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

20 March 2009
[4-09]

PROPOSAL P293
NUTRITION, HEALTH & RELATED CLAIMS
CONSULTATION PAPER FOR FIRST REVIEW

Executive Summary

Purpose

The Final Assessment Report for Proposal P293, including draft Standard 1.2.7 – Nutrition, Health and Related Claims, was approved by the Food Standards Australia New Zealand (FSANZ) Board in March 2008 and the Board's decision notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council). The Ministerial Council considered draft Standard 1.2.7 at its meeting on 2 May 2008 and a request for a First Review of the draft Standard was notified to Food Standards Australia New Zealand (FSANZ) in June 2008.

This Consultation Paper summarises proposed changes which address two of the key issues raised in the First Review Request. These changes are:

- a revised approach for the regulation of general level health claims; and
- revision of the text and structure of draft Standard 1.2.7 for the purpose of improving clarity.

Recommended Approach for the Regulation of General Level Health Claims

It is recommended that the approach for regulation of general level health claims be changed from industry self-substantiation, to an approach where general level health claims are only permitted if they refer to a food-health relationship listed in the draft Standard (and meet other relevant conditions).

The draft Standard will contain a revised schedule that lists general level health claim relationships drawn from the authoritative sources that were outlined in Schedule 2 to the draft Standard in the Final Assessment Report.

In addition, it is proposed that FSANZ will prepare one or more proposals during the transition period for Standard 1.2.7 to assess general level health claim relationships currently in the marketplace. These additional pre-approved general level health claim relationships will be included in Schedule 2 to the Standard.

The revised Schedule 2 will then be expanded by applications made to FSANZ both during and after the transition period based on authoritative scientific source documents, or systematic reviews.

Revision of the Draft Standard

FSANZ has sought to clarify, simplify and improve the ease of use of the proposed Standard 1.2.7. This Consultation Paper contains the revised proposed draft Standard 1.2.7 and also the consequential amendments that are necessary as a result of Standard 1.2.7.

The variations in this consultation draft Standard are, given the regulatory subject matter, necessarily complex and lengthy. The variations should be read together with the explanatory notes which explain the intent of each of the clauses in Standard 1.2.7.

Consultation

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

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

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

Consultation is not required as part of the development of a response to a request for a review but because of the significance of the changes we are recommending, we are inviting submissions from interested parties.

Invitation for Submissions

FSANZ invites public comment on this Consultation Paper and the draft variations to the Code for the purpose of preparing the First Review Report for Proposal P293. The First Review Report will be available to the public after FSANZ's decision has been notified to the Ministerial Council in 2010.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this First Review Request. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 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.

Please note: submitter comments must be confined to the two topics which are the subject of this issues paper. These topics are the clarity of the revised draft Standard 1.2.7, and the regulation of general level health claims. Refer to each of the two sections of the issues paper for further guidance on submissions. **FSANZ will not be considering submitter comments on issues which are outside the scope of the topics presented in this paper.**

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, separate it from your submission and provide justification for treating it as confidential. Section 114 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. 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. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 15 May 2009

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if 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.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy 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

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

CONTENTS

INTRODUCTION

This consultation paper is part of FSANZ's consideration of Proposal P293, which was approved by the FSANZ Board in March 2008. The Proposal involves the insertion of a new standard (Standard 1.2.7 – Nutrition, Health and Related Claims) into the *Australia New Zealand Food Standards Code* (the Code), as well as a number of consequential amendments to other standards in the Code.

Proposal P293 was considered by the Ministerial Council in May 2008. The Ministerial Council requested FSANZ to review draft Standard 1.2.7 and consequential amendments.

In order to address the Ministerial Council's First Review Request, FSANZ is proposing some significant changes to draft Standard 1.2.7 (refer to Attachments 1 to 3 for the amended drafting and explanatory statement), as outlined in this Consultation Paper. Because of the importance of these changes, we are inviting submissions from interested parties.

BACKGROUND

1. Previous consultation

This proposal has been the subject of extensive public consultation since 2004 when the Initial Assessment Report, the first of four assessment and consultation reports, was released for public comment.

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

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

2. The First Review Request

A request for a First Review of draft Standard 1.2.7 was received by FSANZ on 6 June 2008 (refer to Attachment 4 for the media release regarding the First Review Request).

In summary, the grounds given by the Ministerial Council for the First Review Request are that draft Standard 1.2.7:

- is not consistent with existing policy guidelines set by the Ministerial Council;
- does not protect public health and safety:
    - the nutrient profiling scoring criterion is not applied to nutrition content claims and this is inconsistent with the policy guideline about promoting healthy food choices; and
    - endorsements are generally exempt from the operation of the draft Standard without an approval process;

- places an unreasonable cost burden on industry and/or consumers:

    - the new Standard is highly complex and will be difficult to monitor and enforce and resource intensive for industry to comply with;

- is difficult to enforce (and/) or comply with in both practical or resource terms:

    - enforcement of the draft Standard in relation to general level health claims will require substantial resources; and
    - unless claims can be verified simply and quickly with unequivocal evidence, assessment of claims will be an unnecessary burden for enforcement agencies. This will reduce consumer confidence and certainty and will not provide an even playing field for industry; and

- is not consistent with the objectives of the legislation which establishes FSANZ:

    - subjectivity in the weight of evidence to substantiate a food-health relationship and the onus on enforcement agencies with limited capacity to assess claims provides an environment for food products to be marketed in a way that contradicts public health messages and misleads consumers.

3. Timelines

The statutory time period allocated for completing this First Review Request was three months. FSANZ did not consider this would be adequate due to the need to obtain further evidence and conduct stakeholder consultations and so requested an extension of time from the Ministerial Council. In June 2008, the Ministerial Council agreed to extending the period for the First Review Request until 8 April 2009.

At its October 2008 meeting, the Ministerial Council requested the presentation of the First Review Report be deferred until it can be considered concurrently with the outcomes of an independent ministerial review of labelling law and policy being conducted in 2009. The Ministerial Council agreed to extend the reporting timeframe for the review of draft Standard 1.2.7 until March 2010 but agreed that, in the meantime, FSANZ should continue its work to address the issues identified in the First Review Request.

The completed First Review Report will be publicly available on the FSANZ website once the Ministerial Council has been notified of the FSANZ Board's decision.

4. What this consultation paper is about

4.1 The scope of the consultation paper

Our consideration of the issues raised in the First Review Request has resulted in recommendations to make two significant changes to draft Standard 1.2.7. These changes are:

- the approach used for the regulation of general level health claims; and

- a complete revision of the text and structure of draft Standard 1.2.7 for the purpose of improving clarity and user-friendliness.

There are a number of issues raised in the First Review Request that are not addressed by this paper, for example, the Ministerial Council's concerns regarding the application of the nutrient profiling scoring criterion. This matter and others are still under consideration.

4.2 How the paper is set out

The first part of this paper describes FSANZ's legislative objectives. This legislative framework, and that of the whole food regulatory system, necessarily places some limits on what we can do in order to address some of the concerns raised in the First Review Request. This part of the paper explains those constraints.

The second part of this paper concerns the regulation of general level health claims. It discusses the substantiation issues raised in the First Review Request and evaluates the options for dealing with those concerns. The model for a preferred option is discussed in some detail.

The third part of this paper concerns draft Standard 1.2.7 as a legal instrument. We have made fundamental changes to the way the Standard looks and reads. However, we have not changed the way in which the Standard is intended to operate. Some changes were required to clarify and strengthen this intent. The third part of this paper explains the revised drafting, and seeks comments on how the expression, clarity or usefulness of the draft Standard could be further improved. Attachment 5 provides greater detail on the changes and associated reasons.

We are seeking consultation on the two elements discussed in sections 7–9 and sections 10–12 in this Consultation Paper, that is, the regulation of general level health claims and the revised draft Standard. To aid consultation, we have included questions for submitters in section 13 of this paper.

FSANZ'S LEGISLATIVE REQUIREMENTS

5. Our objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are (in descending priority order):

- 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.

6. The effect of our legislation on our consideration of options for the regulation of general level health claims

We recognise that, generally speaking, there is a wide range of ways in which claims about food could be regulated. However, FSANZ was asked by the Ministerial Council to develop a standard for the Code to regulate nutrition, health and related claims (Attachment 6 – Policy Guideline on Nutrition, Health and Related Claims).

In developing such standards, we are required by the FSANZ Act to consider the objectives noted above. Our response to the First Review Request for Proposal P293 is part of the continuum of standards-setting and therefore, we carefully consider our objectives and the relevant matters set out in section 18 of the FSANZ Act. The development of our preferred options (as presented in this paper) is based on our legislative requirements and constraints.

GENERAL LEVEL HEALTH CLAIMS

7. Framework for general level health claims

7.1 The proposal in the Final Assessment Report

The basic approach proposed in the Final Assessment Report was that all health claims were prohibited unless expressly permitted. A general level health claim[1] (GLHC) would be permitted if:

- the food met specified conditions including the nutrient profiling scoring criterion[2];
- the claim met certain wording conditions;
- the 'Scientific Substantiation Framework' was applied to the claim; and
- the records of that substantiation were made available to the relevant authority upon request.

The Scientific Substantiation Framework was set out in Schedule 2 of the draft Standard in the Final Assessment Report. This framework proposed that the food-health relationships would be substantiated to a 'convincing' level of evidence (see Attachment 7 – Levels of Evidence) by any of the four methods listed in the framework (Table 1).

[1] General level health claim means a health claim that does not, directly or indirectly, refer to a serious disease or a biomarker.

[2] The nutrient profiling scoring criterion is a scoring system used to determine the eligibility of foods to carry health claims. This approach restricts the use of health claims on products that are inconsistent with national nutrition guidelines. 'Baseline' points are allocated for increasing amounts of energy, saturated fat, sodium and total sugars. These points are offset by 'modifying' points allocated for the increasing percentage of the product that is fruit/vegetables/nuts/legumes and the amount of fibre, and in some cases protein. The final score determines whether or not a food is eligible to carry a health claim. For example, wholemeal breads, fruits & vegetables, lean meats would be eligible, whereas most confectionery, higher fat hard cheeses, cakes and sweet biscuits would not be eligible.

The substantiation framework proposed in the Final Assessment Report did not prescribe the wording of the claims, nor the relationship between the food or property and the specific health effect; rather it outlined methods for industry to use to self-substantiate food-health relationships underpinning GLHCs (GLHC relationships).

Table 1: Scientific Substantiation Framework as recommended in the Final Assessment Report

Method 1	**List of nutrient function statements –** This method contained examples of pre-approved nutrient function statements primarily drawn from the UK Joint Health Claims Initiative (JHCI) that could be used by industry as the basis of a GLHC.
Method 2	**Prescribed list of pre-approved food-disease relationships for high level health claims –** This method enabled substantiated food-disease relationships supporting high level health claims in the Table to clause 7 of the draft Standard to be re-expressed without reference to a serious disease or a biomarker.
Method 3	**Prescribed list of authoritative source documents –** This method enabled a food-health relationship to be used if it was definitively stated in one of several prescribed, authoritative sources of nutrition and health information. These sources included local and overseas documents including: • health claims approved to the equivalent of a 'convincing' level of evidence in US and Canadian regulations; • Australia, New Zealand and US government reports on nutrient reference values; • the JHCI report; and • relationships filed in the Cochrane database.
Method 4	**Systematic review –** This method required the totality of evidence to be substantiated through a systematic review. This method was anticipated to be used when a GLHC relationship could not be substantiated by any of the other methods.

7.2 The issues identified in the First Review Request

The Ministerial Council sought only minor amendment to Methods 1 and 2 in the Scientific Substantiation Framework for GLHCs. There was some concern about the uncertainty and burden of enforcement of Method 3 but all Council members had serious concerns about Method 4. Overall, the concerns focused on the need for enforcement agencies to assess scientific evidence which would be time consuming, expensive and require costly external expert input.

The Ministerial Council was satisfied with the process for substantiation of high level health claims as drafted. The First Review Request sought no further consideration of high level health claims.

8. Options for dealing with the identified issues

8.1 The regulatory problem

In order to concomitantly meet the demands of the FSANZ Act and the issues raised in the First Review Request, and give due regard to the Ministerial Council Policy Guideline on Nutrition, Health and Related Claims, we needed to develop a system for the regulation of general level health claims that:

- protects public health and safety;
- provides adequate information about food;
- prevents misleading and deceptive conduct;
- is cost effective;
- provides certainty for industry, enforcement agencies and consumers;
- provides a system that is flexible yet enforceable; and
- reflects the principles of minimum-effective regulation.

It was clear to us from the First Review Request that the system proposed in the Final Assessment Report did not address the criteria above to the satisfaction of the Ministerial Council. We therefore consider that the retention of that system is not an option.

Rather, we have developed two further options:

- first, an industry self-substantiation system which provides greater clarity and guidance (which we call **Option 1**); and
- second, a FSANZ pre-approval model for GLHC relationships (which we call **Option 2**).

8.1.1 A third party certification or verification scheme approach

We also considered a third party certification or verification scheme whereby a manufacturer is either required to or voluntarily seeks the certification of a person or body prior to placing a GLHC in the market.

The third party could be:

- FSANZ;
- a committee or body established by FSANZ;
- a committee established by the enforcement agencies of the various jurisdictions;
- a person who meets criteria specified by jurisdictions; or
- a person who meets criteria specified by FSANZ.

A third-party model would address the concerns of the First Review Request about Method 4. Under a voluntary system, a manufacturer would have the option of seeking third-party certification prior to making the claim in the marketplace. That certification could then be used by enforcement agencies in order to assess whether the claim meets the substantiation requirements of the Standard.

Under a mandatory system, Method 4 would be slightly amended to permit only those claims which have been third-party certified. The presence or absence of that certification would form the basis of enforcement action by enforcement agencies.

However, in the current state, federal, and New Zealand legislative and regulatory environment, such a model is not viable. Without suitable legislative backing, the voluntary system would not provide certainty for enforcement agencies or industry and the mandatory system would also require legislative reform. Furthermore, our role is to make standards which set objective criteria in advance. A standard which sets as its measure of compliance the opinion of the third-party does not meet the requirement of setting objective criteria in advance.

Currently, therefore, we are not in a position to progress a third-party certification or verification model any further. However, FSANZ will continue to watch for developments in the regulatory and legislative field in the future that might affect this position.

8.2 Option 1 – Industry self-substantiation as recommended in the Final Assessment Report, with minor amendments

Option 1 retains the industry-based self-substantiation framework but in the light of concerns raised in the First Review Request, this option introduces more explicit guidance for industry on the data requirements for GLHC relationships that would meet a 'convincing' level of evidence (refer to Attachment 7 – Levels of Evidence). Industry would hold the evidence and submit it to enforcement agencies on request. These agencies would then determine whether that evidence met the substantiation requirements.

Amendments to the self-substantiation framework as presented in the Final Assessment Report that would be made under Option 1 are given in Table 2.

Table 2: Amendments to methods for self-substantiation of GLHC relationships

Amended Method 1	Include *all* acceptable nutrient function statements from JHCI to provide an extensive range of statements.
Amended Method 2	Reference or list FSANZ's food-disease relationships underpinning high level health claims, plus food-disease relationships in overseas food regulations that meet a 'convincing' level of evidence. This would include European Commission food-disease relationships.
Amended Method 3	Prescribe a more comprehensive list of authoritative scientific source documents. Provide detailed advice on what information from such authoritative documents could be used to serve as an appropriate basis for GLHC relationships.
Method 4	No change, or delete this method

As is clear from the above table, the further guidance is for Methods 1, 2 and 3 rather than Method 4.

The other conditions applying to general level health claims as proposed in the Final Assessment Report would remain, including that the food meets the nutrient profiling scoring criterion.

8.2.1 Advantages of Option 1

Option 1 would provide for further clarification of the methods of substantiation compared to that proposed in the Final Assessment Report. Whilst it provides flexibility for industry in deciding the timely appearance of GLHCs, the evidential standard that needs to be met remains high. The Standard would need very little maintenance by FSANZ.

8.2.2 Disadvantages of Option 1

Under this option industry still is required to assemble and assess the evidence base for a GLHC relationship to a 'convincing' level of evidence, but an element of uncertainty remains as to ultimate compliance. Although more guidance can be provided for Methods 1 to 3, this option necessarily relies on the discretion of enforcement agencies to decide whether or not a GLHC relationship is substantiated. Furthermore, given that this decision is taken in a compliance and enforcement paradigm, there is little opportunity for GLHC relationships to be permitted on the basis of public health, safety or nutrition factors or other relevant factors. According to this model, the touchstone of legal compliance is whether or not the claim is scientifically substantiated to a 'convincing' level of evidence.

An additional issue with this option is that, because individual enforcement agencies may reach different conclusions about the substantiation of a GLHC relationship, this may result in inconsistent enforcement across the jurisdictions.

Enforcement agencies, through the First Review Request, have expressed concerns about their capacity to fully enforce the Standard because of inherent uncertainty in the interpretation of the four methods of substantiation.

In option 1, a significant enforcement burden still remains because it requires enforcement agencies to investigate and form a view about the substantiation of GLHC relationships as well as to ensure consistency of intent of the GLHCs with the substantiated relationships. For example, Amended Method 2 relies on the ability of domestic and overseas high level health claims to be expressed as GLHC relationships. Some overseas requirements do not translate easily from high level to GLHC relationships or to the Australia New Zealand food regulatory context. In such cases, industry would be required to decide some of the detail themselves and enforcement agencies would need to review GLHCs developed from such sources for internal consistency with the GLHC relationship.

Under this option, Method 4 could remain or be removed. Maintaining Method 4 is apparently not viable given the lack of support for this method in the First Review Request. Deletion of Method 4 would simplify the range of methods in the Standard for enforcement purposes; however it would also significantly reduce the scope of subject matter from which industry could derive GLHCs, to the extent that some scientifically substantiated food-health relationships could not be used as the basis of GLHCs.

8.3 Option 2 – FSANZ pre-approval of GLHC relationships

Option 2 changes the approach for regulation of GLHCs from a framework that outlined various methods for industry to use to self-substantiate GLHCs to a 'convincing' level of evidence, to an approach where a GLHC would only be permitted if its GLHC relationship is prescribed in the Standard (and other specific wording and compositional conditions are met). This means that the responsibility for approval of GLHCs would be transferred from enforcement agencies to FSANZ. We would decide the approval of a GLHC relationship after taking into account the scientific evidence as well as all other relevant factors in order to fulfil our statutory objectives under section 18 of the FSANZ Act. Under this option, the required level of evidence is not prescribed. The methods for substantiation listed in Schedule 2 of the draft Standard in the Final Assessment Report would be removed from the Standard.

This system is based on a 'prohibit unless specifically listed' principle, which is employed elsewhere in the Code (see, for example, Standard 1.5.2 – Food produced using Gene Technology).

If a manufacturer wishes to use a GLHC on his or her product, for which the supporting GLHC relationship is not specifically listed in the Standard, then he or she would need to make an application to FSANZ for the inclusion of that GLHC relationship in the Standard.

FSANZ would assess the application and consider all of the matters we are legislatively required to consider (as described in sections 5 and 6 above).

As with option 1, the other conditions applying to general level health claims as proposed in the Final Assessment Report would remain, including that the food meets the nutrient profiling scoring criterion.

8.3.1 Advantages of Option 2

Due to the certainty afforded by the pre-market determinations of FSANZ, this option provides significantly greater certainty and specificity for industry and enforcement agencies. It provides for greater consumer confidence. It also fully addresses the concerns of the Ministerial Council, especially in relation to Methods 3 and 4 and provides a system in which FSANZ holds the responsibility for pre-approving GLHC relationships. A central decision point for the assessment of GLHC relationships deals with the potential problem of differing views being held by the various enforcement agencies.

The establishment of a pre-approval system potentially enables a greater range of GLHC relationships to be considered. This is because firstly, there is greater flexibility in the level of evidence that may be presented, and secondly, all relevant factors, not just the scientific veracity of the GLHC relationship, must be considered by FSANZ to arrive at a decision about a new GLHC. This is exemplified by the range and type of GHLC relationships that are included in the draft Schedule 2 (refer Attachment 8 for more detail).

Industry would not have to hold the scientific evidence supporting GLHC relationships as is required under option 1. Option 2 also provides enforcement agencies with the certainty to bring a prosecution, based on GLHC relationships contained in the Standard.

8.3.2 Disadvantages of Option 2

A pre-approval system requires industry to follow the guidance of the Application Handbook in making an application to FSANZ for approval of a GLHC relationship. However, under the FSANZ Act, applications for GLHCs are ordinary applications and consequently do not have the protection of confidentiality or first to market advantage that is conferred by the FSANZ Act on applications for high level health claims. This again is likely to be a concern for industry.

Compared with Option 1 in which a minimum level of evidence is prescribed, there is also greater uncertainty for industry in this respect i.e. as to whether the data provided will lead to an approved claim, because a required level of evidence is not prescribed and a greater range of factors (i.e. the section 18 objectives of the FSANZ Act) will be taken into account by FSANZ in its decision-making processes.

This option allows industry less flexibility in bringing a new GLHC to market. Pre-approval of GLHC relationships by FSANZ may take longer than a self-substantiation model as discussed under Option 1. Costs to industry might also increase because manufacturers will be required to assemble evidence as well as pay FSANZ to assess applications if a fee is levied. Whether a fee is levied depends on the application of the provisions of the FSANZ Act in the particular circumstance. These provisions are generic and apply to all applications received by FSANZ.

8.4 Assessment of options and selection of preferred option

Option 1 provides the greatest degree of flexibility for industry with respect to entry of claims into the market, however it also delivers the least certainty for them, consumers and enforcement agencies. It also imposes the greatest enforcement burden on enforcement agencies. Option 1 also trades off industry flexibility with the need for them to substantiate GLHC relationships to a 'convincing' level of evidence. Without inclusion of Method 4, this option would be highly restricted in relation to the range of lawful GLHC relationships that could be made.

Option 2 offers more certainty for all parties and most effectively deals with the Ministerial Council's concerns about Methods 3 and 4. Option 2 also confers benefits from potentially greater flexibility in decision making processes due to factors beyond scientific certainty being able to be taken into account.

Because of pre-market approval by FSANZ, much of the burden on enforcement agencies of option 1 would be relieved; also central decision making would deal with the potential for enforcement agencies to hold disparate views about the lawfulness of a particular GLHC relationship. On the other hand, option 2 might result in more costs and time delays for industry (application process for new GLHC relationship approval) and does not confer protection of the FSANZ Act on confidentiality or first to market advantage, however this could be changed in the future with legislative amendment. Option 2 also poses significant challenges for FSANZ in providing an efficient system of assessment.

Table 3: Summary of key features of the two options (in no particular order)

Factors	Option 1	Option 2
Consistency and certainty in decision making	Lower (each enforcement agency to decide compliance)	Higher (FSANZ prescribes all pre-approved GLHC relationships in the Standard)
Flexibility– market entry (speed, cost and access)	High	Low – application to FSANZ and preapproval required for new GLHCs
Flexibility – data provision	Lower. Must meet 'convincing' level of evidence	Higher. Level of evidence not pre-determined, other factors considered
Burden of implementation (jurisdictions)	High	Low
Burden of implementation (FSANZ)	Low	High

After considering all of the points in favour and against both options, FSANZ concludes that the option which provides certainty for all parties, deals most effectively with the Ministerial Council's concerns and that can be immediately implemented within the current legislative framework is Option 2.

9. Implementation of Preferred Option

The implementation of Option 2 (the Preferred Option) involves:

- insertion of pre-approved GLHC relationships into a Schedule to the draft Standard;
- consideration of an application system for the addition of GLHC relationships to Standard 1.2.7; and

- consideration of GLHC relationships that underpin existing GLHCs in the market, and how these should be assessed during the transition period for Standard 1.2.7.

Following gazettal of the Standard, it is proposed that GLHC relationships not already included in the Standard can be assessed for inclusion during the transition period, either by proposals prepared by FSANZ or by the normal application process. After the end of the transition period, GLHCs could be assessed for inclusion only by application.

Figure 1 outlines how FSANZ envisages implementing the Preferred Option from gazettal to the end of the transition period, and on an ongoing basis.

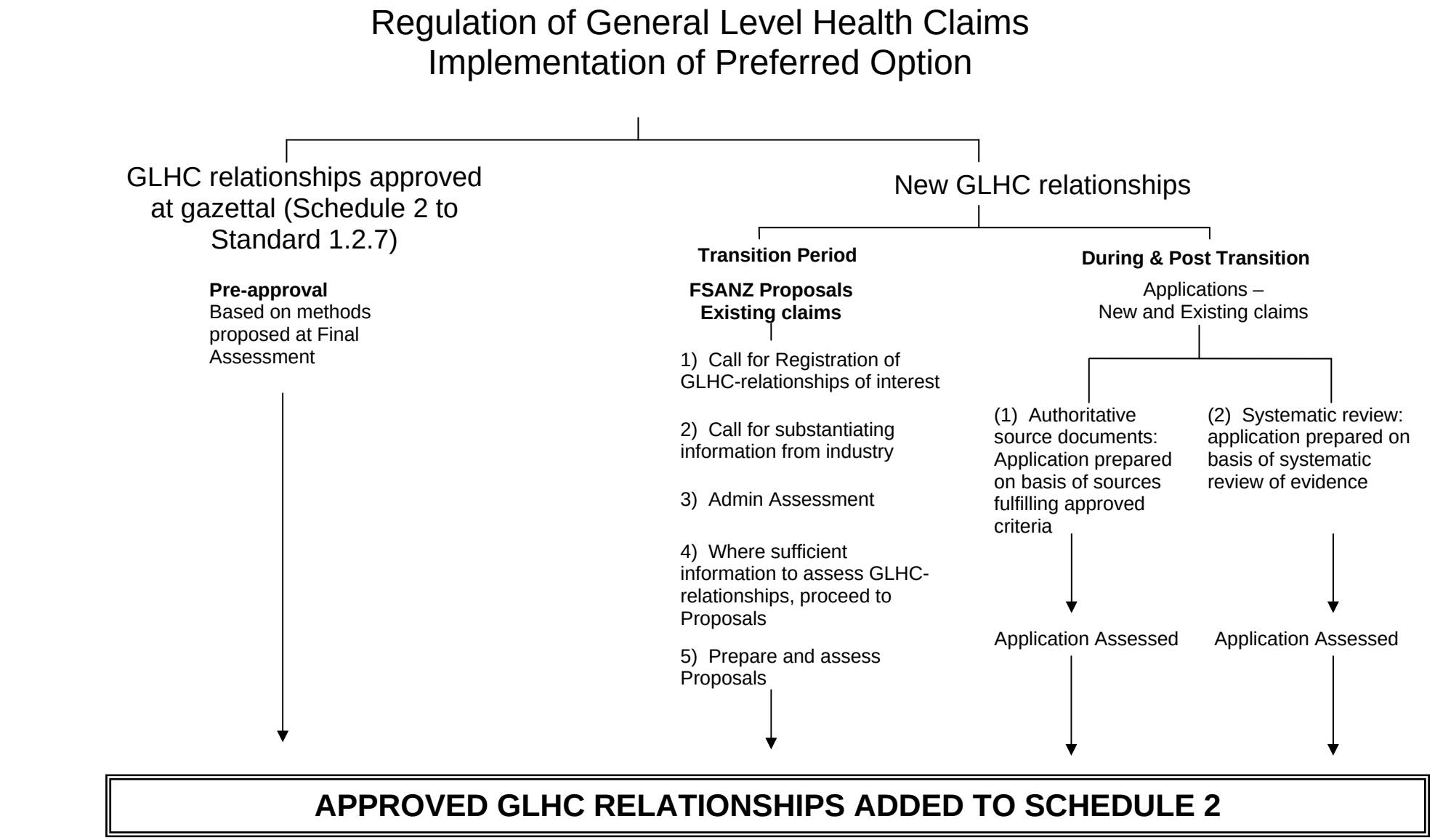


Figure 1: Implementation of preferred option

9.1 Approved GLHC relationships in the Standard at gazettal

Under the Preferred Option, GLHCs would be permitted only if they were supported by GLHC relationships listed in Schedule 2 of the Standard. FSANZ has commenced populating Schedule 2 with approved relationships, their conditions of use and the context in which GLHCs should be stated.

For the initial development of Schedule 2, GLHC relationships were drawn from application of Methods 1, 2 and 3 previously prescribed in Schedule 2 and the Table to clause 12 of the draft Standard as recommended in the Final Assessment Report[3]. GLHC relationships that met at least the 'probable' level of evidence (see Attachment 7) and that were consistent with food and nutrition guidelines were tabulated in a fashion analogous to that developed for high level health claims. Appropriate conditions of use and population and context statements for GLHCs were also developed.

This work yielded over 90 relationships covering the biological roles of nearly all vitamins and minerals and some macronutrients. GLHC relationships based on high level health claims drawn from our own and US high level health claim regulations were also listed but expressed without reference to a serious disease or biomarker. Not all of these high level health claim relationships however, could be used because equivalent general level terms for the specific health effect that did not reference a serious disease or biomarker were not always suitable or available.

Table 4 outlines the rationale for inclusion of the pre-approved GLHC relationships listed in Schedule 2 (see Attachment 1 for the complete Schedule). Attachment 8 provides greater detail on the rationale for the inclusion or exclusion of specific GLHC relationships.

Table 4: Development of pre-approved GLHC relationships

Food/property of the food	Rationale for inclusion in Schedule 2
Joint Health Claims Initiative (JHCI) – approved 'well-established' nutrient function statements: • vitamins; and • most minerals	Most vitamins and minerals have more than one relationship listed. JHCI defines 'well-established' as 'consistent reporting in the majority of source documents of relevant functions'. Because the US Institute of Medicine (IOM) documents and other sources were used to develop the JHCI nutrient function statements, it is likely that all statements from IOM and other sources are already included; therefore this source document was not specifically reviewed in the preparation of Schedule 2. (These relationships were previously available from Methods 1 and 3.)
FSANZ newly identified: • energy; • protein; • EPA & DHA; • carbohydrate; and • dietary fibre.	FSANZ included GLHC relationships for protein, carbohydrate, energy, EPA and DHA, and dietary fibre along with respective nutrition content claim criteria and conditions for use based on the prescribed scientific source documents and with reference to the NHMRC nutrient reference values for Australia and New Zealand. (These relationships were previously identifiable via Methods 1 and 3.)

[3] Refer to the Proposal P293 Final Assessment Report at the following link: http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp293nutritionhealthandrelatedclaims/index.cfm

Food/property of the food	Rationale for inclusion in Schedule 2
GLHC relationships from Table to clause 12 in draft Standard in Final Assessment Report: • weight loss for overweight; • weight maintenance; and • maternal folic acid.	Items from the Table to clause 12 in the draft Standard in the Final Assessment Report were included where a GLHC relationship had been specified.
FSANZ high level health claims re-expressed: • fruits and vegetables	High level health claim reworded into a GLHC relationship. (This relationship was previously available from Method 2.)
US Food and Drug Administration Health Claims (Significant Scientific Agreement): • phytosterols; • beta-glucan; and • sugar or sugars (near absence).	Certain high level health claim relationships from the US were listed where they could be expressed as GLHC relationships and differed from FSANZ-listed relationships. (These relationships were previously available from Method 3.)

9.2 European Commission

The European Commission (EC) has signalled a process by which evidence for both disease reduction and other health claims will be assessed by the European Food Safety Authority (EFSA). Published opinions by EFSA are becoming available now and these will be considered by the EC in due course. Claims found to be acceptable will be published on a register of claims.

At this stage, FSANZ expects the EC register to meet the criteria in the FSANZ *Application Handbook*[4] for an authoritative source.

9.3 Addition of new GLHC relationships to Standard 1.2.7 after gazettal

9.3.1 Applications to amend Standard 1.2.7

The implementation of the Preferred Option requires the FSANZ *Application Handbook* to guide applicants on preparing applications for the inclusion of new GLHC relationships in Standard 1.2.7.

Two approaches are anticipated for the preparation of applications to substantiate a GLHC relationship for pre-market approval. These approaches are similar to those proposed for high level health claims. An applicant would be required, among other things, to prepare a dossier of evidence to support the GLHC relationship on the basis of either:

- information available in authoritative scientific source documents (based on criteria outlined in the FSANZ *Application Handbook*); or

[4] The FSANZ *Application Handbook* provides the essential information required to make an application to vary the Code.

- a systematic review of the proposed relationship.

As amendment to the Application Handbook is likely, consultation would be carried out regarding these amendments around the time of gazettal of the Standard.

9.3.1.1 Applications based on authoritative scientific source documents

Applications may be prepared for GLHC relationships based on sources identified by the applicant using the following indicative criteria[5]*:*

1. Sources are a published review by a scientific body, including but not limited to:

- peer-reviewed reports of substantiation of health claims for foods, including those done by overseas Governments or international agencies;

- national diet policy publications such as dietary guidelines or nutrient reference values published in Australia and New Zealand;

- reports from nationally or internationally recognised scientific bodies such as the National Heart Foundation of Australia, the New Zealand Heart Foundation, the US National Institutes of Health and the World Health Organization;

- reviews done by the Cochrane Collaboration; and

- other reviews published in the peer-reviewed literature.

2. Findings reflect a consensus within the scientific community.

3. Findings are current and produced within the last 5 years.

4. The authoritative sources are reviews, or are position statements based on reviews conducted with a degree of rigour comparable to that required by FSANZ (see Attachment 7).

5. If the authoritative source was not originally published in Australia or New Zealand, the GLHC relationship must be capable of being generalised to the Australian and New Zealand populations.

9.3.1.2 Applications based on a systematic review

Applicants may also carry out a systematic review to substantiate a GLHC relationship using a method that will be outlined in the FSANZ *Application Handbook*[6].

[5] Final criteria will be proposed in the consultation paper for amendments to the FSANZ *Application Handbook* relating to nutrition, health and related claims, and finalised following the receipt of submissions.

[6] The following web reference of the draft methodology for applications for high level health claims is indicative of the methodology which could be developed for GLHCs except there would not be a prescribed level of evidence. See item 10 in the document at http://www.foodstandards.gov.au/_srcfiles/Amendments%20to%20Handbook%20-%20Consolidated%20changes%20for%20consultation1.pdf#search=%22handbook%20consultation%20March%22

9.3.2 Proposals prepared by FSANZ to amend Standard 1.2.7 during the transition period

It is important to ensure that, by the end of the transition period, existing GLHCs in the marketplace are based on GLHC relationships listed in the Standard or are regarded as unlawful. It is desirable to minimise disruption for industry where GLHCs currently in the marketplace are based on GLHC relationships that could be approved.

FSANZ is aware that Schedule 2 to the draft Standard at gazettal may not cover the full range of eligible GLHC relationships underpinning current GLHCs in the marketplace. To streamline the process for expanding Schedule 2 to include GLHC relationships currently in use, the following steps are proposed as outlined in Figure 1:

Steps 1 and 2 – Industry input

Following gazettal of Standard 1.2.7, FSANZ would call for registration of those food-health relationships underpinning GLHCs in the marketplace that were not in Schedule 2 to the Standard. Industry would then be given guidance and time to submit all evidence and other relevant information in support of possible approval of their GLHC relationship.

Steps 3 and 4 – 'Preliminary assessment' of GLHC relationships submitted by industry

The next stage of the process would involve FSANZ conducting a 'preliminary assessment' of the information submitted to assess which of the relationships would have sufficient submitted information to proceed to the usual assessment process.

Step 5 – Assessing proposals

Those GLHC relationships considered to have sufficient information would be compiled into one or more proposals for the usual assessment process.

All approved GLHC relationships would appear in Schedule 2 to the Standard prior to the end of the transition period. Following the transition period, all GLHC relationships that were not approved would become non-compliant. After expiry of the transition period, any new GLHC relationships would require application to FSANZ in accordance with guidance that will be provided in the FSANZ *Application Handbook* (see section 9.3.1).

9.3.2.1 Timeframe for processing proposals

Under the Preferred Option each proposal raised would undergo one round of public consultation and take between 6 and 12 months to complete depending on the number of GLHC relationships contained in the proposal. It is unclear at this stage what the magnitude of the assessment task might be.

Applications could be received during the transition period, and if paid, would be considered without delay. This would mean that FSANZ could be assessing concomitantly proposals dealing with existing claims in the marketplace and applications dealing with a new claim.

In the event that all food-health relationships were not able to be processed by the end of the transition period (which is proposed to be two years), FSANZ will consider whether alternative transition arrangements are required for GLHCs (i.e. the remainder of the Standard would come into full effect).

This would require further discussion with enforcement agencies.

9.3.2.2 What happens if a food-health relationship is not approved?

Under the Preferred Option, for any GLHC relationships not included in Standard 1.2.7 after completion of the transition period for Schedule 2, an application to FSANZ will be required in order for GLHCs based on those GLHC relationships to be legally made.

COMPLEXITY OF DRAFT STANDARD 1.2.7

10. Issues identified in the First Review Request

A recurring theme in the First Review Request was potential difficulties with enforcement. These concerns related to the length, complexity and difficulty of enforcement of and compliance with the draft Standard.

11. Response to identified issues

We have re-drafted the Standard to better achieve the intent, and to improve clarity and ease of comprehension (refer to Attachment 1). The re-drafting has focused on three main areas:

- separation of concepts (so that clauses deal only with one concept, and similar concepts are grouped together);
- standardisation of provisions (similar provisions which are repeated throughout the Standard are expressed in similar language, e.g. the conditions for general level health claims and high level health claims are similar and are therefore expressed in similar language); and
- simplification and clarification (wherever possible, the drafting has been simplified and clarified).

FSANZ has also prepared an Explanatory Statement for the new Standard, to help clarify the intent (refer to Attachment 2).

12. Summary of major amendments

Table 1 in Attachment 5 summarises the major amendments to draft Standard 1.2.7 that have occurred as a result of simplifying and clarifying the drafting since the Final Assessment Report. Tables 2–5 in Attachment 5 explain the major consequential amendments that have been made to other Standards currently in the Code, e.g. Standard 1.2.8 – Nutrition Information Requirements, and the Standards in Part 2.9 – Special Purpose Foods. The Tables do not list all the changes, only those where explanation may be needed to explain the amendment.

CONSULTATION

13. Guidance for submitters

Attachment 1 provides a consultation draft of the variations to the Code proposed as part of Proposal P293. This draft is not final, and has not been formally approved by FSANZ as a variation to the Code. The purpose of this draft is to seek your input before that occurs.

This consultation draft contains the new proposed Standard 1.2.7 and also the consequential amendments that are necessary as a result of Standard 1.2.7.

The variations in this consultation draft are, given the regulatory subject matter, necessarily complex and lengthy. However, FSANZ has sought to clarify, simply and improve the ease of use of the proposed Standard 1.2.7. We welcome your comments and suggestions on how the drafting could be further improved.

The variations should be read together with the explanatory notes which explain the intent of each of the clauses in Standard 1.2.7. We have also prepared a draft of Standard 1.2.8 which shows what that standard will look like when the variations are gazetted.

14. Questions to consider

14.1 Revision of the draft Standard

Comments from submitters regarding the redrafting of draft Standard 1.2.7 and consequential amendments to other Standards in the Code should be confined to comments that address the questions listed below:

1. Does the new drafting improve clarity, and reduce the ambiguity of the draft Standard 1.2.7?

2. Will the new drafting be easier and less resource intensive to monitor and enforce and for industry to comply with?

3. Does the new drafting facilitate compliance by industry and enforcement by regulatory authorities?

Please note that the overall intent of the regulatory approach has been agreed to by the Ministerial Council and is not subject to review.

14.2 Regulation of GLHCs

Schedule 2 of the draft Standard contains details to date of proposed GLHC relationships and their conditions and contexts for use. In relation to the proposed regulation of GLHCs, submitters should consider the questions below:

1. Please indicate your preference for the options presented above in section 8, with your reasons.

2. To what extent does Schedule 2 of the draft Standard cover the GLHCs that are currently in the marketplace?

3. The proposed approach for regulating GLHCs includes provision for more GLHC relationships to be approved during the transition period via proposals and possibly applications. Please comment on the proposed system for transition including what else may be required during the transition period to ensure all valid claims can remain on the market?

CONCLUSION

15. Conclusion and Preferred Option

In response to the First Review Request we are recommending two significant changes to draft Standard 1.2.7. These changes are:

- the approach used for the regulation of general level health claims; and

- a complete revision of the text and structure of draft Standard 1.2.7 for the purpose of improving clarity and user-friendliness.

Our preferred option for the regulation of general level health claims is an approach where FSANZ would pre-approve GLHC relationships. A GLHC would therefore be prohibited unless the GLHC relationship is prescribed in the Standard (and other specific wording and compositional conditions are met). We consider this approach satisfies the concerns expressed in the First Review Request and could be immediately implemented within the current legislative framework. Because of FSANZ's involvement in pre-market approval, much of the burden on enforcement agencies would be lifted. In addition central decision making would deal with the potential for enforcement agencies to hold disparate views about the lawfulness of a particular GLHC relationship.

We also consider the revision of the text and structure of the draft Standard addresses the concerns raised by the Ministerial Council about the complexity of the draft Standard at Final Assessment.

ATTACHMENTS

1. Draft Variations to the *Australia New Zealand Food Standards Code*
2. Explanatory statement – Draft Standard 1.2.7 – Nutrition, Health and Related Claims
3. Draft Variation to the Code – consolidated version of Standard 1.2.8 – Nutrition Information Requirements
4. Ministerial Council Review Request Media Release
5. Summary of proposed drafting amendments
6. Policy Guideline for Nutrition, Health and Related Claims
7. Levels of Evidence
8. Development of Food–Health Relationships

Attachment 1

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

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

[1] ***Standard 1.1.1*** *of the Australia New Zealand Food Standards Code is varied by omitting the definition of* claim *in clause 2, substituting –*

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

[2] *The* ***Australia New Zealand Food Standards Code*** *is varied by inserting –*

STANDARD 1.2.7

NUTRITION, HEALTH AND RELATED CLAIMS

Purpose

This Standard regulates the use of nutrition, health and related claims on food labels and in advertisements for food. It also consolidates a number of requirements relating to such claims that were previously spread across several Standards, such as Standards 1.2.8 and 1.3.2.

The Standard prohibits nutrition, health and related claims from being made unless specifically permitted by this Code. There are some permissions to make nutrition and health claims elsewhere in the Code, but this Standard contains the rules for the majority of permitted nutrition and health claims.

Table of Provisions

44 Simplified outline of this Division

Division 1 – Preliminary

1 Interpretation

(1) In this Standard –

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

cause-related marketing statement has the meaning given in clause 42.

claim has the meaning given in Standard 1.1.1.

claim to which this Standard applies has the meaning given by clauses 5 and 6.

dietary information has the meaning given in clause 45.

endorsement has the meaning given in clause 38.

food group means any of the following groups –

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

fruit means the edible portion of a plant or constituents of the edible portion that are present in the typical proportion of the whole fruit (with or without the peel or water) but does not include nuts, spices, herbs, fungi, dried pulses and seeds.

general level health claim has the meaning given in clause 5.

glycaemic index (GI) means the blood glucose raising ability of the digestible carbohydrates in a given food.

Editorial note:

The method for determining glycaemic index of carbohydrates in foods is described in the Standards Australia Australian Standard Glycemic index of foods (AS 4694 – 2007). In particular, glycaemic index testing is carried out by the determination of glycaemic (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 glycaemic 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) a food or a property of food; and
(b) a health effect.

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

high level health claim has the meaning given in clause 5.

ineligible food has the meaning given in clause 11.

nutrition content claim has the meaning given in clause 5.

n**utrient profiling scoring criterion (or NPSC)** means the criterion set out in Division 9.

nutrition information panel (or NIP) means the nutrition information panel required by Standard 1.2.8.

property of food means any of the following (when associated with a nutrition or health purpose) –

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

reference food means a food that is –

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

Editorial note:

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

An example for paragraph (b) is milk products compared to milk alternatives.

reference value, in relation to a property of food, means the RDI, ESADDI or the reference value under the Table to subclause 7(8) of Standard 1.2.8 for that property.

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

vegetable means the edible portion of a plant or constituents of the edible portion that are present in the typical proportion of the whole vegetable (with or without the peel or water) but does not include nuts, spices, herbs, fungi, dried pulses and seeds.

(2) A reference in this Standard to making a claim means making or including on a label or in an advertisement for food a claim to which this Standard applies.

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

(4) The simplified outlines of divisions in this Standard are provided only to assist in navigating this Standard, and do not alter the legal effect of the provisions of this Standard.

2 Transition

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

(2) A claim to which this Standard applies is taken to comply with this Standard for a period of 24 months after the commencement of this Standard, if the claim otherwise complied with the Code before the Standard commenced.

3 Severability of provisions

The clauses in this Standard are, to the maximum extent possible, to be read so as to be severable from one another.

Division 2 – Claims framework and general conditions

4 Simplified outline of this Division

The following is a simplified outline of this Division.

This Division sets the framework and some of the general principles for the regulation of nutrition, health and related claims. Subdivision 1 defines the 'claims to which this Standard applies', which is a short-hand term used to collectively describe nutrition content claims, general level health claims and high level health claims. Claims to which this Standard applies are prohibited unless expressly permitted by this Code. Even where permitted elsewhere in this Code, this Division imposes an overarching principle that claims must never be misleading or deceptive. A claim permitted outside this Standard is required to comply with that overarching principle, but is not required to comply with any other provision in this Standard. Subdivision 2 of this Division contains some general principles which apply to all claims that are permitted by this Standard.

Subdivision 1 – Claims framework

5 Claims to which this Standard applies

(1) In this Standard –

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

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

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

(2) Subject to clause 6, each of the claims mentioned in subclause (1), is a claim to which this Standard applies.

(3) To avoid doubt, a health claim which refers to a relationship between a food or property of food in Column 1 of Schedule 2 and a corresponding specific health effect in Column 2 is a general level health claim.

6 Certain claims are not claims to which this Standard applies

(1) A claim about or in relation to –

(a) food which is intended for further processing, packaging or labelling prior to retail sale; or
(b) a meal provided to a client of a delivered meal organisation; or

(c) food, other than food in a package, provided to a patient in a hospital or other similar institutions mentioned in the Table to clause 8 of Standard 1.2.1;

is not a claim to which this Standard applies.

(2) Claims about ethical, religious or environmental features of food are not claims to which this Standard applies.

Editorial note:

Examples of claims which are not claims to which this Standard applies under subclause (2) are: vegetarian, halal, kosher and organic.

(3) Claims about –

(a) the risks or dangers of alcohol consumption; or
(b) moderating alcohol intake;

are not claims to which this Standard applies.

7 Prohibition on the making of claims

Unless expressly permitted by this Code, a claim to which this Standard applies must not be made.

Editorial note:

See Division 3 for the circumstances in which nutrition content claims may be made, Division 4 for general level health claims and Division 5 for high level health claims. Division 6 sets out the circumstances in which endorsements may be used. Division 7 (Cause-related marketing statements) deals with claims to which this Standard applies that are presented as statements the that the sale of food will contribute to fundraising for an organisation.

8 Prohibition on related claims

Unless expressly permitted by this Code, dietary information must not be included on a label or in an advertisement for food.

Editorial note:

See Division 8 for the circumstances in which dietary information may be included.

9 Claims permitted elsewhere in the Code

If a claim to which this Standard applies is expressly permitted elsewhere in this Code but not by this Standard, that claim must comply with the clause 10 but is not required to comply with any other requirement in this Standard.

10 Claims must not be therapeutic in nature etc

Unless expressly permitted by this Code, a claim must not be made if –

(a) the claim refers to the symptoms, prevention, diagnosis, cure or alleviation of a disease, ailment, defect or condition; or
(b) the claim compares a food and a therapeutic good.

Subdivision 2 – General principles and conditions

11 Ineligible foods

An ineligible food means a food listed in the Table to this clause.

Table to clause 11

Kava
A food that contains more than 1.15% alcohol by volume
Infant formula products as standardised by Standard 2.9.1

Editorial note:

Ineligible foods are not able to carry nutrition content claims or health claims. See clause 16 for the circumstances in which food containing more than 1.15% alcohol by volume is not an ineligible food.

12 Form of food to which provisions of this Standard apply

Where this Standard imposes a prerequisite, condition, qualification or any other requirement on the making of a claim to which this Standard applies, that prerequisite, condition, qualification or requirement applies to the form of the food determined in accordance with the Table.

Table to clause 12

Food that	Must meet the prerequisite, condition or qualification based on
Can be either prepared with other food, or consumed as sold	The food as sold.
Is required to be prepared and consumed according to directions	The food as prepared.
Requires reconstituting with water	The food after it is reconstituted with water and ready for consumption.
Requires draining before consuming	The food after it is drained and ready for consumption.

Editorial note:

The information on the label for the food including the directions for use and any information provided in an advertisement should be taken into account to determine the form of the food.

See clause 11A of Standard 1.2.8 for additional NIP requirements where a claim is based on food as prepared.

13 Claims about properties naturally present or absent

If a claim is based on, relates to or is about a property of food that is naturally present or absent in other similar foods, the claim must refer to the food and not the brand of food.

Editorial note:

For example, a claim may say 'bananas are cholesterol free' but not '[particular brand of bananas] are cholesterol free'.

14 Claims comparing vitamin and mineral content

A claim that directly or indirectly compares the vitamin or mineral content of a food with that of another food must not be made unless expressly permitted.

Division 3 – Nutrition content claims

15 Simplified outline of this Division

The following is a simplified outline of this Division.

This Division permits four categories of nutrition content claims: (a) a claim about a property of food in Schedule 1; (b) a claim about a property of food with a reference value; (c) a claim about some specific properties which have special rules; and (d) a claim about any other property of food. This Division contains different rules for each different category of nutrition content claim, but the common characteristic of each category is that a nutrition content claim must not be made about an ineligible food.

16 Ineligible foods must not make nutrition content claims

(1) A nutrition content claim must not be made about or in relation to an ineligible food.

(2) Despite clause 11, a food containing more than 1.15% alcohol by volume is not an ineligible food for a nutrition content claim about –

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

17 Nutrition content claims about properties of food in Schedule 1

(1) A nutrition content claim about a property of food mentioned in Column 1 of Schedule 1 may be made in accordance with this clause.

(2) Any claim about the property of food mentioned in Column 1 of Schedule 1 must meet the corresponding general claim conditions in Column 2.

(3) A claim about the property of food mentioned in Column 1 of Schedule 1 which uses a descriptor in Column 3 or a synonymous descriptor must meet –

(a) the general claim conditions for the relevant property of food in Column 2; and
(b) the specific claim conditions in Column 4 for the relevant descriptor.

(4) If for subclause (3) there is an inconsistency between a general claim condition in Column 2 and a specific claim condition in Column 4, the specific claim condition prevails.

18 Nutrition content claims where there is a reference value

A nutrition content claim about a property of food not mentioned in Column 1 of Schedule 1 may be made if there is a reference value for that property of food.

19 Nutrition content claims where there is no reference value

(1) Subject to subclause (2), a nutrition content claim may be made about a property of food –

(a) that is not mentioned in the Column 1 of Schedule 1; and
(b) for which there is no reference value.

(2) A claim under this clause –

(a) must refer only to the presence or absence of a property of food; and
(b) may include a numerical expression of the property of food.

Editorial note:

An example of a nutrition content claim that is a numerical expression of the property of a food is 'GL (glycaemic load) = 12'. Examples of words which refer only the presence of a property of food are 'contains' and 'provides'.

20 Claims about trans fatty acids

Despite any other provision in this Division, a nutrition content claim about low or percentage free trans fatty acids must not be made.

21 Claims about gluten

Despite any other provision in this Division, a nutrition content claim about or in relation to gluten may only be made if –

(a) the claim uses a descriptor in Column 1 of the Table; and
(b) the claim meets the corresponding conditions in Column 2.

Table to clause 21

Column 1	Column 2
Descriptor	**Conditions**
Free	The food must not contain – (i) detectable gluten; or (ii) oats or their products; or (iii) cereals containing gluten that have been malted, or their products.
Low	The food contains no more than 20 mg gluten per 100 g of the food.

22 Claims about lactose

Despite any other provision in this Division, a nutrition content claim about or in relation to lactose may only be made if –

(a) the claim uses a descriptor in Column 1 of the Table; and
(b) the claim meets the corresponding conditions in Column 2.

Table to clause 22

Column 1	Column 2
Descriptor	**Conditions**
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.

23 Diet nutrition content claims must not imply slimming effects etc

(1) A nutrition content claim about energy using the descriptor 'diet' must not use a synonymous descriptor that directly or indirectly –

(a) refers to 'slimming' or other such words; or
(b) suggests that the food has weight loss or weight maintenance properties.

(2) This clause does not affect the operation of Divisions 4 or 5.

24 Comparative claims

(1) In this clause, a comparative claim means a nutrition content claim that directly or indirectly compares the nutrition content of one food or brand of food with another, and includes claims using the following descriptors –

(a) light or lite;
(b) increased;
(c) reduced;

or words of similar import.

(2) A nutrition content claim using the descriptor 'diet' is a comparative claim if it meets the conditions for making that claim by having at least 40% less energy than the same quantity of reference food.

(3) A comparative claim about a food (the claimed food) must state together with the claim –

(a) the identity of the reference food;
(b) the difference between the amount of the property of food in the claimed food and the reference food.

25 Presentation of nutrition content claims

(1) A nutrition content claim must mention –

(a) the property of food; and
(b) the form of the food;

to which the claim relates.

(2) Despite subclause (1), if the form of the food to which the claim relates is the food as sold, the form of the food need not be expressly mentioned.

(3) The entire nutrition content claim must be presented in the one place.

Division 4 – General level health claims

26 Simplified outline of this Division

The following is a simplified outline of this Division.

This Division permits general level health claims to be made in certain circumstances. A general level health claim must be based on a substantiated relationship listed in Schedule 2. Furthermore, the food to which the general level health claim relates must not be an ineligible food and must in most circumstances meet the NPSC. This Division also prescribes the information that a general level health claim must contain.

27 Permission to make certain general level health claims

(1) A general level health claim may be made if –

(a) it is not about or in relation to an ineligible food; and
(b) the food to which it relates meets the nutrient profiling scoring criterion; and
(c) it refers to a relationship between a food or property of food mentioned in Column 1 of Schedule 2 and a health effect mentioned in Column 2; and
(d) it complies with any applicable conditions in Column 3; and
(e) it complies with the other provisions of this Division.

(2) Despite paragraph (1)(b), a general level health claim about a food that is standardised in Part 2.9 of this Code does not need to meet the nutrient profiling scoring criterion.

28 What must a general level health claim say?

(1) Subject to clause 29, a general level health claim must expressly state in the one place all of the elements of a general level health claim.

(2) The elements of a general level health claim are –

(a) the property of the food, or if the claim is based on the food itself, the food; and
(b) the specific health effect claimed for the property of the food or the food; and
(c) if applicable, the population group to which the specific health effect relates; and
(d) the context; and
(e) the form of the food to which the claim relates.

Editorial note: Clause 12 sets out how the form of the food is to be determined.

(3) The elements of a general level health claim must be expressed according to the –

(a) property of food or food in Column 1 of Schedule 2;

(b) specific health effect in Column 2 of Schedule 2;
(c) population statement in Column 4 of Schedule 2, if any; and
(d) principles for a context statement set out in subclause (4).

(4) A context statement must –

(a) meaningfully describe the dietary context that supports achievement of the health effect;
(b) include words to the effect of the relevant context statement in Column 4 of Schedule 2, if any;

as appropriate to the claim being made.

Editorial note:

An example of a context statement for a general level health claim about calcium and strong teeth and bones could be: 'A healthy diet including a variety of foods rich in calcium.'

(5) To avoid doubt, this clause does not prescribe the wording of a general level health claim.

(6) Despite subclause (2), if the form of the food to which the claim relates is the food as sold, the form of the food to which the claim relates need not be mentioned.

29 Split general level health claims

(1) In addition to the statement required by subclause 28(1), the property of the food and the specific health effect may also be presented in a separate statement (a split claim), provided that –

(a) the two statements are on or in the same label or advertisement; and
(b) the split claim indicates where the complete statement required by clause 28 is located.

(2) The split claim must otherwise comply with clause 28.

30 Claim statements for claims about phytosterol esters and tall oil phytosterols

Despite clause 28, a claim statement for a claim about phytosterol esters and tall oil phytosterols need not include a statement to the effect that it should be consumed as part of a healthy diet if the claim appears together with the mandatory advisory statement required by clause 2 of Standard 1.2.3.

31 Nutrition content claims about properties in Schedule 2

(1) Subject to subclause (2), where this Division permits a general level health claim based on a particular property (the relevant property) to be made if certain conditions are met (the relevant conditions), a nutrition content claim about the relevant property may be made if the relevant conditions are met.

(2) A claim under this clause –

(a) must be presented on the same label or in the same advertisement as the general level health claim; and
(b) must refer only to the presence or absence of the property of food; and
(c) may be a numerical expression of the property of food.

(3) This clause does not affect the operation of Division 3.

Division 5 – High level health claims

32 Simplified outline of this Division

The following is a simplified outline of this Division.

This Division permits high level health claims to be made in certain circumstances. A high level health claim must be based on a substantiated relationship listed in Schedule 3. Furthermore, the food to which the high level health claim relates must not be an ineligible food and must in most circumstances meet the NPSC.

This Division also prescribes the information that a high level health claim must contain.

33 Permission to make certain high level health claims

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

(a) the claim is not about or in relation to an ineligible food;
(b) the food to which it relates meets the nutrient profiling scoring criterion;
(c) it refers to a relationship between a food or property of food mentioned in Column 1 of Schedule 3 and a health effect mentioned in Column 2; and
(d) it complies with any applicable conditions in Column 3; and
(e) it complies with the other provisions of this Division.

(2) Despite paragraph (1)(b), a high level health claim about a food that is standardised in Part 2.9 of this Code does not need to meet the nutrient profiling scoring criterion.

34 What must a high level health claim say?

(1) Subject to clause 35, a high level health claim must expressly state in the one place all of the elements of a high level health claim.

(2) The elements of a high level health claim are –

(a) the property of the food, or if the claim is based on the food itself, the food; and
(b) the specific health effect claimed for the property of the food or the food; and
(c) if applicable, the population group to which the specific health effect relates; and
(d) the context; and
(e) the form of the food to which the claim relates.

Editorial note:

Clause 12 sets out how the form of the food is to be determined.

(3) The elements of a high level health claim must be expressed according to the –

(a) property of food or food in Column 1 of Schedule 3;
(b) specific health effect in Column 2 of Schedule 3;

(c) population statement in Column 4 of Schedule 3, if any; and

(d) context statement in Column 4 of Schedule 3.

(4) To avoid doubt, this clause does not prescribe the wording of a high level health claim.

(5) Despite subclause (2), if the form of the food to which the claim relates is the food as sold, the form of the food to which the claim relates need not be mentioned.

35 Split high level health claims

(1) In addition to the statement required by subclause 34(1), the property of the food and the specific health effect may also be presented in a separate statement (a split claim), provided that –

(a) the two statements are on or in the same label or advertisement; and
(b) the split claim indicates where the complete statement required by clause 34 is located.

(2) The split claim must otherwise comply with clause 34.

36 Nutrition content claims about properties in Schedule 3

(1) Subject to subclause (2), where this Division permits a high level health claim based on a particular property (the relevant property) to be made if certain conditions are met (the relevant conditions), a nutrition content claim about the relevant property may be made if the relevant conditions are met.

(2) A claim under this clause –

(a) must be presented on the same label or in the same advertisement as the high level health claim; and
(b) must refer only to the presence of the property of food; and
(c) may be a numerical expression of the property of food.

(3) This clause does not affect the operation of Division 3.

Division 6 – Endorsements

37 Simplified outline of this Division

The following is a simplified outline of this Division.

An endorsement is a claim that can only be lawfully used or made by the supplier making the claim with the permission of an endorsing body. An endorsing body is one which has a nutrition or health purpose or function, is not-for-profit and is not related to the supplier making the claim. The supplier using the endorsement need only comply with the requirements in this Division. Other than clause 10, the other requirements of this Standard do not apply to endorsements.

38 What is an endorsement?

(1) An endorsement is a claim to which this Standard applies that can only be lawfully used or made by a supplier with the permission of another person, body or government agency (the endorsing body) and where that endorsing body –

(a) has a nutrition or health purpose or function; and
(b) operates on a not-for-profit basis; and
(c) is not related to the supplier using the endorsement.

(2) Without limiting the generality of paragraph (1)(c), an endorsing body is related to a supplier if the supplier –

(a) has a financial interest in the endorsing body; or
(b) established, either by itself or with others, the endorsing body; or
(c) exercises direct or indirect control over the endorsing body.

39 Criteria for endorsements

(1) An endorsement may be made if it complies with clause 10 and this Division, but need not comply with any other requirement of this Standard.

(2) Subject to subclause (3), an endorsement must not refer to a serious disease.

(3) An endorsement may refer to a serious disease only if that serious disease is part of the name of the endorsing body.

40 Record keeping requirement

(1) In this clause –

required records means a document or documents that demonstrate that –

(a) the supplier using the endorsement has obtained the permission of the endorsing body to use the endorsement; and
(b) the endorsing body has a nutrition or health function or purpose; and

(c) the endorsing body operates on a not-for-profit basis; and

(d) the endorsing body is not related to the supplier making the claim.

supplier using the endorsement means the supplier who makes or includes an endorsement on a label or in an advertisement for food.

(2) The supplier using the endorsement must –

(a) keep the required records;
(b) upon request by the relevant authority, make the required records available for inspection.

(3) Despite subclause (1), if the label of an imported food makes or includes an endorsement, the importer of the food is taken to be the supplier using the endorsement.

Division 7 – Cause-related marketing statements

41 Simplified outline of this Division

The following is a simplified outline of this Division.

A cause-related marketing statement is claim that is presented as a statement that the sale of a food will contribute to fundraising for an organisation. Cause-related marketing statements do not need to comply with the requirements of the rest of this Standard (other than clause 10) if they carry the appropriate statement set out in this Division.

42 What is a cause-related marketing statement?

A cause-related marketing statement is a claim to which this Standard applies that is presented as a statement that the sale of the food to which the claim relates will contribute to fundraising for an organisation.

43 Criteria for cause-related marketing statements

(1) A cause-related marketing statement may be made if the cause-related marketing statement appears together with a statement to the effect of that in Column 2 of the Table for the appropriate type of cause-related marketing statement in Column 1.

Table to subclause 43(1)

Column 1	Column 2
Type of cause-related marketing statement	**Statement**
Nutrition content claim presented as a cause-related marketing-statement.	[Supplier] makes no claims about [property of food].
Health claim presented as a cause-related marketing statement.	[Supplier] makes no claims about this food being beneficial for managing [health effect].

Editorial note: An example of a cause-related marketing statement could be 'One dollar from the purchase of this food will be donated to the ABC Disease Foundation'. The supplier of the food could then say 'X Foods makes no claims about this food being beneficial for managing A disease.'

(2) A cause-related marketing statement need not comply with any other requirement of this Standard.

(3) A cause-related marketing statement need not appear with the statement required by subclause (1) if –

(a) the cause-related marketing statement appears on or in the same label or advertisement as a claim to which this Standard applies; and

(b) that claim complies with the requirements of this Code.

Division 8 – Dietary information

44 Simplified outline of this Division

The following is a simplified outline of this Division.

Clause 8 of this Standard prohibits dietary information from being included on labels or in advertisements unless specifically permitted. This Division contains the permission to include dietary information. Permitted dietary information about properties of food may only be included if certain conditions are met. Permitted dietary information about anything other than a property of food may be included without restriction (other than the general restrictions in clause 10).

45 What is dietary information and what is permitted dietary information?

(1) In this Division –

dietary information means general dietary information in the nature of dietary guidance, but does not include information about moderation of alcohol intake.

permitted dietary information means dietary information that –

(a) is from an authoritative source; and
(b) is provided for educational purposes;

but does not include information that mentions a biomarker or health effect.

Editorial note: An example of permitted dietary information is some of the information contained in national nutrition guidelines such as – (a) National Health and Medical Research Council dietary guidelines; and (b) New Zealand Ministry of Health food and nutrition guidelines.

(2) In this Division, a reference to including dietary information means including dietary information on a label or in an advertisement for food.

46 Permitted dietary information about properties of foods

Permitted dietary information about a property (the relevant property) of food may be included if –

(a) the food to which the dietary information relates is eligible to carry a nutrition content claim about the relevant property;
(b) the dietary information is on the same label or in the same advertisement as a nutrition content claim about the relevant property; and
(c) the dietary information accords with the nutrition content claim.

47 Permitted dietary information about matters other than properties of foods

Permitted dietary information about matters other than properties of foods may be included.

Division 9 – Nutrient profiling scoring criterion

48 Simplified outline of this Division

This Division describes how to determine a food's NPSC category and how to determine whether a food meets the NPSC. The steps for calculating a food's nutrient profiling score are set out in Schedule 4.

This Division also contains special rules about information that must be declared in a label for foods that are required to meet the NPSC.

49 Calculating a food's nutrient profiling score and determining the category

(1) A food in Column 1 of the Table belongs to the corresponding NPSC category in Column 2.

Table to subclause 49

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

(2) A food's nutrient profiling score is to be determined by applying the formulae in Schedule 4.

50 When a food meets the nutrient profiling scoring criterion

A food belonging to the NPSC category in Column 1 of the Table meets the NPSC if its nutrient profiling score is less than the corresponding figure in Column 2.

Table to clause 50

Column 1	Column 2
For the NPSC category	**The nutrient profiling score must be less than**
Category 1	1
Category 2	4
Category 3	28

51 Additional nutrition information requirements

(1) In this clause, fvnl has meaning given by item 4 of Schedule 4.

(2) This clause applies only where a food must meet the NPSC in order to make a claim to which this Standard applies.

(3) If –

(a) a property of food, other than fvnl, is relied on to meet the NPSC (the scoring property); and
(b) particulars of the scoring property are not otherwise required to be included in the nutrition information panel;

then, by virtue of this subclause, the particulars of that scoring property must be declared in the nutrition information panel.

(4) Subject to subclause (5), if a food scores V points under item 4 of Schedule 4, then the percentage of fvnl must be declared on the label.

(5) The percentage of fvnl need not be declared for –

(a) a general level health claim about fruits and vegetables and heart health; or
(b) a high level health claim about fruits and vegetables and coronary heart disease.

(6) If –

(a) a food is classified in Category 3 for the purposes of determining the food's nutrient profile score; and
(b) the food is a cheese or processed cheese;

then the calcium content of the food must be declared in the nutrition information panel.

SCHEDULE 1

Specific Nutrition Content Claims

Column 1	Column 2	Column 3	Column 4
Property of food	**General claim conditions**	**Specific descriptor**	**Specific descriptor conditions**
Carbohydrate		Reduced or light/lite	The food contains at least 25% less carbohydrate than the same quantity of reference food.
		Increased	The food contains at least 25% more carbohydrate than the same quantity of reference food.
Cholesterol	The food meets the conditions for a nutrition content claim about low saturated fatty acids.	Low	The food contains no more cholesterol than – (a) 10 mg per 100 mL for liquid food; or (b) 20 mg per 100 g for solid food.
		Reduced or Light/Lite	The food contains at least 25% less cholesterol than the same quantity of reference food.
Dietary fibre	A serving of the food contains at least 2 g of dietary fibre unless the claim is about low or reduced dietary fibre.	Good source	A serving of the food contains at least 4 g of dietary fibre.
		Increased	(a) The reference food contains at least 2 g of dietary fibre per serving; and (b) the food contains at least 25% more dietary fibre than the same quantity of reference food.
		Excellent source	A serving of the food contains at least 7 g of dietary fibre.

Specific Nutrition Content Claims (continued)

Column 1	Column 2	Column 3	Column 4
Property of food	**General claim conditions**	**Specific descriptor**	**Specific descriptor conditions**
Energy		Low	The average energy content of the food is no more than – (a) 80 kJ per 100 mL for liquid food; or (b) 170 kJ per 100 g for solid food.
		Reduced or Light/Lite	The food contains at least 25% less energy than the same quantity of reference food.
		Diet	(a) Either – (i) the average energy content of the food is no more than 80 kJ per 100 mL for liquid food or 170 kJ per 100 g for solid food; or (ii) the food contains at least 40% less energy than the same quantity of reference food; and (b) if the food is not a food standardised by Part 2.9 of the Code, the food meets the NPSC.
Fat		% Free	The food meets the conditions for a nutrition content claim about low fat.
		Low	The food contains no more fat than – (a) 1.5 g per 100 mL for liquid food; or (b) 3 g per 100 g for solid food.
		Reduced or Light/Lite	The food contains at least 25% less fat than the same quantity of reference food.

Specific Nutrition Content Claims (continued)

Column 1	Column 2	Column 3	Column 4
Property of food	**General claim conditions**	**Specific descriptor**	**Specific descriptor conditions**
Glycaemic Index	(a) if the food is not a food standardised by Part 2.9 of the Code, the food meets the NPSC; and (b) the claim or the nutrition information panel under Standard 1.2.8 includes the numerical value of the glycaemic index of the food.	Low Medium High	The numerical value of the glycaemic index of the food is indicated at 55 and below. The numerical value of the glycaemic index of the food is indicated between 56 and 69. The numerical value of the glycaemic index of the food is indicated at 70 and above.
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 than the same quantity of reference food; and (b) the reference food meets the minimum conditions for a nutrition content claim about monounsaturated fatty acids.
Omega fatty acids (any)	The type of omega fatty acid is specified immediately after the word 'omega'.		

Specific Nutrition Content Claims (continued)

Column 1	Column 2	Column 3	Column 4
Property of food	**General claim conditions**	**Specific descriptor**	**Specific descriptor conditions**
Omega-3 fatty acids	(a) the food meets the conditions for a nutrition content claim about 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 or eicosapentaenoic acid.	Good Source Increased	(a) the food contains no less than 60 mg total eicosapentaenoic acid and docosahexaenoic acid per serving; and (b) the food may contain less than 200 mg alpha-linolenic acid per serving. (a) the food contains at least 25% more omega-3 fatty acids than the same quantity of reference food; and (b) the reference food meets the minimum conditions for a nutrition content claim about omega-3 fatty acids.

Specific Nutrition Content Claims (continued)

Column 1	Column 2	Column 3	Column 4
Property of food	**General claim conditions**	**Specific descriptor**	**Specific descriptor conditions**
Omega-6 fatty acids	(a) the food meets the conditions for a nutrition content claim about 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 than the same quantity of reference food; and (b) the reference food meets the minimum conditions for a nutrition content claim about omega-6 fatty acids.
Omega-9 fatty acids	(a) the food meets the conditions for a nutrition content claim about 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 than the same quantity of reference food; and (b) the reference food meets the minimum conditions for a nutrition content claim in relation to omega-9 fatty acids.
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 than the same quantity of reference food; and (b) the reference food meets the minimum conditions for a nutrition content claim about polyunsaturated fatty acids.
Potassium	The nutrition information panel indicates the sodium and potassium content.		

Specific Nutrition Content Claims (continued)

Column 1	Column 2	Column 3	Column 4
Property of food	**General claim conditions**	**Specific descriptor**	**Specific descriptor conditions**
Protein	The food contains at least 5 g of protein per serving unless the claim is about low or reduced protein.	Good Source	The food contains at least 10 g of protein per serving.
		Increased	(a) the food contains at least 25% more protein than the same quantity of reference food; and (b) the reference food meets the conditions for a nutrition content claim about protein.
Salt or sodium	The nutrition information panel indicates the potassium content.	Low	The food contains no more sodium than – (a) 120 mg per 100 mL for liquid food; or (b) 120 mg per 100 g for solid food.
		Reduced or Light/Lite	The food contains at least 25% less sodium than the same quantity of reference food.
		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	The food meets the conditions for a nutrition content claim about no added salt.

Specific Nutrition Content Claims (continued)

Column 1	Column 2	Column 3	Column 4
Property of food	**General claim conditions**	**Specific descriptor**	**Specific descriptor conditions**
Saturated and trans fatty acids		Low	The food contains no more saturated and trans fatty acids than – (a) 0.75 g per 100 mL for liquid food; or (b) 1.5 g per 100 g for solid food.
		Reduced or Light/Lite	The food contains – (a) at least 25% less saturated and trans fatty acids as the same quantity of reference food; and (b) both saturated and trans fatty acids are reduced relative to the same quantity of reference food.
		Low proportion	(a) the food contains as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and trans fatty acids; and (b) the claim expressly states in words to the effect of 'low proportion of saturated and trans fatty acids of total fatty acid content'.

Specific Nutrition Content Claims (continued)

Column 1	Column 2	Column 3	Column 4
Property of food	**General claim conditions**	**Specific descriptor**	**Specific descriptor conditions**
Saturated fatty acids		Free	(a) the food contains no detectable saturated fatty acids; and (b) the food contains no detectable trans fatty acids.
		Low	The food contains no more saturated and trans fatty acids than – (a) 0.75 g per 100 mL for liquid food; or (b) 1.5 g per 100 g for solid food.
		Reduced or Light/Lite	(a) the food contains – (i) at least 25% less saturated fatty acids than the same quantity of reference food; and (ii) no more trans fatty acids than the same quantity of reference food.
		Low proportion	(a) the food contains as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and trans fatty acids; and (b) the claim expressly states in words to the effect of 'low proportion of saturated fatty acids of total fatty acid content'.

Specific Nutrition Content Claims (continued)

Column 1	Column 2	Column 3	Column 4
Property of food	**General claim conditions**	**Specific descriptor**	**Specific descriptor conditions**
Sugar or Sugars		% Free	The food meets the conditions for a nutrition content claim about low sugar.
		Low	The food contains no more sugars as standardised in clause 1 of Standard 1.2.8 than – (a) 2.5 g per 100 mL for liquid food; or (b) 5 g per 100 g for solid food.
		Reduced or Light/Lite	The food contains at least 25% less sugars as standardised in clause 1 of Standard 1.2.8 than the same quantity of reference food.
		No added	(a) the food contains no added sugars as standardised in clause 1 of Standard 2.8.1, honey, malt, malt extracts; and (b) the food contains no added concentrated fruit juice or deionised fruit juice, unless the food is standardised in Standards 2.6.1 or 2.6.2.
		Unsweetened	(a) the food meets the conditions for a nutrition content claim about no added sugar; and (b) the food contains no intense sweeteners, sorbitol, mannitol, glycerol, xylitol, isomalt, maltitol syrup or lactitol.

Specific Nutrition Content Claims (continued)

Column 1	Column 2	Column 3	Column 4
Property of food	**General claim conditions**	**Specific descriptor**	**Specific descriptor conditions**
Vitamin or mineral	(a) the vitamin or mineral is mentioned in column 1 of the Schedule to Standard 1.1.1; and (b) a serving of the food contains at least 10% of the RDI or ESADDI for that vitamin or mineral; and (c) a claim is not for more of the particular vitamin or mineral than the maximum claimable amount as prescribed by clause 4 of Standard 1.3.2; and (d) the food is not a food standardised by Standard 2.6.4, Standard 2.9.2, Standard 2.9.3 or Standard 2.9.4.	Good source	A serving of the food contains no less than 25% of the RDI or ESADDI for that vitamin or mineral.

SCHEDULE 2

Permitted General Level Health Claims
Part 1 – Vitamins

Column 1	Column 2	Column 3	Column 4
Food or property of food	**Specific health effect**	**Conditions**	**Population and context claim statements**
Biotin	Contributes to normal fat metabolism and energy production Contributes to normal growth and development	The food meets the general conditions for a nutrition content claim about biotin.	For children
Folate	Necessary for normal blood formation Necessary for normal cell division Contributes to normal growth and development	The food meets the general conditions for a nutrition content claim about folate.	For children
Folic acid (but not folate)	Contributes to normal neural tube structure in the developing foetus	(a) the food contains no less than 40 µg folic acid per serving; and (b) the food is not – (i) soft cheese; or (ii) pâté; or (iii) liver or liver product; or (iv) a food containing added phytosterol esters or added tall oil phytosterols; or (v) a food standardised by Standard 2.6.4; or (vi) a food standardised by Part 2.7; or (vii) a food standardised by Standards 2.9.2 or 2.9.4; or (viii) a formulated meal replacement standardised by Division 2 of Standard 2.9.3.	(a) the population group is women of child bearing age; and (b) a varied diet including food sources of folate and a recommendation that women consume at least 400 µg of folic acid per day, at least the month before and three months after conception.
Niacin	Necessary for normal neurological function Necessary for normal energy release from food Necessary for normal structure and function of skin and mucous membranes Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about niacin.	For children

Permitted General Level Health Claims
Part 1 – Vitamins (continued)

Column 1	Column 2	Column 3	Column 4
Food or property of food	**Specific health effect**	**Conditions**	**Population and context claim statements**
Pantothenic acid	Necessary for normal fat metabolism Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about pantothenic acid.	For children
Thiamin	Necessary for normal carbohydrate metabolism Necessary for normal neurological and cardiac function Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about thiamin	For children
Riboflavin	Contributes to normal iron transport and metabolism Contributes to normal energy release from food Contributes to normal skin and mucous membrane structure and function Contributes to normal growth and development	The food meets the general conditions for a nutrition content claim about riboflavin	For children
Vitamin A	Necessary for normal vision Necessary for normal skin and mucous membrane structure and function Necessary for normal cell differentiation Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about vitamin A	For children
Vitamin B_6	Necessary for normal protein metabolism Necessary for normal iron transport and metabolism Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about vitamin B_6	For children
Vitamin B_{12}	Necessary for normal cell division Contributes to normal blood formation Necessary for normal neurological structure and function Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about vitamin B_{12}	For children

Permitted General Level Health Claims
Part 1 – Vitamins (continued)

Column 1	Column 2	Column 3	Column 4
Food or property of food	**Specific health effect**	**Conditions**	**Population and context claim statements**
Vitamin C	Contributes to iron absorption from food Necessary for normal connective tissue structure and function Necessary for normal blood vessel structure and function Contributes to cell protection from free radical damage Necessary for normal neurological function Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about vitamin C.	For children
Vitamin D	Necessary for normal absorption and utilisation of calcium and phosphorus Contributes to normal cell division Necessary for normal bone structure Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about vitamin D.	For children
Vitamin E	Contributes to cell protection from free radical damage Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about vitamin E.	For children
Vitamin K	Necessary for normal blood coagulation Contributes to normal bone structure Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about vitamin K	For children

Permitted General Level Health Claims
Part 2 – Minerals

Column 1	Column 2	Column 3	Column 4
Food or property of food	**Specific health effect**	**Conditions**	**Population and context claim statements**
Calcium	Necessary for normal teeth and bone structure Necessary for normal nerve and muscle function Necessary for normal blood coagulation Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about calcium.	For children
Copper	Contributes to normal connective tissue structure Contributes to normal iron transport and metabolism Contributes to cell protection from free radical damage Necessary for normal energy production Necessary for normal neurological function Necessary for normal immune system function Necessary for normal skin and hair colouration Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about copper.	For children
Iodine	Necessary for normal production of thyroid hormones Necessary for normal neurological development Necessary for normal energy metabolism Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about iodine.	For children
Iron	Necessary for normal oxygen transport Contributes to normal energy production Necessary for normal immune system function Contributes to normal blood formation Necessary for normal neurological development in the foetus Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about iron.	For children

Permitted General Level Health Claims
Part 2 – Minerals (continued)

Column 1	Column 2	Column 3	Column 4
Food or property of food	**Specific health effect**	**Conditions**	**Population and context claim statements**
Manganese	Contributes to normal bone formation Contributes to normal energy metabolism Contributes to cell protection from free radical damage Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about manganese.	For children
Magnesium	Contributes to normal energy metabolism Necessary for normal electrolyte balance Necessary for normal nerve and muscle function Necessary for teeth and bone structure Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about magnesium.	For children
Potassium	Necessary for normal water and electrolyte balance Contributes to normal growth and development	The food must contain a minimum potassium level of 200 mg/serving.	For children
Phosphorus	Necessary for normal teeth and bone structure Necessary for the normal cell membrane structure Necessary for normal energy metabolism Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about phosphorus.	For children
Selenium	Necessary for normal immune system function Necessary for the normal utilization of iodine in the production of thyroid hormones Necessary for cell protection from some types of free radical damage Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about selenium.	For children
Zinc	Necessary for normal immune system function Necessary for normal cell division Contributes to normal skin structure and wound healing Contributes to normal growth and development	The food meets the general conditions for making a nutrition content claim about zinc.	For children

Permitted General Level Health Claims
Part 3 – Other Relationships

Column 1	Column 2	Column 3	Column 4
Food or property of food	**Specific health effect**	**Conditions**	**Population and context claim statements**
Beta-glucan	Reduces dietary and biliary cholesterol absorption	(a) food product must contain one or more of the following oat or barley foods – (i) oat bran; (ii) wholegrain oats; or (iii) wholegrain barley; and (b) the food product must contain at least 1 g /serving beta-glucan from the whole oat or barley foods	(a) As part of a healthy diet low in saturated fat (b) 3 g of beta-glucan is recommended to be consumed per day to achieve the specific health effect.
Carbohydrate	Contributes energy for normal metabolism	Carbohydrate must contribute at least 55% of the energy content of the food.	
Carbohydrate	Contributes energy for normal metabolism	The food – (a) must be a formulated meal replacement; formulated supplementary food or formulated supplementary food for young children (as standardised by Standard 2.9.3 Div 2, 3 and 4 respectively) (b) must have a maximum 10% of carbohydrate content from sugars.	
Dietary fibre	Contributes to regular laxation	The food meets the general conditions for making a nutrition content claim about dietary fibre.	

Permitted General Level Health Claims
Part 3 – Other Relationships (continued)

Column 1	Column 2	Column 3	Column 4
Food or property of food	**Specific health effect**	**Conditions**	**Population and context claim statements**
Eicosapentaenoic acid (EPA) and Docosahexaenoic acid (DHA) (but not Omega-3)	Contributes to heart health	(a) Minimum of 50 mg EPA and DHA combined in a serving of food (b) 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 than 5 g per 100 g saturated fatty acids and trans fatty acids.	500 mg of EPA and DHA is recommended to be consumed per day to achieve the specific health effect.
Energy	Contributes energy for normal metabolism	The food must a formulated supplementary food or formulated supplementary food for young children (as standardised by Standard 2.9.3 Divisions 3 and 4 respectively).	
Energy	Contributes energy for normal metabolism	Must contain a minimum of 420 kJ of energy per serve.	
Energy	Contributes to weight loss or weight maintenance	The food – (a) meets the conditions for making a diet nutrition content claim; or (b) is a formulated meal replacement as standardised by Division 2 of Standard 2.9.3.	Healthy energy controlled diet and regular exercise.
Fruits and vegetables	Contributes to heart health	(a) the food is not – (i) fruit juice or vegetable juice as standardised by Standard 2.6.1; or (ii) a food standardised by Standard 2.6.2; and (b) the food contains no less than 90% fruit or vegetable by weight.	(a) Healthy diet with an increased intake of both fruit and vegetables and consisting of a variety of foods *or* (b) Healthy diet with a high intake of both fruit and vegetables and consisting of a variety of foods.

Permitted General Level Health Claims
Part 3 – Other Relationships (continued)

Column 1	Column 2	Column 3	Column 4
Food or property of food	**Specific health effect**	**Conditions**	**Population and context claim statements**
Sugar or sugars	Contributes to dental health	The food – (a) is confectionery or chewing gum; and (b) either – (i) contains 0.2% or less starch, dextrins, mono-, di- and oligosaccharides, or other fermentable carbohydrates combined; or (ii) if the food contains more than 0.2% fermentable carbohydrates, it must not lower plaque pH below 5.7 by bacterial fermentation during 30 minutes after consumption as measured by the indwelling plaque pH test, referred to in 'Identification of Low Caries Risk Dietary Components' by T.N. Imfeld, Volume 11, Monographs in Oral Science, 1983.	Healthy diet and good oral hygiene.
Phytosterols	Reduces dietary and biliary cholesterol absorption	(a) the food meets the conditions specified in Columns 1 and 2 of the Table to clause 2 in Standard 1.5.1; and (b) for edible oil spreads standardised by Standard 2.4.2, the food must contain a minimum of 0.8 g phytosterol esters per serving or 0.48 g tall oil phytosterols per serving.	(a) As part of a healthy diet low in saturated fat (b) 2 g of phytosterols from all sources are recommended to be consumed per day to achieve the specific health effect.
Protein	Necessary for tissue building and repair	The food meets the general conditions for making a nutrition content claim about protein.	
Protein	Necessary for normal growth and development	The food meets the general conditions for making a nutrition content claim about protein.	For children aged 4 years and over.

Permitted General Level Health Claims
Part 3 – Other Relationships (continued)

Column 1	Column 2	Column 3	Column 4
Food or property of food	**Specific health effect**	**Conditions**	**Population and context claim statements**
Protein	Necessary for normal growth and development	The food is a formulated supplementary food for young children standardised by Division 4 of Standard 2.9.3	For young children
Protein	Necessary for normal growth and development	The food is a food for infants standardised by Standard 2.9.2.	For older infants

SCHEDULE 3

Permitted High Level Health Claims

Column 1	Column 2	Column 3	Column 4
Food or property of food	**Specific health effect**	**Conditions**	**Population and context claim statements**
Calcium	Reduced risk of osteoporosis or reduced risk of osteoporotic fracture	The food contains no less than 290 mg of calcium per serving.	(a) the population group is persons 65 years and over; and (b) healthy diet with a high intake of calcium from a variety of foods and adequate vitamin D status.
Calcium and Vitamin D	Reduced risk of osteoporosis or reduced risk of osteoporotic fracture	(a) the food contains no less than 290 mg of calcium per serving; and (b) the food meets the conditions for a nutrition content claim about vitamin D.	(a) the population group is persons 65 years and over; and (b) healthy diet with a high intake of calcium from a variety of foods and adequate vitamin D status.
Calcium	Enhanced bone mineral density	The food contains no less than 200 mg of calcium per serving.	The context is a healthy diet with a high intake of calcium from a variety of foods.

Permitted High Level Health Claims (continued)

Column 1	Column 2	Column 3	Column 4
Food or property of food	**Specific health effect**	**Conditions**	**Population and context claim statements**
Folic acid	Reduced risk of foetal neural tube defects healthy diet with a high intake of calcium from a variety of foods and adequate vitamin D status.	(a) the food contains no less than 40 µg folic acid per serving; and (b) the food is not – (i) soft cheese; or (ii) pâté; or (iii) liver or liver product; or (iv) foods containing added phytosterol esters or added tall oil phytosterols; or (v) food standardised in Standard 2.6.4; or (vi) food standardised in Part 2.7; or (vii) food standardised in standards 2.9.2 and 2.9.4; or (viii) a formulated meal replacement standardised in Division 2 of Standard 2.9.3.	(a) the population group is women of child bearing age; and (b) a varied diet including food sources of folate and a recommendation that women consume at least 400 µg of folic acid per day, at least the month before and three months after conception
Saturated fatty acids	Reduction of total blood cholesterol or blood LDL cholesterol	The food meets the conditions for a nutrition content claim about low saturated acids	Healthy diet with a variety of foods low in saturated fatty acids.
Saturated and trans fatty acids	Reduction of total blood cholesterol or blood LDL cholesterol	The food meets the conditions for a nutrition content claim about low saturated and trans fatty acids	Healthy diet with a variety of foods low in saturated and trans fatty acids.
Sodium or salt	Reduction of blood pressure or maintenance of normal blood pressure	The food meets the conditions under clause 11 for a nutrition content claim about low salt	Healthy diet with a variety of foods low in salt or sodium.

Permitted High Level Health Claims (continued)

Column 1	Column 2	Column 3	Column 4
Food or property of food	**Specific health effect**	**Conditions**	**Population and context claim statements**
Increased intake of fruit and vegetables	Reduced risk of coronary heart disease	(a) claims are not permitted on – (i) fruit juice or vegetable juice standardised under Standard 2.6.1; or (ii) non alcoholic beverages and brewed soft drinks standardised under Standard 2.6.2; and (b) the food contains no less than 90% fruit or vegetable by weight.	Healthy diet with an increased intake of both fruit and vegetables and consisting of a variety of foods.
A high intake of fruit and vegetables	Reduced risk of coronary heart disease	(a) claims are not permitted on – (i) fruit juice or vegetable juice standardised under Standard 2.6.1; or (ii) non alcoholic beverages and brewed soft drinks standardised under Standard 2.6.2; and (b) the food contains no less than 90% fruit or vegetable by weight.	Healthy diet high in both fruit and vegetables and consisting of a variety of foods.

SCHEDULE 4

Nutrient Profiling Scoring Criterion

1 Steps in determining a nutrient profiling score

(1) For a food in Category 1, calculate the food's –

(a) baseline points in accordance with item 2 of this Schedule; then
(b) fruit and vegetable points in accordance with item 4 of this Schedule (**V points**); then
(c) protein points in accordance with item 5 of this Schedule (**P points)**; then
(d) final score in accordance with item 7 of this Schedule (**the nutrient profile score**).

Editorial note:

Category 1 foods do not score fibre (F) points.

(2) For a food in Category 2, calculate the food's –

(a) baseline points in accordance with item 2 of this Schedule; then
(b) fruit and vegetable points in accordance with item 4 of this Schedule (**V points**); then
(c) protein points in accordance with item 5 of this Schedule (**P points**); then
(d) fibre points in accordance with item 6 of this Schedule (**F points**); then
(e) final score in accordance with item 7 of this Schedule (**the nutrient profile score**).

(3) For a food in Category 3, calculate the food's –

(a) baseline points in accordance with item 3 of this Schedule; then
(b) fruit and vegetable points in accordance with item 4 of this Schedule (**V points**); then
(c) protein points in accordance with item 5 of this Schedule (**P points**); then
(d) fibre points in accordance with item 6 of this Schedule (**F points**); then
(e) final score in accordance with item 7 of this Schedule (**the nutrient profile score**).

2 Baseline points for Category 1 or 2 foods

(1) Use the information in Table 1 and the formula in sub item (2) to work out the baseline points (up to 10 for each nutrient), for the content of each nutrient in 100 g or 100 mL of the food product (based on the units used in the nutrition information panel).

Table 1
Baseline Points for Category 1 or 2 Foods

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

(2) Calculate the baseline points using the following formula:

Total baseline points = (points for average energy content) + (points for saturated fatty acids) + (points for total sugars) + (points for sodium)

3 Baseline points for Category 3 foods

(1) Use the information in Table 2 and the formula in sub item (2) to work out the baseline points (up to 10 for each nutrient), for the content of each nutrient in 100 g or 100 mL of the food product (based on the units used in the nutrition information panel).

Table 2
Baseline Points for Category 3 Foods

Points	Average energy content (kJ) per 100 g or 100 mL	Saturated fatty acids (g) per 100 g or 100 mL	Total sugars (g) per 100 g or 100 mL	Sodium (mg) per 100 g or 100 mL
0	≤ 335	≤1.0	≤ 5.0	≤ 90
1	>335	>1.0	>5.0	>90
2	>670	>2.0	>9.0	>180
3	>1005	>3.0	>13.5	>270
4	>1340	>4.0	>18.0	>360
5	>1675	>5.0	>22.5	>450
6	>2010	>6.0	>27.0	>540
7	>2345	>7.0	>31.0	>630
8	>2680	>8.0	>36.0	>720
9	>3015	>9.0	>40.0	>810
10	>3350	>10.0	>45.0	>900
11	>3685	>11.0		>990
12		>12.0		>1080
13		>13.0		>1170

Table 2 (continued)
Baseline Points for Category 3 Foods

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
14		>14.0		>1260
15		>15.0		>1350
16		>16.0		>1440
17		>17.0		>1530
18		>18		>1620
19		>19.0		>1710
20		>20.0		>1800
21		>21.0		>1890
22		>22.0		>1980
23		>23.0		>2070
24		>24.0		>2160
25		>25.0		>2250
26		>26.0		>2340
27		>27.0		>2430
28		>28.0		>2520
29		>29.0		>2610
30		>30.0		>2700

(2) Calculate the baseline points using the following formula:

Total baseline points = (points for average energy content) + (points for saturated fatty acids) + (points for total sugars) + (points for sodium)

4 Fruit and vegetable points (V points)

(1) V points can be scored for fruits, vegetables, nuts and legumes including coconut, spices, herbs, fungi, seeds and algae (**fvnl**) including –

(i) fvnl that are fresh, cooked, frozen, tinned, pickled or preserved; and
(ii) fvnl that have been peeled, reduced in size, puréed or dried; and

(2) V points cannot be scored for –

(a) a constituent, extract or isolate of a food mentioned in subitem (1); or
(c) cereal grains mentioned as a class of food in Schedule 4 of Standard 1.4.2.

Editorial note:

An example of a constituent, extract or isolate under paragraph 4(2)(a) is peanut oil derived from peanuts. In this example, peanut oil would not be able to score V points. Other examples of extracts or isolates are fruit pectin and de-ionised juice.

(3) Despite subitem (2), V points may be scored for –

(a) fruit juice or vegetable juice as standardised in Standard 2.6.1 including concentrated juices and purees;
(b) coconut flesh (which is to be scored as a nut), whether juiced, dried or desiccated, but not processed coconut products such as coconut milk, coconut cream or copha; and
(c) the water in the centre of the coconut.

(4) Calculate the percentage of fvnl in the food in accordance with the appropriate method in Standard 1.2.10 and not the form of the food determined in accordance with clause 12 of this Standard.

Editorial note:

The effect of subitem (4) is to make it a requirement to determine the percentage of fvnl using only the appropriate method in Standard 1.2.10. For this subitem only, it is not necessary to consider the form of the food determined by clause 12 of this Standard.

(5) Use Column 1 of Table 3 if the fruit or vegetables in the food product are all concentrated (including dried).

Editorial note:

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

(6) Use Column 2 of Table 3 if –

(a) there are no concentrated (or dried) fruit or vegetables in the food product; or
(b) the percentages of all concentrated ingredients are calculated based on the ingredient when reconstituted (according to subclauses 3(3) or (4) of Standard 1.2.10); or
(c) the food product contains a mixture of concentrated and not concentrated fvnl sources (after following the formula mentioned in subitem (8)); or
(d) the food product is potato crisps or a similar low moisture vegetable product.

(7) Work out the V points (to a maximum of 8) in accordance with Table 3.

Table 3
V Points

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

(8) If the food product contains a mixture of concentrated and non concentrated fvnl sources, the percentage of total fvnl must be worked out as follows –

$$\frac{(\%\text{ non concentrated fvnl}) + (2 \times \%\text{ concentrated fruits or vegetables})}{(\%\text{ non concentrated fvnl}) + (2 \times \%\text{ concentrated fruits or vegetables}) + \%\text{ non fvnl ingredient}} \times \frac{100}{1}$$

where –

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

fvnl has the meaning given by subitem 4(1).

(9) For the formula in subitem (8), potato crisps and similar low moisture vegetable products are taken to be non-concentrated.

5 Protein points (P points)

(1) Use Table 4 to determine the 'P points' scored, depending on the amount of protein in the food product. A maximum of five points can be awarded.

(2) Food products that score >13 baseline points are not permitted to score points for protein unless they score five or more points for fvnl.

Table 4
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

6 Fibre points

(1) Use Table 5 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.

(2) The prescribed method of analysis to determine total dietary fibre is outlined in clause 18 of Standard 1.2.8.

Table 5
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

(3) Category 1 foods do not score F points.

7 Calculating the final score

Calculate the final score using the following formula:

Final Score = baseline points – (V points) – (P points) – (F points)

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

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

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

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

[3.2] *omitting the definition of* nutrition claim *in subclause 1(1)*

[3.3] *omitting the definition of* average energy content *in subclause 1(1), substituting –*

average energy content means the figure worked in accordance with subclause (3)

[3.4] *inserting in alphabetical order the definition in subclause 1(1) –*

claim requiring nutrition information has the meaning given in subclause 4(1).

[3.5] *renumbering subclause 1(2) to 1(4)*

[3.6] *inserting after subclause 1(1) –*

(2) Unless the contrary intention appears, the definitions in Standard 1.2.7 apply in this Standard.

(3) Average energy content is to be calculated by –

(a) multiplying the average amount of each food component per 100 g of the food by the energy factor for that food component; then
(b) adding the amounts calculated for each food component using the following formula –

$$E_{kJ} = \sum W_i F_i$$

Where E_{kJ} is the average energy content expressed in kilojoules per 100 g, W_i is the average weight of the food component expressed in grams per 100 g and F_i means the energy factor assigned to that food component expressed in kilojoules per gram.

[3.7] *inserting after clause 1 –*

1A Application

This Standard does not apply to a food standardised by Standard 2.9.1.

Editorial note:

Infant formula products standardised by Standard 2.9.1 are not required to carry a nutrition information panel in accordance with this Standard, however Standard 2.9.1 prescribes specific nutrition information requirements for those foods.

[3.8] *omitting clause 4, substituting –*

4 Requirements for nutrition information panels when certain claims made

(1) A claim requiring nutrition information means any of –

(a) a nutrition content claim;
(b) a general level health claim; or
(c) a high level health claim;

but does not include –

(d) an endorsement; or
(e) a cause-related marketing statement.

Editorial note:

The definitions of nutrition content claim, general level health claim and high level health claim are contained in Standard 1.2.7. Those definitions include the claims that are permitted by that Standard, but also include claims permitted elsewhere in the code (for example, a claim permitted under subclause 8(3) of Standard 2.6.2).

(2) Subject to subclauses (3) and (4), where a claim requiring nutrition information is made in relation to a food, a nutrition information panel must be included on the label on the package of the food.

(3) Where a claim requiring nutrition information 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 clause 5, 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.

(4) Where a claim requiring nutrition information is made in relation to a food in a small package, the label need not include a nutrition information panel but must comply with clause 8.

[3.9] *omitting from paragraph 5(1)(e) –*

subject to clause 12,

substituting –

subject to subclause (1A)

[3.10] *omitting paragraph 5(1)(g), substituting –*

(g) the name and the average quantity of any other nutrient or biologically active substance in respect of which a claim requiring nutrition information is made, expressed in grams, milligrams or micrograms or other units as appropriate, that is in a serving of the food and in the unit quantity of the food; and
(h) any other matter which this Code requires to be included.

[3.11] *inserting after subclause 5(1) –*

(1A) Where a claim–

(a) is made about a food standardised in Standard 2.4.1 or Standard 2.4.2; and
(b) relates to polyunsaturated fatty acids or monounsaturated fatty acids;

the following properties may be set out in the panel as a minimum or maximum quantity in a serving of the food and per 100 g/mL –

(c) saturated fatty acids;
(d) polyunsaturated fatty acids;
(e) monounsaturated fatty acids; and
(f) trans fatty acids.

[3.12] *omitting from the* Editorial note *after clause 5 –*

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

[3.13] *omitting from subclause 5(4) –*

nutrition claim is made in respect of

substituting –

claim requiring nutrition information is made about or based on

[3.14] o*mitting from subclause 5(5) –*

nutrition claim is made in respect of

substituting –

claim requiring nutrition information is made about or based on

[3.15] *omitting subclause 7(2), substituting –*

(2) Where percentage daily intake information is included in a panel –

(a) the percentage daily intake of dietary fibre per serving 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 per serving; and
(ii) either of the following statements –

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

[3.16] *inserting after clause 7 –*

7A Percentage recommended dietary intake information

(1) This clause applies only where –

(a) a claim requiring nutrition information is made about or based on a vitamin or mineral (the relevant vitamin or mineral);
(b) the relevant vitamin or mineral has a RDI; and
(c) the food to which the claim relates is not a food for infants as standardised by Standard 2.9.2.

(2) The percentage of the RDI for the relevant vitamin or mineral contributed by one serving of the food must be set out in the nutrition information panel.

(3) The percentage RDI under subclause (2) must be calculated –

(a) using the reference values mentioned in the Schedule to Standard 1.1.1; and
(b) using the nutrient values set out in the nutrition information panel.

(4) Despite paragraph (1)(c), percentage recommended daily intake information may be included in the nutrition information panel for a food for infants as standardised by Standard 2.9.2.

7B Percentage DI or RDI information presented outside the panel

(1) In this clause, DI or RDI information means the information in a nutrition information panel that is permitted or required by clause 7 or 7A.

(2) DI or RDI information may be presented outside the nutrition information panel if –

(a) the serving size is presented together with DI or RDI information; and
(b) the food to which the DI or RDI information relates does not contain more than 1.15% alcohol by volume.

(3) If more than one piece of DI or RDI information is presented outside the nutrition information panel, those pieces of information must be presented together.

(4) DI or RDI information presented in accordance with this clause does not constitute a nutrition content claim.

[3.17] *omitting clause 8, substituting –*

8 Food in small packages

(1) This clause applies only where a claim requiring nutrition information is made on or about food in a small package.

(2) The label must include a declaration of the average quantity of the food in a serving expressed –

(a) in the case of a solid or semi-sold food, in grams; or
(b) in the case of a beverage or other liquid food, in millilitres.

(3) In addition to the matters specified in subclause (2), if a claim requiring nutrition information is made about a matter in Column 1 of the Table to this subclause, the label must include the particulars specified in Column 2.

Table to subclause 8(3)

Column 1	**Column 2**
Claim is about	**Label must include**
Any nutrient or biologically active substance (other than a vitamin or mineral with a RDI)	Average quantity of the nutrient or biologically active substance present per serving of the food
Any vitamin or mineral with a RDI	(a) Average quantity of the vitamin or mineral present per serving of the food; and (b) Percentage of the RDI for the vitamin or mineral contributed by one serving of the food, and calculated in accordance with clause 7A
Cholesterol, saturated fatty acids, trans fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, omega-6 or omega-9 fatty acids	Saturated fatty acid, trans fatty acid, polyunsaturated fatty acid and monounsaturated fatty acid content per serving of the food
Dietary fibre, sugars or any other carbohydrate	Average quantity of energy, carbohydrate, sugars and dietary fibre (calculated in accordance with clause 18) present per serving of the food
Energy	Average quantity of energy present per serving of the food
Fat-free	Average quantity of energy present per serving of the food
Omega-3 fatty acid	(a) Saturated fatty acid, trans fatty acid, polyunsaturated fatty acid and monounsaturated fatty acid content per serve; and (b) Source and amount per serving of omega-3 fatty acids, namely, alpha-linolenic acid, docosahexaenoic acid or eicosapentaenoic acid.
Lactose	Galactose content per serving of the food
Monounsaturated or polyunsaturated fatty acid	Saturated fatty acid, trans fatty acid, polyunsaturated fatty acid and monounsaturated fatty acid content per serve

Potassium	Sodium and potassium content per serving of the food
Sodium or salt	Potassium content per serving of the food

(4) The particulars required by clause (3) –

(a) must be set out as minimum and maximum quantities unless specified otherwise in the Table to subclause 8(3); and
(b) must clearly indicate whether the particulars are minimum and maximum quantities or average quantities.

(5) The word 'serving' in a declaration required by this clause may be replaced by –

(a) the word 'slice', 'pack' or 'package'; or
(b) the words 'metric cup' or 'metric tablespoon' or other appropriate word or words expressing a unit or common measure.

(6) To avoid doubt, the information required to be declared in accordance with this clause need not be set out in the prescribed panel format.

8A Carbohydrate claims on small packages

(1) This clause only applies where a claim requiring nutrition information is made about carbohydrate on or about food in a small package.

(2) The label must include a declaration of unavailable carbohydrate where unavailable carbohydrate has been subtracted in the calculation of 'carbohydrate by difference' as defined in clause 1.

(3) The reference to 'unavailable carbohydrate' in subclause (2) does not include dietary fibre.

(4) If –

(a) the food contains any of the substances in Column 1 of the Table to subclause 2(2) other than organic acids (the relevant substances); and
(b) the relevant substances either singly or in combination are present in the final form of the food in an amount no less than 5 g/100 g;

then

(c) the presence of the relevant substances must be declared on the label.

[3.18] *inserting after clause 11 –*

11A Claims on food to be prepared or consumed with other food

If a claim requiring nutrition information is made about a food that is required to be prepared and consumed according to directions, then –

(a) the nutrition information panel must be in accordance with clause 11; and
(b) the weight or volume of the serving size of the food as prepared must be declared in the panel.

[3.19] *omitting Division 3, substituting –*

Division 3 – Deleted

Editorial note:

Division 3 of this Standard has been deleted and the conditions for making nutrition claims are now contained in Standard 1.2.7.

[3.20] *inserting after clause 18 –*

19 Items in panel are nutrition content claims in some circumstances

(1) In this clause –

voluntary item means a particular which is permitted by this Code to be included in a nutrition information panel.

mandatory item means a particular which is required by this Code to be included in the nutrition information panel in some or all circumstances.

(2) To avoid doubt, the inclusion of a mandatory item in a nutrition information panel is not a nutrition content claim.

(3) The inclusion of a voluntary item in a nutrition information panel is a nutrition content claim unless –

(a) this Code provides otherwise; or
(b) the voluntary item is a declaration of –

(i) less than 2 g of dietary fibre; or
(ii) trans fatty acid content.

(4) A nutrition information panel that contains the prescribed declarations in paragraphs 5(1)(a) to 5(1)(f) on a product containing more than 1.15% alcohol by volume is not nutrition content claim.

[3.21] *updating the* Table of Provisions *to reflect the amendments made by this variation*

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

[4.1] omitting from the first sentence of the Purpose –

, and the claims which can be made about vitamin and mineral content of foods

[4.2] *omitting clause 1 substituting –*

reference quantity means –

(a) for a food mentioned in the Table to clause 3 –

(i) the quantity specified in the Table for the food or,

(ii) for a food that requires dilution or reconstitution according to directions – the quantity of the food that, when diluted or reconstituted, produces the quantity mentioned in column 2 of the Table; or

(b) for all other foods –

(i) a normal serving; or
(ii) for a food that requires dilution, reconstitution, draining or preparation according to directions, the quantity of the food which when diluted, reconstituted, drained or prepared produces a normal serving.

[4.3] *omitting clause 4 substituting –*

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

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

[4.4] *omitting clause 5 substituting –*

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

(1) Where a food, containing at least one ingredient with added vitamins or minerals under this Standard, contains more than one ingredient, the maximum claim permitted in relation to a vitamin or mineral present in a reference quantity of the food, is calculated by adding together the quantity calculated for each ingredient in accordance with the formula set out in subclause (2), rounding to the nearest whole number.

(2) In this subclause –

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

A = B1 + B2 …..Bi

Where –

B1, B2, Bi 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

B1 = 120 x 100/200 x 40/100 = 24 mg vitamin C

B2 = 500 x 100/200 x 2/100 = 5 mg vitamin C

A = B1 + B2 = 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

B1 = 2.5 x 100/100 x 115/145 = 2.06 mg iron in 100 g meat

B2 = 3 x 100/50 x 30/145 = 1.24 mg iron/100 g fortified breadcrumbs

A = B1 + B2 = 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).

[4.5] *omitting clauses 6 to 9*

[4.6] *updating the* Table of Provisions *to reflect the amendments made by this variation*

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

[6] ***Standard 2.9.1*** *of the Australia New Zealand Food Standards Code is varied by –*

[6.1] *omitting clause 28, substituting –*

28 Required statements for products under this Subdivision

The label on a product that is specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions must contain a statement that indicates –

(a) that the product is not suitable for general use and should be used under medical supervision; and
(b) the condition, disease or disorder for which the food has been specially formulated; and
(c) the nutritional modifications, if any, which have been made to the infant formula product.

[6.2] *updating the* Table of Provisions *to reflect the amendments made by this variation*

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

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

(e) clause 9.

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

(1A) The conditions in Schedule 1 of Standard 1.2.7 that require the salt, sodium or potassium content of a food to be indicated in the nutrition information panel do not apply to a food standardised by this Standard.

[8] ***Standard 2.9.3*** *of the Australia New Zealand Food Standards Code is varied by –*

[8.1] *inserting after subclause 3(2) –*

(2A) A claim, either express or implied, that a formulated meal replacement is a good source of a vitamin or mineral may be made if –

(a) the vitamin or mineral is listed in column 1 of Table 1 or Table 2 in the Schedule;
(b) a serving of the food contains at least 25% of the RDI or ESADDI of that vitamin or mineral; and
(c) where the vitamin or mineral has been added to the food, the claimed quantity of that vitamin or mineral in a serving is no more than the quantity set out in column 3 of Table 1 or 2.

[8.2] *inserting after subclause 5(1) –*

(1A) In this clause, claimable vitamin or mineral means a vitamin or mineral that is listed in –

(a) the Schedule to Standard 1.1.1; or
(b) Column 1 of Table 3 in the Schedule to this Standard.

[8.3] *omitting from subclause 5(2) –*

one or more of those vitamins or minerals listed in column 1 of Table 3 in the Schedule

substituting –

a claimable vitamin or mineral

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

(2A) A claim, either express or implied, that a formulated supplementary food is a good source of a vitamin or mineral may be made if –

(a) the vitamin or mineral is a claimable vitamin or mineral;
(b) a serving of the food contains at least 25% of the RDI or ESADDI of that vitamin or mineral; and
(c) where the vitamin or mineral has been added to the food, the claimed quantity of that vitamin or mineral in a serving is no more than the quantity set out in column 5 of Table 3.

[8.5] *inserting after subclause 7(1) –*

(1A) In this clause, claimable vitamin or mineral means a vitamin or mineral that is listed in –

(a) the Schedule to Standard 1.1.1; or
(b) Column 1 of Table 3 in the Schedule to this Standard.

[8.6] *omitting from subclause 7(2) –*

one or more of those vitamins or minerals listed in column 1 of Table 3 in the Schedule

substituting –

a claimable vitamin or mineral

[8.7] *inserting after subclause 7(2) –*

(2A) A claim, either express or implied, that a formulated supplementary food for young children is a good source of a vitamin or mineral may be made if –

(a) the vitamin or mineral is a claimable vitamin or mineral;
(b) a serving of the food contains at least 25% of the RDI or ESADDI of that vitamin or mineral; and
(c) where the vitamin or mineral has been added to the food, the claimed quantity of that vitamin or mineral in a serving is no more than the quantity set out in column 3 of Table 3.

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

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

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

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

To commence: two years after gazettal

[11] *The **Australia New Zealand Food Standards Code** is varied by omitting Standard 1.1A.2*

Attachment 2

Explanatory Statement – draft Standard 1.2.7 – Nutrition, Health and Related Claims

Clause 1

Subclause (1) contains the definitions that are used in the Standard. Subclause (2) makes it clear that a reference to making a claim means making a claim on a label or in an advertisement for food.

Subclause (3) applies the definitions in Standard 1.2.8 to the Standard unless the contrary intention appears.

Subclause (4) makes it clear that the simplified outlines of divisions which appear throughout the Standard are provided only for assistance and do not alter the legal effect of the substantive provisions of the Standard.

Clause 2

This clause is intended to make it clear that the stock-in-trade provision in Standard 1.1.1 does not apply to the Standard. Instead, a food product is taken to comply with the Standard for 24 months after the commencement of the Standard if that product otherwise complied with the Code before the Standard commenced.

Clause 3

This clause inserts an interpretive tool which a court can use if, for any reason, a provision of the Standard is found to be legally invalid. It means that only the legally invalid provision is given no operation, and the rest of the Standard can operate regardless.

Clause 5

This clause defines the terms 'general level health claim', 'high level health claim' and 'nutrition content claim'. General level and high level health claims differ in that high level health claims are those which refer to a serious disease or biomarker, whereas general level health claims do not.

Subclause (2) of this clause provides that each of the claims in subclause (1) are claims to which the Standard applies. The phrase *claim to which this Standard applies* is used throughout the Standard as a shorthand way of collectively saying: nutrition content claim, general level health claim and high level health claim.

Subclause (3) makes it clear that the relationships in Schedule 2 are general level health claims.

Clause 6

This clause qualifies clause 5 to make it clear that certain claims are not claims to which the Standard applies. The effect of saying that X claim is not a claim to which the Standard applies is that X claim does not need to comply with the Standard.

First, paragraph (1)(a) excludes food which is intended for further processing, packaging or labelling prior to retail sale. This has the effect that wholesale food, for example, that is intended to be further packaged and labelled for retail sale does not need to comply with this Standard. Likewise, paragraph (b) excludes from the operation of the Standard a meal delivered to a client of a delivered meal organisation, and paragraph (c) food (other than food in a package) provided to a patient in a hospital or other similar institution. The similar institutions are mentioned in the Table to clause 8 of Standard 1.2.1.

Secondly, subclause (2) makes it clear that claims about ethical, religious or environmental features of food are not regulated by the Standard. Examples of this kind of claim are given in the Editorial note and include vegetarian, halal, kosher and organic.

Finally, subclause (3) provides that claims about the risks or dangers of alcohol intake or moderating alcohol intake are also not regulated by the Standard.

Clause 7

This clause contains a general prohibition on making claims to which the Standard applies. The clause makes it impermissible to make claims to which the Standard applies, unless the claim is expressly permitted in the Code. Claims may be permitted in the Standard or elsewhere in the Code.

Clause 8

Clause 8 prohibits cause-related marketing statements and dietary information unless expressly permitted in the Code. Division 7 contains the permissions for cause-related marketing statements, and Division 8 for dietary information.

Clause 9

This provision makes it clear what conditions claims which are permitted elsewhere in the Code must comply with. A claim which is expressly permitted elsewhere in the Code must comply with clause 10, but is not required to comply with any other requirement in the Standard. A clause permitted in another standard must, obviously, comply with any conditions that are imposed by that other standard.

Clause 10

This clause has the effect of prohibiting claims that refer to alleviation of a disease, condition or a symptom of a disease or condition, unless the claim is expressly permitted in the Code. Presently, subclause 8(3) of Standard 2.6.2 permits a claim about the treatment of a condition (namely, mild dehydration). This is presently the only express permission for a claim that refers to the alleviation of a condition. Also, it is not permitted for a claim to compare a food and a therapeutic good.

Clause 11

This clause sets out what foods are ‘ineligible foods’. The concept of ‘ineligible food’ is used for nutrition content claims, general level health claims and high level health claims.

Clause 12

Clause 12 describes how the requirements of the Standard apply to different forms of food. The Table to clause 12 sets out different types of food and which form of food the requirements of the Standard apply. For example, for food that requires draining before consuming, the requirements of the standard apply to the food after it is drained and ready for consumption.

Clause 13

This clause makes it clear that if a claim is based on a property of food that is naturally present or absent in a particular food, that claim must refer only to the food and not to the brand of the food. The example given in the editorial note says that a claim may say *bananas are cholesterol free* but not *[particular brand of bananas] are cholesterol free*.

Clause 14

Clause 14 is designed to prohibit claims that compare the vitamin and mineral content of one food with that of another, unless expressly permitted in the Code.

Clause 16

This clause prohibits nutrition content claims from being made about ineligible foods. However, subclause (2) says that for the purposes of a nutrition content claim about energy or carbohydrate content, a food containing more than 1.15% alcohol by volume is not an ineligible food.

Clause 17

This clause deals with nutrition content claims about properties of food set out in Schedule 1 of the draft Standard. That Schedule has two types of conditions in it: general claim conditions and specific claim conditions. Subclause (2) of clause 17 provides that any claim about a property must meet the corresponding general claim conditions. Subclause (3) says that a claim using a specific descriptor (or a synonymous descriptor) must meet the general claim conditions as well as the specific claim conditions.

Subclause (4) makes it clear that if there are inconsistent obligations imposed by a general claim condition in Column 2 of Schedule 1 and a specific claim condition in Column 4, the specific claim condition prevails. For example, for a claim that a food is an 'excellent source of dietary fibre', the general claim conditions say that a serve of the food must contain at least 2 g of dietary fibre, whereas the specific claim condition says that a serve of the food must contain at least 7 g. In this example, subclause (4) makes it clear that the 7 g requirement prevails.

Clause 18

This clause is designed to allow nutrition content claims about properties of food not mentioned in Column 1 of Schedule 1, but for which there is a reference value. There are no specific rules for this type of nutrition content claim.

Clause 19

This clause deals with nutrition content claims about properties of food that: (a) are not mentioned in Schedule 1; and (b) for which there is no reference value.

The clause is designed to permit nutrition content claims about biologically active substances which are not regulated by clauses 17 or 18. However, subclause (2) provides that a nutrition content claim under this clause must refer only to the presence or absence of the property, and may include a numerical expression of the property of food.

Clause 20

This clause makes it clear that a nutrition content claim about low or percentage free trans fatty acids must not be made. The permitted claims about trans fatty acids are contained in Schedule 1.

Clauses 21 and 22

These clauses deal with nutrition content claims about gluten and lactose. They provide special rules for gluten and lactose nutrition content claims. Other than a claim specifically mentioned in the tables to those clauses, no other gluten or lactose claim may be made. The purpose of these clauses is to ensure that consumers who need to avoid gluten or lactose can rely on consistently expressed claims to do so.

Clause 23

This clause is designed to make it clear that words which imply slimming, weight loss or weight maintenance properties cannot be used as synonyms for 'diet' in a nutrition content claim about energy.

Subclause (2) makes it clear that this clause does not affect the operation of Divisions 4 or 5 which set out the requirements for health claims.

Clause 24

Clause 24 deals with nutrition content claims that are 'comparative': that is, they directly or indirectly compare the nutrition content of one food with that of another. Subclause (1) provides that claims using the descriptors 'light' or 'lite', 'increased' or 'reduced' are comparative claims. Subclause (2) says that a claim using the descriptor 'diet' is a comparative claim in some circumstances.

Subclause (3) sets out some additional information that is required for a comparative claim. The claim must declare the identity of the reference food and the difference between the amount of property in the reference food and the food on which the claim appears.

Clause 25

Clause 25 provides that the nutrition content claim must be presented in the one place and must mention the property of food and the form of the food to which the claim relates. However, it is not necessary to mention the form of the food if the form of the food to which the claim relates is the food as sold.

Clause 27

This clause provides a permission to make general level health claims if certain conditions are met. They are:

- that the claim is not about an ineligible food;
- that the food meets the nutrient profiling scoring criterion (the **NPSC**) (see Division 9);

- that the claim refers to a relationship between a property of food in Column 1 of Schedule 2 and a corresponding health effect in Column 2;

- that the food to which the claim relates complies with any conditions in Column 3; and

- that all other provisions of Division 4 are complied with.

Subclause (2) has the effect that that a general level health claim about a food standardised in Part 2.9 of the Code does not need to meet the NPSC.

Clause 28

This clause sets out what a general level health claim must say. Subclause (1) says that all of the elements of a general level health claim must be expressly mentioned and presented in the one place.

Subclause (2) defines what are the elements of a general level health claim.

Subclause (3) is designed to require the elements of a general level health claim to be expressed according to the corresponding elements in Schedule 2. Subclause (4) gives the principles for constructing a dietary context statement as part of a general level health claim. The Editorial note following that subclause provides some examples.

Subclause (5) makes it clear that the intention is not to prescribe wording for a claim, but rather than the wording must be consistent with the elements in Schedule 2.

Clause 29

This clause allows specific elements of a general level health claim to be presented separately from the complete statement required by clause 28 (called a **split claim**). The separate elements are the property of the food and the specific health effect. However, those elements must appear on the same label or in the same advertisement as the complete statement required by clause 28, and must indicate where the complete statement is located.

Also, subclause (2) makes it clear that the split claim must otherwise comply with clause 28.

Clause 30

Clause 30 deals with the specific situation of a general level health claim about phytosterols. Advisory statements for phytosterols are required by clause 2 of Standard 1.2.3. The effect of this clause is that an additional 'healthy diet' context statement is not required if the general level health claim is presented together with the advisory statement. However, the remaining parts of the context statement for a claim about phytosterols are still required.

Clause 31

This clause ensures that if a general level health claim based on a particular property can be made, then a nutrition content claim about that property may also be made. The clause does not affect Division 3, which means that for nutrition content claims made on their own, clause 31 no has operation at all.

Clause 33 to 36

Clauses 33 to 35 operate in the same way as clauses 27 to 29. However, instead of relating to general level health claims, they relate to high level health claims. Also, because all context statements are listed in Schedule 3, there are no principles to construct dietary context statements for high level health claims.

Clause 36 operates in the same way as clause 31 but again for high level health claims instead of general level health claims.

Schedule 3 contains the approved high level health claims relationships.

Clause 38

This Division is designed to allow endorsements to be made without complying with many of the requirements of the Standard.

Subclause (1) defines an 'endorsement'. An endorsement is a claim to which the Standard applies (that is, a nutrition content claim, general level health claim or high level health claim) that can only be made with the permission of another person or body (called the **endorsing body**). In addition, to meet the definition of an endorsement, the endorsing body must:

- have a nutrition or health purpose;
- operate on a not-for-profit basis; and
- must not be related to the supplier using the endorsement.

Subclause (2) gives some specific examples of when a supplier will be related to the endorsing body.

Clause 39

This clause sets out the requirements for an endorsement to be validly made. An endorsement must comply with clause 10 and the provisions of Division 6, but is not required to comply with any other requirement of the Standard.

Subclauses (2) and (3) provide that an endorsement must not refer to a serious disease unless that serious disease is part of the name of the endorsing body.

Clause 40

This clause is designed to create some record-keeping requirements for suppliers who use endorsements. 'Supplier using the endorsement' is defined in subclause (1). A supplier using an endorsement must keep records demonstrating:

- that the supplier making the endorsement has the permission of the endorsing body to use the endorsement; and
- that the endorsing body has a nutrition or health function or purpose, operates on a not-for-profit basis and that it is not related to the supplier making the claim.

Those records must be presented to the relevant authority on request.

Subclause (3) is designed to deal with the situation of when an endorsement is placed on a label prior to importation. That subclause provides that the importer of the food is taken to be the supplier using the endorsement, and therefore the importer must comply with the record-keeping requirements of this clause.

Clause 42

This clause defines 'cause-related marketing statement'. A cause-related marketing statement is a claim to which the Standard applies that is presented as a claim that the sale of food X will contribute to organisation Y.

Clause 43

The effect of this clause is to not require cause-related marketing statements to comply with many of the requirements of the Standard. However, a cause-related marketing statement must appear with a statement in the terms set out in the table.

Subclause (3) clarifies that a cause-related marketing statement does not need the statement in the table if the cause-related marketing statement appears together with a claim to which the Standard applies, and that claim complies with the requirements of the Code.

Clause 45

This Division sets out the rules for including dietary information on a label or in an advertisement for food. 'Dietary information' is defined by subclause (1).

'Permitted dietary information' is defined by subclause (2). Permitted dietary information is a sub-set of dietary information.

Clause 46

This clause allows permitted dietary information about properties of food to be included in certain circumstances.

Clause 47

This clause makes it clear that there are no restrictions on including permitted dietary information about anything other than properties of food.

Clause 49

This clause describes how to work out which NPSC category a food belongs to, and that a food's nutrient profiling score is to be worked out by applying the formulae in Schedule 4.

Clause 50

This clause provides that a food 'passes' the NPSC if it is less than the score worked out in accordance with the Table.

Clause 51

Clause 51 makes it a requirement that in certain circumstances, additional nutrition information be provided.

Subclause (3) is designed to make it clear that if a property of food is relied on for a food to pass the NPSC, and that property is not otherwise required to be declared in the NIP, then that property must be declared in the NIP.

Subclauses (4) and (5) require that, in certain circumstances, the percentage of fvnl be declared on the label.

Subclause (6) requires that the calcium content of cheese be declared in the NIP for a cheese that is calculated in the NPSC as a category 3 food.

Attachment 3

Draft variations to the Code – consolidated version of Standard 1.2.8 – Nutrition Information Requirements

SEE SEPARATE DOCUMENT

Attachment 4

Ministerial Council First Review Request Media Release

AUSTRALIA AND NEW ZEALAND FOOD REGULATION MINISTERIAL COUNCIL

20 JUNE 2008

FOOD MINISTERS REQUEST A REVIEW OF DRAFT STANDARD – 1.2.7 – NUTRITION, HEALTH AND RELATED CLAIMS THAT HAS RESULTED FROM PROPOSAL 293 – NUTRITION HEALTH AND RELATED CLAIMS

The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) has requested that Food Standards Australia New Zealand (FSANZ) review draft Standard 1.2.7 - Nutrition, Health and Related Claims – that has resulted from Proposal 293 – Nutrition, Health and Related Claims.

Proposal 293 aims to provide regulatory arrangements for nutrition, health and related claims, to expand the range of permitted claims, to ensure products carrying nutrition content and health claims provide adequate information for consumers and to prevent misleading or deceptive claims on food labels or in food advertising.

The Criteria/Ground/s for the review of draft Standard 1.2.7 – Nutrition, Health and Related Claims are that:

It is not consistent with existing policy guidelines set by the Ministerial Council:
The standard is not consistent with certain principles in the Ministerial Policy Guideline for Nutrition, Health and Related Claims which states that:

> - *any intervention by government should support government, community and industry initiatives that promote healthy food choices by the population*" (Policy Principle 3);
>
> - *any intervention by government should be consistent with and complement Australian and New Zealand national policies and legislation including those relating to nutrition and health promotion, fair trading, industry growth and international trade and innovation"* (Policy Principle 4);
>
> - *any intervention by government should contain a process of substantiation which aligns levels of scientific evidence with the level of claims along the theoretical continuum of claims, and at minimum costs to the community* ((Policy Principle 6);
>
> - *any intervention by government should allow for effective monitoring and enforcement* (Policy Principle 9)*;*
>
> - *the system should favour pre-market approval rather that post-market reaction* (Policy Principle 10);
>
> - *claims can be made providing the claim is socially responsible and does not promote irresponsible food consumption patterns* (Claims pre-requisites); and
>
> - *claims can be made providing the eligibility criteria, including qualifying and/or disqualifying criteria (and any excluded categories of foods, such as alcohol and infant foods), are complied with* (Claims pre-requisites).

It does not protect public health and safety

The draft standard exempts Nutrient Content Claims **(NCC)** from being subject to the Nutrient Profiling Scoring Criteria **(NPSC)**, which determine the type of food products that are eligible to carry a claim.

Endorsements are generally exempt from the operation of the draft Standard without an approval process.

It places an unreasonable cost burden on industry or consumers
The standard as a whole is highly complex. It will be extremely difficult and resource intensive for industry to comply with, and for regulators to monitor and enforce.

It is considered that compliance with the draft standard would place an unreasonable cost burden on industry and, potentially, on consumers. Any costs incurred by industry are likely to be passed onto consumers in the form of higher food prices.

It is difficult to enforce (and/)or comply with in both practical or resource terms
Enforcement of the draft standard in relation to general level claims (other than pre-approved statements) will require substantial resources. Unless claims can be verified quickly and simply with unequivocal evidence that will, if necessary, meet the test required by the courts, assessment of the truth of claims and gaining compliance will be an unnecessary burden for enforcement agencies and it will reduce consumer confidence and certainty, not provide a level playing field for industry and also reduce industry certainty. This will result in a lack of confidence in the food regulation system.

It is not consistent with the objectives of the legislation which establishes FSANZ
Any standard where enforcement difficulties are anticipated, provide opportunity for industry to mislead consumers. Subjectivity in the weight of evidence to substantiate a food-health relationship and the onus on regulators with limited capacity to adequately assess claims provides an environment for food companies to market food products in a way that contradicts public health messages.

Misleading or deceptive conduct leads consumers to hold false beliefs or draw the wrong conclusions. The onus is on the Government to ensure that the standard limits the opportunity for consumers to be misled.

Subsection 84 (5) of the *Food Standards Australia New Zealand Act 1991* states that:

> **'If the Council requests the Authority to review a draft standard or variation, the Authority must complete that review, and make a decision under subsection (6):**
>
> **(a) within 3 months after the request was made; or**
>
> **(b) if the Council allows a longer period – within that longer period.'**

On 4 September 2008 the Ministerial Council agreed, to a request from FSANZ, to extend the review period for Proposal P293 – Nutrition, Health and Related Claims until 8 April 2009.

<u>The process for requesting a review</u>

After Food Standards Australia New Zealand (FSANZ) notifies the Australia and New Zealand Food Regulation Ministerial Council (the Council) of a draft standard or variation the Council may request a review if any jurisdiction believes that one or more of the Criteria/Ground/s[1] set out in the Food Regulation Agreement 2000 (as amended in 2002) (the Agreement) or the Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System (the Treaty) applies. The Criteria / Ground/s set out in the Agreement and in the Treaty are:
(i) it is not consistent with existing policy guidelines set by the Ministerial Council;
(ii) it is not consistent with the objectives of the legislation which establishes FSANZ;
(iii) it does not protect public health and safety;

(iv) it does not promote consistency between domestic and international food standards where these are at variance;
(v) it does not provide adequate information to enable informed choice;
(vi) it is difficult to enforce or comply with in both practical or resource terms; and / or
(vii) it places an unreasonable cost burden on industry or consumers.

In exercising this power the Council must comply with the Agreement and the Treaty. Under the Agreement the Council will request a review if any jurisdiction considers that one or more of the Criteria applies. The Council would also, at this point in the process, request a review if New Zealand notifies the Council of concerns that the standard would be inappropriate for New Zealand (Annex C(2) of the Treaty).

If such a review is undertaken and the Council receives notice from FSANZ that the draft standard or variation has been reaffirmed (either entirely or subject to amendments) the Council may request a second [1] review. In exercising this power the Council must comply with the Agreement. Under the Agreement the Ministerial Council will request FSANZ to review the draft standard or variation a second time if it is agreed, by a majority vote, that one or more of the Criteria applies.

[1] This part of the protocol will have to be updated once the 'Agreement between the Government of Australia and the Government of New Zealand Establishing a System for the Development of Joint Food Standards' (the Treaty) has been amended to reduce from two to one the number of occasions on which the Council may request the Authority to review a draft or a variation to a standard. This will harmonize it with the Food Standards Australia New Zealand Amendment Act 2007.

Attachment 5

Summary of drafting amendments since the Final Assessment Report, further to structural changes

Table 1: Summary of amendments to draft Standard 1.2.7 – Nutrition, Health and Related Claims since Final Assessment

Topic	Draft Standard 1.2.7 in Final Assessment Report	New draft Standard 1.2.7 proposed under First Review Consultation Paper
Health effect definition	'Health effect means an effect on the functioning of the human body including a disease state or physical or mental performance or maintenance of a healthy functioning body.'	'presence of' inserted into definition: 'Health effect means an effect on the functioning of the human body including the presence of a disease state or…' This is to clarify that the definition means an effect on the functioning of the human body by a disease state rather than including a disease state.
Glycemic index (GI)	'Glycemic index means the property of the carbohydrates in different foods, specifically the blood glucose raising ability of the digestible carbohydrates in a given food.'	The words 'the property of the carbohydrates in different foods, specifically' have been removed to simplify the definition.
'Food group' definition	Some of the food groups within the definition included the words 'that is one ingredient or more than one ingredient of that class'. This was to indicate that foods comprised of a mixture of foods from that food group were still considered as part of that food group.	This wording has been removed. Without the additional wording, mixtures of foods from within the one food group are still considered as a food from that food group.
Permission for claims on infant formula products	The draft Standard included a clause stating that the Standard did not apply to infant formula products standardised under Standard 2.9.1.	The clause stating that the Standard did not apply to infant formula products has been removed. Instead, infant formula products have been included as an 'ineligible food'. This clarifies that nutrition content claims and health claims are not permitted on infant formula. (Refer to Table 4 for relevant consequential amendments to Standard 2.9.1.)

Topic	Draft Standard 1.2.7 in Final Assessment Report	New draft Standard 1.2.7 proposed under First Review Consultation Paper
Exemption of hospitals and similar institutions from draft standard 1.2.7.	Schedule 3 in the drafting listed and defined different types of hospitals and similar institutions. Its relevance relates to clause 2(2) which stated that the Standard does not apply to food, other than in a package, provided to a patient in any of the facilities listed in Schedule 3.	Schedule 3 is not included because the facilities, with the exception of child care centres, are listed in the Table to clause 8 of Standard 1.2.1. The intent has not been changed with respect to clause 2(2) of the previous drafting; it has simply re-worded it to avoid repetition in the Code by reference to the Table to clause 8 in Standard 1.2.1. Childcare centres are not included as it was never the intent that food provided in these facilities be exempt from draft Standard 1.2.7; they were inadvertently included in the drafting of the Final Assessment Report.
Permission for nutrition content claims when a health claim is made	No explicit permission provided. Nutrition content claims about properties for which health claims were made were permitted if permitted by the conditions for nutrition content claims.	New drafting (clauses 31 and 36) has been included that specifically permits nutrition content claims about properties of food for which health claims are made. This allows a separate nutrition content claim to be made in conjunction with a health claim about properties for which nutrition content claims are not normally permitted. This new drafting will ensure that a nutrition content claim such as 'contains folic acid' can be made in conjunction with a health claim about folic acid (nutrition content claims about folic acid are not permitted under the Code). Although the new clauses are general clauses, they currently apply to folic acid claims only, as this is the only property for which a health claim has been pre-approved but for which a nutrition content claim is not permitted.
Claims permitted elsewhere in the Code	There was a lack of clarity as to whether conditions in the draft Standard also applied to foods carrying claims permitted under other Standards of the Code, e.g. Standard 2.9.4 – Formulated Supplementary Sports Foods.	A new clause has been included that exempts claims permitted in other Standards of the Code from complying with Standard 1.2.7 (however, the prohibition of claims of a therapeutic nature still applies). This provides clarity in terms of what conditions apply when there is a potential inconsistency between the conditions in Standard 1.2.7 and another Standard in the Code.

Topic	Draft Standard 1.2.7 in Final Assessment Report	New draft Standard 1.2.7 proposed under First Review Consultation Paper
Form of the food to which provisions of the Standard apply	The draft Standard prescribed the form of the food to which provisions in the Standard apply. That is, through a number of separate sub-clauses in clauses 5 and 6, it prescribed the form of the food to which conditions apply for making a claim and the form of the food to which nutritional analysis and declarations in the nutrition information panel are applied. The draft Standard also prescribed that the declarations in the NIP reflected the form of the food to which the claim related.	The new drafting provides greater clarity and certainty by capturing the intent under one clause (clause 12). It also clarifies that the requirements apply to the whole standard rather than specifying certain clauses only. The conditions that the declarations in the NIP reflect the form of the food have been moved to Standard 1.2.8 as these relate to requirements for NIP declarations rather than conditions for making a claim per se.
General conditions for use of descriptors when making nutrition content claims	The conditions in clause 5 for the use of 'descriptors' and what was meant by 'descriptors' was not clear.	The drafting relating to the use of descriptors has been amended to refer to claims about the 'presence or absence' of a property of the food. The intent remains the same, i.e. if there is no reference value for the property of the food in the Code or no specific conditions for making claims about the property of the food in the Code, claims indicating the presence or absence only, such as 'source of', 'contains' and 'free', may be used, but claims that describe a level of the property in the food, such as 'good source' or 'increased', may not be used.
Wording conditions for comparative claims	The conditions applied only to certain properties listed in the table to clause 11. As carbohydrate was not listed in the table to clause 11, the conditions for comparative claims did not apply to carbohydrate.	To avoid repetition in the Standard, the conditions for wording of comparative claims have been relocated in one general clause that applies to all 'comparative claims' (defined in the clause). As a result, the conditions have broader application, i.e. they will apply to comparative claims about carbohydrate in addition to the properties of the food they previously applied to. To provide consistency with other comparative claims, conditions for a 25% increase/reduction have been included for 'increased' and 'reduced' carbohydrate claims respectively.
Specific conditions for making nutrition content claims	The meaning of the 'blank boxes' in the table to clause 11 caused some confusion.	The layout of the table to clause 11 has been changed significantly to improve clarity. The table has been moved into a schedule (1) in the new Standard. The general intent remains the same.

Topic	Draft Standard 1.2.7 in Final Assessment Report	New draft Standard 1.2.7 proposed under First Review Consultation Paper
Conditions for general level health claims	General conditions were prescribed in clause 6.	Some of these general conditions have been removed, e.g. the requirement to meet the conditions for making a nutrition content claim about the property of food that is the subject of the health claim, and the condition that the supplier of the food holds the records to substantiate the claim. This is because of the amendments to the method of substantiation of general level health claims and the insertion of Schedule 2.
Conditions for 'split' health claims	The property of the food and the specific health effect could be presented separately to the complete health claim, if this split claim is presented with a statement indicating where the complete health claim is placed. It was not clear that the split claim and the complete claim were required to be placed on the same label or advertisement, although this was the intention.	An additional paragraph has been added that the two statements (the split claim and the complete claim) must be located on the same label or advertisement. This clarifies what was originally intended.
Endorsements	Clause 10A provided that the requirements of the Standard did not apply to endorsements.	The original intent has been clarified in Division 6. We have also clarified who must hold records.
Dietary information	The definition of dietary information was as follows: '…general dietary information that (a) does not relate to a health effect; (b) relates to a food or property of food; (c) is provided for educational purposes.' Dietary information about a food was only permitted if it directly related to the food carrying the dietary information.	The meaning of dietary information has been clarified by adding that dietary information is in the nature of dietary guidance and must come from an authoritative source. This reinforces the original intent of the definition of dietary information, as indicated by the editorial note to this definition. Dietary information about a food (rather than a property of food) is permitted on any food.

Topic	Draft Standard 1.2.7 in Final Assessment Report	New draft Standard 1.2.7 proposed under First Review Consultation Paper
Nutrient profiling scoring criterion	Beverages (category 1 products) could score points for fibre content (F points).	A clause has been inserted to prohibit beverages from scoring fibre points (F points). This is because of fruit drinks/cordial type beverages that contain added fibre, e.g. inulin, being available on the international market (not available in Australia or New Zealand at this stage to our knowledge). The addition of fibre enables the beverage to score F points, and hence pass the NPSC. However in developing the NPSC it has been the intention that fruit drinks and cordials with similar sugar content as juices should not meet the NPSC and be eligible to carry a health claim. It does not appear that this amendment will impact on beverages such as fruit juice that naturally contain fibre, as these products do not rely on their fibre content in order to meet the NPSC.
Claims on formulated caffeinated beverages	Standard 2.6.4 includes a prohibition on claims about the presence or absence of vitamins and minerals.	This prohibition has been moved into Standard 1.2.7. The prohibition refers to both nutrition content claims and health claims about vitamin and minerals. This retains the current approach in the Code.

Table 2: Summary of consequential amendments to Standard 1.2.8 – Nutrition Information Requirements, since Final Assessment

Topic	Standard 1.2.8 in Final Assessment Report	New drafting of Standard 1.2.8 proposed under First Review Consultation Paper
Requirements for nutrient declarations on small packages when claims are made	On small packages, declarations of sugar alcohols, polydextrose and D-tagatose were required when they constitute 5 g per 100 g or more of the food, either singly or in combination and have been subtracted in the calculation of 'carbohydrate by difference' or included in 'available carbohydrate' (clause 8(1)(f)-(g)). It was not clear that these substances need only be declared when carbohydrate is declared on the label.	A change has been made to clarify that sugar alcohols, polydextrose and D-tagatose present need only be declared when carbohydrate is declared (carbohydrate content is only required to be declared on a small package when a claim about carbohydrate, fibre or sugar is made). In this way, the label of foods such as chewing gum must declare the sugar alternatives used when claims such as 'sugar free' are made.
Nutrition information panel (NIP) declaration when claims are based on the food after preparation by the consumer	Weight or volume of a serving size of the food 'as prepared' (i.e. when the optional third column in the NIP is used to display the energy and nutrient values for the food after preparation by the consumer) was not required to be declared in the NIP (weight or volume of a serving size of the food in it's 'as sold' state is required to be declared).	A requirement has been added, that if the claim is based on the food 'as prepared', the NIP must include the weight or volume of a serving of the food 'as prepared'. This is to satisfy the intention that compliance with the conditions relating to the claim (qualifying criteria and NPSC) are able to be determined from the label. If the claim is based on the food 'as prepared', a third column must be added to the NIP to declare the energy and nutrients in the NIP for the food 'as prepared'. This column can be on a per serve basis or on a per 100 g or ml basis. Because some qualifying criteria are based on per serve amounts and the NPSC is based on per 100 g or ml amounts, provision is needed to enable the values declared in the NIP to be determined on both per serve and per 100g/ml amounts. The suggested amendment will allow for this.
Application of Standard 1.2.8 to infant formula products	The Purpose (in the Code currently) states that Standard 1.2.8 does not apply to infant formula products. The Purpose has no legal effect so the intent is not captured by Standard 1.2.8.	An additional clause (1A) has been added to capture the intent that Standard 1.2.8 doesn't apply to infant formula products.
%RDI declarations on infant foods	Currently the intent under the Code is that %RDI declarations are not mandatory on infant foods, but are voluntary. By moving the requirement for %RDI declarations from Standard 1.3.2 into Standard 1.2.8 under Proposal P293, the %RDI requirements applied to infant foods. This was unintentional.	An exemption for infant foods from the requirement to declare %RDI when a claim about vitamin or mineral content is made has been included. %RDI declarations on infant foods remain voluntary. This retains the status quo in the Code and reflects the original intent.

Table 3: Summary of amendments to Standard 2.6.2 – Non-Alcoholic Beverages and Brewed Soft Drinks, since Final Assessment

Topic	Standard 2.6.2 in Final Assessment Report	New drafting of Standard 2.6.2 proposed under First Review Consultation Paper
Electrolyte drinks	A new clause was added stating that a claim that an electrolyte drink is isotonic is not a nutrition content claim. This clause was added to replace an editorial note (stating the same information) which was removed during Proposal P1001 – Omnibus V11 because the editorial note was not considered legally binding.	The new clause is no longer recommended. The editorial note was originally intended (when Standard 2.6.2 was gazetted) to ensure that claims about the tonicity of electrolyte drinks did not trigger the need for a nutrition information panel, as nutrition information panels were only required on foods carrying nutrition claims. The editorial note/clause no longer has relevance as nutrition information panels are now mandated on most foods, including electrolyte drinks, even if a nutrition claim is not made. There are now no consequential amendments proposed for Standard 2.6.2 under Proposal P293.

Table 4: Summary of consequential amendments to Standard 2.9.1 –Infant Formula Products, since Final Assessment

Topic	Standard 2.9.1 in Final Assessment Report	New drafting of Standard 2.9.1 proposed under First Review Consultation Paper
Permission for claims on infant formula products	No consequential amendments recommended.	The reference to 'claim' in Standard 2.9.1 has been replaced with 'statement'. This supports the intent that nutrition content claims and health claims are not permitted on infant formula products.

Table 5: Summary of consequential amendments to Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods, since Final Assessment

Topic	Standard 2.9.3 in Final Assessment Report	New drafting of Standard 2.9.3 proposed under First Review Consultation Paper
'good source' of vitamin and mineral claims on formulated meal replacements and formulated supplementary foods.	The conditions for 'good source' claims prescribed in Standard 1.2.7 applied to formulated meal replacements and formulated supplementary foods.	As outlined in Table 1, a new clause has been added specifying that conditions in Standard 1.2.7 do not apply to claims permitted in other Standards in the Code. Clauses have therefore been added setting conditions for 'good source' of vitamin and mineral claims on formulated meal replacements and formulated supplementary foods. These reflect the same conditions as those prescribed in Standard 1.2.7 for these claims.
Vitamin and mineral claims on formulated supplementary foods	The drafting currently in the Code permits vitamin and mineral content claims on formulated supplementary foods about only those vitamins and mineral listed in table 3 to the Standard. This list of vitamins and minerals is not consistent with the list of vitamins and minerals for which claims are permitted under Standard 1.2.7.	Standard 2.9.3 has been amended to specifically permit nutrition content claims about the vitamins and minerals listed in the Schedule to Standard 1.1.1 on Formulated Supplementary foods. This will provide consistency with the permissions under Standard 1.2.7.
Percentage recommended dietary intake (%RDI) information and percentage dietary intake (%DI) information	There was an exemption under Standard 2.9.3 for Formulated Supplementary Foods for Young Children from the requirement to declare %RDI when a claim about vitamins or mineral is made.	This exemption from the requirement to declare %RDI has been removed. This exemption was initially intended as an exemption only from the requirement to declare %DI (in the Draft Assessment Report when it was proposed that %DI declarations be mandatory if a nutrition content or health claim was made) but inadvertently captured both %DI and %RDI declarations.

Attachment 6

AUSTRALIA AND NEW ZEALAND FOOD REGULATION MINISTERIAL COUNCIL

Policy Guideline on Nutrition, Health and Related Claims

Policy Principles

The policy principles endorsed by Australian New Zealand Food Regulation Ministerial Council (ANZFRMC) for nutrition, health and related claims for food provide that any intervention by government should:

1. give priority to protecting and improving the health of the population;
2. enable the responsible use of scientifically valid nutrient, health and related claims;
3. support government, community and industry initiatives that promote healthy food choices by the population;
4. be consistent with and complement Australian and New Zealand national policies and legislation including those relating to nutrition and health promotion, fair trading, industry growth and international trade and innovation;
5. be cost effective overall, not more trade restrictive than necessary and comply with Australia's and New Zealand's obligations under the WTO Agreements;
6. contain a process of substantiation which aligns levels of scientific evidence with the level of claims along the theoretical continuum of claims, and at minimum costs to the community;
7. draw on the best elements of international regulatory systems for nutrient, health and related claims and be responsive to future trends and developments;
8. provide for collaborative action among enforcement agencies, industry and consumers to optimise educational resources; and
9. allow for effective monitoring and appropriate enforcement.

The following features of any regulatory system for health, nutrition and related claims are also considered desirable. The system should:

1. favour pre-market approval rather than post-market reaction;
2. enable better engagement of sectors other than government in providing nutritional advice and information;
3. promote a partnership between consumers, governments and industry in the delivery and responsible use of nutrition, health and related claims which protects consumers from false and misleading information that may result in distorted diets which harm health and increase health inequalities; and
4. allow for all transition issues to be clearly identified and steps taken to justify and to minimise costs of change and transition.

Claim Pre-requisites

Every health claim made must comply with the following, overarching policy principles, regardless of their claim classification level.
The overarching policy principles are:
1. Claims can be made providing:

- the food and/or component is safe for consumption in recommended quantities as part of the total diet;
- all requirements contained in Food Standards in the Australia New Zealand Food Standards Code are met;
- the claims have been scientifically substantiated;
- there is enough of the specified component to achieve the claimed benefit when consumed as directed;
- the eligibility criteria, including qualifying and/or disqualifying criteria (and any excluded categories of foods, such as alcohol and infant foods), are complied with;
- the claim is socially responsible and does not promote irresponsible food consumption patterns.

2. Except where permitted by the Food Standards Code, claims that a food or component of a food or diet can prevent, diagnose, cure or alleviate a disease, condition, ailment, defect or injury in humans would be considered therapeutic claims and are not permitted (e.g. eating this food protects you from getting 'Q' disease).

3. Claims that a food or component:

   - influences performance and wellbeing;
   - manages, influences, inhibits, or modifies a physiological process;
   - reduces the risk of a disease, condition, ailment, defect, or injury;
   - may only be made in the context of the appropriate total diet (that must be described)
     (*e.g. this food is high in 'S' that may help reduce your risk of 'G' disease. People with 'G' disease should eat a varied diet low in 'A' & 'B' and high in 'S', 'X' & 'Y'. E.g. This food contains 'X' which may improve 'Y' when eaten as part of a varied diet low in 'A' & 'B' and high in 'X' & 'C'*).

4. Claims about a food or component can describe a health benefit for the population but must not:

   - imply or state a universal or guaranteed benefit for all individuals, except where permitted by the Australia New Zealand Food Standards Code;
   - imply or state a health benefit for the population if the claimed benefit applies only to a particular subgroup of the population, unless the population subgroup is stated;
   - lead a consumer to self-diagnose or self-manage a condition or disease that should be medically diagnosed and/or managed;
   - encourage over-consumption of single foods or ingredients;
   - state or imply that a healthy diet is reliant on the inclusion of a single food;
   - arouse unwarranted and/or unrealistic expectations of the benefit to the individual;
   - be alarmist. That is they cannot:

     - contain language that could bring about fear or distress;
     - lead the consumer to believe that they are suffering from a serious ailment or disease;
     - lead the consumer to believe that harmful consequences may result if they do not consume the particular product.

5. A claimed benefit must be:

   - achievable when the food is consumed in quantities which can reasonably be expected to be consumed daily as part of an appropriate total diet;

- derived from the food or component in question for which the claim is made and not from consuming the food with a combination of specific foods.

6. Claims must communicate a specific rather than a broad benefit (e.g. improves recovery from exercise rather than improves sport performance).

7. Claims that refer to:

   - a disease, condition, ailment, defect or injury should include a statement explaining how the claimed benefit is achieved (e.g. high in 'Z', diets high in 'Z' do X which may reduce the risk of 'G' disease);
   - the dietary management of a biomarker, condition or disease that may require the supervision of an appropriate health care practitioner, must have an advisory statement to the effect that a health care practitioner's advice is required.

8. Where advisory or warning statements in relation to the claim are required, they must appear in close proximity to the claim in the same communication medium.

9. Where the information about the claim is separated into sections (split claim) the first part of the claim must direct the reader to further information provided elsewhere in the same communication medium.

10 In a compound claim any part of the claim that falls within a higher claim category results in the totality of the claim falling into that category.

11. Endorsement Programs that state or imply a nutrition, health, or related claim must comply with these principles and the requirements of the relevant category of claim. They will require a statement to explain why the endorsement has been granted (e.g. meets nutrient criteria required by the endorsement program).

12. Marketing activities that promote charities or non-profit organisations (i.e. cause-related marketing programs) that relate to disease or health must have a disclaiming statement to ensure they are not interpreted as a nutrition, health or related claim.

13. Communication to health professionals of a nutrition, health, or related claim about specific food products or food types (e.g. milk, meat etc) must comply with these principles and the requirements of the relevant category of claim.

Claims Classification Criteria

The claims classification framework sets out criteria for two levels of claims: general and high. The categorisation of a claim is based on the degree of promise to the consumer of the claim. That is, the potential benefit to the consumer in consuming that food in preference to other foods and, commensurately, the degree of risk to the consumer (and public health) in following the advice of the claim.

The level of a claim, as determined by the claims classification framework, will determine to what degree the claim is regulated, including the nature of the evidence required for substantiation. Only high level claims will be pre-approved, with approved claims being listed in the standard.

This could be done on a claim-by-claim (i.e. not product-by-product) basis. The standard could also include pre-approved 'generic' high level claims, which refer to serious diseases or conditions, with consideration given to the Australian Dietary Guidelines or the New Zealand Food & Nutrition Guidelines. Flexibility in wording of claims should be considered, provided the overarching principles and claim pre-requisites are satisfied.

Consideration should be given during the FSANZ standard development process for including the criteria for making each level of claim and any parameters (e.g. qualifying and disqualifying criteria, or exclusions for certain categories of food, such as alcohol and baby foods) should be specifically stated in the standard. These parameters will be particularly important to the monitoring and enforcement of nutrient content claims.

General level claims

General level claims are claims where the manufacturer has to make an assessment of the evidence supporting the claim prior to the product going to market, and to hold the evidence (to be produced at the request of enforcement agencies).

General level claims do not reference a serious disease. That is, references to non-serious diseases would be allowed in this category, as would claims that make no reference to a disease at all.

General level claims are those which:

- describe or indicate the presence or absence of a component in that food (Nutrient Content Claims) *(e.g. This food is high in calcium);* or

- refer to maintenance of good health or normal physiological processes (including normal growth and development, or maintenance or other like functions of the human body) (e.g. helps keep you regular as part of a high fibre diet). This includes claims that describe the component and its function in the body (*e.g. Calcium is good for strong bones and teeth*); or

- refer to specific benefits for performance and wellbeing in relation to foods (*e.g. gives you energy*); or

- are whole of diet claims based on the Australian Dietary Guidelines or the New Zealand Food & Nutrition Guidelines which may refer to the relevant benefits as described in the associated Australian Dietary Guideline or New Zealand Food & Nutrition Guideline background papers but do not refer to a serious disease or condition (e.g. A healthy, balanced diet that includes dietary fibre from a number of sources is one that can help reduce your risk of constipation); or

- describe how a diet, food or component can modify a function or body structure beyond its role in the normal growth, development and maintenance and other like functions of the human body but do not state or imply a serious disease *(e.g. exercise and a diet high in calcium and calcium containing foods like product 'X' may help give you stronger bones);* or

- refer to the potential for a food or component to assist in reducing the risk of or helping to control a non-serious disease or condition (*e.g. Yoghurt high in X and Y as part of a healthy diet may reduce your risk of stomach upsets*).

High level claims

High level claims are those claims which make reference to a serious disease, including:

- claims that refer to the potential for a food or component to assist in controlling a serious disease or condition (i.e. those referring to risk reduction or a reduction or improvement in health);

  E.g. this food is high in X, which as part of a diet low in saturated fat and high in soluble fibre may reduce your risk of heart disease.

- claims that refer to the potential for a food or component to assist in reducing the risk of, or improving a serious disease or condition;

  E.g. this food is low in Y, which may reduce your risk of having a stroke through Z.

- are whole of diet claims which refer to a serious disease or condition based on the Australian Dietary Guidelines or the New Zealand Food and Nutrition Guidelines which may refer to the relevant benefits as described in the associated Australian Dietary Guideline or New Zealand Food and Nutrition Guideline Background Papers;

  E.g. a healthy diet that may lower your risk of certain kinds of cancer is one that is low in fats and includes fibre from a number of sources including a variety of fruits and vegetables, and wholegrain and bran cereals.

- biomarker[7] maintenance claims;

  E.g. this food is high in Y, which may help maintain healthy cholesterol levels through Z.

- biomarker enhancement claims; and

  E.g. this food is low in Y, which may reduce your blood pressure through Z.

- biomarker claims that make reference to a serious disease.

  E.g. this food is rich in Y. In conjunction with Z, Y helps to maintain your healthy cholesterol levels and can reduce your risk of heart disease.

Regulatory Model

It is recommended that the following arrangements apply to the regulation and monitoring of nutrition, health and related claims:

- the Australia New Zealand Food Standards Code would set out the high order principles of the health claims system, the definitions of general and high level claims, and provide prescriptive, individual detail for high level claims. The standard may also set out qualifying and disqualifying criteria for certain types of claims (e.g. nutrient content claims) and categories of foods which may be excluded from making claims (e.g. alcohol and baby foods)

[7] A biomarker is one indicator of a person's risk of developing a serious disease (e.g. blood cholesterol is a biomarker for the risk of heart disease).

- a guideline document would provide the majority of the detail surrounding general level claims. This guideline will be designed to assist industry in utilising the system correctly;

- a 'watchdog' body would serve as the public face of the health claims system, and undertake a number of key tasks.

- Jurisdictions would be responsible for receiving complaints in the usual way. Enforcement of the Health Claims Standard, including assessing possible breaches and undertaking prosecutions, would be the responsibility of the State/Territory and New Zealand enforcement agencies. Enforcement agencies would be responsible for coordinating action across jurisdictions, and informing the 'watchdog' body of complaints received and actions taken, and providing feedback on any perceived problems with the regulation of health claims.

The 'watchdog' would:

- assist FSANZ in the creation and maintenance of the guideline document (in consultation with stakeholders);

- provide recommendations to FRSC regarding proposed amendments to the Standard or the guideline document;

- receive complaints via a mailbox and refer any complaint to the relevant jurisdiction(s) for analysis and enforcement action;

- record complaints received (either directly by the watchdog or jurisdictions), and monitor enforcement actions undertaken by jurisdictions in response to those complaints; and

- provide periodic reports to FRSC.

A schematic representation of the proposed Regulatory Arrangements is provided at page 8 of this guideline.

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

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

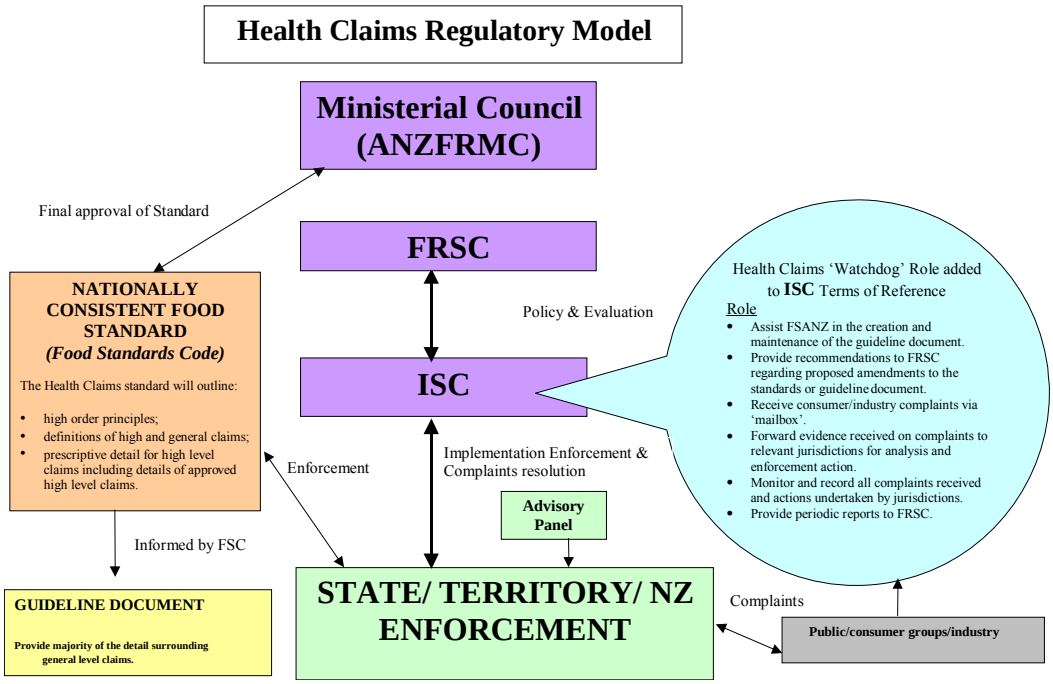
It is recommended that the "watchdog" function be funded by jurisdictions on a pro-rata to population basis, similar to the AHMAC model. This would be re-assessed in a review to be undertaken two years after implementation of the standard.

Advisory Panel

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

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

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



Substantiation Requirements

It is recommended that consideration be given to the following requirements for the type of evidence to be held, and who is required to hold it, for each level of claim.

It is the responsibility of the food manufacturer to refer to the Standard and associated guidelines and to make an assessment as to the classification of the claim they wish to use.

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

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

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

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

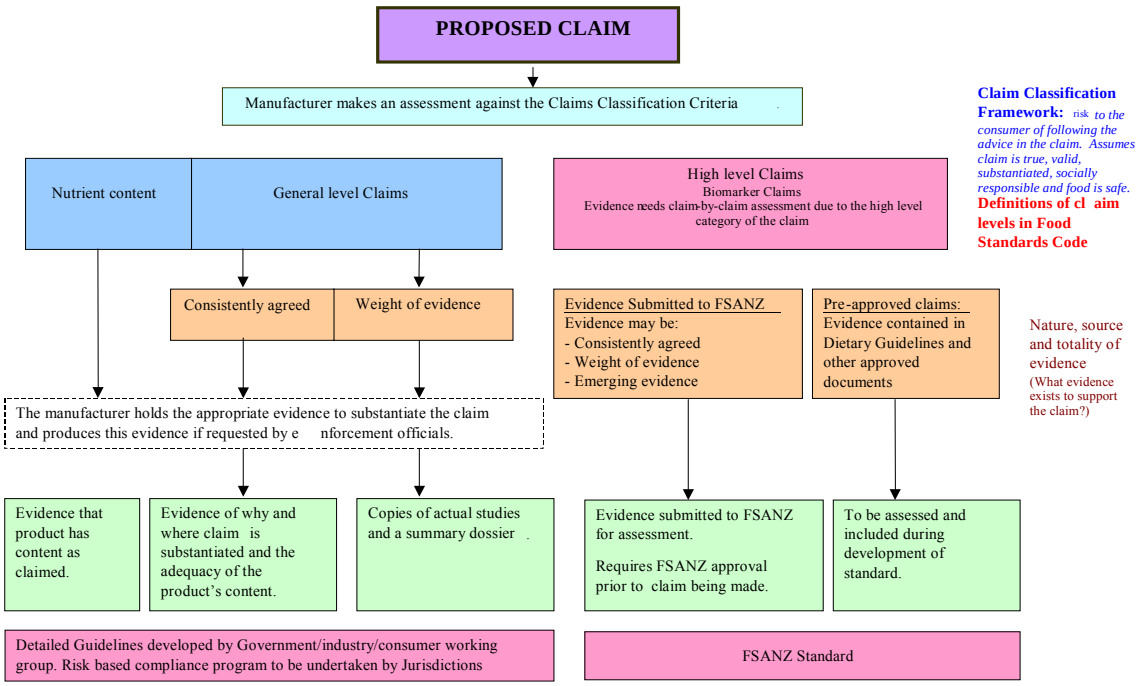
- together with evidence that the product contains an adequate amount of the relevant component(s).

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

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

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

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



Substantiation requirements Diagram

Additional guidance

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

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

- **Compliance and enforcement** to be closely monitored, with claims referring to a biomarker being a particular priority. Jurisdictions will also need to make audits and enforcement a priority, particularly during the introductory period. The Advisory Panel would be available on a user pays basis to jurisdictions needing timely, expert advice. The watchdog body would report to Ministers on the use of biomarker claims and other enforcement issues within 6 months of commencement.

- Further work to be undertaken to provide guidance around the **definitions of 'disease', 'serious disease or condition'** and **'therapeutic claims'**, to include asymptomatic disease and resolve tensions between the TGA and PAG definitions. This will be done in conjunction with the development of the standard.

- Further work is also needed to consider whether **nutrient content claims** can be adequately controlled, monitored and enforced. Consideration should be given whether certain parameters (e.g. qualifying and disqualifying criteria) (or exclusions for certain categories of food e.g. alcohol and infant food) should be specifically stated in the standard. This will be done in conjunction with the development of the standard.

- **Work on pre-approved claims** will be concurrent with the development of the standard. It is envisaged that pre-approved claims based on the National Health and Medical Research Council (NHMRC) Australian Dietary Guidelines or the New Zealand Dietary Guidelines will be considered for inclusion in the Health Claims Standard from its commencement. For the purposes of reviewing the evidence for health claims, FSANZ should look to the NHMRC's recent independent evaluation of nutritional and dietary evidence in developing national dietary guidelines.

- **The standard should not prescribe exact wording** for the pre-approved high level claims. Some flexibility in the wording of claims should be permitted provided there is compliance with the Overarching Principles. In general, approval of high level claims is to be 'claim by claim' and not 'product-by-product', although some products making high level claims may have undergone separate pre-market approval to ensure safety under other standards. Again, it is envisaged that the standard will not prescribe exact wording.

- **The standard should provide sufficient detail to enable enforcement action** to be taken against all breaches, for all levels of claims. However, only the 'high' level category is to include specific pre-approved claims, whilst still allowing for flexibility in wording.

- **The Nutrition, Health and Related Claims Policy Advisory Group should have continued involvement** as an external advisory group to FSANZ during the standard development process.

- Any costs associated with the 'watchdog' function should be funded on a pro-rata basis by jurisdictions. A model similar to the AHMAC model could be used. This will be re-assessed in the review of the system.

- **A review** of the health, nutrition and related claims system should be undertaken within two years of implementation of the standard. The review should take particular note of the effectiveness of the 'watchdog' body and its ongoing role (if any), the Advisory Panel and overall compliance of industry.

Glossary of Terms

It is recommended that consideration be given to the list of definitions for inclusion in the standard and any other guidelines.

Biomarker: any parameter from which the presence, absence or risk of a disease can be inferred by the level of the parameter (rather than being a measure of the disease itself.)

Claim: a stated or implied nutrition, health or related claim that can be communicated through all mediums including statements, symbols, vignettes, print or electronic media, or other forms of communication and or advertising.

Component: a component of a food includes a nutrient (including phytonutrient), non-nutrient or other ingredients.

Compound claim: a claim containing two or more clauses that can stand independently. The clauses are often linked by a conjunction such as 'and', 'by', 'but' etc.

Conditions or diseases that are medically managed: conditions and diseases in which a health care professional would be expected to prescribe and manage therapeutic treatment and monitor progress.

Dietary management of a disease: the selection of foods or food components to optimise the health of an individual with a specific disease or condition.

Disease: an unhealthy condition characterised by clinically significant signs or symptoms.

Dosage: a measured quantity administered at any one time or at stated intervals. A statement about dose or dosage would be considered a therapeutic claim and is therefore not permitted on foods. However, a manufacturer is allowed to state the amount of a component in a serving of the food together with the amount required to be consumed daily to achieve the desired effect. Specified serving sizes should reflect a realistic amount of the food that a person might normally consume. (e.g. a serve contains X g of the component. Consume Y serves per day, which as part of the appropriate total diet provides the claimed benefit).

Eligibility criteria: before a food is permitted to carry a claim, all stipulated eligibility criteria for that food must be met. Eligibility criteria can include qualifying and disqualifying criteria, such as the requirement for the presence and/or absence of components in the food or entire food categories.

Endorsement program: in the commercial sense – an advertising testimonial: an instance of public endorsement of a product for advertising purposes.

Nutrition, health and related claims: include all claims referring to nutrient content, nutrient function, enhanced function, reduction of disease risk or maintenance of normal health.

Serious disease or condition: forms of diseases, conditions, ailments or defects which are generally accepted to be beyond the ability of the average consumer to evaluate accurately and to treat safely without regular supervision by a suitably qualified health care professional.

Socially responsible: meets ethical and moral standards and does not abuse the trust or exploit the lack of knowledge of the general public or contain language, which could bring about fear or distress.

Therapeutic claim: a claim outside the context of the total diet that a specific food or food component will prevent, diagnose, cure or alleviate a disease, ailment, defect or injury; or influence, inhibit or modify a physiological process. Therapeutic claims on foods are not permitted under the Nutrition, Health and Related Claims framework, except where expressly permitted in the Food Standards Code. Therapeutic claims may only be made for goods, which are regulated by the Therapeutic Goods Administration. A statement about dosage is an implied therapeutic claim and is therefore not permitted on foods.

Whole of diet claims: claims that communicate the appropriate total diet required to achieve the stated benefit.

Attachment 7

Levels of Evidence

Levels of evidence are an integral component of FSANZ's assessment of the scientific evidence in support of a potential health claim. A proposed hierarchy of evidence is provided here for information because of its application to health claims and potentially a broader range of FSANZ decision making activities in future.

A draft guide for completing a literature review for application for a high level health claim was previously released by FSANZ for public consultation (http://www.foodstandards.gov.au/_srcfiles/Amendments%20to%20Handbook%20-%20Consolidated%20changes%20for%20consultation1.pdf#search=%22handbook%20health%22.). The process for assembling the literature and drawing a conclusion about a GLHC relationship is anticipated to be similar to that for a high level health claim. Full details will be given in the Application Handbook in due course, however, the basic steps are:

- careful specification of the relationship under consideration and careful definition of the food or property of the food and the specific health effect;

- definition of inclusion and exclusion criteria, and quality criteria for assessing the studies before the commencement of the literature search;

- description of the search strategy to identify the literature; application of the criteria to the literature and documentation of studies excluded and reasons for exclusion; and

- application of the quality criteria to the included studies; lower quality studies might be excluded from final consideration or given low weighting when assessing the totality of evidence.

The following classification scheme is proposed for levels of evidence:

- **Convincing evidence:** There must be a substantial number of human studies of at least acceptable quality. The weight of evidence shows a consistent association between the food or property of the food and the specific health effect. There is little or no evidence to the contrary in the studies. Human studies should preferably include both experimental and observational studies and be conducted in several different population groups. Any intake-response relationship should be supportive of a causal relationship but does not need to be linear. The relationship should be biologically plausible. Any mechanistic or laboratory evidence should be consistent with the human evidence and conducted in relevant animal or other models. Convincing evidence offers reasonable certainty that the relationship is unlikely to be contradicted by additional well-designed adequately-sized studies in humans.

- **Probable evidence:** Human studies must be of at least acceptable quality but there is either a less-than-substantial number and/or only a moderately consistent relationship between the food or property of the food and the specific health effect. Consequently the weight of evidence showing an association does not support a 'convincing' assessment. Human studies should preferably include both experimental and observational studies and be conducted in several different population groups. Any intake-response relationship should be supportive of a causal relationship but does not need to be linear. The relationship should be biologically plausible. Any mechanistic or laboratory evidence should be consistent with the human evidence and conducted in relevant animal or other models.

- **Suggestive evidence:** The weight of evidence shows an association between the food or property of the food and the specific health effect but there is substantial inconsistency across the studies even though they are of acceptable quality. Alternatively the association may be consistent across studies but the available studies are of low quality. The relationship should be biologically plausible.

- **Insufficient evidence:** The human evidence is either small in quantity or of low quality.

'Emerging' evidence would be expected to fall into either the suggestive or insufficient evidence categories, depending on the amount, type and quality of the data.

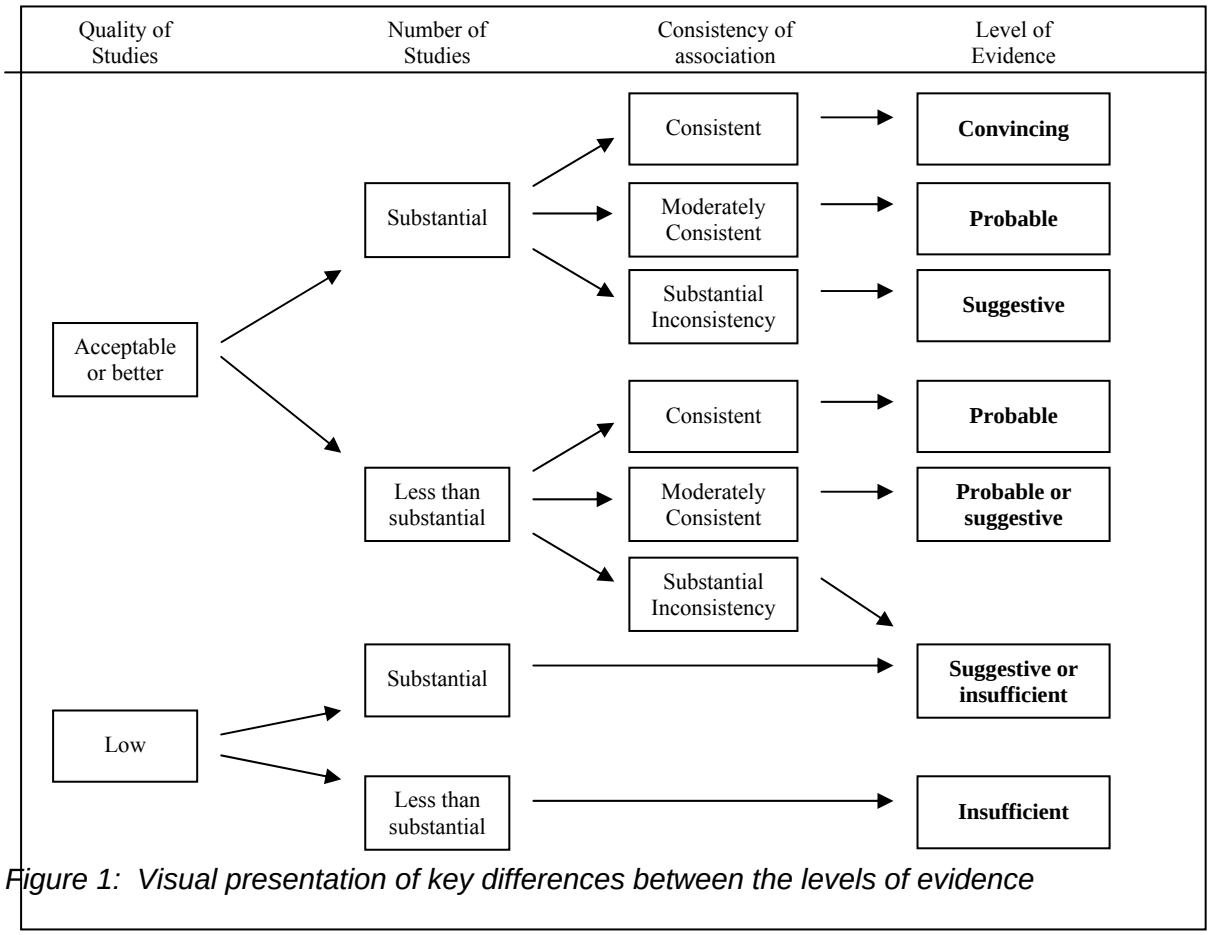


Figure 1: Visual presentation of key differences between the levels of evidence

Figure 1 assumes that there is an association between a food or property of a food and either an increase or a decrease in the likelihood of a health effect and that it is simply a question of the level of evidence. It should be noted that a food or property of a food might have no influence at all on a health effect. The criteria to determine that there is a null relationship are similar to the criteria for convincing or probable evidence of a relationship, but include additional factors such as the width of the confidence interval around the no effect point estimate.

Evidence of a relationship versus strength of a relationship

Previously, FSANZ has received questions as to the number of studies, or their sample size, for achieving a 'substantial number'.

The above criteria describing the assessment of evidence from which to draw a conclusion about a relationship should not be confused with the strength of a relationship, for example, relationships can also be described as strong or weak. A strong relationship is one where a small change in the intake of a food or property of the food leads to a large change in a health effect, whereas a weak relationship is one where the same small change in intake has a smaller influence on a health effect. Both of these relationships could potentially be concluded at various levels, depending on what data are available. Given that the same health effect is being studied, a strong relationship could be concluded using studies of a smaller size than a weak relationship (because the difference between the intervention and control groups is larger in relation to the standard deviation of the health parameter for the strong relationship). Similarly, a consistent association at a particular level of intake would be easier to demonstrate with studies of a smaller average sample size if the relationship is strong rather than weak.

This type of consideration is why it is not possible for us to specify the number of studies, or the sample sizes of those studies, required to approve a GLHC relationship at any of the levels of evidence.

Attachment 8

Development of general level health claim relationships

This Attachment provides the rationale for the inclusion or otherwise of certain GLHC relationships in Schedule 2 of the draft Standard. In compiling the Schedule, we approved a range of relationships that met a minimum level of scientific evidence of 'probable' as described in Attachment 7. We have also taken into account all other relevant factors in order to fulfil our statutory objectives under section 18 of the FSANZ Act. The basis for the selection of the GLHC relationships included in the Schedule relate to their availability from Methods 1-3. However, not all high level relationships in the draft Standard or in the US or Canadian regulations are approved as GLHCs, because they are difficult to translate to a GLHC context or, in the case of some US claims, are under review.

The rationale below includes comments relating to the conditions of use and the specific context for a GLHC where appropriate. The conditions vary according to the relationship but they are commonly based on criteria for nutrition content claims and/or refer to identified special purpose foods. In addition to specific conditions given in the Schedule for use of a GLHC relationship, all foods bearing GLHCs need to satisfy the requirements of the nutrient profiling scoring criterion. Population and context statements are provided only if there is more specific detail or modification required to the generic context statement requirement for a GLHC. Statements of the recommended dietary targets to achieve the specific health effect are required in the wording of the claim for some substances.

1. Inclusions in draft Schedule 2

1.1 Protein, carbohydrates and energy

In proposing a pre-market approval approach for GLHC relationships, certain macro-nutrient food-health approved relationships have been developed for inclusion in the Schedule. Protein, available carbohydrates and energy were selected because they make a positive contribution to health. They are also the subject of existing health claims and so would need to be assessed either now or during the transition phase.

Where possible, the conditions of use rely on existing criteria for nutrition content claims in the Code or draft Standard, otherwise new criteria have been developed, taking account of any criteria established overseas for these macronutrients.

1.2 Eicosapentaenoic Acid (EPA) and docosahexanoic acid (DHA)

FSANZ previously conducted a review of omega-3 fatty acids and cardiovascular disease for possible inclusion as a high level health claim relationship in the draft Standard in the Final Assessment Report. Although the weight of evidence was not enough for FSANZ to determine that the relationship could underpin a high level health claim, the weight is enough for a GLHC to be approved. The evidence base refers to EPA and DHA so these two long chain polyunsaturated fatty acids are specified as the property of the food.

1.3 Phytosterols

FSANZ previously assessed applications for the addition of phytosterols to certain foods, including an assessment of the potential for reduction of blood cholesterol. Given that FSANZ had approved the addition of phytosterols, we therefore gave consideration to approving a GLHC.

Also, health claims for phytosterols are in the marketplace. The equivalent of a high level health claim for phytosterols in both Canadian and US health claims regulations is used as the basis for the entry in draft Schedule 2. Because reference to blood cholesterol, a biomarker, would constitute a high level health claim, the GLHC relationship in the draft Schedule refers to biliary and dietary cholesterol. The conditions for use of the GLHC coincide with the minimum amounts established for addition of phytosterols to certain foods.

1.4 Beta glucan

FSANZ previously reviewed the evidence for a high level health claim relationship for wholegrains and heart disease. The relationship was not approved as a high level health claim because much of the data in the review related to soluble fibres from specific grains rather than from all wholegrains. Because of previous work, FSANZ gave consideration to the possibility of a GLHC relationship also noting that claims for beta glucan are in the marketplace. FSANZ considers that the evidence between dietary and biliary cholesterol absorption and beta glucan from oats and barley is appropriate to approve a GLHC. A similar claim for soluble fibre (principally beta glucan) and heart disease is recognised in the US health claims regulations and this was used to adapt the conditions for use of the claim.

1.5 Vitamins and minerals

The UK Joint Health Claims Initiative (JHCI) monograph, Table 1B, (http://www.jhci.org.uk/[8]) was used to provide the majority of vitamin and mineral GLHC relationships in the draft Schedule. In addition to specific relationships, the JHCI report contained five nutrient function statements in Table 1A that could apply to any vitamin or mineral[9]. Of these, only the statement for normal growth and development was included in Schedule 2, to apply to foods marketed for infants and children. Claims about growth and development are currently made on foods intended for or directed to infants and children.

1.6 Weight loss or weight maintenance

This GLHC relationship is carried over from the Table to clause 12 of the previous draft Standard. The conditions for use of weight loss (in overweight) or weight maintenance claims are amended from the previous draft Standard also to allow such claims on formulated meal replacements. This is because these foods are often formulated specifically for use in weight reduction diets and they currently carry such claims.

1.7 Formulated supplementary sports foods

The specific standard for these foods in the Code currently permits certain GLHCs to be made. These permissions will continue, including any specific conditions of use or requisite context for the claims, and the generic conditions in the draft Standard will not apply to these claims. No other GLHC relationships are currently listed specifically for these foods in draft Schedule 2.

[8] The JHCI website is no longer actively supported in the light of the European development of health claims.

[9] Well-established nutrient function statements common to all vitamins and minerals refer to a role in reproduction, conception, growth, development and body maintenance.

2. Exclusions from draft Schedule 2

2.1 Sodium

The relationships listed in the JHCI monograph for sodium are not included in the draft Schedule because, although well established, they are contrary to public health recommendations which advise a reduction in sodium intake rather than an increase. The food supply in Australia and New Zealand supplies sodium far in excess of daily requirements. High sodium intakes are implicated in elevating blood pressure.

2.2 Fat

Although some overseas jurisdictions provide GLHC relationships for fat as examples for industry, no GLHC relationships for fat are included in the draft Schedule for analogous reasons as for sodium.

2.3 Fluoride

Although the JHCI Monograph contains a GLHC relationship about the enhanced function of fluoride on dental health, it is not included in draft Schedule 2. Although FSANZ recognises the significant impact of fluoride on population dental health, it is considered that GLHCs relating to fluoride would be misleading because much of the municipal water supply of both Australia and New Zealand is fluoridated but cannot feasibly carry a health claim. This issue was considered within Application A588 – Addition of Fluoride to Packaged Water.

No reference value has been set in the Code, nor criteria determined for nutrition content claims about fluoride.

2.4 Biologically Active Substances

Although generically listed in the Table to clause 12 of the previous draft Standard, individual GLHC relationships for biologically active substances have not been included in the current draft Schedule 2. In reviewing the sources available from Methods 1-3 of the previous draft Standard, including the Cochrane Collaboration database, no GLHC relationships for biologically active substances were identified that could be approved. Therefore any biologically active substance–health relationships would need to be approved by way of the transition or application processes previously described (see section 9.3).

2.5 JHCI generic health claims other than for vitamins and minerals

The JHCI monograph included generic health claims for: reduced saturated fat and blood cholesterol; wholegrain foods and heart health; soya protein and blood cholesterol; oats and blood cholesterol; and omega-3 fatty acids and heart health.

These generic claims are not included in the draft Schedule because the level of evidence used in their assessment is not apparent. Some of these relationships are included via other sources, as described above.