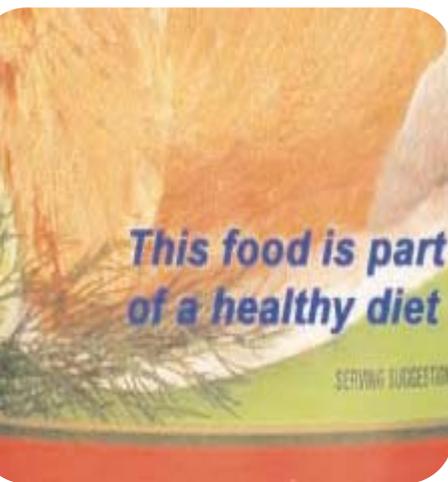


Nutrition, Health and Related Claims

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

November 2005



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Executive Summary

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 the *Australia New Zealand Food Standards Code* and trade practices law and, in Australia, 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-giving 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.

The new measures...

Provide a system to manage nutrition and health claims

Statements, information or other references to nutrients, nutrition, diet or health on food labels or in associated advertising must comply with new provisions in the *Australia New Zealand Food Standards Code*. Education materials will support the standard.

Distinguish between levels of claim

The proposed new measures identify **two** levels of claim (see examples on page 8):

General level claims

Content claims – describe what's in the food (e.g. the presence of a nutrient, vitamin or other substance)

General level health claims – describe the function of a nutrient, vitamin, mineral or other substance in relation to a health effect. These claims do not refer to serious disease or biomarker of serious disease.

High level health claims – describe the function of a nutrient, vitamin, mineral or other substance in relation to a serious disease (e.g. heart disease) or a biomarker of a serious disease (e.g. blood pressure).

Require mandatory substantiation of all claims

Manufacturers must ensure that claims are truthful and supported by adequate scientific evidence. High level health claims must undergo a pre-market assessment and approval, managed by FSANZ. General level health claims do not need a pre-market assessment and approval, but manufacturers must hold the necessary evidence for possible review by enforcement agencies.

Set criteria and conditions for foods for which claims can be made

Foods carrying claims must contain enough of the nutrient, vitamin, mineral or substance to contribute to the claimed effect. Also, FSANZ is proposing limits for certain risk-increasing nutrients, such as salt, saturated fats and sugars in the types of foods that may carry the claims.

And include...

Consolidation of existing claims into the new framework

We propose consolidating existing references to nutrition and health claims in the Code into this food standard to assist industry, government, consumers and public health groups with legal interpretations.

Management of endorsement programs and cause-related marketing

Existing endorsement programs will be pre-approved, providing they are consistent with the nutrition policy and principles of the respective national governments and managed by an independent, non-profit organisation. Future endorsements will be managed within the new framework. We propose excluding cause-related marketing statements from the standard because they serve a different purpose to nutrition and health claims. We will require an appropriate disclaimer if an organisation's name is related to a serious disease to avoid confusion.

Exclusion of certain statements and foods

General dietary advice provided to consumers lies outside the scope of the standard. We will continue to prohibit health claims on alcohol and infant formulas.

A phase-in period

To give industry time to make the required changes to labelling, and to alert consumers to the new rules, we are recommending a **24-month transition period** for implementation after the standard becomes law.

Guide to the proposed food standard

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*.

This Guide provides individuals and organisations with an interest in nutrition, health and related claims with information on the approach being adopted by FSANZ and our recommendations for the content of the standard.

Underpinning this document is a report that sets out in detail the reasons why new regulations are needed, options that we considered during the development of the standard and a draft standard for incorporating into the Code. You can access this information from the FSANZ website at www.foodstandards.gov.au.

The report also includes the policy guidelines that we received from the Australia and New Zealand Food Regulation Ministerial Council to be taken into account in developing the standard.

It also contains our responses to issues raised by the public, industry, government and public health groups during our first period of public consultation in August 2004. We have carefully considered these views. While it is not possible for us to reconcile opposing opinions, we believe that the proposed regulatory measures described in this Guide will provide consumers with information to assist in selecting healthy diets.

We now invite the community to examine the scope and content of the proposed food standard and to comment on our approach. We are also calling for comment from organisations with existing endorsement programs to be pre-approved by FSANZ.

This second period of consultation will operate from **28 November 2005** until **22 February 2006**. 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.

We will be holding public briefings in Sydney, Melbourne, Adelaide, Auckland and Wellington between 28 November and 9 December 2005.

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 22 February 2006.

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 folate and the prevention of neural tube defects in babies. The Code and trade practices law regulates nutrition content claims. Voluntary codes of practices, developed by industry, provide further guidance to food manufacturers.

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 all nutrition and health claims under a unified and mandatory system.

The ministerial council provided FSANZ with policy guidelines to be taken account of in developing the standard. We have reproduced these guidelines in a Draft Assessment Report.

The ministerial guidelines recommend that manufacturers make claims if the food is safe and the claims can be scientifically substantiated. They suggest that there must be enough of the active substance 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 the first consultation document in August 2004 seeking views on how these guidelines should be implemented and options for the way forward. We have considered comments from 147 submitters and have responded to them in the second report, issued on 28 November 2005. This Draft Assessment Report describes our preferred regulatory option and a draft food standard for inclusion in the Code.

We will carefully assess comments received on the second report before producing final recommendations for consideration by the FSANZ Board and, if approved, by the ministerial council.

Regulatory options

FSANZ has identified **three** alternative regulatory approaches to regulate nutrition, health and related claims on food. We canvassed these options during our first round of public consultation. The options currently under consideration differ only slightly from the options originally proposed:

1. Maintain the status quo. Specific nutrition content claims would continue to be regulated in the Code. Other content claims would be regulated by fair trading legislation, supported by voluntary industry practices. Health claims would be prohibited, unless specifically exempted from this prohibition.
2. A new standard in the Code covering prerequisites for all claims, along with criteria and conditions for high level claims. The standard would allow the making of nutrition and healths claims, provided they meet specific conditions and are fully substantiated. Pre-market substantiation and approval would be required for high level claims. A number of pre-approved high level claims would appear in the standard. Nutrition criteria for general level claims, prepared by FSANZ, would be provided in a Guideline document. Use of general level claims would be monitored by a management committee drawn from the food industry, jurisdictions, consumer groups, public health groups and FSANZ. The Guideline would not have the legal force of a standard.
3. A new standard for nutrition, health and related claims. The standard would set the conditions and criteria for the substantiation and approval of high level claims **and** general level claims. As described in option 2, pre-market substantiation and approval would be required for high level claims. Compliance with the conditions set out in the Code would be mandatory and legally enforceable by government.

We commissioned a benefit-cost analysis of the three options, specifically looking at the impact of the options on consumer welfare, the credibility of claims in the marketplace, opportunities for industry innovation, enforcement costs and adjustment costs for industry (see Draft Assessment Report).

The analysis showed that options 2 and 3 achieved significantly greater cost-benefit scores than option 1, maintaining the status quo, while option 2 was slightly ahead of option 3. However, we have selected **option 3** as the preferred option because we believe the legally enforceable nature of the standard will create a greater confidence in the claims system for manufacturers, consumers and jurisdictions.

Examples of nutrition and health claims

General level 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 may not refer to a serious disease or condition or to an indicator of a serious disease (e.g. blood cholesterol). Health claims cannot be made on alcohol or infant formulas. Manufacturers must hold scientific evidence to substantiate such claims and produce this evidence, on request, to enforcement agencies.

Description of the claim	Example
Nutrition content claims describe or indicate the presence or absence of a component in food.	<i>'this food is high in calcium'</i>
General level health claims refer to... ...maintenance of good health.	<i>'helps keep you regular as part of a high fibre diet'</i>
...a component and its function in the body.	<i>'calcium is good for strong bones and teeth'</i>
...specific benefits for performance and well being in relation to foods.	<i>'gives you energy'</i>
...how a diet, food or component can modify a function beyond its role in normal growth and development.	<i>'exercise and a diet high in calcium helps build stronger bones'</i>
...potential for a food or component to assist in reducing the risk of or helping to control a non-serious disease or condition	<i>'yoghurt high in X and Y as part of a healthy diet may reduce your risk of stomach upsets'</i>

High level health claims can 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. They cannot be made on alcohol or infant formulas. Manufacturers must obtain pre-market approval from FSANZ to make high level claims and provide scientific evidence to substantiate the claims.

Description of the claim	Example
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.	<i>'This food is high in calcium. Diets high in calcium may increase bone mineral density.'</i>
Claim refers to the potential for a food or component to assist in reducing the risk of a serious disease or condition.	<i>'This food is low in sodium. Diets low in sodium may reduce risk of elevated blood pressure.'</i>

How the claims system will work

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 (e.g. food carrying a health claim must contain no more than 16g total sugars per serve)
- ❑ specific qualifying criteria for nutrient content claims (e.g. food described as ‘low salt’ must contain no more than 120mg per 100g for solid food)
- ❑ additional labelling for some content claims (e.g. percentage of a daily reference value must be stated)
- ❑ specific conditions for some claims (e.g. a weight loss or weight maintenance claim must state that the specific health effect must be considered 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 endorsement programs, cause-related marketing and dietary advice.

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 content claims, we require suppliers 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 diet-disease relationship has been substantiated, and the associated claim listed in the standard, all manufacturers can use it. We will approve a limited number of high level 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 the responsible agency. A Health Claims ‘Watchdog’ established by the governments of Australia and New Zealand will monitor and record complaints received about food-related health claims.

Issues raised during consultations to date

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 for those foods that can carry health claims. This is to ensure that only appropriate foods may carry claims and to restrict entry of foods with high levels of 'risk-increasing' nutrients like salt, saturated fats and sugar. We have also identified foods ineligible to carry health claims (infant formula and alcohol) to guard against inappropriate consumption of the food.

Will the food standard apply to dietary information from health professionals?

No. Professional advice provided by dietitians and nutrition professionals falls outside the nutrition and health claims standard. There are exceptions to this – for example, if a nutritionist were to appear in an advertisement for a specific product. In such a case, the product would need to meet the health claims standard if a claim was being made.

Will the pre-market assessment process 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 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 are currently under review. FSANZ has decided to defer consideration of the criteria and conditions for all claims relating to vitamins and minerals until those values are finalised. 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 will also require more information about the contribution of the food to the total daily intake of certain nutrients. We 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, and for fair trading legislation, lies with the designated authorities within the states and territories of Australia and with the New Zealand Food Safety Authority.

Will implementation of the claims framework 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.

Having your say

We welcome your views on the issues and approaches outlined in this guide to the development of a food standard for nutrition, health and related claims. You can find other documents relating to this standard on our website at www.foodstandards.gov.au, including:

- Draft Assessment Report for Nutrition, Health and Related Claims (Proposal P293). This report contains a summary of submitters' comments from the first round of consultation.
- 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.

We must receive your submission by **Wednesday 22 February 2006**.

Timeline for the Nutrition, Health and Related Claims Standard

28 November 2005: Draft Assessment Report released for public comment
22 February 2006: Close of submissions
May 2006: Final Assessment Report to be considered by FSANZ Board

Summary of Recommendations Proposed in the Draft Assessment Report for P293: Health, Nutrition and Related Claims

Conceptual Framework for Health, Nutrition and Related Claims

- Claims will be classified as general level (including nutrition content claims and general level health claims) and high level.
- There will be a step-up in regulation from nutrition content claims to general level claims to high level 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 claims.

Regulatory Management for Health, Nutrition and Related Claims

- The proposed new standard for health, nutrition 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 Framework.
- 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 content claims when there are reasons to do this, based on consideration of the national nutritional guidelines and evaluation of consumers’ perception of the claims.
- All other content claims will be regulated only by Fair Trading regulations.
- 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 now be regulated by the new Standard.
- There will not be generic disqualifying criteria for nutrition content claims, but there are specific disqualifying criteria for some claims.
- Percentage daily intake (%DI) of the claimed nutrient is to be declared in the nutrition information panel when any claim is made in relation to protein, fat, saturated fatty acids, carbohydrate, sugars, sodium or salt and dietary fibre.
- The %DI for energy is to be declared in the nutrition information panel whenever

any nutrition content claim is made.

- Analytical methods to substantiate nutrition content claims will not be prescribed, apart from existing methodology for fibre 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 content claims (either 'source of' for risk decreasing nutrients or 'low in' for risk increasing nutrients).
- Foods meeting 'reduced' criteria only will not be permitted to make general level health claims.
- Generic disqualifying criteria will be applied to nearly all general level health claims, with exceptions for lactose and gluten claims and claims on infant foods.
- The disqualifying criteria require the food bearing the claim to be composed of less than or equal to:
 - Sodium – 325mg/serve
 - Saturated fat – 4g/serve
 - Total sugars – 16 g/serve
- At this stage generic disqualifying criteria will not apply to vitamins and minerals, but existing provisions in relation to claimable foods apply.

Ineligibility for General Level Claims

- Restrictions will be placed on nutrition content claims in relation to alcohol. Criteria will be defined for low alcohol claims and claims in relation to low calorie, reduced calorie and associated claims.
- 'Light' and similar claims on alcohol can only be made in respect of alcohol levels and energy.
- Health claims will not be allowed on alcohol.
- Nutrition content claims on infant formula will be prohibited unless expressly permitted. Health claims will not be allowed on infant formula.
- Current permissions for use of claims on formulated sports foods and formulated meal replacements will continue.

Regulatory Framework for High Level Claims

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

Substantiation of Claims

General Level 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 these claims is the responsibility of individual suppliers.
- Pre-approval of any general level health claims will not be required.

High Level Claims

- FSANZ is proposing to approve a number of high level claims that will be available to use at the time the Standard comes into effect.
- To date the following diet-disease relationships have been substantiated:
 - a) Calcium, Vitamin D and Osteoporosis;
 - b) Calcium and Bone Mineral Density;
 - c) Sodium and Blood Pressure;
 - d) Folic acid and Neural Tube Defects;
 - e) Saturated Fatty Acids and LDL-Cholesterol; and
 - f) Saturated and Trans Fatty Acids and LDL-Cholesterol.
- Suppliers may use high level claims based on substantiated relationships, subject to defined specific criteria and conditions.
- Any new high level claims require pre-approval by FSANZ through the application process to vary the Code.

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.
- Wording conditions will be placed around health claims 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.
- The %DI for energy is to be declared in the nutrition information panel whenever any health claim is made.
- The %DI of the claimed nutrient is to be declared in the nutrition information panel when any health claim is made in relation to protein, fat, saturated fatty acids, carbohydrate, sugars, sodium or salt and dietary fibre.
- Specific wording and labelling conditions for general level claims regarding biologically active substances are proposed.
- There will be reduced requirements for small packages.

Transitional Period

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

Criteria and conditions for specific nutrition content claims¹

Claim	Criteria and conditions
'Free' (for all nutrients except gluten, lactose and cholesterol).	No provisions.
'Gluten free' and 'lactose free'	See Standard 1.2.8, Clauses 15 and 16 of the Code.
Cholesterol free	The food must meet the requirements for 'low (in) saturated fat'.
'Reduced', 'less than'	A claim stating that the content in energy or one or more nutrients has been reduced, may only be made where the reduction 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 energy or claimed nutrient in the claimed food compared to the quantity in the reference food must be indicated.
'Increased'	A claim stating that the content of one or more nutrients, other than vitamins and minerals, has been increased, may be made where the product meets the conditions for the claim 'source of' 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.
Diet	The food must meet the disqualifying criteria for general level health claims; and The food must meet the conditions for 'low energy' claims; or <ul style="list-style-type: none"> 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
Light or Lite	<ul style="list-style-type: none"> • The characteristic that makes the food 'light/lite' must be stated adjacent to the claim • 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.
Low calorie, low joule, low energy	<ul style="list-style-type: none"> • The average energy content of the food is no more than 80 kJ per 100 ml for liquids and no more than 170 kJ per 100 g for solids.
'Source of protein'	≥5 grams of protein per serving

¹ Main recommendations only – refer to proposed standard for full details

Claim	Criteria and conditions
'Good source of protein'	≥10 grams of protein per serving
'Increased protein'	As per 'increased' claims but also the food must contain not less than 5.0 g protein per serving of food prior to enrichment with protein.
Low (in) fat	≤3 g per 100 g solid food; and ≤1.5 g per 100 ml liquid food.
% fat free	The food must meet the requirements specified for the 'low fat' claim
Low (in) saturated fatty acid/ Low in saturated and <i>trans</i> fatty acid	≤1.5 g in total of saturated and <i>trans</i> fatty acids per 100 g of solids; ≤0.75 g in total of saturated and <i>trans</i> fatty acids per 100 ml of liquids.
Reduced (in) saturated fatty acid	As per 'reduced' claims but additionally, the food contains no more <i>trans</i> fatty acids as the same quantity of reference food.
Reduced in saturated and <i>trans</i> fatty acids	As per 'reduced' claims but additionally, both saturated and <i>trans</i> fatty acids are reduced relative to the same quantity of reference food.
Polyunsaturated and monounsaturated fatty acids, omega fatty acids	No change from current prescription (Standard 1.2.8). Will review once new Nutrient Reference Values are adopted.
Low (in) cholesterol	≤20 mg cholesterol per 100g. The food must comply with the conditions for a nutrition content claim in relation to cholesterol free.
Low (in) sugar(s)	≤5 g total sugars per 100 g or; ≤2.5 g total sugars per 100 mL of liquid food.
No added sugar/sugars	The 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 or 2.6.2; and (iii) if the food naturally contains sugars, the claim states that the food contains naturally occurring sugars.
Unsweetened	(i) the food complies with the conditions for a nutrition content claim in relation to no added sugar; (ii) the food contains no intense sweeteners, sorbitol, mannitol, glycerol, xylitol, isomalt, maltitol syrup or lactitol
% sugar free	The food must meet the requirements specified for the 'low sugar' claim.
Source of fibre	The food must contain not less than 2.0 g dietary fibre per serving of food.

Claim	Criteria and conditions
Good source of fibre	The food must contain not less than 4.0 g dietary fibre per serving of food
Increased fibre	As per 'increased' claims but also the food must contain not less than 2.0 g dietary fibre per serving of food prior to enrichment with dietary fibre.
Low salt/sodium	≤120 mg sodium per 100 g solid food; and ≤120 mg sodium per 100 mL liquid food.
Very low salt/sodium	No provisions
No added salt/sodium	The food must contain no added sodium compound and no added salt. The ingredients of the food must contain no added sodium compound and no added salt. The nutrition information panel must indicate the potassium content. If the food naturally contains sodium, the claim must state that the food contains naturally occurring sodium.
Unsalted	The food must comply with the conditions for a nutrition content claim in relation to no added salt
Gluten free	No detectable gluten; and no oats or their products; or no cereals containing gluten that have been malted, or their products
Low (in) gluten	No more than 20 mg gluten per 100 g of the food.
Lactose free	No detectable lactose.
Low lactose	FSANZ proposes to increase the criteria for 'low lactose' such that foods must contain no more than 2.0 g lactose per 100g of the food
Reduced lactose	Not permitted
Source of wholegrain	≥ 8 g wholegrain per serve
Good source of wholegrain	≥ 15 g wholegrain per serve
Lean	No criteria

Criteria and conditions for specific types of health and related claims²

Endorsements

- Current endorsement programs will need to be pre-approved by FSANZ to enable their use without being regulated as nutrition or health claims.
- FSANZ has identified several current endorsement programs that meet the criteria for pre-approval.
- Any current endorsement programs that are not pre-approved by FSANZ will have to be regulated as a nutrition content claim or health claim.
- For future endorsement programs, specific requirements of the claims classification framework will need to be met.

Cause-Related Marketing

- There will be a mandatory requirement that a disclaiming statement be used in conjunction with a cause-related marketing statement that references a serious disease on food labels and in advertising.

Biologically Active Substance Claims

- Only 'source of' type claims can be made in relation to the presence of biologically active substances.
- General level health claims for biologically active substances must state the amount of the substance that provides the health effect.
- Generic disqualifying criteria apply to health claims relating to biologically active substances.
- 10% of the amount of the substance that provides the health effect is required to allow a general level health claim.
- A health claim must be substantiated according to the substantiation framework.

Weight Management Claims

- Weight management claims will be allowed.
- Foods with weight management claims will be required to meet the qualifying criteria for 'low calorie/joule/energy and the generic disqualifying criteria.
- The claim will be required to state the importance of exercise.

Dietary Information

- Dietary information means general diet-related information that does not relate a specific health effect to a specific food.
- It will be expressly excluded from the definition of a health claim.
- Dietary information presented in association with a specific product must be supported by a nutrition or health claim.

² Main recommendations only – refer to proposed standard for full details

Glycaemic Index and Glycaemic Load Claims

- Glycaemic index and glycaemic load claims that are linked with an endorsement will be regulated as an endorsement.
- For those not linked with an endorsement the glycaemic index or glycaemic load can only be claimed in the form of an index.
- Reduced, medium, low etc claims will not be allowed.
- If the claim refers to a health effect then it will be regulated appropriately as either a general level health claim or a high level claim.

Whole Food Claims

- Whole foods are defined as foods that consist of at least 90% by weight of primary foods.
- Health claims in relation to whole foods do not need to state the property of the food.
- Generic disqualifying criteria and conditions apply.
- Claims must refer to generic food types.
- They must be substantiated according to the substantiation framework.
- The evidence must point towards the health effects being attributed to the whole food.

Meals

- Specific qualifying criteria are proposed in relation to fibre claims on meals and main dish products.
- Specific disqualifying criteria will apply.

Table of labelling requirements

Claim type	CONTENT CLAIMS	CHANGE
General Requirements	<ul style="list-style-type: none"> Whenever a content claim is made, the %DI for energy has to be declared in the NIP. The statement 'Percentage Daily Intakes are [an alternative maker such as an asterisk may be used] based on an average adult diet of 8700kJ' must accompany the %DI energy declaration. This requirement also relates to small packages (i.e. declared in the abbreviated NIP as per Clause 8 of Std 1.2.8) 	<input checked="" type="checkbox"/>
	<ul style="list-style-type: none"> Where a content claim is made in relation to energy, protein, fat, saturated fatty acids, carbohydrate, sugars, sodium or salt and dietary fibre the %DI for the claimed nutrient must be declared in the NIP. This requirement also relates to small packages (i.e. declared in the abbreviated NIP as per Clause 8 of Std 1.2.8) 	<input checked="" type="checkbox"/>
	<ul style="list-style-type: none"> Where a content claim is made in relation to vitamins and minerals the %RDI has to be declared in the NIP. 	
Comparative content claims ('reduced'/'increased')	<ul style="list-style-type: none"> The identity of the reference food and the difference in the quantity of the claimed nutrient or energy in the claimed food compared to the quantity in the reference food must be indicated <i>E.g. 'Reduced in fat by 25% compared to whole milk'</i> 	
'Diet' Claims	<ul style="list-style-type: none"> The identity of the reference food and the difference in the quantity of energy in the claimed food compared to the quantity in the reference food must be indicated 	
Light or lite claims	<ul style="list-style-type: none"> The claim states the characteristic of the food to which the claim relates. 	
Potassium/Sodium claims	<ul style="list-style-type: none"> The NIP indicates sodium and potassium content 	
No added salt / unsalted; and No added sugar / unsweetened	<ul style="list-style-type: none"> If the food contains naturally occurring sodium/sugars, the claim states that the food contains naturally occurring sodium/sugars. This statement is required for small packages. 	<input checked="" type="checkbox"/>
Lactose Claims	<ul style="list-style-type: none"> The claim states whether it is a lactose free or low lactose claim 	
Content claims in relation to Biologically active substance	<ul style="list-style-type: none"> The amount of the biologically active substance has to be declared in the NIP 	
GENERAL LEVEL AND HIGH LEVEL HEALTH CLAIMS		
General Requirements	<ul style="list-style-type: none"> (1) The health claim must state the property of the food that relates to the health effect (unless the substantiation is based on the food itself in which case the claim states the food). This is a requirement for small packages. 	<input checked="" type="checkbox"/>

Claim type	CONTENT CLAIMS	CHANGE
	<ul style="list-style-type: none"> (2) The health claim must state the specific health effect. This is a requirement for small packages. 	<input checked="" type="checkbox"/>
	<ul style="list-style-type: none"> (3) If applicable, the population group to which the specific health effect relates. This is a requirement for small packages. 	<input checked="" type="checkbox"/>
	<ul style="list-style-type: none"> (4) The health claim must be made in the context of a 'healthy diet consisting of a variety of foods' as appropriate to the type of food and the specific health effect claimed. Small packages are exempt from this requirement 	<input checked="" type="checkbox"/>
	<ul style="list-style-type: none"> The %DI and %RDI requirements in relation to health claims are the same as those specified for content claims above. 	<input checked="" type="checkbox"/>
	<ul style="list-style-type: none"> The % RDI requirements for health claims in relation to vitamin and minerals are the as those specified for content claims above 	
Health Claims in relation to biologically active substances	<ul style="list-style-type: none"> The claim states the level of the substance in the food and the amount of the substance that is required to be consumed per day to achieve the specific benefit and the basis for this statement. <i>E.g. 'When consumed as part of a healthy diet consisting of a variety of foods, oligofructose can contribute to intestinal health. The suggested consumption of oligofructose is 5g a day according to research conducted by [X]'</i> 	<input checked="" type="checkbox"/>
	<ul style="list-style-type: none"> The amount of the biologically active substance has to be declared in the NIP 	
Weight loss or maintenance claims	<ul style="list-style-type: none"> The claim states that the specific health effect must be considered in the context of the importance of regular exercise 	<input checked="" type="checkbox"/>
RELATED CLAIMS		
Cause-related marketing	<ul style="list-style-type: none"> The disclaiming statement '[insert supplier name] makes no claims in relation to this food being beneficial for managing [insert serious disease]' must appear in the same place as the cause relating marketing statement. However, if a high level claim is made that refers to the serious disease mentioned in the cause-related marketing statement then this disclaimer is not required. 	<input checked="" type="checkbox"/>
Endorsements	<ul style="list-style-type: none"> There are no additional labelling requirements for pre-approved endorsements. Others, which will not be pre-approved, will need to be accompanied by a general level or high level claim complying with the requirements specified above. 	<input checked="" type="checkbox"/>