

Nutrition, Health and Related Claims

**A guide to the development of a food standard
for Australia and New Zealand**

March 2007

Introduction

FSANZ is developing a new food standard for nutrition, health and related claims, that is, claims about foods and their nutritional or health benefits. This is a complex issue, requiring wide consultation throughout the community.

Our proposed approach seeks to...

Remove ambiguity and uncertainty in the marketplace

Nutrition content claims are currently regulated by fair trade legislation and some are also regulated by the *Australia New Zealand Food Standards Code*. In Australia, nutrition content claims are also managed by a voluntary industry code of practice.

At present, we prohibit the use of health claims on food labels (except by specific approval). This approach constrains innovation by industry, leading to limitations on consumer choice. The proposed food standard will address these constraints and reduce ambiguity in enforcement.

Provide a comprehensive framework for nutrition and health claims on food

We are proposing a new standard that will allow truthful claims to be made, giving consumers information to make informed choices. Compliance with the new regulations will be mandatory and enforceable.

Protect consumers from misleading or deceptive claims

Statements or symbols on a food label, implying or claiming a nutritional or health benefit for that food, must be truthful and be capable of scientific verification. FSANZ has taken steps to prevent misleading or deceptive claims by developing measures aimed at maintaining public confidence in food labels as a source of credible information.

Assist consumers to select foods for healthy diets

We have built safeguards into the proposed measures to promote healthy food choices in line with nationally accepted guidelines for healthy eating to ensure consumers are not misled by marketing and promotional claims.

Provide new opportunities for industry

To justify the costs of developing new food products, manufacturers need to be able to inform consumers about the benefits of these products. We believe an innovative food industry is in the best interests of Australia and New Zealand.

Ensure due regard is given to costs to consumers and industry

We adhere to the principle of minimum effective regulation when setting food standards. Should a food manufacturer wish to make a voluntary claim, we will ensure that the extra regulatory impost on the manufacturer will be the least possible. In addition, we have recommended appropriate lead-in times to allow food businesses to make the necessary adjustments in an orderly manner.

Develop support in the community for the proposed new rules

An integral part of FSANZ's approach to the development of nutrition and health claims regulations has been the unprecedented level of community consultation on the issue. We have engaged, and continue to engage, individuals and organisations with an interest in the proposed measures, in the knowledge that effective regulation must have broad community support.

What stage are we at with this Standard?

FSANZ has undertaken two rounds of public consultation on the Standard, as well as many targeted consultations. Numerous and extensive comments were received to the last report released for comment. We have considered these comments carefully and, where appropriate, performed some targeted research. Whilst we are 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 our approach to many minor issues, we are recommending modification of some other significant elements. As a result, we have produced a Preliminary Final Assessment Report (PFAR), which we are now opening up to an additional round of consultation.

The areas in which we have revised our recommendations and are now asking for comment on are:

- Nutrient profiling model (previously known as disqualifying criteria);
- Risk management of nutrition content claims;
- Criteria and conditions for some nutrition content claims;
- Endorsements;
- Dietary information;
- Application of the Standard
- Further high level health claims, and
- Other minor changes.

Detail on these consultation issues can be found on page 8 of this guide.

This guide

Food Standards Australia New Zealand (FSANZ) is an independent bi-national agency responsible for setting food standards for Australia and New Zealand, which appear in the *Australia New Zealand Food Standards Code* (the Code).

FSANZ is developing a new standard for regulating nutrition and health claims. This Guide provides individuals and organisations with an interest in nutrition, health and related claims with information on proposed revisions to the approach previously recommended by FSANZ in November 2005.

Underpinning this document is a report that presents the details around the revised recommendations, as well as a revised draft standard for incorporation into the Code. You can access this information from the FSANZ website at: www.foodstandards.gov.au.

The report also contains our responses to some of the issues raised by the public, industry, government and public health groups during our last round of consultation. We have carefully considered these views. While it is not possible for us to reconcile opposing opinions, we believe that the revisions outlined in this guide will contribute to a regulatory measure that provides consumers with information to assist in selecting healthy diets.

We invite the community to examine the content of the revisions to the proposed standard and provide comment.

This third period of consultation will operate from 21 March 2007. If you would like to make a written submission, please see the FSANZ website on how to do this. You should look for the identification number **P293** for more details.

Your views are important to us. They will help shape new regulations for the making of nutrition and health claims in Australia and New Zealand.

We invite you to let us know what you think by 02 May 2007.

Timeline for the Nutrition, Health and Related Claims Standard:

21 March 2007:	Preliminary Final Assessment Report released for public comment
2 May 2007:	Close of submissions
August 2007:	Final Assessment Report to be considered by FSANZ Board

Background

The *Australia New Zealand Food Standards Code* contains regulations – known as food standards – for the composition and labelling of foods sold in Australia and New Zealand.

At present, the Code prohibits the use of claims on food labels that link a food with a health benefit, with the exception of the link between added folic acid and the prevention of neural tube defects in babies. The Code and fair trading law regulates nutrition content claims. Voluntary codes of practices, developed by industry, provide further guidance to food manufacturers in Australia.

In December 2003, the Australia and New Zealand Food Regulation Ministerial Council asked FSANZ to develop a standard and an appropriate management system for the regulation of nutrition, health and related claims. This recognised the increasing complexity of the food supply, especially with the increasing presence of functional foods, and the benefits of regulating nutrition and health claims under a unified and mandatory system.

The Ministerial Council provided FSANZ with policy guidelines to consider in developing the standard. These policy guidelines recommend that manufacturers may make claims if the food is safe, and the claim is socially responsible, does not promote irresponsible consumption patterns, and is scientifically substantiated. They suggest that there must be enough of the specified component in the food to contribute to the claimed benefit. Certain foods are disqualified from health claims, including alcohol and infant formula, and claims must not promote unhealthy food consumption patterns.

We released an initial consultation document in August 2004 seeking views on how these policy guidelines should be translated into food regulations, and options for the way forward. Having considered the comments received, we released a second consultation document in November 2005 describing our preferred regulatory option and containing a draft food standard for inclusion in the Code.

From our second round of consultation we received numerous and detailed comments from 131 submitters. We have now carefully considered these, and in addition have carried out some targeted research to assist our decision making. As a result, we are recommending a number of revisions to our previous recommendations and are now introducing this additional round of consultation.

We will carefully assess comments received from this round of consultation before producing final recommendations for consideration by the FSANZ Board and, if approved, by the Ministerial Council.

How the claims system will work

Claims classification framework

Nutrition, health and related claims will be classified into three categories:

- Nutrition content claims are statements regarding the amount of a nutrient, energy or a biologically active substance in the food;
- General level health claims are claims that describe a relationship between the consumption of a food or constituent and particular benefits of the food in relation to health.
- High level health claims also describe a relationship between the consumption of a food or constituent and particular benefits of the food in relation to health, but these claims reference to a serious disease or condition, or a biomarker of a serious disease or condition.

The category of a claim determines how that claim is regulated, including the evidence required for substantiation (see below).

Regulatory approach

In our first round of consultation, FSANZ canvassed three alternative regulatory approaches to regulate nutrition, health and related claims. Of these, we have decided to approach regulation via a new standard within the Code. The standard will set the conditions and criteria for substantiation and approval of nutrition content claims, general level health claims and high level health claims. Pre-market substantiation and approval will be required for high level health claims, with a number of pre-approved claims appearing in the standard.

This approach will provide a legally enforceable standard, thereby creating a claims system in which manufacturers, consumers and jurisdictions can place a high level of confidence.

Nutrition, Health and Related Claims Standard

The proposed standard will appear as Standard 1.2.7 – Nutrition, Health and Related Claims in the *Australia New Zealand Food Standards Code*. Important provisions include:

- a requirement that all claims be substantiated
- criteria for foods allowed to make claims
- specific qualifying criteria for nutrition content claims (e.g. food described as ‘low salt’ must contain no more than 120mg sodium per 100g for solid food)
- additional labelling for some nutrition content claims (e.g. the level of potassium in the food must be declared if a claim about salt is made)
- specific conditions for some claims (e.g. a weight loss or weight maintenance claim must be made in the context of the importance of regular exercise)

- ❑ substantiated and approved claims about diet-disease relationships (e.g. low sodium diet assists in reducing blood pressure)
- ❑ recommendations for cause-related marketing and dietary information.

Substantiation

All nutrition and health claims on food will have to be scientifically substantiated.

FSANZ has developed a Substantiation Framework, which should be used by manufacturers before making a claim on a food product. For nutrition content claims, we require manufacturers to have proof that the nutrient, substance or property that is the subject of the claim is present at levels referred to in the claim.

For general level health claims, manufacturers can make claims based on a list of nutrient function statements considered by FSANZ to have been substantiated, or based on authoritative, generally accepted information sources.

Substantiation of high level health claims will involve a case-by-case assessment by FSANZ. Once a high level health claim is approved and listed in the standard, all manufacturers will be able to use it. We will approve a limited number of high level health claims to go into the standard before the standard becomes law.

Implementation, compliance and enforcement

In Australia, the proposed Standard will be enforced by state and territory government agencies and by the Australian Quarantine and Inspection Service (AQIS) for imported foods. In New Zealand, the New Zealand Food Safety Authority is responsible for enforcing the Standard. A Health Claims ‘Watchdog’ established by the governments of Australia and New Zealand will monitor and record complaints received about food-related nutrition content and health claims.

Issues we are currently consulting on

Nutrient profiling

Under the new health claims regulations, food eligibility criteria (previously known as disqualifying criteria) will operate in order to avoid the promotion, through the use of health claims, of certain categories of foods that are inconsistent with national dietary guidelines. This approach allows the promotion of food products which can make a positive contribution to a healthy diet. In our previous report, we proposed a very simple scheme to determine which foods could carry health claims – based on foods not exceeding defined levels of total sugar, sodium and saturated fat per serve of food. However, this approach, whilst easy to implement and enforce, also produced significant anomalies. For example, some foods intrinsically high in sugars, such as some fruits and dairy products, were prohibited from carrying health claims.

We have therefore investigated a number of different models and are now proposing to use a nutrient profiling system. This model takes account of the level of sugar, sodium, saturated fat and total energy within a food, but also takes account of levels of beneficial nutrients – fibre, protein and fruit and vegetable content. Extensive testing against more than 10,000 products in the Australian and New Zealand food supply indicates that the model aligns well with the evaluation criteria we defined for assessing its application. FSANZ has made an electronic calculator available on its website to enable industry and others to evaluate this model by applying it to specific products.

Risk Management of Nutrition Content Claims

In our previous report we proposed to mandate an additional labelling requirement, based on percentage daily intake information, to assist consumers in correctly interpreting the nutritional value of a food carrying a nutrition content claim. However, considerable concerns were raised by submitters in relation to the value of this additional requirement. In response, we have conducted further consumer research. Results indicate that this additional labelling measure is not likely to be beneficial to consumer understanding of nutrition content claims.

We have therefore revised our recommendations to remove the mandatory requirement for percentage dietary intake information for foods carrying nutrition content claims. However, we will again consider the need for further risk management in the future. We have also made revisions to the proposed regulations around the voluntary use of percentage daily intake information by industry and have specified conditions for its use. [Food Standards Australia New Zealand: Nutrient Profiling Calculator](#)

Nutrition Content claims

We received a range of comments in relation to the criteria and conditions for specific nutrition content claims recommended in our previous report. We have carefully considered these comments and have revised our recommendations for a number of

nutrition content claims: wholegrain, saturated and trans fatty acids, fibre, ‘no added sugar’ and ‘no added salt’, glycaemic index, light/lite and comparative claims.

Endorsements

A number of objections, including some legal, were raised in relation to the recommendations for endorsements made at our last consultation. We now intend to exclude endorsements (as defined in the regulations) made by endorsing organisations (as defined by the regulations) from needing to comply with the health claims regulations. This is essentially a move towards self-regulation.

Definition of dietary information

A number of shortcomings with the previous recommendations were identified by both stakeholders and our own legal counsel. As a result, we have amended our recommendations to ensure that general dietary information is allowed on food labels or in an advertisement if it is related to an associated nutrition content or health claim, or where the dietary information refers to a whole food. Examples include:

“Dietary guidelines recommend that we eat plenty of fruit” (A related nutrition content or health claim would not be required if this statement was placed on fruit)

“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’.

We have also clarified the situation regarding permission for moderation statements on alcohol.

High level health claims

We are consulting on the outcomes of reviews for three further diet-disease relationships:

- We are proposing two pre-approved high level health claims based on the substantiated relationship between fruit and vegetable consumption and coronary heart disease.
- The evidence relating to wholegrains, bran and coronary heart disease was not considered to be convincing and therefore there will not be a pre-approved high level health claim arising from this relationship.
- The evidence relating to omega-3 fatty acids and cardiovascular disease was considered to be ‘probable’ but not convincing. This is sufficient to support a general level health claim based on dietary consumption of long-chain omega-3 fatty acids and cardiovascular health but there will not be a pre-approved high level health claim arising from this relationship.

Other minor changes

We have also made a number of minor changes:

- extended the classes of ineligible foods to include kava, for which no nutrition content or health claims may be made;
- permitted nutrition content claims in relation to energy, alcohol or carbohydrate on foods containing more than 1.15% alcohol;
- addressed the form of food that can be used as the basis of a claim, that is – as sold, or as prepared;
- clarified that the claims regulations will only apply to food that is for retail sale except for food served to clients in hospitals or similar institutions; or to food for catering purposes;
- revised the conditions for weight management claims and diet claims; and
- altered the wording conditions for small packages and split claims.

Information items

We are providing some information items around issues that have been raised by stakeholders, particularly in relation to: the impact of the new nutrient reference values, the interaction of trademark law and the proposed regulations, the proposed changes to vitamin and mineral conditions, a subsequent review of special purpose foods, and additionally have provided information on changes required to New Zealand's Medicines Act in order to permit health claims on foods in New Zealand.

Issues raised during consultations

What about the diversity of views?

Many interested groups including consumers, industry, public health agencies and jurisdictions have contributed to the development of this standard. Consumers are driven by the need for healthy foods and the appropriate information; industry to innovate; and public health agencies to protect public health. We have had to take these different, and sometimes conflicting, perspectives into account. We have attempted to strike a balance between the views, while maintaining the integrity of the science underpinning the process.

Will all foods be able to carry health claims?

FSANZ has set eligibility rules, known as nutrient profiling, for those foods that can carry health claims. This is to ensure that only appropriate foods may carry claims. Initially we considered introducing a simple system using generic eligibility criteria for health claims on foods based on their levels of salt, saturated fats and sugar. However, as discussed above, a considerable number of stakeholders objected to this simple approach, citing its failure to discriminate between foods that should be able to carry health claims – such as some fruits and some dairy products – and those that should not – such as some biscuits and confectionery. In response, we have undertaken further modelling work and are now proposing to adopt a nutrient profile system. This model takes account of the level of sugar, sodium, saturated fat and total energy within a food, but also takes account of levels of beneficial nutrients – fibre, protein and fruit and vegetable content. This nutrient profiling system will apply to all health claims (both general level and high level), but not to nutrition content claims.

We have also identified foods ineligible to carry health claims - infant formula and alcohol. Following comments made on the draft assessment report we are also proposing to exclude kava from carrying nutrition and health claims.

Why identify individual foods which are considered ‘healthy’ when it is the overall diet which is important?

The nutrient profiling system will permit health claims on food products which make a positive contribution to a healthy diet. FSANZ can not regulate a total diet but can develop food standards which encourage consumption of foods which contribute to a healthy diet.

Couldn't you have developed a simpler method to decide whether foods could carry health claims?

The nutrient profiling model will be simple for users to use. To help industry we have developed an easy to use electronic calculator which will be available on the FSANZ website and which will be linked to the nutrition panel calculator, used to determine the levels of nutrients in different foods for labelling purposes. Consumers will not need to assess the overall healthiness of the food themselves when they see a health claim. A more complex system than that proposed at Draft Assessment was needed in

order to sufficiently discriminate between foods which are contributors to a healthy diet and those which are not.

Why can't you leave it to people to judge the healthiness of the foods themselves?

Consumers will not need to assess the overall healthiness of the food themselves when they see a health claim. That can be a difficult thing to do – to take account of the different levels of a number of beneficial and risk-increasing nutrients. This way the hard work is done for them and it ensures they are not misled by a health claim.

Will the pre-market assessment process for high level health claims protect a company's intellectual property or market advantage?

The pre-market assessment process, as set out in FSANZ's statutory procedures, involves two rounds of public consultation. This means that some information will be widely available. In certain situations, and following special application, we can consider specific scientific data as commercial-in-confidence until any claim is approved. Other forms of intellectual property protection – for example, a patent – can also assist.

Recently the Ministerial Council recommended changes to the FSANZ Act, which when implemented, will mean in the future it will be possible to keep applications for high level health claims confidential, until any claim is approved. The applicant would receive a first to market advantage due to confidentiality of the application process.

What about claims regarding vitamins and minerals?

Reference values for vitamins and minerals have recently been revised. FSANZ has decided to defer consideration of the criteria and conditions for all claims relating to vitamins and minerals until a later date, as the task is complex and also has wide ranging implications for other aspects of food regulation. However one minor change to these claims has been made. This arises from a change in the unit of measure for determining whether there is sufficient of the claimed vitamin or mineral present in the food.

Will consumers have the right information to make healthy choices?

Once the proposed new standard comes into effect, new products and new claims on existing products will be available to consumers. The intent of the new regulation will be to provide consumers with appropriate information to make informed choices when considering products carrying claims.

How likely are consumers to misunderstand or misinterpret the claims?

This issue has been at the forefront of FSANZ work. We believe that the proposed standard provides the framework for the sale of food products with clear, unambiguous claims, made by responsible manufacturers. We will be providing guidance on wording for many claims and the Standard will also prevent the use of implied claims, which could mislead consumers.

How will the new requirements be enforced?

Responsibility for implementation and enforcement of the Code lies with the designated authorities within the states and territories of Australia and with the New Zealand Food Safety Authority.

Will implementation of the Standard be monitored?

An independent ‘watchdog’ body has been appointed to monitor implementation and handle complaints.

What will be done to educate consumers, industry and enforcement agencies?

FSANZ is planning an education program and will assist in briefing interested organisations where required. Our website will act as key means of promoting awareness. In consultation with our regulatory partners, we will explore other awareness programs.

Where to find further information:

- A summary of the changed recommendations which are currently being consulted on is given at Appendix 1.
- Further detail of the changed recommendations can be found within the Preliminary Final Assessment Report for P293, located on the FSANZ website: [insert weblink to PFAR](#)
- A summary of the recommendations proposed in the Draft Assessment Report for Proposal P293, which are not being further consulted on is included at Appendix 2.
- Details of the criteria and conditions for specific nutrition content claims and for specific types of health and related claims can be found in the Draft Assessment Report, on the FSANZ website: [Draft Assessment Report for P293 - Nutrition, Health and Related Claims](#)
- Examples of nutrition and health claims are given in Appendix 3.
- Other documents relating to development of the standard for nutrition, health and related claims standard are also on our website at: www.foodstandards.gov.au, including:
 - Ministerial Policy Guideline on Nutrition, Health and Related Claims.
 - FSANZ Substantiation Framework.
 - Fact sheet: Nutrition and Health Related Claims.
 - Information for individuals and organisations intending to make a submission.

Appendix 1 - Summary of Changed Recommendations in the Preliminary Final Assessment Report for P293: Health , Nutrition and Related Claims

Conceptual framework	<ul style="list-style-type: none"> • Claims will be classified as nutrition content claims, general level health claims and high level health claims.
Issues related to application of the standard	<ul style="list-style-type: none"> • Extension of ineligible foods to include kava. • Nutrition content claims will be permitted for foods that contain 1.15% alcohol, or more, in relation to alcohol, energy or carbohydrate content. • Where a nutrition content claim in relation to energy or carbohydrate is made on an alcoholic beverage (with an alcohol content of more than 1.15%) a Nutrition Information Panel is required • Claims may be based upon a food “as sold” or “as prepared”, under appropriate circumstances.
Issues related to nutrition content claims	<ul style="list-style-type: none"> • Requirement for percentage daily intake labelling on foods carrying nutrition content and health claims removed. • Permissions for voluntary %DI labelling given, under specific circumstances. • Descriptors in relation to the level of the ‘property’ of the food that is present are not permitted unless conditions are given in the health claims standard, or there is a reference value for that property in the Code.
Criteria for specific nutrition content claims	<ul style="list-style-type: none"> • Specific criteria for wholegrain nutrition content claims removed, with wholegrains to be considered as biologically active substances. • Some of the criteria for trans and saturated fatty acid claims revised. Criteria for ‘reduced’ and ‘free’ trans fatty acids are included. ‘Low’ claims for trans fatty acids are prohibited. Foods carrying a ‘free’ claim for saturated fatty acids must also be free of trans fatty acids. • For fibre nutrition content claims the definition of meal/main dish products will be removed and nutrition content claim criteria for “excellent source” of fibre or “very high fibre” claims will be added. • For ‘no added sugar’ and ‘no added salt’ claims there will be no requirement for a disclaimer stating that the food contains naturally occurring sugar or sodium, respectively. • Claims citing the glycaemic index will not have to be linked to an endorsement and manufacturers may use the descriptors ‘low’, ‘medium’ and ‘high’ on foods meeting the criteria. Nutrient profiling requirements will apply to foods carrying these claims. • The criteria and conditions for ‘lite’/‘light’ claims have not changed, but

	<p>the requirements have been repositioned within the Standard.</p> <ul style="list-style-type: none"> • For comparative nutrition content claims between ‘dietary substitutes’, comparisons will be limited to those 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. • Criteria for ‘diet’ claims simplified and made consistent with reduced energy claims
Issues related to health claims	<ul style="list-style-type: none"> • Nutrient profiling model to be applied to ensure foods carrying health claims are not inconsistent with national dietary guidelines. • Qualifying criteria for weight management claims made consistent with ‘diet’ nutrition content claims. • Two further high-level claims pre-approved, in relation to vegetable and fruit consumption and coronary heart disease.
Issues related to related claims	<ul style="list-style-type: none"> • Definition of dietary information revised in order to ensure that general dietary information is allowed on food labels or in an advertisement if it is related to an associated nutrition content or health claim, or where the dietary information refers to a whole food. Permission for moderation statements limited to alcohol. • Endorsements (as defined in the standard) made by endorsing organisations (as defined in the Standard) will be exempt from the regulations.
Issues related to wording conditions	<ul style="list-style-type: none"> • Wording requirements for small packages and split claims have been fine-tuned.
Substantiation of high level health claims	<ul style="list-style-type: none"> • Two new pre-approved high level health claims substantiated: <ul style="list-style-type: none"> ○ A diet high in vegetables and fruit and coronary heart disease ○ Increased intake of vegetables and fruit and coronary heart disease.

Appendix 2 - Summary of Recommendations Proposed in the Draft Assessment Report for P293: Nutrition, Health and Related Claims which are not being further consulted on

Conceptual Framework for Nutrition, Health and Related Claims

- There will be a step-up in regulation from nutrition content claims to general level health claims to high level health claims (relating to criteria, wording and pre approval).
- Claims must meet pre-requisite conditions to be permitted – they must be substantiated, they must refer to the property of the food and, in the case of health claims, they must state the health effect.
- The definition of ‘claim’ captures implied claims.
- Wording conditions will apply to general level health claims and high level health claims.

Regulatory Management for Nutrition, Health and Related Claims

- The proposed new standard for nutrition, health and related claims will specify the criteria and conditions around certain nutrition content claims and all general level and high level health claims.
- The requirements for substantiating claims will be in a guideline, which will be incorporated by reference into the health claims standard. This means claims will be legally required to be substantiated in accordance with the standard.
- A user guide will include interpretive advice concerning the requirements of the standard.

General Regulatory Approach for Nutrition Content Claims

- FSANZ is proposing to only prescribe criteria for nutrition content claims when there are reasons to do this, based on consideration of national nutrition guidelines and evaluation of consumers’ perception of the claims.
- Nutrition content claims and health claims already regulated by the Code will be included in the new draft standard, with some amendments to criteria for some claims.
- Criteria for claims in relation to vitamins and minerals have not been amended, pending consideration of the new nutrient reference values, with the exception of a change to a ‘per serve’ unit of measure.
- Some claims currently covered by voluntary codes of practice will be regulated by the new standard.
- There will not be generic compositional requirements to determine whether a food may carry a nutrition content claim, with the exception of glycaemic index nutrition content claims which must meet the nutrient profile scoring criteria. However there are specific disqualifying criteria for some nutrition content claims.
- FSANZ will not prescribe an exhaustive list of descriptors (‘rich in’, ‘more than’, ‘fewer’ etc) for nutrition content claims but will include a list in a user guide.

Criteria for General Level Health Claims

- Foods carrying general level health claims will need to meet the minimum qualifying criteria for corresponding nutrition content claims (either ‘source’ for risk decreasing nutrients or ‘low’ for risk increasing nutrients).

Ineligibility for General Level Health Claims

- Restrictions will be placed on nutrition content claims in relation to alcohol. Criteria as already defined for low alcohol claims and low energy (joule) will remain.
- ‘Light’ and similar claims on alcohol can only be made in respect of alcohol levels, energy and carbohydrate.
- Health claims will not be allowed on alcohol.
- Nutrition content claims and health claims on infant formula will be prohibited unless expressly permitted.
- Current permissions for use of claims on formulated supplementary sports foods and formulated meal replacements and supplementary foods will continue.

Regulatory Framework for High Level Health Claims

- Qualifying criteria, determined through the substantiation process, and specific compositional criteria (generally based on the nutrient profile model) where appropriate, will be used to determine which foods are eligible to bear specific high level health claims.
- High level health claims must be pre-approved by FSANZ.
- The criteria and conditions that apply to the pre-approved high level health claim for folic acid and foetal neural tube defect will also apply to the equivalent general level health claim.

Substantiation of Nutrition Content Claims and General Level Health Claims

- All general level health claims are either to be based on a list of pre-approved nutrient function statements, authoritative information sources or evidence prepared as specified in the Substantiation Framework.
- Holding the evidence for substantiation of nutrition content claims and general level health claims is the responsibility of individual suppliers.
- Pre-approval of nutrition content claims and general level health claims will not be required.

Substantiation of High Level Health Claims

- FSANZ is proposing to approve a number of high level health claims that will be available to use at the time the Standard comes into effect.
- To date the following diet-disease relationships have been substantiated:
 - Calcium, vitamin D and osteoporosis;
 - Calcium and bone mineral density;
 - Sodium and blood pressure;
 - Folic acid and neural tube defects;
 - Saturated fatty acids and LDL-cholesterol; and
 - Saturated and *trans* fatty acids and LDL-cholesterol.
- Suppliers may use high level health claims based on substantiated relationships, subject to defined specific criteria and conditions.
- Any new high level health claims require pre-approval by FSANZ through the normal application process to vary the Code.

Conditions around wording of health claims

- Wording conditions for health claims are specified – the claim must state the property of the food and the specific health effect in relation to that property. Health claims must also be made in the context of a healthy diet consisting of a variety of foods as appropriate to the type of food and specific health effect claimed.
- The health claim must state the population group to which the health effect relates to, where the evidence suggests that the specific health effect cannot be attributed to the general population.
- 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.
- Specific wording and labelling conditions for general level health claims regarding biologically active substances are proposed.

Transitional Period

- A 24 month transition period for the standard implementation will be applied and this includes a 24 month transition period for stock in trade.

Appendix 3 - Examples of nutrition and health claims

Nutrition content claims are statements regarding the amount of a nutrient, energy or a biologically active substance in the food. Manufacturers must have proof that the nutrient, substance or property that is the subject of the claim is present at levels referred to in the claim.

Description of the claim

Nutrition content claims describe or indicate the presence or absence of a component in food.

Example

'this food is high in calcium'

General level health claims can refer to the presence of a nutrient or substance in a food and to its effect on a health function. A general level health claim cannot refer to a serious disease or condition or to an indicator of a serious disease (e.g. blood cholesterol). Manufacturers must hold scientific evidence to substantiate such claims and produce this evidence, on request, for enforcement agencies.

Description of the claim

...a component and its function in the body.

Example

'calcium is good for strong bones and teeth, when consumed as part of a healthy diet containing a variety of foods'

...specific benefits for performance and well being in relation to foods

'gives you energy, when consumed as part of a healthy diet with a variety of foods'

...how a diet, food or component can modify a function beyond its role in normal growth and development

'exercise and a diet high in calcium helps build stronger bones, when combined with a healthy diet containing a variety of foods'

...potential for a food or component to assist in reducing the risk of or helping to control a non-serious disease or condition.

'yoghurt high in X and Y may reduce your risk of stomach upset, when consumed as part of a healthy diet with a variety of foods'

High level health claims refer to the presence of a nutrient or substance in a food and its relationship to a serious disease or condition or to an indicator of a serious disease. Manufacturers must obtain pre-market approval from FSANZ to make high level health claims and provide scientific evidence to substantiate the claims.

Description of the claim

Claim refers to the potential for a food or component to assist in controlling a serious disease or condition by either reducing risk factors or improving health.

Example

'This food is high in calcium. Diets high in calcium from a variety of foods may increase bone mineral density, which has particular importance for women.'

Claim refers to the potential for a food or component to assist in reducing the risk of a serious disease or condition.

'This food is low in sodium. A healthy varied diet including foods low in sodium may assist in reducing blood pressure.'