.7.1. This would apply to foods that have a minimum of 0.5% alcohol by volume or greater. Foods with an alcohol content of 0.5% or more would be prohibited from carrying other nutrition content claims or health claims.
- Products above this cut-off would be restricted to making nutrition content claims about alcohol and energy, in particular 'low alcohol', 'low energy', 'reduced energy' and 'light' or 'lite' in respect to alcohol or energy content.
- These restrictions would therefore prohibit the use of any other nutrition content claim on foods containing an alcohol content of 0.5% or more, including carbohydrate claims and voluntary nutrition information panels.
- On foods other than those requiring alcohol labelling under Standard 2.7.1, carbohydrate claims would be permitted, but conditions would not be prescribed for such claims.

3.2.3.3 The issue/problem

This section discusses two issues in relation to claims on foods containing alcohol that have been considered by FSANZ since the Draft Assessment Report was released.

The first issue relates to the threshold of 0.5% alcohol by volume proposed at Draft Assessment, which would prohibit some lower alcohol beverages, in particular brewed soft drinks, from making other types of claims (i.e. beyond energy and alcohol content). The alcohol content of such drinks can vary from nil to the maximum allowable level of 1.15%. Permissions for making claims on these lower alcohol beverages would depend on whether or not the alcohol content exceeded the threshold of 0.5% alcohol by volume. This could lead to a potential inequity for brewed soft drinks with different alcohol levels i.e. less than 0.5 % alcohol compared with 0.5 to 1.15% alcohol.

The rationale for prohibiting general level health claims and high level health claims on foods containing alcohol was that such claims were seen to be inappropriate for foods regulated in Part 2.7 of the Code. However, it needs to be considered whether this rationale can be justified in terms of any risk of adverse health effects due to consuming foods with an alcohol content of 1.15% or less. It also needs to be considered whether the presence of claims on such products in the market place would negatively impact on the public health message regarding responsible consumption of alcohol.

The second issue arose as a result of concern expressed by certain industry stakeholders about the restriction on making nutrition content claims on alcoholic beverages, in particular carbohydrate content claims.

The decision at Draft Assessment, to limit permission for claims to alcohol and energy content, was based on FSANZ's interpretation of recommendations in the health claims Ministerial Council policy guideline to consider excluding alcohol from making claims. However, FSANZ has further considered the health claims Ministerial Council Policy Guideline principles in conjunction with FSANZ's objectives which include the provision of labelling requirements that are commensurate with the risk posed to public health and to not unduly restrict industry's ability to innovate.

In addition, at Draft Assessment there was an exemption from the requirement to declare a complete nutrition information panel (including the actual energy content of the food) for alcohol products carrying nutrition content claims in relation to energy content. FSANZ considers it is necessary to reconsider this recommendation to take into account enforcement and consumer information needs.

FSANZ has not reconsidered its position with regards to prohibiting health claims on foods containing more than 1.15% alcohol.

3.2.3.4 Comments from stakeholders at Draft Assessment

Some stakeholders were concerned that variations on alcohol content of some lower alcoholic beverages could lead to some beverages being allowed to make claims whilst others would be prohibited. It was suggested that brewed soft drinks containing up to 1.15% alcohol by volume should be permitted to make claims.

Whilst a number of submitters specifically noted their support of the proposed restriction on making claims on foods containing alcohol (mainly submitters from the government and public health sectors), some industry submitters recommended that nutrition content claims in general be permitted. Some of the reasons provided in support of this recommendation were that:

- there has been no known abuse of the current provisions by industry;
- there is a risk of creating a barrier to trade with the present proposal;
- the proposal cannot be demonstrably justified, given that there is solid scientific evidence of the health benefits associated with moderate alcohol consumption; and
- the proposal implies that alcoholic products are unhealthy, whereas it is only excessive intake of alcohol that is unhealthy.

It was suggested that all nutrition content claims should be permitted rather than allowing only certain claims.

3.2.3.5 Evidence base

There is a large body of evidence that highlights the social and health problems associated with alcohol abuse. The Australian National Alcohol Strategy for 2006-2009 (Commonwealth of Australia, 2006) suggests that regulatory approaches, including effective controls on advertising, can reduce detrimental effects associated with alcohol consumption in the community. The document does not identify the level of alcohol in a food or beverage that would be commensurate with a health risk, but instead provides guidelines for low risk drinking, based on the numbers of a 'standard drink' (equal to 10 g of ethanol) that could be consumed.

An assessment of claims on alcoholic beverages available in the Australian and New Zealand markets in November 2006 found a number of 'low carbohydrate' claims on beers, in addition to the more traditional 'light' beers that contain low or reduced levels of alcohol. Both the low alcohol beers and the low carbohydrate beers result in lower energy content than full strength beers. However, the decrease is not substantial in terms of kilojoules, with a decrease of approximately 52 kJ per 100 mL in the low carbohydrate beers identified by FSANZ. The 'low carbohydrate' beers contained approximately 0.9 g of carbohydrate per 100 mL however, it should be noted that a standard draught beer without a 'low carbohydrate' claim contains approximately 2 g of carbohydrate per 100 g (Athar et al., 2003). There were no claims found in relation to energy content and in addition, none of the products identified by FSANZ would meet the proposed 'low energy' criteria. FSANZ has not been provided with any information from the alcohol industry regarding the cost associated with a prohibition on making these claims.

Internationally, in the EU, the European Parliament has recently agreed to prohibit nutrition claims except those referring to low alcohol levels or the reduction of alcohol content, and the reduction of energy content on beverages containing more than 1.2% alcohol by volume. In contrast, nutrition content claims are permitted on alcoholic beverages in the United States and in Canada.

Recently, new types of products containing alcohol have been observed in international markets, including a new Indian beer called 'Ladybird Bio Beer' (Khoday India Ltd) which contains aloe vera extracts, reported to increase bioavailability of vitamins. The beer, which claims to protect against liver damage, has been marketed in a number of countries, including Canada and the UK. Ladybird Bio Beer is a full strength beer.

Functional beer is an emerging product category identified by Datamonitor[3], with beer manufacturers trying to widen the appeal of beer by launching new products with health benefits. It should be noted that many of the products released appear to be low in alcohol. For example, the US product 'Stampede Light', contains B-vitamins and also makes a zero fat claim, and a German brewer (Karlesberg Brauerrei) has produced a range of functional beer based drinks ('Karla Well-Be') aimed at women, which contain lecithin, folic acid and other vitamins. It should be noted that Karlesberg Brauerei advertises these products as beer-fruit mixed drinks and that the product contains only 1% alcohol.[4] Consequently, under Option 2 (see below) this type of product would be permitted to carry nutrition content claims and health claims consistent with the approach taken for other foods.

The current presence of low-alcohol beer based drinks in the international marketplace suggests it is likely that industry may be interested in promoting similar products in Australia and New Zealand. On the evidence available, it appears that restricting most nutrition content and all health claims to products containing less than 1.15% alcohol would leave sufficient room for industry to develop and/or import innovative products without compromising the Policy Guideline principle that health claims should not promote irresponsible consumption patterns.

[3] Datamonitor is a leading provider of online database and analysis services for key industry sectors.
[4] Under German food law the ingredients permitted in beer are highly restricted (Reinheitsgebot).

FSANZ is not aware of any research that has investigated the impact of claims on alcohol products on levels of consumption, or on the effect that the presence of such claims in the market place has on consumer perception on the health benefits or otherwise of consumption of alcoholic beverages. FSANZ is planning to carry out research on the impact of nutrition content claims in general on consumer purchase behaviour and this may further inform FSANZ's approach to regulating nutrition content claims on foods containing alcohol.

3.2.4 Analysis of Options – percentage alcohol by volume

FSANZ recommends a cut off point of 1.15% alcohol by volume, for determining permission for claims on foods containing alcohol. This alcohol level aligns with the maximum alcohol content that a brewed soft drink may contain and with the requirements for declaration of alcohol by volume currently prescribed in Standard 2.7.1. FSANZ considers that the threshold of 1.15% alcohol by volume is more consistent with the rationale in relation to public health for prohibiting food containing alcohol from making certain claims. In addition, FSANZ suggests that the very low risk from consumption of products with this proportion of alcohol does not warrant a prohibition of nutrition content and health claims on such products.

Analysis of options – permission for nutrition content claims on foods containing more than 1.15% alcohol by volume

Option 1 – Approach taken at Draft Assessment: permit nutrition content claims on foods containing alcohol in relation to alcohol content and energy content only. Voluntary declaration of nutrition information panels would be prohibited and declaration of the energy content when a claim is made in relation to energy would not be required.

Benefits

- The permission to make low alcohol claims provides consistency with public health messages to moderate alcohol consumption.
- Permission to make low alcohol and energy claims limits the promotion of alcohol on the basis of content claims and thus supports the policy guideline principle that 'the claim is socially responsible and does not promote irresponsible food consumption patterns'

Disadvantages

- Reduced consumer choice.
- Less nutritional information provided to consumers.
- Restricts industry ability to market alcoholic beverages and develop new products.
- Loss of market sector/brands with existing claims, and costs associated with relabelling or reformulating.
- Will require relabelling of some existing products which are voluntarily labelling with a nutritional information panel.

Option 2 – Permit nutrition content claims on foods containing alcohol (more than 1.15% alcohol by volume) in relation to alcohol, energy and carbohydrate content only. Permit voluntary nutrition information panels. Require a nutrition information panel when a claim is made in relation to energy or carbohydrate content.

Benefits

- The permission to make low alcohol claims provides consistency with public health messages to moderate alcohol consumption.
- Limiting the types of content claims allowable restricts the use of these for marketing purposes.
- Permits carbohydrate claims and brands developed around those claims to remain in the market place and therefore there is no cost to industry for products carrying carbohydrate claims.
- Provides greater opportunity for industry innovation than Option 1.
- Increased consumer choice in relation to carbohydrate content than Option 1.
- Provides additional nutritional information to consumers when a claim is made.
- For suppliers, alcoholic beverages already labelled with nutrition information panels will not require relabelling and will not incur associated costs.
- Requirement for a nutrition information panel when a nutrition content claim is made will assist with enforcement.

Disadvantages

- Potential to mislead consumers regarding the energy and alcohol content of alcoholic beverages if claims such as 'lite' are used in reference to carbohydrate content since carbohydrate beers are not necessarily lower in energy or alcohol.
- Broadens the market for industry to promote alcohol consumption and therefore potentially conflicts with public health messages to moderate alcohol consumption.

Option 3 –Permit any nutrition content claim on alcohol products and regulate these claims consistently with the approach for nutrition content claims on other foods. Permit voluntary nutrition information panels. Require a complete nutrition information panel when a nutrition content claim is made.

Benefits

- Provides the potential for increased consumer choice compared to Options 1 and 2.
- Permits a wide range of nutrition content claims and brands developed around those claims, to remain in or enter the market place, consistent with current permissions.
- Increased potential for industry innovation compared to Options 1 and 2
- Requirement for a nutrition information panel when a nutrition content claim is made will assist with enforcement.

Disadvantages

- Potentially inconsistent with the policy guideline principle that 'the claim is socially responsible and does not promote irresponsible food consumption patterns'

- Potential to mislead consumers regarding the energy and alcohol content of alcoholic beverages if claims such as 'lite' are used in reference to carbohydrate content since carbohydrate beers are not necessarily lower in energy or alcohol.
- Substantially broadens the market for industry to promote alcohol consumption by using nutrition content claims and potentially change public perception of the properties of alcoholic beverages, which may confuse public health messages to moderate alcohol consumption

3.2.4.1 Recommendation

FSANZ's preferred option at Preliminary Final Assessment is Option 2

For foods containing more than 1.15% alcohol by volume, permit nutrition content claims in relation to alcohol, energy and carbohydrate content, permit voluntary nutrition information panels, and require a nutrition information panel if a nutrition content claim about energy or carbohydrate is made.

This option permits a number of claims that are already in the market place to remain, and therefore does not impose costs to industry of relabelling and repositioning of those products. Permission for making claims about alcohol content will be retained, because such claims have been established for some time and serve a useful purpose in promoting responsible alcohol consumption. Claims in relation to energy content provide an additional choice for consumers of alcohol who are seeking a lower energy alternative.

It is recommended that nutrition content claims about substances other than energy, alcohol and carbohydrate not be permitted on foods containing more than 1.15% alcohol by volume, to avoid a proliferation of claims that may confuse public health messages regarding consumption of alcohol. A variety of nutrition content claims and health claims would still be permitted on foods containing low levels of alcohol and this would provide industry with opportunity to develop innovative products.

Permission for voluntary declaration of nutrition information panels will avoid costs for industry of relabelling alcoholic beverages that are currently labelled with nutrition information panels. In addition, the requirement for a nutrition information panel when a nutrition content claim is made (not proposed at Draft Assessment) will assist with enforcement and provide consumers with adequate information on the nutritional information of the product in order to be able to make an informed choice.

Criteria for carbohydrate claims would not be prescribed because there are no relevant national guidelines or criteria for reduction in carbohydrate intake. This is consistent with the broader approach to regulating carbohydrate claims taken at Draft Assessment and follows the general principle that the risk management approach for specific nutrition content claims in Standard 1.2.7 is based on the public health risk associated with consumption of the nutrient. In all cases, claims still have to conform to fair trading requirements that require claims to not mislead consumers.

4. ISSUES RELATING TO NUTRITION CONTENT CLAIMS

4.1 Conditions for making nutrition content claims – Percentage Daily Intake Labelling

4.1.1 Recommendation

FSANZ proposes the following for percentage daily intake (%DI) labelling at Preliminary Final Assessment:

1. Remove the requirement for %DI labelling on foods carrying nutrition content and health claims.

Policy principles 3 & 12 in the Policy Guideline state that regulation of nutrition, health and related claims should *support government, community and industry initiatives that promote healthy food choices by the population*; and *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*. Although %DI labelling could help some consumers to make healthier food choices, research indicates that %DI information may not be readily understood by many consumers. In addition, since there is currently no strong evidence that content claims can mislead consumers and lead to distorted diets, there is no rationale for requiring additional labelling.

4.1.2 Introduction

Daily intake reference values provide information on the total amount of energy, macronutrients and sodium to be consumed daily by an 'average' adult, based on an 8700 kJ diet and in accordance with national dietary guidelines. Percentage daily intake (%DI) information therefore expresses the percentage of the daily intake for a particular macronutrient, sodium or energy that will be obtained from consuming one serving of the food. It is intended to assist consumers in understanding the relationship between the nutrient content in a serving of the product and targeted intakes of particular nutrients. Percentage daily intake information could provide a tool to assist consumers in identifying for themselves how 'healthy' a food is that is carrying a health or nutrition content claim. Along with per 100g values, %DI can also be used to make comparisons between products. In these respects, percentage daily intake is a similar concept to percent Recommended Dietary Intake (%RDI), which is used for vitamins and minerals, notwithstanding the difference between recommended and target intakes.

Currently there is provision in Standard 1.2.8 to provide %DI information for energy, macronutrients and sodium in the nutrition information panel on a voluntary basis. The %DI values can be included in a third column along with the 'per serve' and 'per 100g' data.

4.1.3 Approach at Draft Assessment

At Draft Assessment FSANZ proposed that:

- %DI labelling for energy and the claimed nutrient (per serve) be declared in the nutrition information panel whenever any nutrition content claim or health claim is made in relation to energy, protein, fat, saturated fatty acids, carbohydrate, sugars, sodium or salt and dietary fibre.
- %RDI labelling for the claimed vitamin or mineral (per serve) be declared in the nutrition information panel, if there is a reference value for the vitamin or mineral in the Code
- %DI labelling be accompanied by the statement *Percentage daily intakes are based on an average adult diet of 8700 kJ* or **based on an average adult diet of 8700 kJ*.

During the early consultation phases of this proposal, some stakeholders expressed the view that there is the potential for nutrition content claims to be misleading which might lead to consumers distorting their diets in response to content claims, to the degree that would contribute significantly to long term health problems such as diabetes or cardiovascular disease. Therefore, it was argued, measures should be taken to reduce consumer confusion. However, evidence of consumer confusion was not provided. At the time of writing the Draft Assessment Report, FSANZ considered that although the extent of consumer confusion with nutrition content claims was unclear, %DI information could be a useful risk management tool in assisting consumers with the interpretation of claims. For instance, information on %DI may alert consumers that while the food is 'reduced' compared to a reference food, it may nonetheless contribute a significant proportion of the targeted daily energy intake.

4.1.4 The issue/problem

The majority of submitters to the Draft Assessment Report opposed the proposed approach requiring %DI labelling on products carrying health and nutrition content claims (see subsection 4.1.5). In addition, at Draft Assessment FSANZ had not evaluated the effectiveness of %DI labelling in assisting consumer interpretation of nutrition content claims. Consequently FSANZ considered it appropriate to review the requirement for %DI labelling on products carrying nutrition content and health claims.

4.1.5 Comments from stakeholders at Draft Assessment

The majority of submitters commenting on %DI (representing all stakeholder groups), opposed the proposed approach at Draft Assessment. The main reasons given for opposing the requirement to include %DI information on products carrying claims were:

4.1.5.1 General issues

- lack of provision of any evidence showing that nutrition content claims have resulted in over-consumption;
- difficulty for imported food to comply;
- additional labelling requirement for 40-60% of stock;
- marketers will not be able to explain that %DI is misleading for children because of Standard 1.1.1 which prohibits any labelling that contradicts mandatory requirements; and;
- education would be essential.

4.1.5.2 Diet context & energy issues

- 8700 kJ criteria inappropriate and potentially misleading;
- in an obesogenic environment including %DI for energy is not helpful;
- %DI for energy may be of questionable value for some products;
- %DI may not reflect the healthiness of the food e.g. nuts; and
- proposed approach does not put foods in the context of the whole diet.

4.1.5.3 Use of nutrition information panel

- product comparisons can already be made using the nutrition information panel;
- likely increase in consumer confusion with the nutrition information panel and %RDI;
- varying sample size stated on product labels increases the difficulty consumers have in using %DI values to compare the nutritional profile of products; and
- unless %DI is mandatory for all foods, consumers cannot access adequate information to make informed choice.

Comment was also made on the proposed approach of not having general food compositional criteria for nutrition content claims. The majority of submitters (mainly public health sector) did not support this approach. The main reasons given were:

- need disqualifying criteria to prevent potentially misleading claims - lack of criteria will pose a risk to public health and safety for some consumer segments;
- the application of disqualifying criteria is consistent with policy guidelines and will protect consumers; and
- system should not rely on consumer ability to interpret the nutrition information panel.

The recommendation in the Draft Assessment on the inclusion of %DI information as the preferred risk management option for nutrient content claims (compared with food compositional criteria, disclosure statements or no conditions) was made on the basis of being a perceived lower cost option, it was commensurate with the assumed low risk of consumers being misled by content claims and it provided valuable information to consumers in making healthy choices. Each of these rationales was queried by submitters.

4.1.6 Evidence base

Given the stakeholder opposition to the proposed approach at Draft Assessment and the paucity of scientific research investigating the use of %DI in the interpretation of claims, FSANZ considered it was necessary to carry out research to evaluate the effectiveness of %DI information in assisting consumers to interpret nutrition content claims. The outcome of this research has been used to reconsider the use of %DI information as a risk management tool.

4.1.6.1 FSANZ Research

Study 1 – Consumer reactions to three different nutrition information panels

In 1998, the then ANZFA conducted four focus group sessions (n=27) to evaluate consumer reactions to the inclusion of %DI information in the nutrition information panel (ANZFA, 1999). The study included both qualitative and quantitative elements. While the results indicated that %DI information was used more frequently for both single food judgements and food comparisons when compared to per 100g and per serve information, and that some people 'strongly liked' such information because they could immediately relate it to their daily requirements, it did not improve decision-making. However, consumer unfamiliarity with %DI and the fact that consumers were not educated about %DI in this study means that the potential value of consumers using %DI in evaluating the healthiness of products was unclear.

Study 2 – Consumer understanding of percentage daily intake – a qualitative study

Recently FSANZ completed a qualitative study investigating consumer understanding and use of %DI (refer to Attachment 3 for the research report).

Key conclusions from FSANZ research:

- when exposed to %DI information for the first time, participants needed assistance and practice before being able to use the information;
- participants showed the potential to respond to education in both the 1998 and 2006 studies;
- the inclusion of %DI information for only energy and the claimed nutrient hindered the participants ability to use the information and interpret content claims;
- %DI for energy is very poorly understood and participants found it difficult to use this information to decide whether or not the product was healthy;
- for those who currently use and understand values in the nutrition information panel, %DI information may add to product purchase decisions after education;
- for those who currently do not use values in the nutrition information panel, %DI information is not likely to be useful because of the complexity of the concept;
- areas of confusion identified include: between %RDI and %DI, inclusion of three columns of data in the nutrition information panel, use of percentages; the use of %DI information to compare products when serving sizes vary;
- %DI information on the front of packages may promote consumer understanding and use of %DI; and
- education on %DI is essential to encourage and facilitate the use of the concept.

4.1.6.2 International Literature Review

Refer to Attachment 4 for the literature review on %DI labelling.

Key Conclusions from the literature review:

- over the period from 1995-98, USA studies indicate 30-50% of consumers understood and/or used % Daily Value (%DV) when shopping;
- it is the more educated/nutrition conscious/higher income consumers who have greater understanding/use of %DV;
- consumer education on %DV is necessary however, even a brief explanation can improve the accuracy with the use of %DV (in a research setting);
- daily reference values and % daily reference values help give consumers dietary context;
- consumers who use %DV tend to focus on one or two nutrients e.g. fat;
- numeric formats tend to be preferred over graphs, charts, descriptors;
- support in the UK for including Guideline Daily Amounts (GDA) for women and men in the nutrition information panel;
- studies comparing the consumer ability to correctly use absolute reference values and % reference values give conflicting results; and
- points of confusion with %DV include: %DV is the percentage of nutrient in entire package; nutrient with highest %DV is the nutrient that is present in greatest amount in package; figures don't apply to me; meaning of percentages; %DI for energy more useful for people trying to lose weight.

The reason for requiring %DI labelling on products carrying nutrition content claims was to provide consumers with additional information which would assist in the interpretation of claims, thereby reducing the risk that potential confusion will lead to distorted diets and long term health problems. FSANZ research suggests that with some education, current users of the nutrition information panel may make appropriate use of %DI information. However, the %DI concept is considered to be relatively complex and cannot be readily used by those who do not understand and use nutrition labelling information.

In addition, only requiring %DI values for energy and the claimed nutrient as opposed to all nutrients, along with only requiring %DI labelling on products carrying nutrition content and health claims, are likely to hinder consumer use and interpretation of the information. Studies from the USA and UK indicate relatively low level of use of %DV/GDA labelling post-introduction of these on product labels. Several studies have also indicated that the consumers most likely to gain from this information (less educated, less nutrition conscious, lower income) are also the least likely to use the information to made informed choices.

4.1.7 Factors relevant to regulatory option

Although a number of stakeholders claim that content claims mislead consumers, there is no substantial evidence to support this assertion to date. There is no research that has been designed to see whether confusion over content claims leads to significantly altered purchase behaviour, which in turn might lead to adverse health outcomes. The regulatory measure for managing risk should be commensurate with the risk to consumers, taking account of the uncertainties. Compositional requirements for foods carrying content claims (i.e. compositional eligibility criteria) are appropriate where there is a significant degree of consumer misunderstanding which could result in adverse health impacts. The level of risk management proposed at Draft Assessment, i.e. additional labelling requirements, could be considered an intermediary level of risk management for these claims. However the evidence base described above indicates there are disadvantages in this approach.

It is apparent there is not sufficient information available to identify the risk of consumers being misled by content claims, whether or not this poses a risk to their health, and what risk management approach would mitigate against this risk. If, as some stakeholders believe, those at most risk are consumers with limited education and consumers unfamiliar the nutrition information panel, then a risk management approach based on the nutrition information panel is unlikely to be an effective measure.

FSANZ has derived its recommendation on the basis of the information available to date. However, FSANZ intends to carry out further research on consumer understanding and use of nutrition content claims in 2007 with the intention that the findings will be available for inclusion in the Final Assessment Report. Should the findings support significant changes to the regulation of content claims, further consultation would be undertaken. In deriving its recommendation, FSANZ has considered policy guidance. There is no explicit guidance relating to risk management of content claims. The approach FSANZ is proposing is consistent with minimal effective regulation, commensurate with risk, and enabling industry to innovate healthy products.

4.1.8 Analysis of options

Given the issues identified in both FSANZ research and international studies over the use of %DI labelling particularly in relation to the interpretation of claims, along with widespread stakeholder opposition to %DI labelling as proposed at Draft Assessment, FSANZ considered it necessary to re-examine the options for %DI labelling.

Option 1 – Approach taken at Draft Assessment: require %DI labelling on products carrying health and nutrition content claims

Benefits

- %DI labelling potentially provides additional information for those who currently use nutrition information panels;
- provides consumer choice for those consumers who can use/understand %DI information to help interpret nutrition content claims;
- potential for %DI information to help consumers assess products in the context of the overall diet;
- potential for public health professionals to use %DI information when educating clients; and
- for industry, %DI information may encourage healthy product innovation.

Disadvantages

- cost to industry with relabelling;
- increased enforcement costs for government agencies;
- %DI labelling not likely to be used by current non-users of nutrition information panel information because of complexity of %DI concept;
- %DI labelling more likely to be used by health conscious and nutrition knowledgeable consumers;
- education campaign essential;
- consumer confusion with only having %DI values for energy and claimed nutrient;

- reduced ability for consumers to make full use of %DI labelling with the information only required to be on products carrying claims;
- third column of data may add to consumer confusion; and
- no broad acceptance from any stakeholder group.

Option 2 – Do not require %DI labelling on products carrying health and nutrition content claims.

Benefits

- this is *status quo* and retains current permissions for voluntary %DI labelling (see section 4.2);
- recognises the need for further evaluation of the extent to which consumers are misled by nutrition content claims and what measure would reduce any confusion, in order to decide on the appropriate risk management approach;
- retention of the simpler nutrition information panel which current research indicates is preferred by consumers, until a more effective approach can be identified through research;
- allows opportunity for efficiencies in implementing changes in nutrition labelling requirements, subject to the review of the nutrition information panel;
- for industry, no costs associated with relabelling of existing products making nutrition content claims in the short term;
- do not need education campaign on %DI; and
- no impact on government agencies.

Disadvantages

- no additional information available for consumers to assist the evaluation of products carrying claims; and
- public health stakeholders likely to object to the lack of a risk management approach to help reduce perceived consumer confusion and associated health risk arising from nutrition content claims.

FSANZ's preferred approach at Preliminary Final Assessment is Option 2.

FSANZ research has indicated that %DI labelling is not likely to be an effective risk management tool in helping consumers to interpret nutrition content claims and notes the potential importance of education and consumer familiarity with the concept. It is therefore appropriate that industry does not incur any relabelling costs for %DI information at this time. Although public health stakeholders have raised concerns that consumers are misled by some content claims to the extent that there may be adverse health effects, there has been no evidence provided. Indeed there has been little research carried out investigating the extent of consumer confusion with nutrition content claims, either overseas or in Australia/New Zealand. Therefore, at this stage FSANZ considers there is insufficient evidence to amend the risk management of content claims from the *status quo*. If further evidence became available on the extent and nature of consumer confusion, then the risk management approach could be reappraised. FSANZ intends to look into this aspect and the risk management interventions that may be effective, as part of a subsequent labelling review, taking account of consumer understanding of food labelling elements.

4.2 Voluntary Percentage Daily Intake Labelling

4.2.1 Recommendation

FSANZ proposes the following for Voluntary Percentage Daily Intake (%DI) Labelling at Preliminary Final Assessment:

1. Continue to allow voluntary %DI labelling in the nutrition information panel with the additional permission of the abbreviated '8700 kJ' statements:

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

2. Permit %DI labelling information for energy alone, to be presented outside the nutrition information panel (without the information being considered a claim) provided %DI information for energy, the macronutrients and sodium are all presented in the nutrition information panel.
3. Permit %DI labelling information for energy together with the macronutrients and sodium, to be presented all in one place, outside the nutrition information panel (without the information being considered a claim) provided all %DI labelling information is also included in the nutrition information panel.

Permission of voluntary %DI labelling both inside and outside the nutrition information panel is supported by policy principle 12 in the policy guideline which states that the regulatory system should: *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*. Industry has shown increasing interest in including %DI labelling on food labels. Although there are some questions about the usefulness of this information from both FSANZ and international research, both FSANZ and industry research have indicated some consumer interest in this labelling approach. FSANZ is therefore supporting this industry initiative at this time, although further research will be undertaken on %DI labelling as part of a subsequent labelling review.

4.2.2 Introduction

FSANZ's preferred approach at Preliminary Final Assessment is not to mandate %DI labelling on products carrying nutrition content and health claims. Because of this decision and recent industry interest in %DI labelling (being presented as 'signposting'[5]), FSANZ has reviewed the current permissions for voluntary %DI labelling as in Standard 1.2.8, clause 7.

4.2.3 The issue/problem

Currently most of the nutrition content claim conditions are covered under CoPoNC, although a few are regulated by the Code.

[5] Refers to use of graphics and numerical representations of per serve %DI or %RDI information outside the nutrition information panel (e.g. front of pack).

For the latter and for all nutrients which will have conditions placed on them when the new Standard 1.2.7 is gazetted, the presentation of %DI signposting on food packages outside the nutrition information panel would not be permitted unless the product meets claim conditions as specified in the Code. Consequently, consideration needs to be given to explicitly allowing signposting on food packages.

4.2.4 Evidence base

The food industry is showing increasing interest in signposting %DI information and some industry commissioned research has indicated consumer support for this, along with the need for education. FSANZ research (see subsection 4.1.6 and Attachment 2) indicates that consumers who do not understand nutrition information panels were confused by %DI labelling. Other consumers do use food labels to make comparisons and choices and some were able, with explanation, to correctly interpret %DI statements. The research has also found that consumer understanding and use of %DI information presented in the nutrition information panel is hindered when %DI values only for energy and for one claimed nutrient are included. Consumer understanding of %DI values of energy appears to be poor, however further research is required to clarify this and investigate the relationship between %DI labelling and purchase intent, if any. Consumers who are interested in this information responded favourably to the presentation of %DI values on the front of packages and in larger font than that normally used in the nutrition information panel. Given industry interest and potential future interest from consumers, FSANZ considers it appropriate to evaluate permitting signposting %DI information.

There are two important aspects to note about %DI values and their use on food products. Firstly %DI values vary with serving size which can complicate consumer interpretation of the energy or nutrient contribution a particular product makes to the diet. For example, the %DI value for energy of a beverage can range from 6.5% for a 200 ml serve size to 19.5% for a 600 ml serve size. Secondly, the overall nutritional profile of the product is not represented by %DI values for energy alone. For example, the %DI value for energy for two breakfast cereals could be the same while the %DI values for sugar could be markedly different (and also markedly higher than %DI for energy). Within a larger future evaluation of the nutrition information panel as a means of conveying nutrition information to consumers, FSANZ intends to incorporate a further evaluation of consumer understanding and use of %DI labelling.

4.2.5 Analysis of options

Option 1 – Prohibit signposting on products that do not meet claim conditions for energy, macronutrients or sodium

<u>Benefits</u>

- reduces the risk of signposting increasing the ‘healthy’ image of foods that may contain higher levels of ‘risk-increasing’ nutrients.

Disadvantages

- restricts the provision of factual information on products not meeting claim conditions and therefore reduces signposting information available for consumers, making it harder to use %DI for product comparisons;
- industry wants to use signposting and has research indicating associated consumer interest; and
- increased resources required for government agencies in monitoring compliance.

Option 2 –

(i) Permit %DI labelling information for energy alone to be presented outside the nutrition information panel, provided %DI values for energy, the macronutrients and sodium are all presented in the nutrition information panel; and

(ii) Permit %DI labelling information for energy together with the macronutrients and sodium, to be presented all in one place, outside the nutrition information panel, (without the information being considered a claim) and also requiring this %DI labelling information in the nutrition information panel.

Benefits

- FSANZ and industry research indicates some consumer support for %DI signposting;
- some consumers may find %DI signposting easier to read than the same information in the nutrition information panel;
- with increased exposure, consumer understanding of the %DI concept may increase and support healthier food choices;
- permitting %DI signposting on all products may increase usefulness of the information for consumers;
- permitting %DI signposting for energy alone may encourage consumers to consider their overall energy intake in the diet;
- when %DI values for energy and all core nutrients are signposted, requiring them to be in the same place on the package will assist consumer use and understanding of the concept; and
- requiring % DI values for energy together with macronutrients and sodium to be included in the nutrition information panel will encourage suppliers to present the information in a consistent manner and allow consumers to more fully evaluate the nutritional profile of the product.

Disadvantages

- signposting may increase the 'healthy' image of foods that may contain higher levels of 'risk-increasing' nutrients;
- inclusion of all values may prevent small packages from signposting %DI information;
- current research indicates the usefulness of %DI signposting in helping consumers evaluate a product's healthiness and its impact on purchase intention is uncertain;
- it is uncertain whether signposting %DI values for energy alone will be understood and used by consumers; and
- effectively allows 'claims' on products that would otherwise not normally qualify. This may disadvantage products making the usual text-based front of pack claims, and create confusion regarding substantiative presence of a nutrient in a product when 'claimed'.

FSANZ's preferred approach at Preliminary Final Assessment is Option 2.

FSANZ recommends that current permissions for voluntary %DI labelling in the nutrition information panel requiring values for energy, macronutrients and sodium continues. Percentage DI labelling for energy alone presented outside the nutrition information panel, will be permitted provided that %DI values for energy, macronutrients and sodium are included in the nutrition information panel. The inclusion of %DI for energy and nutrients in the nutrition information panel will allow informed consumer choice and also reduce the risk that the presentation of %DI for energy alone could mislead consumers. In addition, %DI labelling information for energy together with the macronutrients and sodium, presented all in one place, outside the nutrition information panel will be permitted, regardless of whether claim criteria are met. These permissions will allow industry to signpost %DI information on any product, except alcoholic beverages which will be expressly excluded.

To slightly reduce, and provide more flexibility for, the wording requirements for the '8700 kJ' statement, FSANZ proposes that the abbreviated requirements proposed at Draft Assessment are also proposed at Preliminary Final Assessment, as follows:

- '*based on an average adult diet of 8700 kJ'; or
- 'Percentage daily intakes are based on an average adult diet of 8700 kJ'

Because of the current uncertainty over the value to consumers of percentage daily intake information and which format is most effective for consumer understanding of the nutritional value of a food, it is envisaged that a future review of the nutrition information panel will also include an evaluation of the usefulness and effectiveness of this and whether further regulatory measures are needed.

4.3 Conditions for food as prepared or as sold

4.3.1 Recommendation

FSANZ proposes at Preliminary Final Assessment the following in relation to the state of preparation of the food when applying qualifying and food composition eligibility criteria:

1. Where claims are made about foods that require draining or reconstituting with water before consumption, claims are to be based on the drained or reconstituted form of the food.

2. Where the supplier provides directions for preparation/consumption, and the food could be consumed 'as sold' or 'as prepared', claims can be based either on the food:

   (a) 'as prepared/consumed' according to those directions; or
   (b) 'as sold'.

3. In the absence of directions for preparation or consumption, claims should be based on the food 'as sold' even though the food may be able to be used as an ingredient in the preparation of other foods.

4. The claim must indicate the form of the food to which the claim applies (this will be outlined in a user guide).
5. Both qualifying criteria and nutrient profiling criteria must be met by the same form of the food that is:

    (a) the food 'as sold' meets the qualifying and nutrient profile criteria; or
    (b) the food 'as prepared/consumed' meets the qualifying and nutrient profile criteria.

6. Qualifying criteria and eligibility to make a claim based on the nutrient profile cannot be based solely on added foods in the process of preparation.

7. The nutrition information panel must provide appropriate information to support the form of the food on which the claim is based (for example, a third column for nutrient declarations for the food 'as prepared' may be required).

The Ministerial policy guideline is not explicit on this issue. However claim pre-requisite 5 states that a claimed benefit must be *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*. FSANZ recommends that industry is given the option of meeting qualifying and food eligibility criteria based either on the food as sold or as prepared/consumed which could be interpreted as being inconsistent with policy guidance. However, requirements for labelling information to clearly indicate the basis of any claim are considered to provide clarity for consumers. In addition, there is already provision in the Code for the inclusion of a third column in the nutrition information panel to specify nutritional details of a food as prepared/consumed. The recommended approach therefore provides for consistency of regulation across the Code.

4.3.2 Introduction

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

4.3.3 Approach at Draft Assessment

Draft Standard 1.2.7 did not specifically address whether the qualifying and food composition eligibility criteria for nutrition content and health claims should be based on the food as sold or as prepared/consumed, with the exception of 'low energy' claims, where the conditions included that where the food is to be prepared as directed on the label, the average energy content of the food must be calculated for the food as prepared.

At Draft Assessment, FSANZ did not specify conditions under which content claims can be made, based on the assumption that to do so would be inconsistent with the requirements in the Code which apply to food 'as sold', rather than food 'as consumed' (meaning as drained, reconstituted or prepared as per the directions on the label) (Attachment 5 - Regulatory Framework – Generic Application, of the Draft Assessment Report).

However, with respect to substantiation of nutrition content claims, Attachment 8 of the Draft Assessment Report (Substantiation Framework) stated: *The content should be determined on the form of the food in which it is intended to be consumed. For packaged foods, this will generally be the form suggested in the directions for use included in the label.*

4.3.4 The issue/problem

Stakeholders have raised concerns regarding the form in which the food should be in when determining nutritional content for compliance with claim criteria.

There was some confusion from the Draft Assessment Report and the draft Standard 1.2.7 as to what state of preparation the food should be in when applying qualifying and food eligibility compositional criteria, as generic conditions were not specified in the draft Standard 1.2.7. The exception to this was for 'low energy' claims where conditions were specified for situations when the food is to be prepared as directed on the label. This was a result of this condition being carried over to draft Standard 1.2.7 from its present location in Standard 1.2.8.

Although it was stated in the Draft Assessment Report that it was considered not appropriate to specify conditions under which nutrition content claims can be made, FSANZ now acknowledges that such conditions are regulated in other standards of the Code and could also be regulated under Standard 1.2.7.

4.3.5 Comments from stakeholders at Draft Assessment

Although it was raised in the public consultation sessions there were very few written comments from submitters to the Draft Assessment Report regarding this issue. The submitters that did comment (industry and government) were of the opinion that the claim should apply to the food as prepared/consumed rather than as sold, as FSANZ did not provide any evidence that the claim could be misleading if based on the prepared food. One submitter suggested that for foods such as Milo, the qualifying criteria could be based on the prepared food but the disqualifying criteria be based on the food as sold.

In addition, it was considered that if clear directions for use are provided on the label it should be sufficient that the claim is based on those directions. It was noted that as this was not clear in the proposed Standard, it could be clarified in a user guide. It was pointed out that although the Draft Assessment Report stated that conditions for consumption could not be specified in the Code, such conditions are already specified in other Standards in the Code, for example Standards 1.2.8, 1.3.2 and 2.9.3.

4.3.6 Factors relevant to regulatory option

Clause 9 of Standard 1.2.8 requires that where a food is labelled with directions for reconstituting with water before consumption, the nutrition information panel must relate to the reconstituted food. Clause 10 of Standard 1.2.8 requires that where a food is labelled with directions for draining the food before consumption, the nutrition information panel must relate to the drained food. FSANZ considers that these requirements should also apply to nutrition content and health claims on foods requiring reconstituting with water/draining, and both the qualifying criteria and nutrient profile score should be based on the reconstituted/drained food.

For foods that are intended to be prepared or consumed with at least one other food, Clause 11 of Standard 1.2.8 provides the option to include a third column in the nutrition information panel to specify the nutritional details for that food as prepared or consumed. FSANZ considers that this approach can also be applied to nutrition content and health claims, such that if directions are provided for preparation of the food with at least one other ingredient, both the qualifying criteria and nutrient profile score should be applied to the food as prepared/consumed.

If directions for preparation/consumption are not provided on a label, but an intended use of the food is as an ingredient, it would be misleading to base the claim on the final food product. Hence the claim should be based on the food 'as sold'.

For consistency, it is considered that both the qualifying criteria and nutrient profile score need to be met by the food in the same form, i.e. the food 'as sold' meets both the qualifying criteria and nutrient profile score criteria, or the food as prepared/consumed meets both the qualifying and nutrient profile score criteria. This also means that a health claim cannot be based on the added food alone, for example, a powdered milk flavouring labelled with directions for adding milk could not make a health claim about the protein from the milk unless the powder and the milk combined meet both the qualifying and the nutrient profile score criteria.

In addition, for reasons of clarity for enforcement and consumers, the claim should indicate the state of the preparation of the food it relates to, for example, if the claim is relating to the food as prepared according to the directions on the label, this should be indicated by the wording of the claim. Also, the nutrition information panel must provide appropriate information to support the form of the food on which the claim is based (for example, a third column for nutrient declarations for the food 'as prepared' may be required).

4.3.7 Analysis of options

Option 1 – Approach taken at Draft Assessment: conditions not specified whether the criteria are based on the food as sold or as prepared/consumed, except for 'low energy'

Benefits

- More scope for industry to determine the appropriate form of the food to apply the criteria to, within the constraints of fair trade legislation.

Disadvantages

- More potential for consumers to be misled, if the label on a package does not clarify the state of preparation of that food that the claim applies to, and the nutrition information panel does not reflect the basis for the claim.
- Inconsistency because the conditions regarding the state of preparation of the food are not specified, except in the case of 'low energy' claims.
- Lack of clarity for government enforcement bodies and industry regarding the state of preparation of the food that the qualifying and food composition eligibility criteria should be applied to.

Option 2 – Specify conditions in draft Standard 1.2.7 for eligibility criteria to be based on the food as sold or as prepared/consumed

Benefits

- Reduces the potential for consumers to be misled by claims and provides clarity for enforcement by government bodies because the state of preparation of the food that the claim applies to is required to be clearly indicated on the label, and the nutrition information panel should reflect the nutrient content that is the basis for the claim.
- Prevents claims being made on a form of the food that is not normally consumed, thus providing more useful information to consumers.
- Gives industry the opportunity to base claims on the food 'as prepared/consumed' whilst at the same time provides guidance on how this could be done without misleading consumers.
- Provides for consistency of regulation across the Standard and within the Code.

Disadvantages

- Greater flexibility may lead to confusion for consumers, particularly less attentive label readers.

FSANZ's preferred option at Preliminary Final Assessment is Option 2.

This option provides industry with the opportunity to base claims on the food as sold or as prepared/consumed, but also lays out parameters to facilitate enforcement and to ensure that the claim is presented in a manner that is not misleading to consumers.

5 CRITERIA FOR SPECIFIC NUTRITION CONTENT CLAIMS

5.1 Policy guidance relevant to nutrition content claims

Section 5 presents the rationale for specific changes made since Draft Assessment to recommendations for the regulation of some nutrient content claims. In developing the new recommendations relevant policy guidance has been considered along with stakeholder views, relevant evidence, international approaches and FSANZ objectives. Although the policy guidance does not make specific reference to the content claims covered in this section, a number of the principles listed in the policy guidance were taken into account in the development of the recommended regulatory approaches as follows: the use of scientifically valid claims; consistency with Australia and New Zealand national policies and legislation relating to fair trading, trade and innovation; cost effectiveness and not being more trade restrictive than necessary; using the best elements of international regulatory systems; and promoting a partnership between consumers, governments and industry in the delivery and responsible use of claims which protects consumers from misleading information.

5.2 Wholegrain

5.2.1 Recommendation

FSANZ proposes the following claims and conditions in relation to 'wholegrain' at Preliminary Final Assessment:

1. The conditions for wholegrain nutrition content claims will be removed from draft Standard 1.2.7.

2. Claims regarding the characteristic wholegrain will be regulated by the same conditions as for biologically active substances, as follows:

    (a) 'presence' type claims can be made but descriptors cannot be used to indicate the level of substance that is present;
    (b) general level health claims for biologically active substances must state the amount of the substance that is in the food and the amount that is required to be consumed to provide the health effect;
    (c) 10% of the amount of the substance that provides the health effect is required to allow a general level health claim;
    (d) the supplier must have records to substantiate recommendations provided for consuming a certain amount of the food or substance.

5.2.2 Introduction

Wholegrain foods have been promoted over their refined counterparts in dietary guidelines and other authoritative advice for many years because of increased nutrient content of wholegrain foods, particularly dietary fibre, vitamins and minerals. For instance, the Dietary Guidelines for Australian Adults recommend that adults 'eat plenty of breads and cereals (including breads, rice, pasta and noodles), preferably wholegrain' (NHMRC, 2003a).

As a result of Application A464 – Definition of Wholegrain, the definition of 'wholegrain' has been amended in Standard 2.1.1 of the Code to 'the intact grain or the de-hulled, ground, milled, cracked or flaked grain where the constituents – endosperm, germ and bran – are present in such proportions that represent the typical ratio of those fractions occurring in the whole cereal, and includes wholemeal'.

5.2.3 Approach at Draft Assessment

At Draft Assessment, FSANZ proposed the following claims and conditions for nutrition content claims about wholegrain:

Claim	Conditions
Any presence claim	≥ 8 g wholegrain per serve
Good source	≥ 15 g wholegrain per serve

5.2.4 The issue/problem

The conditions for wholegrain claims used absolute values (i.e. 8 g/15 g per serve). However, there is no reference value for appropriate dietary intake on which to base these conditions. In addition, these conditions were based on criteria that were under consideration in the United States, which have since been rejected by the US Food and Drug Administration (FDA). The FDA has now provided guidance advising that only factual statements about wholegrain claims can be made, for example, '10 grams of whole grains'.

5.2.5 Comments from stakeholders at Draft Assessment

Submitters who made specific comments regarding wholegrain claims (from industry and government sectors) were not in support of the proposed criteria. It was generally considered that there should not be specific criteria because there is no reference value for wholegrain. Some submitters noted that the requirements for percentage labelling of characterising ingredients provides information for consumers and that permission for this declaration should continue with respect to wholegrain.

Some alternative conditions were suggested, including:

- using percentages (25% for source, 50% for good source etc);
- various alternative absolute values;
- 'good source' claim of 7.5g (dry weight)[this was based on a recommended target intake of 30g (dry weight) per day], an outcome of the Go Grains Round Table discussion (Griffiths et al., 2006);
- declaration as a characterising ingredient; and
- FDA approach using factual declarations (e.g. '100% wholegrain) but no descriptors that imply a certain level.

5.2.6 Factors relevant to regulatory option

The term 'wholegrain(s)' is used in general parlance to mean intact grains, where the characteristic of 'wholegrain' may apply to a variety of grains such as oats, wheat, rye etc. Wholegrains are obviously not nutrients as such and do not fit readily within the conditions for nutrition content claims and health claims. However, such claims about 'wholegrain' are commonly used to promote 'healthier' products. In order to allow meaningful 'wholegrain' claims, FSANZ considers that parameters are required. In many ways the issues around managing 'wholegrain' claims are similar to those for biologically active substances. FSANZ therefore proposes that 'wholegrain' claims can be regulated as claims for biologically active substances.

5.2.7 Analysis of options

Option 1 - Approach taken at Draft Assessment (≥ 8 & 15 g wholegrain per serve for 'source' and 'good source' claims respectively)

Benefits

- Uses absolute values thus provides clarity to industry and government enforcement agencies.

Disadvantages

- Is not consistent internationally.
- Is based on arbitrary criteria because of lack of a suitable reference value for dietary intake. The claims have no scientific basis, as it is unknown what level of wholegrain is required for consumers to achieve a beneficial effect.
- Does not fully consider the issue of moisture content in food and therefore tends to favour cereals (including cereals containing significant amounts of sugar) over breads.

Option 2 – Remove specific criteria for wholegrains from draft Standard 1.2.7; regulate wholegrains as biologically active substances

Benefits

- Consistent internationally and with Codex.
- Restricts claims to factual statements about wholegrain content, reducing potential for consumers to be misled by claims with inadequate scientific basis.
- Permits the percentage of wholegrains to be declared as a characterising ingredient according to the requirements in Standard 1.2.10 – Characterising Ingredients and Components of Food, providing consumer information.

Disadvantages

- If making a health claim, industry are responsible for determining the substantiated amount that is required to be consumed each day in order to achieve the specific health effect.

FSANZ's preferred option at Preliminary Final Assessment is Option 2.

This option addresses concerns around the lack of a suitable reference value for dietary intake on which to base criteria, but permits industry to make factual statements about the content of wholegrain in a food.

5.3 Saturated and *Trans* Fatty Acid Claims

5.3.1 Recommendation

FSANZ proposes the following for claims and conditions in relation to saturated and *trans* fatty acid nutrition content claims at Preliminary Final Assessment:

1. Claims regarding 'low' trans fatty acids in isolation will be prohibited (combined trans and saturated fatty acid 'free' or 'low' claims are permitted).

2. Claims of 'x% trans fatty acid free' will be prohibited.

3. Conditions will be prescribed for 'reduced' trans fatty acid claims, as follows:

    (a) the food contains at least 25% less trans fatty acids as the same quantity of reference food. The food contains no more saturated fatty acids as the same

quantity of reference food. The identity of the reference food and the difference between the *trans* fatty acids content in the reference food and in the claimed food must be indicated. The claim must be presented so that all the elements of the claim are in one place.

4. Conditions will be prescribed for the 'free in saturated fatty acids' claim such that the food must also be free of trans fatty acids.

5. Conditions will be prescribed for 'free in trans fatty acids' such that the food must meet the conditions for a 'low in saturated fatty acids' claim.

6. Voluntary declaration of trans fatty acids in the nutrition information panel will be permitted.

7. The conditions that were prescribed for 'low' and 'reduced' saturated fatty acids and combined saturated and *trans* fatty acid claims remain the same as those proposed at Draft Assessment.

5.3.2 Introduction

Saturated fatty acids are the predominant type of fatty acid in dairy products, in some meats, and in palm oil and coconut oil (NHMRC, 2003a).

Trans fatty acids are a form of unsaturated fatty acid where the hydrogen atoms around a carbon-carbon double bond are orientated in a *trans* configuration rather than a *cis* configuration. *Trans* fatty acids occur naturally in the fat of ruminant animals and are also created during some manufacturing processes such as the partial hydrogenation of liquid edible oils to make edible fat spreads.

There is evidence to show that consumption of diets containing saturated fatty acids and *trans* fatty acids, particularly *trans* mono-unsaturated fatty acids, in comparison with other fatty acids, increase the blood concentration of total and low-density lipoprotein cholesterol, and lower high-density lipoprotein cholesterol (EFSA, 2004).

5.3.3 Approach at Draft Assessment

At Draft Assessment, FSANZ proposed the following claims and conditions for saturated and *trans* fatty acid nutrition content claims:

Claim	**Conditions**
Low (in) saturated fatty acids/ Low in saturated and *trans* fatty acids	≤1.5 g in total of saturated and *trans* fatty acids per 100 g of solids; ≤0.75 g in total of saturated and trans fatty acids per 100 ml of liquids.
Reduced (in) saturated fatty acids	The food contains at least 25% less saturated fatty acids as the same quantity of reference food. The food contains no more *trans* fatty acids as the same quantity of reference food. The identity of the reference food and difference between the saturated fatty acids content in the reference food and in the claimed food must be indicated. The claim must be presented so that all the elements of the claim are in one place.

Claim	Conditions
Reduced in saturated and *trans* fatty acids	The food contains at least 25% less saturated and *trans* fatty acids as the same quantity of reference food. Both saturated and *trans* fatty acids are reduced relative to the same quantity of reference food. The identity of the reference food and the difference between the saturated fatty acids and *trans* fatty acids content in the reference food and in the claimed food must be indicated. The claim must be presented so that all the elements of the claim are in one place.
Reduced in *trans* fatty acids/ Low in *trans* fatty acids	Conditions were not proposed. Claims would default to fair trade requirements.
Free in saturated fatty acids/ Free in *trans* fatty acids/ Free in saturated and *trans* fatty acids	Conditions were not proposed. Claims would default to fair trade requirements.

5.3.4 The issue/problem

Given the adverse effect of the intake of both saturated and *trans* fatty acids on the risk of developing cardiovascular disease and that these fatty acids are usually present together in the food supply, both should be considered together when developing applicable claims and conditions. This approach was applied to some saturated and *trans* fatty acid claims at Draft Assessment, however it needs to be considered more broadly across all potential claims in relation to saturated and/or *trans* fatty acids.

5.3.5 Comments from stakeholders at Draft Assessment

It was suggested by the National Heart Foundation (New Zealand and Australia) that if the conditions for 'low' saturated fatty acids could not be met, suppliers would instead make claims in relation to *trans* fatty acids. They considered that this takes the emphasis away from the public health message to reduce saturated fats and increase polyunsaturated fats in the diet. These submitters therefore recommended that *trans* fatty acid claims be prohibited, until suitable daily intake reference values are available to determine conditions for claims in relation to *trans* fatty acids.

5.3.6 Evidence Base

The proposed approach at Preliminary Final Assessment has taken into account factors including stakeholder comments to the Draft Assessment Report, literature reviews carried out as part of the review process for pre-approving high level health claims, international regulation and recommendations made in dietary guidelines.

Details of the saturated and *trans* fatty acids high level health claim review are given in the Draft Assessment Report available on the FSANZ website (Attachment 10, Chapter 2).

Both Canada and the United States include *trans* fatty acid content in their 'saturated fatty acid free' claim criteria (less than 0.2 g and 0.5 g per reference amount respectively). Canada also includes the level of saturated fatty acids in their '*trans* fatty acid free' claim criteria (less than 0.2 g of *trans* fatty acids per ref amount and the food must be low in saturated fatty acids).

The Australian Dietary Guidelines and The New Zealand Food and Nutrition Guidelines make specific recommendations around saturated fat intake and although they both discuss *trans* fatty acids, there are no daily values provided for their intake. The Nutrient Reference Values for Australia and New Zealand do not make specific recommendations for intake of *trans* fatty acids but note that a combined limit of 8-10% of energy from saturated and *trans* fats together would be prudent (NHMRC and Ministry of Health, 2006).

5.3.7 Factors relevant to regulatory option

FSANZ does not mandate declaration of *trans* fatty acids, therefore all claims in relation to *trans* fatty acids will be nutrition content claims.

The Ministerial Council has asked FSANZ to provide a paper based on an evaluation of the levels of *trans* fatty acids in the food supply. FSANZ is preparing a review report on *trans* fatty acids in the Australian and New Zealand food supplies. The report will include a risk assessment and advice on appropriate measures to manage risk. The Review Report will be presented to the May 2007 meeting of the Ministerial Council and will be placed on the FSANZ website following the meeting.

As dietary guidelines do not make recommendations regarding *trans* fatty acids in isolation from saturated fatty acids, *trans* fatty acids should always be considered in association with saturated fatty acids. In addition, criteria cannot be developed for some *trans* fatty acid claims due to lack of a suitable reference value for *trans* fatty acids intake. For these reasons, conditions were not proposed at Draft Assessment for making 'low' claims in relation to *trans* fatty acids in isolation. The approach that saturated and *trans* fatty acids should be considered together when developing applicable claims and conditions needs to be considered more broadly across all potential claims in relation to saturated and/or *trans* fatty acids.

Specifically, inclusion of both fatty acids in the conditions for 'free' in saturated fatty acids and 'free' in *trans* fatty acids should be considered. It also needs to be considered whether other claims that refer to *trans* fatty acids only, for example, 'low' and 'x% *trans* fatty acid free', should be expressly prohibited. Provision for 'reduced' and 'free' *trans* fatty acids claims can be considered. This is because a reference value is not necessary for establishing appropriate conditions. Also, levels for saturated fatty acids can be incorporated into these conditions.

The conditions for a 'reduced *trans* fatty acids' claim could therefore be as follows:

> *The food contains at least 25% less trans fatty acids as the same quantity of reference food. The food contains no more saturated fatty acids as the same quantity of reference food. The identity of the reference food and difference between the trans fatty acids content in the reference food and in the claimed food must be indicated. The claim must be presented so that all the elements of the claim are in one place.*

As it would be almost impossible for a food that was free in *trans* fatty acids to also be free in saturated fatty acids (unless the food was also free in fat), the conditions for a 'free in *trans* fatty acids' claim could be as follows:

The food meets the conditions for a 'low saturated fatty acid' claim (with the 'free' trans fatty acid level regulated by fair trading legislation).

Regarding 'x% free' claims, FSANZ considers that such claims may emerge in relation to *trans* fatty acids, particularly as an alternative to 'low *trans* fatty acid' claims if these claims are prohibited. Because there are no criteria proposed for 'low *trans* fatty acid' claims, the risk management approach applied to 'x% fat free' and 'x% sugar free' claims (that the food is required to be low in fat and sugar respectively) cannot be applied to x% *trans* fatty acid free' claims. For this reason, FSANZ proposes that 'x% *trans* fatty acid' free claims be prohibited.

From a public health perspective and to assist consumer choice, it is considered useful to permit voluntary declaration of *trans* fatty acids in the nutrition information panel. As this voluntary declaration would constitute a nutrition content claim, subclause 5(4) as currently prescribed in Standard 1.2.8 would apply, i.e. the level of monounsaturated and polyunsaturated fatty acids must also be declared in the panel.

5.3.8 Analysis of options

Option 1 – Approach taken at Draft Assessment (trans and saturated fatty acids considered in the conditions for 'low' and 'reduced' saturated fatty acid/ saturated and trans fatty acid claims; no conditions prescribed for trans fatty acid claims in isolation; no conditions prescribed for 'free' in saturated fatty acid claims)

Benefits

- Less prescriptive for industry.

Disadvantages

- Potential for consumers to be misled and impact on public health if claims are made regarding *trans* fatty acids on foods containing relatively high levels of saturated fatty acids.
- *Trans* fatty acids and saturated fatty acids are not consistently considered together for each possible claim, resulting in potential adverse effects on public health and less clarity for enforcement by government.
- Some claims in relation to these fatty acids are regulated by fair trade legislation whereas others will be regulated under Standard 1.2.7 resulting in less clarity for enforcement by government agencies.

Option 2 –

- ***trans and saturated fatty acids considered in the conditions for low and reduced saturated fatty acid claims;***
- ***trans and saturated fatty acids considered in the conditions for low and reduced saturated and trans fatty acid claims;***
- ***conditions prescribed for 'reduced' trans fatty acid claims (including no increase in saturated fatty acids levels);***
- ***conditions prescribed for the 'free in trans fatty acids' claim and the 'free in saturated fatty acids' claim, including levels of both fatty acids;***

- ***claims about 'low' trans fatty acids and 'x% trans fatty acid free' expressly prohibited; and***
- ***voluntary declaration of trans fatty acids in the nutrition information panel permitted.***

Benefits

- Is consistent with public health messages to decrease both saturated and *trans* fatty acid intake and with the nutrient reference values document (NHMRC and Ministry of Health, 2006) that recommends limits for combined levels of intake of these fatty acids.
- Reduces the potential for consumers to be misled about the content of *trans* fatty acids in a food by 'low' or 'x% free' claims in relation to *trans* fatty acids.
- Provides consistency with the conditions for 'low' and 'reduced' saturated and *trans* fatty acid claims, in that levels of both these fatty acids are considered.
- Allows for provision of information to consumers regarding the level of *trans* fatty acids in a food.
- Increases clarity for enforcement by providing specific conditions for claims relating to *trans* fatty acids and by regulating these claims in the same legislation as claims in relation to saturated fatty acids.
- The 'reduced' *trans* fatty acid conditions may encourage the food industry to reduce *trans* fatty acids without consequently increasing the saturated fatty acid level, resulting in benefits to public health.

Disadvantages

- Less information regarding content of trans fatty acids in foods able to be provided to consumers, i.e. no 'low' trans fatty acid claims.
- More prescriptive for industry.

FSANZ's preferred option at Preliminary Final Assessment is Option 2.

This option addresses the issue that both saturated and *trans* fatty acids should be considered together when developing claims and conditions for saturated and/or *trans* fatty acids, for all applicable claims.

5.4 Fibre nutrition content claims

5.4.1 Recommendation

FSANZ proposes the following regulation of dietary fibre nutrition content claims at Preliminary Final Assessment:

1. Remove the proposed specific criteria under dietary fibre nutrition content claims for meals/main dish products.

2. Include a further category for fibre nutrition content claims – 'excellent source', with a qualifying criterion of 7 grams dietary fibre per serve.

3. Removal of the meal/main dish product criteria for fibre nutrition content claims would also remove the need for definition of this category of foods in the new Standard.

5.4.2 Introduction

As detailed at Draft Assessment, the Dietary Guidelines for Australian Adults (NHMRC, 2003a) recommends consumption of a high fibre, low fat diet for maintenance of body weight and prevention of obesity. The New Zealand Ministry of Health recommends consumption of fibre-rich foods in particular for older people and during pregnancy (Ministry of Health, 2006, 1996). Recent nutritional data from both countries indicate that population intakes of fibre and fibre-rich food groups, such as cereals, are generally below target levels.

The new health claims Standard will include criteria for nutrition content claims for fibre. Guidance for the use of fibre nutrition content claims has in the past been provided under CoPoNC. There has generally been strong uptake of these claims by industry, with the number of claims in the most recent labelling survey having increased compared with the previous survey (FSANZ, 2006a).

Fibre nutrition content claims will be based on a per serve unit. This recognises the amount of food an average person actually consumes. It is consistent with the approach to all risk reducing nutrients for which nutrient content criteria are proposed, with a per serve unit also proposed for protein and vitamins and minerals. It is also consistent with the national position taken by Australia in relation to the fibre claim currently under development by Codex, which has recently given support to a per serve unit. It is not known whether this unit will be adopted under the Codex standard, which will not be finalised before the new health claims regulations are in place. A per serve unit was also in use for fibre claims under the CoPoNC guidelines.

The qualifying criteria for fibre nutrition content claims proposed at Draft Assessment are slightly higher than those in use under CoPoNC. This shift ensures that foods carrying the claim contain a higher proportion of the reference value for daily intake of fibre (30 g) than is specified in the Code, and is mindful of the fact that population fibre intakes are currently below target levels. The criteria for 'source' claims (2 g per serve) represents 6.67% of the reference value, an increase from the CoPoNC requirement of 5% of this reference value (1.5 g per serve). The criterion for a 'good source' claim (4 g per serve) represents 13.3% of the reference value, an increase from the CoPoNC requirement of 10% of the reference value (3 grams per serve). The values chosen are lower, as a percentage of the nutrient reference values, than other nutrition content claims, in order to enable a range of products to carry these claims, and thus encourage consumption.

At Draft Assessment, FSANZ also proposed to include specific qualifying criteria for meal/main dish food products to carry fibre nutrition content claims. These products were required to contain a higher level of fibre per serve than other foods, on the basis that they contribute a greater proportion of the overall daily intake. The products within this group were determined by a definition of meal/main dish products based on various nutritional components within a serve of an individual food product.

5.4.3 Approach at Draft Assessment

At Draft Assessment, FSANZ proposed to set qualifying criteria for three levels of fibre nutrition content claims, with specific criteria for meal/main dish products within each level:

Property	Descriptor	Nutrition content claim conditions
Dietary fibre		(a) for meal/main dish products – a serve of the food contains at least 5.5 g of dietary fibre; and (b) for all other foods – a serve of the food contains at least 2 g of dietary fibre.
	Good source	(a) for meal/main dish products – a serve of the food contains at least 11 g of dietary fibre; and (b) for all other foods – a serve of the food contains at least 4 g of dietary fibre
	Increased	(a) for meal/main dish products – a serve of the food contains at least 5.5 g of dietary fibre; and (b) for all other foods – a serve of the food contains at least 2 g of dietary fibre; and (c) the food contains at least 25% more dietary fibre as the same quantity of reference food; and (d) the claim states – i. the identity of the reference food; and ii. the difference between the dietary fibre content of the food and the reference food; and (e) the claim is presented so that all elements of the claim are in the one place.

Meal/main dish products were defined as:

> ***meal/main dish product*** *means a food that contains, per serve –*
>
> *(a) at least 170 g of food; and*
> *(b) at least two ingredients (including compound ingredients) from at least two different food groups, of at least 40 g each.*
>
> ***food group*** *means –*
>
> *(a) bread and other cereal products; or*
> *(b) fruit and/or vegetables; or*
> *(c) milk and milk products; or*
> *(d) meat, fish, eggs, nuts, seeds and legumes;*
>
> *and does not include sauces, condiments, coatings, stuffings or garnishes unless a single ingredient of one of these is –*
>
> *(a) at least 40 g per serve of the meal/main dish product; and*
> *(b) falls within (a), (b), (c) or (d).*

5.4.4 The issue/problem

The conditions proposed at Draft Assessment for fibre nutrition content claims were the only conditions with specific criteria for meals/main dish products. The 'meals/main dish' definition was also applied to the disqualifying criteria for general level health claims. Submitters' responses to the proposed definition (see subsection 5.3.5) related primarily to its role in relation to disqualifying criteria, with many questioning the clarity of the definition. Should it be retained within the new Standard, the proposed definition would require further fine tuning to accurately capture the target group of food products.

Since Draft Assessment, FSANZ has revised the approach for determining the composition of foods eligible to carry general level health claims. FSANZ is now moving towards a more complex model that accommodates a broad range of food products, such that meals/main dish products no longer needs to be defined for this purpose. If it is retained, the sole application of the meal/main dish definition would be within fibre nutrition content claims.

Internationally, specific fibre criteria for meals are not generally used, with the exception of some specific requirements in Canada. The Codex fibre standard currently under development does not contain special provision for meals.

Given that the definition of meals/main dishes is problematic, with the form proposed at Draft Assessment not generally supported by submitters, and that the term would have very narrow application within health claims regulations (and the Code in general), and is not supported by international approaches, an alternate option for capturing an increased fibre content on these products is proposed by FSANZ.

5.4.5 Comments from stakeholders at Draft Assessment and Initial Assessment

Submitter comments at Draft Assessment around meals/main dishes were mainly focused on the definition of meal/main dish product and suggested it would inappropriately exclude products. These comments related primarily to the role of meals/main dish products in relation to the proposed disqualifying criteria for general level health claims. There was only one comment relating specifically to the proposed fibre content claim criteria – this questioned why the qualifying criteria for meals/main dishes were restricted to fibre.

A number of submitters at Draft Assessment commented on the levels of dietary fibre proposed as criteria for nutrition content claims. None of these submitters commented directly on the levels proposed for meal/main dish product criteria.

At Initial Assessment, a number of submitters (mainly from public health, industry and Australian government sectors) indicated that they supported use of specific provisions for meal/main dish products for fibre claims. An increase in the qualifying fibre level for main meal products was recommended but no values were suggested. Some submitters (mainly from industry and New Zealand government sectors) indicated they did not support specific provisions for meal/main dish products.

When the development of specific fibre criteria for meal/main dish products was proposed at Initial Assessment submitters commented both for and against.

Submitters' opinions were also canvassed around criteria for an 'excellent source' or 'very high' source fibre claim, though it is noted that at the time this was not presented as an alternative to definition of specific criteria for meal/main dish products. Of the submitters who commented in relation to this claim, there were some who did not think it was necessary, and some that supported its use.

5.4.6 Evidence base

The extensive food product database that has been developed since Draft Assessment for the analysis of foods considered eligible to carry general level health claims was used to test the options considered by FSANZ (see subsection 5.4.7). This database contains more than 10,000 food products. Fibre content data are available for many, but not all, of the products in the data set, including a range of meal/main dish products.

Testing indicated that the range of meal/main dish food products for which either 'source' or 'good source' content claims could be made was not greatly changed by moving from a per serve to a per 100 g model (Option 2, subsection 5.4.7, which proposes a move to a per 100 g unit for all fibre nutrition content claims). However, a considerable number of non-meal products, notably fruit and vegetable products, which had previously qualified to make fibre claims under the per serve model would be unable to make any fibre claim under the per 100 g model, as they contained less than 2 g of fibre per 100 g.

A possible 'excellent source' or 'very high fibre' claim (Option 3, subsection 5.4.7, which proposes the removal of the definition of meal/main dish products and the addition of criteria for 'excellent source' of fibre or 'very high fibre' nutrition content claims) was also tested using the food product database. A qualifying criterion of 7 g per serve was used. This figure represents a small step-up from the criteria used previously under CoPoNC (6 g per serve) and is therefore consistent with the approach used to set the proposed criteria for 'source' and 'good source' fibre claims in the new health claims Standard. Data from the most recent labelling survey undertaken by FSANZ demonstrated significant industry uptake of the 'excellent source' or 'very high fibre' claim under the CoPoNC criteria of 6 g per serve.

Database assessment indicated that:

- a number of the meal/main dish products would qualify for an 'excellent source' / 'very high fibre' fibre claim, using a qualifying criterion of 7 g;
- a range of other food products could also make the 'excellent' / 'very high' fibre claim, including some breakfast cereals, legumes and nuts; and
- of the meals/main dish products in the database, a number would qualify within each level of fibre content claim – ranging from those unable to make any claim, through to those qualifying for 'source' and 'good source' claims, to those able to carry an 'excellent source' claim.

Assessment of option 3 was also extended to possible inclusion of additional criteria for 'excellent source' / 'very high fibre' fibre claims, with the aim of reducing the potential for manipulation of serving sizes or of less healthy food products carrying the claim. Two possible additional criteria options were explored – fibre density and energy density.

Fibre density was assessed using fibre grams per 100 g of food. Energy density was assessed as kilojoules per 100 g of food. In both cases, nearly all meal/main dish products in the database had relatively low levels compared with products in other food groups. In theory, this would allow selection of a cut-off value above which food products became ineligible to carry the 'excellent source' claim. However, while this would reduce the number of high sugar and/or high fat foods that qualify for the claim, it would also exclude a range of more healthy foods from qualifying for the claim. Excluded foods of particular note included many breakfast cereals, for example bran-based, oat-based, muesli, most nuts, and some dried fruits.

5.4.7 Analysis of options

Option 1 – Criteria for fibre nutrition content claims, and definition of meal/main dish products remain as proposed at Draft Assessment

Benefits

- The use of a 'per serve' unit is consistent with content claim criteria for other risk reducing nutrients.
- The use of the 'per serve' unit is consistent with Australia's stated preference for the Codex fibre claim under development.
- Criteria higher for meals/main dishes, so less potential for manipulation of serving sizes.

Disadvantages

- Definition of meal/main dish products is overly prescriptive.
- Definition of meal/main dish products proposed at Draft Assessment is not well supported by stakeholders.
- Definition of meal/main dish products not relevant elsewhere in the new health claims Standard, or elsewhere in the Food Standards Code; application is confined to fibre nutrition content claim criteria.

Option 2 – Move to a per 100 g unit for all fibre nutrition content claims

Benefits

- Unit is consistent with some international approaches, for example per 100 gram base in use in the United Kingdom.

Disadvantages

- Unit is inconsistent with content claim criteria for other risk reducing nutrients.
- Unit differs from approach in use under CoPoNC guidelines.
- Unit is inconsistent with Australia's stated preference for the Codex fibre claim under development.
- Some fruit and vegetables would be unable to make any nutrition content claim for fibre.

Option 3 – Remove the definition of meal/main dish products and add nutrition content claim criteria for 'excellent source' of fibre or 'very high fibre' claims

Benefits

- Some consistency with other international approaches, for example the United Kingdom 'high fibre' claim (criteria - 6 g of fibre per 100 g of food).
- Removes any need for a prescriptive approach to defining meal/main dish products.
- Provides opportunity for manufacturers to gain recognition for foods containing higher levels than 'good source' criteria of 4 g per serve.
- Provides opportunity for consumers to select foods containing higher levels than 'good source' criteria of 4 grams per serve.

Disadvantages

- Potential manipulation of serve sizes by manufacturers wishing to make claims on their products.

FSANZ's preferred option at Preliminary Final Assessment is Option 3.

After re-consideration, FSANZ is recommending inclusion of criteria for fibre nutrition content claim criteria using the descriptor 'excellent source' or 'very high fibre'. The criteria will be set at 7 g using a per serve unit. The assessment carried out on this option suggests that an 'excellent source' or 'very high' fibre claim is a realistic tool for manufacturers to aim for and to apply to their meal and main dish products. The three proposed gradients of fibre source claims (source, good source, excellent/very high fibre) would differentiate well between the levels currently found in meal/main dish products, and would provide consumers with a relevant tool for comparison of fibre content during meal selection.

As discussed at Draft Assessment, the application of a per serve base for fibre content claim criteria allows manufacturers the option of choosing the serve size of their product/s in order to meet the qualifying criterion. This problem has been previously recognised by FSANZ and is inherent in the use of a per serve base for content claim criteria, as is proposed for risk reducing nutrients – protein, vitamins & minerals, and fibre. All of these nutrients have criteria for 'source' and 'good source' content claims.

FSANZ also notes that criteria based on a per serve unit are currently in use under CoPoNC, including 'source', 'good source' and 'excellent source' / 'very high' fibre claims. The serving size of an individual food product and the number of servings in that food are specified on the nutrition information panel, thereby making information that is independent of serving size available to consumers. However, as noted at Draft Assessment, FSANZ remains concerned by the potential for manufacturers to benefit from increasing the serving sizes of their products and will therefore monitor the market place. Should the outcome show that it is necessary, work will be initiated to standardise serving sizes.

During assessment of the recommended option, possible additional criteria for 'excellent source' / 'very high fibre' claims were considered based on energy density or fibre density. It was concluded that application of one of these countering mechanisms would only be warranted if there was explicit intent of restricting the proposed 'excellent source' / 'very high fibre' claim to meal/main dish type products.

However, while it is intended that the 'excellent source' / 'very high fibre' claim be within the reach of appropriate qualifying meal/main dish products, it is not intended that it be restricted to this group of products alone. Therefore, given that the inclusion of additional criteria related to fibre or energy density did not accurately target the desired food types, and that at present there is an absence of evidence for market failure of the equivalent CoPoNC claim, it is recommended that there be no additional conditions applied to the proposed qualifying criteria for 'excellent source' or 'very high fibre' claims.

It is not proposed that an 'excellent' / 'very high' source criterion be developed for any of the other positive nutrients with content claim criteria – protein and vitamins and minerals. This is consistent with the rationale presented by FSANZ at Draft Assessment, whereby specific criteria for meals/main dish products were not proposed for these nutrients. Fibre represents a particular case amongst these positive content claim nutrients, as it is a nutrient for which increased consumption is actively encouraged under dietary guidelines. Creation of specific criteria that may serve to encourage manufacture and consumption of fibre is therefore mindful of this goal. There is no equivalent aim of increasing population intakes in the case of protein or of vitamins and minerals generally.

5.5 'No added sugar' claim

5.5.1 Recommendation

FSANZ proposes the following for the 'no added sugar(s)' claim at Preliminary Final Assessment:

1. Removal of the requirement for stating that the food contains naturally occurring sugar if the food naturally contains sugar.

2. Other conditions for the claim are as proposed at Draft Assessment, that is:

    (a) the food contains no added sugars (as standardised in 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 under Standards 2.6.1 or 2.6.2.

5.5.2 Introduction

The 'no added sugar' claim has been used for some time on a range of products. CoPoNC refers to the regulations in the former Australian *Food Standards Code* where there is a general prohibition of the claim unless the food contains no added sugar or related products (as defined in Standard K1 of the former Australian *Food Standards Code*), no added honey (as defined in Standard K2 of the former Australian *Food Standards Code*) and no added malt, malt extracts or maltose. The repealed New Zealand *Food Regulations 1984* permitted such claims if the food did not contain added carbohydrate sweetener or added sugar alcohol (>1%) as an ingredient in the food.

At Draft Assessment for Proposal P234 – Review of Nutrient Content and Other Related Claims, FSANZ proposed that a reference to the declaration of the sugars in the nutrition information panel must be made in conjunction with the claim to alert consumers to the sugar content of the food.

However, FSANZ's study on nutrition, health and related claims (FSANZ, 2005a) showed that a disclosure statement 'See nutrition information for fat content' did not significantly improve respondents' understanding of the amount of fat in the product and in addition some respondents appeared to misunderstand the intent of the statement. Consequently, FSANZ proposed at Draft Assessment of Proposal P293 (*Nutrition, Health and Related Claims*) that a disclaimer for the 'no added sugar' claim should instead alert consumers to the presence of naturally occurring sugars. After the release of the Draft Assessment of Proposal P293, FSANZ carried out further research to evaluate the use of this disclaimer and reconsidered all information available relevant to the use of the claim and proposed disclaimer.

5.5.3 Approach at Draft Assessment

At Draft Assessment FSANZ proposed that the 'no added sugar(s)' claims cannot be made unless:

(i) the food contains no added sugars, honey, malt, malt extracts; and
(ii) the food contains no added concentrated fruit juice or deionised fruit juice, unless the food is standardised under Standard 2.6.1 – Fruit Juice and Vegetable Juice or 2.6.2 – Non-alcoholic Beverages and Brewed Soft Drinks; and
(iii) if the food naturally contains sugars, the claim states that the food contains naturally occurring sugars; and
(iv) the claim is present so that all the elements of the claim are in the one place.

5.5.4 The issue/problem

The majority of submitters to the Draft Assessment report who commented on the 'no added sugar' claim opposed the proposed approach requiring the disclaimer that the food contains naturally occurring sugars. In addition, at Draft Assessment FSANZ had not evaluated the impact of the disclaimer on consumer understanding of the 'no added' claim. Hence FSANZ considered it appropriate to review the requirement for the disclaimer.

5.5.5 Comments from stakeholders at Draft Assessment

Submissions on the 'no added' claim came from public health, government, industry and academia. The majority of submitters opposed the requirement for the disclaimer for the following reasons:

- there is no scientific justification for distinguishing between naturally occurring and added sugars;
- disclaimer is confusing as levels of naturally occurring sugar may be insignificant to total intake, however, if the requirement continues a threshold needs to be established;
- if label space is a concern, this statement may be a deterrent from making the claim;
- FSANZ research suggests consumers understand 'no added' claims therefore there is no need for the disclaimer (according to submitter interpretation);
- products containing only natural lactose should be exempt from the requirement for the disclaimer as there is insufficient consumer knowledge that lactose is a sugar; and
- the requirement for the disclaimer is not evidence based and is likely to mislead consumers.

Some submitters questioned or opposed the restrictions on the type of sweeteners which can be added to products carrying 'no added' claims. Reasons given include:

- various forms of fruit juice in processed foods such as deionised and concentrated fruit juices, are not distinguishable by analysis therefore it is difficult to enforce proposed restrictions;
- disqualifying products with added malt, concentrated fruit juice or deionised juice for 'no added sugar' claims should be deleted. Malt is often added for flavour not as a sweetener;
- it is not clear what the distinction is between concentrated fruit juice and concentrated fruit juice that has been reconstituted in the food. Foods that do not contain sufficient water to reconstitute concentrated fruit juice should not be penalised over foods that have sufficient water to dilute the concentrated juice to single strength;
- concentrated fruit juice or deionised juice are superior choices to sugar as they offer nutrition beyond energy; and
- the restriction on the use of different types of fruit sugar may lead to a trend to replace fruit juices with sugar and discourage product innovation.

FSANZ does not propose to change the restrictions on the type of sweeteners which can be added to products carrying 'no added' claims. While malt and malt extract, concentrated fruit juice and/or deionised fruit juice are not sugars, they are largely made up of sugar and used for sweetening purposes. Because FSANZ's consumer research shows that consumers consider 'no added sugar' claims to unequivocally mean that a product has only 'natural' sugars, 'with nothing added', other than artificial sweeteners, ingredients that are used for sweetening purposes should not be included where the 'no added sugar' claim is made (FSANZ 2003a). This intent is similar to the intent in other countries. For instance, the European Union has proposed that a product with the 'no added sugar' claim must not contain any added mono- or disaccharides or any other food used for its sweetening properties. Therefore, an important criterion for the 'no added sugar(s)' claim is that the food must not contain any concentrated fruit juice and/or deionised fruit juice where it does not constitute the essential character of the food.

5.5.6 Evidence base

5.5.6.1 FSANZ Research

In 2003, FSANZ carried out research to investigate consumer understanding of the 'no added sugar(s)' claim. In a quantitative study 1940 door-to door interviews were conducted to explore consumer attitudes, beliefs, interpretation and use of label elements (FSANZ 2003b). Of the 934 respondents who completed the closed question in relation to a single stimuli, that of a 'no added sugar' claim on canned peaches, 28% said the product contained no sugar, 30% said the product contained small amounts of sugar, 38% said the product could either be a low, medium or high sugar food and 4% were not sure. Results suggested that some consumers were confused about what this claim means with responses evenly distributed between the three response options.

In a qualitative study, 10 focus groups of women aged 35-64 yrs who were highly health conscious discussed various nutrient content claims (FSANZ 2003a). The 'no added' claim was unequivocally understood to mean that the product had only 'natural' sugar with nothing added.

It was also widely understood that 'no added' claims did not imply that the product had 'none' of the nutrient in question, although there was an underlying belief that these products would be 'low' in the claimed nutrient. Participants were far less sceptical of 'no added' claims than most other claims and the use of the nutrition information panel to verify 'no added' claims was therefore less necessary. There were mixed views on the value of the disclaimer 'contains natural sugar'. 'Inquirers' and those with special health needs felt the disclaimer was unnecessary while other participants thought the disclaimer was helpful because it removed the ambiguity by clarifying whether the product was free of the nutrient.

In view of the consumer confusion with the 'no added sugar' claim that was identified in the previous studies, and stakeholder opposition to the proposed requirement for the statement about naturally occurring sugar, FSANZ decided to further explore consumer interpretation of the 'no added sugar' claim in a dedicated study (FSANZ, 2006b). Refer to Attachment 4 for the research report. The key conclusions from this study were:

- While there was a high level of awareness amongst respondents that products with the 'no added sugar' claim can contain natural sugar, between 40 and 50 percent of respondents assessed products classified by FSANZ as containing medium and high levels of sugar, to contain either no or low levels of sugar. This finding may be inflated as some respondents may reserve their use of medium and high sugar for products not included among the stimuli, for example sweets;
- The use of the disclaimer 'contains natural sugar' was associated with fewer respondents (10% less) stating that products had no sugar, and slightly more respondents (2-7%) making accurate assessments of sugar content; and
- The study suggests the use of the disclaimer is of no benefit to the majority of consumers in interpreting the 'no added' claim.

Overall conclusions from FSANZ research on 'no added sugar':

- There is evidence of confusion with the interpretation of the 'no added sugar' claim amongst research participants in three consumer research studies investigating consumer perception of this claim;
- Most participants have a good awareness that products with the 'no added' claim do contain some sugar;
- However a considerable proportion of research participants interpret products with the 'no added' claim as containing no or low levels of sugar irrespective of the actual level of the sugar present in the product;
- The presence of the disclaimer 'contains natural sugar' does not result in a major improvement in the interpretation of the 'no added' claim.

5.5.6.2 Product Information

As of August 2006, the 'no added sugar' claim was being used on a range of products including fruit juices, fruit drinks, canned fruit, muesli type bars, frozen fruit, ice cream, peanut butter, yoghurt, vegetable juice, muesli type breakfast cereals, fruit leather, dates, rolled oats, biscuits and fruit spread. Table 1 gives examples of the sugar content of products with and without the 'no added sugar' claim, sampled in a New Zealand supermarket.

Table 1: Sugar content of products with and without the 'no added sugar' claim

Product	No added sugar claim?	Cane sugar added?	Sugar g/100 ml or g
Orange Juice (A)	Yes	No	8.6
Orange Juice (B)	No	No	8.0
Orange Juice (C)	No	Yes	9.0
Flavoured Cordial	No	Yes	8.9
Apple Juice	Yes	No	11.7
Fruit Drink	No	Yes	10.8
Canned Apple	Yes	No	9.4
Canned Peaches (A)	No	No	9.3
Canned Peaches (B)	No	Yes	15.0
Canned Peaches (C)	No	No	11.4
Yoghurt (A)	Yes	No	6.9
Yoghurt (B)	No	Yes	8.3
Muesli (A)	Yes	No	24.3
Muesli (B)	No	Yes	17.7
Peanut Butter (A)	Yes	No	5.6
Peanut Butter (B)	No	Yes	8.2
Peanut Butter (C)	No	No	7.1
Baked Slice (A)	Yes	No	30.0
Baked Slice (B)	No	Yes	35.7
Sweet Biscuits (A)	Yes	No	35.0
Sweet Biscuits (B)	No	Yes	37.4
Muesli bar (A)	Yes	No	43.0
Muesli bar (B)	No	No	32.0
Fruit Leather	Yes	No	64.0
Dates	Yes	No	66.0

There are two key points to note from Table 1:

- within a product type, products with the 'no added' claim can contain sugar at similar or even higher levels compared with products which contain added sugar, for example, juices, canned fruit, yoghurt, peanut butter, muesli, peanut butter; and

- there are some products on the market which carry the ‘no added sugar’ claim and are high in sugar, for example dates and fruit leather.

The product data presented in Table 1 together with the consumer research indicate concerns around the use of the ‘no added sugar’ claim. The manner in which the claim is being used confuses some consumers and therefore does not provide for informed choice and may be misleading or deceptive since products with the claim may not be lower in total sugar (and in some cases may be higher) compared with similar products with added sugar. According to FSANZ research, a considerable proportion of consumers interpret products with the ‘no added’ claim to mean no or low sugar.

5.5.6.3 Fair Trading Laws

FSANZ consulted with the Australian Competition and Consumer Commission and the New Zealand Commerce Commission whilst considering the market information and the findings from the research. Under fair trading laws, it is recognised that it is possible for statements to be literally true but also misleading. A risk management approach combining industry self-regulation and enforcement of the claim under fair trading laws was considered.

5.5.7 Analysis of options

Given the issues raised from stakeholders, the market information, and the findings from FSANZ research, FSANZ considered it necessary to re-examine the options for the regulation of the ‘no added sugar’ claim.

Option 1 – Approach taken at Draft Assessment: require a statement that the food contains naturally occurring sugar on products with the ‘no added sugar’ claim

Benefits

- indicates to consumers that natural sugars are present; and
- FSANZ research indicates disclaimer may slightly reduce the number of consumers assessing products with the ‘no added’ claim as having no sugar.

Disadvantages

- research found the use of the disclaimer is of no benefit to the majority of consumers in interpreting the ‘no added’ claim;
- there is good consumer understanding that ‘no added’ does not mean no sugar, without disclaimer, but a tendency for some to interpret ‘no added’ as ‘low’;
- disclaimer is potentially alarmist on products with low levels of sugar;
- many products with the claim have similar sugar levels to those without the claim, therefore the claim does not support informed choice and may be misleading; and
- intent of disclaimer was to draw attention to sugar levels in the nutrition information panel. Since research indicates consumers may have difficulty with the interpretation of sugar levels, the disclaimer may not be an effective risk management measure.

Option 2 – Status Quo: Permit the 'no added' claim with no disclaimer with industry self-regulating the claim and enforcement provided under fair trading laws.

Benefits

- the claim allows a statement of fact;
- supports the promotion of products containing sugars from fruit; and.
- no changes are required by industry (except for compliance with types of sweeteners that are not permitted to be added).

Disadvantages

- many products with the claim have similar sugar levels to those without the claim and also high sugar products may carry the claim, therefore the claim may not support informed choice for some consumers and may be misleading/deceptive; and
- FSANZ research indicates considerable difficulty for some consumers to accurately interpret the claim.

***Option 3 – Permit the 'no added' claim only on products which meet the criteria for the 'low' sugar claim and do not require the disclaimer. [Criteria for 'low' sugar: no more than 2.5 g sugar per 100 ml for liquid food and 5 g per 100 g for solid food*]**

Benefits

- products with low levels of added sugar which carry the 'no added' claim are not likely to mislead consumers (earlier FSANZ research suggests some consumers are likely to interpret products with the 'no added' claim as having low levels);
- eliminates the risk of consumers being misled by products with 'no added' claims which have medium/high levels of sugar;
- provides for informed consumer choice;
- no added labelling costs for use of disclaimer;
- no consumer education required; and
- may result in use of more meaningful claims e.g. 'sweetened with fruit'.

Disadvantages

- many products would no longer be eligible to carry the claim and would need relabelling (remove claim or add alternative);
- removes 'factual' information from some labels;
- specifically will affect products perceived as healthy, e.g. fruit juices;
- industry opposition to the prohibition of claims on products with medium/high levels of sugar; and
- increased surveillance required by enforcement agencies.

FSANZ's preferred approach at Preliminary Final Assessment is Option 2.

FSANZ research suggests that there is a high level of awareness amongst consumers that products with the claim can contain natural sugar. In addition the disclaimer 'contains natural sugar' is of little benefit to most consumers in interpreting the 'no added sugar' claim.

Although research indicates that a considerable proportion of consumers consider products with the claim to either have no sugar or to be 'low' in sugar we do not know the extent to which consumer purchase behaviour is influenced by 'no added sugar' claims and therefore the extent to which consumer health is being affected by this claim. Market information demonstrates that within a product type, the 'no added' claim is being used on products which may have similar sugar levels to products without the claim (and with added cane sugar), although it is a true statement. Given the uncertainty over the impact of the 'no added sugar' claim on consumer purchase behaviour, FSANZ considers that at the present time the combination of industry self-regulation and provisions under fair trading laws is the most appropriate risk management approach for this claim.

5.6 'No added salt' claim

5.6.1 Recommendation

FSANZ proposes the following for the 'no added salt' claim at Preliminary Final Assessment:

1. Removal of the requirement for stating that the food contains naturally occurring sodium if the food naturally contains sodium.

2. Other conditions for the claim are as proposed at Draft Assessment, that is:

    (a) the food must contain no added sodium compound including no added salt;
    (b) the ingredients of the food must contain no added sodium compound including no added salt; and
    (c) the nutrition information panel must indicate the potassium content.

5.6.2 Introduction

The 'no added salt' claim is currently used on a variety of products including canned fish, canned vegetables, tomato paste, peanut butter and frozen vegetables. The claims are permitted when a food (and all of its ingredients) contains no added sodium compound including no added salt, during processing. 'No added salt' claims are consistent with national dietary guidelines.

5.6.3 Approach at Draft Assessment

At Draft Assessment, FSANZ proposed that products with a 'no added salt' claim which contain naturally occurring sodium, would be required to state the food contains naturally occurring sodium. The rationale for this proposed approach was based on FSANZ research indicating that shoppers do not frequently use the nutrition information panel for 'no added salt' claims and that there is potential for shoppers to be misled if naturally occurring salt levels are high. Submitters to the Initial Assessment Report were divided over the requirement to state the food contains naturally occurring sodium.

5.6.4 The issue/problem

During the consideration of 'no added' claims FSANZ decided it would be appropriate to consider 'no added sugar' and 'no added salt' claims separately, since these claims are used quite differently by industry and consumers. After consideration of stakeholder comments (see subsection 5.5.5), and the sodium content of products with the 'no added salt' claim, FSANZ considered that the requirement for stating the product contains naturally occurring sodium warranted further evaluation.

5.6.5 Comments from stakeholders at Draft Assessment

Submissions were received from public health, government, industry and academia sectors. Comments were mainly focussed on the requirement for the disclaimer for 'no added' claims with submitters opposing this requirement. Reasons given for this opposition include:

- since FSANZ consumer research (FSANZ, 2003a) shows that 'no added' was unequivocally understood to mean that the product had only 'natural salt' and also that 'no added' claims did not imply that the product had none of the nutrient in question, it was not necessary to require any additional information for 'no added' claims;
- if continue to require disclaimer for no added salt claims, a threshold should be established before the extra words are required – if required on all 'no added' products then this is potentially alarmist when product contains a very low level of the nutrient;
- if label space is a concern the extra wording may be a deterrent from making a 'no added' claim;
- disclaimer adds negativity to a positive claim;
- disclaimer for 'no added' claims not evidence based and likely to mislead consumers; any risk is managed by full disclosure on the nutrition information panel; and
- disclaimer for 'no added' claims would be meaningless, as nearly all food contains naturally occurring sodium. An alternative suggestion was that foods without naturally occurring sodium should be required to state they 'contain no naturally occurring sodium'.

5.6.6 Evidence base

Stakeholder comments, results from FSANZ research and market information were taken into account in evaluation of the need for a disclaimer on products with the 'no added salt' claim.

FSANZ's qualitative research (FSANZ, 2003a) found that 'no added sodium/salt' claims were looked for on chips, baked beans and canned vegetables. Respondents were familiar with the claim, though they did not look for it as often as 'no added sugar' claims. They were much less sceptical of the claim compared with most of the other eight content claims examined in the study and therefore used the nutrition information panel less frequently to verify it. They unequivocally understood it to mean the product had only 'natural' salt, with nothing added.

While they also understood that 'no added' products did not imply that the product had no salt, there was an underlying feeling that the product would be 'low' in salt. Participants were uncertain as to whether the 'no added' claim referred to the food itself, such as corn in 'no added salt' canned corn, or whether it also included canning and packing agents such as brine. Reactions to disclaimers were mixed.

'Inquirers' and those with special health needs felt that disclaimers that made reference to the nutrition information panel or to the presence of 'natural salt' where unnecessary as they used the nutrition information panel as needed. Others, however, strongly felt that the disclaimer 'contains natural salt' should appear with 'no added' claims because it removed the ambiguity by clarifying whether the product was free of salt.

A survey of the sodium content of products, carrying the 'no added salt' claim, revealed that for the majority of products, the sodium levels are substantially less than similar products with added salt. For example, the sodium content of peanut butter with 'no added salt' is approximately 20 mg/100 g compared with approximately 360 mg/100 g in a similar product with added salt.

5.6.7 Analysis of options

Option 1 – Approach taken at Draft Assessment: require the disclaimer stating the food contains naturally occurring sodium on products with the claim 'no added salt'

Benefits

- indicates to consumers that naturally occurring salt may be present; and
- FSANZ research (FSANZ, 2003a) indicates shoppers do not frequently use the nutrition information panel to verify 'no added salt' claims, and therefore there is the potential to be misled;

Disadvantages

- many of products with 'no added' claims contain naturally occurring salt at low levels, therefore no need for disclaimer as risk of misleading consumers is low;
- FSANZ research (FSANZ, 2003a) indicates participants unequivocally understood products with 'no added salt' claim only contained 'natural' salt, and therefore there is no need for a disclaimer;
- disclaimer potentially alarmist on products with low levels of salt; and
- additional regulatory measure requires additional enforcement resources for government agencies.

Option 2 – Status Quo - Do not require the disclaimer stating the food contains naturally occurring sodium on products with the claim 'no added salt'

Benefits

- majority of products with 'no added' claims contain naturally occurring salt at low levels, therefore no need for disclaimer as risk of misleading consumers is low;
- less information required on the package;
- no changes for industry; and
- no change for government agencies with regard to enforcement.

Disadvantages

- there may be small (but unknown) risk that consumers may be misled when the 'no added' claim is on the few products which are not naturally low in salt.

FSANZ's preferred approach at Preliminary Final Assessment is Option 2.

Since a survey of products carrying the 'no added salt' claim indicated that there are few products naturally high in salt, the potential for consumers to be misled from this claim is small. In addition, FSANZ research indicated that respondents unequivocally understood 'no added salt' to mean the product had only 'natural' salt, with nothing added. Stakeholders were not supportive of the requirement to state that naturally occurring salt is present. In conclusion, there is no strong evidence to require an additional regulatory measure.

5.7 Glycemic Index

5.7.1 Recommendation

FSANZ proposes the following recommendations for Glycemic Index (GI) at Preliminary Final Assessment:

1. GI claims will be regulated as nutrition content claims, requiring substantiation as such, but with the nutrient profile criteria applied to health claims.
2. The method for determining GI of carbohydrates in foods is described in the Standards Australia Australian Standard® Glycemic Index of foods (AS 4694 – 2007). In particular, GI testing is carried out by the determination of glycemic (blood glucose) responses in human volunteers.
3. The claim itself or the nutrition information panel must include the numerical value of the GI of the food.
4. The claim may include the descriptors low, medium or high:

    (a) for 'low' the numerical value of the GI of the food is indicated at 55 and below;
    (b) for 'medium' the numerical value of the GI of the food is indicated between 56 and 69; and
    (c) for 'high' the numerical value of the GI of the food is indicated at 70 and above.

5.7.2 Introduction

GI claims are becoming more prevalent in the market place and consumer interest in the claim is increasing. The GI is a property of the carbohydrates in foods, specifically the blood glucose raising ability of the digestible carbohydrates. It compares carbohydrates on a weight for weight basis of a food, in the physical state in which the carbohydrate is normally consumed[6]. Low GI foods are characterised by having less impact on blood glucose levels compared with high GI foods. It has been argued that when consumed as part of a balanced meal, low GI foods produce less fluctuation in blood glucose and insulin levels than high GI foods.

[6] Wolever T MS, Vorster HH, Bjorck I, Brand-Miller J. Brighenti F, Mann JI, Ramdath DD, Granfeldt Y, Holt S, Perry TL, Venter C, and Wu X: Determination of the glycaemic index of foods: interlaboratory study. European Journal of Clinical Nutrition (2003) 57, 475-482.

The clinical and practical value of the GI continues to be studied and there is some evidence of health benefits when low GI foods replace high GI foods in a balanced diet[7]. The Australian and New Zealand Dietary Guidelines specifically recommend consumption of low GI cereal-based foods.

To determine the GI of a food, an *in vivo* test is required. Measured portions of the food are fed to healthy people after an overnight fast. Blood samples are then taken at intervals and the results of blood sample analyses are used to construct a blood sugar response curve. It has been suggested that not all GI values on food labels have been reliable because they have been based on extrapolation or inappropriate methodology[8]. There are methods that measure digestibility or derive a hydrolysis index by *in vitro* methods for measuring carbohydrate digestion[9], but the results are not directly comparable to *in vivo* testing. Testing should be carried out in accordance with a recognised methodology to ensure that products are comparable and that consumers can make informed purchasing decisions.

Standards Australia has published a standard for the determination of GI of foods (AS 4694—2007, Australian Standard® - Glycemic Index of foods). The objective of the Standard is stated to be 'to establish the recognised scientific method as the standard method for the determination of the GI of foods'. The Standard specifies a method for determination of the GI of carbohydrates in foods, defines the GI, and provides qualifying factors and requirements for its application. GI testing is appropriate only when the food in question contains relevant amounts of digestible carbohydrate. In the Australian Standard®, the minimum amount is specified as '10 or more grams of glycemic carbohydrate per serving'.

In addition to outlining a detailed methodology for the determination of GI values for foods, the Australian Standard® includes guidance on the interpretation of GI values as follows:

Low GI	55 and below
Medium GI	between 56 and 69
High GI	70 and above

The 'GI Symbol Program' is an endorsement program that was launched in Australia by GI Limited, a non-profit company that qualifies as an *Endorsing Organisation* under the proposed Standard at Preliminary Final Assessment. To be eligible to carry the GI symbol, foods must meet nutrient criteria for the relevant food category[10], and the GI must be determined by the Sydney University Glycemic Index Research Service or other approved laboratory.

It should be noted that GI does not specifically relate to a nutrient or a biologically active substance, nor does it have units of measurement. Whilst it can be considered a content claim because it relates to the property of the food (its carbohydrate composition and level), it implies an effect on the body (i.e. on blood glucose levels).

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[7] Brouns F, Bjorck I, Frayn K, Gibbs AL, Lang V, Slama G, Wolever TMS. Glycaemic Index Methodology. Nutrition Research Reviews 2005 18, p 145-171.

[8] Brand-Miller J, Holt S. Testing the glycaemic index of foods: in vivo not in vitro. Eu J Clin Nutr 2004;58:700-701.

[9] Engylst K, Englyst H, Hudson G, Cole T, Cummings J. Rapidly available glucose in foods: an in vitro measurement that reflects the glycemic response. Am J ClinNutr 1999; 69:448-454.

[10] The GI (GI) Symbol Program 'Guidelines for product acceptability', http://www.gisymbol.com.au/pages/index.asp

For these reasons, GI does not easily fit into the health claims classification framework. Therefore, FSANZ views GI claims as special cases.

5.7.3 Approach at Draft Assessment

Briefly, the proposed approach at Draft Assessment for the regulation of GI claims was as follows:

- GI claims that are linked with an endorsement would be regulated as a pre-approved endorsement (e.g. Glycemic Index Limited symbol);
- for those not linked with an endorsement, the GI could only be claimed in the form of a numerical index and 'reduced', 'high', 'medium', 'low' claims or other descriptors would not be allowed; and
- If the claim refers to a health effect then it would be regulated appropriately as either a general level health claim or a high level health claim.

5.7.4 The issue/problem

In response to the Draft Assessment Report, a number of issues have been raised by stakeholders in relation to regulation of GI claims, which have led FSANZ to reconsider its approach to regulating such claims. In particular, the prohibition on the use of descriptors might confuse consumers who have become accustomed to using such claims. From an industry perspective, the approach taken at Draft Assessment restricts the full use of GI claims by some suppliers.

From a public health perspective, there are concerns that GI claims potentially mislead consumers with regard to the nutritional properties of a food. In particular, some stakeholders considered that it was not appropriate to place low GI claims on foods, which are high in fat. Further, it was argued that any GI claim implied a health effect, or indirectly referred to a biomarker or serious disease.

These considerations, in addition to other concerns that were raised in submissions (see below), necessitate an alternative approach to the regulation of GI claims to that proposed at Draft Assessment. Furthermore, the publishing of the Australian Standard in the intervening period allows the use of qualitative descriptors of GI by providing accepted reference values and thus avoids concerns over use of quantitative measures only.

5.7.5 Comments from stakeholders following Draft Assessment

Stakeholders raised issues in relation to the scope of the regulations and the proposed approach for regulating GI claims at Draft Assessment.

5.7.5.1 Scope of the regulations

- Some stakeholders felt that FSANZ should remain silent on GI claims as they are not content claims and therefore regulation should be left to fair trading legislation.
- Many submitters felt that there was insufficient evidence to support GI claims, and therefore FSANZ should not be regulating GI claims. It was noted that the FAO/WHO had endorsed the use of GI claims.

- Concern was expressed about the use of GI claims when there is an ongoing debate about its use and standard methods are yet to be established.
- It was suggested that FSANZ should wait for the Standards Australia process in developing a standard defining a method for testing GI to be complete before including regulations for GI claims.
- In this context, some stakeholders felt that if there was not sufficient evidence about the levels to attach to descriptors, then manufacturers should not be allowed to make GI claims as it has the potential to mislead consumers.

5.7.5.2 Proposed approach

- Many submitters did not support the proposed approach due to the inequity of the system.
- It was believed to be anti-competitive and trade restrictive by allowing GI claims with a descriptor in the form of the GI endorsement, but not allowing descriptors on any other claims.
- There was broad support for the use of GI claims, but not without the use of descriptors.
- It was strongly felt that a numerical expression of GI alone is not an effective way to communicate GI information to consumers.
- It was suggested that a consumer education program about GI would be required.
- It was proposed that disqualifying criteria need to be applied for any GI claim – at least the criteria for fat.
- GI Limited noted that if there were no disqualifying criteria associated with making GI claims, the 'GI Symbol' endorsement would be disadvantaged, as it does have criteria as part of the program.
- Some stakeholders considered that as GI is not a nutrient or an ingredient, it should not be regulated as a nutrition content claim. It was suggested that any claim regarding GI is a health claim and should be regulated as such.
- Some stakeholders suggested that the GI information in the nutrition information panel could be segregated from the other required information by placing it in a separate box.

5.7.6 Factors relevant to regulatory options and evidence base

The following section presents the rationale for FSANZ's recommended approach to the regulation of GI claims.

5.7.6.1 GI claims as nutrition content claims or health claims?

There are divergent views from stakeholders and professionals regarding how GI claims should be regulated. While some stakeholders consider that GI claims such as 'low GI' are content claims, other stakeholders have opposing views.

The main reasons provided for not considering simple GI claims, which do not include direct reference to a health effect, as content claims revolved around the argument that they are indicators of an effect on the body, rather than just the 'content' of a food. Some stakeholders considered that the GI is not a nutrient or ingredient and therefore GI should not be used as a nutrition content claim. From this reasoning, the conclusion can be drawn that any claim regarding GI is a health claim and should be regulated as such.

On the other hand, not all current nutrition content claims are for nutrients or ingredients, and some are at least partially based on a physiological response. Energy is included on the nutrition information panel, and energy claims can be nutrition content claims, yet energy is not a nutrient or ingredient and the energy value of food is not based on energy content but on the energy available to the body. For example, the energy content of protein is 23 kJ/g but the Code uses a value of 17 kJ/g, which allows for digestibility and urinary loss of energy in the form of urea, ammonia, amino acids and protein[11]. Similar approaches have been taken for nutrition content claims on some vitamins, in which the vitamins are expressed as equivalents based on the physiological activity in the body. Examples are Vitamin A (retinol equivalents) and Vitamin E (α-tocopherol equivalents).

In summary, while the Code already permits some content claims that have been based on physiological responses rather than purely on the specific level of a nutrient, GI claims have been attributed with some of the characteristics of health claims.

FSANZ therefore proposes that GI claims should be regulated as a special type of content claim, combining the simple and brief message of a nutrition content claim and requiring substantiation of its content and the nutrient profile criteria applied to health claims.

5.7.6.2 GI claims on foods high in fat

Some stakeholders were of the opinion that GI claims were used irresponsibly in the marketplace to promote foods that are high in fat, especially saturated fat, and energy. Given that some foods that are high in fat can also have a low GI, it could be argued that this gives a misleading impression of the property of the food. For example, the GI of potato chips is lower than that of baked potatoes. GI Limited have acknowledged this problem and have developed category-based nutrient criteria for fat, sodium and dietary fibre and in some cases calcium, energy and carbohydrate content (in addition to the minimum 10 g per serve required for testing). However, in the absence of imposing criteria and/or conditions around these claims, they could be made outside the GI Symbol endorsement programme, without any restriction on the types of foods carrying the claim.

5.7.6.3 Standard method for calculating GI

Since January 2007, an Australian Standard® for determining GI has become available[12] for use by food manufacturers, testing laboratories, research organisations, regulators, and enforcement agencies in Australia and New Zealand. FSANZ considers that this Standard comprehensively addresses the issue of best industry practice when determining GI and provides the basis for the food industry to provide consumers with appropriate information when a GI claim is made. Whilst the intent is that manufacturers should follow the Australian Standard®, the methodology cannot be incorporated into the Food Standards Code for legal reasons.

[11] 'Atwar factors', Wahlquist M.L Food and Nutrition in Australia. Methuen, Australia.
[12] The Australian Standard is based on the publication of the FAO/WHO Joint Expert Consultation Carbohydrates in Human Nutrition. Geneva: Food and Agriculture Organization, Food and Nutrition; 1998.

5.7.6.4 Use of descriptors

According to submitter comments, it seems evident that to be useful to consumers, the GI should at least be accompanied by an appropriate descriptor, if not replaced by it. The major obstacle for allowing the general use of descriptors at Draft Assessment was the absence of an accepted and documented method for measuring GI, and defined categories to describe 'low', 'medium' and 'high' GI. FSANZ understands that the values for descriptors specified in the Australian Standard® are widely used and accepted nationally and internationally. FSANZ proposes that these values are used for defining descriptors for GI in Standard 1.2.7 of the Code.

5.7.7 Analysis of options

Option 1 – Approach taken at Draft Assessment: GI claims that are linked with an endorsement are regulated as an endorsement; for those not linked with an endorsement, the GI can only be claimed in the form of a numerical index.

Benefits

- Consumers can continue to use GI claims when making food purchases.
- Consumers are protected from misleading claims because the full range of GI claims can only be provided by an appropriate Endorsing Organisation.
- Existing GI based endorsements can continue.

Disadvantages

- Consumers' effective use of the GI could be compromised by the lack of descriptors.
- Consumers may find it hard to interpret numerical values for GI.
- The approach taken at Draft Assessment would have restricted the full use of descriptors in association with the GI to *Endorsements*, effectively excluding many suppliers from using the more descriptive claims.

Option 2 – GI claims using descriptors do not have to be linked to an endorsement; the descriptors 'low', 'medium' and 'high' are permitted in accordance with values provided in Standard 1.2.7; generic nutrient profile eligibility criteria apply; The method for determining GI of carbohydrates in foods is described in the Standards Australia Australian Standard Glycemic Index of foods (AS 4694 – 2007)

Benefits

- Consumers can continue to use GI claims and the familiar descriptors when making food purchases.
- Permits the use of 'low', 'medium' and 'high' descriptors on all foods with GI claims.
- Endorsement programs in regards to GI can continue to be used under the rules proposed for endorsements.
- Consumers are protected from misleading claims because all GI claims regulated by this standard (i.e. apart from those covered by the endorsement programme), are subject to nutrient profiling criteria and because the method for determining GI of carbohydrates in foods is described in an Australian Standard®.

Disadvantages

- Some products will no longer carry GI information, potentially reducing consumer choice.
- Some foods that currently carry GI claims will no longer be able to make such claims, resulting in costs to industry due to reformulation or re-labelling.

FSANZ's preferred option at Preliminary Final Assessment is Option 2.

FSANZ proposes to regulate GI claims as a special type of content claim because such claims cannot be clearly defined as either nutrition content claims or health claims but have characteristics of both types of claims. Therefore, it is proposed the wording conditions applied to health claims do not apply to simple GI claims such as 'low GI' but GI claims must meet the nutrient profile criteria for health claims.

FSANZ considers that the approach taken to regulate the use of GI claims in the Code is commensurate with the risk of consumers having inadequate information to make informed purchasing decisions when selecting foods with GI claims. Furthermore, the approach taken at Draft Assessment is no longer relevant because an Australian Standard® is now available, and FSANZ has substantially changed its approach to regulating endorsements. Consequently, at Preliminary Final Assessment, FSANZ proposes to allow all manufacturers to use descriptors.

A preliminary assessment comparing the disqualifying criteria used by the GI Symbol programme and the FSANZ Nutrient Profile Model (the model is described in section 6.1) indicates that there is a high degree of overlap between the foods eligible under each approach. However, there would be some exceptions (e.g. jam would meet the criteria for the GI symbol but not the nutrient profile model for health claims). Furthermore, there are products currently being marketed with GI claims which are outside the endorsement programme and which would not be permitted to make these claims under the proposal because they would be disqualified by their nutrient profile.

It should be noted that GI claims which refer to a health effect would be considered to be health claims.

Examples

A food manufacturer wishes to use GI on their range of bran based high fibre cereals. The GI of one of the cereals determined following the approved method is 30, and the product meets the nutrient profile scoring criteria. The manufacturer makes a claim by labelling the product as 'Low GI' on the front of the packet and including the GI value in the claim or in the nutrition information panel.

A food manufacturer wishes to use GI in their breakfast bars. The test shows that the product would qualify for a 'low GI' claim; however, the food does not meet the nutrient profile scoring criteria. In this case, a GI claim would not be permitted on the breakfast bar.

5.8 'Lite/light' claims

5.8.1 Recommendation

The approach proposed at Draft Assessment, that 'light' claims are permitted only on foods meeting the conditions for making a 'reduced' nutrition content claim, will be retained but redrafted to clearly limit its application to nutritional properties.

FSANZ proposes the following conditions for 'light/lite' claims at Preliminary Final Assessment:

1. There is a reduction in energy or nutrient content of at least 25% compared to a reference food. The identity of the reference food and the difference in the quantity of the energy or claimed nutrient in the claimed food compared to the quantity in the reference food must be indicated. The claim must be presented so that all elements of the claim are in one place.

2. The drafting of the requirements for 'light' claims will be amended in draft Standard 1.2.7. 'Light' will not be listed as a property of the food in the table to clause 11 but will be co-located with each of the 'reduced' descriptors, for energy, fat, sodium, sugar, saturated fatty acids, trans fatty acids and cholesterol.

3. Claims about 'lite' that relate to properties such as flavour, colour etc, that do not have a health effect, cannot be regulated under Standard 1.2.7.

5.8.2 Introduction

'Light' claims are currently used widely in the market place in Australia and New Zealand, and are regulated by other governments internationally, such as Canada and the U.S. Codex also provides conditions for making 'light' claims.

CoPoNC requires that if the claim refers to a nutrient or to energy, the food complies with the conditions for the corresponding 'reduced' or 'low' claim, and that the characteristic that makes the food 'light' is stated on the label.

5.8.3 Approach at Draft Assessment

At Draft Assessment FSANZ proposed the following conditions for 'light' nutrition content claims:

Claim (property)	**Conditions**
Light or Lite	The characteristic that makes the food 'light/lite' must be stated adjacent to the claim, regardless of whether the term applies to energy, a nutrient or a non-nutritional characteristic of the food. If the claim relates to a nutrient or energy or salt, then the food must comply with the conditions for the corresponding 'reduced' nutrition content claim. The claim must be presented so that all elements of the claim are in the one place.

5.8.4 The issue/problem

Since Draft Assessment it has been recognised by FSANZ that although 'light' is positioned in draft Standard 1.2.7 as a 'property of the food', it is not a property of the food, but is actually an alternative descriptor to 'reduced', for a comparative nutrition content claim.

In addition, as the purpose of Standard 1.2.7 is to regulate nutrition content claims and health claims i.e. claims that can be associated with health effects, 'light' claims that refer to aspects such as the flavour or colour of a food, cannot be regulated by this Standard.

5.8.5 Comments from stakeholders at Draft Assessment

A number of industry submitters objected to the conditions for a 'light' claim, which state that the 'reduced' conditions must be met rather than the conditions for the corresponding 'low' claim. Reasons for this included that:

- it is not consistent with US and UK requirements;
- there is lack of evidence to support the need for less variation in criteria due to consumer confusion; consumer confusion was related to what nutrient the claim referred to rather than whether that nutrient was low or reduced;
- 'lite' claims that meet the 'low' criteria support dietary guidelines; and
- it is inappropriate that a product lower in fat than a product making a 'reduced' claim, cannot be labelled as 'light'.

It was recommended by some submitters that the conditions for 'light' claims that are in CoPoNC are retained.

5.8.6 Factors relevant to regulatory option

On the basis of consumer research FSANZ considers the 'light' claim to be a type of comparative claim, where there is a comparison being made with another food. Therefore such a claim cannot be considered in the same context as a 'low' claim, because the criteria are absolute values rather than a proportional reduction. Accordingly, 'light' claims must meet the conditions for the applicable 'reduced' nutrition content claim, as proposed at Draft Assessment. This is supported by research findings indicating that consumers considered 'light' claims should be accompanied by a comparative claim (FSANZ, 2003a).

As 'light' is not a property of a food, but is actually a descriptor for a certain type of nutrition content claim (or for other characteristics), the drafting of Standard 1.2.7 will be amended to reflect this. 'Light' will be placed with each of the 'reduced' descriptors, for energy, fat, sodium, sugar, saturated fatty acids, *trans* fatty acids and cholesterol, in the Table to clause 11.

The requirement to state the energy or claimed nutrient in the same place as the 'light' claim will potentially minimise confusion amongst consumers as to what the claim is referring to and also clarify the meaning of the claim, when the claim relates to a particular nutrient or energy.

As the purpose of Standard 1.2.7 is to regulate nutrition content claims and health claims i.e. claims that can be associated with health effects, 'light' claims that refer to aspects such as the flavour or colour of a food, cannot be regulated by this Standard. A 'light' claim which is made about a characteristic such as colour but which does not specify this as part of the claim (e.g. light olive oil) may imply to consumers that the food is reduced in a nutrient such as fat. Misleading 'light' claims referring to characteristics other than properties of food which are the subject of nutrition content claims are regulated by fair trade legislation.

5.8.7 Analysis of options

The amended drafting of the conditions for 'light' claims proposed in this report does not reflect a change in the approach to the regulation of these claims. Rather, the change in drafting is intended to correct the reference to 'light' as a claim descriptor, rather than a property of the food and to clarify, within the context of Standard 1.2.7, that it only relates to nutritional properties. There is therefore no change to the impact on industry, consumers, or government, from what was proposed at Draft Assessment.

5.9 Comparative nutrition content claims and definition of 'reference food'

5.9.1 Recommendation

FSANZ proposes the following in relation to comparative claims at Preliminary Final Assessment:

1. The definition of 'reference food' will be amended to include comparisons between foods that can substitute for one another in the diet, as well as between foods that are of the same type.

2. Comparisons between 'dietary substitutes' will be limited to comparisons between foods in the same food group. The definition of 'food group' will be based on the food groups used in Australian and New Zealand food and nutrition guidelines.

3. 'Increased' claims can be made when the reference food meets the conditions of the 'source' claim and the increase in content is at least 25% compared to a reference food.

5.9.2 Introduction

Comparative claims are those claims that compare the nutrient or energy content of a food with the content in another food (the 'reference food'). Examples of comparative claims are those using the terms 'reduced', 'increased', 'more than' and 'less than'. Comparative claims about vitamins and minerals are not currently permitted by Standard 1.3.2 of the Code, and at Draft Assessment it was proposed that biologically active substances also be prohibited from making comparative claims.

Apart from the prohibition in relation to vitamins and minerals, comparative claims are not currently regulated by the Code, but CoPoNC sets out conditions for making these types of claims. These conditions include permission for comparative claims between foods of the same food group or foods that may substitute for one another in the diet.

For example, comparative claims can be made between foods such as beef and chicken, potatoes and rice or orange juice and apple juice, but comparisons between foods such as milk and fruit juice or fruit and nuts are not encouraged.

5.9.3 Approach at Draft Assessment

At Draft Assessment FSANZ proposed the following definition of 'reference food'.

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

The conditions for 'increased dietary fibre' and 'increased protein' claims were not described consistently across various sections of the Draft Assessment Report or in draft Standard 1.2.7. However, the conditions were intended to be as follows:

> *A claim stating that the content in one or more nutrients, other than vitamins and minerals or biologically active substances, has been increased, may be made where the product meets the conditions for the claim 'source of' prior to enrichment and the increase in content is at least 25% compared to a reference food. The identity of the reference food and the difference in the quantity of the claimed nutrient in the claimed food compared to the quantity in the reference food must be indicated. The claim must be presented so that all elements of the claim are in one place.*

5.9.4 The issue/problem

Claims comparing foods that substitute in the diet could not be made in the proposed Standard. There is a lack of clarity in the definition of 'reference food' with respect to the meaning of 'equivalent', 'regular' and 'category of food'.

The drafting of the conditions for 'increased dietary fibre' in draft Standard 1.2.7 did not capture the intent that the reference food must meet the conditions for making a 'source' claim.

5.9.5 Comments from stakeholders at Draft Assessment

5.9.5.1 Definition of 'reference food'

It was noted by some industry submitters that the approach around comparative claims was not the same as in CoPoNC because foods that substitute for one another in the diet can no longer be compared.

Submitters (from the industry, public health and government sectors) expressed concern around the 'reference food' definition in relation to the meaning of the words 'equivalent', 'regular' and 'category of food' within this definition. Comments included that:

- reference food cannot by definition be 'equivalent' to the food to which the claim is being made;
- 'equivalent' could refer to nutritional status, ingredient, composition, or weight etc;
- 'regular' has a number of dictionary meanings such as 'normally expected' but could also mean 'standard', such as 'regular coffee'; and
- according to the dictionary meaning of 'category' a frozen chop could be in the same category as ice cream (frozen foods).

It was suggested that 'equivalent' could be replaced with *the unmodified version of the same brand of food to which the claim refer*s; or that the definition could be simplified to *an equivalent food to the food in relation to which the claim is being made;* or to *a regular product in the same category of food as that food in relation to which a claim is being made*; and that foods that are 'similar' should be considered in the definition.

It was also noted that companies may delete standard reference products (regular product), resulting in the need for monitoring against competitors' products or an industry average.

Conditions for 'increased' claims

One industry submitter expressed concern over the additional criteria to meet 'source of' criteria for 'increased' claims. They stated that FSANZ has:

- no sound rationale for this;
- not demonstrated any benefit to consumers;
- not been consistent in the level of regulation for the associated risk; and
- breached the Council of Australian Governments (CoAG) principles for unnecessary regulation.

5.9.6 Factors relevant to regulatory option

5.9.6.1 Definition of 'reference food'

It is noted that the definition of reference food could be reworded to allow comparative claims about both 'similar foods' and 'dietary substitute foods', where 'dietary substitute foods' refer to foods that substitute for one another in the diet (e.g. tofu instead of chicken, margarine instead of butter) and 'similar foods' refers to the unmodified version of the food carrying the claim (e.g. whole fat milk compared with reduced fat milk).

FSANZ has therefore considered including a second option in the definition of 'reference food', to permit comparisons between 'dietary substitutes'. As the determination of 'dietary substitutes' could be very subjective, it is proposed that such claims need to be limited to comparisons between foods of the same food groups. This will help prevent inappropriate comparisons between foods such as milk and fruit juice. These types of claims were also prohibited under CoPoNC. 'Food group' will need to be defined in Standard 1.2.7 and this definition can be based on the food groups used in Australian and New Zealand food and nutrition guidelines.

The definition of 'reference food' proposed at Draft Assessment has also been reviewed to address submitters' concerns about the meaning of various words within the definition with respect to comparisons made between 'similar' foods.

Relevant international definitions of reference food have been considered in this review. The wording of the definition for 'similar reference food' used by Health Canada captures the intent of the definition of 'reference food' that was proposed by FSANZ at Draft Assessment. This definition is:

> *a food of the same type as the food to which it is compared and that has not been processed, formulated or otherwise modified in a manner that increases or decreases either the energy value, or the amount of a nutrient that is the subject of the comparison.*

This definition does not use the terms 'regular product', 'category of food' or 'equivalent', which were of concern to submitters.

It is therefore proposed that the following definitions be considered in relation to comparative claims:

> ***Reference food*** *means –*
>
> *(a) food that is of the same type as the food making the claim, that has not been further processed, formulated, reformulated or modified to increase or decrease the energy value or the amount of a nutrient that is the subject of the comparison; or*
> *(b) food that is a substitute for the food in the same food group as the food making the claim.*
>
> ***Food group*** *means, in this Standard, any of the following groups:*
>
> *(a) bread (both leavened and unleavened) and other cereal products; or*
> *(b) fruit and vegetables, herbs, spices and fungi, (fresh, cooked, frozen, preserved, pickled, pureed or dried); or*
> *(c) milk and milk products and milk alternatives; or*
> *(d) meat, seafood, eggs, nuts, seeds and legumes; or*
> *(e) fats and oils.*

5.9.6.2 Conditions for 'increased' claims

The intention that the food carrying the claim met the 'source' criteria for that nutrient (protein or dietary fibre) prior to enrichment was to ensure that a minimal amount of the nutrient is present and that the food naturally contains the nutrient in order to be able to make the claim. Since the approach will be changed to permit foods that are dietary substitutes to be compared, the food carrying the claim does not necessarily need to be enriched in order to make the 'increased' claim. For example the protein content in red kidney beans could be compared to that in chick peas, however the higher protein content in red kidney beans is not due to enrichment. The reference to 'prior to enrichment' would therefore no longer be appropriate. In addition, the rationale that the food carrying the claim must naturally contain the nutrient (fibre or protein), no longer applies. It therefore needs to be considered whether this additional condition should still be applied to 'increased' claims.

5.9.7 Analysis of options: 'Reference food' definition

Option 1 – Definition of 'reference food' as at Draft Assessment

Benefits

- Restricts the range of comparisons that can be made, therefore may reduce potential for inappropriate comparisons and consumers being misled.

Disadvantages

- Does not allow comparisons between foods that are dietary substitutes, thus limiting provision of information that could be considered useful and informative for consumers.
- Restrictive for industry.
- The interpretation of the meaning of 'reference food' was not clear to a number of stakeholders, so it would be more difficult for industry to use and for government enforcement agencies to ensure compliance.
- Relies on the presence of a 'regular' reference product (unmodified version of the food making the claim). If a 'regular' product does not exist within a particular brand, the company selling that brand is required to monitor against competitors' products or the industry average.

Option 2 – Definition of reference food clarified and additional option for comparing 'dietary substitutes'

Benefits

- May provide useful information to consumers about the nutritional benefits of a food compared to its dietary substitute, particularly for consumers who have specific dietary requirements or preferences, such as those with lactose intolerance or vegetarians.
- Provides more scope for wider range of claims to be made by industry.
- Does not rely on industry monitoring against competitors' products or the industry average if the 'regular' product goes off the market.
- Clarifies the meaning of 'reference food' in relation to comparisons between 'similar' foods, for ease of interpretation by industry and government enforcement bodies.

Disadvantages

- Is more subjective and permits a wider range of comparisons, thus increasing the potential for inappropriate comparisons that may mislead consumers.

FSANZ's preferred option at Preliminary Final Assessment is Option 2.

This option addresses submitters' concerns about the interpretation of the definition of reference foods and permits a wider range of claims that may be useful for consumers. Additional risk management measures are in place to reduce the potential for consumers to be misled by inappropriate comparisons.

These were proposed at Draft Assessment and include the requirement to declare the reference food in the claim and the prohibition of comparisons about the content of vitamins, minerals (by Standard 1.3.2) and biologically active substances (by draft Standard 1.2.7).

5.9.8 Analysis of options: Conditions for 'increased' claims

Option 1 – require the reference food to be a 'source' of fibre/protein

Benefits

- prevents claims between foods that may be considered inappropriate or misleading from a public health perspective, for example comparing the fibre content of red kidney beans with that in meat (as meat does not contain fibre);
- ensures that the food carrying the claim contains a certain amount of fibre/protein (at least 25% more than the 'source' criteria).

Disadvantages

- more prescriptive for industry;
- does not effectively manage one of the risks that was identified at Draft Assessment, i.e. does not require the food carrying the claim to naturally contain dietary fibre/protein (prior to enrichment).

Option 2 – remove the requirement to meet the 'source of' conditions

Benefits

- less prescriptive for industry;
- consistent with level of risk management for 'reduced' claims.

Disadvantages

- more potential for misleading consumers or inappropriate claims; this is now identified as more of a risk than at Draft Assessment, due to the proposal to permit foods that are dietary substitutes to be compared.

FSANZ's preferred option at Preliminary Final Assessment is Option 1.

This approach requires the food carrying the claim to contain a certain amount of the nutrient referred to in the claim. It is considered to be a further risk management tool to prevent comparisons between foods that could be considered inappropriate, which may otherwise have been permitted as a result of allowing comparisons between foods that are 'dietary substitutes'.

6. ISSUES RELATED TO HEALTH CLAIMS

6.1 Food Composition Eligibility Criteria for General Level Health Claims

6.1.1 Recommendation

The preferred model for determining the eligibility of foods to carry health claims is an across-the-board scoring system (based on the UK Food Standards Nutrient Profiling Model[13]). It uses 100 g or 100 mL as the base unit of calculation. 'Baseline' points allocated for increasing amounts of energy, saturated fat, sodium and total sugars are offset by 'modifying' points allocated for increasing percentage of the product that is fruit/vegetables/nuts/pulses and the amount of fibre, and in some cases, protein. The final score determines whether a food is not disqualified from carrying a general level health claim, assuming that it also meets the qualifying criteria. There are three cut-offs, one used for edible oils and spreads and certain cheeses, a second for other foods and milk and a third for other beverages. These criteria will also be the default criteria for determining the eligibility of foods to make high level health claims.

6.1.2 Introduction

General level health claims are a 'step-up' from content claims because they articulate an anticipated health effect in relation to the property of the food. This view reflects the Ministerial Council policy guidance on health claims which set out the claims classification framework for general level and high level health claims and is supported by FSANZ's consumer research. Therefore, in accordance with the overarching regulatory approach which imposes a higher level of regulatory control on health claims than content claims, generic food compositional criteria will be used so that foods which contain higher levels of 'risk increasing nutrients' will not be eligible to carry health claims. That is, food eligibility conditions will be applied in order to avoid the promotion, through the use of general level health claims, of certain categories of foods that are inconsistent with national dietary guidelines. FSANZ has considered that the approach to determining which foods should carry health claims should be consistent with public health goals to lower the consumption of saturated fat, sugar and salt, and encourage consumption of fruit and vegetables and fibre.

Consideration has also been given to the policy principles in the policy guideline during the development of the model for food composition eligibility criteria. Preventing foods that have high levels of risk increasing nutrients from making health claims is supported by the policy principles which advocate the promotion of healthy food. That is, applying food composition criteria to foods ensures that only food products which can make a positive contribution to a healthy diet are able to carry health claims. The new model allows a greater range of healthier food options to carry health claims. Requiring foods to meet overall compositional criteria also reduces the need for consumers to determine whether the claimed food is a healthy food choice in the overall diet which is supported by the policy principle stating that the regulatory system should promote the responsible use of claims and protect consumers from false and misleading information.

[13] FSANZ gratefully acknowledges permission to use and adapt the UK Nutrient Profiling Model given by UK Foods Standards Agency. The development of this model was funded by the UK Food Standards Agency and was based on extensive work undertaken by Prof Mike Rayner and colleagues

6.1.3 Approach at Draft Assessment

The following simple across-the-board scheme based on three 'risk increasing nutrients' – saturated fat, sodium and total sugars (as a *de facto* measure of nutrient density) was outlined at Draft Assessment:

A food passes the Disqualifying Criteria if it meets all of the following conditions:

- Sodium < 325 mg/serve and
- Saturated fat < 4 g/serve and
- Total sugars < 16 g/serve

Specific criteria will apply to meals and main dish products:

- Sodium < 775 mg/serve and
- Saturated fat < 7 g/serve and
- Total sugars < 31 g/serve

This scheme had the advantage of requiring only three numbers to be used and the only additional definition required was that of a 'meal or main dish'. The size of a serve is not currently regulated by FSANZ but is defined by manufacturers and stated on the product label. Hence the above criteria would be easy to enforce. At Draft Assessment, FSANZ had some concerns over the use of this model but was unable to identify a better approach which met all the requirements of a suitable model. Stakeholders were asked to provide suggestions for an improved approach. Further discussion on the origin of the criteria used in the model presented at Draft Assessment can be found at Attachment 6.

6.1.4 The issue/problem

The scheme outlined at Draft Assessment used across-the-board criteria in combination with serving size. This resulted in discrimination against foods with large serving sizes and in favour of foods with small serving sizes. Hence a number of types of fruit (for example, large apples, large pears and mangoes) would not be able to carry a health claim whereas various types of foods commonly regarded as 'less healthy' than fruit (for example, sugar-based confectionery, butter, sweet biscuits and potato crisps) would be allowed to carry a health claim.

6.1.5 Comments from stakeholders at Draft Assessment

Among the comments received, there was widespread opposition to the approach taken at Draft Assessment. The comments were mainly on the appropriateness of the foods which would be prohibited or allowed to make claims, the choice of the nutrients chosen to set the disqualifying criteria (particularly total sugars) and the use of a per serve model. Submitters were concerned that many foods consistent with national nutritional guidelines would be excluded: some fruit (sugar levels); some dairy (sugar and/or saturated fat), fish (sodium, saturated fat); nuts (saturated fat); avocadoes (saturated fat), olives (saturated fat), bread (sodium). A lot of data were supplied on inappropriate exclusions and inclusions.

There was a view that the methodology used for deriving the disqualifying criteria was flawed because it was based on individual foods rather than the total diet.

Some submitters suggested any approach should take account of the fact that some foods which are high in the 'bad three' nutrients are also high in positive nutrients e.g. lean meat, oils, low fat milks and yoghurts and so there is a need to have a system which takes into consideration both positive and negative elements.

Suggestions were made that the food components which are the subject of disqualifying criteria should be changed. In particular there was disquiet over the use of the total sugars criterion on the basis of the foods excluded. Significant differences in the pharmacokinetics of intrinsic and added sugars were claimed. It was also suggested the only disease associated with high sugar consumption independent of energy is tooth decay. Another submitter suggested that the use of a total sugars criterion was inappropriate because many starch-derived polysaccharides would not be analysed as 'total sugars'. Some starch polymers are rapidly converted to glucose during digestion and yet have very similar physiological effects to an equal portion of ingested glucose (for example, rapidly digestible starch). However the analytical issues over including digestible starch were acknowledged. There was also some concern that the use of total sugars could give rise to an increased use of artificial sweeteners.

It was suggested that an alternative approach would be to replace total sugars with energy density (as this offers an indirect way of controlling the amount of sugar that can be added to a products and is much more strongly correlated with bodyweight). Another suggested approach was to replace total sugars with added sugars (or exclude lactose). However, it was acknowledged that this approach poses analytical problems. Some submitters preferred energy density because of the ease of enforcement (since energy/100g is readily available on food labels and can be verified indirectly from macronutrient composition).

Comments were also made in relation to the saturated fat criterion with some submitters suggesting the criterion be altered to reflect appropriate fatty acid profiles (or to include *trans* fatty acids). Some suggested changing the values for the levels for nutrients and energy to reflect the new Nutrient Reference Values (NHMRC and Ministry of Health, 2006).

A number of comments expressed opposition to the use of non-standardized serving sizes. The comments were based on the possibility of manipulation (with some evidence provided); enforcement issues; the ability of products with small serve sizes to meet the disqualifying criteria (confectionery, biscuits etc) and this was highlighted as a specific possible issue for food products targeted at children which had smaller serve sizes; the unequal application to the same product retailed in different serve sizes (baked beans, crisps); the possibility that serve sizes would be reduced for food types such as dairy products in order to meet the criteria and this would contradict nationally accepted serve sizes for these products.

6.1.6 Evidence base

A database was constructed from 4500 foods from the Australian AUSNUT database, 2500 generic New Zealand Foods and Beverages from Crop and Food Research's Foodfiles and a privately developed database compiled from the Nutrition Information Panel information on approximately 9000 current products in a major Australian Supermarket in August-October 2005. After further refining a database of 10949 foods and beverages was available for testing alternative models for food composition criteria. Attachment 6 includes further details of the database development.

Eight models falling into four types were tested. The details of the testing of the models are given in Attachment 6. The compilation of the database and the initial testing of the models were performed by an independent contractor, Alan Barclay.

6.1.6.1 Models tested

The first type included the model proposed at Draft Assessment, which was used for comparative purposes (Model 1). Two variants of this model with more stringent criteria were also tested (Models 2 and 3). All three of these models are per serve models.

In response to FSANZ's request for alternative approaches, the Dietitians Association of Australia developed a food category-based model which, along with a variant of the model, was included in FSANZ's model testing (Models 4 and 5). Both of these used 100 g as the base of calculation. Model 4 had nine food categories and Model 5 had 12 food categories. Various levels of two or three of the following nutrients were used as criteria for the categories: energy, saturated fat, sodium and calcium. In Model 5, fibre was used as a fourth criterion for one category. A food-category based system classifies foods as more or less desirable within categories but does not allow comparison of foods that lie within different categories.

The third model type was a profiling model adopted by the UK Food Standards Agency[14] in 2006 for control of broadcast advertising of foods high in saturated fat, sugar and salt to children (Model 6) and a FSANZ derivation of it (Model 7). This type uses 100 g as the base unit of calculation and an across-the-board scoring system with 'baseline' points allocated for increasing amounts of energy, saturated fat, sodium and total sugars that are offset by 'credit' points allocated for the percentage of the product that was fruit/vegetables/nuts/pulses and the amount of fibre, and in some cases, the amount of protein. The final score determines whether a food is eligible to carry a general level health claim, assuming that it also meets the qualifying criteria. As predicted by its developer, this model would need some modification if used for a different purpose (M Rayner, personal communication).

Many composite foods could not be classified by Model 6 because nutrient databases do not contain the ingredient information required and so some targeted label reading was done by FSANZ staff to fill in certain gaps. Examination of the results of Model 6 indicated certain failures of the model for FSANZ's purposes (possibly relating to its original and differing purpose in the area of advertising to children) and modifications using foods defined in the Code were explored to see whether these defects could be rectified. Some further refinements were necessary to align the model with existing provisions in the Code (Model 7).

The fourth model (Model 8) was a composite model, based on threshold values partly based on energy density, but also allowing some more lenient criteria for some types of food.

There are two fundamentally different approaches to classifying foods. A system (such as Models 1, 2, 3, 6, 7) that does not use food categories, allows foods to be compared across all categories but may or may not always identify what some may see as 'better' choices within any category (for example, if a salted version of a product is very low in salt it might not be classified differently from an unsalted version).

[14] Nutrient Profiling Model developed by the UK Food Standards Agency. http://www.food.gov.uk/healthiereating/advertisingtochildren/nutlab/nutprofmod

Conversely, a food-category based system (such as Models 4 & 5) identifies 'better' choices within categories but may lead to different classification of foods that have the same nutrient profile but lie in different categories. The two approaches are also different from an implementation point of view: the category-based system requires the development of exhaustive and mutually-exclusive categorisation definitions that can be legally defined whereas the other system does not. Model 8 is a hybrid of these two approaches, incorporating common cut offs across the board, with a few product types being assigned different values.

6.1.6.2 Factors relevant to the regulatory option

To aid selection of the preferred model, a set of desirable characteristics of a feasible and appropriate system were articulated. There is a recognition that no system is perfect and that compromises and anomalies will be inevitable and the preferred model should therefore be one which achieves the highest degree of concordance with the desired characteristics.

The important characteristics fell into several theme groupings:

Overall

- The system will endure into the future. It is not so strongly aligned to products currently on the market that future products will be unclassifiable.
- It will encourage innovation of manufactured products by rewarding changes in composition that move in the direction of supporting current health advice.

Nutrition-related criteria

- Nutrient-based criteria are defendable in relation to some external criteria relating to nutritional recommendations.
- The system acknowledges the major current public health problems relating to chronic disease rather than being based solely on micronutrients.
- It does not unduly penalise foods which are recommended in dietary guidelines, which have beneficial attributes but are also naturally high in some risk increasing nutrients (i.e. fruit and milk with intrinsic sugars).
- It has credibility for both the general public and health professions. Where there is important divergence from 'expected' classification, the reasons for divergence are explicable (e.g. public misperception about the composition of a product possibly due to changes in composition or because a change in scientific evidence has made some previous advice obsolete).

Implementation-related criteria

- To be implemented, a set of food eligibility criteria must be both converted into a clear set of regulations and be enforceable.
- Criteria which are difficult to draft (e.g. complex food categorisations not already in the Food Code) potentially leave unclear boundaries between categories which might then lead to different enforcement decisions among the 10 jurisdictions that enforce food regulations in Australia and New Zealand.

- Criteria which are based on many compositional items which are not normally presented on a label might have difficulties displaying the additional information on the package, which is a requirement for ease of enforcement.
- For consistent and simpler enforcement non-variable characteristics are preferred over characteristics that are open to interpretation or manipulation such as:

    - per 100 g or 100 mL is preferred over per serve;
    - across the board criteria are preferred over food category-based criteria; and
    - food categories already defined in regulation are preferred over food categories that must have new regulatory definitions developed.

Practical aspects of use by industry

- Criteria based on compositional characteristics that are currently required or commonly used on the label are preferred over criteria that would require substantial redesign of the label.
- Nutrients that are easily measured in laboratories are preferred over nutrients that are difficult.

6.1.7 Analysis of options

It was agreed that the model proposed at Draft Assessment classified some foods in inappropriate ways (for example many biscuits, types of confectionery and potato crisps would be eligible to carry health claims while some fruit would not). The stricter Models 2 and 3 did not improve this defect. Models 4, 5 and 6 performed better although not identically. They were consistent in classifying foods such as fruit, vegetables, low fat milk, and wholemeal bread as eligible to carry health claims, whilst foods such confectionery, salty snack foods, cream-filled biscuits, butter and sugary drinks and breakfast cereals would not be eligible. They also differed with respect to classifying various other products because of their essentially different viewpoint with Models 4 & 5 classifying foods relative to each other within food groups and Model 6 classifying foods across all groups.

There were two features of Models 4 and 5 that detracted from using either of them: the first being that food groups would need extensive descriptions of food categories to ensure an exhaustive and mutually-exclusive set of definitions and which therefore might be open to different interpretations by manufacturers and the various enforcement agencies in Australia and New Zealand; and the second being that they have a large group of 'all other foods' to which a single set of cut-offs is applied. This does not distinguish between a number of foods which have quite desirable profiles (e.g. fruit and nut bars with little sugar) from those which do not and so it does less to encourage innovation by manufacturers.

The testing of Model 8 was conducted after the testing of the other models. It had some features which clearly distinguished it from the other models: the use of per energy as the basis; incorporation of an 'added sugar' criterion; and consideration of *trans* fatty acids in conjunction with saturated fat as a criterion. However, it did not improve discrimination between foods consistent with national dietary guidelines and those which are recommended to be consumed at lower levels. In addition, *trans* fatty acids did not improve selection and there were analytical problems associated with the use of an 'added sugar' criterion. Consequently, this model was not developed further.

Therefore other criteria relating to the factors listed in subsection 6.1.6 and discussed further in section 6.1.8, such as ease of enforcement, dictated further development of Model 6 which resulted in the preferred approach, Model 7.

As predicted, there are still some anomalies in Model 7. The introduction of a different set of criteria for edible oils and spreads and hard cheeses means that some inconsistencies have been introduced and the scheme is a hybrid of an across-the-board and a category system.

6.1.8 Discussion

The nutrient profiling Model 7 is the preferred option because it most clearly aligns with the articulated desirable characteristics. It also addresses a number of the suggestions and criticisms made at Draft Assessment:

- it includes energy density;
- although total sugars are used, this is offset by a favourable score for % fruit which addresses the criticism that total sugars includes intrinsic fruit sugar;
- although total sugars are used, this is offset by a favourable score for protein for many foods and this addresses the criticism that total sugars includes lactose in milk;
- it uses 100 g rather than serving size as the base of calculation; and
- it recognises positive as well as negative nutrients but more simply than scoring many different micronutrients individually. The two-year development process outlined in Attachment 6 shows how nutrients such as iron and calcium were specifically included as such in early versions of the model and how they were able to be subsumed.

It supports dietary recommendations:

- Recommendation to increase consumption of fruit, vegetables, nuts and pulses is directly supported. The score allocated to these ingredients makes the distinction between foods containing fruit sugars and those with added sugars;
- Recommendation to increase consumption of wholegrains is indirectly supported by the favourable score allocated for fibre;
- Lean meat/chicken/fish recommendations and importance of iron are supported by the protein score allowed for foods with a low score for the negative nutrients;
- The importance of calcium is supported by the use of protein in the score for foods with low scores of the undesirable nutrients and a separate cut-off for high calcium hard cheeses;
- Recommendations relating to increasing consumption of poly- and mono-unsaturated fats are further supported by a separate cut-off for edible oils and spreads made from them; and
- The cut points in the scoring system are based on various dietary recommendations and include risk increasing nutrients and also desirable micronutrients. Unexpected results relating to many hot chips and salted canned vegetables being scored as eligible to carry health claims are due to manufacturers having changed to using polyunsaturated fat in frozen chips and reducing the amount of salt in a wide range of products.

It encourages innovation by manufacturers to support dietary recommendations:

- Highlights possibilities for innovations in the direction of adding fruit, vegetables, nuts, pulses and fibre-containing ingredients rather than simply pointing to reductions of some nutrients to meet the specifications.
- A sliding scale scoring system allows foods to achieve the same score via various different compositional profiles. This may provide more scope for manufacturers to reformulate products to become eligible to carry health claims than a system with only one cut-off for each scoreable nutrient.

It is easier to use than a category based approach:

- Using the same scoring system across categories does not discriminate against foods which contain many different ingredients and which, therefore, are hard to classify into a food categories system based on foods with only a small number of ingredients.
- Non-use of food categories obviates the need to decide how to classify composite foods now and in the future as new food products are developed.
- It meets the overall criteria because it does not require categorisation of new products into groups and also distinguishes among the multi-ingredient non-core foods according to their desirable characteristics.

It is enforceable:

- Enforcement will be more difficult than for the system proposed at Draft Assessment, but simpler than for a food-category based system, and is based on information that can be easily included on the label. All food groupings used are defined already in the Code (e.g. Standard 2.4.1 - Edible oils). The main possible source of contention is the restriction on counting some forms of processed fruit/vegetables/nuts/pulses.
- All the nutrients used in the recommended model are either compulsory on the label or commonly declared. Manufacturers' recipes will provide the remaining information – the percentage of the product that is fruit/vegetables/nuts/pulses. In many cases this might already be included in the ingredient list owing to the requirements around characterising ingredients. However, fibre, calcium and percentage fruit/vegetables/nuts/pulses (the non-compulsory items) would only be required to be listed where a product relies on this information to be eligible to carry a health claim.

A step-by-step guide to performing the calculation of whether a food will meet the nutrient profile score criteria is given in Appendix 7. A 'Health Claims Nutrient Profile Scoring Calculator' is available on the FSANZ website for assessing foods for eligibility to carry health claims. It is intended this will be linked to the Nutritional Information Panel Calculator after gazettal of the Standard to enable easy calculation of the nutrient profile score.

6.2 Weight management claims and 'Diet' claims

6.2.1 Recommendation

FSANZ proposes the following in relation to **weight management claims** at Preliminary Final Assessment:

1. Weight management claims will be allowed;

2. Weight management claims will be general level health claims;
3. The nutrient profile scoring criteria for general level health claims apply;
4. Claims are required to state the importance of exercise;
5. The food must a) meet the conditions for 'low energy' claims; or b) contain at least 40% less energy compared to the same quantity of the reference food; and
6. The claim states the identity of the reference food and the difference between the energy value of the food and the reference food.

FSANZ proposes the following in relation to '**Diet' claims** at Preliminary Final Assessment:

1. Diet claims will be allowed;
2. Diet claims are nutrition content claims;
3. The nutrient profile scoring criteria for general level health claims apply;
4. The food must a) meet the conditions for 'low energy' claims; or b) contain at least 40% less energy compared to the same quantity of the reference food; and
5. The claim states the identity of the reference food and the difference between the energy value of the food and the reference food.

6.2.2 Introduction

Weight management is a concern for a substantial percentage of the population. In the context of draft Standard 1.2.7, weight management means weight loss, measurement reduction, and weight control/maintenance.

The Transitional Standard 1.1A.2- Health Claims states that the label on or attached to a package containing or an advertisement for food shall not contain a claim or statement that a food is a slimming food, or has intrinsic weight reducing properties. Given this existing prohibition, FSANZ considered it important to raise the issue of weight management claims at Initial Assessment. Specifically, FSANZ sought comments from submitters on how such claims should be regulated and for them to provide rationale and supporting evidence for their views.

At Draft Assessment, FSANZ proposed that weight management claims would be permitted and regulated in accordance with the Claims Classification Framework. Claims that refer to a biomarker or serious disease would be regulated as high level health claims while those that do not refer to a biomarker or serious disease would be regulated as general level health claims.

For regulatory purposes, FSANZ considers 'obesity' to be a serious disease and 'overweight' to be a non-serious disease. Thus weight management claims will be either general level health claims or high level health claims depending on whether they refer to obesity or not. As a minimum, weight management claims will be regulated as general level health claims and, as such, they must be substantiated according to the substantiation framework for general level health claims, and meet all the requirements of a general level health claim.

At Draft Assessment, FSANZ proposed that weight management claims should be permitted if foods with such claims met the qualifying criteria for 'low calorie/joule/energy' and the generic disqualifying criteria for general level health claims. In addition, claims would have to state the importance of exercise in weight management.

Following Draft Assessment, stakeholders raised a variety of concerns to the proposed approach to regulating weight management claims which are detailed below. After further consideration, FSANZ considers that the general approach to weight management claims taken at Draft Assessment is appropriate, however, the qualifying criteria set for such claims were reviewed.

At Draft Assessment, FSANZ carried over the qualifying criteria for 'Diet' claims given in the Code of Practice on Nutrient Claims in food labels and advertisements (CoPoNC). CoPoNC specified that to make a 'Diet' claim on a food the energy content of the food must not be more than 60% of the energy content of the reference food (40% reduction in energy) and, in addition, there must be a reduction in energy content of at least 170 kJ per 100 g of food (80 kJ per 100 g of liquid) compared to a reference food. However, a similar additional CoPoNC qualifying criterion for reduced energy claims was not included in the proposed approach for regulating reduced energy claims.

Following Draft Assessment, it became clear that the approach to setting qualifying criteria for reduced energy and 'Diet' claims were inconsistent, and that a simplified and consistent approach might be more appropriate to regulate claims based on reduction in calorific content.

6.2.3 Approach at Draft Assessment

The proposed approach at Draft Assessment for weight management claims was as follows:

(a) Weight management claims will be allowed;
(b) Weight management claims are general level health claims;
(c) Disqualifying criteria for general level health claims apply;
(d) Claims are required to state the importance of exercise; and
(e) Foods are required to meet the qualifying criteria for 'low calorie/joule/energy'.

The proposed approach at Draft Assessment for 'Diet' claims was as follows:

1. The food must meet the disqualifying criteria for general level health claims; and

2. The food must meet the conditions for 'low energy' claims; or

    (a) the food must contain at least 40% less energy compared to the same quantity of the reference food; and
    (b) there must be a reduction in energy content of at least 170 kJ per 100 g or 80 kJ per 100 mL; and
    (c) the claim states the identity of the reference food and the difference between the energy value of the food and the reference food;
    (d) The claim must be presented so that all elements of the claim are in one place.

6.2.4 The issue/problem

With the approach taken at Draft Assessment, only products meeting 'low energy' criteria would qualify to make weight management claims. Some healthy option foods, such as dairy products (particularly skimmed milk), would not qualify to make such claims because of their energy content.

The qualifying criteria for 'Diet' claims proposed at Draft Assessment are overly complex and inconsistent with the qualifying criteria for reduced energy claims which are only based on a percentage reduction in energy.

6.2.5 Comment from stakeholders at Draft Assessment

Submitters made the following comments with regard to this issue:

- Many 'Diet' products (such as jams, soft drinks etc) will qualify which means that the focus will be on nutrient poor foods.
- Skimmed milk and other milk products would be excluded by either the disqualifying or qualifying criteria. Dairy is an important part of a healthy diet and should be allowed to make claims.
- Under the proposed disqualifying criteria, many fruits would not be able to make a weight management claim, which supports the recommendation that fruits and vegetables should be exempt from disqualifying criteria.
- Weight management claims should have to meet reduced energy rather than low energy criteria.
- A different energy criterion should be developed.
- Qualifying criteria for 'low joule' should be omitted completely. Other conditions applicable to weight management claims would seem to provide sufficient information to the consumer to provide for informed choice for those on weight management programs.

6.2.6 Factors relevant to regulatory option

FSANZ considers that weight management claims are, to all intents and purposes, very similar to 'Diet' claims and it is therefore appropriate that products carrying weight management claims are subject to similar criteria to those carrying 'Diet' claims i.e. the criteria that are applied to 'Diet' content claims should also apply to general level health claims referring to weight management.

This would have the effect of setting less stringent criteria than those for low energy claims, but more stringent criteria than those for reduced claims. This approach will allow products that do not meet the criteria for low energy to make weight management claims, but does not qualify foods that are relatively high in energy, thereby striking a balance between consumer protection and choice.

Foods that do not meet the qualifying criteria may be able to make other claims to assist consumers in making healthy choices, such as 'reduced energy', or 'light'.

At Preliminary Final Assessment, FSANZ is proposing a new approach to setting food composition eligibility criteria for general level health claims. This new approach will address the concerns raised by stakeholders in relation to foods eligible to make health claims, including allowing core foods to make weight management claims.

In addition, FSANZ is proposing to simplify the qualifying criteria for 'Diet' claims by requiring foods with such claims to have 40% less energy than a reference food, without specifying a minimum reduction of energy of 170 kJ per 100 g of food, or 80 kJ per 100 g of liquid food.

This is because at Draft Assessment, FSANZ carried over the full qualifying criteria for 'Diet' claims given in CoPoNC, however, this approach was not applied to reduced energy claims.

6.2.7 Analysis of options

Option 1 – Approach taken at Draft Assessment: Weight management claims – the foods are required to meet the qualifying criteria for 'low energy'. 'Diet' claims – the foods are required to meet the qualifying criteria for low energy <u>or</u> the food must have 40% less energy as the same quantity of a reference food, and a minimum reduction of energy of 170 kJ per 100 g of food, or 80 kJ per 100 mL of liquid food.

<u>Benefits</u>

- The overriding factor in weight management is energy balance. The use of tight qualifying criteria ensures that only low energy foods can make weight management claims.
- Consumers are protected from misleading claims because only low energy foods can carry claims.
- The requirements of the regulatory framework for making general level health claims, and the additional requirement to declare the importance of exercise in weight management provide protection to the consumer.
- Qualifying criteria for 'Diet' claims are consistent with current industry practice.

<u>Disadvantages</u>

- Many nutrient poor foods will qualify, but many core foods will not qualify to make claims.
- Consumer choice is limited by a narrow range of food that can make claims.
- Inconsistent with the qualifying criteria for 'Diet' claims.
- Consumer choice is reduced because weight management claims can not be used on some basic foods because of the stringent criteria.
- Different approach to qualifying criteria for reduced energy and 'Diet' claims.

Options 2 –Foods making weight management claims or 'Diet' nutrition content claims are required to meet the qualifying criteria for 'low energy' <u>or</u> must have 40% less energy as the same quantity of a reference food. The criterion of a minimum reduction of energy of 170 kJ per 100 g of food, or 80 kJ per 100 mL of liquid food does not apply to 'Diet' nutrition content claims or weight management claims.

<u>Benefits</u>

- Consistent qualifying criteria set for 'Diet' claims and weight management claims
- By changing the qualifying criteria to allow claims on a wider variety of foods consumers will have access to an increased range of foods carrying weight management claims.

- The combination of qualifying and nutrient profile criteria, the requirements of the regulatory framework, and in the case of weight management claims, the additional requirement to declare the importance of exercise provide protection for the consumer, and effectively balance potential negative public health impacts with consumers' ability to make informed decisions.
- The new qualifying criteria proposed in conjunction with the proposed more flexible generic nutrient profiling criteria for general level health claims allow more products to make weight management claims. This provides a direct benefit to industry by allowing the use of claims on a wider variety of products, and by reducing the need for reformulation.
- Consistent approach of using percent reduction in energy to set qualifying criteria for 'Diet' and reduced energy claims.

Disadvantages

Given that the overriding factor in weight management is overall energy balance, the qualifying criteria in regard to reduced energy content allows weight management claims on a range of foods which may still be relatively high in energy, albeit reduced compared to their counterparts.

FSANZ's preferred approach at Preliminary Final Assessment is Option 2 on the basis of consistency between weight management and 'Diet' claims and reduced energy and 'Diet' claims, and recognising that foods reduced in energy have a role in weight management.

Example

A brand of yoghurt contains 180 kJ/100 g. This is half the kilojoules of a reference yoghurt. The yoghurt meets the nutrient profile scoring criteria, but does not meet the criteria for a low energy claim. Following the approach taken at Draft Assessment, the yoghurt could carry a 'Diet' claim but not a weight management claim. Following the new qualifying criteria the yoghurt may make a, reduced energy claim, 'Diet' claim, or a health claim regarding weight management claim such as:

Yoghurt X contains ½ the kilojoules of Reference Yoghurt Y. As part of diet that is low in energy and combined with regular exercise, Yoghurt X can assist you in managing your weight.

6.3 New diet-disease relationships

6.3.1 New diet-disease relationships

Four high level diet-disease relationships were described in the Draft Assessment Report. These were:

- calcium and bone health;
- folic acid and neural tube defects;
- saturated and *trans* unsaturated fatty acids and LDL-cholesterol; and
- sodium and blood pressure.

As noted at that time, three further reviews of diet-health relationships had been selected and were under examination. These were:

- fruits, vegetables and coronary heart disease;
- wholegrain and bran intake and coronary heart disease; and
- long chain omega-3 fatty acids and cardiovascular disease.

The outcome of these three additional reviews is summarised below and given in detail in Attachment 5.

6.3.2 Review of diet-disease relationships

FSANZ commissioned an expert review on each topic. These reviews were then examined by a Scientific Advisory Group which provided advice on the substantiation, or otherwise, of the possible claim.

6.3.2.1 Fruits, vegetables and coronary heart disease

FSANZ considers that there is convincing evidence for an inverse relationship between a diet containing vegetables and fruit and coronary heart disease. There is consistent evidence indicating that people who consume diets containing moderate amounts of vegetables and fruit have less heart disease than people who eat diets containing low amounts. However, there is less consistent evidence indicating that high levels of intake confer additional risk reduction compared to moderate amounts.

There are two potential variant claims that flow from this evidence. The first is a claim advising an increase in vegetables and fruit intake. The second is a claim advising consumption of a diet rich in vegetables and fruit (i.e. consistent with national dietary guidance, recognising that these specific quantities are different in Australia and New Zealand). These two forms of claim may have different impacts in different segments of the population and so both are permitted.

6.3.2.2 Wholegrain and bran intake and coronary heart disease

FSANZ considers that the evidence relating to wholegrains, bran and coronary heart disease is not convincing. Some experimental studies showed that oats or oat bran lower cholesterol levels, however wheat does not have this effect. The small number of observational studies included in the review measured variable intakes and types of wholegrain food. Therefore the evidence base is insufficient to support a claim generally relating to wholegrains, particularly as wheat is the predominant form of wholegrain in the Australian and New Zealand diet. There may be sufficient evidence to support a relationship with respect to total fibre and/or types of fibre and/or specific foods and/or vascular disease but this relationship was not specifically investigated as part of the review.

6.3.2.3 Long chain omega-3 fatty acids and cardiovascular disease

FSANZ considers that the evidence relating to long chain omega-3 fatty acid consumption and reduction in risk of cardiovascular disease (CVD) is 'probable' but not 'convincing'. Thus there is sufficient evidence to support a general level health claim for the diet-disease relationship between long chain omega-3 fatty acids and cardiac health but there will not be a pre-approved high level claim relating omega-3 fatty acids and reduced risk of CVD.

The long chain omega-3 fatty acids considered for a diet-disease relationship were eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), and docosapentaenoic acid (DPA). EPA and DHA are marine-derived oils and DPA is present in red meat. Sources of isolated DPA are not readily available and there has been little evaluation of its health effects, hence there is insufficient information to determine whether there is a diet-disease relationship for this fatty acid. In contrast, there is a substantial body of literature describing observational and experimental studies of EPA and DHA on CVD risk factors and a more limited amount of evidence relating EPA and DHA intakes to CVD morbidity and mortality.

There is convincing evidence that supplemental omega-3 fatty acids in relatively high doses of about 1 g per day or more modestly reduce blood pressure and triglycerides. However, at average omega-3 fatty acid intakes by Australians and New Zealanders of around 170 mg/d, even a doubling or tripling of omega-3 from food sources would likely have a marginal effect on blood pressure or concentrations of circulating triglycerides. Omega-3 intakes, even at supplemental doses, have little or no effect on cholesterol concentrations. A major biological mechanism proposed to link omega-3 fatty acids and CVD is an anti-arrhythmic effect, but the evidence for this is limited and contradictory. Overall, there are insufficient randomised controlled trials with consistent findings in favour of omega-3 fatty acids and reduced CVD risk to substantiate a diet-disease relationship. Whilst there are several observational studies linking high fish intake to reduced CVD events and mortality, the evidence base is incomplete and associations could be influenced by confounding factors independent of omega-3. Therefore, on the basis of current evidence, a high level health claim relating long chain omega-3 fatty acids and cardiovascular disease is not supported.

6.3.3 Conditions and criteria relating to diet-disease relationships

The compositional and wording conditions for the new pre-approved health claims arising from the reviewed diet-disease relationships are given in Table 2.

As a result of the changed approach to the food compositional criteria for general level health claims (refer section 6.1) the default situation for high level health claims is that all foods bearing an approved high level health claim should meet the generic criteria based on the nutrient profile model (Attachment 7). However, whether or not the generic criteria apply will be considered on a case-by-case basis for each future high level health claim. At Draft Assessment, FSANZ proposed that some of the high level health claims were allowed on claimable foods only. Under the current recommendation, high level health claims that refer to a vitamin other than folate or a mineral, the requirement for those claims which were previously based on claimable foods (i.e. calcium, vitamin D and osteoporosis; calcium and enhanced bone density) will be made consistent with the other high level health claims. However, if a food bearing a high level health claim also carries a nutrition content claim or general level health claim related to a vitamin or mineral, the claimable foods approach also still applies for the time being.

FSANZ has previously indicated it intends to review the use of the claimable food approach as part of its review of the new Nutrient Reference Values (see section 11.1).

6.4 Substantiation Framework

Many of the comments received on the Draft Assessment Report in relation to substantiation were related to a need for further clarification and information. These points will be addressed in the Final Assessment Report.

The substantiation framework document, which can be accessed from the following link: Draft Assessment Report for P293 - Nutrition, Health and Related Claims, indicated that approval of high level health claims was likely to require convincing scientific evidence of a diet-disease relationship. In relation to the principles for general level health claims, the level of evidence was not explicitly stated. Given the range of evidence sources that can be used to substantiate a general level health claim other than by systematic review of the totality of evidence, and the step up approach to regulation of health claims, FSANZ is recommending that the minimum level of evidence to support a general level health claim be established at 'probable'. The substantiation framework document will be amended at Final Assessment to reflect this.

Table 2: Application of the Regulatory Framework to the new pre-approved high level health claim

	Restriction on Use of Claim	Food Compositional Criteria	Wording Conditions in the Standard				Additional information on lifestyle factors	EXAMPLE CLAIM
			Property of Food	Specific Health Effect	'Healthy Diet' Context	Population Subgroup		
Increased intake of vegetables and fruit and coronary heart disease	This claim is not permitted on fruit juice	The food contains no less than 90% vegetable and/or fruit by weight. Meets the generic scoring criteria for making a health claim	Not applicable (vegetables and fruit must always be stated within the claim, even though the claim may be carried on fruit without the product containing vegetables (and vice versa).	Reduced risk of coronary heart disease	A healthy diet with an increased intake of both vegetables and fruit and consisting of a variety of foods (both vegetables and fruit must be listed in the claim, and in that order).	General population (does not need to be included in the wording of the claim)	N/A	*An increase in vegetable and fruit intake may reduce the risk of coronary heart disease, when consumed as part of a healthy diet consisting of a variety of foods.*
A diet rich in vegetables and fruit and coronary heart disease	This claim is not permitted on fruit juice	The food contains no less than 90% vegetable and/or fruit by weight. Meets the generic scoring criteria for making a health claim	Not applicable (vegetables and fruit must always be stated within the claim, even though the claim may be carried on fruit without the product containing vegetables (and vice versa).	Reduced risk of coronary heart disease	A healthy diet rich in both vegetables and fruit and consisting of a variety of foods (both vegetables and fruit must be listed in the claim, and in that order).	General population (does not need to be included in the wording of the claim)	N/A	*Consumption of a diet rich in vegetables and fruit may reduce the risk of coronary heart disease, when consumed as part of a healthy diet consisting of a variety of foods.*

7. ISSUES RELATING TO RELATED CLAIMS

7.1 Dietary Information

7.1.1 Recommendation

FSANZ proposes the following for dietary information at Preliminary Final Assessment:

1. The definition of dietary information will be simplified through the removal of the reference to 'brand', and amended to clarify that it does not include claims that make references to health effects15. The amended definition is as follows:

   Dietary information *means general dietary information provided for educational purposes including information from national nutrition guidelines relating to foods or properties of foods, but not including associated health effects.*

2. Dietary information may only be provided in a label on food, or in an advertisement for food:

   (a) if it relates to an associated nutrition content claim or health claim. The dietary information should not imply benefits of the food beyond the level of the associated nutrition content claim or health claim; or
   (b) where dietary information refers to a whole food. In this case a related nutrition content claim or health claim is not required, but the dietary information must be directly relevant to the type of food with which it is associated.

3. Food labels or advertisements for food carrying moderation statements in relation to alcohol consumption are exempt from the requirement to make a related nutrition content claim or health claim.

4. Provisions around dietary information apply exclusively to food at the point of retail sale to the public (including food sold in restaurants) and have no application in respect of foods for hospital food services or delivered meal organisations, as regulated by the Application provisions of draft Standard 1.2.7.

5. 'Dietary information' will be more clearly identified through a set of guiding principles and examples provided in user guidance.

'Dietary information' is not specifically referred to (or excluded) in the policy guideline, however, the guideline does refer to dietary guidelines (from which dietary information may be drawn) within the context of claims. For example, the policy guideline states for high level health claims: 'high level claims include ….. *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 Guidelines or the New Zealand Food and Nutrition Guidelines background papers.'*

[15] Reference to national guidelines does not include reference to health effects. Whilst this information is found in the background papers to the guidelines, such information is not to be presented as dietary information on food labels or advertisements.

This exemplifies the potential overlap (and scope for confusion) between dietary information and high level health claims. A similar overlap exists for general level health claims. FSANZ therefore considers that it is important to delineate dietary information more clearly from nutrition content claims and health claims to enable the continued dissemination of genuine dietary information, without it being constrained by the requirements of Standard 1.2.7.

7.1.2 Introduction

Dietary information needs to be distinguished from nutrition and health claims as it serves a different purpose. It is important to manage dietary information in a manner that would enable companies to avoid compliance with the criteria and conditions of nutrition content or health claims. Attempts have been made to define 'dietary information' such that it is clearly distinguished from nutrition and health claims. However, dietary information is conceptually very broad, and may for all intents and purposes appear very similar to nutrition content claims or health claims.

Although an approach was proposed at Draft Assessment to address this, dietary information has proven to be a particularly difficult area to adequately manage. Stakeholders and FSANZ's Legal Counsel have identified a number of shortcomings with the recommendations provided at Draft Assessment. FSANZ has reconsidered the draft Standard and amended it, with the aim of improving its effectiveness with respect to dietary information.

7.1.3 Approach at Draft Assessment

In draft Standard 1.2.7 – Nutrition, Health and Related Claims, dietary information was defined in order to be expressly excluded from certain requirements of the Standard, that is, dietary information was excluded from the definitions of health claim and nutrition content claim. Dietary information was defined to refer to generalised information that does not link a specific brand of food to a health effect. If such a link was made, the information would fall outside this definition and would be captured by the Standard as a 'health claim', and must fulfil the requirements of a health claim in order to be compliant.

If an association was made between general dietary information and a specific product (for example, by a statement appearing on the label of a particular food or in associated advertising), the product was to be supported by a nutrition content claim or health claim pertaining directly to the subject matter of the dietary information.

Dietary information was exempted from these conditions if reference was made to moderating the consumption of the food.

The draft Standard at Draft Assessment included the following conditions:

Draft Standard 1.2.7, clause 1 – Interpretation

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

Clause 9 – Conditions for dietary information

(1) *Subject to subclause (2) and (3), if dietary information is provided on a label or in an advertisement, it must relate to the property of the food that is the subject of a claim.*
(2) *If the property of the food is not part of the claim under subparagraph 5(2)(d)(i)*[16]*, then any dietary information provided must relate to the food.*
(3) *This clause does not apply where dietary information relates to moderating the consumption of food.*

7.1.4 The issue/problem

The specific issues which have arisen are as follows:

- the definition and status of 'dietary information' are unclear;
- a health effect could be linked to a generic food (unbranded) and meet the definition of dietary information. This conflicts with the intent of the draft Standard, as such a statement could be interpreted as a health claim but not be subject to the criteria and conditions applying to health claims; and
- the drafting was ambiguous with respect to the legal interpretation of the related sub-clause allowing moderation statements for foods. (This provision was specifically drafted to allow for moderation statements in relation to alcohol.)

Another issue relates to determining whether dietary information is regulated by draft Standard 1.2.7 or not. The vehicle on which dietary information is provided and the intended audience need to be considered. It was the intention that dietary information provided in situations other than food labels or advertising which was not promoting the food for retail sale to the public would not be captured by Standard 1.2.7. This has been addressed under the application clause of draft Standard 1.2.7 – refer to section 3.1 of this report for details.

A further issue is that claims such as 'suitable for diabetics', which are not explicitly addressed by draft Standard 1.2.7, might be wrongly construed as dietary information. The treatment of these claims needs to be addressed.

7.1.5 Comments from stakeholders at Draft Assessment

A number of issues have been raised at Draft Assessment. In summary these are:

- there is ambiguity in the proposed definition;
- the proposed definition is too restrictive when contrasted with the definition of 'claim', which is very broad. It was also considered that it could hamper the provision of important information to consumers;
- several industry stakeholders expressed concern about the scope of the term 'brand', which is used to exclude such foods from the proposed definition of dietary information. In particular, they were unsure whether or not trademarked varieties of fruit, or produce that has been named after the location in which it is grown, would be captured by 'brand'; and

[16] Subparagraph 5(2)(d)(i): the food complies with any applicable conditions under Division 3 of this Standard for – making a general level claim, other than a nutrition content claim

- there are difficulties in the interpretation of Clause 9 (conditions for dietary information) and concern this clause would be ineffective in the current approach.
- It was also suggested that the requirement for dietary information to relate to the property of the food that is the subject of a claim should be broadened to permit the referencing of a complementary product on another product's packaging, for example, a statement such as 'use reduced fat milk' on a cereal box.

Submitters to the Draft Assessment Report suggested that dietary information should allow for inclusion of a manufacturer's name and corporate brand, for example where such information is provided by a food supplier.

7.1.6 Factors relevant to the regulatory option

7.1.6.1 Value of Dietary Information

FSANZ values the role dietary information can provide in educating and informing the public on the nutrition and health related effects of foods, and also acknowledges that government does not have the capacity to perform this task alone. The endeavours of non-government agencies and the food industry in this regard are appreciated and there is no intent to hamper such activities through food regulation. FSANZ is concerned, however, that allowances for dietary information should not inadvertently allow information on labels which promotes the sale of proprietary foods, without being subject to the same regulatory hurdles as other claims on foods.

In response to submitters' comments at Draft Assessment, FSANZ considers that leaflets, brochures etc, that carry corporate branding may provide dietary information, subject to the dietary information statements being primarily for educational purposes. Therefore, to be considered to be 'dietary information' and not subject to the requirements for nutrition content claims or health claims the information itself must not directly refer to (i.e. 'advertise') specific brands of foods. However, it is arguable that once dietary information is on a label or in associated advertising, it is 'by association' promoting the sale of that specific food and could be seen as an implied nutrition content or health claim. For example, the statements 'include foods rich in calcium' and 'eat a diet low in saturated fat' are taken directly from dietary guidelines, but when present on a food label could reasonably be seen as nutrition content claims about calcium/saturated fat for that particular product.

In order to address this difficulty, it was proposed at Draft Assessment that if a supplier wishes to place dietary information directly in association with a product (including on product labels and advertisements such as brochures), this may be done provided the product meets all the requirements for an associated nutrition content or health claim, and this be demonstrated by having a compliant related nutrition content or health claim on the product. FSANZ recommends that this approach be maintained at Preliminary Final Assessment, and it is important that the dietary information statements do not 'exceed' the associated claim. That is, if a nutrition content claim about one nutrient only is made, the dietary information should not refer to more nutrients, nor suggest any associated health effects.

FSANZ also considers it desirable that dietary information be permitted on whole foods where reference to a specific property of the food is not made, without the need for an associated claim (see examples in box).

In this situation, the dietary information must directly relate to the type of food on which it appears. In addition, the information (as for any labelling information) must be in accordance with fair trading practices and hence not be misleading. Consequently, care should be taken that such information is not provided on inappropriate products.

7.1.6.2 Examples of dietary information statements

- *Dietary guidelines recommend that we eat plenty of fruit*

  This dietary information could be stated on a label of fruit such as oranges, and would not need to be accompanied by a nutrition content claim or health claim.

- *National nutrition and dietary guidelines recommend we eat at least two servings of milk or milk products a day*

  This dietary information could be stated on the label of a bottle of milk or a milk product such as cottage cheese, and would not need to be accompanied by a nutrition content claim or health claim.

- *Choose snacks that are low in salt*

  Foods labelled with this statement would have to meet the criteria for 'low salt' nutrition content claims, and would also need to carry a nutrition content claim or health claim in relation to 'low salt'.

- *Dietary guidelines recommend limiting the intake of high sugar foods*

  Foods labelled with this statement would need to meet the criteria for 'low sugar' nutrition content claims and would also need to carry a nutrition content claim or health claim in relation to 'low sugar'.

- If dietary information discusses the recommendations around intake of fibre on a biscuit packet, the biscuit packet must be able to support, and must carry, a fibre claim.

- *Include calcium-rich foods in your diet* could be used in conjunction with a general level health claim such as 'Calcium assists in building and maintaining strong bones, when consumed as part of a varied diet rich in calcium.'

The statement 'Aim for a diet that is low in fat' could only be on a product that qualifies for and carries a 'low fat' nutrition content claim.

Note however that statements relating a class of food with a specific health effect (such as fruit and vegetables reducing the risk of cancer) would not be regulated as dietary information but would need to meet health claims criteria and conditions.

User guidance will also clarify that the form of the food should be in accordance with that intended by the dietary guidelines (for example, fruit jam would not qualify as fruit).

Example of dietary information in a brochure

A vegetable grower wants to publish a brochure to inform consumers about the importance of vegetables in the diet. In order to meet the definition of dietary information, the information in the brochure may focus on a food group or class of foods (vegetables and fruits), and must be presented in the context of Australia's or New Zealand's Dietary Guidelines. The grower may identify its corporate brand (Brand X) of the company and Brand X vegetables in the brochure. However in order to meet the definition of dietary information, the dietary information statement should be educational and should not make direct reference to a particular brand of food, for example, the claim 'Eat three serves of Brand X vegetables a day' would not be considered dietary information.

7.1.6.3 Application of provisions for dietary information

Regarding the application of the clause regulating dietary information, the intent is that only dietary information in food labels or in advertisements for foods sold directly to the public should be captured by Standard 1.2.7. Therefore, general dietary information not involving the direct sale of food to the public would not be captured by the clause regulating dietary information in the current draft. This has been addressed by the Application clause of draft Standard 1.2.7 (refer to Section 3.1 for more information).

7.1.6.4 'Suitable for' Claims

FSANZ considers claims such as 'suitable for diabetics' are potentially misleading, as there are currently no parameters around the types of foods carrying these claims. If foods are to be promoted as being suitable for addressing particular conditions in certain population subgroups, they should be subject to the same conditions as any other health claim and are captured by the definition of a health claim (clause 1, draft Standard 1.2.7). Further information on this matter will be provided in user guidance.

However, 'suitable for …' type statements have a legitimate role in circumstances, such as in hospitals and for some delivered meals. In these special cases, FSANZ intends that such statements can be used without being subject to Standard 1.2.7 (refer to section 3.1 of this report for further details).

7.1.6.5 Moderation statements

At Draft Assessment, a subclause addressing moderation statements was included: *This clause does not apply where dietary information relates to moderating the consumption of food*. This is not relevant to foods other than alcohol. To ensure greater clarity, it is proposed the subclause be amended to be more specific.

7.1.7 Analysis of options

Option 1 – Approach taken at Draft Assessment, as described in subsection 7.1.3.

This option is rejected because of multiple difficulties with the approach, as discussed above.

Option 2 – Redefine dietary information and amend the conditions as described in subsection 7.1.6.

FSANZ's preferred approach at Preliminary Final Assessment is Option 2.

The rationale for this amended approach is outlined below.

The amendments to the definition of dietary information:

- place the emphasis on the requirement that dietary information must be provided for educational purposes; and
- clarify that any claim that makes reference to a health effect would not meet the definition of dietary information (by removing the reference to 'brand').

The amended conditions maintain the approach at Draft Assessment, which allows flexibility for industry, while addressing concerns from public health around implied claims and misleading information, by directly linking dietary information to a nutrition content claim or health claim. However a number of amendments have been made as follows:

- an additional requirement that the claim provided in association with the dietary information does not exceed the level of information provided by the dietary information has been prescribed;
- the wording of the provision that whole foods which have dietary information are not required to carry an associated claim but the dietary information must relate directly to the food carrying the claim has been clarified; and
- the intent that dietary information relating to moderating the consumption of food relates to moderating consumption of alcohol only, has been clarified.
- The clause exempting dietary information relating to moderation of food consumption has been deleted. Moderation statements may be made on food products when accompanied by an associated nutrition content claim or health claim e.g. 'Reduce your daily intake of fat and saturated fat' should have an accompanying 'low fat' or 'reduced fat' claim.

The application clause of draft Standard 1.2.7 has been modified and the proposed Standard now only applies to food labels and advertising of food for retail sale. This permits the provision of dietary information about a food from an ingredient supplier to a manufacturer (unless the food is not intended for further processing, packaging or labelling prior to retail sale), without the need for an associated claim or for the dietary information to be provided in conjunction with an appropriate food. The draft Standard has also been amended to exempt packaged meals provided to clients of a delivered meal organisation such as 'meals on wheels' and meals provided in hospitals or similar institutions.

7.2 Endorsements

7.2.1 Recommendation

1. Endorsements are excluded from the regulation of the Standard.

2. Endorsements and Endorsing Organisations are defined as follows:

> ***endorsement*** *means a design used, or intended to be used, to distinguish food certified by an endorsing organisation in relation to its nutrition or health features from other foods not so certified, and includes a certification trade mark, but does not include –*
>
> *(a) a design that distinguishes food in relation to ethical, religious or environmental features including vegetarian, halal, kosher or organic designs; or*
> *(b) a design that includes a reference to a serious disease other than as part of the name of the endorsing organisation.*
>
> **endorsing organisation** means an independent organisation, including a government organisation, formed for nutrition or health purposes, the name of which may include a serious disease, but does not include an organisation established or controlled by a supplier or their representatives of food or food ingredients.

The policy guideline includes guidance on endorsements as follows*: 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).* There has been some deviation from the policy guidance based on the FSANZ consumer research and submitters' comments in response to the Assessment Reports. To force endorsements to comply with all elements of the claim classification framework would be too restrictive, and would deny the merit of many endorsement programs in their current forms.

7.2.2 Introduction

FSANZ recognises the key role that both government and many non-government organisations have in educating the public about aspects of health and nutrition using a variety of approaches, including the use of endorsements. Given limited resources for education of the public in nutrition and health, FSANZ believe such organisations can be relied upon to carry out activities appropriately.

If more restrictive criteria for making health claims, such as the food compositional criteria, were to be applied to endorsement programs currently in existence, most of them would not be able maintain their programs. Endorsements such as the National Heart Foundation 'Pick the Tick' program has been shown to have significant consumer benefit in promoting more healthy options of foods within categories. Therefore, prescriptive restrictions on such programs through Standard 1.2.7 may be disadvantageous to both industry and consumers.

7.2.3 Approach at Draft Assessment

The definitions of *endorsement* and *endorsing organisation proposed at Draft Assessment* were:

> ***endorsement*** *means a design used, or intended to be used, to distinguish food certified by an endorsing organisation in relation to its nutrition or health features from other foods not so certified, and includes a certification trade mark, but does not include –*
>
> *(a) a design that distinguishes food in relation to ethical, religious environmental features including vegetarian, halal, kosher or organic designs; or*
> *(b) a design that includes a reference to a serious disease other than as part of the name of the endorsing organisation.*
>
> ***endorsing organisation*** *means an independent, non-profit or not-for-profit organisation formed for nutrition, health, community or government purposes, the name of which may include a serious disease, but does not include an organisation established by suppliers or their representatives.*

It was proposed in the draft Standard that a number of existing endorsements be pre-approved by FSANZ and exempted from the operation of the Standard. To be pre-approved, the endorsement would:

- Satisfy the definition of *endorsement* (which incorporates the definition of *endorsing organisation*); and
- the endorsement program's nutrition criteria would be consistent with national nutrition policy principles in Australia and New Zealand.
- Six pre-approved endorsements were listed in the draft Standard 1.2.7. The conditions for pre-approval were deliberately based on broad nutrition and health principles and not based on prescriptive requirements. This assisted FSANZ to capture the broader range of endorsement programs currently in existence.
- It was decided at Draft Assessment that, like pre approved endorsements, endorsements that had not been pre-approved, would need to satisfy the definition of endorsement under the Standard. In addition to this:
- the endorsement would need to meet the general level health claim substantiation framework;
- the food carrying the endorsement would need to meet the general level health claim disqualifying criteria; and
- the food carrying the endorsement would need to meet relevant qualifying criteria, if the endorsement specifically related to a property of the food.

FSANZ recognised that the management of pre-approved endorsements and additional, not pre-approved endorsements were not equivalent in terms of the ease in which endorsements could comply with the set conditions. That is, the requirements for pre-approval were principle-based while those for endorsements after the Standard was gazetted had more prescriptive criteria to satisfy i.e. principles, substantiation requirements and nutritional disqualifying criteria.

It was intended that FSANZ pre-approval of endorsements would cease once the Standard was gazetted and also that post gazettal, all endorsements would have to satisfy the conditions outlined in Standard 1.2.7.

7.2.4 The issue/problem

Under the FSANZ Act, no standard in the Code may be immune from being amended. The proposed pre-approved endorsement system was based on the view that the proposed list of endorsement in Standard 1.2.7 would be an exclusive list. However, after further consideration it has been identified that the FSANZ Act does not provide for such exclusivity.

Applicants could apply to have their endorsements listed in the Standard. FSANZ would be required to consider such applications within the same principle based parameters that were relied upon to place the original pre approved endorsements on the list.

These legal considerations, in addition to other concerns raised by stakeholders (see subsection 7.2.5), necessitate an alternative approach to the management of endorsements to that proposed at Draft Assessment.

Additionally, FSANZ considers an endorsement made by a supplier of an ingredient in a food should not be exempt from the health claims Standard and therefore the relevance clauses need redrafting.

7.2.5 Comments from stakeholders at Draft Assessment

In response to the draft Standard, a number of issues have been raised by submitters in relation to endorsements. These include:

- Agreement with the approach, although many of those were submitters who had had their endorsement pre-approved;
- The FSANZ approach seemed inconsistent, anti-competitive and trade restrictive;
- Pre-existing endorsements should be open to scrutiny;
- Exemption should apply to the endorsement logo only and not whole program as this allows the program to breach the Standard in other ways;
- There was support for definitions of endorsements and endorsing organisations;
- There was some opposition to the exclusion of ‘serious disease’ in definitions of *endorsement* and *endorsing organisation*;
- Support for new endorsements being able to be added to the list of endorsements;
- Endorsements that are exempt should make conditions of the endorsement program transparent to the general public – particularly when the criteria for the endorsement is not as restrictive as they are for health claims; and
- Endorsements should fall outside the Standard. They are contractual arrangements and should be regulated under trademark legislation.

Following the Draft Assessment Report, FSANZ was provided with additional endorsements to assess for pre-approval. These included:

- The International Diabetes Institute ‘Go For Gold’ endorsement;

- The New Zealand Nutrition Foundation 'eMARK';
- The FDI World Dental Federation 'Recognition Program';
- Nuts For Life endorsement; and
- 'Go for 2 & 5'

7.2.6 Relevant factors and evidence base

The proposed approach for endorsements needs to take account of many factors including legal constraints, the policy guideline, stakeholder comments at Draft Assessment, results of the FSANZ consumer research and international practice.

A key objective of consumer research carried out by FSANZ was to investigate the influence of endorsements on respondents' perceptions in relation to the health benefits of the product (FSANZ, 2005b). The results indicated that consumers appear to give credence to endorsements. This supports the need for some risk management measures. Details of the consumer research and other evidence available at Initial and Draft Assessment are given in the Draft Assessment Report available on the FSANZ website (Attachment 5, Chapter 6).

The health claims Standard puts in place criteria and conditions around nutrition and health claims. Requiring products carrying endorsements to meet these criteria and conditions could be incompatible with the aims of a credible and worthy endorsement program. Placing compositional criteria on foods carrying health claims has been proposed in order to restrict the use of claims to foods which have a more beneficial overall nutrient profile. Endorsement programs with valid nutritional aims may nevertheless not fulfil the nutrient profile criteria to be eligible for a claim e.g. an endorsement program to encourage lower sugar to prevent tooth decay may allow some higher salt products to carry tooth-related endorsements. Another example is the National Heart Foundation Tick program, a program with high credibility as demonstrated by our consumer research. The aim of that program is to encourage consumption of more healthy options within defined food categories, as a means to move towards a more healthy food supply. However some foods which carry a 'tick' may not be eligible to carry health claims. During the development of the proposed standard FSANZ has considered the option of requiring an alignment of endorsement programs and the health claims standard. Whilst such an approach may have public health benefits in the long term, the considerations above, in terms of the value of existing programs has taken precedence in formulating the decision regarding the regulation of endorsements.

7.2.7 Analysis of Options

Option 1 – Approach taken at Draft Assessment: a number of existing endorsements are pre-approved and exempted from the operation of the Standard. Subsequently, new endorsements have to comply with the relevant clauses of the Standard.

<u>Benefits</u>

- Meets the needs of many (but not all) existing endorsement programs; and
- Consumers and industry would be able to continue using many existing endorsements.

Disadvantages

- Restricting the use of endorsements by making programs subject to the full set of criteria that apply to health claims would reduce consumer choice. Some existing endorsement programs have wide acceptance in Australia and New Zealand, and have been widely used by consumers;
- Resource intensive approach which would require FSANZ to approve endorsement programs, followed by ongoing review;
- Two tiered approach to regulating endorsements;
- Perceived as anti-competitive, restrictive and unfair;
- Needs complex criteria/conditions for use; and
- Legal constraints on pre-approving claims.

Option 2 –Exclude all endorsements made by endorsing organisations as defined in the Standard from the regulation of the Standard

Benefits

- The proposed approach follows the minimal effective regulation principle;
- The proposed approach protects consumers' use of established endorsement programs and allows similar programs to be developed in the future. This increases consumer choice and helps meet consumer demand for simple labelling;
- Consistency in regulatory approach for both current and future endorsements;
- Eliminates the need to establish criteria/conditions for use;
- Reduces the impact on government agencies by decreasing the resource requirements for administration and enforcement;
- Eliminates the need for listing specific endorsements in the Standard and incorporating a review process of those endorsements listed in the Standard; and
- Little or no negative impact on industry because endorsements that would have been pre-approved following the previous approach remain available for use.

Disadvantages

- Relies on clear and enforceable definition of endorsing organisation; and
- Enforcement agencies have to investigate the endorsing organisation – compliance cannot always be readily determined from the label alone.

FSANZ's preferred option at Preliminary Final Assessment is Option 2.

This approach eliminates the need for criteria and therefore eliminates the dilemma of how to manage current and future endorsements in an equitable way. It would also ensure that the principles incorporated within the definitions of *endorsement* and *endorsing organisation* have to be met. An endorsing organisation would have to be independent, formed for nutritional or health purposes, and structured in a way that guarantees that suppliers of foods carrying the endorsement cannot influence the criteria used by the endorsement program. FSANZ considers *bona fide* endorsement programs are professional and responsible in their approach and application and that prescriptive requirements beyond defining the role and character of endorsing organisations are not warranted.

Consumers are protected from misleading endorsements because endorsements can only be made by an independent organisation, which are formed for nutritional and health purposes, and suppliers of foods carrying the endorsement cannot influence the criteria used by the endorsement program.

Furthermore this approach avoids the unintended consequence of effectively prohibiting many endorsement programs that are useful to consumers. The definitions and clauses included in the proposed draft Standard provide the minimum effective regulation to align nutritional and health related endorsements with nutrition policy principles.

Additionally, the definition has been redrafted to address the need to exclude suppliers of ingredients from being considered an endorsing organisation. FSANZ intends to provide further advice around the definition of an endorsing organisation, including the reference to 'independent' organisation, in user guidance.

Examples

The National Heart Foundation Tick has considerable acceptance and inherent credibility in Australia and New Zealand, and the Heart Foundation wish to continue their program. While it receives some financial benefit from products carrying their endorsement, the Heart Foundation can demonstrate its independence, that it is formed for nutrition or health purposes, and that it is not controlled or established by suppliers.

The National Heart Foundation Tick can continue to be used as an endorsement. The endorsement is not subject to the qualifying and nutrient profiling criteria that apply to health claims.

A group of trans-Tasman food processors want to set up an endorsement program using a 'VegHealth' design to promote consumption of vegetables based on nutrition guidelines. The endorsement would be exclusively available to the processors to place on their products

The processors (or the entity set up by the processors to manage the program) do not meet the definition of 'endorsement organisation' because they lack the necessary independence and/or were formed predominantly for commercial reasons by suppliers. The processors can still use the design, but the design may be considered a health claim and regulated accordingly.

8. ISSUES RELATING TO WORDING CONDITIONS

8.1 Small packages

8.1.1 Recommendation

FSANZ proposes the following conditions in relation to small packages at Preliminary Final Assessment:

Nutrition content claims

Small packages are exempt from:

1. including a full nutrition information panel (this is status quo, and is regulated by clause 8 in Standard 1.2.8); and

2. declaring %RDI/serve for the claimed vitamin/mineral.

Small packages are required to declare:

1. the amount of claimed nutrient/energy/biologically active substance and, depending on the claim, other specific nutrients, per 100 g or 100 mL, as required for small packages in clause 8 of Standard 1.2.8;
2. the source of omega 3 when claims regarding omega 3 fatty acids are made (by clause 8 in Standard 1.2.8);
3. for comparative claims, the reference food and difference in claimed nutrient;
4. potassium content in relation to low salt/sodium, no added salt/sodium claims and reduced salt/sodium claims;
5. sodium content in relation to potassium claims; and
6. galactose content if making a lactose claim.

Health claims

Small packages are exempt from:

1. providing the additional statement about regular exercise for weight management claims; and
2. including the 'dietary context' information in the health claim.

Small packages are required to declare:

1. any applicable requirements for nutrition content claims;
2. if applicable, the appropriate population group;
3. the substantiated daily amount to achieve the health effect for claims in relation to biologically active substances; and
4. the required disclaimer for cause-related marketing statements.

If applicable, the claim may be split, but the statement indicating where the complete health claim is located, must be on the label.

Any advertising material associated with the food in a small package must comply with the full requirements for advertising associated with normal sized packages.

8.1.2 Introduction

Small packages are defined in the Code as a package with a surface area of less than 100 cm^2. Special consideration was given to small packages at Draft Assessment. Due to limited labelling space on small packages it was proposed that in this special case exemptions from some of the labelling requirements in draft Standard 1.2.7 would be appropriate.

When determining these exemptions, the need for essential elements of information to be provided to consumers was a major consideration.

8.1.3 Approach at Draft Assessment

At Draft Assessment, FSANZ proposed the following conditions in relation to small packages claims:

8.1.3.1 For nutrition content claims

- 'contains naturally occurring sugar' statement to be declared in relation to 'no added sugar' claims;
- claims about lactose must include the reference to lactose and galactose levels;
- where required, advisory or warning statements must be made in conjunction with the claim; and
- requirements for small packages as per Clause 8 of Standard 1.2.8 (i.e. an abbreviated Nutrition Information Panel) apply, including the new requirement for %DI.

8.1.3.2 For health claims

As required for content claims, in addition:

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

8.1.3.3 Small packages are exempt from:

- identifying the reference food where a comparative nutrition content claim is made;
- mentioning the population sub-groups to which the health effect relates; and
- providing the context of a healthy diet.

Any advertising material associated with the food in a small package is to comply with the full requirements for advertising associated with normal sized packages.

8.1.4 The issue/problem

At Draft Assessment the actual drafting associated with small packages (clause 10) in draft Standard 1.2.7 included incorrect cross references to the rest of the Standard and it was inconsistent with the intent for labelling requirements for small packages. In the Draft Assessment Report the intent in relation to all labelling requirements or exemptions with respect to small packages was not clearly outlined, and there were inconsistencies between the Draft Assessment Report text and the drafting. One particular issue of concern is the drafted exemption for declaration of the reference food when making comparative claims.

In addition, at Preliminary Final Assessment, FSANZ is proposing to change the approach to certain labelling requirements for normal sized packages, such as those relating to %DI and the 'contains naturally occurring sugar' statement for 'no added sugar' claims. This will also affect the requirements that were proposed at Draft Assessment for small packages.

8.1.5 Comments from stakeholders at Draft Assessment

Submitters made the following comments with regard to this issue:

- Some submitters supported the lessening of information requirements for small packages when claims are made.
- Others felt that food in small packages should not be given further exemptions from labelling requirements.
- If room is 'found' for health claims then other existing statutory requirements should have been given preference.
- It was noted that legibility issues could be a problem where claims are made, with the more complex the claim, the more space it will take up on small packages.
- It was suggested that small packages should not have wording exemptions as they are able to provide additional information in the form of a fold out label or shelf information.

8.1.6 Factors relevant to regulatory option

8.1.6.1 Requirements for labelling of small packages not clearly defined at Draft Assessment

- potassium content in relation to low salt/sodium, no added salt/sodium claims and reduced salt/sodium claims; and sodium content in relation to potassium claims.
- the source of omega 3 when claims regarding omega 3 fatty acids are made.
- %RDI/serve for the claimed vitamin/mineral.
- the required disclaimer for cause-related marketing statements.

8.1.6.2 Additional requirements proposed at Preliminary Final Assessment

- for comparative claims, the reference food and difference in claimed nutrient are to be declared.
- If applicable, the appropriate population group is to be declared.

8.1.6.3 Additional exemption proposed at Preliminary Final Assessment

- exempting the additional statement about regular exercise for weight management claims.

8.1.6.4 Changes and clarification of nutrition content claims requirements

There are additional labelling requirements under Standard 1.2.8 for %RDI for the claimed vitamin or mineral, and under draft Standard 1.2.7 for specific nutrition content claims:

- for omega-3 fatty acid content claims, the source of the fatty acids;

- for comparative claims, the reference food and difference in claimed nutrient;
- potassium content in relation to low salt/sodium, no added salt/sodium claims, and reduced salt/sodium claims;
- sodium content in relation to potassium claims; and
- galactose content if making a lactose claim.

FSANZ considers that each of these labelling requirements should also apply to small packages if the applicable claims are made, for the following reasons:

- The source of omega-3 is currently required to be declared on small packages by clause 8 in Standard 1.2.8, to provide consistency with current provisions in the Code.
- FSANZ now considers that the exemption for comparative claims proposed at Draft Assessment is inappropriate, as a comparative claim must state the reference food and the difference in claimed nutrient in order not to mislead or be deceptive.
- The requirement for the declaration of potassium when making a sodium claim, and vice versa, stems from the inter-relationship between sodium and potassium, and the public health significance of potassium for some vulnerable consumers, in particularly renal patients.
- Galactose content must be declared if a claim is made about lactose because a food that is claimed to be lactose free or reduced in lactose may not also be galactose free (e.g. soy products). Some consumers who are lactose intolerant also need to avoid consuming galactose, because they suffer from galactosemia. Requiring disclosure of galactose content is an appropriate risk management measure to provide protection for a vulnerable section of consumers.

FSANZ considers that these are significant public health issues and cannot justify an exemption from these extra labelling requirements for small packages, also noting that nutrition content and health claims are not mandatory impositions.

It is proposed at Preliminary Final Assessment that the statement 'contains naturally occurring sugar/sodium' that was proposed for no added sugar/sodium claims at Draft Assessment will no longer be required. This will also apply to small packages.

8.1.6.5 Changes and clarification of health claims requirements

With respect to health claims, it was proposed at Draft Assessment that small packages be exempt from including the 'dietary context' information in the health claim, but that weight management claims must include the additional statement about regular exercise. It is now considered that the reasons for requiring these statements are similar, and therefore they should be treated consistently. Therefore, it is proposed at Preliminary Final Assessment that in addition to the exemption for dietary context, small packages will also be exempt from declaring the statement about regular exercise for weight management claims.

Given that the substantiation for certain health claims may only apply to certain groups of the population, it is considered that the population group must be specified as part of the claim, if applicable, and that this requirement should be extended to small packages.

In terms of health claims about biologically active substances, the claim is required to include the substantiated daily amount required to achieve the specific health effect.

This is considered as important to provide consumers with adequate information about the claim and FSANZ considered it should be equally applied to such claims on small packages.

FSANZ's (2005a) quantitative consumer research investigated perceived health benefits communicated by the cause-related marketing statement *Proceeds from this product will go to the Royal Society for Diabetes*. Some respondents believed that a product with a cause-related marketing statement was more beneficial to health than a product without a cause-related marketing statement. FSANZ considers that this result supports the use of a disclaiming statement in conjunction with a cause related marketing statement on all food packages and cannot justify an exemption from this requirement based on the size of the package.

8.1.7 Analysis of options

Option 1 – Approach taken at Draft Assessment: require all additional labelling from draft Standard 1.2.7 and the status quo of other relevant regulations, except identifying the reference food where a comparative nutrition content claim is made, mentioning the population sub-groups to which the health effect relates; and providing the context of a healthy diet

Benefits

- Provides core information to consumers, especially information relevant to meet public health requirements.
- Allowing a shortened form of a health claim provides more scope for industry to be able to make health claims on small packages.
- Allowing a shortened form (i.e. declaration of reference food not required) for comparative claims provides more scope for industry to be able to make such claims on small packages.

Disadvantages

- Health claims are not fully put into dietary context for consumers.
- Consumers are not provided with adequate information to assess comparative claims.
- Consumer subgroups are not provided with information that may be relevant to making an informed choice.
- Consumers do not get all relevant information for products carrying cause related marketing statements.
- Potential difficulty for suppliers in providing all required information on the small package if making certain claims, such as weight management claims.

Option 2 – Require all additional labelling from draft Standard 1.2.7 and the status quo of other relevant regulation, except the dietary context, regular exercise statements, but must provide if applicable, the reference food for comparative claims, the appropriate population group and the required disclaimer for cause-related marketing statements

Benefits

- Provides core information to consumers, especially information relevant to meet public health requirements.

- Provides additional relevant information to consumers in regard to comparative claims.
- Provides consumer subgroups with information relevant to them.
- Consumers are provided with the full context for cause-related marketing statements.
- Allowing a shortened form of a health claim provides more scope for industry to be able to make health claims on small packages.

Disadvantages

- Health claims are not put into dietary context for consumers.
- Potential difficulty for suppliers in providing all required information on the small package if making certain claims, in particular comparative claims and when using cause-related marketing statements.

FSANZ's preferred approach at Preliminary Final Assessment is Option 2, because it addresses the identified public health risks and provides more information to consumers, but still does not require the longer health claim statements that industry may find difficult to fit onto small packages.

Furthermore, the exact wording of statements, such as the cause-related marketing disclaimer and the comparative claims declarations, are not prescribed. This gives industry the option to develop short statements that will fit legibly on the labels of small packages, whilst fulfilling all labelling requirements.

It is also proposed that Standard 1.2.8 is amended to clarify what declarations are required when certain nutrition content claims are made, for example, galactose must be declared when a nutrition content claim about lactose is made on a small package.

8.2 Split claims

8.2.1 Recommendation

FSANZ proposes the following amendments in relation to 'split' claims at Preliminary Final Assessment:

1. The requirement for the accompanying statement that directs the consumer to the health claim in its entirety, if the property of the food is expressed alone, will be removed.

2. The requirement for the health claim in its entirety to be presented so that all the elements of the claim are in the one place, will remain as proposed at Draft Assessment.

3. The requirement for the accompanying statement that directs the consumer to the health claim in its entirety, if the property of the food and the specific health effect are stated separately to the entire claim, will remain as proposed at Draft Assessment.

The policy guideline specifically refers to split claims as follows: *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.* FSANZ's recommendation is in accordance with the policy guidance since the accompanying statement directing consumers to the health claim in its entirety is required.

The only change being made at Preliminary Final Assessment refers to permitting the property of the food to be repeated (on its own) somewhere else on the label.

8.2.2 Introduction

The property of the food, the specific health effect and the healthy diet context are considered to be essential elements of the claim that must always be presented together in order to assist consumers to make an informed choice and relate the information to their own health status or health concerns. Furthermore, there may be additional wording conditions (on a case-by case basis) such as the requirement to communicate that the specific health effect only relates to certain population groups. The intended context of the claim may be lost if these essential elements are permitted to be separated.

However, if all these elements are presented together, the claim itself together with additional warning or advisory statements may mean the total message becomes long and wordy. The food industry has emphasised to FSANZ the importance that claims be succinct, user friendly and flexible. In order to allow flexibility for suppliers' use of claims, at Draft Assessment FSANZ proposed that the property of the food or the property of the food and the specific health effect could be presented separately from the whole health claim, as long as there was a statement that directs the consumer to the health claim in its entirety. This option applied to both high level and general level health claims and was provided to allow succinct claim statements on the front of the package, such as *good source of calcium* or *rich in calcium for strong bones and teeth*.

8.2.3 Approach at Draft Assessment

At Draft Assessment FSANZ proposed the following conditions for 'split' claims:

- The wording of the health claim in its entirety must be presented so that all the elements of the claim are in the one place.
- In addition there was an option to present the property of the food or the property of the food and the specific health effect separately to the entire health claim. However there must be an accompanying statement that directs the consumer to the claim in its entirety.

8.2.4 The issue/problem

Submitters to the Draft Assessment Report expressed concern around the requirement for the statement indicating where the complete claim is on the package.

The property of the food is unlikely to be expressed separately to the health claim, except as a nutrition content claim. Nutrition content claims are permitted elsewhere in draft Standard 1.2.7 as stand-alone claims, without the need for an associated health claim. The requirement for the accompanying statement directing the consumer to the claim in its entirety, if the 'property of the food' is stated separately to the health claim, is therefore not consistent with the regulation of nutrition content claims.

8.2.5 Comments from stakeholders at Draft Assessment

Although there was some support for allowing part of the claim to be presented separately, there were also objections to this. Reasons for these objections included that:

- it negates the benefits of having the claim in one place;
- consumers should only be able to read the claim in its entirety; and
- it could be misleading.

There were also some objections to the requirement to include a statement indicating where the complete claim is. Reasons for this included that:

- it was unnecessary text;
- it was too cumbersome; and
- consumers will learn, with education, where to find the claim.

In addition it was questioned how the property of the food could be presented alone.

8.2.6 Analysis of options

Option 1 – Approach taken at Draft Assessment: if the property of the food is stated separately from the whole health claim, an accompanying statement must direct the consumer to the health claim in its entirety

Benefits

- May assist consumers by indicating where the entire health claim is located on the label, which will provide further information about the specific health effects, dietary context and, depending on the type of claim, the population group the health claim applies to, in relation to the nutrition content claim.

Disadvantages

- More difficult for government enforcement agencies to enforce due to inconsistencies with the level of regulation of nutrition content claims.
- Industry are required to provide additional wording on the label that is not required if the same nutrition content claim is made on a package not carrying a health claim.

Option 2 – If the property of the food is stated separately from the whole health claim (as a nutrition content claim), the accompanying statement to direct the consumer to the health claim in its entirety, is not required. The requirement for the health claim to be presented in its entirety in one place, and the requirement for the accompanying statement that directs the consumer to the health claim in its entirety, if the property of the food and the specific health effect are stated separately to the entire claim, would remain as proposed at Draft Assessment.

Benefits

- Provides a balance between ensuring the full context of the claim is provided and the information is meaningful to consumers, whilst allowing industry the flexibility to use short impact/marketing statements.
- Is consistent with the regulation of standalone nutrition content claims.
- Industry will not be required to provide additional wording if only stating the property of the food separately to the entire health claim.

Disadvantages

- If a health claim is made elsewhere on the label about the property of the food specified in the nutrition content claim, consumers are not directed to where that additional information is located.

FSANZ's preferred option at Preliminary Final Assessment is Option 2.

FSANZ considers that expressing the property of the food alone would constitute a nutrition content claim and permission is provided in draft Standard 1.2.7 for nutrition content claims to be made without the need to associate them with health claims. This approach will therefore achieve consistency with the regulation of nutrition content claims. Apart from this amendment, the requirements around 'split' claims will remain as proposed at Draft Assessment.

9. CHANGES TO DRAFTING

9.1 Introduction

At Preliminary Final Assessment, minor changes to the drafting were required to account for the changes that have been made since Draft Assessment. These amendments are reflected in Tables 3, 4 and 5, in relation to changes made to Standard 1.1.1, to draft Standard 1.2.7 and to Standard 1.2.8, respectively.

Table 3: Changes to Standard 1.1.1

Topic	Relevant clause of Standard 1.1.1 at Draft Assessment	New drafting of Standard 1.1.1 at Preliminary Final Assessment	Intent of change and rationale
Definitions	**Clause 2 - Interpretation**	**Clause 2 – Interpretation** The following definitions have been moved from Standard 1.2.8 to Standard 1.1.1: • Average energy content • Carbohydrate • Dietary fibre • Fat • Gluten • Monounsaturated fatty acids • Polyunsaturated fatty acids • Saturated fatty acids • *Trans* fatty acids	These definitions are used in both Standards 1.2.7 and 1.2.8. They have therefore been relocated to Standard 1.1.1 which includes definitions that have general application to the Code. The actual wording of the definitions has not been amended.

Table 4: Changes to draft Standard 1.2.7

Topic	Relevant clause of draft Standard 1.2.7 at Draft Assessment	New drafting of draft Standard 1.2.7 at Preliminary Final Assessment	Intent of change and rationale
Purpose	**Purpose** This Standard is designed to regulate nutrition content claims, health claims, endorsements and cause related marketing statements….	Reference to ‘endorsements’ has been omitted and ‘dietary information’ inserted.	To reflect the new approach for exempting endorsements from the Standard and to indicate that ‘dietary information’ is regulated by the Standard.

Table 4: Changes to draft Standard 1.2.7 (continued)

Topic	Relevant clause of draft Standard 1.2.7 at Draft Assessment	New drafting of draft Standard 1.2.7 at Preliminary Final Assessment	Intent of change and rationale
Interpretation	**Clause 1** In this Code -	Addition to **Clause 1** as follows: In this Code, unless the contrary intention appears, -	This wording is used on the assumption that the terms are used as defined unless those terms are used other than as defined in another place in the Code.
Definition of 'cause-related marketing statement'	**Clause 1** Cause related marketing statement means a statement that the sale of the food will contribute to fundraising for an organisation, the name of which refers to a serious disease.	Definition amended slightly in **Clause 1:** Cause-related marketing statement means a statement that the sale of the food will contribute to fundraising for an organisation, where the name of the organisation refers to a serious disease.	Due to submitter concerns, the definition has been amended to clarify that for the purposes of Standard 1.2.7, the definition is limited to cause-related marketing statements for organisations where the name of the organisation references a serious disease rather than other types of organisations or individuals.
Editorial note to definition of dietary information	**Clause 1** Editorial note referred to a number of New Zealand Ministry of Health Food and Nutrition Guidelines	**Clause 1** The references to the different New Zealand Ministry of Health Food and Nutrition Guidelines have been reduced to one, and an explanatory note has been added to the effect that the reference to the dietary guidelines does not include the background papers.	The documents that were listed as New Zealand Ministry of Health Food and Nutrition guidelines were the names of the background texts rather than the short educational dietary guidelines themselves, which were the intended references. The references were therefore simplified and an explanatory note added to clarify that the reference to national nutrition guidelines does not include reference to the dietary guideline background texts.
Definition and use of 'general level health claim' and 'high level health claim'	**Clause 1** and where 'general level claim' and 'high level claim' are mentioned throughout Standard 1.2.7	'General level claim' now referred to as 'general level health claim' 'High level claim' now referred to as 'high level health claim'.	This amendment has been carried out to simplify the wording used in the Standard, in particular to remove the complex wording of 'a general level claim, other than a nutrition content claim'. There are now three distinct levels of claims: • Nutrition content claim; • General level health claim; and • High level health claim.

Table 4: Changes to draft Standard 1.2.7 (continued)

Topic	Relevant clause of draft Standard 1.2.7 at Draft Assessment	New drafting of draft Standard 1.2.7 at Preliminary Final Assessment	Intent of change and rationale
Definition of 'health claim'	**Health claim** means a claim that directly or indirectly refers to a relationship between – (a) a food; or (b) a category of food; or (c) a property of a food, and a health effect, but does not include an endorsement, dietary information or a cause related marketing statement.	**Health claim** means a claim that directly or indirectly refers to a relationship between – (a) food; or (b) a property of the food, and a health effect, but does not include an endorsement, dietary information or a cause-related marketing statement.	Submitters raised concerns around the meaning of 'category of a food' and requested it to be defined in the draft Standard. FSANZ considers that reference to 'category of a food' in the draft Standard is not necessary. The word 'food' implies a singular entity; however the Model Food Act definition of 'food' is very broad and would capture multiple foods and categories of foods. Reference to (b) 'a category of food' can therefore be deleted from the definition of health claim. As a result, in (a), 'a' has been omitted, to clarify that the word 'food' can mean both singular foods and multiple/categories of foods.
Definition of 'property of a food'	**Clause 1** Property of a food means energy, a nutrient, or a biologically active substance, or (a) a component; or (b) an ingredient; or (c) any feature or constituent of the food; that is associated with a health effect, including glycemic index and glycemic load.	**Clause 1** Property of the food definition amended – 'health effect' has been replaced with 'a nutrition or health purpose'.	Although both health claims and nutrition content claims include a reference to a property of the food in their definitions, 'health effect' is referred to only in the definition of health claim. The definition of property of the food was therefore amended to capture both types of claims.
Definition of 'sugars'	**Clause 1** Sugars not defined	**Clause 1** Definition of 'sugars' included	'Sugars' is defined twice in the Code, in Standards 1.2.8 and 2.8.1. For clarity, the definition used in Standard 1.2.8 is also referenced in Standard 1.2.7.
Definitions of 'fruit' and 'vegetable'	**Clause 1** Fruit and vegetable not defined	**Clause 1** Definitions of 'fruit' and 'vegetable' included	The terms 'fruit' and 'vegetable' are used for different purposes within draft Standard 1.2.7. The generic definition of 'fruit and vegetables' in Standard 2.3.1 does not provide sufficient clarity around what is meant by a fruit or a vegetable for the purposes of draft Standard 1.2.7.

Table 4: Changes to draft Standard 1.2.7 (continued)

Topic	Relevant clause of draft Standard 1.2.7 at Draft Assessment	New drafting of draft Standard 1.2.7 at Preliminary Final Assessment	Intent of change and rationale
Application	**Clause 2**	**Clause 2** Food product in subclause 5 means a food product produced either before or after the commencement of this standard.	This ensures that food produced before the commencement of the Standard is covered by the Standard.
'Source of' and 'good source' type claims about substances with no reference values or conditions	**Clause 5 Conditions for general level claims** (1) A nutrition content claim may be made if the following conditions are complied with – (c) for claims that the food is a 'source' of the property, there is a reference value for the property in the Code; and (d) for claims that the food is a 'good source' of the property – (i) there is a reference value for the property in the Code; or there are criteria in the Code for use of a good source claim in relation to the property; and	**Clause 5** Amended so that nutrition content claims using descriptors (for example 'good source', 'reduced' and 'low') are only permitted if there is a reference value for the property of the food in the Code, or there are conditions for making the claim, in the table to clause 11. Claims indicating the presence of a substance, for example 'source of', will be permitted. Permission is provided for the use of descriptors in relation to the level of alcohol. Editorial note added.	To clarify the intention to permit claims for substances such as omega-3 fatty acids that have conditions for making such claims in the Code, but no reference value, and to prohibit claims (using descriptors) about substances that do not have reference values in the Code or do not have conditions prescribed for making such claims, for example, claims (using descriptors) about individual amino acids. As there is no reference value for alcohol and no conditions for 'low' alcohol claims in the table to clause 11, specific permission must be provided for the use of descriptors to describe the level of alcohol (e.g. 'low' or 'reduced'). The editorial note was added to clarify the type of claims that are permitted.
Claims about properties of the food that are naturally present or absent in similar foods	**Paragraph 5(1)(e)** (1) A nutrition content claim may be made if the following conditions are complied with – (e) if the claim relates to a property of a food that is present or absent in similar food in the same category, the claim must refer to the category of food and not the individual food.	**Paragraph renumbered to 5(1)(d) and amended as follows** (1) A nutrition content claim may be made if the following conditions are complied with – (d) 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.	Submitters commented that this wording needed clarification, because all properties are present or absent in food, and also with respect to the terminology 'similar food in the same category'. The drafting was therefore amended to reflect that it applies to properties of the food that are *naturally* present or absent. In addition, the word 'individual' was substituted with the word 'brand', to clarify that the nutrition content claim could not directly refer to the brand of food carrying the claim. Category of the food was omitted, as 'foods' also captures categories of food.

Table 4: Changes to draft Standard 1.2.7 (continued)

Topic	Relevant clause of draft Standard 1.2.7 at Draft Assessment	New drafting of draft Standard 1.2.7 at Preliminary Final Assessment	Intent of change and rationale
General level health claim qualifying criteria	**Subclause 5(2)** A general level claim, other than a nutrition content claim, may be made if the following conditions are complied with – (d) the food complies with any applicable conditions under Division 3 of this Standard for – (i) making a nutrition content claim in relation to the property of the food that is the subject of the general level claim; and	**Subclause renumbered to 6(1)(c) and** amended to clearly indicate which conditions in the table to clause 11 apply when general level health claims are made about particular nutrients.	The intent at Draft Assessment, as outlined in Attachment 5 of the Draft Assessment Report, was that in order to make a general level health claim in relation to a nutrient where increased consumption is recommended (e.g. protein, dietary fibre), it will be necessary to meet the minimum requirements set for nutrition content claims in relation to the nutrient. General level health claims that relate to nutrients where decreased consumption is recommended (e.g. fat, sodium) will be required to meet the relevant 'low' content claim criteria. These conditions were not reflected in the drafting. The drafting has therefore been amended to reflect this intent.
Whole food claims	**Paragraph 5(2)(b) and 5(2)(e)(i)** 5(2) A general level claim, other than a nutrition content claim, may be made if the following conditions are complied with – (b) if the claim relates to a food rather than a property of a food, the food consists of no less than 90% by weight of primary food; and (e)(i) the claim states – the property of the food (unless the substantiation is based on the food itself and the specific health effect, in which case it states the food itself); and	Paragraph 5(2)(b) will be omitted. Paragraph 5(2)(e)(i) (renumbered to 6(e)(i))will be amended to include the wording 'unless the substantiation *can only be* based on the food itself…'	Identification of whole foods through the use of the definition of primary foods (as defined in Standard 1.3.2), and by the application of a threshold of 90% or higher of primary food was considered problematic and limiting by some submitters, e.g. would not allow suitable foods such as tea. Reference to primary food in the context of whole foods has therefore been removed. Subclause 5(2)(e) was strengthened to show that the only circumstances in which a general level health claim can refer to a whole food is when the whole food only, and not a property of the food can be reasonably substantiated as providing the health effect.

Table 4: Changes to draft Standard 1.2.7 (continued)

Topic	Relevant clause of draft Standard 1.2.7 at Draft Assessment	New drafting of draft Standard 1.2.7 at Preliminary Final Assessment	Intent of change and rationale
Wording conditions	**Paragraph 5(2)(e)(i)&(ii) and Paragraph 6(1)(c)(i) & (ii)**Wording conditions for general level and high level health claims	Paragraphs have been renumbered to 6(1)(e)(i) and 7(1)(c)(i) where (i) and (ii) have been combined for both general level and high level health claims	To clarify that the property of the food must be expressed in association with the health effect, but does not need to be expressed again within the claim, as a nutrition content claim i.e. a nutrition content claim is not an essential component of the wording of a health claim.
Requirement for wording of a claim to be in one place	Wherever the requirement for the wording to be 'in the one place' appears	Amended to read the claim is presented so that all elements of the claim are 'in the one place *on the label'*	To clarify that all the elements of the claim must be located in the same place on the label, rather than the various elements being separated over different parts of the label.
High level health claim wording conditions – property of the food	**Paragraph 6(c)(i)** 6(1) A high level claim may be made if – (c) the claim states, in words to the effect of those listed in column 3 of the Table to this subclause- (i) the property of the food;	**Paragraph 7(c)(i)** 6(1) A high level health claim may be made if – (c) the claim states, in words to the effect of those listed in column 3 of the Table to this subclause- (i) the property of the food *if applicable*	Incorporates permission for high level health claims to refer to the health effect and dietary context only, as a result of the approval of the high level health claim about vegetable and fruit consumption. 'Vegetables and fruit' must both be referred to in all such high level health claims as part of the dietary context, however if the food carrying the claim is just a fruit or a vegetable, the property of the food (vegetable and fruit) is not applicable.
High level health claim wording conditions – general population	**Paragraph 6(1)(c)(iii)** the population group to which the specific health effect relates; In the **Table to Clause 6,** (c) *the population group is the general population* in Column 3 in relation to claim statements for the calcium and enhanced bone density high level health claim and the saturated/*trans* fatty acids and LDL cholesterol high level health claim	'*If applicable'* inserted into **Paragraph 7(1)(c)(iii)** Reference to the general population omitted from the **table to clause 7.**	The intent at Draft Assessment was that if the specific health effect can be attributed to the general population, there does not need to be reference to the 'general population' as part of the wording of the high level health claim. This was not clearly reflected in the drafting. The drafting has therefore been amended to reflect this intent.

Table 4: Changes to draft Standard 1.2.7 (continued)

Topic	Relevant clause of draft Standard 1.2.7 at Draft Assessment	New drafting of draft Standard 1.2.7 at Preliminary Final Assessment	Intent of change and rationale
High level health claim – calcium, vitamin D and osteoporosis, conditions	**Table to clause 6, column 2,** (a) the food contains no less than 300 mg of calcium per serve;	**Table to clause 7, column 2,** (a) the food contains no less than *290 mg* of calcium per serving;	Some submitters to the Draft Assessment Report noted that the qualifying criteria of 300 mg/serve means that most whole milks will not meet the criteria, however the claim is aimed at an aging population for whom it may be more appropriate to drink whole milk in preference to fat reduced varieties. FSANZ has acknowledged this discrepancy and propose that the qualifying criteria are revised from 300 mg calcium/serve to 290 mg calcium/serving to include a greater range of milks, including whole milks.
High level health claim – folic acid and neural tube defect, wording conditions	**Table to clause 6,** Column 3, claim statement (d) the context is a recommendation that women consume at least 680µg of dietary folate equivalents per day or 400µg of folic acid per day, at least the month before and three months after conception.	**Table to clause 7** The dietary folate equivalents per day has been reduced to 670 µg	For consistency with FSANZ's work on mandatory fortification with folic acid, the claim statement part (d) for the folic acid and neural tube defect high level health claim has been revised from 680 to 670 µg of dietary folate equivalents.
High level health claim – sodium and blood pressure	**Table to clause 6 for the sodium and blood pressure high level claim** Column 2 (a) the food complies with the conditions under clause 11 of this Standard for a nutrition content claim in relation to low salt Column 3 (a) the property of the food is sodium; and (d) the context is a healthy diet of a variety of foods low in salt	**Table to clause 7 for the sodium and blood pressure high level health claim** The wording conditions have been amended to refer to *sodium* or *salt.*	These amendments permit the use of either 'salt' or 'sodium' interchangeably within the wording of the claim.

Table 4: Changes to draft Standard 1.2.7 (continued)

Topic	Relevant clause of draft Standard 1.2.7 at Draft Assessment	New drafting of draft Standard 1.2.7 at Preliminary Final Assessment	Intent of change and rationale
Nutrition content claims - biologically active substances	**Table to clause 11, column 3,** conditions for nutrition content claims in relation to biologically active substances (a) the claim refers to the presence of the substance (c) if any statement is made indicating that a certain amount of the food or property be consumed in a given period of time, the supplier of the food has records substantiating the basis for this statement and the statement describes this basis.	**Table to clause 11, column 3,** conditions for nutrition content claims in relation to biologically active substances The requirements that the claim refers to the presence of the substance and describes the basis for the substantiation of the claim have been omitted.	The requirement to declare the presence of the substance constitutes a nutrition content claim and therefore does not need to be included as a condition to make the claim. The requirement to state the basis for recommendations that a certain amount of food or property be consumed in a given period of time has been removed, because it is now considered to be too cumbersome and impractical as a labelling requirement.
Cholesterol free claims	**Table to clause 11**	**Table to clause 11** The reference to 'free' has been removed from the table.	To clarify that for any claim regarding cholesterol, including 'free' claims, the food must meet the conditions for a 'low saturated fatty acid' claim, and to remove confusion around the conditions for 'cholesterol free'.
Nutrition content claims - 'Low cholesterol'	**Table to clause 11** (b) the food contains no more than 20 mg cholesterol per 100 g	**Table to clause 11** Conditions for liquid foods added: The food contains no more than 10 mg per 100 mL for liquid foods	The addition of criteria for liquid foods provides consistency with Codex (as intended at Draft Assessment) and with the approach used for most other risk increasing nutrients as proposed in Standard 1.2.7 i.e. there are separate criteria for solid foods and liquid foods.
Nutrition content claims – all fatty acids	**Table to clause 11**	**Table to clause 11**	Amended so that the reference to the fatty acid is plural or singular as appropriate.

Table 4: Changes to draft Standard 1.2.7 (continued)

Topic	Relevant clause of draft Standard 1.2.7 at Draft Assessment	New drafting of draft Standard 1.2.7 at Preliminary Final Assessment	Intent of change and rationale
Nutrition content claims - reduced salt/sodium	**Table to clause 11** Conditions for making a 'reduced sodium' claim	**Table to clause 11** Conditions for making a 'reduced sodium' claim: Requirement to declare potassium omitted Requirement for the claim to be presented in the one place on the label, inserted. Inclusion of permission to state difference in the salt content of the food, instead of sodium content	The condition to declare potassium was already required in the general conditions applying to all salt or sodium claims, so was deleted from these conditions. The requirement for the claim to be presented in the one place on the label was inadvertently left out at Draft Assessment. This requirement has now been included for consistency with other 'reduced' claims. If the claim is about 'reduced salt' the claim should state the reduction in salt content, so permission to do this has been added.
Nutrition content claims – reference to 'sugars'	**Table to clause 11**		The appropriate definition of 'sugar' has been referenced in the conditions for low, reduced and no added sugar nutrition content claims, to clarify which definition in the Code applies.
Comparative claims about fatty acids	**Table to clause 11**	**Table to clause 11** Conditions added for 'increased' claims in relation to polyunsaturated, monounsaturated, omega 3, 6 and 9 fatty acids	These additional conditions provide consistency with the approach for other comparative claims already proposed in draft Standard 1.2.7. Other claims and conditions relating to these fatty acids will be considered at the time of the review being undertaken to incorporate new nutrient reference values into the Code, however as conditions for comparative claims are not based on nutrient reference values, it is considered that they can be drafted without the need to wait for this review.
Clarification of nutrition content claims that are permitted	**Clause 11**	**Clause 11** Editorial note added to the end of this clause	Editorial note added to clarify that the Standard does not prohibit nutrition content claims for which there are no specific conditions prescribed, for example, claims regarding carbohydrate content are permitted under the Standard and would be regulated by fair trade legislation.

Table 4: Changes to draft Standard 1.2.7 (continued)

Topic	Relevant clause of draft Standard 1.2.7 at Draft Assessment	New drafting of draft Standard 1.2.7 at Preliminary Final Assessment	Intent of change and rationale
General level health claims - biologically active substances, conditions	**Table to clause 12, column 2,** conditions for general level health claims in relation to biologically active substances (a) the claim states – (i) the level of the substance in the food; and (ii) the amount of the substance that is required to be consumed per day to achieve the specific benefit; and (iii) the basis for the statement under (ii); and	**Table to clause 12, column 2,** conditions for general level health claims in relation to biologically active substances The requirement to state the basis for the recommendation relating to the amount of substance to be consumed in a given period of time, has been removed, '*Health effect'* has replaced '*benefit*'	The requirement to state the basis for the recommendation relating to the amount of substance to be consumed in a given period of time, has been removed, because it is now considered to be too cumbersome and impractical as a labelling requirement. The word 'benefit' has been replaced with 'health effect', to clarify the meaning of this term and align it with the interpretation in clause 1.
Calculation of maximum quantity of a vitamin or mineral that may be claimed	**Clause 13** (1) where a claimable food contains more than one ingredient, ……	**Clause 13** (1) Where a claimable food, *containing at least one ingredient with added vitamins or minerals under Standard 1.3.2*, contains more than one ingredient,…	As part of Proposal P293, it is proposed that this clause be moved from Standard 1.3.2 – Vitamins and Minerals, and as a result it is no longer clear that the clause only applies to foods that have had vitamins or minerals added to them, or that contain ingredients with added vitamins or minerals. The wording has therefore been amended to clarify when this clause should be applied.

Table 5: Changes to Standard 1.2.8

Topic	Relevant clause of Standard 1.2.8 at Draft Assessment	New drafting	Intent of change and rationale
Purpose	**The Purpose included the statement:** Standard 1.3.2 (Vitamins and Minerals) sets out the labelling requirements for claims made about the vitamin and mineral content of foods.	**Purpose** The reference to Standard 1.3.2 has been omitted, and a reference to Standard 1.2.7 added.	The labelling requirements for claims made about vitamins and minerals will be prescribed in Standard 1.2.7, and Standard 1.2.7 includes some additional labelling requirements when certain claims are made. The Purpose of Standard 1.2.8 has therefore been amended to outline this.
Declaration of certain fatty acids as a minimum or maximum	**Subclause 5(2A)** …. fatty acids may be set out in the panel as a minimum or maximum quantity in a serve of the food	**Subclause 5(2A)** …. 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.	This subclause has been clarified to indicate that if the fatty acids are declared as a minimum or maximum quantity per serve, they should also be declared as a minimum or maximum per 100 g or ml in the nutrition information panel.
%RDI declarations	**Clause 7 Percentage intake information** (1) Where a nutrition content claim or health claim is made, the following matters must be included in the panel – (b) the percentage daily intake or RDI of any property that is the subject of the claim, if there is a reference value for the property in the Code, per serve; and (2) Where a nutrition content claim or health claim is not made, information relating to the percentage daily intake or RDI of nutrients may be set out in a nutrition information panel.	**7A Percentage Recommended Dietary Intake** New clause added to address the specific requirements for declaration of %RDI, i.e. %RDI must be declared when a nutrition content claim is made	The decision to remove the requirement for %DI labelling on products carrying nutrition content and health claims has resulted in amendments to the proposed clause 7 of Standard 1.2.8 (see section 4.1 of this report). As a result of these amendments, it was not appropriate to include the requirement associated with declaring %RDI, in Clause 7 – Percentage Daily Intake Information. Clause 7A has therefore been incorporated into Standard 1.2.8 to require %RDI declarations when a nutrition content claim is made regarding a vitamin or mineral that has an RDI prescribed in the Schedule to Standard 1.1.1. Clause 7A gives permissions for signposting of %RDI, similar to the permission for signposting of %DI as outlined in section 4.2 of this report. Percentage RDI signposting is not required to be located in the same place on the label as the signposting of %DI values.

Table 6: Changes to other Standards

Topic	Relevant clause at Draft Assessment	New drafting	Intent of change and rationale
Standard 1.3.1	**Editorial note after clause 4** The editorial note refers to reduced/low joule claims found in Standard 1.2.8 and ANZFA's Code of Practice on Nutrient Claims in Food Labels	**Editorial note after clause 4** Amended reference from 'joule' to 'energy', refer to Standard 1.2.7, and remove reference to ANZFA's Code of Practice.	As a result of moving criteria for energy and no added sugar claims to Standard 1.2.7.
Standard 2.6.2	**Editorial note after subclause 8(3)** A claim that an electrolyte drink is isotonic is not considered a nutrition claim for the purposes of Standard 1.2.8 of this Code.	This section of the editorial note has been reworded.	Nutrition claims will be referred to as nutrition content claims and they will be regulated under Standard 1.2.7
Standard 2.9.2 – cross reference to certain clauses in Standard 1.2.8	**Editorial note to clause 6** Average energy content is defined in Standard 1.2.8	**Editorial note to clause 6:** Average energy content is defined in Standard 1.1.1	The definition of average energy content has been moved from Standard 1.2.8 to Standard 1.1.1.
Standard 2.9.2	**Paragraph 9(1)** The following provisions of Standard 1.2.8 do not apply to this Standard – (f) subclause 17(2)	**Inserting after subclause 9(1)** (1A) The conditions in the Table to clause 11 of Standard 1.2.7 which refer to the salt, sodium or potassium content of a food do not apply to this Standard.	Subclause 17(2) of Standard 1.2.8 has been moved to the table to clause 11 of Standard 1.2.7.
Standard 2.9.4	**Paragraph 5(2)** The label on a package of formulated supplementary sports food may only claim the presence of a vitamin or mineral in the food if – (c) the label on the package of the food includes a statement in accordance with clause 9 of Standard 1.3.2.	**Paragraph 5(2)(c) has been omitted.**	Clause 9 of Standard 1.3.2 has been incorporated into Standard 1.2.8.
Standard 2.10.2 - cross reference to Standard 1.2.8	**Subclause 5(2)** A declaration in accordance with subclause (1) does not constitute a nutrition claim for the purposes of Standard 1.2.8.	**Subclause 5(2)** A declaration in accordance with subclause (1) does not constitute a nutrition content claim or health claim for the purposes of Standard 1.2.7.	To accommodate changes in terminology and regulation of claims under Standard 1.2.7 instead of Standard 1.2.8.

10. OPTIONS PROPOSED AT PRELIMINARY FINAL ASSESSMENT

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sections of the community, including consumers, food industries and governments. The regulatory options available for this Preliminary Final Assessment are as follows:

Option 1 – maintain draft Standard 1.2.7 for Nutrition, Health and Related Claims as proposed at Draft Assessment

This option maintains all the requirements proposed at Draft Assessment by not changing the draft Standard.

Option 2 –Modify the requirements for Nutrition, Health and Related Claims proposed at Draft Assessment by amending draft Standard 1.2.7 as proposed at Preliminary Final Assessment with regard to:

(a) application of Standard 1.2.7
(b) ineligible foods
(c) conditions for making content claims (%Daily Intake)
(d) criteria of specific Nutrition Content claims
(e) 'No added' claims
(f) nutrient profile model
(g) weight management and 'diet' claims
(h) pre-approved high level health claims
(i) substantiation
(j) dietary Information
(k) endorsements
(l) wording conditions
(m) minor editing to drafting

FSANZ's preferred approach at Preliminary Final Assessment is Option 2.

This option would result in amendments to draft Standard 1.2.7 by modifying a number of clauses based on evidence and rationale presented in the Preliminary Final Assessment Report. FSANZ will conduct an assessment of the impact of the proposed Standard, incorporating these modifications, prior to finalisation of the Standard.

11. ITEMS FOR INFORMATION

11.1 Consideration of new Nutrient Reference Values

New Nutrient Reference Values (NRVs) for Australia and New Zealand were published in May 2006 (NHMRC and Ministry of Health, 2006). Currently the Code prescribes nutrient 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.

The new NRVs developed by the NHMRC have an expanded range of values encompassing 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 process of updating the reference values contained in the Code to reflect the new NRVs will need to consider many factors since one value per nutrient will need to be selected from the broad range of NRV values for each of the specified population groups.

FSANZ has given consideration to the work involved in revising the NRVs in the context of health claims regulations. Revision of these reference values also has wide implications for other aspects of food regulation, including voluntary fortification of both general foods and special purpose foods. Given the extent and complexity of the project, it has been decided not to include any revision of NRVs within this proposal as it would considerably broaden the scope of the current project and delay its timeframes.

FSANZ is committed to maintaining a solid nutritional rationale underpinning health claims regulations, as for all food regulations, and is mindful of minimising any cost to industry resulting from ongoing regulatory changes around health claims. For these reasons, the process of updating the NRVs in the Code will be accorded high priority as resources and workload permit.

11.2 Trade marks

11.2.1 Background

There are numerous registered trade marks that may constitute nutrition or health claims. The *Trade Marks Act 1995* provides for the registration of trade marks in Australia and the *Trade Marks Act 2002* for the registration of trade marks in New Zealand. The rights which attach to registration in both countries include exclusive rights to use the trade mark, and to authorise other persons to use it in relation to the goods in respect of which it is registered.

The registration and opposition to registration processes are similar in both countries and are described below.

It is not a requirement that trade marks be registered.

11.2.2 Registered Trade marks

11.2.2.1 In Australia

When a trade mark is registered, section 20 of the *Trade Marks Act* confers on the registered owner a right to use that trade mark. If the trade mark is registered, the owner has the right to use it and State or Territory food laws could not validly prevent its use, whether it is registered before or after the relevant State or Territory food laws law which enforce the proposed health claims standard take effect.

A State or Territory food law that purported to merely regulate the owner's use of the trade mark and not prevent the owner's use of it, e.g. a health claim standard merely requiring information to be provided on the label would probably not be held to be inconsistent with the *Trade Marks Act.* However, where for example a health claim is only permissible for foods that do not exceed certain criteria, e.g. fat, sugar or salt levels, this would be likely to prevent trade marks that consist of health claims from being used at all for certain categories of foods, e.g. confectionery. In this case, State or Territory legislation giving effect to the draft standard would purport to prohibit the registered owner of a trade mark that constitutes a health claim in relation to such products from using the trade mark at all. This aspect of the draft standard would not merely regulate the use of a trade mark, and any State or Territory provisions giving effect to the draft standard would be at risk of invalidity on constitutional grounds. This is because enforcement of the Code is through relevant State and Territory food laws, and where there is any inconsistency between Commonwealth and State or Territory laws, Commonwealth law prevails.

Since 23 October 2006, the Registrar has the capacity to initiate court action to amend or remove a trade mark from the Register, under certain circumstances, where this is clearly in the public interest. Previously, only an 'aggrieved person' could apply to a prescribed court for certain actions to be taken.

A court has the power to order the rectification of the Register on any grounds on which the registration could have been opposed. Rectification may include cancellation of a trade mark or entry of a condition or limitation on the use of the trade mark.

An application can be made to have a trade mark removed from the Register if:

- the trade mark has not been used for 3 years; or
- if trade mark has not been used and the person had no intention of using it when the application was filed.

11.2.2.2 In New Zealand

New Zealand does not have the constitutional limitations that apply in Australia (where State or Territory food laws giving effect to the proposed health claims standard risk invalidity on the basis of inconsistency with the Australian *Trade Marks Act).*

In New Zealand, once a trade mark is registered under the *Trade Marks Act 2002*, it may be possible that the use of a registered trade mark which infringes a provision of the Health Claims Standard when it comes into operation could be challenged as part of the enforcement process under New Zealand law such as the *Food Act 1981*.

A trade mark registration can only be challenged by an aggrieved person. The Commissioner or the Court may on the application of an aggrieved person or on the Commissioner's own motion, make an order that cancels or alters the registration of a trade mark on the ground of failure to comply with a condition entered on the register in relation to the trade mark, or that it is not in the public interest for the trade mark to be registered. A registered trade mark can be cancelled on the grounds that it would be contrary to law or likely to deceive or cause confusion.

A person who has an interest may make an application for rectification of an error or omission in the register, however, an application for rectification may not be made in respect of a matter that affects the validity of the registration of the trade mark.

11.2.3 Before Registration

In both Australia and New Zealand there are similar procedures in place to enable objections to be lodged by interested parties against applications for the registration of a trade mark. It is during this application period that objections could be lodged on the basis that a proposed trade mark is making a claim that is not in accordance with a provision or requirement in the Health Claims Standard.

In both Australia and New Zealand a person who wishes to oppose registration has three months from when the application is advertised to oppose that application. It clearly will be possible to lodge objections once the new standard has been finalised and gazetted. It is less clear whether it would also be possible to lodge objections having regard to the standard before it is gazetted. Discussions with IP Australia and the Intellectual Property Office of New Zealand have raised the possibility of FSANZ providing input at the registration stage to identify applications for registration which might be in breach of the proposed health claims standard. In the period before the standard comes into force, it might be possible for example as part of the registration process to have certain conditions placed on registration.

11.2.3.1 Opposition Process

Contrary to law

In both Australia and New Zealand the registration of a new trade mark may be refused if the use of the trade mark in relation to the goods for which it is sought to be registered is contrary to State or Territory law (Australia) or New Zealand law giving effect to the health claims standard. In Australia the Registrar is obliged when assessing whether use would be contrary to law to take into account valid State and Territory legislation. Therefore, if a person seeks to register a new trade mark that constitutes or includes a health claim, the use of which would contravene State and Territory legislation giving effect to a health claims standard, registration of the trade mark must be rejected. In New Zealand, if the use of the trade mark is contrary to New Zealand law giving effect to the health claims standard or would otherwise be disentitled to protection in court, registration must be refused.

Likely to deceive or cause confusion

Applications for registration may be rejected on this ground if the trade mark suggests the goods and services in question have characteristics or qualities which they do not possess.

Application made in bad faith

In Australia, since 23 October 2006 registration of a trade mark may be opposed on the basis that it has been applied for in bad faith. This ground is intended to cover situations where an applicant applies for a trade mark with bad intentions, for example, where a person deliberately sets out to take advantage of the reputation of another trader.

In New Zealand, the Commissioner can refuse to register a trade mark if the application is made in bad faith.

In Australia, an application for registration must be rejected if the proposed trade mark contains or consists of scandalous matter or if a trade mark is not capable of distinguishing the goods or services of the applicant.

In Australia, decisions to reject are determinations made by the Registrar of Trade Marks which are judicially reviewable by the Federal Court.

In summary

It is noted that:

- registration of a new trade mark may be refused if the use of the trade mark in relation to the goods for which it is sought to be registered, would (in the absence of registration) be contrary to legislation giving effect to the health claims standard.
- relevant legislation enforcing the health claims standard could not prevent the use of a registered trade mark, whether it is registered before or after the standard commences in Australia, but it may be possible that use of a registered trade mark in New Zealand which infringes a provision in the proposed health claims standard could be challenged as part of the enforcement process;
- meetings with IP Australia and the Intellectual Property office of New Zealand indicate that it there is a likelihood of putting consultative arrangements in place whereby FSANZ could have input at the registration stage to identify applications which might infringe the proposed standard; and
- relevant legislation enforcing the proposed health claims standard could prevent the use of an un-registered trade mark in both Australia and New Zealand.

11.3 Vitamin and mineral claims

At Draft Assessment, it was proposed to amend to the conditions for vitamin or mineral nutrition content claims that are currently regulated in Standard 1.3.2 of the Code. Currently, nutrition content claims about vitamins and minerals are permitted only where a minimum specified percentage of the Recommended Dietary Intake (RDI) or Estimated Safe and Adequate Daily Dietary Intake (ESADDI) of the vitamin or mineral is contained in a 'reference quantity' of the food; this is a prescribed quantity for fortified foods. However, this requirement for fortified foods is now proposed to be based on a 'serving' of the food, as it is for unfortified foods because the amount of nutrient (with a corresponding RDI) is declared per serving.

The amendment is designed to prevent nutrition content claims being made on foods containing less than 10% RDI or ESADDI **per serving**, even though such foods contain at least 10% RDI or ESADDI per reference quantity. Currently, this can occur where the reference quantity is relatively large (e.g. 600 mL) and the package and therefore serving size is small (e.g. 200 mL); in these circumstances, a serving of the food as labelled could contain less than 10% RDI or ESADDI and still carry a nutrition content claim. Calculating on the basis of a serving of the food rather than its reference quantity ensures that foods that bear a 'source' nutrition content claim always contain at least 10% RDI per serving, and foods that bear a 'good source' nutrition content claim always contain at least 25% RDI/serving.

Foods that have greater serving sizes than their prescribed reference quantity are not affected by this amendment.

11.4 Nutrition, Health and Related Claims on Special Purpose Foods

In the Code, Part 2.9 – Special Purpose Foods provides for the labelling requirements for infant formula, foods for infants, formulated meal replacements and formulated supplementary foods and formulated supplementary sports foods. Claims allowable in relation to these foods are specified in each standard. At Draft Assessment the approach taken was to prohibit general level and high level health claims unless permitted by the draft Standard 1.2.7 or by Part 2.9 of the Code (clause 3). Clause 4 specifically excluded health claims on infant formula products.

A few submitters raised comments in relation to the eligibility of foods regulated by Part 2.9 to make claims, particularly in relation to disqualifying criteria and formulated supplementary foods, which would not be able to make claims because of the disqualifying criteria. Some of the submitters' comments are provided below to indicate the concerns raised:

- Need to consider link and need for consistency between Standard 1.2.7 with Standards 2.9.3, 2.6.4, and 2.9.4, and proposed standards within Proposals P235 – Food-type Dietary Supplements, P242 – Foods for Special Medical Purposes and P260 – Non Culinary Herbs.
- Within Standard 2.9.4 – Formulated Supplementary Sports Foods, there is a prohibition on certain claims being made which is inconsistent with the proposed health claims Standard. For example claims are not permitted about the enhancement of athletic performance or about any beneficial physiological effect. Such claims appropriately substantiated would be permitted within the proposed health claims Standard. Recommends that Standard 2.9.4 be modified to permit claims in the same way as other foods.
- Notes that foods for special medical purposes have yet to be considered under Part 2.9 - Special Purpose foods. Products of this nature have been in the market place for many years and legitimately carry the names of serious diseases. Under current drafting of the proposed health claims standard, these products would be considered to be carrying high level health claims and therefore require pre-market approval and substantiation via application. Foods for Special Medical Purposes are a unique regulatory classification and should not be regulated by the same standards applied to conventional foods or foods advertised directly to consumers.
- Recommends that FSANZ either proceeds to gazettal of the Standard for Foods for Special Medical Purposes prior to gazettal of the health claims standard or make transitional arrangements to exempt those foods under the proposed health claims standard, until the Standard for Foods for Special Medical Purposes is finalised.
- Consistent with international definitions and practice, believe that Foods for Special Medical Purposes, as well as any claims related to the dietary management of diseases, disorders or medical conditions, should not be governed by the proposed Standard 1.2.7 but be governed by a specific vertical standard being developed under Proposal for Foods for Special Medical Purposes.

FSANZ's preferred approach is to continue with the approach presented at Draft Assessment.

Standards 2.9.3, 2.9.4 and 2.9.5 are on FSANZ's work program for review and at that time permission for nutrition, health and related claims will be addressed. The function of the health claims proposal is to develop a horizontal standard, not focus on vertical applications such as Part 2.9 Standards. When Part 2.9 is addressed, if the horizontal provisions for claims as provided by Standard 1.2.7 are not considered suitable, specific provisions around claims can be provided in the Part 2.9 Standards and these will automatically override Standard 1.2.7. Part 2.9 of the Code is further complicated by its relationship to the Transitional Standard 1.1A.6 – this addresses special purpose foods for New Zealand only (i.e. foods under the New Zealand dietary supplement regulations). This is also an area of current activity and provides further reason to leave Part 2.9 of the Code alone at this time.

11.5 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 proposed 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 Food Standards Treaty requires New Zealand to take legislative or other steps as are necessary to adopt or incorporate foods standards that are developed and approved by the FSANZ.

12. COMMUNICATION STRATEGY AT PRELIMINARY FINAL ASSESSMENT

Consumers, industry and other key stakeholders have expressed diverse views on the requirements for a new standard and the content and regulatory framework for health, nutrition and related claims. Raising awareness and understanding of the proposed standard and its preferred approach among consumers and industry is a significant challenge for FSANZ. A guide to the development of the new Standard is available to help interested parties to understand the process used to develop the Standard, how they can participate in the process and the key components of the Standard. Effective implementation of the proposed Standard will depend on strong collaboration between FSANZ and its jurisdictional partners, industry and consumer groups.

To meet this challenge, FSANZ has prepared a strategy to guide its communication and education initiatives. The strategy addresses a range of issues, including food eligibility criteria, endorsements, dietary information, diet-disease relationships and the transition period.

The strategy draws on discussions with key stakeholders about the most effective ways of communicating information about the proposed standard to consumers, industry, health professionals, governments and the media. It is informed by research, particularly research FSANZ commissioned into use of claims by industry, and consumer perceptions and understanding of these claims.

Target audiences for the strategy include: consumers; industry; health professionals, including those who provide consumer advice on dietary and nutrition issues; enforcement and monitoring agencies; and the media. In keeping with advice received through submissions to the Draft Assessment and stakeholder consultations, FSANZ will ensure that clear, consistent messages about the proposed standard are delivered to these audiences through a range of mechanisms, including print and electronic media (radio and internet).

FSANZ will give priority to updating existing consumer education materials—fact sheet/brochure, the 'Official Shopper's Guide to Food Additives and Labels' now titled 'Choose the Right Stuff', the food labelling poster and the FSANZ website. It will also develop new materials for consumers and industry including a consumer wallet card, industry poster, and industry fact sheets, in consultation with industry bodies. These resources are intended to educate and inform consumers and industry about what is expected under the proposed standard and to reduce the risk of inappropriate claims or complaints. All resources will be promoted through: the FSANZ website; *Food Standards News* (over 9,500 subscribers); and the email Update subscription service (over 5,900 subscribers). FSANZ will encourage consumer and industry groups to promote these resources through their own networks.

FSANZ will continue to work with its jurisdictional partners to promote awareness of its education/information materials among consumers and industry. It will also maintain close collaboration with the Health Claims Watchdog and its Working Group to advise on the most appropriate means of communicating the role of the Watchdog to key stakeholders, and monitor the complaints-handling process. FSANZ will continue to provide information to industry through the FSANZ Advice Line.

FSANZ will provide accurate, timely information to its media contacts in response to enquiries about the proposed standard. It will also initiate media briefings and conduct a program of interviews with selected print and electronic media to encourage responsible, accurate reporting. FSANZ spokespeople will be briefed regularly so that they can engage effectively with the media.

13. CONSULTATION SINCE DRAFT ASSESSMENT

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

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

In total, FSANZ received 131 submissions. Table 7 below illustrates the spread of submissions across stakeholder groups and between Australia and New Zealand.

Table 7: Submissions received in response to the Draft Assessment Report

Country	Government	Industry		Consumers	Public Health*	Other #	TOTAL
Australia	7	Food	49	2	12	4	79
		Therapeutic	4				
		Media	1				
		TOTAL	54				
New Zealand	2	Food	9	9	11	5	37
		Therapeutic					
		Media	1				
		TOTAL	10				
Trans-Tasman	-	Food	10		-	-	10
		Therapeutic					
		Media					
		TOTAL	10				
International	-	Food	5	-	-	-	5
		Therapeutic					
		Media					
		TOTAL	5				
TOTAL	9	79		11	23	9	131

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

13.2 Advisory Groups

13.2.1 Standards Development Advisory Committee

The FSANZ Act includes a provision under section 43 for the establishment of Standards Development Advisory Committees, for the purpose of providing advice to FSANZ during the standards development process. The Nutrition, Health and Related Claims Standards Development Advisory Committee met on several occasions after the publication of the Initial Assessment Report and provided advice on issues that contributed significantly to the Draft Assessment Report and the development of the draft Standard 1.2.7.

Recent membership was essentially unchanged from the period prior to the Draft Assessment Report, where Committee membership comprised of representatives from industry, consumer groups, governments and public health professionals. Subsequent to the Draft Assessment Report, two face-to-face meetings of the Committee were held, one in New Zealand and one in Australia, to discuss the key issues to be addressed in the Preliminary Final Assessment Report. As a result of these meetings, Committee members provided valuable contributions towards the refinement of the draft Standard 1.2.7.

13.2.2 Scientific Advisory Group

The Scientific Advisory Group was established to provide advice to FSANZ on the Substantiation Framework for nutrition, health and related claims and on seven external reviews of diet-disease relationships commissioned by FSANZ. These reviews were of high level health claims being considered for inclusion in the new Standard and were carried out using the process set out in the Substantiation Framework.

Membership of the Scientific Advisory Group comprised experts from a range of scientific disciplines, including nutrition and epidemiology. The group has met four times and considered draft reports of all seven reviews. The first group of four diet disease relationships has been published on the FSANZ website, and a further three that were reviewed after Draft Assessment are also planned to be available on the FSANZ website.

As a result of experience in applying the Substantiation Framework, the group has endorsed some improvements and simplification and provided advice on how it may be applied to the substantiation of general level health claims.

13.3 Stakeholder briefings

Stakeholder interest in the Nutrition, Health and Related Claims draft Standard remained strong following the release of the Draft Assessment Report. Briefings on the Draft Assessment Report were held immediately after its release in Sydney, Melbourne, Adelaide, Auckland and Wellington.

FSANZ responded to those stakeholders that requested additional briefings for clarification of the specific issues raised in the draft Standard and its expected impact.

Workshops, and briefings and conference presentations included:

- Confectionery Manufacturers of Australasia Limited in Melbourne
- Food Technology Association in Melbourne
- Dietitians Association of Australia in Sydney
- Natural Products Summit in Nelson
- New Zealand Institute of Food Science and Technology in Auckland
- Australian Institute of Food Science and Technology in Adelaide
- National Heart Foundation of Australia in Sydney
- Complementary HealthCare conference, Wellington
- Seafood Services Australia in Cairns
- International Life Sciences Institute (ILSI), Sydney and in Malaysia
- Jurisdictions and Commonwealth Agencies in Australia and New Zealand
- Food Industry Association of Queensland, Brisbane
- Australian Institute of Public Health Officers, Sydney

13.4 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.

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 at Draft Assessment 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 (TBT) Agreement. Other WTO member countries were invited to comment by 22 February 2006 on the proposed Standard where it might have a significant impact on them. No comments were received.

14. CONCLUSION

The Preliminary Final Assessment report includes a number of modifications to the recommendations proposed at Draft Assessment, some alterations for clarity and information on areas of stakeholder interest or concern. The amended recommendations take account of stakeholder views expressed during consultation or by written submissions to the Draft Assessment Report, additional consumer research and work modelling alternative approaches to food compositional eligibility criteria. It is noted that there is a diversity of views around many of the main issues of nutrition, health and related claims, particularly in relation to the risk management of content claims. Further consideration of this aspect by FSANZ indicated there is uncertainty in the degree of consumer confusion or misunderstanding of these claims and the extent to which they result in alterations of consumer behaviour with a resultant adverse health impact. Furthermore research recently conducted by FSANZ on the risk management option proposed at Draft Assessment (additional labelling requirement for daily intake information) was shown to be ineffective at improving consumer understanding of content claims. It is therefore proposed to remove this additional requirement from the proposed Standard 1.2.7 but to reconsider whether a risk management approach is needed in the context of additional research on consumer understanding and use of nutrition content claims.

Recommendations for a change to the approach to determining the composition of foods which may carry health claims are also contained in this report. A preferred model, based on a fairly simple nutrient profile, is proposed on the basis of its favourable performance when tested against approximately 10000 Australian and New Zealand food products. This model has also been assessed favourably against a number of criteria considered to be important for a practical approach to determining eligibility of foods to carry health claims. The change in food eligibility criteria has impacted on the disqualifying criteria specified for the pre-approved high level health claims and it has been decided to move to the generic nutrient profiling approach for those high level health claims based on vitamins and minerals at this time, for consistency across these claims.

An amended approach to endorsements is recommended, based on a largely self-regulatory approach which depends on the characteristics of the endorsing organization.

A number of changes to content claims, and some specific health claims and their wording conditions are proposed. These changes are based largely on a reappraisal of the recommended approach in response to comments from stakeholders.

FSANZ recommends that the approaches for the individual issues as set out in this Preliminary Final Assessment Report are adopted at Final Assessment.

They take account of the evidence base, the cost-benefit of alternative options and the diversity of stakeholder views. Therefore FSANZ's preferred regulatory option, as set out in Chapter 10, is to amend the draft Standard 1.2.7 as detailed in the individual sections.

ATTACHMENTS

1. Draft Standard to the Australia New Zealand Food Standards Code
2. Technical Report: Consumer research %DI
3. International Literature Review of Percentage Daily Intake labelling
4. Technical Report: Consumer Research Added Sugar
5. Technical report: Diet-Disease relationships
6. Modelling of compositional criteria to determine the eligibility of foods to carry a health claim
7. Calculation method for foods eligible to make health claims

WEB LINKS TO EXTERNAL DOCUMENTS

Nutrition, Health and Related Claims Policy Guideline
Draft Assessment Report for P293 - Nutrition, Health and Related Claims

Reports of the reviews commissioned by FSANZ:

a. 'Dietary fruit and vegetable intake and risk of coronary heart disease'.
b. 'Relationship between whole grain intake and risk of coronary heart disease'.
c. 'Long chain omega-3 fatty acids and cardiovascular disease'.

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Attachment 1

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

To commence: on gazettal

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

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

[1.2] *inserting in clause 2 –*

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

Average energy (kJ/100 g) = $\sum$ Wi Fi

Where –

Wi means the average weight of the food component (g/100 g food); and
Fi means the energy factor assigned to that food component (kJ/g).

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

carbohydrate means –

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

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

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

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

(a) (i) primary foods; or
(ii) foods listed in the Table to clause 2 of Standard 1.3.2; or

(b) (i) a mixture of primary foods; and/or
(ii) water; and/or;

(iii) foods listed in the Table to clause 2 of Standard 1.3.2 excluding butter, cream and cream products, edible oils, edible oil spreads and margarine.

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

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

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

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

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

fat means total fat.

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

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

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

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

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

reference quantity means –

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

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

reference value means RDI, ESADDI or a reference value under the Table to subclause 7(9) of Standard 1.2.8.

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

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

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

[3] *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 and cause-related marketing statements, whether appearing on food labels or in advertisements. It also consolidates a number of requirements relating to claims made under the Code that were previously spread across a number of standards, such as Standards 1.2.8 and 1.3.2.

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

Table of Provisions

Division 1 – Preliminary

Clauses

1 Interpretation

In this Code, 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 means a statement that the sale of the food will contribute to fundraising for an organisation, where the name of the organisation refers to a serious disease.

dietary information means general dietary information provided for educational purposes including information from national nutrition guidelines relating to food or properties of food but not including associated health effects.

Editorial note:

National nutrition guidelines include –

(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, and includes a certification trade mark, but does not include –

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

endorsing organisation means an independent organisation, including a government organisation, formed for nutrition or health purposes, the name of which may include a serious disease, but does not include 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) and other cereal products; or
(b) fruit, vegetables, herbs, spices and fungi (fresh, cooked, frozen, preserved, pickled, pureed, or dried; or
(c) milk, milk products and milk alternatives; or
(d) meat, seafood, eggs, nuts, seeds and legumes; or
(e) fats and oils.

fruit means the sweet, fleshy edible portion of a plant that arises from the base and flower and surrounds the seed, where the constituents are present in such proportions that represent the typical edible fractions occurring in the whole fruit (with or without peel).

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 [referred to as the GI of the 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
(b) a property of the food, and

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

health effect means –

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

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

high level 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, but does not include an endorsement, dietary information or a cause-related marketing statement.

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

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

that is associated with a nutrition or health purpose, including glycemic index and glycemic load.

reference food means a food that is –

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

Editorial note:

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

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

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

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

sugars means monosaccharides and disaccharides.

vegetable(s) means all leafy greens, members of the crucifer family, all root (including potatoes) and tuber vegetables, edible plant stems, gourd vegetables, allium vegetables, peas, beans and corn, and refers to either the whole edible portion or where the constituents are present in such proportions that represent the typical edible fractions occurring in the whole vegetable (with or without peel).

2 Application

(1) This Standard applies to food for retail sale which includes food at the time it is manufactured or otherwise prepared, or distributed, transported or stored prior to retail sale, where the food is not intended for further processing, packaging or labelling.

(2) This Standard does not apply to trade marks registered in Australia or New Zealand before or after the commencement of this Standard.

(3) This Standard does not apply to endorsements made by an endorsing organisation.

(4) This Standard does not apply to:

(a) packaged meals provided to clients of a delivered meal organisation; or
(b) food, other than in a package, provided to patients in hospitals or other similar institutions listed and defined in the Table to clause 8 in Standard 1.2.1.

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

(6) 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.

(7) Food product in subclause 6 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 general level health claim, a high level health claim, a nutrition content claim, dietary information or a cause-related marketing statement must not be made on a label or in an advertisement for food.

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

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

4 General and high level health claims and nutrition content claims - ineligible foods

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

(a) a food that contains more than 1.15% alcohol by volume; or
(b) an infant formula product as standardised under Standard 2.9.1; or
(c) kava as standardised under Standard 2.6.3.

(2) A nutrition content claim that refers to –

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

may be made in relation to a food that contains more than 1.15% alcohol by volume.

(3) On a food that contains more than 1.15% alcohol a nutrition information panel which contains the prescribed declarations in paragraphs 5(1)(a) to 5(1)(f) of Standard 1.2.8 is permitted and does not constitute a nutrition content claim.

5 Conditions for nutrition content claims

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

(a) the supplier of the food has records that substantiate the claim; and
(b) the food meets any applicable conditions under clause 11 of this Standard for making the nutrition content claim; and
(c) the claim does not include any descriptors in relation to the level of the property of the food that is present unless:

(i) there is a reference value for the property of the food in the Code; or

(ii) there are conditions in the Table to clause 11 in relation to the property of the food; or
(iii) the property of the food is alcohol; and

(d) 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
(e) the nutrition information panel must include particulars of the average energy content and average quantities of nutrients and biologically active substances for the form of the food to which the conditions for making the claim apply in accordance with the Table to clause 6; and
(f) the conditions for making the claim set out in the Table to clause 11 apply to the food in accordance with the Table to clause 6.

Editorial note:

For paragraph 1(c), examples of descriptors that refer to the level of the property of the food present are listed in Column 2 of the Table to clause 11. 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, or, 'lean', 'trim' or 'skim' to describe a nutritional aspect of the property of the food.

6 Conditions for general level and high level health claims

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

(a) the food meets the scoring criteria for making a health claim as specified in the Schedule to this Standard based on the food's nutrient profile, except for a claim in relation to a vitamin, mineral, gluten or lactose, or foods for infants as standardised under Standard 2.9.2; and
(b) the supplier of the food has records that substantiate the claim or the claim is based on the nutrient function statements in [Title of FSANZ pre-approved list of nutrient function statements], dated [dd mm yyyy]; and
(c) the food complies with any applicable conditions under Division 3 of this Standard for making a nutrition content claim in relation to the property of the food that is the subject of the general level health claim, when the property of the food is –

(i) 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 criteria in the applicable conditions must be met;
(ii) 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

(d) the food meets any applicable conditions under Division 3 of this Standard for making a general level health claim; and
(e) the claim expressly states –

(i) the property of the food (unless the substantiation can only be based on the food itself and the specific health effect, in which case it states the food itself) 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 associated 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 and the specific health effect claimed; and

(f) the claim is presented so that all elements of the claim are in the one place on the label; and

(g) despite paragraph (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 (f) is placed.

(2) For general level and high level health claims, the nutrition information panel must include particulars of the average energy content and average quantities of nutrients and biologically active substances for the form of the food to which the conditions for making the claim apply in accordance with the Table to clause 6.

(3) The following information, for the purpose of enabling a food to be eligible to make a health claim as calculated in accordance with the Schedule to this Standard, 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 fruit, vegetables, nuts or legume ingredients where applicable, calculated and expressed in accordance with Standard 1.2.10.

(4) Paragraph 3(c) does not apply to high level health claims in relation to vegetables and fruit and coronary heart disease.

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

(6) For the purposes of meeting the scoring criteria for making a health claim as specified in the Schedule to this Standard, the conditions set out in the Table to clause 6 do not apply for calculating the percentage of fruit, vegetables, nuts and legumes that are present in the food.

(7) 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.

Table to clause 6

Form of the food	Form of the food to which conditions apply for making a claim
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
Food that is intended to be consumed with other food	The claim is based on the food as consumed
Food that is intended to be either prepared with other food , or consumed as sold	The claim is based on either form of the food

Editorial note:

The information on the label for the food including the directions for use and the information provided in the advertisement for the food is taken into account in ascertaining the intended use of the food to which the claim is to apply.

7 Conditions for specific high level health claims

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

(a) the diet-disease relationship that is the subject of the claim is listed in column 1 of the Table to this clause; and

(b) the food complies with any conditions listed in column 2 of the Table to this clause; and

(c) the claim expressly states, in words to the effect of those listed in column 3 of the Table to this clause –

(i) the property of the food, if applicable, and the specific health effect claimed in relation to that property of 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 and the specific health effect claimed; and

(d) the claim is presented so that all elements of the claim are in the one place on the label; and

(e) despite paragraph (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 (d) is placed.

Table to clause 7

Column 1	Column 2	Column 3
Substantiated diet-disease relationship	**Conditions**	**Claim statements**
Calcium, vitamin D and osteoporosis	(a) the food contains no less than 290 mg of calcium per serving; and (b) the food meets the scoring criteria in the Schedule to this Standard for making a health claim based on the food's nutrient profile.	(a) the property of the food is calcium; and (b) vitamin D may also be included as the property of the food if the food complies with any applicable conditions under clause 11 of this Standard for making a nutrition content claim in relation to vitamin D; and (c) the specific health effect is reduced risk of osteoporosis, enhanced bone mineral density or reduced risk of osteoporotic fracture; and (d) the population group is persons 65 years and over; and (e) the context is a healthy diet with a high intake of calcium from a variety of foods and adequate vitamin D status.
Calcium and enhanced bone density	(a) the food contains no less than 200 mg of calcium per serving; and (b) the food meets the scoring criteria in the Schedule to this Standard for making a health claim based on the food's nutrient profile.	(a) the property of the food is calcium; and (b) the specific health effect is enhanced bone mineral density; and (c) the context is a healthy diet with a high intake of calcium from a variety of foods.
Folic acid and neural tube defect	(a) the food contains no less than 65µg folate and/or folic acid per serving; and (b) the food meets the scoring criteria in the Schedule to this Standard for making a health claim based on the food's nutrient profile; and (c) the food is not – (i) soft cheese; or (ii) pâté; or (iii) liver or liver product; or (iv) regulated in Standard 2.4.2 containing phytosterol esters or tall oil phytosterols; or (v) food standardised in Standard 2.6.4; or (vi) food standardised in Part 2.7; or (vii) food standardised in Standard 2.9.1, 2.9.2 or 2.9.4; or (viii) a formulated meal replacement standardised in Standard 2.9.3.	(a) the property of the food is folate; and (b) the specific health effect is reduced risk of foetal neural tube defects; and (c) the population group is women of child bearing age; and (d) the context is a recommendation that women consume at least 670 µg of dietary folate equivalents per day or 400 µg of folic acid per day, at least the month before and three months after conception.

Saturated fatty acids and LDL cholesterol	(a) the food meets the conditions under clause 11 of this Standard for a nutrition content claim in relation to low saturated fatty acids; and (b) the food meets the scoring criteria in the Schedule to this Standard for making a health claim based on the food's nutrient profile.	(a) the property of the food is saturated fatty acids; and (b) the specific health effect is may help reduce blood cholesterol, total blood cholesterol, blood LDL cholesterol, serum LDL cholesterol, total serum cholesterol or serum cholesterol levels; and (c) the context is a healthy diet with a variety of foods low in saturated fatty acids.
Saturated and trans fatty acids and LDL cholesterol	(a) the food meets the conditions under clause 11 of this Standard for a nutrition content claim in relation to low saturated and trans fatty acids; and (b) the food meets the scoring criteria in the Schedule to this Standard for making a health claim based on the food's nutrient profile.	(a) the property of the food is saturated and trans fatty acids; and (b) the specific health effect is may help reduce blood cholesterol, total blood cholesterol, blood LDL cholesterol, serum LDL cholesterol, total serum cholesterol or serum cholesterol levels; and (c) the context is a healthy diet with a variety of foods low in saturated and trans fatty acids.
Sodium and blood pressure	(a) the food meets the conditions under clause 11 of this Standard for a nutrition content claim in relation to low salt; and (b) the food meets the scoring criteria in the Schedule to this Standard for making a health claim based on the food's nutrient profile.	(a) the property of the food is sodium or salt; and (b) the specific health effect is maintenance of normal blood pressure or reduced blood pressure; and (c) the population group is the general adult population; and (d) the context is a healthy diet with a variety of foods low in salt or sodium.
Increased intake of vegetables and fruit and coronary heart disease	(a) claims not permitted on fruit juice; and (b) the food contains no less than 90% vegetable and /or fruit by weight; and (c) the food meets the scoring criteria in the Schedule to this Standard 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 with an increased intake of both vegetables and fruit and consisting of a variety of foods; and (c) the claim must refer to vegetables before fruit.
A diet rich in vegetables and fruit and coronary heart disease	(a) claims not permitted on fruit juice; and (b) the food contains no less than 90% vegetable and /or fruit by weight; and (c) the food meets the scoring criteria in the Schedule to this Standard 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 rich in both vegetables and fruit and consisting of a variety of foods; and (c) the claim must refer to vegetables before fruit.

8 Conditions for cause-related marketing statements

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

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

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

9 Conditions for dietary information

(1) Subject to subclause (2), (3) and (4) dietary information may only be provided in a label on, or in an advertisement for the food if it relates to the associated nutrition content claim or health claim.

(2) 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.

(3) For dietary information about the food otherwise provided –

(a) where the dietary information refers to a whole food, a related nutrition content claim or health claim is not required; and
(b) the dietary information must directly relate to the associated food.

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

10 Conditions for small packages

(1) Where a health claim is made in relation to a food in a small package, the label on that package is exempt from conditions specified in –

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

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

11 Conditions for specific nutrition content claims

(1) Subject to meeting the conditions in column 3 of the Table to this clause, a nutrition content claim may be made –

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

Table to clause 11

Column 1	Column 2	Column 3
Property	**Descriptor**	**Nutrition content claim conditions**
Biologically active substance	Not applicable	(a) the claim does not include any descriptors in relation to the level of the substance that is present.
Cholesterol		(a) the food meets the conditions for a nutrition content claim in relation to low saturated fatty acids.
	Low	(a) the food contains no more cholesterol than – (i) 10 mg per 100 mL for liquid food; and (ii) 20 mg per 100 g for solid food.
	Reduced or Light/lite	(a) the food contains at least 25% less cholesterol as the same quantity of reference food; and (b) the claim states – (i) the identity of the reference food; and (ii) the difference between the cholesterol content of the food and the reference food; and (c) the claim is presented so that all elements of the claim are in the one place on the label.
Dietary fibre		(a) a serving of the food contains at least 2 g of dietary fibre.
	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 as the same quantity of reference food; and (b) the reference food meets the conditions for a nutrition content claim in relation to 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 claim is presented so that all elements of the claim are in the one place on the label.
	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; and (ii) 170 kJ per 100 g for solid food.
	Reduced or Light/Lite	(a) the food contains at least 25% less energy as the same quantity of reference food; and (b) the claim states – (i) the identity of the reference food; and (ii) the difference between the energy content of the food and the reference food; and (c) the claim is presented so that all elements of the claim are in the one place on the label.

	Diet	(a) the food meets the scoring criteria in the Schedule to this Standard for making a health claim based on the food's nutrient profile; and (b) the information in subclause 6(3) must be provided; and (c) the food – (i) meets the conditions for a nutrition content claim in relation to low energy; or (ii) contains at least 40% less energy as the same quantity of reference food; and (d) if (b)(ii) applies, the claim states – (i) the identity of the reference food; and (ii) the difference between the energy content of the food and the reference food; and (e) the claim is presented so that all elements of the claim are in the one place on the label.
Fat	% Free	(a) the food meets the conditions for a nutrition content claim in relation to low fat.
	Low	(a) the food contains no more fat than – (i) 1.5 g per 100 mL for liquid food; and (ii) 3 g per 100 g for solid food.
	Reduced or Light/Lite	(a) the food contains at least 25% less fat as the same quantity of reference food; and (b) the claim states – (i) the identity of the reference food; and (ii) the difference between the fat content of the food and the reference food; and (c) the claim is presented so that all elements of the claim are in the one place on the label.
Gluten		(a) the claim states whether it is a gluten free or a low gluten claim.
	Free	(a) the food contains – (i) no detectable gluten; and (ii) no – (A) oats or their products; or (B) cereals containing gluten that have been malted, or their products.
	Low	(a) the food contains no more than 20 mg gluten per 100 g of the food.

Glycemic Index		(a) the food meets the scoring criteria in the Schedule to this Standard for making a health claim based on the foods nutrient profile; and (b) the information in subclause 6(3) must be provided; and (c) the claim refers to the presence of the property of the food; and (d) the claim or the nutrition information panel under Standard 1.2.8 includes the numerical value of the glycemic index of the food; and (e) the claim may include the descriptors low, medium or high.
	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.
Lactose		(a) the claim states whether it is a lactose free or low lactose claim.
	Free	(a) the food contains no detectable lactose; and (b) the nutrition information panel indicates the lactose and galactose content.
	Low	(a) the food contains no more than 2 g of lactose per 100 g of the food; and (b) the nutrition information panel indicates the lactose and galactose content.
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 at least 25% more monounsaturated fatty acids as the same quantity of reference food; and (b) the reference food complies with the minimum conditions for a nutrition content claim in relation to monounsaturated fatty acids; and (c) 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 (d) the claim is presented so that all elements of the claim are in the one place on the label.
Omega fatty acids		(a) the type of omega fatty acid is specified immediately after the word ‘omega’.

Omega-3 fatty acids		(a) the food meets the conditions for a nutrition content claim in relation to omega fatty acids; and (b) the food contains no less than – (i) 200 mg alpha-linolenic acid per serving; or (ii) 30 mg total eicosapentaenoic acid and docosahexaenoic acid per serving; and (c) other than for fish or fish products with no added saturated fatty acids, the food contains – (i) as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and trans fatty acids; or (ii) no more saturated fatty acids and trans fatty acids than 5 g per 100 g; and (d) the nutrition information panel indicates the source and amount of omega-3 fatty acids, that is, alpha-linolenic acid, docosahexaenoic acid and/or eicosapentaenoic acid.
	Good source	(a) the food meets the conditions for a nutrition content claim in relation to omega-3 fatty acids; and (b) the food contains no less than 60 mg total eicosapentaenoic acid and docosahexaenoic acid per serving.
Omega-3 fatty acids	Increased	(a) the food contains at least 25% more omega-3 fatty acids as the same quantity of reference food; and (b) the reference food complies with the minimum conditions for a nutrition content claim in relation to omega-3 fatty acids; and (c) the claim states – (i) the identity of the reference food; and (ii) the difference between the omega-3 fatty acid content of the food and the reference food; and (d) the claim is presented so that all elements of the claim are in the one place on the label.
Omega-6 fatty acids		(a) the food meets the conditions for a nutrition content claim in relation to omega fatty acids; and (b) 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% omega-6 fatty acids.
	Increased	(a) the food contains at least 25% more omega-6 fatty acids as the same quantity of reference food; and (b) the reference food complies with the minimum conditions for a nutrition content claim in relation to omega-6 fatty acids; and (c) the claim states – (i) the identity of the reference food; and (ii) the difference between the omega-6 fatty acid content of the food and the reference food; and (d) the claim is presented so that all elements of the claim are in the one place on the label.

Omega-9 fatty acids		(a) the food meets the conditions for a nutrition content claim in relation to omega fatty acids; and (b) 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% omega-9 fatty acids.
	Increased	(a) the food contains at least 25% more omega -9 fatty acids as the same quantity of reference food; and (b) the reference food complies with the minimum conditions for a nutrition content claim in relation to omega-9 fatty acids; and (c) the claim states – (i) the identity of the reference food; and (ii) the difference between the omega-9 fatty acid content of the food and the reference food; and (d) the claim is presented so that all elements of the claim are in the one place on the label.
Polyunsaturated 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% polyunsaturated fatty acids.
	Increased	(a) the food contains at least 25% more polyunsaturated fatty acids as the same quantity of reference food; and (b) the reference food complies with the minimum conditions for a nutrition content claim in relation to polyunsaturated fatty acids; and (c) the claim states – (i) the identity of the reference food; and (ii) the difference between the polyunsaturated fatty acid content of the food and the reference food; and (d) the claim is presented so that all elements of the claim are in the one place on the label.
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.
	Good source	(a) the food contains at least 10 g of protein per serving.
	Increased	(a) the food contains at least 25% more protein as the same quantity of reference food; and (b) the reference food complies with the conditions for a nutrition content claim in relation to protein; and (c) the claim states – (i) the identity of the reference food; and (ii) the difference between the protein content of the food and the reference food; and (d) the claim is presented so that all elements of the claim are in the one place on the label.

Salt or sodium		(a) the nutrition information panel indicates the potassium content.
	Low	(a) the food contains no more sodium than – (i) 120 mg per 100 mL for liquid food; and (ii) 120 mg per 100 g for solid food.
	Reduced or Light/Lite	(a) the food contains at least 25% less sodium as the same quantity of reference food; and (b) the claim states – (i) the identity of the reference food; and (ii) the difference between the sodium or salt content of the food and the reference food; and (c) the claim is presented so that all elements of the claim are in the one place on the label.
Salt or sodium (continued)	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 in relation to no added salt.
Saturated and trans fatty acid	Low	(a) the food contains no more saturated and trans fatty acids than – (i) 0.75 g per 100 mL for liquid food; and (ii) 1.5 g per 100 g for solid food.
	Reduced 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 claim is presented so that all elements of the claim are in the one place on the label.
Saturated fatty acid	Free	(a) the food must be free of 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; and (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 as the same quantity of reference food; and (ii) no more trans fatty acids as the same quantity of reference food; and (b) the claim states – (i) the identity of the reference food; and (ii) the difference between the saturated fatty acid content of the food and the reference food; and (c) the claim is presented so that all elements of the claim are in the one place on the label.
Trans fatty acids	Free	(a) the food meets the conditions for a nutrition content claim in relation to low saturated fatty acids.
	Reduced or Light/Lite	(a) the food contains – (i) at least 25% less trans fatty acids as 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 claim is presented so that all elements of the claim are in the one place on the label.
Sugar or Sugars	% Free	(a) the food meets the conditions for a nutrition content claim in relation to low sugar.
	Low	(a) the food contains no more sugars as standardised in clause 1 of Standard 1.2.7 than – (i) 2.5 g per 100 mL for liquid food; and (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 1.2.7 as the same quantity of reference food; and (b) the claim states – (i) the identity of the reference food; and (ii) the difference between the sugars content of the food and the reference food; and (c) the claim is presented so that all elements of the claim are in the one place on the label.
	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 under Standard 2.6.1 or 2.6.2.

	Unsweetened	(a) the food meets the conditions for a nutrition content claim in relation to no added sugar; and (b) the food contains no intense sweeteners, sorbitol, mannitol, glycerol, xylitol, isomalt, maltitol syrup or lactitol.
Vitamin or mineral		(a) the vitamin or mineral is listed in column 1 of the Schedule to Standard 1.1.1; and (b) the food is a claimable food; and (c) a serve of the food contains at least 10% of the RDI or ESADDI, for that vitamin or mineral; and (d) a claim must not be made – (i) comparing, whether expressed or implied, the vitamin or mineral content of the food with that of any other food except where expressly permitted in this Code; or (ii) that a food listed in column 1 of the Table to clause 2 of Standard 1.3.2 to which a vitamin or mineral has been added, contains in a reference quantity of the food, that vitamin or mineral, both added and naturally present, in greater proportion than that specified in column 4.
	Good source	(a) the food meets the conditions for a nutrition content claim in relation to that vitamin or mineral; and (b) a serve of the food contains no less than 25% of the RDI or ESADDI for that vitamin or mineral.

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.

(2) Claims solely relating to percentage free or low trans fatty acids must not be made.

(3) To avoid doubt, ‘slimming’ is not synonymous with ‘diet’.

12 Conditions for making specific general level health claims

Subject to meeting the conditions in column 2 of the Table to this clause, a general level health claim that refers directly or indirectly to a matter listed in column 1 of the Table to this clause may be made.

Table to clause 12

Column 1	Column 2
General level health claim	**General level health claim conditions**
Biologically active substance	(a) the claim states – (i) the level of the substance in the food; and (ii) the amount of the substance that is required to be consumed per day to achieve the specific health effect; and (b) a serve of the food contains at least 10% of the amount stated under (a)(ii); and (c) the supplier of the food has records substantiating the basis for the statement under (a)(ii).
Maternal folate consumption and normal foetal development	(a) the food meets the conditions for a high level health claim in relation to folic acid and neural tube defect; and (b) the claim states the context as required for a high level health claim in relation to folic acid and neural tube defect.
Weight loss or maintenance	(a) the food – (i) meets the conditions for making a low energy claim in the Table to clause 11; or (ii) contains at least 40% less energy as the same quantity of reference food, and (b) if a(ii) applies, the claim states – (i) the identity of the reference food; and (ii) the difference between the energy content of the food and the reference food; and (c) the claim states that the specific health effect must be considered in the context of the importance of regular exercise.

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

(1) Where a claimable food, containing at least one ingredient with added vitamins or minerals under Standard 1.3.2, contains more than one ingredient, the maximum claim permitted in relation to a vitamin or mineral present in a reference quantity of the claimable food, is calculated by adding together the quantity calculated for each ingredient in accordance with the formula set out in subclause (2), rounding to the nearest 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:

$$\mathbf{A = B_1 + B_2 \ldots . B_i}$$

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 x 100 g/reference quantity x 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 x 100/200 x 40/100 = 24 mg vitamin C

B_2 = 500 x 100/200 x 2/100 = 5 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 x 100/100 x 115/145 = 2.06 mg iron in 100 g meat

B_2 = 3 x 100/50 x 30/145 = 1.24 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).

SCHEDULE X

SCORING CRITERIA

There are several steps which must be completed in order to determine if a food product is eligible to carry a health claim. These steps are outlined in Table 1.

Table 1: Steps to determine if a food meets the scoring criteria

Section	Steps Involved
PART A **To be completed for all food products.**	Determine the category of food product
PART B **To be completed for category 1 and 2 food products only.**	Calculate baseline points Calculate the fruit and vegetable points (V points) Calculate protein points (P points) Calculate fibre points (F points) Calculate final score
PART C **To be completed for category 3 food products only.**	Calculate baseline points Calculate final score
PART D **To be completed for all food products.**	Assess the final score to determine whether the food meets the scoring criteria

PART A – Determine the category of food product

Part A is to be completed for all food products.

Table 2: Food Product Categories

Category	Food Products Included	Scoring criteria
Category 1	Beverages (excluding milk which meets the definition for a category 2 product).	Category 1 food products meet the scoring criteria if the final score is < 1 total point.
Category 2	Foods other than those included in category 1 or 3; and Milk as defined in Standard 2.5.1 or evaporated milks or dried milks as defined in Standard 2.5.7. These may be fortified with vitamins and minerals as listed in Standard 1.3.2 or have food additives added as listed in Standard 1.3.1 or permitted processing aids added as listed in the Tables to Standard 1.3.3, but no other food additives or substances can be added..	Category 2 food products meet the scoring criteria if the final score is < 4 total points.

Category 3	Cheese and processed cheese as defined in Standard 2.5.4 (with calcium content >320 mg/100 g)* and; Edible oil as defined in Standard 2.4.1; and Edible oil spreads as defined in Standard 2.4.2; and Margarine as defined in Standard 2.4.2; and Butter as defined in Standard 2.5.5.	Category 3 food products meet the scoring criteria if the final score is < 28 total points.

* All other cheeses (with calcium content ≤320 mg/100g) are classified as a category 2 food product.

PART B – Calculate points for category 1 and 2 food products

Part B is to be completed for category 1 and category 2 food products only.

Step 1. Calculate baseline points

Use Table 3 to determine the baseline points scored, depending on 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) and in accordance with the Table to clause 6. A maximum of ten points can be awarded for each nutrient.

Table 3: Baseline points for category 1 and category 2 food products

Points	Average energy content [17](kJ) per 100 g/100 mL	Saturated fatty acids (g) per 100 g/100 mL	Total sugars (g) per 100 g/100 mL	Sodium (mg) per 100 g/100 mL
0	≤335	≤1	≤4.5	≤90
1	>335	>1	>4.5	>90
2	>670	>2	>9	>180
3	>1005	>3	>13.5	>270
4	>1340	>4	>18	>360
5	>1675	>5	>22.5	>450
6	>2010	>6	>27	>540
7	>2345	>7	>31	>630
8	>2680	>8	>36	>720
9	>3015	>9	>40	>810
10	>3350	>10	>45	>900

[17] Average energy content is defined in Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions

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

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

What can count towards V Points?

Fruits, vegetables, nuts, coconut, spices, herbs, fungi, seeds and legumes can count towards V points. These are referred to as 'fruits, vegetables, nuts and legumes' throughout this step.

Fruits, vegetables, nuts and legumes that are fresh, cooked, frozen, preserved, pickled, pureed or dried and have undergone minimal processing (e.g. sliced, tinned, frozen, pure juices including concentrated juices and purees) can be included for the purposes of counting V points. Fruits, vegetables including potatoes and root vegetables and nuts which are whole, roasted, chopped, grated and ground can also be included for counting towards V points.

Fruit and vegetables that have been subject to further processing (e.g. deionised fruit juice sugars, powders which do not meet the definition of a fruit or vegetable, protein isolates, leathers or oils) cannot be used for V points. For example, a 100% spreadable fruit jam (ingredients figs (55%), deionised grape juice, fruit pectin and lemon juice) cannot score the maximum V points, as deionised fruit juice and fruit pectin cannot be used for V points.

Oils derived from fruits or vegetables (e.g. walnut oil, peanut oil), and ingredients derived from fruits and vegetables (e.g. powdered tomato, potato starch) cannot be used for V points.

Coconut should be treated as follows:

(i) the fresh coconut flesh should be scored as fruit;
(ii) the water in the centre of the coconut should be scored as 100% fruit juice;
(iii) the juice squeezed from the flesh (coconut cream) is comparable with fruit juice and should be scored as 100% fruit juice;
(iv) coconut milk that is coconut cream diluted with water should be scored based on dilution;
(v) desiccated and dried block coconut are equivalent to dried fruit and should be scored as dried fruit; and
(vi) coconut which is processed beyond the original product being juiced or dried cannot be used for V points (e.g. copha).

How to calculate V Points

Use Table 4 to determine the 'V points' scored. The percentage of fruits, vegetables, nuts and legumes in the food should be calculated in accordance with the appropriate method in Standard 1.2.10.

Use column 1 if the fruit, vegetables and legumes in the food product are all concentrated (including dried). For example, if dried fruit and tomato paste etc are the only fruit, vegetable, nut and legume component of the food product column 1 should be used.

Use column 2 if –

(i) there are no concentrated (or dried) fruit, vegetables or legumes in the food product, or
(ii) the percentage of all concentrated ingredients are calculated based on the ingredient when reconstituted (according to subclause 3(3) or 3(4) of Standard 1.2.10); or
(iii) the food product contains a mixture of concentrated and not concentrated fruit, vegetable, nut and legumes sources (after following the formula below in Table 4); or
(iv) the food product is potato crisps or a similar potato product.

A maximum of five points can be awarded.

Table 4: Fruit and Vegetable Points (V Points)

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

If the food product contains a mixture of concentrated and not concentrated fruit, vegetable, nut and legumes sources, the formula below must be followed in full.

% fruit, vegetables, nuts and legumes (fvnl) in column 2 of Table 4 =

$$\frac{\text{(\% non concentrated fvnl) + (2 x \% concentrated fvnl)}}{\text{(\% concentrated fvnl) + (2 x \% concentrated fvnl) + \% non fvnl ingredients}} \times 100$$

where % non concentrated/concentrated **fvnl** means the percentage of fruit, vegetables, nuts and legumes in the food determined using the appropriate calculation methods outlined in Standard 1.2.10.

For the purposes of the formula above, potato crisps and similar potato products should be treated as non concentrated.

After the %fvnl has been calculated, use column 2 in Table 4 to determine the V points.

Step 3. Calculate Protein Points (P Points)

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.

Food products that score ≥11 baseline points are not permitted to score points for protein unless they score the maximum number of points allowed for fruit, vegetables, nuts or legumes.

Table 5: Protein Points (P Points)

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

Step 4. Calculate Fibre Points (F Points)

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.

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

Table 6: Fibre Points (F Points)

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

Step 5. Calculate Final Score

Final Score = baseline points – (V points) – (P points) – (F points)

Determine whether the food product meets the scoring criteria set out in Table 8 in Part D in order to be eligible to carry a health claim.

PART C – Calculate points for category 3 food products

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

Step 1. Calculate baseline points

Use Table 7 to determine the baseline points scored, depending on the content of each component in the food product.

Table 7: Baseline points for category 3 food products

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	≤ 4.5	≤ 90
1	>335	>1	>4.5	>90
2	>670	>2	>9	>180
3	>1005	>3	>13.5	>270
4	>1340	>4	>18	>360
5	>1675	>5	>22.5	>450
6	>2010	>6	>27	>540
7	>2345	>7	>31	>630
8	>2680	>8	>36	>720
9	>3015	>9	>40	>810
10	>3350	>10	>45	>900
11	>3685	>11		>990
12		>12		>1080
13		>13		>1170
14		>14		>1260
15		>15		>1350
16		>16		>1440
17		>17		>1530
18		>18		>1620
19		>19		>1710
20		>20		>1800
21		>21		>1890
22		>22		>1980

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
23		>23		>2070
24		>24		>2160
25		>25		>2250
26		>26		>2340
27		>27		>2430
28		>28		>2520
29		>29		>2610
30		>30		>2700

Total baseline points =

(points for average energy content) + (points for saturated fatty acids) + (points for total sugars) + (points for sodium)

Step 2. Calculate Final Score

Final Score = Baseline points

Refer to Part D to determine whether the food product meets the scoring criteria in order to be eligible to carry a health claim.

PART D – Assessment of the Final Score

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

Table 8: Scoring criteria for food categories

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

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

[4.1] *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 and health claims.

This Standard does not apply to infant formula products where either Standard 2.9.1 – Infant Formula Products or Standard 1.1A.1 – Transitional Standard for Infant Formula Products otherwise provides. Standard 2.9.1 sets out specific nutrition labelling requirements that apply to infant formula products.

[4.2] *omitting clause 1, substituting* –

1 Definitions

In this Standard –

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

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

[4.4] *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 –

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

(2) Subject to subclause (3), where a nutrition content claim or health claim is made in relation to a food which is not required to bear a label pursuant to clause 2 of Standard 1.2.1, the information prescribed in clauses 5 and 7A, must be –

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

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

[4.5] *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		

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

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

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

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

(2A) For foods for which there are compositional requirements specified in Standard 2.4.1 or Standard 2.4.2, the quantity of saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids and trans fatty acids may be set out in the panel as a minimum or maximum quantity in a serving of the food and per 100g/ml.

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

[4.10] *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) Where percentage daily intake information is included in a panel –

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

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

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

(ii) 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) Where the percentage daily intake of nutrients and energy is included in a nutrition information panel, the same information may also be presented outside the nutrition information panel, provided -

(a) the percentage daily intake information in paragraph 2(b)(i) is provided; and

(b) the information is presented in the one place on the label; and

(4) The percentage daily intake for energy may be presented outside the nutrition information panel provided the percentage daily intake for energy, fat, saturated fatty acids, protein, carbohydrate, sugars and sodium are all included in the nutrition information panel.

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

(6) Where the percentage daily intake of nutrients and energy is provided according to subclause (3) or subclause (4), the same information is not a nutrition content claim.

(7) Where the percentage daily intake of nutrients and energy is presented both in the nutrition information panel and outside the nutrition information panel, the values must be based on the same form of the food.

(8) The percentage daily intake values must be calculated based on the nutrient values declared 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 – saturated	g g	% %	g g
Carbohydrate – sugars	g g	% %	g g
Sodium	mg (mmol)	%	mg (mmol)
(insert any other nutrient or biologically active substance to be declared)	g, mg, μg (or other units as appropriate)	%	g, mg, μg (or other units as appropriate)
*based on an average adult diet of 8700 kJ			
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 – saturated	g (%DI) g (%DI)	g g
Carbohydrate – sugars	g (%DI) g (%DI)	g g
Sodium	mg (mmol) (%DI)	mg (mmol)
(insert any other nutrient or biologically active substance to be declared)	g, mg, μg (or other units as appropriate) (%DI or RDI as appropriate)	g, mg, μg (or other units as appropriate)
*Percentage daily intakes are based on an average adult diet of 8700 kJ		
Reference to glycemic index, if not in claim		

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

Table to subclause 7(9)

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) Where a nutrition content claim or health claim is made in relation to the presence of a vitamin or mineral, the information relating to the percentage RDI 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 vitamins or minerals that are included in the panel must be calculated using the reference values specified in the Schedule to Standard 1.1.1 and using the nutrient values declared in the nutrition information panel.

(3) Where the percentage RDI of vitamins or minerals is included in a nutrition information panel, the same information may also be presented outside the nutrition information panel.

(4) The percentage RDI of vitamins or minerals of a food that contains more than 1.15% alcohol by volume, may not be presented outside the nutrition information panel.

(5) Where the percentage RDI of vitamins or minerals is also presented outside the nutrition information panel the information must be presented in the one place on the label.

(6) Where the percentage RDI of vitamins or minerals is provided according to subclause (3), that information is not a nutrition content claim.

(7) Where the percentage RDI of vitamins or minerals is declared both in the nutrition information panel and outside the nutrition information panel, the values must be based on the same form of the food.

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 and a percentage RDI declaration is not required.

[4.10] *omitting clause 8, substituting –*

8 Food in small packages

(1) Subject to subclause (3), where a nutrition content claim or health claim is made in relation to a food in a small package, the label on that package must include a declaration, expressed in accordance with clause 5 of this Standard of –

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

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

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

(c) the saturated fatty acids, trans fatty acids, polyunsaturated fatty acids and monounsaturated fatty acids content per unit quantity of the food where a nutrition content claim or health claim is made in respect of –

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

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

(2) Subject to subclause 3 where a nutrition content or health claim is made in relation to –

(a) the omega-3 fatty acid content of a food in a small package, the label must indicate the source and amount per unit quantity of omega-3 fatty acids, namely, alpha-linolenic acid, docosahexaenoic acid and/or eicosapentaenoic acid; or

(b) the potassium content of a food in a small package, the label must indicate the sodium and potassium content of the food per unit quantity; or

(c) the lactose content of a food in a small package, the label must indicate the galactose content of the food per unit quantity.

(3) The information required to be declared in subclauses (1) and (2) need not be set out in the prescribed panel format in clause 5 of this Standard.

(4) Where a nutrition content or health claim is made in relation to a vitamin or mineral in a food in a small package, the label on that package is not required to set out % RDI of vitamins and minerals in accordance with clause 7A of this Standard.

Editorial note:

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

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

Division 3 – Miscellaneous

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

(1) Subject to subclause (2), the methods set out in the Table to this subclause are the prescribed methods of analysis for the determination of total dietary fibre and any specifically named fibre content of food for the purposes of nutrition 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, 17th Edition, 1st Revision (2002)
Inulin and fructooligosaccharide	Section 997.08 of the AOAC, 17th Edition (2000).
Inulin	Section 999.03 of the AOAC, 17th Edition (2000).
Polydextrose	Section 2000.11 of the AOAC, 17th Edition, 1st Revision (2002)

(2) The results obtained using the analytical methods outlined in column 2 of the Table to subclause 12(1) must be 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.

[5] ***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.

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

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

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

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

Table of Provisions

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

[6.3] *omitting clause 1*

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

1 Prohibition on adding vitamins and minerals to food

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

2 Permitted addition of vitamins and minerals to food

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

Table to clause 2

[6.7] *omitting clauses 4 to 9*

[7] ***Standard 2.6.2*** *of the Australia New Zealand Food Standards Code is varied by omitting the* Editorial note *after subclause 8(3), substituting –*

Editorial note: A claim that an electrolyte drink is isotonic is not considered a nutrition content claim for the purposes of Standard 1.2.7 of this Code. For New Zealand purposes, if a claim is made on a product under subclause 8(3), the claim would contravene the New Zealand Medicines Act, unless the claim has been approved by the Minister.

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

[8.1] *omitting the* Editorial note *after subclause 6(3), substituting* **–**

Editorial note: Average energy content is defined in Standard 1.1.1.

[8.2] *omitting paragraph 9(1)(f)*

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

(1A) The conditions in the Table to clause 11 of Standard 1.2.7 which refer to the salt, sodium or potassium content of a food do 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 –*

[10.1] *omitting from paragraph 5(2)(b)* ; and, *substituting* .

[10.2] *omitting paragraph 5(2)(c).*

[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) does not 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*